Study on workability issues concerning the implementation of Annex VIII of Regulation (EC) No 1272/2008 on harmonised information relating to emergency health response and preventative measures

European Commission (DG GROW D2)
Final Report

Version linguistique	Numéro de catalogue	ISBN	DOI
EN	ET-04-19-434-EN-N	978-92-76-03840-5	10.2873/574339

Europe Direct is a service to help you find answers to your questions about the European Union.

Freephone number (*)**:**

00 800 6 7 8 9 10 11

(*) The information given is free, as are most calls (though some operators, phone boxes or hotels may charge you).

Luxembourg: Publications Office of the European Union, 2019
ISBN 978-92-76-0384-5
doi:10.2873/574339

Main Contributors

Caspar Corden (Wood)

Robert Whiting (Wood)

Ilona Kirhensteine (Wood)

Nikul Pandya (Wood)

Hiba Arshad (Wood)

Company Details

Report prepared by Wood (trading as Amec Foster Wheeler E&I GmbH)

Document Revisions

No.	Details	Date
1	Final report	24/06/2019
2	Revised final report	19/07/2019
3	Revised final report	31/07/2019

Report Document Details

Title	Details
Study Title	Study on workability issues concerning the implementation of Annex VIII of Regulation (EC) No 1272/2008 on harmonised information relating to emergency health response and preventative measures
Version linguistique	English (EN)
Numéro de catalogue	ET-04-19-434-EN-N
ISBN	978-92-76-03840-5
DOI	10.2873/574339
Report No.	2019.2747

Executive Summary Document Details

Title	Details
Version linguistique	English (EN)
Numéro de catalogue	ET-04-19-435-EN-N
ISBN	978-92-76-03844-3
DOI	10.2873/477186

Resumé

Cette étude

Ce document présente le rapport final d'une étude sur les problèmes de mise en œuvre concernant l'implémentation de l'annexe VIII du règlement (CE) n ° 1272/2008 relatif aux informations harmonisées concernant la réponse à apporter en cas d'urgence sanitaire. Ce rapport a été préparé par Wood sous contrat avec la Commission européenne.

Le contexte

En vertu du règlement CLP, les États membres sont tenus de mettre en place des organismes désignés pour recevoir des informations utiles pour une intervention sanitaire urgente, y compris en ce qui concerne les mélanges dangereux mis sur le marché de l'UE par les importateurs et les utilisateurs en aval. Selon le pays de l'UE, les médecins, les utilisateurs professionnels et les consommateurs peuvent contacter ces organismes désignés et / ou centres antipoison pour obtenir des recommandations sur le traitement médical en cas d'empoisonnement.

Le règlement (UE) n ° 2017/542 a modifié le règlement CLP en ajoutant l'annexe VIII sur les informations harmonisées relatives aux interventions d'urgence sanitaire. Celle-ci implique que les entreprises fournissent des informations uniformes sur la composition du produit et créent un identifiant unique de formulation (UFI) , qui permettent aux centres antipoison d'identifier exactement le produit en cas d'empoisonnement, menant à une meilleure intervention médicale, plus appropriée .

Lors de sa finalisation et du vote sur le règlement (UE) 2017/542, un certain nombre de secteurs de l'industrie ont exprimé leurs préoccupations quant aux problèmes potentiels de mise en œuvre. Pour certains secteurs, des dispositions spécifiques ont été prises dans le projet de texte juridique. Cependant, à un stade très tardif, certains autres secteurs ont exprimé des préoccupations quant à cette mise en œuvre. Le comité de réglementation a décidé de voter en faveur du projet de texte juridique, à condition que la Commission s'engage à étudier ces problèmes de faisabilité et à modifier le règlement si nécessaire.

Objectifs

Les objectifs de cette étude étaient:

i) Analyser la faisabilité de certaines dispositions de l'annexe VIII du règlement CLP dans certaines industries dont les matières premières et les chaînes d'approvisionnement sont compliquées; et

ii) Examiner et proposer des options pour résoudre les problèmes de mise en œuvre soulevés par certaines parties prenantes, s'ils sont confirmés, sans compromettre les informations nécessaires pour que les organismes désignés / centres antipoison exercent leurs fonctions conformément à l'article 45 du règlement CLP.

Identification des problèmes de maniabilité

Cette étude a nécessité une vaste consultation avec l'industrie et les autorités (centres antipoison, organismes désignés, autorités compétentes, ECHA) sur les problèmes de mise en œuvres soulevés par les secteurs suivants:

- Produits pétroliers
- Gaz industriels
- Produits de construction (comprenant les matériaux à base de ciment et autres produits de construction)
- Peintures
- Parfums

- Savons et détergents
- Autres

En termes de problèmes de mise en œuvre soulevés, l'objectif de l'étude était de:

- Évaluer l'exactitude des déclarations de l'industrie
- Estimer les coûts associés pour les entreprises concernées, liés à la mise en œuvre de l'annexe VIII
- Évaluer les avantages liés à une information meilleure et plus détaillée contribuant à une intervention sanitaire d'urgence et une action préventive

Ce rapport souligne d'abord l'importance des cas d'empoisonnement dans un certain nombre d'États membres pour les secteurs de l' industrie ci - dessus, ainsi que les besoins des centres antipoison. Ensuite, pour chaque secteur, les informations suivantes sont fournies:

- Un aperçu de l'industrie
- Problèmes de mise en œuvre soulevés par le secteur
- Les impacts de ces problèmes de mise en œuvre
- Suggestions de l'industrie sur les solutions possibles à ces problèmes de mise en œuvre
- Retour d'information des parties prenantes sur les problèmes de mise en œuvre

Le rapport couvre également les mélanges intégrés par un formulateur en aval dans un cadre industriel à un mélange destiné au consommateur / à usage professionnel ('mélange final'). L'interprétation de la Commission est que ces mélanges doivent être considérés comme des mélanges pour l'usage des consommateurs / professionnels. Ils ne peuvent donc pas bénéficier de la "soumission limitée" pour les mélanges utilisés de manière industrielle, ni au dernier délai de notification (2024 par rapport à 2020/2021 pour les mélanges grand public / professionnels)[1]. L'industrie a soulevé ce problème en termes de complexité et de capacité à se conformer dans les délais impartis.

Le rapport examine les chaînes d'approvisionnement affectées par ce problème de "mélange dans le mélange" (ci-après 'MIM', 'mixture in mixture') ainsi que l'ampleur de ce problème. Il considère la différence entre les informations disponibles pour une intervention sanitaire d'urgence si les dispositions relatives à la soumission limitée sont appliquées, c'est-à-dire en limitant les informations sur la composition du mélange à celles figurant dans les fiches de données de sécurité. Le rapport considère notamment une exemption possible de notification pour les mélanges , soit en raison de la dilution du mélange dans le mélange final, soit en raison du mélange final étant exempt du règlement CLP (tels que les cosmétiques).

Dans l'ensemble, les problèmes de mise en œuvre identifiés ont été inclus dans l'une des cinq catégories suivantes:

- Variation du produit due au changement naturel / incrémental des composants du mélange
- Composition exacte inconnue dans les chaînes d'approvisionnement complexes / avec des mélanges à plusieurs étapes
- Multiples fournisseurs de composants de mélange avec les mêmes propriétés techniques et les mêmes dangers

1 Au moment de la rédaction du présent document, un amendement à l'annexe VIII était en cours d'examen, dont le projet de texte juridique inclurait le report du premier délai d'applicabilité au 1 er janvier 2021. Toutefois, l'amendement n'ayant pas été adopté au moment de la rédaction, le La date limite de conformité initiale de 2020 est mentionnée dans l'étude.

- Limites d'utilisation des méthodes de soumission de groupe
- Mélanges dans un mélange - Usage industriel vs usage professionnel / consommateur

Identifier les solutions potentielles aux problèmes de maniabilité

Développement d'options

Ce rapport examine et résume ensuite l'importance et l'ampleur des problèmes de mise en œuvre. Il fournit ensuite des solutions possibles aux problèmes de mise en œuvre suggérés par l'industrie et les autorités, ainsi que les avantages (et les inconvénients) de ces solutions possibles.

Les problèmes identifiés pour ces secteurs se chevauchent considérablement, et aucun des problèmes de mise en œuvre n'est en principe propre à un secteur spécifique. Compte tenu de cela et du désir de traiter tous les secteurs équitablement, des options permettant de résoudre les problèmes de mise en œuvre ont été identifiées dans le but d'adopter des approches novatrices ne nécessitant pas de dispositions spéciales pour un secteur spécifique.

Les options présentées dans ce rapport sont basées sur les différentes tâches et activités de l'étude, notamment:

- Les problèmes de mise en œuvre identifiés par l'industrie et l'évaluation de leur importance et ampleur.
- Les solutions potentielles proposées par l'industrie pour résoudre les problèmes de mise en œuvre, pendant la phase de consultation initiale. Les solutions suggérées étaient spécifiques à un secteur à ce stade.
- Les opinions des centres antipoison et des organismes désignés sur les problèmes de mise en œuvre et sur les solutions proposées par l'industrie, identifiées au cours de la phase de consultation initiale.
- Discussions lors d'un workshop, y compris les suggestions avancées par l'industrie et le point de vue des autorités sur ces suggestions.
- Les réactions des centres antipoison, des autorités et de l'industrie après le workshop (février / mars 2019) ainsi que sur le projet de rapport (mai / juin 2019), y compris des suggestions nouvelles et / ou modifiées pour résoudre les problèmes de mise en œuvre.

Les différentes options ont été développées dans le but de trouver des solutions qui limitent les coûts pour l'industrie sans compromettre la capacité de fournir une réponse sanitaire d'urgence adéquate. Les trois options suivantes sont proposées pour un examen plus approfondi par la Commission et autres parties prenantes. Le rapport décrit comment ces options permettraient de résoudre les problèmes de mise en œuvre soulevés par l'industrie, ainsi que les besoins des centres antipoison et des organismes désignés en matière d'intervention sanitaire d'urgence. Il décrit également les avantages et les inconvénients potentiels de chaque option.

Option A: possibilité d'utiliser une soumission limitée pour certains MIM qui sont finalement utilisés dans des produits grand public et professionnels

Cette option est destinée à résoudre le problème suivant: les mélanges originaux initialement utilisés (pour la formulation) en milieu industriel ne peuvent pas bénéficier des dispositions relatives à la soumission restreinte car ils sont utilisés comme MIM dans les produits de mélanges finaux vendus aux consommateurs ou aux professionnels.

Cette option impliquerait la possibilité, dans les cas où un mélange est fourni initialement pour une utilisation (en formulation) en milieu industriel, d'appliquer les exigences de soumission limitée, à condition qu'il puisse être démontré que le mélange n'est jamais utilisé dans des mélanges finaux destinés aux consommateurs ou usage professionnel à des concentrations supérieures à un certain seuil (seuil à déterminer, par exemple 5%). Cela pourrait être inclus par le déclarant / fournisseur comme condition préalable à la fourniture du mélange initial à son client.

Les fournisseurs de mélanges ne connaîtront souvent pas l'utilisation finale exacte de tous les mélanges qu'ils fournissent; si l'utilisation dans des produits de consommation / professionnels ne peut être exclue, alors une notification complète de la composition serait nécessaire pour tous ces produits. Un nombre important de mélanges pourraient bénéficier de la possibilité d'utiliser une soumission limitée, comme présenté sous cette option. En cas d'incident d'empoisonnement, les centres antipoison auraient toujours accès aux informations sur la composition des fiches de données de sécurité des MIM concernés, ainsi qu'au service obligatoire 24h/24 et 7j/7 pour un accès rapide à des informations complémentaires détaillées sur le produit.

Option B: Utilisation de plusieurs UFIs pour des produits grand public et professionnels en point de vente

Cette option vise à résoudre le problème suivant: pour les mélanges de peintures en point de vente, des millions de notifications individuelles doivent potentiellement être générées et soumises à l'avance, ou doivent être générées chaque fois qu'une nouvelle couleur est obtenue par mélange et vendue (par exemple dans un magasin de rénovation) à un consommateur ou à un professionnel. Alors que ce problème fut identifié spécifiquement pour les peintures, une approche non spécifique à un secteur particulier est jugée appropriée étant donné que d'autres secteurs pourraient être confrontés au même problème.

L'option consisterait à autoriser l'utilisation d'une seule UFI pour le produit de base (par exemple, la peinture de base) et de plusieurs UFI distinctes pour les colorants individuels lorsque les mélanges sont produits à la demande des consommateurs et des professionnels sur le lieu de vente. La fourchette de concentration des composants devra également être spécifiée.

Une telle approche est basée sur une proposition de l'industrie et semble être soutenue par les commentaires des centres antipoison. Cela ressemble notamment à une approche appliquée en France.

Cette option pourrait réduire de manière significative les coûts très élevés attendus liés au grand nombre de notifications, ainsi que les difficultés pratiques liées à la notification des mélanges sur mesure produits au point de vente.

Option C: Écart par rapport aux limites de concentration pour les composants de mélange variables ou techniquement interchangeables

Cette option serait conçue pour les cas où les composants du mélange (provenant de fournisseurs multiples, par exemple) sont considérés techniquement équivalents et interchangeables (et présentent un danger équivalent), ainsi que les composants du mélange qui sont intrinsèquement variables en raison, par exemple, de variations naturelles des concentrations de composants du mélange.

Tout écart par rapport aux limites de concentration fixées à l'annexe VIII serait autorisé, selon un pourcentage indiqué, pour de tels composants dans le mélange. Dans de tels cas, une nouvelle notification ne serait pas nécessaire lorsqu'un composant de ce mélange est modifié, à condition que certaines conditions soient remplies, telles que:

- Lorsque les composants du mélange sont interchangeables ou intrinsèquement variables au sein de ce groupe, tous les composants du mélange (substances / MIM) doivent être répertoriés (avec identificateurs de produit / UFIs) dans le cadre de la notification.
- Tous les autres composants du mélange doivent rester les mêmes et à la même fourchette de concentration.
- L'auteur de la notification devrait pouvoir démontrer, sur demande, qu'il n'y a pas de différence de mode d'action toxicologique, d'activité, de classification du danger, etc. des composants du mélange interchangés, ni de différence de traitement en cas d'intoxication, ni aucun changement dans la classification de danger du mélange final.
- Cette option pourrait être limitée aux composants du mélange qui ne sont pas classés pour certains dangers (par exemple, les composants dangereux extrêmement

préoccupants en cas d'intervention d'urgence en matière de santé conformément au point 3.4.1 de la partie B de l'annexe VIII ne pourraient pas bénéficier de cette option).

- Un seul UFI couvrant le mélange et toutes ses variantes anticipées serait alors créé.

Cette option réduirait le nombre de notifications similaires, ce qui profiterait à la fois à l'industrie et aux centres antipoison. Il incomberait à l'industrie d'assurer qu'aucune différence de traitement n'est faite en cas d'empoisonnement par l'exposition à l'une des variantes dans les plages de concentrations / composants spécifiés. Les autorités n'auraient pas besoin de définir d'autres identificateurs génériques de produit / formules de groupe (FG), ce qui a été évoqué comme une préoccupation potentielle pour ces autorités.

Cette option adresserait également, du moins en partie, les problèmes résolus par les options A et B. La façon dont le texte légal est formulé et son champ d'application défini, pourrait également adresser certains cas additionnels, en particulier ceux résolus par l'Option B.

Implications pour la balance des coûts et des avantages

Les options présentées dans ce rapport réduiraient le nombre de notifications et de mises à jour (options B et C) dans le but de réduire la charge (coûts) imposée à l'industrie et sans compromettre les mesures sanitaires d'urgence. Elles permettraient également (option A) de réduire la complexité des soumissions dans certains cas où les mélanges sont vendus pour une utilisation initiale dans des environnements industriels mais peuvent (en partie) se retrouver finalement dans des utilisations grand public.

S'il n'a pas été possible de quantifier la variation des coûts pour les différents secteurs, associés à l'une ou l'autre des annexes VIII telle que finalement approuvée[2], ou avec les options proposées, il est possible de conclure ce qui suit:

- En termes de coûts et d'avantages quantifiés, l'étude précédente (2015) sur les coûts et les avantages concluait que l'économie nette liée à l'harmonisation des informations transmises aux centres antipoison ainsi qu'à l'introduction de l'UFI pourrait se situer autour de 550 millions d'euros par an pour l'ensemble de l'UE.

- Sur la base des informations relatives aux problèmes de mise en œuvre soulevée par les secteurs, les dispositions de l'annexe VIII telles qu'elles ont finalement été convenues impliquent que beaucoup plus de notifications et de mises à jour que celles initialement envisagées seraient nécessaires. Les coûts associés à ces notifications et mises à jour pourraient être suffisants pour réduire considérablement, voire annuler, les avantages nets identifiés dans l'étude de 2015.

- Les options proposées pour résoudre les problèmes de mise en œuvre réduiraient le nombre de notifications et de mises à jour, tout en ne compromettant pas les avantages obtenus en termes d'intervention d'urgence en matière de santé.. Cela rend plus probable que le rapport avantages / coûts reste positif. De plus, quelques-unes des difficultés pratiques liées à la conformité (c'est-à-dire des défis techniques conduisant à des perturbations de la chaîne d'approvisionnement importante ou des changements majeurs d'infrastructure) n'auraient plus lieu d'être.

- Néanmoins, ces options entraîneraient une certaine perte d'informations qui pourraient autrement être disponibles à des fins de toxicovigilance. Un examen plus approfondi des questions de toxicovigilance est prévu au sein du groupe d'experts CARACAL.

Possibilité d'établir un système de toxicovigilance de l'UE

L'Organisation Mondiale de la Santé (OMS) définit la toxicovigilance comme étant le processus actif d'identification et d'évaluation des risques toxiques existant dans une communauté et l'évaluation des mesures prises pour les réduire ou les éliminer. En effectuant une évaluation médicale approfondie des intoxications aiguës ou chroniques, la toxicovigilance contribue à

2 Cela n'entrait pas dans le cadre de l'étude.

identifier les problèmes toxicologiques émergents résultant, par exemple, de la reformulation d'un produit ou d'une modification de son emballage ou de son étiquetage; la disponibilité d'une nouvelle drogue; ou un problème environnemental. Cela permet de détecter rapidement les effets néfastes potentiels sur la santé et de mettre en œuvre des mesures préventives ou correctives, notamment une communication plus large des problèmes rencontrés dans l'ensemble des centres antipoison de l'Union européenne.

Au sein de l'UE, la toxicovigilance est contrôlée au niveau national et varie de plusieurs manières. Ceci comprend:

- La manière dont la toxicovigilance est déclenchée - Cela peut être à la demande directe d'études émanant d'agences médicales et d'autorités compétentes, mais aussi à l' initiative d'autres organisations.
- La forme de toxicovigilance utilisée - Ceci comprend les études rétrospectives sur les tendances identifiées, l'étude prospective pour la surveillance continue ainsi que des éléments d'analyse d'horizon pour de nouveaux produits.
- Comment la toxicovigilance est utilisée - Les centres antipoison ont souligné que leur rôle principal est de fournir une réponse de santé d'urgence, et par conséquent, leurs ressources pour toxicovigilance varient dans l'UE.
- Les sources d'information utilisées pour toxicovigilance - Ceci inclut les journaux d'appels des centres antipoison, ainsi que Les données médicales de hôpitaux, et d'autres enquêtes de suivi avec les patients après que le traitement ait été reçu.

Il n'existe actuellement aucune forme de toxicovigilance centralisée sous forme de directives ou d'exigences définies. Cependant, sur la base de discussions avec les centres antipoison, il est évident que la communication informelle joue un rôle et est fortement appréciée par les centre antipoison, notamment via l'Association européenne des centres antipoison et des toxicologues cliniciens (European Association of Poisons Centres and Clinical Toxicologists) et les échanges bilatéraux. En outre, des travaux ont été menés pour faciliter le partage d'informations sur la toxicovigilance, notamment la mise au point d'une terminologie commune et de groupes pour les symptômes par le biais du dictionnaire médical des activités de réglementation (MedDRA). L'étude a également exploré les possibilités de développer la coopération de l'UE afin de renforcer la toxicovigilance dans l'ensemble de l'UE, avec trois options potentielles identifiées:

Option 1: Un système de toxicovigilance à l'échelle de l'UE serait créé à l'aide d'une base de données centralisée de l'UE pour toutes les demandes de renseignements des centres antipoison des États membres. Ceci serait complété par l'établissement d'une équipe de toxicologues experts issues de l'UE pour mener à bien la toxicovigilance.

Avantages: La normalisation des données du journal des appels dans une base de données centrale constituerait une ressource utile en matière de toxicovigilance. Un ensemble plus complet d'exigences et d'orientations en matière de toxicovigilance profiterait à l'ensemble de l'UE.

Défis: L'étude a révélé qu'une variété de systèmes de journaux d'appels différents sont utilisés, avec des différences dans les données collectées. La création d'un tel portail centralisé entraînerait des coûts importants. En outre, il existe une question sur la disponibilité des ressources à l'échelle nationale pour aider à constituer l'équipe d'experts toxicologues.

Option 2: Cette option suggère un système de toxicovigilance à l'échelle européenne similaire à l'option 1, mais avec des critères de filtrage supplémentaires. Les centres antipoison s reçoivent des milliers d'appels par an, dont bon nombre fournirait moins de valeur à une telle base de données centralisée. Une autre option serait de permettre aux centres antipoison de signaler les appels qui, à leur avis, pourraient être importants pour un référentiel central / ou d'obtenir un accord sur les critères de ce qui devrait ou ne devrait pas être soumis.

Avantages: cette option présente des avantages similaires à l'option 1, mais nécessiterait le jugement d'experts sur ce qui est soumis de manière centralisée.

Défis: Cette option est moins onéreuse que l'option 1 pour la gestion au jour le jour, mais présente les mêmes coûts de mis en place et de gestion.

Option 3: un organe au niveau européen devrait fournir une guidance et donner une ligne directrice aux systèmes nationaux de toxicovigilance existants, ainsi que des exigences et objectifs définis. Cette option laisserait la gestion de la toxicovigilance (y compris les données) au niveau national, mais fournirait un système plus formalisé pour la manière dont la toxicovigilance est réalisée et partagée.

Avantages: la formalisation de guidance et de l'approche améliorerait la cohérence des systèmes et des échanges d'informations entre les parties, sans avoir besoin de nouveaux systèmes ou des ressources supplémentaires importantes.

Défis: il y aurait probablement encore des problèmes de comparabilité inhérents importants entre différents systèmes, ce qui nécessiterait une l'interprétation d'experts. Comme mentionné ci-dessus, les ressources disponibles sont variables au sein de l'UE, certaines étant mieux équipées et plus actives que d'autres. Le principal risque serait que certains États membres soient laissés pour compte.

Executive summary

This study

This is the final report for a study on workability issues concerning the implementation of Annex VIII of Regulation (EC) No 1272/2008 on harmonised information relating to emergency health response and preventative measures. It has been prepared by Wood under contract to the European Commission.

Context

Under the CLP regulation, Member States are required to set up appointed bodies for receiving information relevant for emergency health response, including on hazardous mixtures placed on the EU market by importers and downstream users. Depending on the EU country, physicians, professional users and consumers can contact these appointed bodies and/or poison centres to get recommendations for medical treatment in cases of poisoning.

Regulation (EU) No 2017/542 amended the CLP Regulation by adding Annex VIII on harmonised information relating to emergency health response. It requests companies to provide uniform information on product composition as well as to create a unique product identifier (UFI), enabling poison centres to exactly identify the product in case of a poisoning incident, leading to a better and more appropriate medical response.

In the run up to finalising and voting upon Regulation (EU) 2017/542, a number of industry sectors raised concerns about potential workability issues. For certain sectors, specific provisions were taken up in the draft legal text. However, at a very late stage, concerns regarding workability were raised by a number of other sectors. It was agreed in the regulatory committee to vote on the draft legal text, provided that the Commission committed to studying those workability issues and amending the Regulation if deemed necessary.

Objectives

The objectives of this study were:

i) To analyse the workability of certain provisions of Annex VIII to the CLP Regulation in relation to certain industries with complex material inputs and supply chains; and

ii) To investigate and propose options to address the workability issues raised by some stakeholders, if they are confirmed, without losing necessary information for appointed bodies/poison centres to perform their duties in accordance with CLP Article 45.

Identification of workability issues

The study has involved extensive consultation with industry and with authorities (poison centres, appointed bodies, competent authorities, ECHA) related to workability issues raised by the following sectors:

- Petroleum products
- Industrial gases
- Construction products (disaggregated to cementitious materials and other construction products)
- Paints
- Fragrances
- Soaps and detergents
- Others

In terms of the specific workability issues raised, the aim of the study was to:

- Assess the correctness of the claims made by industry
- Estimate the related costs for concerned businesses associated with implementation of Annex VIII

- Evaluate the benefits related to better and more detailed information for emergency health response and preventative action

This report first sets out the significance of poisoning incidents across a number of Member States for the above industry sectors, as well as the needs of poison centres. Then, for each sector, information is provided on the following:

- An overview of the industry
- Workability issues raised by the sector
- The impacts of those workability issues
- Industry suggestions on possible solutions to those workability issues
- Feedback from stakeholders on the workability issues

The report also covers mixtures which are integrated by a downstream formulator in an industrial setting into a mixture for consumer/professional use ('final mixture'). The Commission's interpretation is that such mixtures are to be considered as mixtures for consumer/professional use. They therefore cannot benefit from the 'limited submission' provisions for industrially-used mixtures, nor the later notification deadline (2024 compared to 2020/2021 for consumer/professional mixtures)[3]. Industry has raised this as a concern in terms of complexity and ability to comply within the available timescales.

The report considers the supply chains affected by this 'mixtures-in-mixtures' (MIM) issue and the scale of the issue. It considers the difference in information available for emergency health response if the limited submission provisions are applied, i.e. limiting information on mixture composition to that included in the safety data sheets. It also considers possible exemption of mixtures from notification, due to either dilution of the mixture in the final mixture, or due to the final mixture being exempt from the CLP Regulation (such as with cosmetics).

Overall, the workability issues identified were included in one of the following five categories:

- Product variation due to natural/incremental change in mixture components
- Inability to know exact composition in complex supply chains / with mixing at multiple stages
- Multiple suppliers of mixture components with "same" technical properties and hazards
- Limitations on use of group submission approaches
- Mixtures in mixtures – Industrial vs professional/consumer use

Identifying potential solutions to workability issues

Development of options

This report reviews and then summarises the significance of the workability issues. It then goes on to summarise the possible solutions to the workability issues put forward by industry and by authorities, and the merits (and drawbacks) of those possible solutions.

There was considerable overlap in the issues identified for specific sectors, and none of the workability issues are in principle unique to any specific sector. Given this, and the desire to treat all sectors fairly, options to address the workability issues have been identified with the intention of taking forward approaches which do not require special provisions for any specific sector.

The options set out in this report are based on the various study inputs and activities including:

- The workability issues identified by industry and the appraisal of their significance.
- The potential solutions put forward by industry to address the workability issues during the initial consultation phase. These potential solutions were sector-specific.

3 At the time of writing, an amendment to Annex VIII was being considered, the draft legal text of which would include postponement of the first applicability deadline to 1 January 2021. However, the amendment had not been adopted at the time of writing, so the original compliance deadline of 2020 is referred to in the study.

- Poison centres' and appointed bodies' views on the workability issues and on industry's proposed solutions identified during the initial consultation phase.
- Discussions at the study workshop, including suggestions put forward by industry and the views of authorities on those suggestions.
- Feedback from poison centres, authorities and industry after the study workshop (February/March 2019) and also on the draft report (May/June 2019), including new and/or modified suggestions to address the workability issues.

These options have been developed with a view to finding solutions that limit the costs on industry without compromising the ability to provide emergency health response. The following three options are proposed for further consideration by the Commission and other stakeholders. The report describes how these options would address the workability issues raised by industry, as well as the needs of poison centres and appointed bodies in terms of emergency health response. It also outlines the benefits that could be realised and the potential drawbacks of each option.

Option A: Ability to use limited submission for certain MIMs that are ultimately used in consumer and professional products

This option is intended to address the issue whereby original mixtures that are initially used (for formulation) in industrial settings cannot benefit from the limited submission provisions because the original mixtures are used as MIMs in final mixture products sold to consumers or professionals.

This option would involve the possibility, for cases where a mixture is supplied initially for use (in formulation) in industrial settings, to apply the limited submission requirements, provided that it can be demonstrated that the mixture is never used in final mixtures for consumer or professional use at concentrations above a certain level (threshold to be determined e.g. 5%). This could be included by the notifier/supplier as a precondition of supply of the original mixture to their customer.

Mixture suppliers reportedly often do not know the exact final use of all of the mixtures that they supply; if possible use in consumer/professional products cannot be ruled out then a full notification of composition would be needed for all such products. A significant number of mixtures could benefit from the ability to use a limited submission under this option. In case of poisoning incidents, poison centres would still have access to the information on composition from safety data sheets of the MIMs concerned, as well as the mandatory 24/7 service for rapid access to detailed additional product information.

Option B: Use of multiple UFIs for bespoke point-of-sale consumer and professional products

This option is intended to address the issue whereby, for mixing of paints at point-of-sale, potentially millions of individual notifications would need to be either generated and submitted in advance, or would need to be generated each time a new colour is mixed and sold (e.g. at a home improvement store) to a consumer or professional. Whilst the issue has been identified specifically for paints, a non-sector-specific approach is considered appropriate given that other sectors might face the same issue.

The option would be to allow the use of a single UFI for the base product (e.g. base paint) and additional, separate UFIs for individual colourants where mixtures are produced on-demand at point-of-sale for consumers and professionals. The concentration range of the components would also need to be specified.

Such an approach is based on an industry proposal, and seems to be supported by feedback from poison centres. It is also similar to an approach being applied in France.

This option could significantly reduce the very high expected costs associated with the large number of notifications, as well as the practical difficulties of notifying bespoke mixtures produced at point-of-sale.

Option C: Deviation from concentration limits for inherently variable or technically interchangeable mixture components

This option would be designed to address cases where mixture components (e.g. from multiple suppliers) are considered technically equivalent and are interchangeable (and where they have equivalent hazard), as well as where mixture components are inherently variable due, for example, to natural variations in concentrations of mixture components.

Deviation from the concentration limits in Annex VIII would be allowed, by a specified percentage, for such mixture components. In such cases, there would be no need for re-notification when such a mixture component changes, provided that certain conditions are fulfilled, such as:

- Where mixture components are interchangeable or inherently variable within this group, all such mixture components (substances/MIMs) would need to be listed (with product identifiers / UFIs) as part of the notification.
- All other mixture components would need to remain the same, and in the same concentration (ranges).
- The notifier would need to be able to demonstrate, on demand, that there is no difference in toxicological mode of action, potency, hazard classification, etc. of the interchanged mixture components, and no difference in treatment in the event of poisoning, as well as no change in hazard classification of the final mixture.
- This option could be limited to mixture components that are not classified for certain hazards (e.g. hazardous components of major concern for emergency health response as per 3.4.1 of Part B of Annex VIII would not be able to benefit from this option).
- A single UFI covering the mixture and all its expected variants would then be created.

This option would reduce the numbers of very similar notifications, which would be of benefit to both industry and poison centres. The burden would be on industry to ensure no difference in treatment in the event of poisoning if exposure occurs to any of the variants within the ranges of concentrations/components specified. There would be no need for the definition of additional generic product identifiers / group formulas (GFs) by the authorities, something which has been raised as a potential concern for them.

This option would also address, at least in part, the issues addressed by Options A and B. Depending on the exact scope and wording of the option in the legal text, additional cases, in particular those covered by Option B, could be addressed as well.

Implications for balance of costs and benefits

The options set out in this report would reduce the number of notifications and updates (options B and C) with the aim of reducing the burden (costs) for industry, and without compromising emergency health response. They would also (option A) reduce the complexity of submissions in certain cases where mixtures are sold for initial use in industrial settings but which may (in part) ultimately end up in consumer uses.

Whilst it has not been possible to quantify the change in costs for the individual sectors, associated with either Annex VIII as finally agreed[4], or with the proposed options, it is possible to conclude the following:

- In terms of quantified costs and benefits, the previous (2015) study on costs and benefits concluded that a net saving associated with the harmonisation of information submitted to poison centres as well as introduction of the UFI could be around €550 million per year for the EU as a whole.
- Based on the information on the workability issues raised by industry, the provisions of Annex VIII as finally agreed, mean that many more notifications and updates than were originally envisaged would be required. The costs associated with these notifications

4 Indeed this was not within the scope of the study.

and updates could be sufficient to significantly reduce, or even reverse, the net benefits identified in the 2015 study.

- The proposed options to address the workability issues would reduce the numbers of notifications and updates, while not compromising the benefits achieved in terms of emergency health response through harmonisation. This makes it more likely that the balance of benefits to costs would remain positive. Moreover, and arguably more importantly, some of the practical difficulties associated with compliance (i.e. technical challenges leading to significant supply chain disruption or major infrastructure changes) would be removed.
- Nonetheless, the options would entail some loss of information that might otherwise be available for toxicovigilance purposes.

Possibility of establishing an EU toxicovigilance scheme

Toxicovigilance is defined by the World Health Organisation (WHO) as the active process of identifying and evaluating the toxic risks existing in a community, and evaluating the measures taken to reduce or eliminate them. By conducting an in-depth medical assessment of acute or chronic intoxications on an individual basis, toxicovigilance contributes to identifying emerging toxicological problems resulting from, for example, the reformulation of a product or a change to its packaging or labelling; the availability of a new drug of abuse; or an environmental problem. This allows for rapid detection of potential adverse health impacts and the implementation of preventative or corrective measures, including wider communication of issues across the EU community of poison centres.

Within the EU, toxicovigilance is controlled at national level and varies in a number of ways. This includes:

- How toxicovigilance is triggered – This can be as a direct request for studies from medical agencies and competent authorities, but can be based on organisations' own initiative.
- The form of toxicovigilance used – This includes retrospective studies on identified trends, forward-looking work for continued monitoring or even horizon scanning elements for new products.
- How active toxicovigilance is utilised – Poison centres highlighted that their primary role is to provide emergency health response and so resources for toxicovigilance vary across the EU.
- Information sources used for toxicovigilance – Primarily this includes call logs from poison centres, but can include medical data from hospitals, and further follow-up investigations with patients after treatment has been received.

Currently no centralised form of toxicovigilance with set guidelines or requirements exists. However, based on discussion with the poison centres, it is clear that informal communication is happening and is strongly valued by the poison centres, in particular through the European Association of Poisons Centres and Clinical Toxicologists and bi-lateral exchanges. Furthermore, work has been carried out to aid the sharing of information on toxicovigilance including the development of common terminology and language groupings for symptoms through the Medical Dictionary for Regulatory Activities (MedDRA). The study further explored the possibilities for how EU co-operation could be developed to strengthen toxicovigilance across the EU, with three potential options identified:

Option 1: An EU-wide toxicovigilance system would be created using a centralised EU database for all Member State poison centre enquiries. This would be complemented by establishing an EU-wide team of expert toxicologists to carry out the toxicovigilance.

Benefits: Standardisation of call log data within a central database would provide a powerful resource for toxicovigilance. A more complete set of requirements and guidance for toxicovigilance would benefit the whole EU.

Challenges: The study identified that a variety of different call log systems are in use, with differences in data being gathered. Creation of such a centralised portal would carry significant cost implications. Additionally, there is a question over availability of resources nationally to help populate the expert team of toxicologists.

Option 2: For an EU-wide toxicovigilance system is similar to Option 1, but with additional filtering criteria. Poison centres receive thousands of calls per annum, many of which would provide less value to such a centralised database. An alternate option would be to allow poison centres to flag which calls they believe might be important for a central repository / or alternatively to gain agreement on criteria for what should and should not be submitted.

Benefits: Largely similar to option 1, but would require expert judgement over what is submitted centrally.

Challenges: Less onerous than option 1 for day-to-day management, but would have similar set-up and management costs.

Option 3: EU level body to provide guidance and steer to existing national toxicovigilance schemes with set requirements and targets. This option would leave the management of toxicovigilance (including data) at the national level but provide a more formalised system for how toxicovigilance is carried out and data shared.

Benefits: Formalisation of guidelines and approach would improve consistency in systems and further exchange of information between parties, without the need for new systems or significant additional resources.

Challenges: There would likely still be significant inherent comparability issues between different systems, which would require expert interpretation. As highlighted, available resources vary across the EU with some better equipped and more active than others. The main risk would be that some Member States may get left behind.

Table of contents

Appendix A Copy of project terms of reference

Appendix B Proposed Room paper for workshop co-ordinated by AISE

Appendix C Feedback from appointed bodies and poison centres following workshop

Glossary

Abbreviation	Definition	Reference
AISE	International Association for Soaps, Detergents and Maintenance Products.	AISE website
Annex VIII	Refers to Annex VIII of CLP regarding 'Harmonised information relating to emergency health response and preventative measures'.	Annex VIII of CLP (EU 2017/542)
Appointed Body	Body or bodies responsible for receiving information relevant, in particular, for formulating preventative and curative measures, in particular in the event of emergency health response, from importers and downstream users placing mixtures on the market. As per Article 45 of CLP.	CLP regulation (EC 1272/2008)
BfR	The German Bundesinstitut fur risikobewertung, appointed body for Germany.	-
CEFIC	European Chemical Industry Council.	CEFIC website
Cembureau	The European Cement Association.	Cembureau website
CEPE	The European Council of the Paint, Printing Ink and Artist's Colours Industry.	CEPE website
CLP	The Regulation on the classification, labelling and packaging of substances and mixtures (EC 1272/2008).	CLP regulation
Concawe	Concawe is a division of the European Petroleum Refiners Association, with the aim of carrying out research on environmental, health and safety issues relevant to the oil industry, including support to allow informed policy and decision making.	Concawe website
Downstream formulator	Downstream formulators are users within the value chain utilising mixtures previously manufactured or imported by other companies in the further formulation of new mixtures. These new mixtures can be further supplied to other downstream formulators or placed on the market as final mixture (product).	-
ECHA	European Chemicals Agency.	ECHA
EFCA	European Federation of Concrete Admixtures.	EFCA website
EFCC	European Federation for Construction Chemicals.	EFCC website
EIGA	The European Industrial Gases Association.	EIGA website
EMO Mortar	European Mortar Industry Association.	EMO Mortar website
Eurogypsum	The European Manufacturers of Gypsum Products Association.	Eurogypsum website
FEICA	Association of the European Adhesive and Sealant Industry.	FEICA website
Final Mixture	Refers to the mixture (containing a mixture-in-mixture) for a given product which is ultimately placed on the market.	-

Abbreviation	Definition	Reference
Fuels Europe	Fuels Europe is a division of the European Petroleum Refiners Association, with the aim of promoting economically and environmentally sustainable refining, supply and use of petroleum products.	Fuels Europe website
GPI	Generic Product Identifier.	CLP – Annex VIII (EU 2017/542)
IFRA	International Fragrance Association.	IFRA website
Importer	Any natural or legal person established within the Community who is responsible for import.	REACH regulation (EU 1907/2006)
INTCF	Instituto Nacional de Toxicología y Ciencias Forense, the appointed body for Spain	-
Interchangeable substances	Refers to a mixture component which has similar composition and the same technical function (including same hazard classification) provided by different suppliers.	-
Manufacturer	Any natural or legal person established within the Community who manufactures a substance (or mixture) within the Community.	REACH regulation
Mixture	Refers to a mixture or solution composed of two or more substances. This can be used within the same site of production for further formulation to produce final mixtures, or placed on the market for downstream formulators to use in production of further mixtures.	REACH regulation
Mixture component	Refers to a substance or mixture which is used as a component of a mixture. May be a substance or a "mixture in mixture".	-
Mixture in Mixture	When a mixture is used in the composition of a second mixture placed on the market, the first mixture is referred to as a mixture in mixture (hereinafter MIM).	CLP Annex VIII (EU 2017/542)
NACE	Nomenclature statistique des activités économiques dans la Communauté européenne. Statistical classification of economic activities in the European Union.	NACE website
Poison Centre	A poison control centre is a facility that is able to provide immediate, free, and expert medical advice and assistance over the telephone in case of exposure to poisonous or hazardous substances.	WHO
POS	Point of Sale.	-
Product	A product is a formulated mixture placed on the market for final use or further formulation in the production of final mixtures.	-
REACH	Regulation on the Registration, Evaluation, Authorisation and restriction of Chemicals (EC 1907/2006).	REACH regulation
SDS	Safety Data Sheet.	REACH regulation
SKU	Stock Keeping Unit. An identifier (usually an alphanumeric code) used to identify a particular product or service within a company for inventory purposes.	-

Abbreviation	Definition	Reference
SME	Small and Medium sized Enterprises.	EU recommendation 2003/361
Toxicovigilance	Toxicovigilance is the active process of identifying and evaluating the toxic risks existing in a community, and evaluating the measures taken to reduce or eliminate them.	WHO
UFI	Unique Formula Identifier.	CLP Annex VIII (EC 2017/542)
UMC Utrecht	University Medical Center, Utrecht. Appointed body and poison centre for the Netherlands	-
UVCB	Substance of unknown or variable composition, complex reaction products and biological materials.	REACH Regulation

1. Introduction

1.1 Study background

1.1.1 Introduction to the CLP Regulation and background to Annex VIII

The Regulation on the classification, labelling and packaging of substances and mixtures (EC 1272/2008) (CLP) is intended to provide a high level of protection to human health and the environment through a standardised approach for identification, classification and communication of hazards on chemical substances and mixtures. It places direct obligations on industry to carry out the assessment of their goods for classification and reporting through labels.

The CLP Regulation also sets in place provisions under Article 45(1) for creation of appointed bodies (which in some cases also act as poison centres). The role of appointed bodies is to receive information submitted by industry (importers and downstream users) for hazardous mixtures placed on the market and to formulate preventative and curative measures, in particular for emergency health response. This information is then used by poison centre operatives during live incidents to provide safety critical information to citizens and medical professionals. For example, during a poisoning case the hospital may only have the brand name of the good involved with no further information. The poison centre would hold further information on the composition of the good and toxicological expertise to be able to advise the attending doctor the likely effects and action that needs to be taken.

Articles 45(1) and (2) state that an appointed body should be created and that:

- Information provided by industry operators should include chemical composition and chemical identification.
- Information should be kept confidential and only used to (a) meet medical demand by formulating preventative and curative measures, in particular in the event of an emergency; (b) where requested by the Member State, to undertake statistical analysis to identify where improved risk management measures may be needed.

The specific wording of Article 45(1) has meant that the poison centres in operation across the 28 EU Members are diverse both in their structure (e.g. some are specialist units in hospitals, some are civil service government administrations, and some are contracted third parties) but also in the kind of information that is collected from industry. Furthermore, for some Member States, more than one poison centre exists with efforts co-ordinated over a wider geographic area (for example Germany has eight regional poison centres).

For industry this diversity in data requirements and structure represents an additional administrative burden with varying kinds of information needed in different formats or levels of detail for each country they place their mixtures on the market. The level of administrative burden placed on industry varies widely from operations in Member States with less data-intensive systems to those with more data-intensive systems. For example, in some Member States provision of a safety data sheet suffices (Croatia, Czech Republic, Denmark, Estonia, Finland, Hungary, Ireland, Romania, Poland, Slovakia, and United Kingdom), while others have systems with more strict requirements on compositional information (such as Belgium, Cyprus, France, Germany, Hungary, the Netherlands and Spain) [5]. Furthermore in other cases, additional information such as photos of product labels is required (such as in Belgium and Spain), and some Member States charge fees for administration (such as Belgium, Finland, Hungary and Spain), while others are not.

Article 45(4) of the CLP Regulation includes a further requirement to review the possibility for harmonisation of data requirements once the CLP Regulation had been in operation for some

[5] Amec Foster Wheeler (2015) 'Study on the harmonisation of the information to be submitted to Poison Centres, according to article 45 (4) of the regulation (EC) No. 1272/2008 (CLP Regulation)', ISBN 978-92-79-35803-6 DOI 10.2769/90437.

time. Following a cost-benefit study designed to assess the implications of a harmonised approach with more prescriptive breakdown of notification requirements, Regulation (EU) 2017/542 was adopted – adding Annex VIII to CLP - to provide details of the harmonisation and what information should be provided to appointed bodies by industry.

Under Annex VIII, the date from which the obligation starts to apply depends on the end use of the mixture. These are 1 January 2020 for mixtures for consumer use; 1 January 2021 for professional use; and 1 January 2024 for industrial use. Notifications for mixtures that have already been notified under national legislation remain valid until 1 January 2025, though if the mixture is changed before this date, companies may need to make a notification according to Annex VIII[6].

The overall results from the cost-benefit study illustrated that, even with the additional costs of implementing the UFI[7], harmonisation of data requirements (assuming a middle position on the sliding scale between very data-intensive systems and very data-loose systems) would bring net cost savings for EU businesses of €550 million annually[8]. There would also be further benefits in providing a standardised approach such as comparable data between Member States, allowing comparable levels of advice/treatment throughout the EU, as well as facilitating emergency health response when mixtures are sold or otherwise moved into different Member States.

Given the complexity of the study, diversity of the industries involved and available cost data, the study results did also make use of some clear assumptions and caveats which are detailed in the study report. The study report did also identify some specific effects for some sectors, as well as assumptions and provisions of the harmonisation that could affect the balance of costs and benefits, such as sectors with large product ranges based on small incremental variations to a basic formula (e.g. the paints and inks and the soaps and detergents sectors). The study report concluded that grouping approaches for such sectors would limit the burden of reporting each and every discrete final mixture, with cost savings being important to the balance of costs and benefits (assuming such grouping was appropriate).

Additionally, the Commission has contracted further studies to look at the implementation of the UFI, in particular the use of IT tools which could be provided to industry to help standardise the approach to implementing the UFI and limit the cost impact on industry of developing their own bespoke systems. This was seen as particularly beneficial to limit the impacts on SMEs. ECHA has also commissioned studies to consider e.g. the feasibility of developing a central notification portal.

1.1.2 Reaction to Annex VIII and workability issues

In the run up to finalising and voting Regulation (EU) 2017/542, a number of industry sectors raised concerns about potential workability issues. For certain sectors specific provisions were taken up in the draft legal text. Only at a very late stage concerns regarding workability were raised by a number of other sectors. It was agreed in the regulatory committee to vote on the draft legal text provided that the Commission committed to studying those workability issues and amending the Regulation if deemed necessary. The study contract terms of reference (Appendix A) provide a summary of the issues identified by specific industry sectors.

[6] At the time of writing, an amendment to Annex VIII was being considered, the draft legal text of which would include postponement of the first applicability deadline to 1 January 2021. However, the amendment had not been adopted at the time of writing, so the original compliance deadline of 2020 is referred to in the study.

[7] A Unique Formula Identifier (UFI) is a 16 character alphanumeric code that unambiguously identifies the composition of a given mixture placed on the market. The UFI needs to be printed or affixed to the product.

[8] Study on the harmonisation of the information to be submitted to Poison Centres, according to article 45 (4) of the regulation (EC) No. 1272/2008 (CLP Regulation), 2015, ISBN 978-92-79-35803-6; DOI 10.2769/90437

1.1.3 Role of the current study

The original cost-benefit study completed by AMEC on behalf of the Commission identified that harmonisation of data submission requirements for poison centres was a positive step. The study findings illustrated potentially significant cost savings for industry (with some caveats), and a general consensus from both industry and poison centres that harmonisation was a desirable step to take (though with a small number of stakeholders disagreeing on this, and differences in opinion on the form that a harmonised system might take).

However, the abovementioned workability issues raised by industry present new issues which were not included within the consideration of the original cost-benefit study, since the latter study did not fully reflect the final adopted requirements of Annex VIII. Therefore there is a need to review the potential workability issues raised by industry and detailed in the study terms of reference (ToR) (see Appendix A).

The aims of the current study are to assess those specific workability issues raised by industry (and mentioned in the terms of reference) to define how significant they might be, the magnitude of costs associated with each issue and – if the issues are considered significant - potential options for their resolution. This is Task 1 of the study.

In addition to the specific workability issues raised by industry, the study is to examine the issues associated with 'mixture-in-mixture' provisions and, in particular, the implications of the interpretation that mixtures produced in an industrial setting upstream ('original mixture') and integrated by a downstream formulator in an industrial setting into a mixture for consumer/professional use ('final mixture') are to be considered as mixtures for consumer / professional use. In certain cases, due to the dilution of the 'original mixture' in the 'final mixture' the information contained in the Safety Data Sheet, if any, could be sufficient to provide the necessary information on the relevant mixture components.

In specific cases (i.e. cosmetics) it is also possible that the final mixture may be exempt from the scope of CLP as it is already covered under other related legislation. In these cases where the final mixture placed on the market for consumer/professional use is not covered by CLP, only the setting of the original mixture should determine the kind of notification required. Therefore if a mixture is initially used for formulation under industrial settings, to become a "mixture in mixture" by incorporation into professional/consumer use products (as the final mixture) outside of the scope of CLP, the original mixture should be notified as per the requirements for mixtures for industrial use.

The current study also includes further modules of work relating to toxicoviligance and the possibility of an EU-wide toxicoviligance system. Currently most Member States operate some form of toxicoviligance scheme to assess the types of incidents that occur and allow early identification of trends where action may be needed. However, the aims and approach of different schemes can be diverse (e.g. separate schemes for pharmaceuticals, pesticides, consumer goods) and so there could be a benefit in establishing an EU-wide scheme following a more standardised approach. The current study will explore the obstacles and benefits to creating such a scheme.

1.2 Study objectives

The objectives of this study are as follows:

I. To analyse the workability of certain provisions of Annex VIII to the CLP regulation in relation to certain industries with complex material inputs and supply chains; and

II. To investigate and propose options to address the workability issues raised by some stakeholders if they are confirmed, without losing necessary information for appointed bodies/poison centres to perform their duties in accordance with CLP Article 45.

1.3 Structure of this report

This report is structured as follows:

- Section 2 provides a high -level overview of the study methodology and approach.
- Section 3 provides the findings for Task 1 on workability issues. This section is structured into the specific industry sectors identified in the terms of reference in sequence.
- Section 4 provides the findings for Task 2 on mixtures in mixtures (MIMs)
- Section 5 provides the findings for Task 3 on toxicovigilance.
- Section 6 provides the final summary and further analysis of options suggested by industry, appointed bodies and poison centres
- Section 7 provides a final review of amalgamated options and possible way forward

2. Overview of methodology

2.1 Introduction

This section provides a high-level overview of the study methodology against the terms of reference (see Appendix A). The study commenced with an inception meeting held at the Commission's offices in Brussels on 17 July 2018. The overall approach and scope of work was discussed and agreed, which covers four discrete tasks:

- Task 1: Assessment of workability issues of certain provisions of Annex VIII
- Task 2: Analysis of provisions for mixtures in mixtures
- Task 3: Investigation of possible EU toxicovigilance systems
- Task 4: Organisation of a workshop

The study team also recognised the synergies and linkages between Tasks (particularly Task 1 and 2) and therefore have followed an approach which has utilised desk-based research, stakeholder contact, surveys, analysis and development of findings which culminate in a study workshop (Task 4). Following the workshop, delegates were invited to provide a further round of feedback and additional data which has been used to further refine the study outputs. This report provides the finalised findings of the study and details the workability issues, proposed potential solutions from industry, appointed bodies and poison centres, together with overall conclusions.

2.2 Study approach

2.2.1 Initial literature review

The study included an initial round of literature review. For Task 1 and 2 this included review of the position papers already provided by industry to better understand the workability issues raised during the development of Annex VIII. For Task 3 this included a review of information made available on the websites of EU poison centres, and contact with all EU appointed bodies listed on the ECHA website[9], to identify information on national toxicovigilance schemes.

Completion of this step provided an initial set of research upon which to further build and develop the study further.

2.2.2 Stakeholder engagement

The study has included two rounds of stakeholder engagement. Throughout July – September 2018 telephone conference calls and face-to-face meetings were held with all of the major EU trade associations for the sectors covered by Task 1. These meetings were used to further talk through the workability issues from the previous step and discuss the fine details of the issues identified. We also sought further information on any workability issues being addressed by industry or by industry in collaboration with poison centres.

Upon completion of this stakeholder round contact was established with all of the appointed bodies based on the ECHA website listings in late October 2018 and a series of telephone interviews held with appointed bodies/poison centres in November 2018. These conference calls were deliberately staged at a later point to use the findings from discussion with industry to further explore the potential impacts for appointed bodies/poison centres and again any solutions already being suggested.

2.2.3 Survey window

Following discussions with industry a set of survey questionnaires was developed (in conjunction with the Commission services) to gather both qualitative and quantitative information about the

9 https://poisoncentres.echa.europa.eu/appointed-bodies

workability issues, their impacts and possible options to address the workability issues. The study team recognised that the issues presented included both issues unique to specific sectors as well as cross-cutting issues. To provide the correct level of detail sector specific surveys were developed for seven sectors and disseminated through the EU trade associations for the Task 1 workability issues. These surveys went through three rounds of review and comment including the Commission and the trade associations before finalisation. The questionnaires were launched in mid-October 2018 and the survey ran for a period of 6 weeks, concluding on 7 December 2018.

Additionally, one further questionnaire aimed at further exploring the MIMs issue (Task 2) was developed based on the primary set of surveys. This was disseminated through Cefic in mid-November and ran for 3 weeks.

A total of 211 responses were received for the Task 1 surveys and 34 for the Task 2 survey. Note however for some sectors the industry associations collated all member responses and provided a single response as representative of their membership. This covers the industrial gases (EIGA) and the soaps and detergents (AISE) sectors. Also note that the responses also include 14 national trade associations who have provided consolidated responses on behalf of their memberships.

Telephone interviews were held with representatives of appointed bodies/poison centres from six Member States, with one additional Member State representative providing feedback in writing. Some face-to-face meetings were also held in order to obtain more detailed information on the workability issues.

2.2.4 Analysis and development of options

Following completion of the survey window data was collated and analysed to further help provide an understanding of the workability issues including quantitative data to further detail potential impacts. Section 3 of this report provides the findings of this analysis along with the options for solutions already being developed by industry and appointed bodies/poison centres.

2.2.5 Workshop

A study workshop was held in Brussels on 13th February 2019, attended by approximately 60 delegates, which represented national and European level trade associations, companies, appointed bodies, poison centres, the European Chemicals Agency and the European Commission. Prior to the workshop a background paper was developed and disseminated providing a high-level summary of the specific workability issues per industry sector and the proposed potential solutions. The issues identified were further grouped into five sets of common themes (which spanned industry sectors).

The workshop involved a combination of plenary sessions to present the preliminary findings of the study, break-out sessions to discuss each of the five groupings and feedback sessions to relay the discussions and seek further input. Following the completion of the workshop those in attendance were invited to provide further comments on the second interim study report, and in particular additional quantitative information on the scale of the impacts created by the workability issues. It was intended that this further feedback would be used to refine and finalise the study findings presented within the current report.

2.2.6 Further refinement

Following the study workshop (Task 4) further feedback was received from both industry representatives and representatives of appointed bodies and poison centres. This information has been used to further refine the study findings, in particular the quantitative data on the scale of the impact of the workability issues, and feedback from appointed bodies and poison centres on the potential solutions proposed by industry and discussed at the workshop.

As part of the further refinement of the study results a further targeted round of stakeholder engagement was held with selected appointed bodies and poison centres to develop Task 3

(toxicovigilance), in particular further characterisation of the costs and staff effort implemented by different appointed bodies under existing national systems.

3. Workability issues

3.1 Introduction

This section provides details of the workability issues raised across the sectors identified as being in scope. The aim of the section is to:

- Assess the correctness of the claims made by industry in terms of workability issues.
- Estimate the related costs for concerned businesses associated with Annex VIII
- Evaluate the benefits related to better and more detailed information for emergency health response and preventative action.

Annex VIII of the CLP Regulation defines the requirements for submission of information to appointed bodies based on the concentration ranges for mixture components within Tables 1 and 2 of Part B of the Annex. Furthermore, Table 3 provides details as to when a notification should be updated based on variations within the composition. Annex VIII of the CLP Regulation also sets regulatory deadlines for notifications depending on their end use (mixtures for consumer use, professional use or industrial use), as described in Section 1 of this report. For those mixtures produced and used only within industrial settings it is further possible to make use of a limited submission of data, using compositional information from the safety data sheet (SDS).

Sections 1.4 and 1.5 of Part A of Annex VIII further state that, if a notification has been made to an appointed body before specified compliance dates, even if not in accordance with Annex VIII, there is no need to comply with Annex VIII until 1 January 2025. However, if the product changes according to section 4.1 of Part B (e.g. change in any identified mixture component or change beyond the relevant concentration thresholds), then compliance is required for the notification update before placing that mixture, as changed, on the market.

As set out in Section 1, In the run up to finalising and voting Regulation (EU) 2017/542, a number of industry sectors raised concerns about potential workability issues. These issues are set out in the study terms of reference (Appendix A) and relate to the following sectors:

- Petroleum products
- Industrial gases
- Construction products (disaggregated to cementitious materials and other construction products)
- Paints
- Fragrances
- Soaps and detergents
- Others

Firstly, some context is provided on the needs of poison centres regarding notification of information (linked to the workability issues raised).

Following this, a description of the workability issues raised by industry is provided in a sub-section for each of the above sectors. Each sub-section provides an overview of the sector in question including the use of data gathered from industry specific surveys and bilateral discussions with industry associations for the purposes of this project. It then sets out the specific workability issues identified; the impacts of those workability issues for industry (as described by the industry); and potential solutions to address these issues (as suggested by industry). Note that the study has relied upon estimates provided by industry (e.g. on numbers of notifications expected to be required, and associated costs). It has not been possible to independently verify these estimates (because compliance with Annex VIII has not yet started); though the assumptions and results have been checked and challenged with the industry sectors where practicable.

This is followed by a section on feedback on the workability issues and industry-proposed solutions at the project workshop, and further feedback provided after that workshop, including additional possible solutions provided by poison centres and appointed bodies.

Note that the workability issues are summarised in Chapter 6 of this report, including conclusions on a possible way forward, taking into account the costs for industry.

Each subsection also includes discussion of any other issues identified which are considered to be out of scope of the current study but for which the Commission may nonetheless wish to be aware. These additional issues are provided for completeness but are not considered further under the current study.

Section 3.10 provides details of other sectors not specifically identified in the terms of reference, but which also wished to contribute to the study and have identified workability issues which align closely to those seen by the sectors covered under the study scope.

Finally, a summary of the significance of the workability issues is provided in section 3.11.

3.2 Context and needs of poison centres

3.2.1 Significance of poisoning cases in the sectors within scope

In order to provide context on the significance of the workability issues raised for industry against the implications in terms of emergency health response, some information is available on numbers of poisoning cases in each of the above sectors.

Information has been provided for Ireland, Italy, Finland, Germany, the Netherlands and Spain. Additionally, via CEPE the Portuguese poison centre (CIAV) has also provided data for paints. Table 3.1 provides the aggregated data for number of calls received per sector per country per year and Table 3.2 provides these values as percentages of the overall total calls received.

Those providing information commented that based on their respective call databases further disaggregation of construction products into 'cements, mortars and concrete' and 'other construction' was not possible. The respondents also commented that, while fragrances can have multiple applications, so in reality calls relating to fragrances may be spread across multiple product categories and therefore it was not possible to provide reliable total numbers of calls relating specifically to fragrances. However, Ireland and the Netherlands did provide some further examples for call rates linked to specific types of fragrances such as air fresheners and aftershave.

One further important point to note is that data for Italy and Germany within Table 3.1 has been provided for selected regional centres (for Italy data for the Milan and Bergamo centres was consolidated, while for Germany data from GIZ-Nord, one of eight centres, was provided). These data provide a sub-set for Italy and Germany respectively, but are understood to be representative of the situation at the national scale.

Table 3.1 Overview of the number of calls received by sector for those within the study scope for selected poison centres and appointed bodies

	IE*	IT**	FI	DE***	NL****	PT #	ES ##
Petroleum	<101	688	664	227	469	-	396
Industrial gases	No data	No data	400 toxic gases	15	No data	-	250
All construction products ###	<101	76	No data	144	124	-	824
Paints	69	382	915	354	334	53	327
Fragrance	137 (air fresheners) 42 perfumes and aftershave 172 essential oils	No data	No data	No data	563	-	No data
Soaps and detergents	1,267	892	4,801	4,931	1,931	-	15,403
Total calls received by poison centre	10,144	44,789	30,380	36,563	47,593	26,236	82,761
Year	2017	2014	2018	2017	2017	2018	2018

Data provided by National poisons information centre of Ireland, the Italian Ministry of health, the Finnish Safety and Chemicals Agency (TUKES), GIZ-Nord Germany, the Dutch Poison Centre and Instituto Nacional de Toxicologia y Ciencias Forenses (INTCF) in Spain.

*Ireland: Responses for Ireland were provided as percentage rates for different sectors against total calls received. For continuity these values have been converted to call rate values. Where <101 is seen this denotes <1% per annum.

**Italy: Data provided by the Italian Ministry of health covers information from two regional poison centres (Milan and Bergamo) as a sub-set of Italy, noting that the Milan Centre represents 75% of all Italian poison centre calls and that five regional poison centres exist (Milan, Bergamo, Pavia and two in Rome). The information provided is expected to be representative for Italy as a whole.

***Germany: https://www.giz-nord.de/cms/images/JaBe/2017/Anhang1.pdf. Translations kindly provided by BfR (personal communication, 9 May 2019). Data represent c. 17% of calls to all poison centres in Germany (eight regional poison centres exist in total) but are understood to be representative of data in Germany as a whole. Note, no data are available for fragrances specifically; they are incorporated into a wide range of different products e.g. cosmetics (2,458 cases but note that cosmetic products are exempt from the notification requirements under Annex VIII as there is a separate notification process).

**** Netherlands: Dutch Poison Centre (personal communication, 16 May 2019). Note that fragrances may be used in many different sectors, the data for fragrances provided in Table 3.1 is based on fragrances used in air fresheners. Also note that the estimates for construction do not count incidents involving adhesives and sealants which are managed within a different category under the EuPCS. Note that for petroleum the number of exposures is probably an underestimation since petroleum containing products are split over many categories of intended use in the Dutch PCS. Note that for soaps and detergents the Dutch PC included the Dutch PCS categories 'laundry detergents', 'all-purpose cleaners' and 'dishwashing detergents'. Finally, please note that around 50% of all calls received to the Dutch poison centre relate to medicines.

Portugal: Call rate data for Portugal was provided by CEPE for the paints sector via CIAV.

Spain: Data provided by INTCF notes that data provided covers total number of calls received for the poison centre in Spain. INTCF wished to make clear that 52.7% of all calls received in Spain relate to poisonings related to therapeutic drugs.

Further disaggregation of data for construction products was not possible.

Table 3.2 Number of poison centre calls expressed as a percentage of total number of calls received

	IE	IT	FI	DE	NL	PT	ES	Average
Petroleum	<1%	1.5%	2.2%	0.6%	1%	-	0.5%	1.1%
Industrial gases	No data	No data	1.3%	0.04%	No data	-	0.3%	No estimate
Construction products*	<1%	0.2%	No data	0.4%	0.3%	-	1%	0.6%
Paints	0.7%	0.8%	3%	1%	0.7%	0.2	0.4%	0.9%
Fragrance	3.5%**	No data	No data	No data	1.2%	-	No data	No estimate
Soaps and detergents	12%	2%	15.8%	13.5%	4%	-	18.6%	11%

* Further disaggregation of data for construction products was not possible.
** Covers calls related to air fresheners, perfumes and aftershave, and essential oils

3.2.2 Needs of poison centres in the context of workability issues

Overview

Under Article 45 of the CLP Regulation, Member State Competent Authorities are obligated to create appointed bodies, responsible for receiving information relevant to emergency health response. Member States may also voluntarily appoint one (or more) poison centres tasked with providing emergency health response during real incidents. In some cases the appointed body and poison centre are one and the same institution. In other cases they are separate bodies where one institution will receive and collate the notifications from industry and the other will use that data to provide responses.

Representatives from the appointed bodies and poison centres were actively involved in the discussion during the development of Annex VIII as the information requirements are key to providing responses effectively. Therefore, this set of stakeholders represents a key group to seek further feedback regarding the workability issues.

As indicated within our methodology (see section 2) first contact was made with industry to fully understand each workability issue (and described in the later sections in the present chapter). Subsequently contact was established with appointed bodies and poison centres using the official contact list on ECHA's website[10]. A series of interviews was then held to discuss the workability issues, potential impacts to appointed bodies/poison centres, and any solutions to the workability issues already developed by appointed bodies/poison centres alone or in collaboration with industry.

Based on the contact made interviews were held with the Centres in:

- Belgium (Belgisch antigiftcentrum);
- France (Centre hospitalier régional et universitaire de Nancy);
- Germany (Bundesinstitut für Risikobewertung);
- Ireland (Irish National Poisons Information Centre);
- The Netherlands (University Medical Centre Utrecht); and
- Spain (Instituto Nacional de Toxicología y Ciencias Forenses)

Written comments were also provided by the Bureau of Chemical Substances in Poland (appointed body).

This section provides summarised feedback of the key discussions and points raised during the interviews held and takes into account the written feedback from the Polish Centre. It is intended

[10] https://poisoncentres.echa.europa.eu/appointed-bodies

to provide context on the needs of poison centres. Feedback on specific workability issues is provided in the later subsections on each sector.

Importance of data

The first topic explored with the appointed bodies/poison centres was the importance of data and full composition provided by Tables 1 and 2 of Annex VIII. The feedback from the different representatives varied based on personal opinion but all agreed that obtaining the full composition of products was of high importance, and thus the compositional ranges quoted within Tables 1 and 2 were appropriate for the needs of emergency response.

Two interviewees highlighted that a safety data sheet provides the major classified (i.e. hazardous) components of a product, but that this leaves a 'gap' between the information provided and full composition. Where such gaps exist poison centre responders have to respond cautiously, which means a less effective response and potentially over-treatment. Another issue is that, due to the variable quality of safety data sheets, key data such as pH (if applicable) can be missing. This then requires responders to complete further searches for information on the internet, which can delay response and, if unsuccessful, means that once again a more limited and cautious set of advice has to be provided.

The standardisation of data requirements was seen as being of significant benefit by all the interviewees. One interviewee highlighted that currently each Member State implements its own system with its own requirements. As international trade and travel become more common, the potential for goods bought in one country to be used in another country increases. The incidence of needing to request information from other poison centres can therefore be expected to increase. Under the existing system they report that it can be difficult to predict what kind of information may be supplied and in what format, which makes providing response more challenging.

All of the interviewees also highlighted the importance of the UFI to quick identification of the full composition. They all agreed that this was an important tool and welcomed its implementation.

Importance of low concentration mixture components

Discussions were also held on the importance of knowing mixture components that are present in low concentrations, which can cover both hazardous and non-hazardous mixture components. The workability issues described later in this chapter highlight that, in a number of cases (for different reasons), there may be frequent updates to UFIs and submissions created by variations in low-concentration mixture components. Therefore the importance (to emergency health response) of knowing the low concentration mixture components was discussed. This highlighted mixed opinions with the salient points raised being:

- It can be very difficult to determine the importance of low concentration mixture components. This is because the nature of the hazard, product type and type of exposure all vary. In some cases, for some products (e.g. pesticides), this information could be needed. Therefore in order to have a fair and simple system some poison centres suggested that all information on low concentration mixture components should be provided. This includes any updates following changes in composition.
- Emergency response calls typically last between three and four minutes, meaning that the responder has to quickly assess and understand what hazards may be present and what advice is needed. If the product composition provides a long list of mixture components at 0.1% w/w or less it is less likely that this information might be useful, particularly if the higher concentration components pose greater concern.
- Data on low concentration mixture components is important, but so too is clarity. For example, it is possible to provide compositional data of a mixture component (a MIM) separately. This means that the responder has to perform calculations to work out whether the individual mixture components are important to the response.

The question on the role of low concentration mixture components in formulating emergency health responses provoked a range of opinions, particularly when further considering need for data on hazardous or non-hazardous components. One interviewee further referred to the EAPCCT guidelines drawn up in 2013, which formed the basis for discussions during the early development of Annex VIII of the CLP regulation, and included a note to industry on why low concentration mixture components may be of importance for emergency health response[11]. This note provides further context to the importance of data on low concentration mixtures.

Another point raised by one interviewee was the role of the data. The interviewee noted that around 25% - 40% of the centres in operation act as both an appointed body and poison centre, and therefore complete both tasks of providing emergency health response and formulating preventative measures (based on toxicovigilance), but for 60- 75% of the EU, appointed bodies and poison centres are different organisations or departments of organisations.

For the poison centres the primary focus will be providing emergency response where the key thing will be to have full sight of the complete composition. The appointed bodies conduct a different role, which includes taking receipt of the information provided by industry and collating this for use by the poison centres. Furthermore, however, the appointed bodies also have a role to manage toxicovigilance. Low concentration mixture components and updates to reflect varying composition affecting such components would be of importance for toxicovigilance to identify whether these substances were the source of an issue. The interviewee commented that care is therefore needed to consider who is using the data and for what purposes as different data users will have different opinions over what is considered of importance. For example, a SDS might provide 60% of the composition with 40% unknown (i.e. the non-classified portion). This may create an issue for how an emergency response is formulated. The interviewee highlighted that provided there is no gap or the gap in known composition is very small it is possible to provide an accurate emergency health response and avoid over-treatment. On this basis they conclude that information on very low concentration mixture components at or below 0.1% w/w would be less useful. The interviewee suggested that for toxicovigilance there may be greater interest to collect all information including all mixture components classified as hazardous even when at or below the 0.1% w/w concentration.

Importance of data for large product ranges based on similar composition

As part of the interviews conducted, the discussion also explored the topic of the expected submission of notifications for large product ranges but with only small incremental changes to composition (e.g. with paints). The requirements of Annex VIII allow for the use of GPIs but only where mixture components are not classified for health hazards. The interviewees had mixed opinions on this issue, depending on their perceived importance of the data to provide emergency health response.

Most considered that it is of high importance to have a full and complete breakdown of composition for all mixture components in order to assess the product swiftly and provide a targeted response. However, all interviewees also agreed that it would be less beneficial and useful to have a notification for each and every type of e.g. paint on the market. Therefore, they consider that grouping approaches are needed to limit the number of notifications.

[11] Note to industry (based on comments received from Dutch Poison Centre):

Poison Centres request a complete composition because Poison Centres perform individual risk assessments after exposure and take into account all ingredients in a mixture. Information on non-classified ingredients can be of concern in case of: intake of large doses; unusual exposure routes (e.g. parenteral); presence of substances causing equal toxic effects – each below the 1% threshold, but above the 1% threshold if concentrations are added up; interference with metabolism (enzyme inhibitions e.g.) or mode of action of accompanying toxic ingredients. Besides, even if substances are not classified as hazardous, Poisons Centre experience from human exposures can differ and can show more serious effects. Especially if substances are not classified due to lack of data.

Increase in the volume of notifications

Industry expects a significant increase in the number of notifications made to appointed bodies as Annex VIII is implemented. Therefore, a discussion was held on whether such an increase would present any issues for the appointed bodies in terms of managing the administrative burden. All of the interviewees (save for one) highlighted that they expected the number of notifications to increase compared to the situation prior to implementation of Annex VIII.

The interviewees at poison centres and appointed bodies commented that the current rate of notifications per annum ranged from 10,000 to 45,000 notifications per Member State. In terms of the amount of additional notifications expected, the interviewees commented that it was very hard to predict as the new system is not yet in place. However, the majority of interviewees expected the volume of notifications to at least double, and possibly be as high as four times the current volume of notifications. One interviewee commented that, with implementation of Annex VIII, the increase in notifications could be expected to be 2-4 times the current rate received, but factoring in the workability issues highlighted could be as much as 10 times the current rate of notifications[12].

In terms of what practical or administrative burdens this might represent, many of the appointed bodies/poison centres commented that existing systems were already unlikely to be able to suitably manage the changes presented by Annex VIII and would likely need revision anyway. The majority of the interviewees commented that they were currently (in late 2018) in the process of upgrading their IT systems and aligning these to the new ECHA portal. Once complete the new systems would be fully automated and mean that the increase in notifications would not present any specific practical difficulties[13]. However, one interviewee commented that they had no specific plans to put new IT infrastructure in place and instead planned to take data directly from the ECHA portal during an incident. This would limit the need for additional local servers or databases.

One interviewee commented that the current system for notifications involved processing emails from industry and was very labour intensive. The new system would therefore represent a decrease in administrative burden as it was more automated. However, there would also need to be new resources put in place for the maintenance of the new IT systems. The same interviewee indicated they may need two more full time equivalents to manage the additional management of systems, but this would depend on how much the workload really increased.

3.3 Petroleum products

3.3.1 Overview of sector and relevance to poison centres

Industry Overview

Data from Eurostat states that in 2016 there were 270 companies across the European Union involved in crude oil extraction (including drilling, transport/shipping, and refining) and 1,019 downstream companies manufacturing refined petroleum products (based on the applicable NACE code[14]). The extraction of crude petroleum had a turnover in 2016 of €15.2 billion while manufacturing of refined petroleum products had a turnover of €416 billion.

[12] See also sections 3.3 – 3.10 for the specific industry sectors covered by the scope of the current study that have provided their own estimates for potential increase in rate of notifications under Annex VIII.

[13] The study team contacted all appointed bodies, but only held interviews and discussions with a sub-set that expressed willingness to do so. Those that took part in interviews highlighted that work was ongoing to upgrade IT systems in line with the new ECHA portal. However, it is not possible to comment that this is the case for all EU appointed bodies.

[14] Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) [sbs_na_ind_r2]

Fuels Europe[15], which represents the oil refinery sector (as a subset of the overall extraction and processing of oil) provides further statistical data in their 2017 report. This report states that there are 79 refineries active in the EU of which 11 are operating in Germany, 9 in each of Spain and Italy, 7 in France and 6 in each of the UK and the Netherlands. The report also states the total number of fuel stations in Europe was around 116,000 stations in 2016 with Italy, Germany, France and Spain accounting for 50% of these.

The survey (for this study) for the petroleum products sector was completed by 26 respondents including Concawe[16], one national trade association (based in Germany, Mineralölwirtschaftsverband[17]) and 24 companies of which 18 are active across multiple EU countries. Companies operating in a single Member State were operating in Germany, Austria, Sweden, Italy and Romania. All of the 24 companies that completed the survey were in the large company size bracket. No responses were received directly by SMEs, although it is unclear whether the national trade associations responding also cover SMEs.

Based on the questionnaire responses:

- The number of products (hazardous mixtures which are to be notified under Annex VIII) per respondent was between 3 and 750, with an average of 196 hazardous mixtures per respondent. It should be noted that the companies surveyed represent different roles within the supply chain, which is one of the factors influencing the number of mixtures per company.
- On average, 83% of products (mixtures) are subject to the requirements of Annex VIII due to the health hazard classifications of components included. However, on average 97% of fuels and 38% of lubricants are affected.

Respondents were reported to fulfil a variety of roles[18] dependent on their business model with 17 out of 24 companies operating across all the supply chain as manufacturer, importer and downstream user.

According to the industry, petroleum products placed on the market include REACH registered substances such as gasoline, diesel, base oils and fuel blending components. The sector also includes formulators of lubricating oils and mixtures such as blended fuels and fuels with additives (e.g. oxygenates and complex performance additives). The sector works in compliance with the Fuels Quality Directive 2009/30/EC (FQD) and the Standards EN590 (automotive diesel) and EN228 (automotive unleaded petrol). Many of the products concerned are therefore treated as equivalent if they meet one of these standards. Industry did also highlight that while the FQD forms an important part of fuel development within the industry, not all fuel mixtures placed on the market are required to meet the standards, this includes in particular blend stocks, which are then further blended to meet final specifications for finished fuels. No further information was provided on what proportion of petroleum products are non-standardised in this way. Industry comment that, in cases where there is an absence of standards, all fuels and lubricant products are governed by technical and product specifications which limit their compositional variability.

[15] Fuels Europe is a division of the European Petroleum Refiners Association, with the aim of promoting economically and environmentally sustainable refining, supply and use of petroleum products. Fuels Europe represents 41 companies in the EU accounting for 100% of refining and 75% of EU motor fuel retail sales.

16 Concawe is a division of the European Petroleum Refiners Association, with the aim of carrying out research on environmental, health and safety issues relevant to the oil industry, including support to allow informed policy and decision making. Concawe represents 41 companies that operate petroleum refineries in the European Union.

17 Mineralölwirtschaftsverband represents 14 companies based in Germany involved in the refining of oil and distribution of petroleum products.

18 Role as defined under CLP (manufacturer, importer, downstream user, distributor), a mixture formulator being a downstream user.

Relevance to poison centres

To help further characterise the relevance of the sector for emergency response, appointed bodies and poison centres have been asked to provide data on the volume of emergency calls received per annum related to petroleum products. Responses were received from appointed bodies and poison centres in six Member States (Ireland, Italy, Finland, Germany, the Netherlands and Spain). Based on the reported data an average of 1.1% of all calls to poison centres relate to the petroleum sector. See also Table 3.1 and 3.2.

3.3.2 Workability issues raised by industry

Issue PP1: Mixture variation in continuous blending process

According to the industry, oil is a naturally occurring substance, which by its nature will vary in composition. The manufacture of petroleum substances (including lubricant base oils and insulating oils) are produced to EN standards and/or technical specifications. This means that while the major mixture components are well understood, specific composition (as per the Annex VIII requirements) may vary due to the natural variations in the natural base material (crude oil). Petroleum products (i.e. mixtures) are produced as a continuous blending process meaning that there can be frequent small incremental compositional changes. Industry asserts that these small but frequent incremental changes are sufficient to mean that there would be a need for frequent notification updates.

The respondents to the survey highlighted that petroleum products are regulated under the Fuel Quality Directive 2009/30/EC (FQD), which works toward a single fuel market and compatible fuels produced by different manufacturers. The industry reports that finished petroleum mixtures that are placed on the market need to comply with European and/or international standards or technical specifications. Petroleum mixtures sold as feedstock for further processing or as a component for blending are typically made to a technical specification defined at the level of the industry sector or by individual customers.

According to the respondents, the standards mostly describe physical properties and required performance and do not typically contain concentration ranges for individual petroleum substances in a mixture. However, a number of standards establish concentration ranges for some components such as FAME[19], alcohols and ethers, and oxygenates. Permissible concentration ranges of additives in petroleum products are currently standardised through regulatory and industry bodies such as the European Committee for Standardisation (e.g. EN228 for motor gasoline and EN590 for automotive diesel fuel), API (SEA classes such as 15W-40 engine oil viscosity specification) and DEFSTAN for jet fuel. In particular:

- Standard EN228 allows blending gasoline with ethers and oxygenated compounds in concentrations up to 30% v/v (e.g.: 0-10% ethanol, 0-1% benzene, ETBE 0-22%, MTBE 0-15%).
- Standard EN590 allows blending of diesel with FAME and renewable fractions in concentrations up to 30% v/v.
- DEF STAN 91 allows blending of kerosene with biofuels up to 50%.

One point that should be made clear is that the objectives of the EN standards and Annex VIII differ, so as indicated the EN standards are primarily concerned with physical properties affecting performance. The standards do include compositional information for some mixture components found within petroleum products on the market, which would be useful, but it is unclear how directly attributable to the needs of emergency health response the EN standards might be in practice.

The industry further suggests that different batches of what industry considers to be the 'same' commercial product (under relevant standards such as EN590) can have sufficiently different chemical composition to necessitate separate Annex VIII notifications. Industry asserts that this would also result in multiple UFI numbers being generated for the 'same' commercial product,

containing the same ingredients (albeit in different concentrations). Industry has also indicated that it applies a hazard classification based on the worst-case composition of the ranges of hazardous components identified in technical standards.

A specific illustrative example has been provided by one of the respondents in Table 3.3 (below).

Table 3.3 Case study from petroleum industry on product variation in continuous blending process

Standard EN228 allows up to 0-10% ethanol while Annex VIII would only allow a 3% range for a given notified product. For lubricants, packages of the same product made from different base oils would require different notifications, different UFIs (and thus labels), Stock Keeping Unit (SKU) identifiers, and warehouse logistics (i.e. systems to track and manage goods within the warehouse, particularly if produced as different product sizes but have the same UFI).
Consider an example of a gasoline product 002D1924 "Shell FuelSave Super E10" with the following concentration ranges conforming with EN228:
Ethyl tert-butyl ether 637-92-3: 0-22%
Ethanol 64-17-5: 0-10%
Etherified Light Cracked Naphtha EC# 464-490-1: 0-35%
Gasoline 86290-81-5: 65-100%
Methyl tert-butyl ether 1634-04-4: 0-22%
Tert-amyl methyl ether 994-05-8: 0-22%
Concentration range widths stipulated in Annex VIII would result in about 600 possible permutations for such a product (excluding some permutations that are impermissible due to maximum oxygen limit). It should also be noted that not all listed ether components would be present in every single batch as these substances are interchangeable. For lubricants the number of permutations is around 3 (the number of interchangeable base oils per product).

The industry suggests that the frequent mixing of what industry considers to be technically the same product throughout the value chain, combined with the natural variations possible within petroleum products that use a natural feedstock (crude oil), would create the need for frequent updates to notifications. This would also include the need for many UFIs and analysis of fuels to confirm composition, which while possible, would pose a very significant practical challenge and economic cost. This is in comparison to the potential benefits of generating this data against a small number of emergency incidents (the Poisons Information Centre of Ireland indicates calls relating to petroleum products equates to 1% of total calls received).

The industry reports that it is concerned about ensuring compliance as it simply will not know the actual composition of the different batches unless each and every batch is subject to chemical analysis, due to variability of the composition of petroleum products because of blending of mixture components (including additives); the use of interchangeable mixture components; and continuous blending in tanks (mixing various batches of the same fuel). This will be especially problematic when filling tanks in depots and retail stations

Issue PP2: Complex distribution network

The petroleum industry sector highlighted that they use a complex distribution network, which includes reprocessing at many stages of the value chain (e.g. production of gasoline, blending with other mixture components (e.g. ethanol, detergents, other additives)), mixing of products during loading at terminals, and potentially at the filling (retail) stations themselves, noting that there are tens of thousands of filling stations across Europe.

The composition of petroleum products, can therefore change through the value chain as non-petroleum mixture components, such as ethers, FAME and ethanol, are blended into the product to meet technical specifications and as petroleum products from different suppliers are mixed.

The industry assert that the same infrastructure is used for products from different sources (with different compositions) and for example any residual petroleum products from previous batches will be present in new batches. For the industry this is currently not an issue as the blended products are considered the same (e.g. petrol according to EN 228). However, in order to identify/confirm that the product at any stage in the value chain is 'the same' according to Annex VIII, they would need to test each and every individual batch at each stage in the value chain where such mixing occurs. If such testing did identify relevant differences, this would trigger an update to the notification.

Survey respondents highlight that there are typically several suppliers of different additives that are introduced at different stages of the value chain and mixed in pipelines or in tanks. Most of these additives occur at lower than 1% concentration, but it would not be possible to know the exact concentration of these mixture components without further analysis at each stage where mixing occurs, and for each batch where composition may vary. The number of tests (and potentially notification updates) required as a result would create a significant logistical challenge for the industry. By the time the petroleum product reaches the depot it will contain a blended mixture from multiple suppliers (with multiple UFIs) and it will not be possible to know the precise composition of the blended product without such testing.

An illustrative example (France) was provided by one of the respondents as a potential worst case scenario. The example provided is intended to illustrate specifically what is meant by an industry with a 'rapid and high turnover' of products (as stated by the industry), and how the logistical and practical challenges of meeting compliance with Annex VIII of the CLP regulation may manifest.

Table 3.4 Example from petroleum industry highlighting complex distribution network

An illustrative example was provided for the supply chain involving primary depots (where correction additives are added), secondary depots (where company specific additives are added), distribution trucks and delivery to petrol stations, aiming to illustrate the impact of product composition changes due to supplier origins and variations in concentrations. The example covers:
300 days/deliveries in primary depots per year
5 suppliers of semi-finished petroleum base product
6 base products, Gasoil (GO, Diesel B7 & B0), Gasoline (E5 & E10) and GNR
1 UFI change per batch (one per day)
This results in 9,000 notifications to poison centres per year [Note 1] covering raw petroleum substances (no changes assumed to occur from suppliers).
At the secondary depot each batch delivered from the primary depot is stored in a tank. When a company specific additive for GO and Gasoline is added this results in a new product created for each of the base products (E5, E10 and GO). Referring to the 5 sources of base product supply, each tank at the secondary depot would generate further 4,500 notification (3*300*5).
There are more than 100 depots in France, which would result in around 1 million notifications per annum. As a further consequence of these notifications this would also mean that each and every fuel station in France would need to manage 260 SDS per annum for the same technical product. If the example of France is applicable to other EU countries, the number of notifications for just a few products will reach millions.
Note 1: In practice, it is understood that there would be a need to confirm the composition 9,000 times (presumably through testing) at each stage). Some of these may necessitate a new notification. Without such testing, it would presumably not be practicable to know from e.g. the UFI and other data supplied whether the composition remains the same in the context of Annex VIII.

The issue of traceability is of significant concern to the industry. Continuous blending of large volumes of fuel directly into pipelines means that the producer does not have information on whether the volumes blended are stored in one or several tanks at the other end of the pipeline. Furthermore where blended mixtures are stored in several tanks, there is no information available to the original formulator on which part of the blend is stored in which tank and in

some cases tanks are filled on top of a "heel" of product from a previous batch. Without this knowledge, in all cases where concentrations of blending components vary during the blend, no possibility exists for the blender to calculate overall concentrations of blending components in the final product.

The survey respondents, therefore, believe that it would be highly challenging (in their view impossible) to track the exact composition of every mixture. The industry view is that this would be a very burdensome bureaucratic task and would lead to very high numbers of notifications being submitted even for products with the same hazards (and which are considered by the industry to be the same from a technical perspective)[20]. The industry indicates that this could also lead to substantial delays/disruption to supply chains.

Issue PP3: Ongoing further mixing of different batches of petroleum products in storage tanks

The above issue is further complicated at the bulk storage stage. Bulk storage tanks such as retail filling stations are used to hold petroleum products. Industry highlight that these tanks have to be maintained at all times, meaning they rarely run empty, and that new deliveries will be placed in the same tank as the previous batch. This issue is presented separately from PP2 above because fuels from storage at filling stations are placed on the market to consumers directly, whereas the previous issue concerned mixing within the (industrial) value chain.

The industry suggests that if Annex VIII is followed to the letter, including consideration of mixture components with low concentrations, this will result in the potential need for each fuel retail filling station to notify poison centres after each fuel delivery, because of changes in the composition. (In practice, the fuel would need to be tested in order to identify the composition, and then notified if the composition had changed outside the thresholds in Annex VIII.)

An example calculation suggests that when a delivery is taking place once a week for 5 different fuel products this could result in 260 potential updates per year per station. When considering that there are tens of thousands of such retail filling stations across Europe, it is possible to extrapolate that the number of updates to poison centre notifications could reach the millions of notifications. Note, however, that this also assumes that the operators of such retail filling stations will be able to accurately calculate the exact composition based on the mixing of the remaining fuel in the tank with the next new delivery. Industry highlight that in practice this would be extremely challenging.

The industry also questions whether there would be any additional benefit in terms of emergency response from additional notifications required under Annex VIII due to only incremental changes in composition and toxicity.

Industry highlights that the fuel retail filling station will usually act as the only point of communication between the final customer and the petroleum fuel value chain. The industry highlights that where fuels are manufactured to technical standards (such as EN228), hazard classifications for the final mixture will vary little. (Note that feedback from the poison centres made clear that they would not only need to know the hazard classification but also details of the toxicological mode of action of the mixture components, in order to determine whether the same emergency response is required.).

Using the previous example of 260 updates per annum, industry argue that there would be a significant administrative burden with limited or no extra benefit. An emergency responder acting off a commercial trade name / technical product identifier may even be confronted with 260 entries for the mixture meaning that the responder will have to check these documents for differences in composition to formulate a response, which would delay emergency medical advice during a real incident. Feedback from poison centres on this issue was mixed, with some highlighting the importance of exact composition (particularly for toxicovigilance), while others highlighted that an over burden of data would create logistical problems (storage of data and

[20] See also section 3.3.6, and concerns raised that hazard classification alone does not provide information on potency, mode of action, etc.

speed of data systems for those member states that opt to create local databases and download copies from the ECHA database), as well as delay to response which is not desirable.

3.3.3 Impacts of workability issues

The industry survey respondents provided information on the current and anticipated number of new notifications and updates to notifications under Annex VIII[21]:

- The respondents taking part in the survey who provided data for the number of new notifications were all multi-nations companies. The responses provided cover companies headquartered in 10 EU Member States, while some stated that they traded in all EU Member States. The current number of new notifications as per Article 45 of CLP ranged from 50 – 6,800 per company, with an average of 2,000 per company. The responses also make clear that lubricants make up the majority of these notifications with fuels being a small fraction of the total.
- Based on the full requirements of Annex VIII the respondents commented that the number of notifications would increase. However, the complexity of the value chain made it hard to estimate what the likely increase may look like. Based on the responses an increase of between 3-fold and 25-fold on the current rate of notifications could be expected. The wide variation in this case may reflect the uncertainty over which variations in composition would trigger an update.
- A significant number of respondents also commented that they currently submit an SDS[22] to the appointed body and make zero notifications currently.
- The majority of respondents noted that they very rarely (or not at all) provide updates to their first notification as changes to formulations that would trigger the update are very rare at present under the current national requirements. Other respondents commented that updates to notifications were primarily driven by factors other than composition (e.g. change in product name).
- Expected frequency under Annex VIII will increase significantly for companies that are currently providing an SDS only. However, again, based on an analysis of the responses, the respondents do also highlight the difficulty in providing estimates due to the complexity of the workability issues already outlined. The responses from the survey reflects this fact with a very wide range quoted for potential numbers of notifications (hundreds to millions), and therefore due caution is needed in making use of such estimates.

Furthermore, the Annex VIII requirements will lead to frequent notification updates where frequent incremental changes occur, due to the use of interchangeable substances in petroleum products. Under Annex VIII this may be entirely appropriate, as poison centres have already highlighted that often an SDS is insufficient and that greater detail on composition is needed to provide an accurate and timely response. Survey respondents note that, for fuels, changes in composition as frequently as daily or even hourly were identified as potentially triggering a resubmission, while for lubricants, weekly to monthly frequency was indicated. Industry indicate that there would be a significant logistical and practical challenge to develop the information needed given the fast-paced turnover of product. Industry asserts therefore that a measured approach is needed to manage the potential practical issues against the potential benefits for poison centres.

Therefore, industry asserts that the main impacts associated with these workability issues are a vastly increased number of submissions/UFIs, with very rapid changes, but also that compliance

[21] 24 companies out of hundreds/thousands of companies involved in refining, blending and distribution of petroleum products, and hundreds of thousands of sites supplying fuels to professional and consumer users.

[22] Note that the feedback from poison centres highlighted that for emergency response requiring medical intervention, often an SDS is insufficient as only the mixture components classified as hazardous are required to be listed (with concentration ranges). This can leave big gaps in the compositional information which affects emergency response.

will be very challenging (in their view impossible) due to the blending and mixing of comparable and interchangeable (i.e. the same technical function and hazard) – but compositionally different - products throughout the value chain.

The survey also asked respondents to provide further information on the expected costs of completing notifications and updates of notifications under Annex VIII. Eight (out of 26) respondents provided data for these questions, again stressing that providing estimates was highly challenging as the requirements of Annex VIII were not yet in place and details of practical implementation requirements for submission had not been finalised. Table 3.4 provides a summary of the responses provided with the caveat that the estimates provided are subject to significant uncertainty and should be used with some caution. Furthermore it is important to acknowledge that they represent a response from only a small part of the overall industry sector.

As a further example of costs, Concawe[23] has provided an example for motor fuels. Concawe comments that motor fuels are first produced at refineries (or imported to refineries for further processing), subsequently they are distributed across the supply chain including storage tanks (where further blending can occur) and finally to fuel stations. The storage tanks at fuel stations never run empty and new deliveries are placed in the same tank as existing stocks leading to further blending. Therefore, the only way to provide specific composition of the final mixture sold to consumers would be to undertake sampling and analysis at fuel stations each time a new delivery is added to a fuel tank. The specific composition and UFI could then be generated at this point.

Typical analysis per sample will cost €200-250 for petroleum and €50-70 for gas oils (diesel). Analysis would be completed using gas chromatography (GC) and infra-red spectroscopy (IR). On average four fuels (two petroleum and two gas oil) are stored at each fuel station and refilled every other day. Therefore the following cost calculation can be used to illustrate the potential scale of costs:

Petroleum

€200 (petrol analysis) x 2 (fuels) = €400 for both fuels.

182.5 sampling events per annum (refuelling every other day).

€400 x 182.5 = €73,000 per year per filling station.

Diesel

€60 (diesel analysis) x 2 (fuels) = €120 for both fuels.

182.5 sampling events per annum (refuelling every other day).

€120 x 182.5 = €21,900 per year per filling station

Total

Total cost per fuel station = €94,900 (€73,000 + €21,900) per year

As an example, Germany has 15,000 fuel stations, which would mean total annual costs for analysis of €1.4 billion per annum. For the EU as a whole, there were 74,340 service stations at the end of 2017[24], which would give costs of sampling of €7.0 billion per year[25, 26].

[23] Concawe, Letter dated 28th February 2019 following the study workshop held in Brussels on the 13th February 2019 (and in response to requests from the Commission for provision of additional data).

[24] FuelsEurope, number of petrol stations in Europe – end of 2017 (figure 51), https://www.fuelseurope.eu/dataroom/static-graphs/, accessed 26 March 2019.

[25] Note that EU-wide data have been added by the authors, based on extrapolation from the Concawe data.

[26] There would of course be benefits to the companies undertaking testing and providing relevant equipment to undertake such testing, as well as other socio-economic impacts associated with increased fuel prices, delays at service stations, etc.

However, note this approach would also equate to 770 samples for analysis annually, per fuel station (11.5 million samples annually for Germany, 57 million for the EU as a whole). GC/IR capacity to meet the needs of this analysis is not currently expected to be available. Concawe comment that a further investment of €770 million would be needed to expand analytical capacity to meet the needs of this analysis for Germany alone.

Additionally, costs would be incurred as staff time to complete the notification and generation of the UFI. A specialist technician (chemical engineer) would also be needed to carry out the sampling suitably. Industry indicate that this would require each fuel station to close for 90 minutes for analysis, impacting consumers.

Concawe comment that if this is not practical the only other alternative would be stricter control of the supply chain to reduce the further blending of petroleum mixtures. This would require an increase in capacity for storage tanks to avoid different mixtures being stored together. Based on Concawe's estimates one storage tank for petroleum products would cost around €6 million. France and Germany have more than 100 such depots, with double the current capacity required to manage the issue at a cost of €1.2 billion for France and Germany combined.

*Table 3.5 Estimates of submission costs for petroleum products**

Cost element	Estimated value
Analytical costs	Only two responses were received for this question: one respondent estimated costs of €30,000 per annum for their total product range. The other respondent estimated €34,000 per annum, provided as €50 per product, per annum.
UFI generation	Three Respondents reported costs in terms of working hours (0.5 FTE) per annum. Two other respondents provided data as total costs per annum, which based on estimated number of UFIs needed equates to €3,700 and €4,000 per UFI respectively. Further detail of what is covered by these costs was not provided. Six other respondents commented that material costs in terms of updating the UFI on SDS would be minimal, but would use staff time. An estimate of how much staff time was not provided.
Labels (label update to include UFI)	Three respondents highlighted that they do not currently print the kind of labels that would be needed. Therefore there will be both capital costs to buy new equipment needed as well as running costs. Two respondents both quoted capital costs of €30,000 – €40,000 for new printers. Two respondents commented on costs for labels, with one quoting €15 per new label and the other quoting €1,000 per label change.
Information technology	Only four respondents provided a response to this question, highlighting two things. Firstly, the IT systems in place are integrated to manage multiple aspects of operations, so it is very challenging to separate out the costs related to Annex VIII and the UFI. Secondly, new IT systems carry significant capital costs and then maintenance costs. Two respondents provide estimated costs of €4,000 and €1 million (unclear if this is annual or one-off). Two respondents provided time estimates.
Admin fees for appointed bodies	€ Only one respondent provided an estimate for the question. Not quoted here due to high level of uncertainty in being representative for whole sector.
Staff time	Four respondents provided time estimates ranging from 20-350 minutes / submission Four respondents commented that additional staff would be needed; three of these estimated between 1-2 FTE would be needed annually to manage the new processes.
Others	21 Respondents left blank or cannot provide a value Respondents listed SDS generation cost (2 FTE) and translation costs

* Table 3.5 provides the collated results from the industry survey conducted with the petroleum products sector. In a number of cases only a small number of responses have been received. Therefore extrapolation of collated responses for the entire sector is likely inappropriate. The data provided within Table 3.3 is intended to provide indicative costs recognising the uncertainty attached with a small sample set.

The survey respondents highlighted that, fundamentally for petroleum products and for fuels in particular, the issue is not so much cost (although this is very significant) but the impossibility to comply because of the lack of full traceability of compositions of individual batches.

3.3.4 Other workability issues raised

In addition to the above workability issues, the respondents participating in the survey have identified other workability issues. These are not considered to be within the scope of the current study but are noted here in order to allow possible further consideration by the Commission. These issues included:

Product composition confidentiality

The industry respondents highlighted that the content of some products, such as lubricants, is typically confidential. Providing information on product composition using narrow concentration ranges within the supply chain in order to enable the Annex VIII notification would, in their view, reveal confidential business information (e.g. from companies blending outside the EU to

importers in the EU or between competitors). However, ECHA has clarified that companies only need to supply the UFI within the supply chain; the detailed composition will be provided to appointed bodies and poison centres only receive the information relevant to performing their tasks[27].

UFI generation and use

The industry also seems to be unclear whether the previous submission (and associated UFI) becomes inactive following an update and what happens if a subsequent change in composition reflects previously submitted notifications (whether this would entail a new resubmission and generation of a new UFI). The obligation to submit the update and to update the SDS would affect individual batches and would create additional work for manufacturers including in relation to labelling.

The respondents also highlighted that in the case of consumer petroleum products (e.g. gasoline) the UFI number will not be readily known to consumers as there would be no specific label or packaging to place the UFI number on. However, as an alternative it has been suggested that the UFI could be added to fuel receipts as part of the commercial transaction.

A more general issue (broader than the scope of the current study alone) highlighted by the poison centres, is that the general public will be unfamiliar with what a UFI is or where to find it, especially during an emergency. Some Member States, in particular France, have already indicated that they plan to launch national awareness campaigns to help the generic public understand what a UFI is and its importance. This could also be managed in part by industry (i.e. at fuel filling stations) to manage communication

3.3.5 Industry suggestions on solutions to workability issues

Possible solution PP-A: Generic UFI

The industry proposed a number of solutions to address the need under Annex VIII for frequent updates and generation of multiple UFI numbers for petroleum product variations that have comparable composition and equal hazards.

Industry's suggested alternative solutions including the use of a single UFI per product which is representative of the composition and hazards (reflecting the worst case scenario i.e. the named substances with the worst hazard classifications present at the highest concentrations). The industry argues that the hazard classification and labelling as well as the management of emergencies are described in detail in the SDSs that (currently) present the most severe hazard classification and labelling recommendation. They propose to include this information in the notification to the poison centres fully covering all combinations of % w/w ranges for a particular, standardised petroleum product (e.g. according to EN 228).

However, poison centres have pointed out that, even if different mixtures have the same hazard classification, this alone is not sufficient to determine that the emergency health response should be the same (and hence obviating the need for multiple notifications for what is 'technically' considered the same product. Instead, information on wider aspects of toxicity, such as mode of action, is needed.

Using this approach generation of a new UFI would take place when the incremental change in the composition of a petroleum product would result in a change to the hazard (i.e. difference in hazard classification, toxicological mode of action and potentially other factors).

Industry suggest that this solution would reduce the burden on industry without compromising the quality of emergency health response information. They suggest that it would also avoid creating unnecessary burden on poison centres in relation to processing of multiple submitted notifications and updates.

[27] https://poisoncentres.echa.europa.eu/questions-and-answers.

Alternatively, the respondents suggested allowing a group identification to cover equivalent products with the same hazard by grouping closely related mixture components with the same hazards such as some of the base oils in lubricants and oxygenates in fuels. In particular, the respondents highlighted that most petroleum substance are made from natural substances and are inherently variable. Currently, for the purposes of classification and hazard assessment these substances are grouped into categories, however it is recognised that this approach is the subject of debate. The industry suggests that it would be entirely consistent with this approach to allow "families" of equivalent substances (in terms of hazard) to be grouped together in Annex VIII notifications.

The industry believes that Annex VIII should allow the acceptance of interchangeable substances in order to avoid triggering UFI changes and updates when using mixture components that are technically interchangeable and that also do not change the hazard classification or treatment options of the mixture when interchanged. A single notification would then be associated with a mixture with interchangeable Mineral Oils, or petroleum product components resulting in a single notification to be referred to in case of an emergency.

Possible solution PP-B: Compositional ranges in Tables 1 and 2 superseded by pre-existing technical standards

To address the issue of small incremental changes in composition of petroleum products resulting in frequent updates, the industry proposed to widen concentration ranges for petroleum products set out in Tables 1 to 3 of Annex VIII, for all mixtures subject to Annex VIII. In particular, some survey respondents referred to the proposal by CONCAWE through which Annex VIII would state that "The limits on concentration range widths in Tables 1, 2 and 3 of Annex VIII shall not apply to petroleum products, provided that a reference to a relevant specification or standard is included in the information submitted according to Section 1.2 of Part C of this Annex".

The respondents believe that the thresholds which trigger generation of a new UFI/update to notification should be compatible with the ranges of the classification so that small variations in the product composition (including due to variations in the feedstock) that do not cause a change in classification and labelling do not lead to resubmission.

Some survey respondents advocated removing the range width limits specifically for petroleum mixtures from Annex VIII including allowing a range of 0-100% as an option in instances where it does not impact hazard classification of the product[28]. They suggest that this could be applicable to fuels and interchangeable base oils for lubricants. More specifically, the respondents proposed that the notification system should recognise the 0 value (or a value close to 0 such as 0.00001%) to enable adding possible interchangeable components for Base Oils of petroleum fuel/gasoil bases. For instance, for Base Oils, where several very similar substances (same chemical family and classification), can be present interchangeably, the substances could be declared within a single submission. This would require including all interchangeable components in the notification that can possibly be present at 0% concentration accompanied by a commentary within the notification. This would allow notifying components that are not present in each and single batch of a mixture.

The respondents also referred to the approach used in France (French Tool SYNAPSE) that has been built without technical restrictions on concentration ranges. The approach allows for submissions indicating ranges that are wider than those stipulated in Annex VIII. Other documents and comments are provided in conjunction with the submission setting out the reason for wider ranges. In these documents, companies typically refer to EU or international standards and provide detailed descriptions of all components of a Petroleum Product (PP) and how the product is controlled according to quality standards. This allows the national authority to be fully aware of all possible chemicals and how/why these are used in a given petroleum product. This technical solution in France involves developing a generic UFI for each semi-finished base

[28] Note poison centres made clear that hazard classification alone is insufficient for emergency response, and different modes of action for mixture components with the same classification lead to different treatment options. Therefore consideration of these aspects also needs to be included.

petroleum product (for which there is a standard). The generic UFI is then provided for each standard via the National Industry sector for downstream formulators. This means that the downstream formulator is able to use the generic UFI for the base petroleum product plus a new UFI for the additives. Both UFIs plus the compositional amounts of base petroleum product and additive within the final mixture are then provided to the appointed body, hence reducing the overall number and burden of submissions.

3.3.6 Feedback from workshop participants on industry-proposed solutions

The study workshop held on 13 February 2019 further explored all of the workability issues and proposed solutions from industry (and included solutions put forward by poison centres). Delegates were also asked to provide further feedback in writing, particularly around the workability issues themselves and the solutions (PP-A (Generic UFI) and PP-B (Compositional ranges in Tables 1 and 2 superseded by pre-existing technical standards) referred to in Section 3.2.5. above) presented at the workshop.

The key points of discussion during the workshop highlighted the variable composition of petroleum products because of the natural content and the continuous blending process. Based on the requirements of Annex VIII it was highlighted that this would lead to very high numbers of notifications which represented both an issue for industry but also appointed bodies, who would have to manage and store all of the notifications received. Industry highlighted the issues went beyond economic impacts and represented a significant technical challenge, particularly for fuels stored together in the same tank where further blending was possible. It was commented that it could be practically very challenging to track and notify composition through the supply chain with the current infrastructural setup and working practice.

Further feedback on the proposed solutions to the workability issues identified was provided by the following competent authorities, appointed bodies and poison centres:

- Health Belgium (competent authority) wished to make a distinction between complex mixtures (which may contain significant amounts of natural components which are of variable composition by nature) and mixtures where in reality the mixture composition is known. For complex mixtures (such as petroleum, cement, mortar and perfumes) their complexity needs to be taken into account within the way that Annex VIII is applied. For other issues such as changing a supplier of a given mixture component, if there is really no change in composition, toxicology or mode of action then a notification update should not be needed. For appointed bodies, very high volumes of notifications will have impacts for storing data which ultimately may lead to slower systems and responses, which is undesirable.
- BfR (appointed body), highlighted concerns around a generic UFI or grouping approach for all petroleum products (PP-A). This was chiefly because such an approach would, in their view, render the UFI useless because a range of different mixtures with different toxicology and mode of action and treatment options could be banded under one UFI. BfR also highlighted that data submitted to appointed bodies is used for both emergency health response and toxicovigilance. The proposed option PP-A would lead to a significant loss of data which would be unacceptable to them. Regarding the second solution PP-B, BfR comment that more needs to be known about how the petroleum technical standards work in practice, but grouping mixtures with different modes of action and treatment options should be avoided. As an alternative, BfR proposed a new solution which expands upon PP-B:

  > *"The German AB solution 'G6' proposes that a new set of GPIs could be defined. This would involve a set of additional GPIs that represent predefined Group formulations (GFs) with wider concentration ranges and/or variable, but similar substances. Existing technical specifications might be applicable for the definition of these GFs, if appropriate for decision making in emergency health response".*

- The Dutch Poison Centre also raised concerns that a generic UFI / grouping for petroleum products (PP-A) would not be acceptable, again because of the risk that different mixtures

with different toxicological profiles and modes of action could be grouped under one UFI. The Netherlands stated that the proposed solution PP-B could be more acceptable, particularly if technical standards existed. The Netherlands was also supportive of the proposed solution from Germany which further amends PP-B (as quoted above).

- The poisons information centre of Ireland (appointed body and poison centre) comment that less than 1% of emergency calls received in Ireland related to petroleum-based fuels and therefore if implementation of Annex VIII to CLP would create very large numbers of submissions following minor changes in composition, this would create disproportionate amounts of effort for industry and appointed bodies. The proposed approach PP-A for a generic UFI or grouping would therefore have merit in their view, provided it was implemented in a fashion that did not affect emergency health response. In particular, the fact that technical standards already exist was seen as important.

To summarise, the feedback from competent authorities, appointed bodies and poison centres confirms that the workability issues identified would require a disproportionate level of effort required from both industry and appointed bodies, linked to the likely very high numbers of notifications. Concerns around the PP-A solution were raised and a suggestion made that this may not be an appropriate solution. However, solution PP-B may be more acceptable, including a possible new solution 'G6' proposed by the German appointed body (BfR) which would allow wider concentration ranges for pre-defined group formulations (see Section 3.2.6).

3.4 Industrial gases

3.4.1 Overview of sector and relevance to poison centres

Industry overview

The industry input to the study has been co-ordinated through EIGA[29], which represents the industrial gases sector (and which also includes medical gases). EIGA has 124 member companies and 30 national associations which cover the European, Middle-East, and North African markets. This includes all of the EU's largest manufacturers of industrial gases. EIGA note that 60 of their 124 members have a turnover of less than €40 million annually[30].

In 2008, the global industrial gases market was valued at €51 billion of turnover[31]. Within Europe, the sector employs approximately 45,000 people with 220,000 tonnes of industrial gas produced per day. Use of industrial gases varies by global geographic region, but for Europe the most common gases in use include:

- Air gases (such as oxygen, nitrogen and argon);
- Rare gases (such as helium, krypton, xenon and neon);
- Hydrogen;
- Oxides of carbon (monoxide and dioxide);
- Nitrous oxide;
- Chlorine and hydrogen chloride;
- Sulphur dioxide; and
- Fuel based gases (such as acetylene, methane and propane)

[29] The European Industrial Gases Association

[30] Companies with ≤€50 million turn over (and <250 employees) are considered as being in the SME bracket.

[31] https://www.eiga.eu/our-industry/industry-characteristics/

Based on the industry survey responses:

- EIGA comment that for their members' mixture portfolio, 57,000 different formula compositions[32] are placed on the EU market annually by 124 companies.
- 95% of the formulations placed on the market are produced as 'on demand' compositions to meet the specific technical requirements of clients, and are produced as blends of basic feedstocks often with short turnaround times of 1-3 weeks. Special case urgent orders can have a turnaround time of 48 hours or less.
- Based on the survey response for hazard classification, 30% will be classified for health hazards (17,100 product formulations) and 70% will be classified for physical hazards only, primarily flammable or oxidising properties (39,900 product formulations).
- Formulations can have as many as 300 mixture components at maximum (most have less than 75 mixture components). However, the average number of mixture components per product is five.

EIGA's members will fulfil the role of manufacturer or importer within the supply chain; however all of EIGA's members will also fulfil the role of formulator. All of the industrial gas products produced within the EU are blends based on mixture components that are either manufactured in the EU or imported.

Relevance to poison centres

Appointed bodies and poison centres were asked to provide further information on the proportion of emergency calls per sector covered by the scope of the study. Data provided by GIZ-Nord (one of Germany's regional poison centres), stated that for the year 2017 a total of 36,563 emergency calls were received, of which 15 (0.04%) related to industrial gases. Further data provided by Finland identified that in 2018 a total of 400 calls relating to industrial gases (1.3% of the total calls) had been received. Spain also provided data for 2018, with a total of 250 calls (0.3% of the total volume received) relating to industrial gases.

3.4.2 Workability issues raised by industry

Issue IG1: Poison Centre notifications for gases with physical hazards

Under section 2.2 of Annex VIII it was agreed that 'gases under pressure' and 'explosives' (which would include explosive gases) are exempt from the notification requirements of Annex VIII. Instead a SDS would be provided down the supply chain as a means of hazard communication. While physical hazards such as gases under pressure or gases with explosive properties are exempt, other physical hazards such as flammable and oxidising gases are covered by Annex VIII.

Industrial gases are produced as blends to meet the specific requirements of the industry's clients; this can include both simple and more complex blends. Within the industrial gases sector these products are referred to as 'on demand' products, and produced often with short turnaround times, with 1-3 weeks from receiving the order to providing the goods. The compositional ranges quoted within Tables 1 and 2 of Annex VIII would mean that each batch of goods would need to be treated as a separate product with its own UFI and notification to appointed bodies.

Monitoring the specific composition of each batch and completing a poison centre notification represents a practical and logistical challenge to the industry given these short turnaround times. This issue can further be exacerbated depending on the specific chemistry of the mixtures produced, noting that natural feedstocks can also be used in the manufacture of mixture

[32] Annex VIII excludes gases under pressure and explosive gases, but flammable and oxidising gases are included. The estimate is based on only those formulations requiring notifications under Annex VII.

components. Industry note that goods are produced to meet specific technical and physical properties which is reflected in their complexity.

Furthermore, compliance with the full requirements of Annex VIII also represents an administrative burden and cost to the industry. The response from EIGA notes that as part of its own due diligence a database of emergency incidents using data provided by members has been maintained since the 1970s. As part of EIGA's response under the current study the database was consulted for incidents involving industrial gases where it was necessary to seek the assistance of a poison centre. No such incident was identified in the database held by EIGA.

As a counter-factual, further information has also been provided from one poison centre in Germany (GIZ-Nord), where in 2017 a total of 15 emergency calls related to industrial gases were received, this amounted to 0.04% of the total calls for that year. No further information was available on whether the 15 incidents involved any gases with only physical hazards.

Therefore, the industry is concerned that it will be very challenging in terms of timing to complete and submit data and that there will be substantial administrative costs, while the benefits seem less clear.

3.4.3 Impacts of workability issues

The industry survey aimed to gather further data on the impacts of the workability issues by asking questions around the current number of notifications versus the number of notifications expected under Annex VIII. The response co-ordinated by EIGA for its members comments the following:

- EIGA assert that their members do not hold data on the number of notifications currently made to appointed bodies. However, the systems in place across Europe vary and in many cases submission of an SDS has historically been sufficient to meet their notification obligation.
- Under Annex VIII a total of 57,000 notifications annually would be expected (one per product), however further data on specific Member State sales was not available. This could include the need for provision of notifications in multiple languages (noting that this is already the case under the current system).
- EIGA comment that for the 57,000 notifications, 30% will be classified for health hazards, and the majority (70%) will be classified for physical hazards (flammability and oxidising properties). EIGA note that while the likelihood of needing a response from a poison centre on a gas with only physical hazards is very low, there would still be a significant administrative effort required of the industry, with only limited potential benefits to poison centres.
- The response from EIGA asserts that its members indicated that the industrial gas market is dominated by products produced as 'on demand' goods and used as such. This means that there would not be updates made to the appointed body for a given product, rather each new batch of goods would be treated as a new product with a new UFI and notification.

The survey also asked questions regarding the estimated costs of completing poison centre notifications. EIGA[33] as the industry sector association held meetings with its members and then collated the data to provide aggregated results, which are presented in Table 3.5. EIGA noted that developing cost calculations per submission was challenging, and that therefore estimates are provided for the entire sector (57,000 notifications annually).

Table 3.6 provides a breakdown of these costs provided by EIGA, including extrapolation to per-submission costs for continuity with other sectors (assuming 57,000 notifications per annum).

[33] EIGA – Letter dated 6th March 2019 as a response to the study workshop held on the 13th February 2019

Table 3.6 Estimates of total sector costs for industrial gases (EIGA) with extrapolated costs per notification in brackets.*

Cost element	Estimated value	Explanation
Development and submission of notifications**	€690,000 (€12 per notification)	Staff time to evaluate need for submission, creation of the submission file, submitting the file, following the acknowledgement/rejection of the AB, tracking the need for changes. Cost based on assumed hourly rate.
UFI generation	€71,000 (€1.25 per notification)	Cost based on assumed hourly rate.
Labels	€4.6 million (€80 per notification)	This includes capital costs for new printers, plus consumables, software license fee, etc., staff time needed to create and affix the label on the cylinder. Cost based on assumed hourly rate.
Information technology	€270,000*** (€4.75 per notification)	This includes development, deployment and testing of new systems, plus license fees, servers and storage fees
Staff time	€63,000 (€1.10 per notification)	Only staff time not mentioned in items above. Estimate is the result of the number of hours based on required process steps multiplied with an assumed hourly rate
Others	€350,000 (€6.14 per notification)	Staff time to update SDS
Total costs	€6.04 million per annum (€106 per notification)	-

*EIGA also provide estimates for associated administrative fees charged by appointed bodies as a total industry cost of €620,000 per annum. This information is provided for interest only as it falls outside the scope of the current study.

** Further discussion with one major manufacturer, an EIGA representative highlighted that during the discussions with EIGA those involved had developed cost estimates for the full process of developing and submitting notifications. As part of the industrial gas sector, the company in question noted that monitoring (analysis) of gas mixtures is commonplace to determine final mixtures for technical specifications, so analysis of mixtures is already in part routine to the function of the sector. No additional analysis would be expected for compliance with Annex VIII.

***Information technology costs assumed to be presented as annualised operating costs.

EIGA has also indicated, however, that the impacts of the workability issue are not only economic. The short turnaround times for developing 'on demand' gases, means that there is a practical time constraint in completing monitoring of gases to provide a full compositional breakdown, and completion of the administrative steps needed to submit a notification to the new ECHA portal. While most products have a turnaround time of 1-3 weeks, in specific cases the turnaround time can be 48 hours or less, making it extremely challenging to complete the necessary work for a notification.

3.4.4 Other workability issues raised

No other workability issues outside the scope of the current study were identified in the response provided by EIGA.

3.4.5 Industry suggestions on solutions to workability issues

Possible solution IG-A: Amendment of Annex VIII for physical hazards

EIGA highlight that products with some physical hazards (gases under pressure and explosives) are already exempt from the requirements of Annex VIII. A proposed solution to the workability issue identified by EIGA could be the following:

- For gases only with physical hazards a derogation could be added to Table 2 (possibly as a footnote) to allow deviation from the compositional ranges. The deviation would align with the CLP classification ranges for physical hazards, so that all gases with the same mixture components and same hazard classification could carry the same notification and UFI. So for example if an industrial gas contained hydrogen and nitrogen, where the proportion of hydrogen in the gas meant it was classified as 'highly flammable', then all other hydrogen and nitrogen mixture products with varying composition but the same classification could use the same notification and UFI.

Alternatively, another solution could be:

- The current exemptions under section 2.2 could be further extended to include the remaining physical hazards (flammable and oxidising) on the basis that they pose a similar level of risk, and that the likelihood of a response from poison centres covering these hazards is likely to be low.

3.4.6 Feedback from workshop participants on industry-proposed solutions

The key points of discussion during the workshop highlighted the large product range based on small incremental variations to the same mixture components. This issue is in part exacerbated by the short turnaround times associated with the on-demand market for industrial gases. The issue regarding gases with only physical hazards was also raised as part of the discussion.

Further feedback on the proposed solutions to the workability issues identified was provided by the following appointed bodies and poison centres:

- The German appointed body, BfR commented that the proposed IG-A solution (Amendment of Annex VIII for physical hazards) using a grouping strategy to allow all gases with the same mixture components and hazard classification to be notified in one group notification would not be acceptable as the loss of granularity in information may be problematic for appointed bodies and poison centres.
- The Dutch Poison Centre (appointed body and poison centre) commented that wider concentration ranges for gases with only physical hazards may be acceptable. The Netherlands also commented that, provided the gas only had physical hazards, it could also be possible to include further exemptions from notification obligation.
- The poisons information centre of Ireland (appointed body and poison centre) comment that, for gases with only physical hazards, the likely need for an emergency health response from poison centres would be very limited. Based on the described magnitude of the impacts a solution is needed according to the Irish poison centre, with either of the proposed solutions[34] an acceptable option for limiting burden for industry without significant impacts for poison centres. The Irish poison centre further suggested the IG-A proposed solution could be an acceptable option to limit burden while providing enough information for poison centres to formulate medical advice in an emergency.

To summarise, the feedback from appointed bodies and poison centres makes a clear distinction between all industrial gases and industrial gases only with physical hazards. For the latter category a grouping strategy such as that described with IG-A or a full exemption from notification could be suitable.

[34] IG-A or the extension of exemptions under Section 2.2, as above.

3.5 Construction products (cements (including mortar, gypsum and readymix concrete)

3.5.1 Overview of sector and relevance to poison centres

Industry overview

The industry input to the study has been developed in co-ordination with the major trade associations for the construction sector, which includes Cembureau, ERMCO[35], EMO Mortar, EFCC[36], EFCA[37], EuroGypsum, and FEICA[38]. Further input was also provided by the national associations for cements and construction chemicals in Austria (Austrian Cement Association), Bulgaria (The Bulgarian Association of cement), France (Syndicat National du Béton Prêt à l'Emploi), Germany (Deutsche Bauchemie e.V. (DBC) and Verein Deutscher Zementwerke e. V), Italy (AITEC), Poland (The Polish Cement Association), Portugal (Associação Técnica da Indústria de Cimento), Spain (Asociación Nacional de Fabricantes de Mortero and OFFICEMEN) and the United Kingdom (MPA) for a possible solution to the workability issues. During early discussions with industry, specific workability issues were identified for the manufacture of cement (including mortar and readymix concrete) which are distinct from issues for other construction products. Therefore, separate surveys were developed for (a) cement and (b) other construction products. These were disseminated via the aforementioned European trade associations. This section focuses on the workability issues for cement, with workability issues for all other construction products discussed in section 3.6.

Following the study workshop, it was agreed that while the same workability issues are presented for the cements sector as a whole (including also mortar and readymix concrete), the impacts will differ for different sub-sectors. In particular, it is necessary to disaggregate between the manufacture of cement as a commodity and readymixed products, in particular readymixed concretes. Furthermore, the production processes for mortar vary in terms of the number of mixture components, number of suppliers per mixture component and size of the potential product range. Therefore, this section is further disaggregated to provide the results for cements, mortars and readymix concrete separately.

- *Cement:* Data from Eurostat indicates that there are 348 companies across the European Union involved in the cement production sector (based on NACE codes) which would include both production and further processing of cement. The European Commission (2017) report on the 'competitiveness of the European cement and lime sectors[39]', comments that production for 2015 was between 105 million tonnes (Eurostat) and 125 million tonnes (industry estimates). Production is primarily focussed in Germany, France, Spain, Poland and Belgium which combined account for 71% of EU production. The Global Cement (2018)[40] publication for October 2018 further comments that there are 219[41] sites across the EU manufacturing cement. The European Commission (2017) report on competitiveness comments that the market is made up of approximately 20 major producers of cement but also includes a high number of medium sized enterprises. The industry employs 47,000 staff in the manufacture of cement across the EU.

[35] European Ready Mixed Concrete Organisation

[36] European Federation for Construction Chemicals

[37] European Federation of Concrete Admixtures

[38] Association of the European Adhesive and Sealant Industry

[39] European Commission, 2018, Competitiveness of the European Cement and Lime Sectors, ISBN 978-92-79-64665-2

[40] http://www.globalcement.com/news/itemlist/tag/European%20Union

[41] The Eurostat NACE code includes all companies involved in the manufacture of cement and lime, this will include the initial manufacture and subsequent blending, batching and redistribution of cement and lime. The data from the global cement production relates only to sites actively involved in cement manufacture. This will explain the difference in values quoted.

- In 2015, based on Eurostat data, the manufacture of cement was estimated to account for €15.2 billion turnover and €4.8 billion in added value to the EU. However, the European Commission (2017) competitiveness report also highlights a decline in production and turnover since the economic crisis of 2008, estimated to account for a decline in turnover by 37% between 2008 and 2015. The global cement (2018) publication also reflects this position and comments on the potential closure of manufacturing sites due to economic pressures and tightening regulation related to climate change mitigation.
- *Mortar:* EMO[42] states that 'mortar' is a generic term comprising masonry and repair mortars, plaster and renders, adhesives and screeds[43]. They are manufactured with a variety of technical performance levels to meet the requirements defined by the individual end use conditions (climatic, mechanical, etc.). Especially renders and plasters, which often contribute to architectural appearance, may in addition to their technical variety also be produced in a wide range of colours. EMO represents associations and manufacturers from 12 Member States (including EU and EFTA), which covers 70% of the total EU mortar production. Based on EMO membership, 195 manufacturers are operating within the 12 Member States[44] identified, with each company owning between 1 and 20 production sites. Each production site produces between 2 and 1000 products (average of 190). This equates to 40 million tonnes of mortar produced in the EU annually, with a combined turnover of €6 billion.
- *Gypsum:* Gypsum is a naturally occurring mineral which has important use in both the cement and mortar sector. EuroGypsum[45] is a European federation of national associations of producers of gypsum products (i.e. plaster and plasterboard). The companies which mine gypsum also process it and manufacture the value-added products and systems used extensively in construction and other industries. The Gypsum sector has a turnover of €7 billion per year. The European gypsum and anhydrite industry operates some 160 factories and 154 quarries and generates employment directly to 28,000 persons and indirectly for 300,000 persons. The gypsum industry provides jobs to 1,100,000 plasterers and plasterboard installers. It trains around 25,000 persons per year across Europe.
- *Readymix concrete:* ERMCO[46] comment that the use of Readymix concrete within the European Union has grown since the 1960s. This has evolved from around 2% of use of total European cement production to a current use of 65% of all cement produced. This equates to the production of 350 million cubic metres of readymix concrete per annum. The industry is made up of a set of large multi-national companies and 6,000 SMEs. ERMCO represents the national trade associations in fifteen of the EU Member States, with the members of ERMCO having a combined turnover of €13.2 billion per annum.

The survey was completed for the different sub-sectors as follows:

- For cement 23 respondents including eight national trade associations and 15 companies active across the EU completed the survey. All of the 15 companies that completed the survey were in the large company size bracket. No responses were

[42] EMO letter dated 4 March 2019, 'Feedback to the 2nd Interim Progress Report of the Study on workability issues concerning the implementation of Annex VIII of Regulation (EC) No 1272/2008 on harmonised information relating to emergency health response and preventative measures as well as to the workshop on 13 February 2019 in the context of it'.

[43] Note the feedback from EMO also references thermal insulation composite systems (ETICS), such systems include multiple mixture components (including mortar). However, this section will focus on the manufacture of mortar only, rather than further use by downstream formulators.

[44] Austria, Belgium, Czech Republic, Denmark, France, Germany, Iceland, Luxembourg, Netherlands, Portugal, Spain and the United Kingdom.

[45] EuroGypsum letter dated 28 February 2019, 'Eurogypsum's comments on workability issues – Implementation of CLP Annex VIII'

[46] http://ermco.eu/new/about/

received directly by SMEs, although it is unclear whether the national trade associations responding also covered SMEs.

- For mortars, 14 respondents completed the construction survey, including four large size companies, seven SMEs, and three national associations. Further comment has also been provided by EMO.
- For gypsum, Eurogypsum provided a response on behalf of their members.
- For Readymix concretes responses were received from ERMCO and the French national association (Syndicat National du Béton Prêt à l'Emploi).

Based on the completed questionnaires and input from EU level associations, Table 3.7 provides an overview for each of the sub-sectors covered by cements. This is intended to allow comparison of the differences.

Table 3.7 Overview of production for cements, mortars and readymix concrete

	Cement	**Mortar**	**Gypsum**	**Readymix concrete**
Number of products per company	Average 14 (range between 5 and more than 100)	Average 190 (range between 2 and 1,000)	150-350	150 – 200
Number of mixture components per product	3-10 (based on EN197-1)*	3 - 12	10-20	Average 8 (ranges from between 4 and 165)
Number of suppliers per mixture component	3-5	2-3 (two respondents claimed 5-10 and 'up to 13' respectively)	3-5	1-2
Proportion of products subject to requirements of Annex VIII	100%	100%	60%	100%

* The cement industry survey did not specifically include a question on the number of mixture components. Extrapolation from technical standard EN197-1identifies seven major mixture components in cement (clinker, slag, silica fume, clays, fly ash, burnt shale and limestone) plus additionally minor concentration (0-5%) mixture components such as chrome reducers).

Relevance to poison centres

As indicated in the preceding chapters, poison centres were asked to provide data on the total number of calls received by poison centres and what proportion of those calls came from the industry sectors covered by the current study. This is intended to provide an indication of relevance. Information has been received from appointed bodies and poison centres in Ireland, Italy, Germany, the Netherlands and Spain. Those providing data indicated that it was not possible to disaggregate between cements, mortars, gypsum, readymix concrete and other construction products. Data provided for emergency calls relates to all construction products and therefore will represent an overestimate for this sub-sector. However, despite that being the case the data provided indicated an average of 0.6% (range from 0.2 to 1%) of all emergency calls are related to all construction products.

3.5.2 Workability issues raised by industry

Issue CM1: Incremental variation of natural feedstocks in continuous production processes (affects cement and gypsum only)

Annex VIII of the CLP Regulation defines the requirements for submission of information to poison centres based on the concentration ranges for mixtures within Tables 1 and 2 of Part B of Annex VIII. Furthermore, Table 3 of Annex VIII provides details of when submission updates are required due to variations within the formula for the goods placed on the market. Industry have indicated that the manufacture of cement uses natural feedstocks (such as limestone, marl, chalk, shale, clay, bauxite, and iron ore) which are ground into fine materials for two reasons. Firstly, they are blended as part of continuous process in kilns at high temperature to produce the new substance "Portland cement clinker", which consists of several different mineralogical phases, in variable composition. Second, clinker and other components are mixed together according to the cement standard EN 197-1.

Feedstocks are based on natural materials and are sourced from different suppliers and locations. This means that there can be incremental variations within the composition which would mean that differences in composition from one batch to the next could trigger an updated notification to appointed bodies while the overall composition (from a technical perspective) and the hazards (and hazard classification) are unchanged.

The same issue is also identified for the other related cementitious sub-sectors. For example, Eurogypsum comment that gypsum is manufactured as a natural material (made up of calcium carbonate, magnesium carbonate, sand and clay). During the blending and manufacture of gypsum binders and mortars, variable quantities of additives (such as calcium hydroxide) are required to offset any natural variations in the gypsum to maintain the technical specifications and quality of the final mixture. This can lead to frequent changes depending on specific natural composition of the raw materials.

The industry survey highlights that cements are standardised to the technical standard EN 197-1. This standard divides cements into 27 different products based on set compositional ranges of the main constituents and technical performance of each cement type[47]. Additionally it is recognised that all cements conforming to the EN 197-1 standard will contain gypsum (as a set retarder), present in a concentration range of 5-10% by mass[48]. Variation in the clinker and in the composition of the other cement components (limestone, slag, fly ash, clay, burnt shale, puzzolans, gypsum, etc.) makes it necessary to vary the composition of these components to keep the technical performance consistent. This could trigger updated notifications to appointed bodies under Annex VIII, while the variations would be within the allowed scope of the technical standard.

Industry assert that it represents an excessive burden upon industry to track compositional changes and make notifications to appointed bodies, while providing information following small changes in composition which do not change hazard classification will present limited benefit to poison centres in terms of emergency health response.

Based on the survey results the main constituents likely to trigger the need for such an update include:

- The cement clinker itself – based on changes within the raw feedstocks
- Flue dust – which is collected and blended back into the cement.

[47] Manufacture of cement is a continuous process which can be affected by a number of variables including weather, and it can thus be necessary to correct the composition mid-process to meet technical specifications under EN 197-1, which will also have a direct effect on the final composition of the final product.

[48] Letter from Cembureau dated 26th February 2019, 'Second Interim Progress Report on "Study on workability issues concerning the implementation of Annex VIII of Regulation (EC) No 1272/2008 on harmonised information relating to emergency health response and preventative measures" Comments from the cement industry

- Chromate reducers (These have a maximum allowable concentration of 1.0% w/w but will vary in cement composition. This means the chromate reducer can be between 0.02% and 1.0% thus falling in different concentration ranges under Annex VIII)

The survey results also provide information on the frequency of updates likely triggered based on such incremental changes. The opinions provided by respondents vary greatly but suggest that updates could be triggered as frequently as between two to three times a year at one end of the scale to as often as weekly in other responses.

As a clarification of the workability issue, Cembureau (letter dated 28 February 2019) provide a further example:

> *"In a typical cement plant, approx. 1500 tonnes of clinker and from it approx. 2000 tonnes of cements are produced per day (data from Germany). The production of cements is a continuous process. Clinker, gypsum and other components are milled and / or mixed together and filled afterwards into large silos (silo size up to 10,000 tonnes for main cement types). At the same time, the cement is removed from the silo at another point of the silo as required. Cement is placed on the market either as bulk goods (tankers) or packaged in 25 kg bags. Variations in the composition, which are controlled by the process automation, can no longer be assigned to individual tankers or bags at a later point during loading / packaging. Therefore, a cement manufacturer cannot technically implement the requirements of Annex VIII with regard to the requirements for updating its submissions."*

Issue CM2: Multiple suppliers for mixture components (affects cement, mortars and readymix concrete)

Industry have noted that, to maintain business continuity, it is necessary to have multiple suppliers for different mixture components. Further communication with the European trade associations has highlighted that sourcing of materials can be affected by geographic location of materials, price, availability and logistical considerations. Since each raw material comes from natural origins, the composition can vary between different suppliers. In the cases where raw materials are mixtures, each original mixture will have a different UFI from one supplier to the next[49].

The previous workability issue (CM1) highlighted that, because of the natural origin of the raw material themselves and the continuous production process, incremental changes are possible, either due to the natural geography of the raw material or the production process itself.

Industry claim that the workability issue in this case is that further incremental changes are possible where multiple different suppliers of the same goods are used. Specifically, each raw material from each supplier will be assigned a UFI to denote its composition. Since the raw materials from different suppliers (which are technically equivalent but which have different UFIs) are used interchangeably, additional notifications/updates would be required whenever changes to the supplier of a given raw material are made despite there being no change to the hazards.

EMO comment that this issue is further exacerbated where mixture components from different suppliers are stored within the same silo. For example, mortars are produced using between 3 and 12 mixture components. The raw materials are mostly stored in and automatically dosed from fixed silos or tanks. Raw materials are less frequently used or used in lesser concentrations, but may also be stored and dosed manually from smaller, mobile containers (e.g. barrels or big packs). The number of fixed silos and tanks for storing the constituents depends on the size of the manufacturing site as well as the number and complexity of manufactured mortar mixtures. At these sites mixture components which are considered equivalent will be stored in the same silo allowing further mixing.

[49] Further comment from Cembureau: The issue of changing UFI between different suppliers, particularly for natural feedstocks is of importance if the raw material is a hazardous mixture. Therefore the issue of the same mixture component (as a MIM) from multiple suppliers has greater impact for the downstream formulators of products that contain cement (i.e. readymix concretes).

The survey results comment that, for each raw material used in the product of cement, there are typically between 3- 5 different suppliers (for mortars this is 2-3, and readymix concretes this 1-2). A very large number of notifications would be required to cover all of the possible variations of mixture components from different suppliers, which are currently used interchangeably.

3.5.3 Impacts of workability issues

Cements:

The industry survey results provide details for both the current number of new notifications and the expected frequency of updates under Annex VIII:

- The current number of notifications is given as one per product per Member State per annum. A number of respondents also commented that they do not make notifications currently and only provide an SDS due to the fact that their goods remain within industrial settings.
- For some responses the respondent provided identical answers to the questions on current and expected annual notifications versus expected number of updates suggesting that they were perceived as interchangeable.
- Furthermore, the majority of respondents stated that they do not currently need to provide updates annually beyond the first notification, and only make an update if there is a change to SDS (which occurs less than once a year).
- The expected frequency for updates to the first notification under Annex VIII is 2-4 notifications per product per Member State per annum.

The reason for this increase is cited as being changes in formulation linked to the workability issues highlighted in the sections above. One respondent highlighted that chrome reducers in particular are highly affected by the compositional ranges within Annex VIII and only small variations were needed to trigger an update.

Based on extrapolation of the data taken from the industry survey, we assume 348 companies with an average of 14 products per company. Further data on how many countries are traded into by these 348 companies was not available, and therefore the calculation below is based on an assumed single Member State.

- No. of companies: 348.
- No. of products per company (average): 14.
- No. of total notifications (assuming one Member State): 4,872
- Current No. of updates: 0.
- Expected No. of updates under Annex VIII (based on extrapolation): 9,744 – 19,488.

The survey also asked respondents to provide further information on the expected costs of completing notifications and updates of notifications under Annex VIII. In this case no cost data has been received. Many of the respondents commented that the unknown or open nature of how frequently updates may be needed meant that it was not possible to provide cost estimates in this case.

The respondents from industry were also asked to provide further information on the practical difficulties that the workability issues present which may provide some further indication of how costs may occur. The EN 197-1 standard that manufacturers work to provides the compositional requirements for 27 products based on set mixture components detailed under the standard. It further stipulates rules for minor components within the 1-5% range. However, the compositional tables within Annex VIII have an additional layer of disaggregation. A number of the respondents highlighted that real time monitoring of low concentration constituents (which would be needed for a continuous process) within cements would be extremely resource intensive.

Mortars:

The survey results (based on 14 respondents and additional feedback from EMO) highlighted similar issues to those received for cements, namely that in a number of cases the respondent

provided the same answer for both new notifications and updates, suggesting that they were perceived as interchangeable. A small number (four responses) did provide some additional insight into the ratio of updates on new notifications. This ranges from 10% - 200%. i.e. one company stated that they make 3,000 new notifications per annum, of which 300 will need to be updated annually due to formulation changes. A different respondent makes 10 new notifications per annum, with a total of 20 updates annually due to formulation changes.

Respondents also highlighted that they either only submitted an SDS or made no notification currently (as the product was perceived as for industrial use only).

When asked about the estimated number of notifications to be provided under Annex VIII the survey results provide variable responses which range from little/no change compared to current rates and an increase of between 40 and 500 times the current rate (i.e. an increase from 300 notifications annually to 12,000 – 150,000)[50].

EMO has provided some further clarifications and cost data to explain how the workability issues described may affect their members. EMO state that approximately 195 manufacturers exist with an average of 3 sites (range is 1 to 20) per manufacturer. Each production site produces on average 190 distinct final mixtures per annum (range between 2 and 1,000). Therefore:

195 manufacturers x 3 sites = 585 sites.

Each site produces 190 distinct final mixtures per annum.

585 sites x 190 mixtures = 111,000 different mixtures in total requiring notifications).

For factory-made mortars, industry comment that each mortar final mixture contains between 3 and 12 mixture components which are stored in fixed silos and blended as part of an automated dosing process to produce the final mixture. Different suppliers are used for specific mixture components and may be stored within the same fixed silo. This means further mixing of mixture components from different suppliers is possible with the changes in composition potentially triggering the need for an updated notification. This creates a significant traceability issue for manufacturers to define the specific composition of each final mortar mixture as supplied, and therefore the possibility that hundreds of thousands of notifications may be needed.

EMO state that costs associated with upscaling of IT systems and managing traceability of composition have not been calculated as it would be highly variable from manufacturer to manufacturer. However, as an illustration, it may be necessary to expand the existing infrastructure to have separate silos for mixture components from different suppliers to avoid further mixing of mixture components that perform the same specific function:

- Planning application, calculations, permission €120,000
- Works on Infrastructure €80,000
- Works on foundations €200,000
- Steel work, cladding €150,000
- Stair tower €40,000
- 4 silos each 100 m³, with equipment €200,000 (4 x €50.000)
- 4 dosing screws €80,000 (4 x €20.000)
- 4 silos each 34 m³ with equipment €140,000 (4 x €35.000)
- Electrics, controls €200,000

[50] The variation in the increased rate of submissions appears to be linked to two separate workability issues. The first relates to the continuous production process and naturally varying mixture components (CM1), however, the issue of pigments used in coloured mortars is also an issue linked to use of the GPI (OC1). Further disaggregation of which issue causes the greater severity of impact is not available.

- Pressurised air €20,000
- Total €1,230,000 (potentially, additional weighing container €30,000)

Gypsum:

Correspondence with Eurogypsum has indicated that the natural fluctuation in gypsum can occur in qualities such as grain size distribution, crystal growth, natural inclusions / impurities and water content. This variation is controlled through additives that are added continuously to give defined properties to the product. After manufacture, updates to the poison centre notification are expected to be needed for each batch whose content in a given mixture component differs from the concentration ranges specified in Annex VIII.

For the gypsum sector to ensure traceability of the product compositions, the respective batch would have to be temporarily stored in separate silos. Industry estimate that this would require new investment in 3-5 silos per product or a continuous analysis of the product's composition when poured into the packaging.

Furthermore, Eurogypsum explained that the gypsum sector uses multiple suppliers for the same mixture components; potential small variations in composition between different suppliers will likely trigger notification updates to the poison centres. For recycled materials, the chemical composition cannot be determined exactly and no information except the general safety data sheet on the main components is available from the supply chain. Quality requirements on batch delivery are based on minimum content and physical parameters, not the full chemical composition. The composition will vary between batches depending on sources of construction and demolition. Depending on the availability of the raw materials, the poison centre notifications must be updated according to the supplier used, although in technical terms the industry would perceive that the commercial final mixture (and the associated health hazards) has not changed.

The industry states that cost for labelling products with the UFI number will cost between €40-€160 per notification.

Readymix concrete:

ERMCO and the French national association for readymix concrete (Syndicat National du Béton Prêt à l'Emploi) highlight that readymix concretes are manufactured based on five performance criteria (environmental exposure, strength, consistency, air entrainment and chloride content) which are defined as critical values or classes with ranges of values. Depending on the specific use of a readymix concrete or the environmental conditions where it will be placed on the market, the composition of the concrete can be varied. Therefore composition of the final mixture will change frequently (daily) based on incremental changes from a standard set of mixture components. Where multiple suppliers are used for mixture components with the same technical function, differences in composition from different suppliers are likely to exacerbate this issue.

The rate of notifications varies dependent on national requirements. Both industry respondents highlight that in many cases no notifications currently take place as the final mixture is considered an industrial product. Under Annex VIII, all possible formulations would require notification. Across the entire sector this could equate to as many as a million notifications per member state.

A further breakdown of costs has been estimated per notification as shown below. This assumes cost savings on the basis of large numbers of notifications (more than 100,000 per annum) being managed as a group:

- Analytical costs: €0,02
- UFI generation: €0,02
- Labels: €0,02
- IT (standard running costs): €0,02

- Staff time: 5 minutes per notification (assumed to be €36/hour, i.e. €3 per notification)
- Total cost per submission = €3,08
- Total costs per updated notification= €3,04[51]

Industry comment that these cost estimates do not take into account the need to upscale IT systems to manage the very high volume of notifications or admin fees that may be charged by some Member States on a per notification basis.

While the costs per notification are low at around €3 per notification, the high number of notifications (running into millions) means that the total costs per company may be significant. ERMCO (2016 statistics) estimated that the total number of plants in operation across the EU is greater than 12,000, with up to 15 different formulations being produced daily per plant, each needing its own UFI. The EU plants in operation across the sector are managed by a set of large multi-national companies, but the sector also includes 6,000 SME status companies.

Based on these estimates it is possible to extrapolate the total costs to the sector as follows:

12,000 plants in operation with an average of 15 different formulas per plant = 180,000 formulations. These formulations can vary daily triggering the need for an update. Assuming 249 working days per annum[52] = 44 million notifications at a cost of €3 per notification. Total costs to the sector would therefore equal €134 million annually.

Aside from costs, the impacts of the workability issues identified also represent a significant logistical challenge to maintain traceability and audit records for the large number of UFIs which would be in operation. ERMCO further clarify the practical aspect of the workability issue as below:

- "To fulfil client requests, a traditional ready mixed concrete plant has two silos with two different types of cement, one silo with an addition (either fly ash or ground granulated blast slag), and one volumetric dispenser of admixtures. Cement characteristics vary due to seasonal variation of the production process. For a given cement type and class, the water/cement dosage in a mix varies from 0,45 to 0, 65 with intervals of 0,05 (5 values), additions vary from 100 to 150 kg/mc with intervals of 10 kg/mc (6 values), admixtures vary from 1,5 to 3 l/mc with ranges of 0,25 l/mc (7 values). There will be changes in cement content in addition to those resulting from changes in the w/c ratio e.g. to account for differences in the end use of the concrete, e.g. diaphragm wall concrete has a higher minimum cement content than normal concrete. This makes (5x6x7) = 210 potential combinations – [however] the real number of potential mixes for a plant is between 150 and 200".
- The workability issue in this case reflects the need for frequent updates (potentially daily) to reflect changes in composition to meet specific needs. ERMCO highlight that the health hazard is essentially the same regardless of the concrete composition.
- The readymix concrete sector also highlights similar issues with management of labels and packaging when handling frequent variations to composition and need for UFIs to be issued on a daily basis.

3.5.4 Other workability issues raised

In addition to the above workability issues, the respondents from the survey have identified other issues. These are not considered to be within the scope of the current study but are noted here for the sake of completeness. These issues are:

- Printing and material costs for the UFI:

[51] For updates to notifications only, analytical and IT costs can be discarded (i.e. 0,02 + 0,02 = 0,04), all other costs remain – therefore for each mixture a repeated submission will cost (3,08 – 0,04) = € 3,04.

[52] 365 days per annum = 260 week days (105 weekend days). Average number of public holidays in the EU is 11. Total number of working days is therefore 249.

- The respondents highlighted that bags used for stocking finished cements are printed in advance. Frequent changes to the UFI due to variations in composition represents a significant logistical challenge for manufacturers. Only a small number of respondents were able to provide cost estimates, and this is expected to be hundreds of thousands of euros per company per annum.

3.5.5 Industry suggestions on solutions to workability issues

Possible solution CM-A: Comparable MIMs

This solution is intended to address the need for frequent updates in the case of mixtures where the mixture components can vary incrementally between different suppliers of the same mixture component. This occurs for a number of reasons, but primarily because the mixture components used to manufacture cement come from natural raw materials. The mixture components from different suppliers are often comparable ('the same'), both in terms of technical function and hazard classification. This also recognises that some mixture components may themselves be mixtures (I.e. they will be mixture-in-mixtures in the finished cement product).This approach would work using the following approach:

- Appointed body (or ECHA portal) receives notification for all mixture components (intended for use in manufacture of cement) from all suppliers in use.
- The cement manufacturer notifies its composition including details of which suppliers are used for which mixture components.
- Appointed body (or ECHA portal) assesses these different suppliers, based on data submitted, for comparability[53] using an automated checking system to limit burden.
- Appointed body confirms which supplier's raw materials are comparable.
- Assuming that they are comparable, if a cement manufacturer switches supplier for an agreed raw material, no new UFI or update is required.

This approach would avoid the need for raw material suppliers to provide full compositional information to cement manufacturers which can create issues of confidentiality. It would also allow some additional flexibility for small incremental changes in composition of mixture components (due to natural variations and use of products from different suppliers) for raw feedstocks, particularly where the composition and hazards could be judged as comparable.

This would benefit the industry by reducing the need to check real time composition of minor constituent components, particularly where there are changes in supplier of technically comparable raw materials (without change to hazard classification). It would also reduce the quantity of update notifications reducing burden on industry while not losing any granularity in data needed by the poison centres to provide emergency health response.

3.5.6 Feedback from workshop participants on industry-proposed solutions

The key points of discussion during the workshop highlighted the practical issues created by the continuous production process for cements and mortars. This is exacerbated by the variations that occur within natural mixture components, an issue which also affects gypsum. The discussion also focused on the impacts created by use of multiple suppliers for the same mixture components and issues around how many UFIs are managed, particularly for mixture components stored in the same silos. The issues affecting the ready-mix concrete sector were not discussed directly during the workshop but are considered within this report and detailed already.

[53] The specific details of what could be considered 'comparable' would need to be agreed, but the intention is that the comparability check would be performed as an automated process to limit the burden on ECHA. Possibilities include looking at compositional differences between 'the same' mixture component from different suppliers, and this would also include consideration of any impacts for hazard classification as part of comparability (of which there should be none).

Further feedback on the proposed solutions to the workability issues identified was provided by the following appointed bodies, poison centres and ECHA:

- The second interim report noted that, while the main solution proposed for cements (including mortars and readymix concrete) was 'comparable MIMs' (CM-A), the continuous production process and workability issues for cements was not dissimilar to those seen in the petroleum sector. Therefore the proposed PP-A (generic UFI) and PP-B (wider concentration ranges based on pre-existing standards) could also be used for cements. Feedback on the PP-A and PP-B proposed potential solutions is provided in section 3.3.6
- BfR (appointed body) commented that the proposed approach for comparable MIMs (CM-A) was an acceptable way of limiting many updates without reducing benefit to appointed bodies and poison centres. However, to make this possible, an automated evaluation mechanism would be needed and further discussion was needed specifically on how 'comparability' between mixture components from different suppliers would be assessed.
- The Dutch Poison Centre (appointed body and poison centre for The Netherlands) commented that the proposed solution CM-A seemed reasonable, however, it is important that 'comparable MiMs/substances' have similar toxicological properties (e.g. mode of action) and same diagnostics/treatment options after exposure. The same hazard classification is not enough: two substances both classified for e.g. acute toxicity can have an entirely different toxicological profile. Companies may know when substances/MiMs are technically interchangeable but it would be more challenging to assess when these are toxicologically interchangeable. As an alternative the solution proposed by BfR 'G6', could be a good approach according to the Netherlands.
- The poisons information centre of Ireland (appointed body and poison centre) commented that providing appointed bodies/poison centres with a long list of MIMs which would likely have similar composition would be impractical. Therefore, things would need to be assessed in advance. The proposed solution CM-A may be complex to implement in practice, principally because due care is needed to assess whether MiMs are really comparable; hazard class alone would not be enough. While the poison information centre of Ireland agreed that an automated system could be developed, they felt that the complexity and level of effort to develop such an approach may be disproportionate and that a better option may be look at the solution PP-A (generic UFI).
- ECHA (via personal correspondence 05/06/19) wished to highlight some concerns with the practical implementation of the comparable MIM solution. Notwithstanding the technical and financial resources that would need to be set aside to establish a new process to assess comparability; there are a number of practical and legal issues which may make this solution problematic. While ECHA will host the portal for notifications, in order to carry out a comparability assessment (even using a computer algorithm or automated process) it will be necessary to have access to both sets of data. This would include confidential business information that needed to be managed sensitively, and therefore it is foreseeable that some companies may voice concerns over how their data is used and such a direct comparison of composition. More importantly, based on experience from related legislation, establishing sameness or comparability is often a highly technical and scientific endeavour which is difficult to automate and may require manually assessing cases one at a time, which would be labour intensive and create long waiting times for industry.

In summary, the feedback on the proposed solution CM-A was met with caution. While it was agreed that having many suppliers for the same mixture component represents a significant workability issue, the issue itself is not unique to one sector. The 'comparable MIMs' approach would indeed be useful, but agreement over how 'comparability' is defined was raised as an issue and people highlighted the complexity of comparability, which goes beyond hazard classification alone. The feedback highlighted that, while the option has merit, more discussion

and detail around implementation was needed before a decision could be reached on its implementation.

The feedback from appointed bodies and poison centres suggested that PP-A or PP-B (with further discussion – see section 3.2.6) or the BfR 'G6' solution would be preferred to manage the issue of continuous production involving natural materials.

3.6 Construction Products (Other)

3.6.1 Overview of sector and relevance to poison centres

Industry overview

Discussions with the major trade associations for the construction sector highlighted distinct workability issues which affect the cement manufacture sector and other construction products differently (see section 3.5). Therefore two separate surveys were developed to explore these different workability issues, with the issues affecting cement detailed in the previous section.

The construction sector (excluding cement and concrete) covers a very broad set of products and applications. However, based on the survey results received, these goods can be grouped into two main categories:

- Adhesives and sealants
- Construction chemicals (including goods such as resins, protective coatings, admixtures for cement and concrete, water proofing membranes and colourants for construction goods). Note that paint is managed as a separate sector within the study (see section 3.7)

FEICA report that the EU adhesives and sealants business is worth €14.5 billion annually in turnover within the EU, with the major market uses covering building and construction (29%), paper and board (20%), assembly operations (18%), consumer DIY (12%), transport (11%), wood working (8%) and footwear (2%)[54]. There are 450 adhesive and sealant companies operating at 700 sites across Europe. This includes a combination of large and SME sized companies. However, 82% of EU production is produced by 60 companies, with the remaining 18% spread across the SME sector which is made up of hundreds of companies. The industry employs 41,000 people across Europe, with 85% of these based in the top 60 companies and the remainder across the SME sector.

The EFCC[55] covers members which include large scale construction chemical companies as well as national trade associations. Deutsche Bauchemie (the German construction chemicals association) which is a member of EFCC state that they represent 130 companies in Germany with an annual turnover of €8.5 billion. These companies represent one half of the EU market for construction chemicals based on market volume of goods supplied. This includes a full range of both large and SME sized companies. By extrapolation this suggests that there are approximately 260 companies Europe wide with a turnover of €17 billion.

The survey for other construction chemicals was completed by 35 respondents including one national trade association and two European associations (FEICA and EFCC). This included 4 responses from the adhesives and sealants sector (including FEICA who responded behalf of all its members[56]) and 31 construction chemical associations and companies.

Based on the industry questionnaire responses:

- The number of products per company was between 30-150 for adhesives and sealants.

[54] FEICA, 2017, The European Adhesive and Sealant industry, growth by end-use markets. FEICA publication.

[55] http://www.efcc.eu/about-us/our-members/

[56] FEICA represents 16 of the largest adhesive and sealant manufacturers in Europe.

- The product range sizes for construction chemicals are wider, this ranges from 50-200 products in some cases (linked partly to company size), but other respondents indicate that they have product ranges in excess of 1,000 items and one respondent commented their product range includes 5,000 items.
- Responses from the adhesives and sealants sector provided feedback for the proportion of their product range which is classified for health hazards or physical hazards. The responses identified a wide range across the products on the market (20% - 100%).
- For the construction chemicals sector the respondents commented that >80% of their product ranges would be classified as hazardous under CLP summed across all companies.
- Based on the survey responses, adhesive and sealant products typically contain between 5-10 mixture components, and the sector typically uses 2-3 suppliers for each mixture component.
- For the construction chemicals sector, products typically contain between 5-20 mixture components; in a high number of cases the goods produced contain MIMs. The majority of respondents commented that they have 1-4 suppliers for each mixture component, with four respondents using more than this. The highest response received was 20 suppliers per mixture component.

In terms of their role within the supply chain, all of the companies covered by the adhesives and sealants sector would be considered 'downstream users' under the REACH definition. All of the companies covered for adhesives and sealants in the survey act as formulators of adhesive and sealant products using chemical goods manufactured or imported from higher up in the supply chain. Responses received from the construction chemicals sector covered all parts of the supply chain including manufacturers, importers and downstream users who formulate goods based on pre-manufactured/imported mixture components. A number of respondents stated that, in many cases, they relied on mixtures blended together to formulate their goods, meaning that their products will contain MIMs.

Relevance to poison centres

Only data covering all construction products is available, please see section 3.4.1 which provides a breakdown on the numbers of emergency calls relating to construction products.

3.6.2 Workability issues raised by industry

Issue OC1: Use of colourants and the generic product identifier

Under Part B section 3.2.3 of Annex VIII, it is possible to make use of the derogation from sections 3.2.1 and 3.2.2. (covering information requirements for substances and MIMs) for 'colouring agents', provided that these mixture components do not carry classifications for any health hazard and that the total concentration of components covered by the generic product identifier 'colouring agent' is not more than 25%. Construction industry products may be used in domestic, business or public properties, and, in such cases, there will be an aesthetic element to their use, meaning colour will be important. Industry have indicated that often product ranges will include a range of coloured goods where the only changing mixture component between different products is the colouring agent.

Furthermore, industry highlight that pigment pastes are primarily used to add colour for construction products. In these cases, the paste itself will typically be classified as hazardous, and the pigments added to the paste may further also be classified as hazardous, meaning it is not possible to make use of the GPI for these colourants. This means that a notification would be needed for each and every colour of the same basic product creating a significant burden for industry with only limited additional benefit to poison centres. Companies would effectively not be able to make use of the generic product identifier.

The survey asked respondents what proportion of their products contained pigment pastes/granules classified as hazardous for human health under CLP:

- For construction chemical products that contain pigment pastes classified under CLP, data were received from 28 respondents (all companies, no trade associations). 10 respondents provided the response '0' or 'none' to indicate that they did not make use of such pigment pastes/granules. The remaining 18 respondents provided responses ranging from 1 – 95%, with an average summed across all companies (not providing a 0/none) of 21%.
- FEICA comment that their members typically offer clients a choice of colour which is based on 8 to 15 different colours, with pigment pastes added to the final product to achieve the desired colour. Therefore, manufacturers will have a standard product range of 30-150 products, which can be further varied based on colour depending on client needs. Each product/colour combination would need its own UFI and notification even though in practice there may be negligible difference in terms of health hazards for many of these combinations.

Issue OC2: Multiple suppliers for MIMs

In similar fashion to the cement manufacture sector (see Issue CM2 under section 3.5), operators for production of other construction products will also use multiple suppliers for the same mixture components. The discussion with industry associations highlighted that there could be incremental changes to the final mixture composition triggering the need for a new UFI and update as a result of changing supplier. However, the technical specification and hazard classification of the final mixture would remain unchanged. Discussions with the industry associations (which mirror the survey responses) also highlighted that for many mixture components used in the manufacture of construction products, the mixture component is itself a mixture (i.e. a MIM).

In cases where mixture components are themselves mixtures (i.e. MIM), comments provided within the survey highlight that where there are multiple suppliers for the individual mixture components (as either substances or MIM), the potential for variation is greater and thus the likelihood of needing an update increases: companies may need separate notifications for each combination of (equivalent technical and hazard classification) raw materials from different suppliers, which can reach many possible combinations as each of several raw materials may have multiple suppliers and hence multiple product identifiers / UFIs.

This presents two issues for industry. Firstly, industry will be required to track and quantify composition of mixtures on a regular basis to allow identification of when an update is needed. Secondly, they will need to generate the update and notification to the appointed body, which would include a new UFI and a need to update all product packaging accordingly.

The survey provided to industry included questions around the current number of notifications, expected number of notifications under Annex VIII and if an increase is expected, what is the cause of this increase. The responses received did indicate that there would be an increase in the volume of notifications for both the sealants and adhesives and construction chemicals, however, the responses also identified an additional issue.

All respondents to the survey highlighted that, under the current system, the notification requirements differ across the Member States with a number of exemptions in place. In particular, for professional products, many Member States only require an SDS to be provided down the supply chain and no notification to poison centres. Under Annex VIII, all hazardous goods for consumers, professional users and industrial settings are required to make notifications.

Therefore, the responses provided give the following:

- Current rate of notifications to appointed bodies ranged from 0 to 1 notification per product. As indicated in many cases this was because the current systems often do not require notifications for professional users.

- The current rate of update of notifications follows in kind. So in the cases where no notification is made there will currently be no update. Where a notification is made the responses suggest updates at less than once per year per product.
- The expected rate of notifications to appointed bodies under Annex VIII illustrated a range of responses. This included moving from 0 to 1 per product, no change in volume of notifications, and an increase in the rate of notification which was expected to be between double and up to five times the current number of notifications.

The main reasons stated for the increase in the rate of notifications was linked to managing MIMs and possible frequent changes to composition to be notified where different suppliers of the same mixture components are used.

3.6.3 Impacts of workability issues

The industry survey included questions regarding the cost impacts of the workability issues identified. Only a limited amount of cost estimate data has been provided by respondents, with many stating that the situation presented is complex and ongoing issues with the finalisation of IT issues making it difficult to comment further. The survey also however provided an opportunity to provide comment on the practical issues created by the workability issues, which does give further insight into where cost impacts may be felt. The commentary below focuses on the practical issues for the adhesives and sealants sector, while Table 3.7 provides cost data for the chemical construction products with further commentary on practical issues.

Adhesives and sealants

FEICA highlight that the main concern raised by their members will be the significant increase in the number of updates needed and as a consequence new UFIs. The creation of a new UFI will require an update of all product packaging. The industry notes that this can be more complex than first expected. For example, in some cases the manufactured good is provided in different size product packaging to suit the needs of different clients. While a single UFI can be used to cover the same final mixture irrespective of products supplied in a range of different sizes, if an updated UFI is needed this can create administrative issues for labelling used, particularly if there are practical and economic constraints for producing labelling on different sizes and types of packaging. FEICA also note concerns from their members that maintaining current data for frequently changing formulations and UFI updates may be challenging and create delays for delivery of goods to clients for 'on demand' products which have shorter turnaround times. Therefore the key cost impact areas will be:

- Staff time and costs to track variations in composition
- Labelling costs from frequently changing UFIs
- Business impacts from delays in client deliveries created in managing poison centre updates against other work

Other construction chemical products

Table 3.8 sets out the estimated costs provided by respondents to the survey for compliance with Annex VIII. This includes both capital costs for labels and information technology systems as well as operating costs which have been provided per notification (with the exception of maintenance costs for IT which are annual per company).

The responses to the practical difficulties created by the workability issues are similar to those already stated for the adhesives and sealants sector. Many UFIs and notifications to the appointed bodies will be required. The respondents comment that this will be due to both cases where pigment pastes are used across large product ranges, but also due to frequently changing final mixture compositions as a result of using different suppliers of comparable raw materials but which have different product identifiers (CLP Regulation Article 18(2) for substances) or UFIs (for mixtures).

Table 3.8 Estimates of submission costs for construction chemical products (based on survey results)

Cost element	Estimated value
Analytical costs	Variable depending on product, but may require frequent monitoring which would be significant.
UFI generation	€4/6 per UFI. (staff time)
Labels (annual operating costs)	€40 – €160 per notification [see note A]
Information technology	€25,000 – €30,000 (no disaggregation for Capex/Opex)
Admin fees for appointed bodies	Variable (information is publicly available)
Staff time	60 to 120 minutes per submission [See note B]
Others	None noted

Notes: [A] Information provided by respondents is based on annual costs within their product range which was €45,000-€80,000. The value in the table is a mean average of all responses, following a calculation based on the annual costs divided by size of the product range, and further divided assuming one or four notifications per product per annum based on survey results to provide a minimum and maximum range. [B] Complexity of submission is the key variable in this instance.

3.6.4 Other workability issues raised

In addition to the above workability issues, the respondents to the survey have identified other issues. These are not considered to be within the scope of the current study but are noted here in order to allow possible further consideration by the Commission. These issues are:

- Aspects of the Annex VIII implementation are still open ended. In particular, the respondents identified that the IT tools and ECHA portal are still under development and guidance is pending. This has made it challenging for industry to prepare for notification and invest in suitable software. In order to maintain compliance with deadlines, systems will either have to be implemented more quickly (at greater cost) or amended once the full details are clear (again incurring development costs).
- Respondents also raised concerns over data security where full compositional data is required and highlight that existing systems have been hacked in the past[57]. This poses concerns to industry in developing options to protect confidential data. However, ECHA has clarified that companies only need to supply the UFI within the supply chain; the detailed composition will be provided to appointed bodies and poison centres only receive the information relevant to performing their tasks[58].

3.6.5 Industry suggestions on solutions to workability issues

Possible solution OC-A: Comparable MIMs

The primary solution to the workability issues highlighted within this section is the use of comparable MIMs. Further detail on this solution is provided in section 3.5.5. Note that the respondents to the survey indicate that use of comparable MIMs should be able to address both the issue related to pigment pastes and that related to multiple suppliers of mixture components.

As the issue for pigment pastes relates to the GPI for colourants we also expect the workability issue to be similar to the workability issue detailed for paints, and also to that for perfumes/fragrances in detergents. See also the section for paints and solutions to workability issues under the paints section (section 3.7) and for soaps and detergents (section 3.9).

[57] https://www.bundestag.de/presse/hib/2017_01/-/487344

[58] https://poisoncentres.echa.europa.eu/questions-and-answers.

3.6.6 Feedback from workshop participants on industry-proposed solutions

The key points of discussion during the workshop highlighted the practical issues created by the use of colourants (particularly pigment pastes) as the only changing mixture component in a range of products. There was also detailed discussion around the issue of using multiple suppliers for the same mixture component and the potential workability issues created by this.

Further feedback on the proposed solutions to the workability issues identified was provided by the following appointed bodies and poison centres:

- The discussion around the proposed potential solution of 'comparable MIMs' used for both CM-A and OC-A is discussed as part of the feedback to the CM-A option under cements. See section 3.5.6 for further details.
- The poisons information centre of Ireland (appointed body and poison centre) added one further piece of feedback specifically for "other construction". They noted that the Irish poison centre received very few emergency calls from use of either adhesives, sealants or other construction chemicals. It could therefore be useful to have a discussion on whether this sector should be allowed to make use of the limited submission.

In summary the same concerns and issues around the complexity of the proposed 'Comparable MIMs' solution were raised as for the previous section, in particular how 'comparability' would be defined and complexity of implementing such a system, which would need an automated checking system. The second issue of using colourants and how the GPI is implemented is detailed more under paints (see section 3.7), however, appointed bodies and poison centres made clear that they had concerns about allowing modification of the GPI for excluding only those substances/mixtures classified as severely hazardous for human health hazards. This was primarily because hazard classification alone does not address mode of action, and that it is entirely possible for two substances to have the same hazard classification but different modes of action requiring different treatment options.

3.7 Paints

3.7.1 Overview of sector and relevance to poison centres

Industry overview

Data from Eurostat states that in 2016 there were 3,865 companies across the European Union involved in manufacturing of paints, varnishes and similar coatings, printing ink and mastics (based on NACE[59]).

In 2016, based on Eurostat data, manufacturing of paints, inks and coatings had a turnover of €40.8 billion. The average turnover reported by survey respondents for the current study is €157 million per company (ranging from €45,000 to €1.5 billion per company). The average turnover reported by companies in the large company size bracket is €364 million per company (ranging from €35 million to €1.5 billion). The average turnover reported by companies in the SME company size bracket is €23 million per company (ranging from €45k to €90 million).

CEPE represents 85% of the market value for the paints, printing inks and artists' colours industry, with an estimated aggregated turnover of €17 billion[60]. The industry survey was disseminated by CEPE amongst their members with responses from 87 companies. Based on the answers from 77 respondents (10 left the question blank):

[59] Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) [sbs_na_ind_r2]

[60] Personal comms, 28/02/2019 with CEPE

- 60 are active across multiple EU countries. This includes 32 'large' size companies (based on the REACH definitions), 27 SME sized companies, and 1 who did not provide details of company size.
- 17 operate only nationally, with respondents' companies active in Germany, France, Italy, the Netherlands, Spain, Portugal, the United Kingdom and Ireland. This includes 3 large size companies and 13 SME sized companies and one who left company size blank.

Based on the questionnaire responses:

- The number of products per respondent ranged between 4 and 900,000, with an average of 31,000 products per respondent.
- The average number of products in large companies ranged between 300 and 900,000, with an average of 66,800 products per respondent.
- The average number of products in SME ranged between 4 and 200,000, with an average of 8,800 products per respondent.
- On average, 61% of products are subject to the requirements of Annex VIII due to the health hazard classifications of components included, though some respondents have as many as 100% of products affected.

Based on the answers from 81 respondents (six left the question blank), the companies taking part in the survey fulfil a variety of roles dependent on their business model with 51 respondents act as formulators of paint products (i.e. they purchase mixture components to blend together to form final mixtures), 17 manufacturing paint mixture components and 13 companies operating across the entire supply chain.

Relevance to poison centres

As indicated in the preceding chapters, poison centres were asked to provide data on the total number of calls received to poison centres and what proportion of those calls came from the industry sectors covered by the current study. This is intended to provide an indication of relevance. Information has been received from appointed bodies and poison centres in Ireland, Italy, Finland, Germany, the Netherlands and Spain, (noting that data for Italy and Germany came from regional PCs as a sub-set of national totals, although call rates are expected to be representative of national position). Based on the data received, an average of 0.9% (range of 0.4 - 3%) of all calls received by the poison centres related to paint products (see Tables 3.1 and 3.2). Additionally, CEPE have provided data taken from the Portuguese poison centre (CIAV) which received 24,683 calls in 2017, and 26,236 in 2018. Calls relating to paints for 2017 and 2018 respectively totalled 48 and 53 (0.2% of all calls received).

3.7.2 Workability issues raised by industry

The paints, inks and dyes sector comprises a wide variety of products including ready-made paints and inks that are sold on the market and colour mixing systems that entail tinting on demand or at the point of sale (e.g. decorative/architectural paints, vehicle refinish paints, etc).

Issue P1: Inability to use the generic product identifier for 'colouring agents'

Annex VIII (Part B, 3.2.3) of the CLP Regulation provides an opportunity for duty holders to use a generic product identifier "colouring agents" for mixture components used to add colour to final mixtures provided stipulated conditions are met. These conditions state that mixture components used to add colour must not be classified for any health hazards and that the total concentration of such mixture components should not exceed 25% within the final mixture.

Survey respondents manufacturing colour mixing schemes suggested that based on a weighted average 85%[61] of their total product portfolio would not be able to use the generic product identifier for 'colouring agents' because some or all of the mixing components (tints) are classified for human health hazards. However, this ranged from 0 to 100% with companies being either significantly affected or unaffected due to the presence or absence of such products in their portfolio.

Industry expressed widespread concern about the inability to use the generic product identifier for 'colouring agents' to reduce the number of submissions (as the colouring agents used contain hazardous chemicals above thresholds for classification, even if the final mixture is not so classified). One of the respondents with a portfolio of 40 million tinting formulas / paints combinations highlighted that, as they operate across multiple Member States, they cannot restrict potential new customers by only notifying existing formulas into the relevant countries. Instead, the entire product range (40 million formulations) would need to be notified across all countries it operates in before any sales can take place.

Given the extremely high number of notifications, this issue is of serious concern to the industry, affecting not just the initial number of submissions but also provision of updates due to further incremental changes in product formulations. (See also issue P3, which relates to changes in composition where tints from different suppliers are used for the same mixture component).

The industry highlights that the use of grouping and the generic product identifier is essential to reducing the number of notifications and avoiding submitting thousands of notifications for products with very similar composition based on incremental changes to achieve different shades. It should be noted that these products typically have the same hazard classification.

The respondents to the survey provide examples of the potential magnitude of the impact of not being able to use the GPI for their products. One respondent commented that if they were able to use the GPI for colouring agents within their paint range they could submit two notifications to cover all their paint products. Without the GPI they will need to submit 1,000 notifications to cover each and every final mixture. A second respondent commented that the difference between using and not being able to use the GPI would mean instead of submitting hundreds of notifications they would need to submit 80,000.

Companies with a smaller product range are equally concerned; one respondent estimated that the possibility of using the GPI for "colouring agents" would allow them to reduce the number of submissions by a factor of 6. However, as many of their products include artistic paints which contain more than 50% pigments, they will not be able to use this option.

Issue P2: Colour mixing systems on demand

Colour mixing systems that entail mixing at the point of sale (bespoke products) using a base paint and tinting (colouring) agents, or by mixing of fully formulated paints/inks, can result in many thousands to millions of discrete mixtures. Further information from CEPE estimates that in total 12.5 billion unique potential product formulations may be possible for the whole of Europe. Industry has asserted that the tints used will contain mixture components that are classified for human health (i.e. the GPI for colouring agents cannot be used), leading to an extremely high number of notifications. The survey responses indicate that it is not practical or timely to develop UFIs and notifications at the point of sale, so the only option will be to calculate all possible combinations and discrete mixtures in advance and submit these to ECHA or the MS appointed bodies as part of the requirements of Annex VIII. Additionally, alongside the first notifications for an entire potential product range, there would also need to be updates following any change in composition (as per table 3 of Annex VIII). This could occur for example if different

[61] The survey responses showed a very wide range in proportion of hazardous final mixtures in the portfolio (as low as 0% and as high as 98%). A simple mean average of 54% can be derived based on hazardous proportions alone. However, this is misleading as there is also a correlation between size of product range and proportion that is classified as hazardous. For companies with small product ranges (less than 200 products) the proportion that was hazardous is low (less than 20%); while for larger product range sizes the proportion that is classified as hazardous increases. The weighted average has been derived based on size of the product range against proportion that is classified as hazardous.

suppliers were used for the same functional mixture component. Industry highlights that in particular changes to the base paint would affect the entire range, meaning that updates would have a magnifying effect on the total number of notifications that might be needed, leading ultimately to millions of notifications per annum (see also workability issue P3).

However, industry, also argue that this approach would effectively be impossible in practice due to the number of potential theoretical combinations (ranging from millions to billions per company[62]). A specific illustrative example has been provided by one of the respondents in Table 3.9 (below).

Table 3.9 Case study from paints industry on colour mixing system at point of sale (PoS)

A company has 167 tintable products and 7.8 million existing colour formulations. The number of possible combinations at the point of sale is 1.3 billion (167x7.8 million) making an advance submission to poison centre unfeasible.

Survey respondents also noted that, if only pre-declared (notified) colours are accepted for sale, this restricts the possibility of creating new colours on demand at point of sale. If a new UFI is generated for the new colour at the point of sale it would not be instantly communicated to appointed bodies as shops will not be able to supply this information instantly. The consumer, on the other hand, is likely to use the tinted paint promptly after purchase.

Similarly, customers are able to create special colours without a pre-set colour formulation from the formulator of the paint meaning that no notification and UFI generation can take place pre-emptively.

The industry also noted that if in colour mixing systems (point of sale systems) one component of the base or a colorant changes hazard classification, the entire range of colour permutations would have to be submitted anew.

This also creates additional technical challenges; the industry notes that updating tinting formulas may take weeks depending on the timetable of service technicians and internet connection between retailer and manufacturer (which is often absent). In such instances, updates need to be done manually in the shops.

A further challenge is associated with a situation when point of sale mixing involves products from different manufacturers (e.g. a base paint from one manufacturer and a tinter from another). Such practice of "cross-tinting" prevents either of the manufacturers of the products used from generating a UFI and submitting notification to poison centre except for the individual mixture components.

An alternative option of generating/printing UFIs for tinted products at the point of sale seems equally challenging. Survey respondents highlight that this would require companies to have an appropriate printer installed in the premises. While this is the case for the high majority of cases, the survey respondents indicated that based on their experience there are some tinting machines on the market that do not have a computer or a label printing system. There are likely to be many thousands of companies/sites offering paint mixing at point of sale.

The industry believes that there is not sufficient time to adapt the tinting machines and train the staff and unless steps are taken to facilitate implementation and address this workability issue, it is not clear to them how individual shops will be able to communicate in real time new colour formulae created for the customer.

[62] These estimates are based on all theoretical colour combinations, multiplied by all the required EU languages, multiplied again by all the variations to composition as a result of changes to composition (i.e. updates).

Issue P3: variations in mixture components (including MIMs)

The industry has expressed concerns about:

- Regular, sometimes weekly, variations in mixture components including the base paints and/or tinting agents that would lead to needing frequent updates to the poison centres and generation of new UFIs.
- Use of the same and/or interchangeable mixture components (including substances and MIMs) from different suppliers with different UFIs. If the full composition of the MIM is not known, its UFI should be used in the submission for the paint/ink, but the respondents are unclear about which UFI to use given that different (but technically interchangeable) products are often mixed within storage systems.

As an example of the workability issue, CEPE provided a further two responses[63], the first from a printing ink manufacturer. The respondent comments that, based on practical experience, they try to have at least two suppliers for each raw material and for high volume components (like binders and solvents) they have both multiple suppliers and alternative substitute chemicals. Binders and solvents are most frequently substituted with alternatives (either supplier or chemical), Changes are less frequent but also possible with photoinitiators, and pigments (such as carbon black and titanium dioxide). The primary reason for changing supplier is availability of stock to meet demand, particularly to ensure continuity of production.

The respondent further added that, for 2018, a total of 200 component exchanges, by either chemical or supplier substitution, took place. These changes could affect multiple products, particularly if the change was to a base component used across a range. So, for example, a change in supplier for a base component could affect as few as 300 formulations, or as many as 30,000 formulations. The company explains that the impact of component exchange on volume of products is hard to estimate. The impact may be on a high number of low volume formulations or a single high volume product.

The second respondent, from a manufacturer of paints and coatings, commented that it is common practice for them to use as many as three suppliers for the same raw materials which are stored on the same site. Raw materials are purchased as 'technical grade[64]' products and the full composition is not always known, particularly for non-hazardous components. When the raw materials are viewed as being interchangeable they can be stored in the same bulk container involving further mixing. Alternatively where raw materials are supplied as barrels, during production when one barrel is consumed a new barrel is simply opened and added to the production (irrespective of the supplier), meaning that composition can change mid-batch.

The respondents to the survey highlight that regular changes in mixture components mean that a new UFI must be generated for every batch and a notification update submitted to the poison centres.

The industry also reports that mixture components (including substances and MIMs) from different suppliers are frequently blended in the same storage tanks (as indicated in the example provided by CEPE). The industry is concerned about ensuring compliance as it simply would not know the actual composition of the different batches due to variability of the composition of mixture components; the use of interchangeable components; and mixed storage in tanks (mixing various batches of the same mixture).

Companies further reported that when a new batch of mixture component is delivered, it is stored in the same tank as the old material, with tanks rarely being allowed to run empty. This will allow further blending to take place. From a practical perspective mixture components from

[63] Letter dated 28/02/2019 as a response to comments on the interim study report and study workshop held on 13 February 2019.

[64] CEPE comment that raw materials in the paint sector are purchased as 'technical grade' products, which means around 5% of the composition is of another non-hazardous component (such as acetone, ammonia or linseed oil) which is not declared under the current legislation for SDS.

different suppliers that serve the same function are often technically interchangeable (including the same hazard classification). However, composition (particularly for MIMs) can vary, especially if natural ingredients are used in the production of the mixture component, or with other minor changes in properties (e.g. different versions of essentially the same substance with different CAS numbers). This further blending will mean that during storage a new mixture is created with a different composition, and that therefore it is very challenging for formulators to know which UFI should be used for the specific mixture.

Survey respondents believe that regular and highly frequent variations in raw materials used in formulation of their mixtures would lead to an unsustainable workload associated with UFIs and notification updates due to such changes in composition.

Furthermore, the industry highlighted significant challenges associated with supply chain communication. In particular, downstream formulators perceive that they have to report full compositional breakdown of their products while relying on information from their suppliers regarding mixture components[65]. At present there is no legal requirement to disclose the details of non-hazardous substances in mixture components. Existing systems for notification allow the supplier to submit confidential information directly to competent authorities without providing information to their downstream users.

3.7.3 Impacts of workability issues

The survey responses reported a total of 148,184 submissions to poison centres per year are made today, under the currently existing obligation of Art. 45 of CLP. Note that this is only the number reported by survey respondents, not those for the sector as a whole and it is not known what proportion of the total mixtures on the market this represents.

Based on aggregation of the industry survey results the total theoretical number of new notifications is expected to increase to 44.5 million submissions per year[66] under the provisions of Annex VIII (however, note the earlier discussion that in practical terms this represents a significant challenge to the industry to be compliant). This is a 300 fold increase of the current annual number of notifications made to appointed bodies. However, also note that these estimates are based on the responses received which will be a subset of the industry as a whole, and therefore the total number submissions for the industry as a whole could potentially be higher.

In replying to the survey, respondents were asked how many notifications are made for new products under existing national systems for CLP Article 45, and how many would be expected under Annex VIII, which has been detailed above. They were also asked for a given product how many submissions would be made annually and how frequently formulations might vary triggering the need for a re-submission (update).

Analysis of the results highlights firstly that there is a difference in how the respondents perceive notifications. Many respondents commented that they do not make updates and that rather any change in composition would be considered a new product, with a new UFI which would be submitted to the appointed body.

Secondly, it is possible for both the composition of the base components for the paints and the composition of the tints to vary, triggering an update. For example, one change to the base component of the paint which affects its concentration in the final mixture means all of the tints will also change in concentration for the final mixture to offset the changing concentration of the base component. This could trigger as many as 100,000 updates per company to account for these changes.

[65] Annex VIII requires a full compositional breakdown of the final mixture placed on the market. However, where some of the mixture components are MIMs it is recognised that this may be more challenging. Part B, 3.2.1. of Annex VIII states that where MIMs are used in final mixtures, if the full composition of the MIM is not known then available information on the known components can be provided without needing full compositional details.

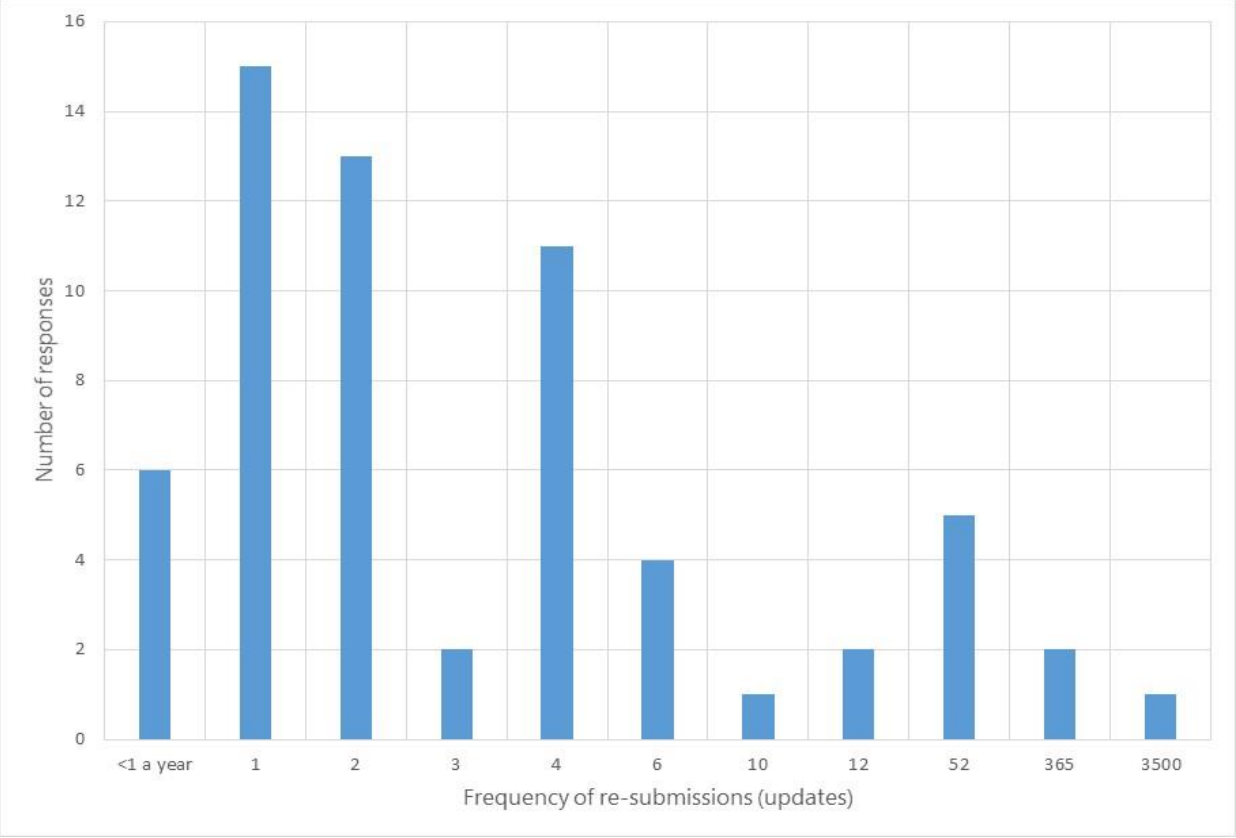
[66] Does not include PoS paint mixtures, which would be additional.

The respondents commented that the reason for the significant increase in the volume of notifications (in total, both new notifications and updates) is due to the perceived narrow concentration ranges in Tables 1 and 2 for Annex VIII and the fact that formulators cannot usually make use of the GPI for colouring agents.

The response to the question on frequency of variations triggering a re-submission (update), provides some further insight as to the frequency of updates. The results to this question are illustrated in Figure 3.1 based on the answers from 62 respondents. The majority (47 respondents (75%)) comment that the typical number of updates is quarterly or less. The median of the responses is twice a year, with responses ranging from once every other year (0.5 annually) to 3,500 times a year (one respondent).

The key issue to note is that the frequency of updates may have a magnifying effect. Where industry have asserted that the GPI for colouring agents cannot be used, and that each and every discrete final mixture would need its own UFI, the number of new notifications for the full product range is much greater in the initial instance than currently reported under national schemes for Article 45 of CLP. Any update to mixtures (as a result of changing supplier for example) would be applied to some or all of that full product range, meaning based on the aggregated results of the industry survey, the total number of notifications per annum (both new notifications and updates) would be much greater still, hence the 44.5 million estimated.

Figure 3.1 Frequency of re-submissions (updates) for paints sector based on 62 responses.



Survey respondents noted that the expected frequency of updates under Annex VIII will increase for companies in the paints product sector, due to factors such as incremental changes in composition, changes in material suppliers, and reclassification of product components. The survey indicated that the average number of suppliers for mixture components was 3.6 suppliers

per mixture component. Furthermore, each company was using on average 18 mixture components[67] to manufacture their products.

The respondents expressed concern that there will be different UFI numbers for each supplier of individual mixture components (MIMs) leading to new notifications for the same product each time there is a change of supplier and/or incremental change in the composition of different components.

While there is a disparity within the results over whether data refers to new notifications, updates, or both, a small number of companies were able to provide clearer disaggregation on the estimated number of updates expected under Annex VIII and they indicated that:

- The total annual number of submission updates (as a consequence of formulation changes) is currently around 37,100 (904 per company on average).
- This is expected to increase to 1.69 million submission updates (about 42,292 per company on average) under Annex VIII, from 2020 onwards.

Therefore, the main impacts associated with these workability issues are a vastly increased number of submissions/UFIs. The survey responses suggest that companies engaged in Point of Sale (POS) tinting and tinting on demand (to order) will be highly affected.

As indicated above, there is also a practical difficulty/impossibility with identifying specifically which ingredients (e.g. MIM with a UFI) are present in a given batch, due to the mixing in storage of technically equivalent raw materials from different suppliers (including no change to hazard classification).

The survey also asked respondents to provide further information on the expected costs of completing notifications and updates of notifications under Annex VIII. The responses summarised in Table 3.10 illustrate that, in many cases, the respondents found providing information on cost elements challenging. Following the study workshop, CEPE consulted with their members to assist in providing further indicative cost estimates.

CEPE comment that cost estimates vary, due to continued uncertainty and unavailability to date of the necessary submission tools. The lowest estimate per poison centre notification (including staff time costs) as €295; and the highest estimate per poison centre notification (including staff time costs) as €615. However, it is important to note that costs generally across all industry sectors illustrate wide variations in cost estimates. Further comparison of costs is provided in section 3.11).

Assuming the 44.5 million notifications annually calculated from the survey results, this would indicate an estimated total cost to the paints, inks and dyes sector of between €13.1 and €27.1 billion annually. Based on data from Eurostat (2016) the paints sector has a turnover of €40.8 billion, and gross operating surplus[68] of €4.6 billion. It is clear that the costs would be significant (more than three times the gross operating surplus)[69].

Even if these costs are significantly overestimated by industry, it is clear that they would still cause significant practical and financial difficulties for the sector, given the potential 44.5 million notifications[70]. CEPE have indicated that in practice the significant workload that this would create means that in practical terms compliance would be unfeasible. Furthermore, feedback

[67] Please note that 8 respondents reported that they are using between 200 and 2,500 components, but it is likely to refer to the total number of components used by the company.

[68] As a measure of profit.

[69] As a measure of affordability, it is more appropriate to compare costs to profitability. For example, suppose the industry has estimated / overestimated costs by a factor of 10 and actual costs would be €1.3 to €2.7 billion per year, this would still represent 3-7% of turnover. However, more importantly, assuming an average profit (EBIT) of 11.4% (based on turnover vs gross operating surplus), the costs would be around three – six times greater than profits.

[70] Note that this figure is based on an aggregation of the survey results and therefore the total numbers may be higher if those companies who did not take part in the survey are also included.

from the poison centres highlighted that it would be undesirable for them to need to manage and store very high numbers of notifications for very similar mixtures.

Table 3.10 Estimates of per submission costs for paints

Cost element	Estimated value
Analytical costs	67 blank or could not give estimate. 19 respondents able to give values. Reported values ranged from €1 to €200 per product. The costs per company ranged from €5,000 to €80,000 per annum *
UFI generation	63 blank or could not give estimate. The reported values ranged from €<0.5 to €50 per product. Values of €1k-€2.2k were also reported.
Labels	57 blank or could not give estimate. The reported values ranged from €<10 to € millions. Costs per label ranged from €0.01 to €10. Costs per product were between €50 and €200 per product. The costs per company ranged from €10,000 to €6 million per annum * Many respondents in between too, no difference by role in supply chain or company size
Information technology	52 blank or could not give estimate. The reported values ranged from €<10 to hundreds of thousands Euros (€200,000) Higher costs are related to respondents expecting to upgrade IT system/software Majority of higher costs reported by large companies and more SMEs reporting lower costs
Admin fees for appointed bodies	68 blank or could not give an estimate. Eight qualitative comments and 13 numerical responses with respondents highlighting that fees depend on the Member State. Of 13 numerical responses: 10 reported values ranging from €0 to €300** (depending on Member State) with another response (1) providing a value of about €1,100**** 2 reported a value of €10,000-€15,000#.
Staff time	55 blank or could not give estimate. Respondents detailing time generally reported 60 minutes / submission (ranging from 10 minutes to 270 minutes)
Others	67 blank or could not give an estimate, 7 qualitative comments and 15 numerical responses. Specified other costs: consultants, data gathering through supply chain, internal admin and storing data. Of 15 numerical responses: 4 provided time-based estimates ranging from 1h to ½ day per submission; 7 reported values ranging from €2.5 to €20 per submission (with an average of €6.26 per submission); 3 reported values ranging from €414 to €1,815 with one respondent clarifying that the value is per product per annum (and not per submission); 1 respondent reported a value of €30,000##.

Notes: * It was not always clear when respondents were reporting - price per product or for their business. ** No further details were provided in the response, but the value is likely to be per product or per submission. *** One of the respondents noted that in Spain new product notification costs €15 and €30 euros for each modification. **** No further details were provided in the response, but the value is likely to be per product per year. # No further details were provided in the response, but the value is likely to be per company per annum rather than per submission. ## No further details were provided in the response, but the value is likely to be per company per annum rather than per submission.

Furthermore, generation of new UFI numbers following each incremental change would require changing product labels. In practice, it will not be possible to change the labels on a batch / daily level (though it has been clarified that the UFI may be printed on the packaging, rather than on the label).

One of the respondents notes that, for artistic paints, labelling is particularly problematic as the label forms part of the packaging itself with very limited space. Any update of the UFI would require the entire packaging to be updated by the marketing department, printed and any excess stock with the previous UFI would need to be destroyed. The minimum order size mandates the company to have at least one year of stock for each label and destroying unused labels several times a year would be financially infeasible.

CEPE further comment that the scale of impact is disproportionate to the benefits (in their view), based on the frequency of calls to poison centres for incidents involving paint. Table 3.1 and 3.2, provided at the beginning of section 3 (based on data from seven Member States), highlighted that the average proportion of emergency calls relating to paint products is very low (0.9%).

3.7.4 Other workability issues raised

In addition to the above workability issues, the respondents participating in the survey have identified other workability issues. These are not considered to be within the scope of the current study but are noted here in order to allow possible further consideration by the Commission. These issues included:

Composition of raw materials and MIMs

- The industry is not clear about how to report full composition for raw materials that contain substances without CAS or EC numbers such as polymers. Some Member States do not accept generic chemical names e.g. acrylic or polyester resin as part of notifications.

UFI generation and use

- Industry is also concerned that they are required to notify products using the name of the re-branded product, as distributors and re-branders are not obliged to submit their own notifications. The industry is not, however, in the position to know where their customers sell the products to further, as they are not legally obliged to inform them of this. Nonetheless they are obliged to make notifications in the Member States in which their customers sell their products, which makes compliance impossible.
- The industry also has raised a concern about the labelling. In particular, product labels are already full of information and very little or even no extra space is available to insert the UFI number. This is particularly relevant for paints products sold in small packages such as artists paints (e.g. 250 ml and below). The respondents note that UFIs could be affixed to the packaging by stickers, but given the size of the container these may cover up other essential information. One suggestion from the industry was to allow printing the UFI on the bottom of aerosol cans. This could be realised more easily than printing on the sides of an aerosol canister.

Use of IUCLID

- One of the respondents highlighted the issue of using IUCLID for submitting Annex VIII information as it will create a huge administrative burden on industry. They consider that the system is cumbersome, slow and time consuming to use due to the way that IUCLID accepts documents and data etc. If used, they suggest that it will be of critical importance to automate data upload process to IUCLID, particularly given that the paints sector has wide ranges of products due to incremental changes to composition.

3.7.5 Industry suggestions on solutions to workability issues

Possible solution P-A: Refinement of generic product identifier criteria for 'colouring agents'

Annex VIII (Part B, 3.2.3) states that the GPI for colouring agents can only be used provided that none of the mixture components are classified for human health and that the concentration of mixture components identified as colouring agents is ≤25% of the final mixture. Industry asserts that currently the GPI cannot be used as the majority of tints will contain mixture components classified for human health.

One possible solution to the workability issue may be to allow further disaggregation of the GPI so that all mixture components with the same classification can be grouped (e.g. colouring agents classified as skin sensitisers). This would allow developing a single submission for a product in multiple shades as long as the hazard remains the same. Reducing limitations imposed on the use of Generic Identifier for mixture components with same classification but different components would reduce number of notifications required.

Possible solution P-B: Use UFIs for the base paint and colourants in colour mixing systems on demand

To address issue P2, the industry proposed a range of solutions to address the challenges and workability issues associated with point of sale mixing systems.

One proposed solution was to use the UFIs assigned for the mixture components for the base paint and tints separately, rather than a single UFI covering the final mixture. At the time of tinting, a sticker would be printed containing the UFI for the base paint plus the UFI for each additional tint that is added. During the workshop it was discussed that a further rule could be added that the sum of tints would not exceed a set aggregated concentration in the final mixture. Such a rule would help provide guidance on likely composition (base paint vs aggregated tints) for emergency health response.

Such an approach would ensure that correct components are presented on the label without stopping the process every time the formula changes (as a result of on demand or POS tinting). The UFI for the base paints / colourants would change if there is a change in hazard classification. This would mean that no UFI-generating-process at the PoS would be needed and the UFI can be generated on manufacturer's premises (e.g. in the head-office).

The process, nonetheless, would put additional burden on retail personnel and would entail acquisition of appropriate equipment (e.g. printers, point of sale tinting machines linked to a computer or a label printing system).

The industry argues that, for the vast majority of paints, there will only be a limited number of medical treatments, after exposure, and that solution P-A would be the preferable choice over P-B.

Possible solution P-C: Supply chain information sharing and use of comparable mixture components approach

The industry proposed a number of solutions to address the issue of variable composition of raw materials and MIMs leading to frequent updates and generation of multiple UFI numbers for paints products despite there being no change in hazard classification.

In particular, a range of alternative suggestions have been expressed by survey respondents including:

- The industry argues that the policy of not needing to notify non-hazardous materials and mixtures, but then needing to disclose them in final hazardous products is extremely difficult for manufacturers of hazardous materials containing some non-hazardous components. Therefore two solutions are possible:
    - The notification of all non-hazardous components should be mandatory throughout the supply chain. This would enable downstream users to produce complete and accurate notifications to poison centres.

  - All non-hazardous materials should be excluded from reporting (even if components of hazardous final products). This would mean that only changes to composition of hazardous mixture components would trigger an update.

- Mixture components (including MIMs) with the same technical formulation but originating from different suppliers should be allowed interchangeably in the final mixture without the need for update. New UFIs for the final mixture should only be obtained, when changes in the mixture components lead to a change in the hazard classification of the final mixture.
- If information on non-hazardous components is required by poison centres, changes in the composition could possibly be reported to the centre by means other than changing the UFI It has not been explored how specifically this might be done.
- A concept of "comparable raw materials" could be introduced. This would allow reporting of a product containing similar, interchangeable raw materials and would involve stating that a product contains 20-25% MIM A with UFI xxx or MIM B with UFI yyy (where MIM A and MIM B are technically equivalent and have the same hazard classification, but which have different UFIs). (Again, it is not yet clear how this could work in practice.)
- Some respondents have suggested that a single UFI could be used per product representing the most commonly used raw material/supplier. This would decrease the number of notification updates required. A possibility to add multiple UFIs for one component in the new product could be provided.

P1-P3: Technical solutions

Survey respondents also proposed a range of technical solutions aiming to streamline implementation of Annex VIII and provision of emergency medical advice. These are not directly relevant for the workability issues within the scope of the current study. They are included here for completeness but are not considered further.

One of the proposed solutions included development of a central repository for all submissions in Europe to which all national Poison centres would have access. The industry believes that submissions should be made centrally, for free and automatically apply to all Member States and for free. Annex VIII should include a "no fee" rule which would supersede national legislation.

Some respondents argued that the use of SDS should provide all necessary information for emergency response as emergency measures can be derived based on the classification of the mixture, the hazardous ingredients and the physical data. Other industry representatives suggested the use of the existing SDS format but reporting full composition.

Survey participants also called for the development of IT tools to assist in bulk notification / bulk UFI generation and labelling including adaptation of software routines for recurring generation of the UFI code. In particular, one respondent argued that there is a need for an IT-communication between companies and poison centres which works independent of human resources. A permanent hot line sending the UFIs and the composition automatically was suggested. Software which automatically uses new UFIs from a supplier and automatically creates new product UFIs avoiding manual processing was suggested.

3.7.6 Feedback from workshop participants on industry-proposed solutions

The key points of discussion during the workshop highlighted, that for the paints sector in particular wide product ranges (based on small incremental changes to the mixture components) are used to provide every possible colour and shade to their clients. The inability to take advantage of the GPI for colourants could lead to very high numbers of notifications (millions). The issue of PoS paints was also discussed and the fact that it was not practical to generate a UFI and notification at the time of sale. Instead operators would need to notify for all possible combinations in advance. Industry asserts that this may be counter-intuitive for toxicovigilance as the full set of notifications (millions) would not reconcile with the products available on the market and hence the actual calls received. i.e. the number of actual incidents (small quantity)

would be dwarfed by the number of entries on record (millions), masking any real issues, as proportionately it would appear that any real incidents were a tiny fraction of the total market.

Further feedback on the proposed solutions to the workability issues identified was provided by the following appointed bodies and poison centres:

- Health Belgium (competent authority) wished to highlight that, for the purposes of emergency response, it is critical to have a complete composition. While the GPIs have been agreed to help limit the impact on sectors with very wide product ranges (based on incremental changes of the same mixture components), it should be noted that hazard classification alone is not sufficient for response, in particular, because different substances with the same hazard classification may require different treatment options. If the GPI was amended to allow substances/mixtures with certain types of health hazard it would represent a loss of information which would be unacceptable for emergency health response.
- BfR (appointed body) commented that proposed potential solution P-A (refinement of generic product identifier criteria for 'colouring agents') may be acceptable, but more information is needed on how it would work in practice. In particular, hazard class alone would not be acceptable as different substances with the same hazard classification can have different modes of action. The solution P-B ('use UFIs for the base paint and colourants in colour mixing systems on demand') has merit and could be a good solution, however, the number of UFIs would have to be limited to no more than three in their view[71]. A greater number of UFIs on a given tin of paint would delay and complicate response, which is not considered acceptable.
- The Dutch Poison Centre commented that proposed solution P-A would not be acceptable. Again, as others note, allowing amendment of the GPI by hazard class would create a loss of information. For example if the notification only refers to colourants classified as harmful, this does not provide any further information on the nature of the toxicity, i.e. how toxic and by what mode of action? The proposed potential solution P-B could be used but with caveats. It would not be acceptable for example to have 15 different UFIs on a tin of paint. If the number of UFIs were limited to at most three or four, then this could be a useful option to limit the impacts on PoS paints. Feedback on the idea of comparable raw materials is provided as per 'Comparable MIMs' under option CM-A (see section 3.4.6)
- The poisons information centre of Ireland commented that proposed potential solution P-A may have some merit. However, specifically which human health hazard classifications could be allowed would need careful review. In particular, a GPI should not be used for any mixture components that have systemic toxic effects, in their view.

In summary, the feedback from appointed bodies and poison centres highlighted significant concerns about the proposed potential solution P-A, primarily because information beyond a simple hazard classification would be needed for emergency response. Discussion held during the workshop further highlighted that there had already been discussion and agreement on the GPIs when Annex VIII was being negotiated. Further amendment to exclude only severely hazardous mixture components would revert what had already been agreed by Member States. The counter-point to this is that appointed bodies and poison centres also felt that very high numbers of notifications for paints of similar composition was undesirable. The feedback suggested that the proposed option P-B has merit, but needs some refinement in how it would be implemented (specifically the number of UFIs allowed per tin of paint). The proposed potential

[71] As further feedback from industry, CEPE would be supportive of such a limitation, but highlighted that based on their discussions this would mean that not all mixture components are covered. Feedback highlighted that a limit of three UFIs (base paint + two tints), would mean that only 40% of the tints would be covered, a limitation of four UFIs would cover about 80% of the tints used in a final mixture. Therefore, a limitation on the number of UFIs used would be welcome on the caveat that the UFIs associated with the lowest concentration mixture components could be omitted. (However, note that this may represent a misinterpretation, as an alternative interpretation is that the variable mixture components for which multiple UFIs are provided could be limited to e.g. three alternative UFIs (with no limit on the number of mixture components being present in total.)

option P-C, was agreed to be similar to CM-A, and again the same issues were raised regarding complexity of implementation, need for automated checking and agreement on what is meant by 'comparable raw material'.

3.8 Perfumes

3.8.1 Overview of sector and relevance to poison centres

Industry overview

The industry input to the study has been co-ordinated through IFRA Europe, which represents the formulators of fragrance products in Europe.

In 2010, sales of unique fragrance blends in Europe were estimated to be €1.7 billion and the industry supported around 7000 jobs directly. IFRA estimate that €34 billion of manufacturing output depended on fragrances, including in fine fragrance and beauty (43%), personal care (27%), household care (23%), and I&I (industrial and institutional) products (7%)[72].

IFRA estimates that there are around 500 fragrance formulators in Europe, many of which are SMEs[73]. Fragrance products may contain up to around 200 or more individual substances per fragrance formulation. IFRA members typically produce fragrance products which are then supplied in drums to other firms that formulate products, using the fragrance and other components, including products for consumers, professionals and industrial use. The fragrance is usually substantially diluted in the final products (sometimes more than 200 times).

IFRA Europe distributed the study questionnaire and a total of 23 responses were provided, including responses from 5 large companies and 17 SMEs (and 1 that did not specify), with annual turnover ranging from €45,000 to several billion Euros. Based on the questionnaire responses:

- The number of products per respondent was between 350 and 30,000, with an average of around 6,500 products per respondent. Across the 18 companies that provided a response a total of around 120,000 products have been identified.
- Of the 22 companies that provided a response, between 20% and 99.9% of their fragrance products are classified for health or physical effects under the CLP Regulation. However, only 2 of those companies had fewer than 80% of their products classified as such.
- 17 of the 22 companies that provided a response indicated that over 80% of their products are considered by the industry themselves to be mixtures for industrial use[74].
- Companies reported that there are on average 90 substances[75] contained per fragrance/perfume mixture, with a range from 2 to 500.
- Of those companies that were able to provide a quantitative response (6 companies), in general between 10% and 30% of the final products containing those hazardous fragrance mixtures would themselves be classified as hazardous based on their health or physical effects, taking into account dilution rates in the final products. The main health hazard mentioned was skin sensitisation. It seems that a higher percentage of certain end products (fine fragrances, air fresheners, for example) are classified compared to

[72] The socio-economic impact of fragrance technologies in Europe, IFRA, September 2012.

[73] IFRA, personal communication, 24 September 2018.

[74] The response was complicated by the fact that a large proportion of these fragrances are formulated into mixtures which are then sold on to consumers, with the fragrance substantially diluted. Several companies indicated that none of their products will be considered as mixtures for industrial use as a result.

[75] This is a simple average of the reported average numbers from each company that provided a response (22 companies).

others (household care and cosmetics products for example seemingly have very few final products classified).

- On average, just over 40% of companies' products were estimated to be exported out of the EEA (range 5% to 80%). Only around 3% were retained on-site for companies' own use in final mixtures. Around 50% of products were sold on to other EU formulators (range 0% to 95% across the companies).

Relevance to poison centres

A request for total number of calls received and proportion relating to fragrances was submitted to poison centres. In practice providing data on the fragrance sector is more challenging than for other sectors because fragrances can be sold as a product in its own right, but are more commonly found as part of a final mixture across a range of different sectors. This makes aggregating total numbers of incidents very challenging. BfR on behalf of GIZ-Nord provided data for cosmetics and soaps and detergents, noting that some of the calls relating to soaps and detergents could be argued are actually linked to the fragrance.

However, for cosmetics only, in 2017 GIZ-Nord received 2458 calls (6.7%) of the total received 36,563. The Netherlands reported 1.18% of calls as coming from air fresheners alone, and Ireland reported receiving emergency calls for air fresheners (137), cologne and aftershave (42), and essential oils (172) which all contain fragrances. The total volume of calls received by the Irish centre in 2018 was 10,144, of which the aggregated air fresheners, colognes and aftershaves and essential oils relate to 3.5%. (Table 3.2and Table 3.3).

3.8.2 Workability issues raised by industry

Issue FR1: Industrial mixtures treated as mixtures for consumer/professional use

The implementation of Annex VIII sets in place regulatory deadlines and data requirements for mixtures under different intended uses (mixtures intended for industrial, professional and consumer uses). For mixtures manufactured and used within industrial settings only, this includes the possibility to opt for a more limited set of submission requirements (see Part A, section 2.3 of Annex VIII) and a deadline to provide information to poison centres no later than the 1st January 2024.

However, mixtures which ultimately end up within products intended for consumer use (even if initially used in industrial settings), are considered to be mixtures for consumer use, and the full requirements of Annex VIII apply, including the deadline of 1 January 2020.

Furthermore, Annex VIII of the CLP Regulation provides an opportunity for duty holders to use a generic product identifier "fragrance" or "perfume" for certain mixture components if stipulated conditions in relation to health hazard classification and total concentration of such components (i.e. max. 5% within the mixture) are met.

Industry notes that, while mixtures of fragrances and perfumes used solely within industrial settings will present a higher level of hazard than the typically more diluted consumer or professional goods, in an industrial setting there is usually a greater knowledge of hazards and suitable measures such as medical treatment are more likely to be in place to control the risks. However, since it is possible that the original fragrance/perfume will ultimately be included in a mixture for consumer use (and the fragrance/perfume producer does not always know what the end product is), the fragrance/perfume produced is expected to be subject to the full data requirements as a mixture for consumer use, and the earlier compliance deadline. In addition, it should be taken into account that fragrance mixtures supplied to downstream users are greatly diluted within the final mixture consumer product, but as the original mixture (MiM) is classified as hazardous for human health, the notification obligation still applies.

Fragrances contain a variety of mixture components, a number of which are classified as hazardous for human health. This means that in most cases it is not possible to take advantage of the generic product identifier for 'perfumes and fragrances'.

It is claimed by industry that this represents a number of workability issues for the fragrances and perfumes sector which are:

1) Supply chains are complex and it is not always possible to tell the type of final product an industrial fragrance/perfume mixture is incorporated in by downstream formulators (i.e. in a mixture for consumer, professional or industrial use) nor its classification as hazardous or not. This will necessitate treating all fragrance mixtures as mixtures for consumer/professional use, with shorter submission deadlines[76]. In addition, companies would not be able to take advantage of the limited submission provisions. Rather full information as per Tables 1 and 2 of Annex VIII would apply.

2) Fragrance mixtures within consumer/professional products are greatly diluted, (possibly below CLP classification thresholds for the final mixture into which they are incorporated) meaning that the hazard classification for the same mixture components within industrial mixtures is no longer relevant for consumer/professional mixtures, but still must be reported. The final product may not itself require notification (because it is not classified) even though the intermediate fragrance mixture (MIM) would require a full notification.

All 23 companies that provided a questionnaire response confirmed that the above description of the workability issues faced is accurate for their company. A number of companies provided information on additional issues faced, as highlighted in section 3.8.4

Note that, for final mixtures that are exported outside the EU (40% on average based on the survey), these could benefit from the reduced information provision requirements for mixtures used in industrial settings, although the industry may not know which mixtures are ultimately exported or if the whole amount will be exported.

3.8.3 Impacts of workability issues

The main impacts of the above workability issue highlighted in the questionnaire responses were as follows:

- Significant additional time and cost requirements needed in order to process the additional information requirements and undertake the submissions (compared to the current situation and compared to the limited submission requirements for mixtures used in industrial settings).
- The interpretation that mixtures intended for industrial use but which are subsequently incorporated at industrial sites into mixtures for consumer (or professional) use will mean notifications are needed by the start of 2020. Any solution developed to address the workability issues identified may well require further adjustments to the format of the IT tools that ECHA developed, meaning greater challenges to meet the compliance deadlines. One company indicated that, they would need to notify all 15,000 of their formulations, as well as informing downstream users so that they can also notify their products[77].
- Several SMEs with only a small number of employees indicated that they would need to employ 1 to 3 additional full-time staff simply to process the notifications.
- 22 of the 23 companies indicated that it would be more practicable, in the case of mixtures for industrial use only, to opt for the limited submission provided for by Annex VIII to CLP, combined with the obligation for a 24/7 emergency phone availability. However, several indicated that this would not be possible, because of the potential for mixtures to be subsequently incorporated into mixtures for consumer or professional use.

[76] IFRA further clarified at the project workshop and in a subsequent written submission (28 February 2019) that 100% of fragrance mixtures will have to be considered as consumer mixtures, given that perfumes always end up in consumer and/or professional products.

[77] Informing downstream users is not a requirement of Annex VIII; downstream users can make their own notification regardless of whether the upstream supplier has provided additional information.

- Of companies that provided a response, most indicated that they were aware of the final uses of the products containing the fragrances when selling to downstream users for between 50% and 100% of their products. However, the figures differed significantly according to product type, with good knowledge for uses in cosmetics but often little knowledge for fragrances used in detergents, air-care products and household care products.
- IFRA subsequently clarified that companies will not be able to take advantage of the reduced requirements for submission for mixtures that end up in products outside the scope of CLP (such as cosmetics), because the composition of the final fragrance mixture and all possible uses of the fragrance is not always known. (i.e. some uses of the mixture may be in uses within the scope of CLP, even if other uses of the same mixture are not).

Aggregated information from company responses on the per-submission costs for fragrances is set out in Table 3.11.

Table 3.11 Estimates of per submission costs for fragrance formulations

Cost element	Estimated value
Analytical costs	17 Respondents left blank or cannot provide a value Other respondents gave a cost between €1-75 One respondent detailed a cost of €60/product and when annualised the cost would be €210,000 / year [ID 11] ID 23 detailed a €125 equipment cost
UFI generation	18 Respondents left blank or cannot provide a value The reported values ranged from €1 to €10
Labels	18 Respondents left blank or cannot provide a value The reported values ranged from €1 to €15
Information technology	18 Respondents left blank or cannot provide a value The reported values ranged from €2 to €60
Admin fees for appointed bodies	20 Respondents left blank or cannot provide a value The reported values ranged from €2 to €15 One respondent highlighted current difference in cost for Spain compared to Italy [ID13]
Staff time	8 Respondents left blank or cannot provide a value Respondents reported values between 30 minutes to 4 hours per submission Some presented costs instead of time, ranging from €9 to €600 per submission. One respondent claimed annualised cost will be €100,000 / year
Others	1 respondent highlighted "Headcount cost"

As a result of the above workability issues, the survey responses indicated that:

- A total of around 31,000 submissions to poison centres per year are made today, under the currently existing obligation of Art. 45 of CLP.
- This is expected to increase to around 54,000 submissions per year under the provisions of Annex VIII (an increase of 1.75 times).

- Companies varied considerably in their responses on the average frequency of expected formulation changes leading to a need for re-notification, with responses ranging from a weekly to an annual basis.
- Most companies were not able to estimate the number of submission updates that will be required under the provisions of Annex VIII. However, of those that were able to respond, the annual number of submission updates (as a consequence of formulation changes) is currently around 9,400 and this is expected to increase to 28,000 submission updates under Annex VIII, from 2020 onwards.

However, it is important to highlight that the main issue for this sector is the amount of additional information that will now be required (compared to e.g. simple submission of an SDS), and the earlier deadlines, rather than the increase in absolute numbers of submissions required.

3.8.4 Other workability issues raised

Some additional issues were raised, such as:

- In certain products (e.g. air-care products) the concentration of fragrances is much higher (even approaching 100%). In such cases there is pressure on the industry to develop fragrances with no health hazard classification, as a result of the requirements of Annex VIII.
- Concerns regarding disclosure of confidential information to the notification portal were raised by several companies.
- Frequent changes to individual components (e.g. only one of sometimes several hundred) leading to a need to update UFIs and notifications frequently.

3.8.5 Industry suggestions on solutions to workability issues

Possible solution FR-A: Limited submission for mixtures where data requirements are comparable to SDS in final consumer/professional mixture

Although responses were differently phrased/interpreted, the majority (16 of 23) of companies responding indicated that they favoured allowing use of the limited submission provisions for their fragrances, which are sold initially for use in industrial sites, but many of which may subsequently be incorporated into mixtures for consumer or professional use. There were a number of variations around this proposal[78]. The rationale behind this proposal is that the workload for the sector would be much lower and potentially confidential information would not need to be disclosed[79]. Companies argued that the data contained in the SDS would provide sufficient information for the formulator of the final consumer product to provide information to allow emergency health response for that product.

3.8.6 Feedback from workshop participants on industry-proposed solutions

The key points of discussion during the workshop explored the themes of fragrances manufactured within industrial settings, which are ultimately intended for or incorporated in products for consumer/professional markets. This included discussions around dilution of fragrances within final mixtures, why information about fragrances may be needed before the 2024 deadline and the magnitude of the impact for industry if they need to assume that all of their mixtures may ultimately be used in consumer/professional uses.

Further feedback on the proposed solutions to the workability issues identified was provided by the following appointed bodies and poison centres:

- The poisons information centre of Ireland (appointed body and poison centre) suggested that possible solution FR-A would not cause difficulties for poison centres for many final

[78] For example, some companies referring to simply providing the SDS itself, others to removing the requirement for a 24/7 emergency phone number in the case of limited submission as stipulated in Annex VIII.

[79] Note that there is no explicit legal obligation requiring the full composition to be provided to the downstream user.

mixtures in particular where the concentration of fragrances in the final mixture is low. They highlighted that it could cause problems where the final concentration of the fragrance remains high, such as in air fresheners. They suggested that limited notification could be permitted for fragrances, with the requirement to make a full notification if requested by ECHA or an appointed body, for example if the fragrance mixture was present at a high concentration in a final mixture for consumer or professional use.

- Likewise BfR (appointed body) considers that industry-proposed solution FR-A (limited submission for hazardous mixtures comparable to SDS) is not generally acceptable, but could be if the industrial product were limited to a maximum concentration in the final mixture, (consumer product), such as 5%. They note that there is no need to restrict this solution to just fragrances.

Feedback at the workshop itself reinforced the descriptions in the previous sections on the impacts of the workability issues for industry.

In summary, based on the above feedback, there appears to be merit in considering the solution proposed by industry further. However, it is clear that poison centres would require information on hazardous fragrances where they are not present in only very low concentrations.

3.9 Soaps and detergents

3.9.1 Overview of sector and relevance to poison centres

Industry overview

The industry input to the study has been co-ordinated through AISEAISE[80], which represents the household care and professional cleaning and hygiene products industry. AISE represents approximately 900 companies across Europe, via a network of 29 national association members, 18 corporate members and 6 value chain partners. Large manufacturers in this sector produce an average of 150 to 250 consumer detergent formulations each whilst SMEs produce an average of 40 to 60 consumer detergent formulations each.

In 2018, the market value of the sector was €36,7 billion, comprising €29,1 billion for household care products (comprising laundry care, surface care, dishwashing, maintenance products and bleaches), and €7,6 billion for professional cleaning and hygiene products and services (covering healthcare, food/beverage/agriculture, kitchen/catering, technical cleaning, building care and laundry).

AISE provided a response to the study questionnaire based on a collation of responses from 10 companies, representing 64% of the annual revenues of the sector, and including several large, multinational companies but also a number of SMEs.

Based on the questionnaire responses:

- The number of products per respondent was between 85 and 2,800, with an average of 1,130 products per respondent.
- There are estimated to be 31,500 to 51,500 consumer detergent formulations in the EU/EEA, and >31,500 professional cleaning and hygiene product formulations[81].

[80] Inputs from AISE include discussions on 18/07/2018, 24/08/2018, and 27/11/2018. Written submissions include completed questionnaire responses of 26/11/2018 and case studies provided 05/12/2018. Further information was provided after the study workshop, in a written communication of 04/03/2019.

[81] Survey respondents included large manufacturers of professional cleaning and hygiene products. Portfolios of products in this sector tend to be larger than in the consumer sector. As such, cleaning and hygiene products were conservatively be expected to add > 31,500 additional products to the figures for consumer detergents. No upper end of the range was given.

- The number of individual components (substances or mixtures) was in the range from 2 to around 100.
- Respondents had on average 3 suppliers for each raw material, but often in the range 5-15 suppliers for business-critical raw materials.
- On average, 71% of products are subject to the requirements of Annex VIII, though some respondents have as many as 90% of products affected.

Respondents were reported to fulfil a variety of roles dependent on their business model and size. Typically, they were mid-level in the supply chain and undertake formulation of finished cleaning and/or maintenance products using substances and/or mixtures that have been purchased from suppliers. However, some respondents also manufacture components in-house prior to formulation. Product formulation activities can be conducted either for direct sale, further distribution or in the capacity of toll formulator for a third party.

Relevance to poison centres

Data has been provided by the appointed bodies and poison centres for Ireland, Italy, Finland, Germany, the Netherlands and Spain regarding both total numbers of emergency calls received annually, but also the proportion relating to soaps and detergents. Based on the responses from these bodies and centres soaps and detergents on average make up 11% (range of 2% to 18.6%) of all emergency calls received. See also Table 3.1 and 3.2 for further details.

3.9.2 Workability issues raised by industry

Issue SD1: Limited potential for use of group submission and use of GPI

Under Section 4.3 of Part A, a group submission is allowed where the difference in the composition between different mixtures in the group only concerns perfumes or fragrances, provided that the total concentration of perfumes and fragrances contained in each mixture does not exceed 5%. However, the industry has indicated that only a small number of mixtures will qualify for group submission.

Another possibility to reduce the number of submissions where the only difference between mixtures is in use of different fragrances or perfumes is the use of the generic product identifier (GPI). However, although, according to Section 3.2.3 of Part B, the generic product identifiers "perfumes" and "fragrances" may be used for mixture components used exclusively to add perfume or fragrance, this applies only where the mixture components are not classified for any health hazard. AISE has clarified that the limited ability to use the group submission approach is in part due to the limitations on use of the generic product identifiers.

The perfumes/fragrances used in the detergents industry are typically odorous and, according to AISE, most of them carry some form of health hazard classification. AISE comment that based on data provided by the fragrance industry (see section 3.8), 17 out of 22 companies highlighted over 90% of their product portfolios were classified for human health. Fewer than 10% of mixtures will therefore be able to make use of either the group submission approach or the GPI. A separate notification and UFI will therefore be required for almost all mixtures.

Linked to this issue, because fragrances are typically incorporated into detergent products as mixtures-in-mixtures (which are complex and may contain up to 50 individual components), companies indicate that they will be required to report on the full MIM composition, and will not be able to make use of the derogation in Section 5.1 of Part A, meaning that submissions will be much more onerous (because the industry indicate that they will not be able to use the group submission approach).

The implication of this workability issue is that the detergents industry estimates that there will be many more (and more complex) submissions required than would have been the case if it were possible to use the group submission approach more widely.

Furthermore, the inability to use the Generic Product Identifier or group submission means that if the composition of a fragrance component changes (or if a confidential MIM fragrance changes UFI), changes to the final product UFI and submission will also be required. AISE members consider this unnecessary.

The industry highlights that many additional notifications and UFI changes will be required, even where there is no change in the hazard classification of the mixtures concerned. AISE members report that perfumes are used in the majority of mixtures and typically the full composition of the fragrance is not known (companies will often only have access to information on ingredients listed in SDS, with only broad ranges for concentration given). (Note that if the full composition is not known, then the UFI of the MiM is to be provided, or the known components.)

Table 3.12 AISE case study on the workability of GPI and group submissions

AISE provide an example of a liquid laundry detergent product, which is currently placed on the EU market for consumer use, consisting of 12 components, 11 of which are non-odorous while the 12th, the perfume, is an odorous perfume mixture, which is classified for Eye Irritation Category 2 (H319), Skin Irritation Category 2 (H315) and Skin Sensitisation. Category 1 (H317).

The perfume is used at a concentration of 2.2% w/w and consists of 111 separate components.

Under the originally-proposed criteria for use of the GPI, the product formulator would have been able to identify the perfume using the GPI "perfume". Under Annex VIII, GPIs must not be classified for any human health endpoint. The product formulator will not be able to use the GPI "perfume" for this component from January 2020 due to its hazard classification. The nature of fragrance chemistry means a non-classified substitute will not be available.

Consequently, the formulator will need to report this component as a mixture in mixture (MIM) in accordance with Part B, Section 3.2.2. The number of components included in the notification for this formulation will therefore increase from 12 components to 122 components (11 mixture components and 111 MIM components). The majority of the disclosed MIM components will occur at < 0.001 % of the overall final product mixture.

AISE highlights the following two issues:

1. The use of the GPI is effectively unavailable for fragrance mixtures because of the requirement that mixture components should not be classified for any health hazard. This means that there is limited potential to reduce the number of submissions through use of the GPI. Furthermore, because of the constraints on use of the group submission approach (same hazard classification, same product category, same components contained in the same concentration range, as per section 4 of part A), this again is unlikely to be a means of reducing the number of submissions for mixtures which are essentially the same, differing only in fragrance added.

2. The inability to use the GPI will significantly increase the number of components disclosed, the number of components that may be subject to variance and which can trigger a submission update.

AISE suggest that, if the Annex VIII requirements were to revert to the GPI classification criteria originally proposed during the development of Annex VIII (i.e. human health classifications of major concern: Acute Tox (Cat 1 – 3), STOT SE (1 or 2), STOT RE (1 or

2), Skin Corr (Cat 1, 1A – C), Eye Dam (Cat 1), CMR (1A or 1B)), the impact of the workability issue could be limited significantly (i.e. the number of required notifications would be significantly reduced). In the above example, the number of components would in that case be:

Perfume component level: 122 components notified (11 mixture components and 111 MIM)

Detergent mixture level: 12 components notified (11 mixture components and 1 GPI component)

AISE highlight that a perfume mixture can have up to 200 mixture components. Typically, in the region of 60 % of perfume components are classified for a human health endpoint. They indicate that reverting to the original conditions for the GPI would lead to no reduction in the ability of a national appointed body to undertake emergency response, since classification, label elements and toxicology of the final mixture are the primary tools in an emergency response.

Source: AISE.

Issue SD2: Regular product variation

AISE report that most products are formulated using substances and mixtures sourced from multiple suppliers. This is to ensure continuity of supply and, as above, the number of suppliers per for each raw material may be high.

Raw materials from different suppliers are used interchangeably across batches as they are considered to be technically equivalent (in terms of hazard profile, physical properties, effectiveness, etc.) and yield a final product that is within defined tolerances for product performance, behaviour and appearance. Furthermore, versions of a technically equivalent raw material with the same hazard classification from different suppliers may be stored in the same vessel prior to product formulation, meaning that any given product may have a mix of different but technically equivalent raw materials. Raw material suppliers may be changed frequently (e.g. as often as weekly).

Different raw material substances often identify their "technically equivalent" (including hazard classification) raw materials using different numeric identifiers (EC number or CAS number for example). However, such changes do not result in technical changes to the final product, nor to a change in hazard classification. Nonetheless, a new submission and new UFI would be triggered under Annex VIII.

AISE report that companies are then faced with one of two options:

- Submitting a significant volume of notifications / updates on a regular basis to report changes to composition, despite the changes being to technically equivalent raw materials (with the same hazard classification), in turn leading to frequent changes of UFI on labels and packaging (multiple layers).
- Move towards mono-sourced supply chains, in order to reduce notification obligations. This would reportedly pose risks for both formulators and end users in terms of continuity of supply, material costs and product performance.

As a result, AISE indicate that significant additional effort would be required (or significant disruption to supply chains) without any improvement to emergency health response.

AISE have provided a case study example, shown below.

Table 3.13 Case study from AISE on multiple submissions with change in product formulation

AISE provide an example of a product placed on the market which can contain one of nine equivalent surfactants sourced from multiple supply chains. These surfactants belong to the same category of surfactants (alcohol ethoxylates – as identified by CESIO (Surfactants Europe)) and carry the same hazard classification. Each surfactant differs by carbon chain (length range and extent of branching) or in one instance extent of ethoxylation (EO).

Name:	CAS No	Hazard classification (health)
Fatty Alcohol (C14-15) Ethoxylate 7 EO	64425-86-1	Acute Toxicity Category 4 (H302) Eye Damage Category 1 (H318)
Fatty Alcohol (C13-15) Ethoxylate 7 EO		
Fatty Alcohol (C14-15) Ethoxylate > 5-10 EO	68951-67-7	
Fatty Alcohol (C14-15) Ethoxylate 7 EO		
Fatty Alcohol (C12-15) Ethoxylate 7 EO	68131-39-5	
Fatty Alcohol (C12-18) Ethoxylate 7 EO	68213-23-0	
Fatty Alcohol (C12-16) Ethoxylate 7 EO	68551-12-2	
Fatty Alcohol (C12-14) Ethoxylate 7 EO	68439-50-9	
Alcohols, C12-13, branched and linear, ethoxylated 7EO	160901-19-9	

AISE report that, despite the differences between each of these complex surfactants, they are used interchangeably by the product formulator. This group of surfactants are considered to be technically equivalent, sharing the same hazard profile, comparable physical properties and technical function. Consequently, they yield a product for the end user that has a consistent appearance, performance and shelf-life (regardless of which surfactant is used). This consistency extends to the classification of the (final) mixture, label elements and toxicology (as required per Annex VIII, Part C, Section 1.3) information reported to national appointed bodies.

As this information on mixture classification, labelling and toxicology is the preeminent data source for national appointed bodies when responding to accidental exposure, AISE consider that there is no added value to the emergency response capability of these bodies when notifying them of regular component variation within an intentional and well-defined group of components.

3.9.3 Impacts of workability issues

Overview

AISE has indicated that, if unresolved, the workability issues are expected to lead to:

- Significant ongoing resourcing requirements and associated costs due to an increase in the number of submissions; and
- An unfeasible increase in plant footprint and multi-million-Euro capital expenditure to address the issue of product variation.

These two issues are described in turn below.

Increased resource requirements due to greater number of notifications

As a result of the above workability issues, the survey responses (covering 64% of the market turnover but much less than 64% of the total number of products on the market):

- A total of 21,155 submissions to poison centres per year are made today, under the currently existing obligation of Art. 45 of CLP.
- This is expected to increase to 47,064 submissions per year under the provisions of Annex VIII.

In terms of the need for resubmission, the implications are more significant (i.e. a greater increase). AISE report that surfactants and fragrances/perfumes are the components that are most likely to trigger a resubmission. Enzymes, optical brighteners and preservatives were also identified. Typically, changes to these components were expected to result in a resubmission between one and four times a year. For some mixtures, changes in composition as frequently as every week were identified as potentially triggering a resubmission.

As a result, the survey responses indicated that (again based on 64% of the market turnover, but much less than 64% of the total number of products on the market):

- The annual number of submission updates (as a consequence of formulation changes) is currently 8,502.
- This is expected to increase to 47,420 submission updates expected under Annex VIII, from 2020 onwards.

The industry report that the changes to submissions and updates are due to:

a) composition changes not currently triggering re-submission at Member State level, in most cases;

b) currently broader concentration ranges compared to those in Annex VIII in those Member States that do currently require composition information;

c) increased composition disclosure requirements meaning that more constituents (in total) will be subject to update requirements, promoting the likelihood of additional updates; and

d) information changes relating to MIMs will cascade down a supply chain, potentially triggering related updates across multiple supply chains and at multiple levels.

AISE provided aggregated information from members on the per-submission costs for detergents, as set out in the Table 3.13.

Table 3.14 Estimates of per submission costs for detergent formulations (AISE)

Cost element	Estimated value
Analytical costs	Variable [Note A]
UFI generation	Negligible generation cost [Note B]
Labels	€2000 - €4000 per label for design/artwork change [Note C]
Information technology	≤€250 000 per company [Note D]
Admin fees for appointed bodies	Variable (information is publicly available)
Staff time	60 to 180 minutes per submission [Note E]
Others	None noted

Notes:
[A] Dependent on formulation and product type. A combination of standard formulation analysis/assays in conjunction with supplier disclosures would be used.
[B] Administrative tasks highlighted include: sourcing, identification tracking and documenting of internal formula codes and generated UFI.
[C] Significant difference in accounting and procurement practises mean that label costs vary depending on factors such as whether the product is new or existing, if label update is comprehensive artwork update or a UFI update; the size and complexity of the stock-keeping unit (SKU) and its labelling requirements. The quoted range reflects a change of label artwork. It does not include printing costs or change management costs.
[D] IT costs vary significantly depending on the use of licenced software vs in-house software. Further, the cost of licenced software is dependent on charging model (pay-per-use vs annual subscription). AISE noted that larger companies would generally invest in new IT systems whereas smaller companies would generally make manual submissions.
[E] Complexity of submission is the key variable in this instance.

AISE members reported that cost and time estimates remain challenging due to notification requirements not being fully clarified (e.g. applicability of group submissions, frequency of updates) and given that the submission portal was only made available from April 2019. They also highlighted that frequent updates will be required, with associated costs for both new and existing products, which could increase the cost of final products.

AISE provided a case study on an SME, highlighting the additional resource requirements arising from the anticipated increase in the number of notifications. Details are provided below.

Table 3.15 Case study from AISE on impacts of increase in notifications for an SME

AISE provided information on an SME currently producing around 100 formulations per year, of which some are own label products and some are as private label formulations for third parties. The company changes around 30% of their formulations each year, either brand-new formulations (around 20) or revision of existing formulations (around 10). Under the current situation, the company only makes notifications for around 15 of these "new" formulations each year.

The company currently devotes around 1.5 full-time equivalents (FTE) to all aspects of regulatory affairs linked to REACH, CLP, Biocidal Products and transport legislation. Under national poison control notification requirements, the company currently makes around 50 notifications per year for 15 of their own label formulations (in between 2 and 4 EU member states). They estimate that this requires around 0.05 FTE of the 1.5 FTE above.

Under the new Annex VIII, the company estimates that they will require at least 372 notifications per year, comprised of the following:
90 notifications for "new" own label formulations based on 15 formulations notified in on average 3 member states (= 45), plus an update for each submission each year (a further 45).
282 notifications for 47 "existing" formulations, updated twice per year (i.e. 94 updates in on average 3 member states).

The number of formulations that need to be notified does not change in the above example, rather it is the number of updates required that is predicted to lead to a significant increase in submissions.

The company estimates that the additional resource requirements for on average an additional 7 notifications (updates) per week would require the use of third party support, equating to 1.0 to 2.0 FTE per year, or around €40,000 to €80,000 per year. These costs are significant for an SME, where margins are typically low. (Note that this equates to on average €212 per submission (range €142-€284) in 3rd party consultants' fees. It is assumed that the costs per submission would also increase compared to the current situation, where submissions are done in-house.

AISE highlight that detergent formulations often consist of a "base formulation", which is adjusted for colour and fragrance. The increase in number of submissions is due in large part to the need for separate submissions for each of these variants. (While group submissions can be made where only fragrances differ between products, as indicated earlier in this section, AISE's members do not expect to be able to make extensive use of the group submission provisions.)

Source: AISE, 4 March 2019.

Increase in plant footprint and capital expenditure

As a result of workability issue SD2 (regular product variation), AISE has highlighted that the detergents industry sources technically equivalent raw materials from on average 3 suppliers (and 5-15 suppliers for business-critical raw materials). These are stored in the same storage silos prior to use. Since these silos are never allowed to run dry, the technically equivalent raw materials become mixed in storage and it is then in their view impossible to know the exact composition of the mixture, and hence it is impossible to comply with Annex VIII. (In principle, the raw materials could be analytically tested each time any such mixing took place, but in practice this is understood to be unfeasible without significant disruption to production processes and additional capital costs for analysis.)

In order to know the exact composition of a given product, AISE indicate that detergents formulators would need to expand their raw material storage capacity. They provide an example, for a (hypothetical) product consisting of 6 mixture components. Using an average of 3 silos for each mixture component, the number of silos required would increase from 6 to 18 (this assumes one silo for each supplier). Based on estimates from a third-party engineering firm, a typical new silo would occupy a footprint of 30m^2 and would entail capital expenditure of around €380,000. For an additional 12 silos, therefore, there would be a requirement for an additional footprint of 360m^2 and capital expenditure of €4,560,000.

Based on a preliminary review, the increase in numbers of formulations may represent an overestimate (e.g. some of the interchangeable mixture components will be substances with the same CAS number, etc. and so no additional infrastructure would be needed). AISE, however,

note that the estimates provided by their members represent a conservative set of values for potential increase, and in practice the overlap for mixture components with the same composition (i.e. not triggering an update) would be less than 25%.

In any case, if such an approach is adopted the potential impact across the soaps and detergents industry could be very high, given that:

- There are over 900 detergent formulators represented by AISE
- SMEs typically have ≤100 products and large companies typically have ≥100 products.

Assuming that each of AISE's members had to increase storage capacity for just one additional product based on the assumptions (i.e. 900 products), the total capital expenditure could be in the order of €4,000 million[82]. Since this estimation represents < 1.5 % of the cleaning products on the market (estimated 63,000), the infrastructure costs imposed on the soaps and detergents sector can be expected to be substantially higher.

AISE highlight the benefits estimated in the study on costs and benefits of harmonising information submitted to poison centres (AMEC, 2015) indicated a cost saving of €550 million per year for the EU as a whole. The above cost increases would substantially outweigh those savings[83].

3.9.4 Other workability issues raised

In addition to the above workability issues, AISE have raised further workability issues for their sector. These are not considered to be within the scope of the current study but are noted here in order to allow possible further consideration by the Commission. These issues are:

IT Tool roll out/implementation:

- AISE suggest that the timeline for roll out of notification IT tools is short. AISE have concerns regarding delivery timelines being met for roll out of the notification portal, its likely robustness and reliability; the usability of the IT tools; industry having sufficient time prior to the deadline to assimilate the notification tools; and the scheduled release of substantial updates during November 2019.
- They suggest that significant adaptation and development time would be needed to ensure that in-house product formulation codes can be tracked using a formulation code that is compatible with the UFI generation algorithm and a UFI. They suggest that less than one year is insufficient time to ensure the availability of robust IT infrastructure.
- As a result, AISE have proposed (by letter to the Commission of 15 October 2018) postponing the Annex VIII implementation deadlines by 12 months.

On-label UFI printing:

- AISE highlight that development of label content can take several weeks, and is a costly process that does not easily accommodate frequent changes e.g. to print the UFI on the label itself. They highlight the potential for process breakdown and production stoppages if new labels are unavailable on time.

AISE have therefore welcomed the Commission's proposal that it will be possible to print the UFI on either the label or on the package.

[82] €4.56 million x 900 companies.

[83] Note that, even if the capital expenditure costs were amortised over 25 years assuming a discount rate of 4%, the additional (hypothetical) costs of these silos (for < 1.5 % of all detergent products on the market) would be around €260 million per year for the detergents sector alone. Once other sectors are included, it is clear that significant additional costs would be incurred with the potential for such costs to more than outweigh the savings calculated in the previous study for harmonisation of data requirements.

3.9.5 Industry suggestions on solutions to workability issues

Possible solution SD-A: Refinement of general product identifier criteria

To address issue SD1 above (limited potential for use of group submission and use of GPI), AISE have proposed that the generic product identifier criteria related to "perfumes" and "fragrances" would allow greater use to be made of these generic product identifiers.

Since most fragrances are classified (see also section 3.8) for some health hazards (often skin sensitisation and/or aspiration hazard), use cannot currently be made of the GPI, even if the detergent mixture sold is not itself classified for those health hazards. AISE suggest that the GPI criteria should be amended such that the GPI could not be applied if the fragrance/perfume mixture is classified for:

- acute toxicity, category 1, 2 or 3,
- specific target organ toxicity single exposure, category 1 or 2,
- specific target organ toxicity repeated exposure, category 1 or 2,
- skin corrosion, category 1, 1A, 1B or 1C,
- serious eye damage, category 1.
- carcinogen, mutagen, reproductive toxin, category 1A or 1B

AISE suggest that this approach would be consistent with the original proposal from the Commission for Annex VIII. AISE suggest that the poison centres generally do not require information on skin sensitisers when present in very low volumes, although some reportedly do require such information for toxicovigilance purposes (AISE suggest that such information is available from other sources e.g. perfume oil notifications). This aspect is to be checked in consultation with the poison centres.

Please note that AISE, along with other industry associations, provided an elaborated suggestion to address this workability issue at the project workshop. This is reproduced in Appendix B and is further analysed in Chapter 6 of this report.

Possible solution SD-B: Substantially similar components

To address issue SD2 above (regular product variation), AISE have proposed that a concept of "Substantially Similar Components" be incorporated into Annex VIII. As with other sectors, and as highlighted above, the detergents industry has multiple suppliers of the same or equivalent raw materials (both substances and mixtures).

Under this proposed approach, when reporting a formulation composition, the notifier could identify substantially similar components (substances or mixtures) that may be subject to change within a list of nominated alternatives (e.g. multiple alternative CAS numbers for what are technically equivalent surfactants, with the same human health hazard classification and which are currently used interchangeably). The notifier would identify all nominated similar components in advance of placing on the market in accordance with Part C, Paragraph 1.4. Such an approach would need to include a number of conditions in order to avoid inappropriate use, such that substantially similar components would need to:

- Serve the same technical function
- Be within the same "hazard envelope" i.e.:
    - Carry the same health and physical hazard classification
    - Be used at the same concentration ± a defined concentration limit
    - Be of a comparable potency
    - Have the same toxicological mode of action

AISE suggest that these would need to be complemented with a technical completeness check at the time of submission[84], a retrospective evaluation by a relevant body and industry guidelines to support the "hazard envelope" concept by defining safe, acceptable categories of comparable constituents.

AISE propose that submission update requirements would be in line with the existing requirements under Annex VIII, meaning key information on the hazards of mixture components and overall composition would still match the objectives of Annex VIII without loss of detail. However, it would allow additional flexibility for mixture components that were substantially similar, reducing the burden on industry in terms of submitting multiple updates to notifications.

They suggest that this concept would afford industry multiple workability improvements with no reduction in the quality of emergency response information available to poison centres. They suggest that this would lead to updates where there is new emergency response information while reducing the number of poison centre notifications that do not lead to such new information. It would also reportedly minimise costs associated with artwork changes and label printing[85].

Please note that AISE, along with other industry associations, provided an elaborated suggestion to address this workability issue at the project workshop. This is reproduced in Appendix B and is further analysed in Chapter 6 of this report.

3.9.6 Feedback from workshop participants on industry-proposed solutions

The key points of discussion during the workshop explored how the GPI has been implemented under Annex VIII and workability issues for soaps and detergents that use fragrances. In particular this included discussion around the development of the GPI and the original suggestion in the discussion stages of the draft legal text which only excluded severely hazardous classifications. The issue of multiple suppliers for the same mixture component and frequent variations (particularly for fragrances) was also discussed.

Further feedback on the proposed solutions to the workability issues identified was provided by the following appointed bodies and poison centres:

- Health Belgium (competent authority) raised concerns similar to those already voiced for amendment of the GPI for colourants, in particular that widening the GPI to allow use of the GPI for certain hazardous components would create a loss of key information and is therefore unacceptable. Health Belgium stressed that hazard classification alone does not provide further information on the true nature of the hazard (i.e. how toxic) and its mode of action. It would be necessary to know specifically which substances were in use to formulate an appropriate response. For the proposed potential solution SD-B (substantially similar components), Health Belgium also raised concerns that a long list of interchangeable MIMs would be impractical during an emergency and therefore this option is also unacceptable.
- BfR (appointed body) raised similar comments as discussed for P-A (refinement of GPI for colouring agents), i.e. that the proposed option SD-A (refinement of GPI criteria) may be possible, but more information is needed specifically how it would operate. BfR noted that in general this option would not be acceptable and highlighted that the use of GPIs had already been discussed and agreed previously. For proposed potential option SD-B, BfR commented that they had similar concerns to the similar option 'Comparable MIMs', in that the approach seems reasonable but would need full automation and agreement

[84] This would require adaptation of the IT system.

[85] Specifically, under the current legal text, updates to the labels themselves could not be made in time to accommodate rapidly changing UFIs (labels require 12 weeks on average to generate and check). Companies would therefore need to print the UFI on the pack, which would necessitate (a) new equipment to allow the UFI to be printed and (b) often a slow-down in production speeds to accommodate printing the 23 digit UFI, which is substantially longer than codes that are currently printed on packaging (e.g. expiry dates).

on what is an 'equivalent', this need to include not only technical function but toxicology and mode of action.

- The Dutch Poison Centre (appointed body and poison centre for The Netherlands) commented that proposed solution P-A is not feasible. The proposed exclusions only for severely hazardous substances was the original starting position and had been discussed already during negotiation on Annex VIII. While some Member States were happy with this option, others were not, primarily related to toxicovigilance issues. Amending the GPI as proposed would revert what had already been agreed. However, the Dutch Poison Centre also commented that many alternative GPIs were discussed and agreed in quick succession. Given the scale of the workability issues for paints, other construction and soaps and detergents it may be necessary to revisit how the GPIs are implemented. The Dutch Poison Centre also commented that solution proposed by BfR 'G6' should be considered.
- The poisons information centre of Ireland (appointed body and poison centre) commented that the proposed potential solution P-A, particularly for skin sensitisers only, could be acceptable. It was noted that often when such a product contains a skin sensitiser it is listed on the label anyway. If this were the case would it help make the case for amending the GPI as such? For the proposed solution P-B the idea of having a long list of MIMs which are technically equivalent would make emergency response extremely challenging. The proposed solution is therefore impractical, for example if a mixture contains 10 components and each component has three equivalents, this would equate to 30 MIMs which need to be reviewed in order to formulate a response. The poisons information centre of Ireland further highlighted that the proposed solution would also need to consider modes of action as part of the technical equivalence, which in reality would be very challenging for a company.
- The Croatian appointed body commented that the proposed potential solution SD-B would be unworkable in practice as a long list of MIM components of technical equivalence would significantly complicate the response. In this case a SDS would be preferable.

In summary the feedback above highlights concerns around how the proposed potential solution SD-A might be implemented. However, at least one appointed body recognised that there may be a need to revisit how the GPI has been implemented and that it is equally undesirable for appointed bodies to receive very high number of notifications for similar final mixtures (be they paints or in this case soaps and detergents). Another appointed body also highlighted that there may be a way forward to accept use of the GPI with skin sensitisers at least. For the second proposed solution on mixture components of technical equivalence there was strong agreement that the solution may have significant problems in its implementation (particularly if a long list of MIMs and UFIs is included).

3.10 Other sectors

3.10.1 Overview

The study terms of reference identified specific sectors that have raised concerns regarding workability issues for the implementation of Annex VIII. During the industry consultation additional sectors also indicated they wished to provide input on the basis that the workability issues identified within the scope of the study could also affect them in a similar fashion.

3.10.2 Premixtures for animal feed

FEFANA[86] comment that, while animal feed is exempt from CLP, premixtures used to produce animal feed are covered by CLP and Annex VIII. Premixture products are produced as blends (with 20-50 mixture components) largely from natural minerals and nutrients. Companies manufacturing such products can have 300-1000 different formulations intended for different

[86] The EU association of specialty feed mixtures and their ingredients.

animals, stages of life cycle, and nutrient requirements; with development of such formulations being time critical. Furthermore, production of the final animal feed product can be completed within industrial settings but also directly by farmers (who would use the premixture with other food stuffs) categorising the premixtures as intended for professional use under Annex VIII. Premixtures are never supplied to the consumer market.

It is possible for premixture components to be classified as hazardous under CLP, although FEFANA also note that the industry is regulated under Food and Feed Safety legislation and has to apply HACCP principles (Hazard Analysis and Critical Control Points) to prevent contamination from biological, chemical or physical agents which could result in potential adverse health effect on animals and ultimately on humans.

Real-time monitoring of specific composition and completion of notifications will likely be challenging, both in terms of timing and cost. Even small changes to composition could trigger the need for many updates of notifications. This is further exacerbated where multiple suppliers are used for mixture components (as is the case with some of the other sectors highlighted above).

FEFANA have suggested possible solutions to the workability issue could be covered by:

1. Categorisation of farmers producing the final animal feed as industrial settings[87] comparable to work completed in such settings, thus allowing the reduced notification.
2. Use of comparable MIMs (see section 3.5.5 for cement), particularly where mixture components can themselves be mixtures.
3. Creation of a new GPI for non-hazardous premixture components (which could make up 50% of the product).

3.10.3 Firefighting products

EuroFeu[88] represent manufacture and sale of fire-fighting materials (gases, gas mixtures, dry chemical powders, and foam agents). These are intended primarily for professional use with a smaller sub-set (estimated ≤10% of the product range) for consumer use. The industry is made up of approximately 20 large sized manufacturers across Europe, but beneath this are hundreds of distributors.

The manufacture of dry powders and foams makes use of naturally occurring compounds such as mono ammonium phosphate, and hydrolysed proteins. Where these naturally occurring mixture components are manufactured by other sectors (such as agricultural companies) from naturally variable feedstocks, the mixture component can vary frequently, while the members of EuroFeu may receive only limited information from their suppliers on the specific composition. This issue is exacerbated where mixture components are themselves also mixtures (i.e. the components are MIMs in the final mixture).

The workability issue created is that it means the composition of dry powder and foam-based fire-fighting materials can vary frequently. It would require a significant amount of effort to monitor and track composition on a frequent basis, which would likely trigger the need for updates on an equally frequent (potentially daily) basis and mean that many UFIs would be in circulation for products with very similar composition and the same hazard classification. For example, in dry chemical powders, one of the key components is mono ammonium phosphate (from fertiliser production, which is made from rock using a primitive technical process, so the variation in phosphate content varies significantly from one area to another). The industry thus cannot know the exact composition at any given time. Other ingredients with variation in composition include silicon dioxide, ground marble and barium sulphate. The same is true for fire-fighting foams which often contain naturally occurring raw materials.

[87] This may not currently be possible based on the assumed definitions for 'consumer', 'professional' and 'industrial' settings in Annex VIII of CLP.

[88] European Committee of the Manufacturers of Fire Protection Equipment and Fire Fighting Vehicles

EuroFeu did not provide further suggestions for solutions to this workability issue, but would welcome the findings of the study and input from other sectors (in scope) that have the same issue.

3.11 Summary of significance of workability issues

Introduction

The preceding sections have provided a detailed breakdown of the workability issues that have been reported by industry under different industry sectors, proposed solutions from industry and feedback provided by appointed bodies and poison centres on those possible solutions.

This section aims to provide an overall summary to help detail the potential scale and significance of the workability issues, both in terms of economic impacts for the specific industry sector, but also in the practical issues of compliance against Annex VIII of CLP.

Based on analysis of the data provided and reported in the preceding sub-chapters, four key sets of issues have been identified for further discussion within this summary:

- Comparison of cost estimates and challenges in developing cost estimates.
- How the workability issues relate back to the previous study on harmonisation of notifications to poison centres.
- Which workability issues are genuinely sector-specific, and which issues are much broader, likely affecting multiple / all industry sectors.
- Classifying workability issues in a fashion that helps to better understand how the impacts manifest.

Analysis of cost comparison across sectors

The first key issue to explore is the development of costs for potential impacts of the workability issues, which has proved highly challenging for industry. It should be noted that costs provided are industry estimates based on best judgement for a system that has not yet been implemented in practice but reflects an understanding of the issues and costs linked to current (similar) activities. The study has been primarily reliant on industry to provide these cost estimates of the likely effort required (e.g. numbers of submissions and associated time and cost requirements) under Annex VIII. Independent verification of estimates at this stage is not straightforward given that the requirements of Annex VIII are not yet being implemented.

The industry survey results from across all sectors highlight that part of the reason that it has been challenging to provide cost estimates is due to the uncertainty of how to implement Annex VIII, due in part to ongoing development of the IT submission portal but also further reflection on the complexity of specific situations which can be hard to predict. The cost estimates provided do show a wide variation for similar tasks across different sectors; however, care is needed to understand the underlying situation and that while the specific task (e.g. generating a UFI) may be the same across sectors, the specific circumstances can be different and this does affect cost. For example, identifying the composition (where analytical testing is required) of a simple mixture with a small number of readily identifiable components is significantly different from identifying the composition of a mixture with tens or hundreds of components, which may vary naturally in composition and which may vary across batches due to continuous mixing and topping-up of vessels.

Table 3.16 provides a high level summary illustrating costs per notification per sector, with some further explanation. This highlights the variations and why care is needed when comparing costs between different sectors. For example, estimates from the cement sector (including mortars, gypsum and readymix concrete) have provided a very low cost estimate of €3.06 per notification, but this excludes the fact that to manage CM2 (Multiple suppliers of same mixture components) where mixture components of the same technical function from different suppliers are stored in

the same silo, would require significant infrastructure investment for new silos at an indicative cost of €1.2 million per site, which is not included in the €3.06 per notification estimate. Essentially, each sector has only been able to estimate some components of the costs, and the components that could be quantified varied between sectors.

Conversely the estimate from the paints sector of €295-€615 per notification, at first glance, seems significantly overstated. However, based on aggregation of the survey results, when the breakdown of costs per task are analysed (excluding IT system costs), a revised cost of €4 - €285 per notification is calculated. The paints sector have made clear that if each and every product needed to be notified this will run into millions of notifications (e.g. for point-of-sale mixing systems), and that in realistic terms the current infrastructure in terms of both IT systems and sufficient manpower is not in place. This would require very significant investment in new systems and would likely be labour intensive. Therefore, this suggests that estimated costs of €295-€615 per notification might not be unrealistic. The sector also quoted very wide ranges for analytical costs of between €1 - €200 per product, suggesting an equally complex situation in terms of technical challenges for analysis of composition[89]. A review of all sectors suggested that in particular label updates are a major part of the costs of new notifications, while analytical costs can also vary widely.

89 Further feedback from CEPE commented that for paint formulators it is unusual to conduct any kind of chemical analysis on their products. More commonly paint formulators would rely on the technical/compositional data provided by their suppliers. Therefore estimating costs of analysis may be challenging for this sector a) because it is not routine and b) because it is unclear whether different respondents have assumed that they will either have to do their own analysis or continue to rely upon their suppliers' data.

*Table 3.16 High level summary of costs per notification for different sectors**

Sector	Cost per notification (€)	Further comments
Petroleum	€75 - €1200	Cost data has proved challenging to obtain for this sector, while data on analysis (€60-€200) is relatively straightforward, cost estimates for labels (€15 – €1000 per label change) and IT systems is more difficult reflecting complexity of the supply chain and potential uncertainty of how much input might be needed. A primary issue for this sector is natural variation in mixture components and regular mixing throughout the value chain.
Industrial gases	€106	The major cost for the industrial gas sector is labels (€80 per notification). Other costs are lower. The industry have highlighted the important issue is practical application for short-turnaround on demand products (as well as concern regarding the value of notification for gases with only physical hazards).
Cement (mortar, gypsum, and readymix concrete)	€3.06 (excl. capital costs)	Costs look very low for the cement/mortar/gypsum/readymix concrete sector, however, this excludes the infrastructure changes that would be needed to manage different mixture components in separate silos. This is estimated at €1.2 million per site as an indicative cost. Therefore the figure of €3.06 is likely understated.
Other construction	€44-€166 (excl. staff time and capital costs)	The major cost for this sector is investment in new IT systems to manage the process and audit record for UFIs and notifications.
Paints	€295 - €615	Further analysis of the individual costs provides a revised estimate of €4 - €285 per notification, however, this excludes investment for new IT systems to manage the issue. The paint sector have highlighted that if each and every product needs notification this may run into millions of notifications. To manage such a process would require very significant investment in new systems and be labour intensive to set-up. The costs also indicate a wide range in analytical costs (€1 - €200 per product) potential reflecting complex chemistry for the mixture components used.
Fragrances	€14 -€760	Major costs are linked to analysis and in particular staff time. This may reflect the fact that fragrances are complex mixtures (e.g. up to 200 components) and that tracking full composition on a real time basis is challenging and labour intensive.
Soaps and detergents	Not estimated	The response from AISE comments that analytical costs may be highly variable making 'per notification' costs highly challenging to estimate. For other costs such as labels and IT systems it is possible to provide more indicative data. But a per notification estimate has not been possible.

*The previous study (Study on the harmonisation of the information to be submitted to Poison Centres) further explored the potential cost impacts for SMEs. This highlighted in particular negative impacts for SMEs which trade only nationally within certain Member States would face a data burden rather than savings from harmonisation. The workability issues identified and detailed in the current study can be expected to impact SMEs proportionately to larger size companies. Please also refer to the previous study for further details.

Comparison to 'costs and benefits' of harmonisation study

The cost per notification is one useful metric to help explore the potential impacts of the different workability issues and understand how the situation varies between different sectors. However, the cost per notification does not take into account the total number of notifications per sector which may also have a significant role in the scale of the impact. The industry survey responses estimate that for a number of sectors (i.e. petroleum, cement, paints, and soaps and detergents)

frequent variations in composition will trigger regular need for notification updates, totalling high numbers of notifications annually for specific sectors. This does also highlight that a number of the workability issues are not necessarily sector specific, but likely to affect multiple sectors.

The study on harmonisation of information to be submitted to Poison Centres (2015)[90], reviewed a variety of different industry sectors and existing national systems to understand the costs and cost savings of harmonisation, assuming a data burden on industry broadly in the middle range of the existing systems in place (low data burden being only a SDS, and high data burden being full specific composition to narrow ranges) at that time. The study concluded that harmonisation of data requirements could lead to a potential saving of €550 million per year for the EU as a whole[91]. However, this was contingent on specific caveats, in particular the study identified for some sectors (primarily paints and soaps and detergents) with wide product ranges, that if each and every product needed to be notified this would raise costs significantly and mean that overall the increase in such costs would outweigh any net savings for the EU.

The workability issues identified within the current study specifically for those sectors with wide product ranges, suggests that access to the existing grouping strategies in Annex VIII are limited, and therefore without intervention the caveats underlined in the study from 2015 will not be met, and the potential cost saving of €550 million per year, will also not be met.

It is of note that the per-notification costs from the 2015 study are within the range of those quoted above as identified for the current study. These were €70 for submission of an SDS only, €700 for a more advanced system and €300 for a mid-complexity scenario.

The key factor driving differences in (quantifiable) costs is in the numbers of submissions, which industry has identified as being much higher than expected when the 2015 study was undertaken, due to some of the workability issues identified and investigated for the current study.

It should also be recalled that some of the workability issues do not relate to costs that can be readily quantified but rather to practical issues of compliance.

As a further analysis and comparison to the previous study, it is worth focusing specifically on the paints and the soaps and detergents sectors. As set out in the previous study report (Table 5.4, page 67), of the total €550 million per year estimated cost savings of harmonisation, around half (€261 million) was linked to the paints and varnishes sector and €51 million linked to the soaps and detergents sector. Both of these sectors have highlighted that there is significantly less potential to use grouping approaches in submissions than was originally envisaged (as described earlier in this section). There is a risk, therefore, that many of the envisaged net benefits of harmonisation would be lost without the ability to submit group notifications in these sectors in particular and in other sectors as well.

Analysis of sector specific workability issues

A different issue to explore relates to whether the workability issues raised are genuinely sector specific or have broader impact. During the development of Annex VIII detailed discussions on the scope and form of Annex VIII were held prior to implementation. Further identification of specific workability issues were raised by a number of industry sectors late in this process warranting further investigation, which forms the core part of the scope for the current study.

Therefore it is important to understand which workability issues are genuinely sector specific and which issues have broader impact. This is not to say that all of the issues identified and

[90] Study on the harmonisation of the information to be submitted to Poison Centres, according to article 45 (4) of the regulation (EC) No. 1272/2008 (CLP Regulation), report for European Commission, 2015.

[91] The study also calculated costs to industry for implementing the UFI. However, cost savings were sufficient to cancel out any costs for the implementation of the UFI and still achieve net savings of €550 million per annum for the EU as a whole.

covered within the current study do not warrant investigation or discussion, but it is important to understand which issues have broader cross-cutting impacts.

Additionally for the workability issues identified and detailed within section 3, there will be commonalities which manifest in different ways, which make the issue sector specific. For example, the petroleum sector and cements sector (including mortars, gypsum and readymix concrete) manufacture mixtures using continuous processes utilising natural feedstocks which will vary. This means that there is a commonality in the workability issues experienced by these sectors. However, factors such as infrastructure and distribution networks mean that the workability issues will manifest themselves in different ways in different sectors. Further exploration of commonalities and grouping of workability issues is discussed in section 6.

Based on an analysis of the workability issues detailed in section 3, while the way the workability issues manifest may have industry specific components, there are commonalities for a number of the issues. Other sectors which have not been included within the current study may also experience the same workability issue. Notably the main commonalities include:

- For a number of sectors (cements (including mortar, gypsum and readymix concrete), petroleum and industrial gases) the use of natural feedstocks within processes involving continuous blending creates many discrete batches, which are technically equivalent but differ sufficiently in composition that they would trigger many updates on a frequent basis. There are sector specific components that may alter how the workability issue manifests, but the issue itself is intrinsically the same. Other sectors which work to this model have not been identified within the scope of this study, but it is feasible that other such sectors exist and would experience similar issues.
- A number of sectors (cements, other construction, paints, and soaps and detergents) have identified issues with multiple suppliers for either the same mixture component or mixture components with the same technical function. These variations are expected to trigger many notification updates, while presenting a practical and technical issue for managing mixture components from different suppliers and tracking composition of any new mixtures produced.

  This particular workability issue is likely therefore to be common across all industry sectors, including those not currently included within the scope of the current study. This assumption can be made on the basis that utilising multiple suppliers for the same mixture component/components with same technical function is a common practice across the chemicals-using industries, not least for business continuity and pricing reasons.

  However, the current study does identify some cases where this workability issue can exacerbate other sector specific workability issues, and therefore it is possible that for some of the sectors within the scope of the current study this particular workability issue is felt more strongly. In particular where the manufacture of cement (which includes natural feedstocks) can use gypsum (which is itself a natural feedstock) from multiple suppliers, the workability issues for CM1 and CM2 can be seen to be tightly inter-linked.
- Task 2 (see section 4) identifies an issue where mixtures initially used under industrial settings may then go on to be used by downstream formulators for final mixtures which will be placed on the market for consumer/professional use. Under Annex VIII of CLP the final mixture's intended use would mean that the original mixture (used as a mixture component) produced under industrial settings has to comply with Annex VIII for the final intended use (consumer/professional) (according to the Commission's interpretation).

  Due to the complexity of supply chains and distribution networks for many sectors in operation across the EU, this particular workability issue is likely to affect more than one sector. However, as indicated earlier in this sub-section the specific nature of a given sector can affect how a workability issue manifests. Therefore the magnitude of this potential workability issue is also likely to vary across different sectors.

Within the current study the perfumes and fragrances sector in particular have highlighted that this workability issue may be problematic for them. However, based on the industry survey disseminated with the assistance of Cefic, other industry sectors have also identified the same workability issue. This is discussed in greater detail in section 4.

Categorisation of impacts of workability issues

Finally it is important to explore in more detail how the impacts of the workability issues manifest themselves. For some sectors the workability issue has been stated to be likely to create the need for many notifications, or notification updates, which represents a significant administrative burden and challenge to tracking composition. In other cases the workability also includes technical and practical challenges such as the need for frequent chemical analysis during continuous processes with multiple supply chain stages. In yet other cases the workability issue presents issues where the current existing infrastructure makes compliance very challenging (or as industry asserts impossible). Therefore it is important to understand where these differences fall. Table 3.17 is intended to provide a high level summary exploring how the potential impacts of different workability issues manifest.

Table 3.17 Overview of how different workability issues impact. See also footnote to the table for explanation of categories.

Workability issue	Short title	Sector	Administrative burden	Administrative burden + Technical challenge	Administrative burden +technical challenge + change required to whole infrastructure
PP1	Product variation in continuous blending process	Petroleum	x	Continuous blending of mixtures including natural feedstocks creates both an administrative burden but also a technical challenge to monitor composition.	x
PP2	Complex distribution network	Petroleum	x	Re-blending at multiple stages represents a significant technical challenge to track composition.	x
PP3	Continuous mixing of different batches of petroleum products in storage tanks	Petroleum	x	Need for continuous sampling and analysis at fuel stations represents a significant technical challenge.	x
IG1	Bespoke on-demand mixtures based on incremental changes to same mixture components	Industrial gas	Impact is primarily on administrative burden and many notifications. However for 'on demand' products the short turnaround time also represents a technical challenge. Unclear how significant a proportion of the industrial gas business is on demand complex mixtures in reality.	Technical challenges created for on-demand products due to short turnaround times.	X

Workability issue	Short title	Sector	Administrative burden	Administrative burden + Technical challenge	Administrative burden +technical challenge + change required to whole infrastructure
CM1	Product variation in continuous blending process	Cement, mortar, gypsum and readymix concrete	x	x	Continuous production process using natural materials which can vary frequently. Storage of goods in same silo has been indicated by industry would mean need significant infrastructure changes (i.e. new silos).
CM2	Multiple suppliers of same mixture components	Cement, mortar, gypsum and readymix concrete	x	x	Industry indicate significant challenge to track composition with multiple suppliers for the mixture components with same technical function, stored in the same silos.
OC1	Use of colourants and the generic product identifier	Other construction	Primarily an administrative burden where inability to be able to use the GPI will create the need for many notifications. Particularly where only varying mixture component is colour.	x	x
OC2	Multiple suppliers of same mixture components	Other construction	For the other construction sector managing the issue of multiple suppliers can be expected to be largely an administrative burden. In some cases it may also require additional analytical testing but unclear how significantly this affects the sector.	x	x

Workability issue	Short title	Sector	Administrative burden	Administrative burden + Technical challenge	Administrative burden +technical challenge + change required to whole infrastructure
P1	Inability to use the product identifier for ‘colouring agents	Paints	x	x	While this could be perceived as largely an administrative only burden, the very high numbers of notifications means that the existing systems and infrastructure will not be sufficient without wide scale upgrades and investment.
P2	Bespoke on-demand mixtures based on incremental changes to same mixture components	Paints	x	x	For PoS paints it is not practical / infrastructure not in place to manage UFI and notification at time of sale. Hence will need to notify all possible combinations in advance. This runs into millions of notifications and existing infrastructure would not be capable of achieving compliance with Annex VIII.
P3	Multiple suppliers of same mixture component	Paints	x	x	Industry indicate significant challenge to track composition with multiple suppliers for the mixture components with same technical function, stored in the same bulk containers
FR1	Industrial mixtures treated as mixtures for consumer/professional use	Fragrances and perfumes	Significant administrative burden, which would require assuming all final mixtures are intended for consumer market and need the earlier, full notification requirements.	x	x

Workability issue	Short title	Sector	Administrative burden	Administrative burden + Technical challenge	Administrative burden +technical challenge + change required to whole infrastructure
SD1	Fragrances classified as hazardous for human health	Soaps and Detergents	Complex fragrance mixtures cannot use the GPI and thus would need to be notified. This represents a significant challenge and burden to keep track of composition and notification.	x	x
SD2	Multiple suppliers of same mixture component	Soaps and Detergents	x	x	Industry indicate significant challenge to track composition with multiple suppliers for the mixture components with same technical function, stored in the same vessels

*__Administrative burden__ (i.e. the only workability issue is the fact that a high number of notifications needs to be submitted), degree depending on size of product portfolio. **Administrative burden + technical challenges** or technical adaptations required (e.g. daily sampling of large number of samples). **Administrative burden + technical challenges + change required to entire infrastructure** (e.g. purchase of several new silos, different production lines need), i.e. with current infrastructure very challenging / impossible to comply with Annex VIII.

4. Mixtures in mixtures (Task 2)

4.1 Overview

4.1.1 Understanding

When a mixture is used in the composition of a second mixture placed on the market, the first mixture is referred to as a mixture in mixture (MIM).

This element of the report concerns mixtures produced in an industrial setting ('original mixtures') which are integrated by a downstream formulator in an industrial setting into a mixture for consumer/professional use ('final mixture').

The Commission's interpretation is that mixtures produced in an industrial setting ('original mixtures') and integrated by a downstream formulator into a mixture for consumer/professional use ('final mixtures') are to be considered as mixtures for consumer/professional use.

However, in certain cases, due to the dilution of the 'original mixture' in the 'final mixture' the information contained in the Safety Data Sheet (where applicable) could be sufficient to provide the necessary information on the relevant mixture components in order to facilitate emergency health response. Moreover, some of these original mixtures may end up exclusively in final mixtures which are subject to notification to appointed bodies under other legislation than the CLP regulation and therefore their notification under CLP may be unnecessary[92].

Annex VIII implements different deadlines for mixtures used within industrial (2024), professional (2021) or consumer (2020) settings. Moreover, mixtures only for industrial use may benefit from alternative (lesser) submission requirements. This is because, while the associated hazards for industrial-use chemicals may in some cases be higher, typically the risk management measures and understanding of the chemicals in use is also greater[93]. Only a small number of calls concerning mixtures for industrial use are received by poison centres[94].

The reduced notification requirements for mixtures for industrial use include:

- Limiting information provided on composition to the information contained in the safety data sheet (SDS), provided that additional information on the components is rapidly available on request in emergencies[95]; and
- The option to place the UFI on the SDS, rather than on the label of the mixture.

The current interpretation of Annex VIII is that mixtures that will end up either on the consumer market or the professional user market should be treated as either consumer or professional user mixtures respectively. For manufacturers of mixtures that are used initially in industrial settings but which are incorporated as MIMs in final mixtures for consumer/professional use, the potential impacts are therefore two-fold:

[92] As set out in the February 2019 guidance, when original mixtures end up in final mixtures which are not subject to submission obligations (e.g. the final mixture is a cosmetic product, or the final mixture is not classified for health or physical hazards), the uses of these final mixtures do not need to be considered for submission purposes with regard to the original mixture (ECHA Guidance on harmonised information relating to emergency health response – Annex VIII to CLP, version 1.0).

[93] Industrial users are subject to occupational health and safety legislation and also have access to e.g. safety data sheets explaining safe use.

[94] As per the preamble (11) to Regulation 2017/542 "Most calls to poison centres and other appointed bodies concern accidental exposure to hazardous mixtures used by consumers and to a lesser extent by professionals. Only a small number of calls concern mixtures for industrial use, which are used in industrial installations. In addition, on industrial sites there usually is a greater knowledge of the mixtures used and medical treatment is generally available. Therefore, importers and downstream users of mixtures for industrial use should be allowed to fulfil limited information requirements."

[95] Note that in such cases the UFI would still need to be provided but this can be included in the safety data sheet

- For those mixtures produced for industrial settings, but which then end up as MIM in consumer / professional products, the earlier deadlines will apply. Therefore, many more mixtures will need to be notified in 2020/2021 instead of 2024.
- Many more mixtures (from industrial use settings) will not be able to benefit from the limited submission requirements as they become a MIM in consumer / professional user products.

Task 2 of the study explores the implications of the interpretation that mixtures should be treated as intended for consumer/professional use, even if they are initially supplied for industrial use.

4.1.2 Structure of this section

This section is structured to help explore the potential workability issues created by the treatment of MIMs according to their ultimate use in different settings. The section provides findings based on discussions with industry, poison centres and surveys issued as part of the study.

The following topics are the focus of this task:

- Review of the equivalence of information contained in Safety Data Sheets compared to that included in a full notification under Annex VIII.
- Possibility of excluding MIMs from full notification obligations under Annex VIII, either because:
    - The hazardous components are so diluted that the final mixture does not need to be classified as hazardous; or
    - The MIM is used in products that are exempt from the CLP regulation and hence from the notification requirements under Annex VIII

4.2 Supply chains affected

4.2.1 Types of products likely to be affected

The main industry sectors that have expressed concerns (through the current study) with the provisions on MIMs are the chemical manufacturers/suppliers (via Cefic), the perfumes/fragrances industry (via IFRA) and the animal feed industry (via FEFANA).

It is likely that many chemical products contain hazardous mixtures, which are initially used in industrial settings in producing those products, but which ultimately end up in consumer or professional products. By way of example, the product categories used under the REACH use descriptor system are listed in the table below, along with an indication of whether at least some final mixtures might ultimately end up being used by consumers or professionals.

Table 4.1 Indication of possible consumer / professional use for different product categories

Product category	Poss C/P Use?	Product category	Possible C/P Use?
1 Adhesives, sealants	Y	24 Lubricants, greases, release products	Y
2 Adsorbents	Y	25 Metal working fluids	?
3 Air care products	Y	26 Paper and board treatment products	?
4 Anti-Freeze and de-icing products	Y	27 Plant protection products	Y
7 Base metals and alloys	?	28 Perfumes, fragrances	Y
8 Biocidal products	Y	29 Pharmaceuticals	Y
9a Coatings, paints, thinners, paint removers	Y	30 Photo-chemicals	?
9b Fillers, putties, plasters, modelling clay	Y	31 Polishes and wax blends	Y
9c Finger paints	Y	32 Polymer preparations and compounds	?
11 Explosives	?	33 Semiconductors	?
12 Fertilizers	Y	34 Textile dyes, and impregnating products	Y
13 Fuels	Y	35 Washing and cleaning products	Y
14 Metal surface treatment products	Y	36 Water softeners	Y
15 Non-metal-surface treatment products	Y	37 Water treatment chemicals	?
16 Heat transfer fluids	Y	38 Welding and soldering products, flux products	Y
17 Hydraulic fluids	?	39 Cosmetics, personal care products	y
18 Ink and toners	Y	40 Extraction agents	?
20 Processing aids such (e.g. pH-regulators)	?	41 Oil and gas exploration or production products	?
21 Laboratory chemicals	?	42 Electrolytes for batteries	?
23 Leather treatment products	?		

Note: The above is based on a judgement by the consultants as to whether some chemical products in each category might feasibly end up in mixtures used by consumers or professionals. Where it is considered feasible that this might be the case, a "Y" is indicated. The product categories are those used for use description under the ECHA REACH Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.12 of December 2015. The above has not been based on any form of survey/verification and is intended only to indicate the potential scale of the issue.

4.2.2 Specific sectors highlighting issues

Chemicals manufacturers/suppliers

Substantial industry input to the study has been co-ordinated through Cefic, which represents companies across the chemicals industry in Europe. There are in total 670 members[96] and affiliates represented by Cefic, including corporations, businesses and national non-governmental federations.

In 2017, EU chemicals sales totalled €542 billion with sales from petrochemicals (27%) and specialty chemicals (27%) accounting for over half. Sales from consumer chemical products accounted for 14% and the remaining sales in the EU came from polymers (21%) and inorganics (11%). The chemicals sector employed 3.3 million individuals and the sector invested €9.7 billion on research and development in 2017[97].

Cefic distributed the study questionnaire and a total of 34 responses were provided, including responses from 11 large companies and 19 SMEs (four did not specify), with annual turnover ranging from several millions to several billion Euros. Given the size of the sector, therefore, the information presented here should be treated as indicative, rather than fully representative.

The bulk of respondents (41%) operated as all three roles in the supply chain, meaning these companies are manufacturers, importers and downstream users of chemical products. 18% did not specify a role in the supply chain.

Industry reported that an average of 2,000 submissions per company will be necessary by the earlier 2020 deadline resulting from downstream users incorporating original mixtures into mixtures for consumer or professional use. The responses ranged from several hundreds to several thousands of submissions (highest value reported was 8,000). The lower end of the range includes companies from the cosmetics, fertiliser and petroleum sectors; these respondents are a mix of company sizes and operations across the supply chain. The highest values of submissions are reported from the construction sector who reported between 6,000 and 8,000 submissions will need to be submitted for the earlier 2020 deadline. Similarly, a petrochemicals and bulk chemicals company reported 7,000 submissions will require submission to the earlier 2020 deadline. These respondents are all large companies which operate in multiple roles in the supply chain, meaning that respondents are manufacturers, importers and downstream users as defined in the REACH regulation. The figures detailed within questionnaire responses correspond to the sector specific questionnaire, however a direct cross check between responses is not possible as the questionnaires investigate distinct issues.

The respondents also indicated that an average of 45% of their product portfolio will be affected by the earlier submission deadline resulting from mixtures for industrial use being incorporated into mixtures for consumer or professional use. Small and Medium Enterprises typically predicted a lower proportion of their products will be affected and these respondents are from the fragrance, cosmetics and fertiliser sectors. Conversely, a higher percent of products predicted to be impacted was reported by large companies from construction, paints, inorganic and speciality chemicals sectors. The respondents with greater proportion of their product affected operated across all roles in the supply chain; however, those reporting a smaller share of products affected tended to have a singular role in the supply chain such as Importer.

Very little impact or no impact was reported by some respondents from the fertiliser sector. One respondent specifically stated they are downstream users with products for the consumer market only; consequently they would not have utilised the limited submission and extended deadline.

[96] Cefic (2018) About Cefic. http://www.cefic.org/About-us/About-Cefic/

[97] Cefic (2018) Fact & Figures of the European chemical industry http://www.cefic.org/Documents/RESOURCES/Reports-and-Brochure/Cefic_FactsAnd_Figures_2018_Industrial_BROCHURE_TRADE.pdf

Fragrances/perfumes

Section 3.7 of this report provided details of the specific issue raised by the fragrances sector, including information on the implications for the sector. This was workability issue FR1.

IFRA highlight that essentially all of their member companies' mixtures would need to be treated as consumer/professional use, because they typically end up in consumer/professional uses, even if the final mixtures are not themselves classified as a result of the fragrance.

Animal feed pre-mixtures

Animal feed is exempt from the CLP regulation[98] (and hence the requirement for notification under Annex VIII) as it is covered by its own legislation (Regulation EC No 1831/2003 on animal nutrition). Regulation 178/2002 sets out provisions on food and feedstuffs, and applies to 'food business operators' and 'food businesses', which include any undertaking, whether for profit or not, and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food.

Although, animal feed is exempt from the CLP regulation, it contains mixture components which are incorporated as MIMs in the final product and which are covered by CLP and which do require notification under Annex VIII. These mixture components include what are termed 'pre-mixtures'. These are used to provide technical functions such as enhancement of feed (vitamins and minerals), water carriers, and preservatives to the feed. Importantly pre-mixture components cannot be directly fed to animals and will be manufactured under industrial settings. The final animal feed may also be supplied to consumers and professionals.

FEFANA has provided information on the EU premixture industry, detailing that there are around 300 plants, employing about 10,000 full-time equivalent workers and producing about 200,000 different premixtures. These premixtures comprise about 0.5% of the total compound feed of 200 million tonnes, i.e. around 1 million tonnes of premixtures. Based on an average value of €1,500 per tonne, the turnover of the premixtures represents around €1.5 billion per year.

FEFANA estimates that between 1,000 and 3,000 notifications per plant, per year are expected to be required[99], with a total annual cost of around €0.4 to €2.1 million per plant, per year[100] (9% to 42% of annual turnover). In addition, they highlight that there would be costs of additional storage, and printing on bags (rather than labels), though no estimates could be provided of these costs. Note that these are costs estimated by the industry sector, and they have not been verified by the authors of this report.

Other sectors

As indicated above, there are various other sectors where mixtures may be initially used in industrial settings and the resulting final mixtures are subsequently used by consumers or professionals. In addition to those sectors above, companies from the detergents and petroleum

[98] CLP applies to all additives and premixtures but feeding stuffs 'intended to be used by the final users' (animals), i.e. to be fed directly to animals, such as feed material or compound feeding stuffs are exempted from the scope of CLP, provided they are in the finished state. See https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/CLP/Scope+and+exemptions+under+CLP (question on 'Do feeding stuffs have to be classified, labelled and packaged in accordance with the CLP Regulation, and their substances notified to the Classification and Labelling Inventory?', 20/07/2018.

[99] It is understood that some premixtures will be produced at multiple plants and by multiple companies, hence the total number of notifications would be 300,000 to 900,000.

[100] Based on the range of 1,000 to 3,000 notifications, the cost estimate is broken down according to estimates for analytical costs (€20,000-€50,000); UFI generation (€4,000-€18,000 related to administrative tasks including sourcing, identification tracking and documenting of internal formula codes and generated UFI and updates of SDS; labels (printers) (€40,000-€80,000 for new in-line printer), labels (annual operating costs) (€40,000-€480,000 based on €40 to €160 per notification); IT (capital and start-up costs of €125,000-€250,000 and annual operating costs of €5,000-€30,000 per company); administrative fees for appointed bodies (€100,000-€300,000 based on €100 per notification and per member state); staff time (€100,000-€900,000 based on 60 to 180 minutes per submission). This gives a total of €434,000 to €2,108,000. FEFANA have clarified that these costs are per plant and that the total cost would be derived by multiplying by the 300 plants noted above. [The assumed cost per notification is therefore understood to be between around €430 and €700 based on 1,000 to 3,000 notifications per plant.]

sectors also raised concerns with mixtures intended for industrial use being incorporated into mixtures for consumer or professional use, and thus the lack of ability to benefit from the reduced notification requirements.

4.3 Scale of the issue reported by industry

The questionnaire provided to industry described the issue as follows: "Supply chains are complex and it is not always possible to tell the type of final product an industrial mixture is incorporated in by downstream formulators (i.e. in a mixture for consumer, professional or industrial use) nor its classification as hazardous or not. This ambiguity could necessitate treating all industrial mixtures as mixtures for consumer / professional use. This would mean companies would not be able to take advantage of the limited submission provisions, rather full information as per Tables 1 and 2 of Annex VIII would apply and an earlier compliance deadline (2020 or 2021 instead of 2024)."

When presented with the workability issue all but two respondents agreed that supply chains are such that it is not always possible to tell or have control over the type of final product that a mixture will be incorporated into downstream, resulting in effectively all industrial mixtures being treated as mixtures for consumer or professional use. The two industry responses which did not accept the issue as problematic stated this was because they will treat their mixtures for consumer or professional use; these responses are from the specialty chemicals and petrochemical sectors.

When asked about the practical difficulties of treating mixtures for industrial use as mixtures for consumer or professional use, 11 responses from across different sectors, company sizes and supply chain roles stressed concerns over time and the short deadlines (2020 / 2021). Other respondents highlighted that if they had to treat their products as being for consumer/ professional use rather than industrial use, it would create workability issues similar to those already detailed in the previous section (Task 1). In particular, respondents had concerns regarding UFI management, concentration ranges and the difficulty of communicating across the supply chain if full notifications are required[101], particularly when detailing business confidential information. A total of 65% (22) of the respondents emphasised a limited submission would be more practical than a full submission resulting from treating all mixtures as mixtures for consumer or professional use.

A total of 18 out of the 34 respondents were aware of the final use of some of their product portfolio when selling downstream. For these 18 respondents, they were aware of the final use for on average 68% of their product portfolio, the remaining 16 respondents could not provide details on the final use of their products.

Industry proposed several solutions, the most common being delaying the deadline and providing greater time to adapt. Another solution recommended using the next actor or next intended user in the supply chain to govern notification obligations.

Respondents provided information on the costs associated with submission of notifications for these mixtures, as set out in Table 4.2.

[101] Rather than the limited submission possible for mixtures used in industrial settings.

Table 4.2 Estimates of costs of notification for mixtures intended for industrial use being incorporated into mixtures for consumer or professional use

Cost element	Estimated value
Analytical costs	30 respondents could not answer or reported no cost €100 to €3,000 (not clear if price refers to per product or annualised)
UFI generation	29 respondents could not answer or reported no cost Low: €20 , €60 High: €750€ for all products, €500 per UFI
Labels	27 respondents could not answer or reported no cost Low: €20 High: €5,000, €128,000 Cost of replacing old packaging (€5 / ton product)
Information technology	25 respondents could not answer or reported no cost Low: €3, €20, €33 High: €15,000, €100,00, €160,000
Admin fees for appointed bodies	26 respondents could not answer or reported no cost Variable dependent on MS
Staff time	13 respondents could not answer or reported no cost 30-95 mins per submission, €20-€35 / product
Others	No respondents could answer or reported a specific other cost

Some examples of the implications for individual companies that responded to the questionnaire provide an insight into some of the supply chains in which mixtures used initially in an industrial setting are integrated into a mixture for consumer/professional use, as follows:

- An SME paint manufacturer has highlighted that they are a downstream user (formulator) of substances and mixtures. They produce their own product but also sell products to other formulators to produce distinct tints. The respondent stated that in their opinion, 70% of their products are mixtures for industrial use. However they will report all mixtures as if the final use could be a consumer use.
- A formulator of polyurethanes, adhesives and other speciality chemicals stress that they do not know all possible end-uses down the supply chain and consequently estimate that over 80% of their products will require full notification. The large company produces between 5,000 and 6,000 mixtures and indicated that there would be a difficultly of contacting all customers and distributors to identify the end user. The respondent also noted the considerable manpower required to constantly keep in contact with all downstream clients on these issues. (It is also important to note that some companies will not wish to disclose the precise end use of a mixture, for reasons of commercial sensitivity.)
- A large producer of bulk and speciality chemicals believe 20% of their product portfolio are mixtures intended for industrial use; however, they estimate that only 5% of their product portfolio would be considered mixtures intended for industrial use under the Commission's interpretation (understood to be because the mixtures may ultimately be

incorporated into final mixtures for consumer/professional use). The company explained that they are unaware of the composition of their customers' mixtures[102].

- A large polymer formulator claims they cannot exclude the possibility of mixtures ending up in professional or consumer markets and will adapt a "worst case approach" (assumed to mean provision of all information according to Annex VIII by 2020 / 2021).
- Further to the questionnaire distributed through Cefic, analysis on workability issues in Task 1 revealed that companies from fragrances, detergents and petroleum sectors also raised concerns with mixtures intended for industrial use being incorporated into mixtures for consumer or professional use.
- A petroleum sector respondent, a large organisation operating across all roles in the supply chain with respect to oil and lubricant products, highlighted the problem of "end-use approach" to classifying mixtures. The company produces mixtures for industrial use but expressed they cannot know if their mixtures end up in products for consumer or professional users.

4.4 Equivalence of information in SDS and full Annex VIII notification

4.4.1 Overview

As indicated previously, mixtures used exclusively in industrial settings may benefit from reduced information requirements (submission of an SDS provided that additional information on the components is rapidly available on request), as well as having a later compliance deadline).

If this reduced information were to be submitted for mixtures that are initially used in industrial settings but which are subsequently incorporated into mixtures for consumer products, it would be important to understand whether the reduced information available to poison centres would enable an equivalent level of emergency health response.

This section includes a comparison of the requirements for information to be provided through the SDS against the information to be provided as part of Annex VIII notifications. It then explores some hypothetical examples of cases where an SDS may be required but an Annex VIII notification is not required, and vice-versa. Finally it includes some conclusions on whether the information in the SDS would ever provide an equivalent level of information to that in an Annex VIII notification.

4.4.2 Comparison of requirements

Under Article 31 of the REACH Regulation, suppliers of a hazardous substance or mixture are required to provide the recipient with a safety data sheet containing the information stipulated within Annex II of REACH. Under section 3 of the safety data sheet, for mixtures, this includes details of composition (including concentration or concentration range[103]) for the main constituents and any other individual constituents which are classified under CLP and which contribute to the overall classification of the mixture. The safety data sheet further contains information on the hazards (section 2), first aid measures (section 4), physical properties (section 9) and toxicology (section 11). As per the requirements of REACH the formulator of the original hazardous mixture will provide a SDS to the downstream formulator, who in turn will provide a SDS for the final mixture if that is hazardous.

Under Annex VIII of the CLP Regulation, the notification requirements are governed by the concentration ranges quoted in Tables 1 and 2. Furthermore, under Part B 3.3, mixture components classified as hazardous on the basis of health effects present at 0.1% w/w or greater needed to be notified. For mixture components present below 0.1% w/w, these substances must also be notified unless the submitter can demonstrate that those components are irrelevant for

[102] They would presumably need to know this in order to identify whether the mixtures only end up in industrial uses.

[103] The size of the concentration range to be used is not specified, so broad concentration ranges may sometimes be used.

the purposes of emergency health response and preventative measures. Mixture components that are not classified as hazardous which are identified also need to be included when present at a concentration of 1% or more.

Table 4.3 provides a further comparison of the requirements covered by a REACH Annex II (SDS) and CLP Annex VIII respectively.

Table 4.3 Information to be notified under CLP Annex VIII and inclusion within requirements for SDS

Information to be notified to Poison Centres	Included in SDS?
General information	
Product identifier	**Yes**
Identifiers (e.g. CAS, EC number…) of mixture components	**Yes (some)**
Unique Formula Identifier (UFI)	**Potentially ***
Contact details of the submitter	**Yes**
Hazards identification	
Classification of the mixture and label elements	**Yes**
Toxicological information	**Yes**
Information on mixture components	
Components of the mixture and their concentration, including those not classified as hazardous.	**Only those classified as hazardous; less strict concentration reporting requirements**
Concentrations can be expressed as exact percentages or as a range of percentages.	
Major concern components have tighter concentration ranges than other components (acute toxicity, category 1, 2 or 3; specific target organ toxicity, single and repeated exposure, category 1 or 2; skin corrosion, category 1, 1A, 1B or 1C; serious eye damage, category 1).	
Additional information	
Type(s) and size(s) of the packaging	**Yes ****
Colour(s), physical state and pH of the mixture	**Yes *****
Product category according to the EU Product Categorisation System	**No**
Use (consumer, professional, industrial)	**No**

* There is no default requirement to place the UFI in the SDS. However, for unpackaged mixtures, the UFI shall be included in the SDS. For industrial mixtures there is the option to include the UFI in the SDS instead of on the label.
** REACH Annex II only specifies, where relevant, advice on packaging compatibilities and the UN Model Regulations packing group number.
*** The list of colours allowed within the PCN format is restricted to 14; companies may report colour in the SDS according to their own practices. Furthermore, in ECHA's Annex VIII validation rules working group, industry has indicated that the way pH is currently reported in SDS does not reflect the needs of poison centres as the ranges are often too broad, and thus the information would not be suitable in 20% of cases (ECHA, personal communication).

As set out above, full submission under Annex VIII requires more information than is required for SDS alone, in particular with regard to information on mixture composition. Some of the key additional requirements of Annex VIII for information to be submitted to poison centres include:

- Concentration ranges for mixture components classified as hazardous are more strictly controlled within Annex VIII compared to Annex II of REACH. In particular the concentration ranges under Annex II of REACH are not specifically defined (beyond change of classification) allowing wider concentration ranges to be used at the duty holder's discretion.
- Potentially a requirement to provide compositional information at lower concentrations in Annex VIII compared to Annex II of REACH. Note that Annex II of REACH refers to classification under CLP which begins at a threshold concentration (e.g. 0.1% w/w). Under Annex VIII of CLP substances present at very low levels (e.g. below 0.1% w/w) also have to be notified unless the notifier can demonstrate the mixture component is irrelevant for emergency response.
- Annex VIII requires compositional information for mixture components which are not classified as hazardous (Table 2 of Annex VIII), while Annex II of REACH refers only to classified mixture components. It is possible for non-classified mixture components (including concentration) to be named in section 3 of the SDS, but this is voluntary.
- Specific examples include the following:
    - For acute toxic 1, 2 and 3 components, according to Annex VIII, information on concentration needs to be reported within very narrowly-defined intervals (0.1% intervals at low concentrations), and information is needed at concentrations below 0.1%. For SDS, REACH Annex II refers to the classification requirements under Table I of Annex I of CLP, which applies a classification threshold of 0.1% w/w, above which the individual constituent would be classified and therefore need to be named in the SDS, and also the concentration range to be reported is not defined.
    - Likewise for STOT 1 or 2, skin corrosion 1, 1A, 1B, 1C and serious eye damage substances in mixtures, there is a need to provide information at lower concentration limits than in the REACH Annex II concentration limits (e.g. at below the 1% thresholds in section 3.2.1).
    - Moreover, there is a need to provide information on the identity and concentration of non-hazardous components and on other hazardous components (including acute toxicity cat 4, skin sensitisation cat 1, 1A or 1B and aspiration) at specified concentration ranges as per table 2 of Annex VIII. In practice this implies that all components need to be included, even those present at <1% (although the range 0-1% could be specified).

Annex VIII (Part A, 2.3) makes provisions for a limited submission for those mixtures used only within industrial settings. This allows the duty holder to limit information on composition to that included in the SDS (instead of the full Annex VIII requirements under Tables 1 and 2) provided that additional information on the components is rapidly available on request in emergencies. Those original mixtures provided to and used by downstream formulators and placed on the market for consumer/professional use must provide information as if the original mixture were intended for consumer/professional use and cannot make use of the limited submission.

Based on the identified differences between CLP Annex VIII and REACH Annex II listed in the bullet points above, it may be the case that such additional information would not be readily available, representing a challenge to the duty holder. This is further exacerbated if the final end use of original mixture is unknown, meaning the duty holder will likely have to assume all original mixtures are destined for use as MIMs in professional/consumer final mixtures.

4.4.3 Effects of component concentration on need for submission under Annex VIII

The previous section highlighted that the Annex VIII information requirements for composition of mixtures exceed those for an SDS. In the case of mixtures in mixtures, the original mixture will form part of the overall final mixture, and the mixture components (where known) will also need to be provided, specifically for non-hazardous mixture components present above 1% and for hazardous components present above 0.1% (and below 0.1% unless it can be demonstrated that they are irrelevant for emergency health response and preventative measures). In the case of SDS, information needs to be reported depending on the concentration of hazardous substances, with thresholds depending on the endpoints in question. The concentration ranges of those components to be reported in SDS are not specified in REACH Annex II.

The original mixture will be diluted within the final mixture. This may limit the information that is required under Annex VIII as the concentrations of specific mixture components within the final mixture will be lower than in the original mixture and potentially lower than the values set out in Section 3.3 of Part B to Annex VIII. This poses the question of whether the information that would be available for the mixture components within the final mixture would be comparable if the information provided for the SDS of the original mixture were used rather than the full information on composition of the original mixture according to Annex VIII.

This section considers dilution factors above which a safety data sheet would be required for the original mixture and for the final mixture, and compares this with the information required under an Annex VIII notification (both when the composition of the original mixture is known and when it is not).

Three variables are key to exploring this issue, namely the concentration of substances within the original mixture (MIM); the concentration of the MIM within the final mixture; and the hazard classification of the substances within the original mixture. Below certain concentrations, such substances would no longer cause the original mixture to be classified, depending on the specific health hazard. Therefore, in understanding what information will be available on the final mixture (if only the information in the SDS is supplied compared to the full Annex VIII requirements), it is necessary to understand dilution factors. These factors will be specific to hazard types, since different health hazards have different trigger values for classification.

To provide an example of identifying such dilution factors, we have used data for perfumes (covered by Task 1 – see section 3.7). Discussion with the fragrances association (IFRA) indicated that fragrances are complex mixtures with up to 200 different substances used in combination to produce different perfumes within industrial settings as an original mixture for use by downstream formulators of final mixtures. Table 4.4 provides an overview how perfumes are used as a mixture component within different final products, at concentrations between 0.2% w/w and 100% w/w.

Table 4.4 Typical perfume dosages in consumer products

Product	Dosage (wt %)	Product	Dosage (wt %)
Aerosol A/F	0.2–0.6	Laundry liquid	0.3–0.6
Aftershave	2–3	Laundry powder	0.2–0.8
Antiperspirant	0.2–1	Lipstick	0.03–0.6
Bubble bath	1–3	Liquid electrical A/F	30–100
Candle	3–6	Parfum/Extrait	15–40
Concentrated aerosol A/F	5–10	Polishes	0.05–0.3
Deodorant	0.2–1	Shampoo	0.4–0.8
Fabric refreshers	0.01–0.1	Shower gel/Body wash	1–1.5
Fabric softener	0.3–1.5	Skin cream	0.05–0.3
Fine fragrance (EdC)	3–7	Soap	0.75–1.5
Fine fragrance (EdT)	5–12	Toilet rim blocks	5–10
Hair spray/conditioner	0.2–0.6	Tumble dry sheets	0.5–3
Hand dishwash	0.3–0.5	Wick A/F	4–8
Hard surface cleaners	0.2–1	Window cleaners	0.03–0.1

Source: Kirk-Othmer Encyclopedia of Chemical Technology. Notes: A/F = air freshener; EdC = Eau de Cologne; EdT = Eau de Toilette. Note: This table includes some products that do not require notification under Annex VIII because they are exempt from the CLP Regulation (such as cosmetics); however, they are included here for completeness and also because they may be formulated by incorporating mixtures that are subject to notification requirements.

Table 4.5 and 4.6 provide worked examples for health hazards associated with Table 1 and 2 of Annex VIII and how the dilution factor may affect whether the final mixture is classified or not because of the presence of a classified original mixture This includes both the requirements under the development of the SDS and the Annex VIII requirements under CLP. Two example products are included in each table, to demonstrate both the differences between Annex VIII and SDS within one product, and also differences in requirements for information provision between products, depending on concentration. In this example, one can see that:

- Based purely on classification requirements, there could be differences between the two products according to the dilution rates, even though the concentration of the fragrance in the "fragrance compound" (i.e. "original mixture") is the same.
- Similarly, the requirements for reporting on the "final mixture" under Annex VIII of CLP would differ, assuming that companies would generally choose to report concentrations in ranges rather than exact values.
- In the example in Table 4.6, the dilution factor for the surface cleaner product (i.e. dilution of the fragrance compound at 1% i.e. a factor of 100) is at the threshold of requirements for classification and reporting under both Annex VIII and the SDS).

Table 4.5 Example of dilution for fragrances as a MIM within different consumer sector products, and impact on SDS and CLP Annex VIII requirements (Table 1 health hazard, i.e. hazards of major concern for emergency health response)

	Liquid electrical A/F	**Fabric softener**
Hazardous substance (skin corrosion Cat 1, 1A, 1B or 1C) conc. in fragrance compound (MIM)	5%	5%
Fragrance compound (MIM) conc. in final product	40%	1.5%
Hazardous substance conc from fragrance MIM in final product	2.0%	0.075%
Fragrance compound (MIM) would be classified?	Yes	Yes
Final product would be classified based on above substance?	Yes	No**
SDS required for fragrance compound (MIM)?	Yes	Yes
SDS required for final product?	Yes	No
Hazardous substance needs to be listed in SDS for MIM? (REACH Annex II, 3.2.1)	- Yes (concentration >= 1.0%) - To be reported with concentration or concentration range (not further specified)	- Yes (concentration>=1.0%) - To be reported with concentration or concentration range (not further specified)
Hazardous substance needs to be listed in SDS for final product?	- Yes (concentration >= 1.0%) - To be reported with concentration or concentration range (not further specified)	N/A
Annex VIII requirement for hazardous substance in the fragrance compound (MIM) (Annex VIII, Part B, 3.3 and Table 1)	- Substance to be indicated - Conc. range max 1% units	- Substance to be indicated - Conc. range max 1% units
Annex VIII requirement for hazardous substance in the final product (Annex VIII, Part B, 3.3 and Table 1)	- Substance to be indicated - Conc. range max 1.0% units	- Substance to be indicated if identified - Conc. range max 0.1% units
Annex VIII requirements for MIM in the final product (in case full composition of MIM is not known) (Annex VIII, Part B, 3.3 and Table 1)	- MIM to be indicated - Conc. range max 5% units	- MIM to be indicated - Conc. range max 1% units

* The generic concentration limit of a skin corrosive substance triggering classification of the mixture is >= 1%

** If the final product is not classified, Annex VIII notification would not be required. However, for this hypothetical example is it assumed that notification would be required due to hazard classification based on other (non-specified) mixture components.

Table 4.6 Example of dilution for fragrances as a MIM within different consumer sector products, and impact on SDS and CLP Annex VIII requirements (Table 2 health hazard, i.e. other hazardous components)

	Laundry aid	**Surface cleaner**
Hazardous substance (Skin sensitiser 1A) conc. in fragrance compound (MIM)	10%	10%
Fragrance compound (MIM) conc. in final product	0.25%	1%
Hazardous substance conc from fragrance MIM in final product	0.025%	0.1%
Fragrance compound (MIM) would be classified?	Yes	Yes
Final product would be classified?	No**	Yes
SDS required for fragrance compound (MIM)?	Yes	Yes
SDS required for final product?	No	Yes
Hazardous substance* needs to be listed in SDS for MIM? (REACH Annex II, 3.2.1)	- Yes (concentration >= 0.1%) - To be reported with concentration or concentration range (not further specified)	- Yes (concentration>=0.1%) - To be reported with concentration or concentration range (not further specified)
Hazardous substance needs to be listed in SDS for final product?	N/A	- Yes (concentration >= 0.1%) - To be reported with concentration or concentration range (not further specified)
Annex VIII requirement for hazardous substance in the fragrance compound (MIM) (Annex VIII, Part B, 3.3 and Table 2)	- Substance to be indicated - Conc. range max 10% units	- Substance to be indicated - Conc. range max 10% units
Annex VIII requirement for hazardous substance in the final product (Annex VIII, Part B, 3.3 and Table 2)	- Substance to be indicated *if identified* - Conc. range max 1% units	- Substance to be indicated - Conc. range max 1% units
Annex VIII requirements for MIM in the final product (in case full composition of MIM is not known) (Annex VIII, Part B, 3.3 and Table 2)	- MIM to be indicated - Conc. range max 1% units	- MIM to be indicated - Conc. range max 3% units

* The generic concentration limit of a skin sensitiser 1A triggering classification of the mixture is >= 0.1% (the value is 1% for category 1B skin sensitisers).

** If the final product is not classified, Annex VIII notification would not be required. However, for this hypothetical example is it assumed that notification would be required due to hazard classification based on other (non-specified) mixture components.

4.4.4 Feedback from industry on equivalence of information

A series of questionnaires and interviews with industry associations have been conducted to identify an overview of how information demanded in the Safety Data Sheet (SDS) compares with information detailed in a full composition submission across different sectors and supply chains.

Section 3 of a SDS details composition information of chemical products and several companies from across different sectors have raised the issue of duplicating information[104]. Three responses from the fragrance sector claimed that in their opinion section 3 of the SDS sufficiently covers all information needed for emergency health response. They indicate that dilution of the fragrance in the final mixture will mean only those mixture components named in the SDS would have an impact upon the hazards of the final mixture. These industry responses were from both SMEs and large organisations, who all operate as manufacturers with one a manufacturer and downstream user at the same time.

The soaps, detergents and maintenance products industry representative AISE similarly claims that the MIM approach duplicates information from section 3. AISE argue that information on the MIM component will already have been submitted to appointed bodies and the current requirement for downstream users to resubmit composition information is a duplication of workload. (Note that if the supplier of the MIM did not make a full notification, because the mixture was assumed to be used in industrial applications only, the information available would be less detailed.)

A SDS section 3 only details the composition of hazardous substances which is a lesser requirement than the full submission under Annex VIII. A large downstream user within the paints sector has highlighted the lesser requirement would cover all hazardous components within their products[105] and help lessen the burden on their industry.

Across all sectors, industry have argued that using the information in an SDS would be a sufficient Annex VIII notification for practical reasons, reducing time and costs. Some Member States currently accept SDS notification as a mechanism to collect data on final mixtures which includes both those final mixtures classified as hazardous and those not classified as hazardous. Industry has raised concerns that full implementation of Annex VIII may mean that Member States focus only on hazardous mixtures (as Annex VIII only applies to mixtures classified for human health or physical hazards) and cease to collect SDS anymore, which would mean SDS for final mixtures not classified as hazardous would fade out.

The cement industry has highlighted that they currently utilise the SDS for notifications. They indicate that the new process will require greater information but will not change hazard classification (i.e. no new information on hazards would be available). Similarly, respondents from the "other" (non-cement) construction products sector stressed the much greater data requirement in the full submission under Annex VIII[106].

A large downstream user within the paints sector currently uses one SDS to cover 3000 products which would not be possible under Annex VIII submission process. They would require individual notifications for each of them.

4.4.5 Conclusions on comparability of information

Safety data sheets have been used by several sectors and in several member states for notification under Article 45. It is clear from the above, however, that the level of information currently included in SDS will never be completely comparable to that in a full Annex VIII notification. For example, a full notification requires information on mixture components not

[104] As with most of the information available for this study, the results are considered indicative rather than statistically representative.

[105] Note that other components may also be relevant for emergency health response.

[106] Understood to be related to the detailed compositional information required, which is not straightforward to collect due to natural variations in composition, and continuous mixing processes, etc. (as described under Task 1).

classified as hazardous (where available), has a requirement for notification of substances at lower concentrations, and has more closely defined concentration ranges for reporting (those under REACH Annex II are not specifically defined).

It is also clear from Table 4.5 and Table 4.6 that there are cut-off values that can be defined whereby the presence of a hazardous substance within an original mixture would lead to classification of the final mixture and would hence be included in an SDS for the final mixture. Where the concentration of the hazardous substance is lower than that cut-off value, however, no SDS would be required for the final mixture, unless needed for other mixture components. Depending on the level of information available on the hazardous substance in the original mixture (e.g. exact concentration or range), notification under Annex VIII could still be required, but this will vary on a case-by-case basis. Arguably, below that concentration, notification of such information is of low (or sometimes no) relevance for emergency health response. However, information in that notification is also of relevance for toxicovigilance purposes[107].

The cut-off values for which an SDS is required are those that are set out in Annex II of REACH, as reproduced in the table below.

Table 4.7 List of hazard classes, hazard categories and concentration limits for which a substance shall be listed in SDS as a substance in a mixture

Hazard class and category	Concentration limit
Acute toxicity, category l, 2 and 3	≥0.1
Acute toxicity, category 4	≥1
Skin corrosion category l, sub-categories IA, 1B, IC and category 2	≥1
Serious damage to eyes/eye irritation, category I and 2	≥1
Respiratory/skin sensitisation	≥0.1
Germ cell mutagenicity category IA and 1B	≥0.1
Germ cell mutagenicity category 2	≥1
Carcinogenicity category IA, 1B and 2	≥0.1
Reproductive toxicity, category IA, 1B, 2 and effects on or via lactation	≥0.1
Specific target organ toxicity (STOT) exposure, category I and 2	≥1
Specific target organ toxicity (S TOT) exposure, category I and 2	≥1
Aspiration hazard	≥10

Source: REACH Regulation, Annex II, Section 3. Note: Excludes environmental hazard classes.

While a number of sectors have argued that a safety data sheet (e.g. for the original mixture) should provide sufficient information to allow effective emergency health response for the final mixture, it has also been noted that non-hazardous components (included in an Annex VIII notification) may also be relevant for emergency health response, and also that below the cut-off values for listing in an SDS, hazardous mixture components may still be of importance, e.g. for toxicovigilance purposes.

[107] As set out in the CLP regulation, information is collected under Article 45 both for emergency health response (Article 45(2)(a) and for analysis to identify where improved risk management measures may be needed i.e. toxicovigilance (Article 45(2)(b)).

4.5 Exemption from notification for final mixtures due to dilution

Industry has raised a concern that, even in cases where a 'final mixture' is not classified because hazardous substances in a MIM are only present at a low concentration, the original mixture (MIM) may require full notification under Annex VIII, as if it were a mixture for consumer/professional use. The concern raised is that a very significant amount of effort (and cost) would be required for notification of the original mixtures (as opposed to simply providing SDS if it were treated as an industrial mixture), and this would be of no value to emergency heath response because the final mixture is not classified and does not therefore need to be notified. Information provided by industry to support this was described earlier in this section.

The previous section on equivalence of information in SDS compared to an Annex VIII notification highlighted that there are cases where an Annex VIII notification would be required even if the presence of hazardous substances in the mixture does not exceed the concentration limit for having to be listed in an SDS. The extent to which a formulator of a final mixture is able to identify whether a notification and/or classification of the final mixture is required is dependent on the level of information in the SDS or other information provided by supplier following notification for the original mixture. Obviously, an SDS with precise information on concentration ranges would make it easier to identify whether classification of the final mixture is required.

Information provided by the fragrances industry and the chemical suppliers (via Cefic) included information on the extent to which final mixtures would be classified as hazardous:

- For the fragrances industry:
    - 17 of 22 of companies (around 80%) that provided a response to the relevant question had over 90% of their products (original mixtures) that were classified as hazardous, with the remainder having 80% or more.
    - Most companies could not answer what proportion of the final mixtures formulated using their products were also classified as hazardous, illustrating the point that companies often do not know exactly how their products are used.
    - However, for the 7 companies that were able to provide an estimate, these all indicated that the proportion of final products that would also be classified would be in the range 0-30% of products (with an exception for small parts of some respondents' portfolios for aircare products such as air fresheners, where the fragrance concentration is much higher, and hence classification is more likely to be needed).
- For the chemical suppliers (responses received from Cefic members):
    - Of the 28 responses where the relevant question was answered, 50% (both mean and median, range 3%-100%) of companies' products were estimated to be classified as hazardous for health and/or physical effects.
    - Again, most companies could not answer this question, but 12 of the above companies were able to provide a response, indicating that they estimate between 1% and 100% of final mixtures would also be classified as hazardous (mean 39%, median 20%).

Although the responses received cover a large number of products and large turnover (due to several very large companies responding in each of the two cases), the information received is not considered sufficiently detailed to provide statistically robust conclusions. Nonetheless, these figures do suggest that a significant proportion of hazardous original mixtures will not lead to the need for classification of the final mixture based on the presence of these MIMs. Again with the above caveats regarding representativeness, the issue seems to be particularly pronounced for the fragrances sector, but it is also true for the wider chemicals supply sector.

What does this then mean in terms of the level of information that should be provided for suppliers of hazardous original mixtures which are initially used in industrial settings, but which

may then be incorporated into final mixtures for consumer/professional use and which are not classified as a result of the original mixture? It appears difficult to find a one-size-fits-all solution, but one option to consider could be for a limited submission to be permitted (i.e. assumption that the original mixture is for industrial use), provided that mixture is never included in a final mixture at a concentration above which the hazardous original mixture components would lead to the classification of the final mixture.

4.6 Exemption from notification for final mixtures due to exempt end-uses

In a number of industry sectors, original mixtures typically end up (sometimes exclusively) in consumer/professional mixtures exempt from notification obligations under Annex VIII (and exempt from the CLP regulation as a whole). The main sectors where this has been raised as an issue in the consultation for the current study are as follows:

- Cosmetics
- Food and feed

There are other sectors, such as pharmaceuticals and phytopharmaceuticals where this is also a potential issue; however, input from these sectors for the current study has been limited.

Firstly, for the cosmetics sector, a large amount of the information provided relates to the information previously indicated for fragrances (see the previous section). It should be made clear, however, that where a company supplies a fragrance compound for incorporation into final mixtures, there are cases where the same mixture (fragrance MiM) will end up in both cosmetics products exempt from the CLP regulation, but also in other products which are not exempt.

Cosmetics are exempt from CLP and are covered by their own legislation (Regulation EC 1223/2009 on cosmetic products – the Cosmetics Regulation). All cosmetic products will be destined for the consumer (or potentially professional) market. However, they may contain fragrances, colouring agents or other mixture components manufactured within industrial settings but latterly used by downstream formulators to produce cosmetics. This could mean that the original mixture components would have to be treated as mixtures for consumer / professional use and apply Annex VIII as required, while the final mixture placed on the market would be exempt from notification.

Consultation for the current study has indicated that companies typically report the following for their cosmetic products, as required under Article 13 of the Cosmetics Regulation:

- the category of cosmetic product and its name or names, enabling its specific identification;
- the name and address of the responsible person where the product information file is made readily accessible;
- the country of origin in the case of import;
- the Member State in which the cosmetic product is to be placed on the market;
- the contact details of a physical person to contact in the case of necessity;
- the presence of substances in the form of nanomaterials and:
    - their identification including the chemical name (IUPAC) and other descriptors as specified in point 2 of the Preamble to Annexes II to VI to this Regulation;
    - the reasonably foreseeable exposure conditions;
- the name and the Chemicals Abstracts Service (CAS) or EC number of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), of category 1A or 1B, under Part 3 of Annex VI to Regulation (EC) No 1272/2008;

- the frame formulation allowing for prompt and appropriate medical treatment in the event of difficulties.

Companies have highlighted that equivalent information is already notified for cosmetics, to enable emergency health response. The cosmetic products notification portal (CPNP), to which companies notify information on all mixture components, is already designed with poison centres in mind (https://webgate.ec.europa.eu/cpnp/public/tutorial.cfm)[108].

The cosmetics industry also indicated that it has voluntarily, to date, made use of what are termed 'scaling cards'. These detail the major functional groups and composition (e.g. emulsifier) within a product as an expansion of the compositional information found under section 3 of an SDS. Around 200 scaling cards have been produced to cover all cosmetic products on the market and are provided to appointed bodies to aid any emergency response that may be required.

Another example of where the final mixture is exempt from the scope of CLP but contains mixture components which are covered by CLP relates to animal feed. Animal feed itself is exempt from CLP and is covered by its own legislation (Regulation EC 1831/2003 on animal nutrition). However, it is possible for animal feed products to contain a number of different mixture components. This includes what are termed 'pre-mixtures', used to provide technical functions (such as enhancement of feed (vitamins and minerals), water carriers, and preservatives) to the feed. Importantly pre-mixture components cannot be directly fed to animals and will be manufactured under industrial settings. Therefore:

- Animal feed that includes pre-mixtures is exempt from the scope of CLP (as it is covered under its own legislation)
- Pre-mixtures themselves are not exempt from CLP and must be notified as per the requirements of Annex VIII.

In terms of a requirement to notify to competent bodies under the animal nutrition legislation, Annex III to Regulation 1831/2003 includes requirements for labelling of e.g. the active substance level for nutritional additives and for technical and sensory additives. It also includes the following requirements for notification of information for labelling and information requirements for additives consisting of preparations and premixtures containing such preparations for various additives:

- the indication on the packaging or container of the specific name, the identification number and the level of any technological additive contained in the preparation for which maximum levels are set in the corresponding authorisation;
- the following information via any written medium or accompanying the preparation:
    - the specific name and the identification number of any technological additive contained in the preparation, and
    - the name of any other substance or product contained in the preparation, indicated in descending order by weight.

For premixtures containing various additives and consisting of preparations there is a requirement for information on:

- if appropriate, the indication on the packaging or container that the premixture contains technological additives included in additive preparations, for which maximum levels are set in the corresponding authorisation;

[108] Note that the fact that a cosmetics product is safe does not mean it is not hazardous (safety takes into account exposure elements, while hazard does not). The safety of a cosmetics product is assured under normal or reasonably foreseeable conditions. Poison Centres operate in situations where there was an accidental or non-normal use or conditions (e.g. under normal conditions one would not ingest an ointment or a cream, but in a poisoning case a baby or child could).

- upon request from the purchaser or the user, information on the specific name, the identification number and an indication of the level of technological additives referred to in point (i) of this paragraph included in the additive preparations.

As with the requirements for notification of information in cosmetic products, the legislation on additives for animal nutrition is intended to protect human health (as well as animal health and the environment). However, the information to be provided under the animal feed legislation relates to labelling information (for the user of the product), rather than provision of information directly to poison centres. The information is not identical to that under Annex VIII e.g. there is not an equivalent requirement for detailed information on concentrations (ranges) as per Annex VIII.

4.7 Experiences from existing national systems

Alongside the surveys conducted with industry, appointed bodies and poison centres were contacted and invited to take part in telephone interviews to further explore the workability issues identified. Details of the outcome of those discussions and conclusion of key points made by those that took part are provided elsewhere in this report.

In terms of the issue of MIMs there was a limited amount of feedback. Many of the interviewees commented that they do not currently collect data from industrial settings, or that only a SDS is collected. Further key points raised included:

- Appointed bodies and poison centres may have different focus. So while the poison centres are focussed specifically on emergency health response and the necessary data to provide this, appointed bodies/poison centres (where the centre fulfils both roles) will also be interested in data quality checking and toxicovigilance. It may be the case that compositional ranges quoted in Tables 1-3 and in particular low concentration mixture components would be important for toxicovigilance activities, even where such detailed information is not needed for emergency health response.
- One interviewee commented that they do not currently receive information on MIMs which is perceived as a gap within the data-set. Collection of this data could be very valuable for them (in terms of understanding composition).
- Poison centre responses are focussed on providing advice for medical incidents. This by and large affects the consumer market most as the risk of exposure is at its greatest. Calls from industrial settings are far less common. Specific analysis of data was not available to provide details of what proportion are from industrial settings.

Overall the authorities responsible under existing national systems commented that detailed information on composition of mixtures is of value in terms of both emergency health response and toxicovigilance. This point was reinforced at the study workshop where it was commented that often the information in SDS is not always sufficient for poison centres in terms of being able to provide emergency health response.

4.8 Conclusions

A large proportion of mixtures that are initially used in industrial settings may ultimately be incorporated into mixtures for consumer and/or professional use, based on the product categories included in EU chemicals legislation.

Suppliers of chemicals in general (via Cefic) and for fragrances (via IFRA) and feed additives (via FEFANA) in two specific cases have highlighted significant concerns that the earlier compliance deadline (2020/2021 instead of 2024) and the greater information requirements (with the current interpretation on MIMs) will cause significant concerns for their sectors. They have stated that there would be significant additional costs for their sectors and have provided some information to substantiate this.

The use of SDS[109] to provide information rather than a full notification has been advocated in various industry inputs. Poison centres have pointed out that the reduced level of information on concentrations of hazardous substances as well as the lack of information on non-hazardous substances (which may still be of relevance for emergency heath response) could cause problems in terms of toxicovigilance and emergency health response. Provision of SDS alone therefore could reduce the potential for effective emergency health response.

While there are cut-off values or dilution factors above and below which the information on the presence of hazardous substances included in SDS would be required as well as an Annex VIII notification, these are largely determined by the concentration limits for listing of a substance in an SDS under Annex II to the REACH regulation. See section 4.4.5 for more information on this issue. Overall, it does not seem to be practicable to specify endpoint-specific cut-off values above or below which different levels of information provision could be acceptable.

Section 4.5 highlights that a significant number of hazardous 'original mixtures' will ultimately be included in final mixtures for consumer or professional use that are not classified as hazardous on the basis of the original mixture. This is true for the fragrances sector but also for other sectors. In such cases, the notification for the original mixture would not ultimately be useful in terms of providing emergency health response. Likewise, there are various mixtures that are initially used (in further formulation) in industrial settings but which are ultimately used in applications outside the scope of the CLP regulation (such as cosmetics and animal feed). In the case of cosmetics, the information provided appears to be comparable in terms of level of detail for providing emergency health response. In the case of animal feed, the information requirements do not seem to be comparable, and are not specifically focused upon emergency health response provision by poison centres.

For both of the above cases, the added value of requiring notification of information for the original mixture as if it were a mixture for consumer/professional use is questionable in terms of emergency health response[110] (with the 2020/21 deadline and lack of an option for reduced information). However, it is often the case that the suppliers of the original mixture do not know whether some or all of the mixture sold will end up in final mixtures that are either exempt from the CLP regulation or which do not themselves require hazard classification (and are therefore exempt from the notification obligation under CLP). If this issue cannot be resolved, it cannot be ruled out that valuable information for emergency health response would be unavailable for mixtures within the scope of Annex VIII.

[109] Or the information on composition from the SDS.

[110] At least insofar as the original mixture only used in non-classified final mixtures.

5. Possibility of establishing an EU toxicovigilance scheme (Task 3)

5.1 Introduction

The objective of Task 3 is to provide a comparative analysis of national toxicovigilance systems with an overview of the types of products covered, parallels in approach and links to other systems. This includes examples of specific actions undertaken (as case studies) to illustrate the drivers behind toxicovigilance, the benefits of the toxicovigilance undertaken and obstacles. This analysis has also considered the development options for the establishment of an EU toxicovigilance system, including consideration of how this might work in practice and the costs and benefits of such an EU scale system.

Toxicovigilance is defined by the World Health Organisation (WHO) as the active process of identifying and evaluating the toxic risks existing in a community, and evaluating the measures taken to reduce or eliminate them. By conducting an in-depth medical assessment of acute or chronic intoxications on an individual basis, toxicovigilance contributes to identifying emerging toxicological problems resulting from, for example, the reformulation of a product or a change to its packaging or labelling; the availability of a new drug of abuse; or an environmental problem. This allows for rapid detection of potential adverse health impacts and the implementation of preventative or corrective measures[111].

Poison centres play a key role in toxicovigilance as an analysis of poison centre enquiries helps to identify whether there are specific circumstances or agents giving rise to poisoning, or certain populations suffering a higher incidence of poisoning. Poison centre statistics are essential to defining the cause and severity of poisoning incidents occurring in a population. Moreover, poison centres are usually amongst the first institutions to identify unusual incidents or emerging trends and are well placed to alert the appropriate authorities so that necessary preventative or regulatory measures can be taken.

A good example of toxicovigilance is when a rising trend of incidents was noticed with liquid laundry detergent capsules (liquitabs) and small children. Toxicovigilance detected issues with small children being exposed to such tabs significantly more often than to traditional liquid laundry detergents resulting in a number of fatalities and several life-threatening poisonings linked to irritant action of concentrated detergent; which in small children can have a corrosive-like effect on the linings of the mouth and oesophagus. Working with Member State authorities and the Commission, industry took both voluntary and mandatory steps to introduce new safety measures including opaque packaging for liquitabs and additional warnings on packaging and advertising for parents.

It is relevant to recall here that Article 45(2) of the CLP Regulation provides for the establishment of appointed bodies not only for emergency health response, but also, where requested by a Member State, to undertake statistical analysis to identify where improved risk management measures may be needed.

5.2 Study approach

A review of the national toxicovigilance systems in place in Member States is covered in Section 5.3. In order to review the current national toxicovigilance systems in place in Member States, the websites for the national appointed bodies for each of the EU Member states were checked for relevant information. This was followed by a general online search for literature for each Member State, using the search terms "toxicovigilance" and the name of the EU Member State. It should be noted here that different terminology for toxicovigilance is used across the EU and

[111] World Health Organisation. (n.d.). Toxicovigilance. [online] Available at: https://www.who.int/ipcs/poisons/centre/toxicovigilance/en/ [Accessed 12 Dec. 2018].

so the search terms "monitoring", "surveillance", "poison centres", "emerging trends", "poisonings" were also used. This approach proved to be the most useful and led to a number of relevant journal articles, reports and websites providing information on national toxicovigilance schemes across different EU Member States. Toxicovigilance was also discussed during the interviews that were conducted with the appointed bodies and poison centres regarding workability issues[112]. The information provided by the interviewees on national monitoring schemes was also used to inform this section.

In order to gauge the impact of toxicovigilance at the national level, toxicovigilance practices of four countries were reviewed through a comparison of case studies in Section 5.4. The International Congress of the European Association of Poison Centres and Clinical Toxicologists (EAPCCT) annual conference abstracts[113] were used to identify the actions undertaken along with their impact and the benefits. The impact was investigated by looking at the drivers which triggered the toxicovigilance, the products investigated, and the method used. The incident numbers and severity were examined to gauge the benefit from the analysis. Comparison of the case studies give an indication on the role and importance of an EU toxicovigilance system. The interviews with member state appointed bodies also provided useful inputs.

The challenges and options for a possible EU-wide toxicovigilance scheme are discussed in Section 5.5. This section was informed by a detailed literature review and follow-up interviews with poison centres.

A general online search for literature related to an EU-wide toxicovigilance scheme, using the terms "EU wide", "toxicovigilance", "poisonings", "monitoring" and "surveillance" led to several reports and journal articles on the 'Alerting System and Criteria for Development of a Health Surveillance System for the Deliberate Release of Chemicals by Terrorists' (ASHT) project[114], which was a study launched by DG SANTE and partially funded by it and studied the feasibility of an EU-wide poisoning case collection system. In turn, reports on the ASHT project cited various reports outlining the importance and need for an EU-wide toxicovigilance system.

Contributors to the ASHT project were also contacted for further information on the project and on barriers towards implementation of an EU-wide scheme. This consultation identified a set of additional research papers with further information on the RASCHEM (Rapid Alert System for Chemicals) database system created under the ASHT project for the notification, alerting and risk assessment of chemical incidents with potential cross border public health significance. This also identified the work to develop the MedDRA (Medical Dictionary for Regulatory Activities)[115] a standardised medical terminology facilitating grouping of terms for symptoms to allow more effective toxicovigilance.

Lastly, follow-up calls were made with Member State poison centres for further information on their national toxicovigilance systems, including the costs and resources involved, and to gauge whether there is potential to scale them up on an EU-wide level.

5.3 Review of national systems

Table 5.1 below was compiled using the information gathered in the preliminary review of toxicovigilance schemes currently in place in EU Member States. It should be noted that this

[112] Interviews were held with Belgium (Belgisch antigiftcentrum); France (Centre hospitalier régional et universitaire de Nancy); Germany (Bundesinstitut für Risikobewertung); Ireland (Irish National Poisons Information Centre); The Netherlands (University Medical Centre Utrecht); and l Spain (Instituto Nacional de Toxicología y Ciencias Forenses)

[113] The International Congress of the European Association of Poison Centres and Clinical Toxicologists (EAPCCT) abstracts from annual conference. https://www.eapcct.org/index.php?page=congress1

[114] https://www.giz-nord.de/cms/index.php/research-and-projects/108-asht-public-health-project-.html

[115] https://www.meddra.org/

table contains information only on Member State toxicovigilance schemes for which there was information readily available online in English.

All the national toxicovigilance systems identified are sophisticated and often have a specific objective, e.g. a focus on certain types of products. Based on the information gathered, it can be assumed that all toxicovigilance systems identified monitor risks in real-time and alert the appropriate authorities when an unusual incident or an emerging trend is identified.

In addition to monitoring risks and identifying unusual incidents and emerging trends when and where they occur, the toxicovigilance systems identified also involve carrying out surveillance of risks which involves continuous and systematic collection, reporting and analysis of poison centre inquiries. This surveillance is often retrospective, triggered by a potential identified concern by appointed bodies/poison centres/hospitals or competent authorities. However, it can also be forward-looking. Once a potential concern is identified, analysis (monitoring) often continues proactively to review, with the possibility to conduct a follow-up study in which the physician/patient is contacted afterwards to gather further information on the exposure (e.g. outcome). On the other hand, continuous forward-looking monitoring of certain product groups takes place to quickly identify potential risks. In the Netherlands, for example, new psychoactive substances and food supplements are continuously monitored.

Toxicovigilance can therefore be based solely upon requests made for vigilance to appointed bodies/poison centres by other parties such hospitals and competent authorities or based on the own initiative of the appointed bodies/poison centres based on emerging concerns, or in some cases both. Therefore, the toxicovigilance systems identified can be categorised into:

- Surveillance based solely on requests made from medical agencies or other competent authorities
- Surveillance based both on own initiative and on requests from competent authorities, e.g. UK and France

Table 5.1 below also outlines the type of surveillance undertaken under each of the identified national toxicovigilance systems.

Table 5.1 EU Member State national toxicovigilance systems

Member State	Overview of toxicovigilance scheme	Type of surveillance
Belgium	The Belgian poison centre keeps a general review on the calls received and relays back information to manufacturers and competent authorities when an unusual or emerging trend is identified. For example, a call was recently received by the poison centre where a small child received a corrosive burn from a product with faulty safety catch. This issue was reported to the manufacturer to review and test to avoid further such incidents. Additionally, the Belgian competent authority can request the poison centres to conduct specific reviews of incidents relating to particular uses or products, for example a review of all incidents involving e-cigarettes.	Surveillance based both on own initiative and on requests from competent authorities

Member State	Overview of toxicovigilance scheme	Type of surveillance
Denmark	The Danish Poison Information Centre (DPIC) holds a local database into which all telephone enquiries are registered with detailed information about the poisoning and registration of the enquirer and/or the patient. Registration includes demographic patient data, a description of the poisonous agent (amount, mode of exposure, etc.), clinical status, risk assessment and management. The database was designed primarily for documentation and feedback within the DPIC. A study published in the Danish Medical Bulletin in 2011 pointed out that registration of patient demographics, route of poison exposure and severity of the poisoning were found to be partly missing in the DPIC database. It also recommended that the DPIC database should be more detailed so that a shift in poisoning trends can be noticed at an earlier stage than allowed currently.	Surveillance based both on own initiative and on requests from competent authorities
Finland	The Finnish Poison Information Centre produces statistics on the list of substances that cause frequent inquiries or which are the most common cause of poisonings in humans. The list also provides information on the toxicity of the substance towards small children. The list is publicly available on the Helsinki University Hospital website, on which substances are listed alphabetically and can also be searched.	Surveillance based both on own initiative and on requests from competent authorities
France	Since 2016, the National Agency for Food Safety, Environment and Labour (ANSES) has been responsible for coordinating the national toxicovigilance scheme and the vigilance activities of the French poison control centres (CAPs). The work is overseen and coordinated by the Toxicovigilance Coordination Committee (CCTV) and by the Strategic Committee for CAP Vigilance Activities, which both report to ANSES. The main missions of the toxicovigilance system are to: Investigate health signals and alerts forwarded by the CAPs or coming from other sources (French health authority, health authorities of other countries, automated detection, spontaneous reports, monitoring of indicators, etc.); Respond to specific formal requests from the Ministry of Health and other medical agencies (i.e. hospital trusts); Provide expertise and contribute to monitoring of the toxic effects for humans of products, natural substances and pollution. Each teleconsultation is recorded in the national poison centre information system (SICAP) in the form of a medical file. As part of their follow-up, these files are supplemented by the data needed for vigilance, in particular an assessment of the clinical severity of the cases, a causality assessment (i.e. on the strength of the causal link between exposure and the observed health problems), and precise documentation on the agents involved and the exposure context. Toxicovigilance stakeholders have access to anonymised data from the poison control centres' information system. When one or more cases of poisoning attracts the attention of the CAP network and of ANSES, a search in the information system and identification of similar cases enables this signal to be confirmed or refuted. Moreover, any additional work carried out by ANSES is published on the ANSES website.	Surveillance based both on own initiative and on requests from competent authorities

Member State	Overview of toxicovigilance scheme	Type of surveillance
Germany	German poison centres record cases in local databases and review call log data annually to look at trends in calls received and feed back to the federal level. It should be noted that each poison centre uses its own template, so information is not necessarily comparable across the different German centres. The poison centres and the German Federal Institute for Risk Assessment (BfR) cooperate on the national reporting of the risks of poisoning for the population. In addition, the BfR collects and evaluates poisoning reports from German medical doctors that have been directly submitted on a legal basis	Surveillance based both on own initiative and on requests from competent authorities
Italy	The Italian National Institute of Health (ISS) and the National Poisons Control Centre (PCC) in Milan implemented in 2006 the National System for Surveillance of Hazardous Exposures and Poisonings (SIN-SEPI). Each year, SIN-SEPI receives detailed information about 42,000 incident cases of human exposures handled by the Italian PCCs. Yearly reports describing the main characteristics of cases detected by SIN-SEPI are published in Italian (Sistema Informativo Nazionale per la Sorveglianza delle Esposizioni Pericolose e delle Intossicazioni, Rapporti ISTISAN, available at www.iss.it).	Surveillance based both on own initiative and on requests from competent authorities
Netherlands	The Dutch poison centre makes use of an early warning system that carries out an automated daily search on reported cases in the past day (as compared to average figures in the month/year before) to identify any immediate issues or interesting calls that need investigation. As additional input for daily meetings, this can trigger both retrospective analysis as well as forward-looking monitoring of specific exposures. Reports are published both annually and ad hoc, charting trends from throughout the year(s) on all kinds of consumer products (medicines, household/DIY products, pesticides, cosmetics, drugs, plants/animals). The Dutch poison centre also carries out focused projects throughout the year, focusing on topics that are of special interest or in collaboration with the Food and Consumer Product Safety Authority. These projects involve doing follow-up calls with patients to get further information about a poisoning incident.	Surveillance based both on own initiative and on requests from competent authorities
Spain	Each call to the Spanish poison centre is recorded in a database, which is screened on a monthly basis to spot any emerging trends or issues of concern. Particular poisoning concerns may require immediate interaction with stakeholders to recover further information on the mixture. A thorough statistical analysis is carried out every six months and a report summarising the results is published each year. When the evaluation of collected data identifies exposure risk concerns, these are followed up with stakeholders to inform them and to devise strategies to address the risk concerns. Industries may also request to perform joint projects to estimate risk/exposure impact.	Surveillance based both on own initiative and on requests from competent authorities

Member State	Overview of toxicovigilance scheme	Type of surveillance
Sweden	The Swedish Poisons Information Centre (GIC) constantly scans available literature, reviews its treatment guidelines and monitors poisoning trends. Recently, special focus has been given to e-cigarettes, laundry detergent capsules and internet drugs. They have also continuously monitored cases of extravasal injections and intravenous dosing errors, incidents with new pharmaceuticals and cases involving sustained release formulations of paracetamol. A report is published annually that provides results on the cases collected in the GIC case database	Surveillance based both on own initiative and on requests from competent authorities
UK	The National Poisons Information Service (NPIS) presents trends in poisonings ever year and looks out for new developments to make clinicians aware of. A special area of focus for the NPIS is to understand the potential adverse effects, particularly amongst children, of exposures to potentially harmful household products, which continue to be common. Examples are dishwasher tablets, liquid laundry capsules, automotive screen washes, oven cleaners and button batteries. The NPIS publishes a report annually, which reveals that between 2008 and 2015 almost 500 phone queries were received about soluble film automatic dishwashing tablets, with 92% relating to young children.	Surveillance based both on own initiative and on requests from competent authorities

5.4 Impact of toxicovigilance at a national level

5.4.1 Overview

In this subsection, a further analysis of why and how toxicovigilance is undertaken at national level is explored. Part of the comparative analysis of national systems is to better understand the current work undertaken, and in particular the drivers, approach, benefits and obstacles and how they can differ. To provide this analysis the abstracts provided by appointed bodies / poison centres to the annual conference of the EAPCCT have been used to develop four case studies. These case studies are also compared on the basis of whether the full specific composition of products was needed or was not needed as this is linked to the implementation of Annex VIII

The preceding chapters on workability issues and the study workshop highlighted that information submitted to appointed bodies has a dual role of aiding emergency health response and also toxicovigilance. The responses from appointed bodies / poison centres highlighted strongly that the full composition of products is needed to aid toxicovigilance, and therefore the case studies have explored how the full composition of products may be needed to help fully identify issues and level of risk posed by specific products under certain scenarios.

5.4.2 Case studies

Case Study 1 – Acute pulmonary injuries from chlorine-based swimming pool disinfectants, Germany, 2015[116]

Drivers. Within Germany there is a mandatory requirement to disinfect swimming pool water in order to maintain water quality and protect human health from infection. This includes both municipal pools but also pools for private use. To maintain disinfection of water a range of chlorinated products are available. These products typically use a concentrated chlorine compound (such as trichloroisocyanuric acid (symclosen) or dichloroisocyanuric acid (troclosen)) which is added to water. The concentrated nature of the product and potential manual application meant that Giz-Nord (poison centre) raised concerns about possible exposures, particularly inhalation of corrosive vapours, even under expected normal working conditions. However, the scale of the issue and severity of impact linked to composition required further analysis and validation.

Approach. An analysis of poison centre call records for the period 2000-2014 was carried out. This analysis focussed on all cases with accidental, inhalational exposure of chlorine-based swimming pool disinfectants reported to the GIZ-Nord Poison Centre. Conditions of exposure, severity of symptoms, ToxIndex, age distribution and annual and seasonal distributions were analysed. Based on this review of call records, 139 cases were identified that met the study criteria and were used to derive results.

Results. During the analysis period, GIZ-Nord Poison Centre observed an increasing number of incidents with chlorine-based pool chemicals. The results illustrated that 60% of the exposure occurred while inhaling fumes from just opened containers, the rest occurred from inhalation of the product dissolved in water or were not well documented. According to the Poisoning Severity Score 12% had no, 66% minor, 13% moderate, 1% severe symptoms and 8% were not well documented. No fatalities occurred. The ToxIndex is defined as the sum of all cases classified as lethal, severe or moderate in relation to the number of all exposure cases. This index for pool products was quite high with 14%. Analysis of age range showed a strong correlation of incidents linked to adult use (i.e. during occupational or consumer application of the product), while the results also confirmed that in the majority of the cases injury had occurred while products were being used as intended.

Benefits. The analysis concluded that, in the poison centre's opinion, an issue had been identified that swimming pool disinfectants represent an unacceptable risk for the consumer market with further action needed. The results of the study were passed on to the national surveillance authorities in Germany, with further feedback through the EAPCCT to encourage other Member States to complete similar studies. The results of such work may inform the need for an EU wide initiative to be launched.

The ultimate benefit of this study is the identification of a potentially unacceptable risk scenario and the opportunity for intervention to minimise that risk and reduce the occurrence of health incidents. Further information on subsequent numbers of incidents and severity were not captured by the study in this particular incidence.

Obstacles. The results from the received call records database highlight incomplete data in a number of cases (i.e. 8% of calls had no symptoms documented). Furthermore, the research is confined to one area of Germany as more of a pilot study (note the analysis is based on 139 calls over a 14 year period). The authors highlight the need for other Member States to repeat the analysis to help build a bigger data-set and confirm whether the issue is of significant importance that an EU wide initiative is needed.

[116] Ebbecke et al GIZ-nord poison centre Germany, 2015, 'Acute pulmonary injuries from chlorine-based swimming pool disinfectants', presentation at 2015 EAPCCT conference.

Case Study 2 – Pharmacovigilance: a 4-year Poisons Information Center pilot survey of atypical antipsychotics, Netherlands, 2018[117]

Drivers. The Dutch Poison Centre (DPIC) highlighted that there is a growing use of pharmaceutical products in general within Europe, and that young children may represent a vulnerable target group in terms of accidental ingestion. Pharmacovigilance studies have been conducted to look at a range of different issues, however, one potential gap identified was the use of common antipsychotic drugs such as quetiapine, risperidone, olanzapine, aripiprazole, and clozapine. DPIC database was identified as a valuable tool to allow a vigilance study to explore this potential issue in more detail. It should also be noted that although antipsychotics are not CLP-relevant mixtures, this study is still relevant to demonstrate the role that toxicovigilance can play.

Approach. All calls received on mono-intoxications (i.e. only the prescribed drug) between 2013-2016 for quetiapine, risperidone, olanzapine, aripiprazole, and clozapine were extracted from the DPIC. Severity of intoxications was estimated using the DPIC dose-effect value, which are based on medical literature and toxicological experience. The DPIC uses higher exposure limits for frequent clozapine users (due to tolerance) than for children and non-clozapine users. The number of registered antipsychotic users was derived from the Dutch National Health Care Institute. This allowed a correlation to be derived between numbers of incidents and total numbers of prescribed patients.

Results: The relative number of consultations to the DPIC in relation to the registered number of users was 0.16% on average for quetiapine, risperidone, olanzapine, and aripiprazole. For clozapine, however, this percentage was considerably higher, averaging 0.45%. Furthermore, the proportion of potentially severe intoxications was considerably higher, with 79.9% of all clozapine intoxications classified as moderate/severe, compared to 31.2% for the other atypical antipsychotics. Moderate/severe clozapine intoxications were especially frequent in children and non-clozapine users, with 86.3% compared to 10.9% for frequent clozapine users.

DPIC therefore concluded that the results illustrate that substantial differences were found between the frequency and estimated severity of clozapine intoxications versus other atypical antipsychotic drugs. Clozapine causes relatively more intoxications in relation to registered users compared to other antipsychotic drugs, and more severe intoxications in children and non-clozapine users compared to frequent clozapine users.

Benefits. The study provides a valuable analysis which highlights that a potential issue has been identified. Worryingly the study also indicates the number of calls received relating to intoxication of children and non-users is particularly high for one of the antipsychotic drugs included in the study. The results of the study allow for further investigation and intervention to minimise these risks. DPIC comment that the results may be used to improve medicine safety information provided to patients, urging safe storage to reduce the risk of accidental poisoning of relatives and co-residents.

Obstacles. The study provides valuable insight into a potential issue with one of the antipsychotic drugs included within the scope of the analysis. However, to fully characterise why there is a significantly higher rate of intoxication of clozapine, particularly with non-target users such as children, more information is needed to characterise how incidents have occurred. The study is also limited to one Member State so comparison to sales/use in other Member States would be needed to determine if this is an EU wide issue.

[117] Oerlemans et al, University Medical Center Utrecht, 2018, 'Pharmacovigilance: a 4-year Poisons Information Center pilot survey of atypical antipsychotics', presentation to the EAPCCT 2018 conference.

Case Study 3 – A toxicovigilance study based upon 8 years of NPIS Pesticide Project, United Kingdom, 2013[118]

Drivers. The National Poisons Information Service (NPIS) UK highlighted that a disparity existed internationally for the use of two pesticides, with potential health implications as a result. Bendiocarb, a potent acetylcholinesterase inhibitor, is banned in the USA while clopyralid, an herbicide with the potential to cause severe eye damage, is subject to strict regulations in several US states. Both are however authorised for use in the UK. Therefore, a need was identified to quantify the risks from use of these two pesticides within the UK given the disparity between UK/USA regulatory regimes.

Approach. Call record data from the NPIS database between 2004 and 2012 was extracted. In total 6689 exposures linked to pesticides were recorded over this period (of eight years), of which 175 (2.6%) were to bendiocarb and 30 (0.4%) to clopyralid. Incidents were also assessed on the level of severity for poisoning cases using a scoring system to help gauge the significance of incidents. This also included consideration of symptoms and types of injuries linked to exposure (in particular noting that clopyralid can cause severe eye damage).

Results: Based on the analysis conducted, 17 (9.7%) cases of exposure to bendiocarb were graded as moderate severity (no severe or fatal cases were recorded). Of the remainder 70 (40%) were graded as minor severity, 84 (48%) as no injury and 4 (2.3%) were unclassified. For these cases the majority (58%) were linked to amateur use of bendiocarb, with fewer cases linked to professional use (24%), and the remainder (18%) where use was unclear. For clopyralid two cases (7%) were graded as moderate severity (with no cases graded as severe or fatal). For the remainder 19 (63%) were graded minor, eight (26%) were graded no injury, and one was unclassified. For clopyralid specifically, four cases related to eye injuries but all were graded as of minor severity.

The NPIS therefore concluded that exposure incidence and severity was low for both pesticides. Despite safety concerns, all eye exposures to clopyralid were minor. However, the data did highlight a potential area of concern regarding exposures to professional bendiocarb products being used in the home.

Benefits. The study helped validate whether a significant risk existed based on the exposure rate and calls received for help. The study also identified a potential sub-issue with professional grade products being used by general public consumers in domestic settings. This would allow further intervention for this specific issue.

Obstacles. The study notes the use of a significant sized database of information (more than 6,600 calls). However, for the analysis it also highlights in a number of cases the call records are incomplete (i.e. for bendiocarb four cases where severity was not recorded). Another potential obstacle is that the analysis relies an evaluation only against NPIS records and may miss cases where patients were admitted to hospital but no call for assistance placed to the NPIS.

Case Study 4 – Rate estimates and trends of pediatric exposures to liquid laundry detergent capsules in Italy, Italy, 2016[119]

Drivers. The study was developed as a joint effort between the National Institute of Health (Rome), National Poison Control Center (Milan), and Department for Public Health and Infectious Diseases (University of Rome). The authors highlighted that internationally within Europe an issue had been identified as early as 2010 relating to the use of concentrated liquid laundry detergent capsules and small children. In particular where the capsules were brightly coloured they could be mistaken for confectionary and ingested by children. The concentrated nature of the detergent was recognised as being severely hazardous to particularly young children with a

[118] Perry et al, NPIS, 2013, 'A toxicovigilance study based upon 8 years of NPIS Pesticide Project', Presentation at the EAPCCT 2013 conference.

[119] Settimia et al, National Institute of Health, Rome, 2016, 'Rate estimates and trends of pediatric exposures to liquid laundry detergent capsules in Italy', Presentation at the EAPCTT conference 2016.

number of fatalities. The Italian authorities had worked closely with industry and others to put in place a number of preventative measures. The purpose of this study was to review how successful these measures had been and the continued rate of exposure post adoption of measures. Similarly, multi-centre studies were carried out by AISE between 2014 to 2017 to achieve a better understanding of the circumstances of accidental exposures with liquid laundry detergent capsules and to investigate the effectiveness of the implemented safety measures[120].

Approach. Call records from the Italian poison centre database (NPCCM) covering exposure to small children and liquid laundry detergent capsules were extracted for a five year period. This covered the period from when the capsules were first placed on the market in 2010 up to and including the end of 2014. During this period different measures were adopted at different times, for example precautionary statements on packaging and information campaigns were launched in 2011, changes to outer product packaging (to restrict easy access) were implemented in 2012 and opaque outer packaging was implemented in 2012. The call rates were studied to assess changes in both the rate of calls received as well as the nature of the incidents at each critical milestone for different measures. This allowed the authors to assess which measure had been the most successful and overall decline in call rates.

Results: The study results indicated a significant overall fall in calls received for exposure of small children to liquid laundry detergent capsules. However, there were also significant differences in the efficacy of different measures. The study showed that implementation of opaque outer packaging for capsules had marked a 50% fall in incidents, while the use of precautionary statements and informative campaigns had little or no effect on the rates of incidents.

Benefits. The study provides a valuable piece of analysis. While many of the toxicovigilance studies completed are intended to help identify if an issue exists and further characterise the issue identified, the current study helps examine efficacy of measures. In particular the study helps identify which measure has made the greatest impact with further application in other Member States.

Obstacles. One caveat to the study results is that the different measures implemented may have had a cumulative benefit (i.e. where the precautionary statements and awareness campaign was launched first, it may have a cumulative benefit with the next measure). Therefore some care is needed in how the results are interpreted, particularly where the most successful measure was the last to be implemented.

5.4.3 Comparison of case studies

The four case studies presented above aimed to reduce cases of poisoning by retrospective analysis of database information. Table 5.2 below presents an overview of the different toxicovigilance case studies.

[120] UMC Utrecht (2017). Exposures to liquid capsules (laundry, dishwashing and all-purpose cleaning). [online] Available at: https://www.umcutrecht.nl/getmedia/4af7633c-b8cc-4417-838b-8aea3850f5a5/NVICrapport-03_2017-Exposures-to-liquid-capsules-(laundry,-dishwashing-and-all-purpose-cleaning)-2012-2016-VERSTUURD.pdf.aspx?ext=.pdf [Accessed 18 Jun. 2019].

Table 5.2 Overview of toxicovigilance case studies from four Member States

	Case study 1 (Germany)	Case study 2 (Netherlands)	Case study 3 (United Kingdom)	Case study 4 (Italy)
Aim	Evaluate health risk and nature of exposure	Evaluate health risk and nature of exposure	Evaluate health risk and nature of exposure	Examine efficacy of control measures
Product	Swimming pool disinfectants	Antipsychotic medicines	Two pesticidal products	Liquid laundry detergent capsules
Data	Cases of exposure	Cases of exposure + literature toxicology data	Cases of exposure + ranking scheme for severity	Cases of exposure + supplementary information on measures
Full composition needed	Yes – in order to link effects to chlorinating agent	Yes – in order to understand dosage within products	No – Study focused only on the active ingredient itself.	No – Only call rates
Benefits	Potential unacceptable risk identified, even under normal conditions of intended use.	Specific issue identified with one type of drug and in particular non-target users including children.	Potential risk quantified and ruled out. However, a secondary issue was identified.	Identified which measures had the biggest impacts to reduce numbers of incidents
Obstacles	Some call records incomplete, study confined to one region of Germany.	Further information needed to help understand the issue more fully.	Some call records incomplete. Relied only on reported cases to the NPIS. Possible other non reported cases missing.	Assumptions needed in order to apply data. While these may be fair, some care needed in how data is interpreted.

Two of the toxicovigilance studies required full compositional data in order to derive results, in particular the case studies for Germany and the Netherlands highlight that compositional data was needed to carry out further toxicological analysis of data. The Netherlands study in particular highlighted that for prescribed users of antipsychotic drugs tolerance could be expected to be higher, and therefore the full composition was needed to assess potential impact between different target groups.

The other two studies for the UK and Italy respectively were more strongly focussed on call rates linked to a specific active ingredient or type of product. In these cases the full compositional information of a given product was less important.

In terms of obstacles there are some common themes which are identified by the four case studies, which have been further supplemented by the interviews conducted with appointed bodies and poison centres. These issues would also have further bearing on how a possible EU level toxicovigilance scheme might work. The obstacles identified by the case studies are as follows:

- Completeness of call record data to allow analysis. During an emergency there can be a variety of factors which mean the full information is not available to the emergency responder. Such factors include patient panic or disorientation, (which would affect the patients' ability to provide the emergency responder with full and accurate information) or where the patient no longer has the product packaging with them to be able to provide full details.

  - Further discussion with the appointed bodies and poison centres also highlighted that different templates and call record databases are in use. For Member States with regional poison centres and without a national database these differences exist within the Member State itself.
  - Also it is possible for call record data to be aggregated in different ways, this may mean that the individual poison centres hold more detailed records with summaries aggregated and provided at national level.

- Studies may be limited to one Member State / region meaning that it is challenging to extrapolate further. For example, the first case study relied on 139 cases over a 14 year period. While the results of the study are significant, a greater pool of data is needed to establish whether the issue has wider impact. Note that completing similar studies in other Member States may be challenging if there are differences in terminology and approach.
- Further information is needed to help characterise an issue. For example, the second case study found a significant issue with one of the antipsychotic drugs including within the scope. However, poison centre call record data alone may be insufficient to help further understand why there is an issue. This poses a question about compatibility of poison centre call records with other data-sets, such as REACH and the CLP inventory. Note that case study 3 highlighted that the analysis was based solely on NPIS call records highlighting a potential gap from hospital admittance records where the NPIS was not contacted for example.
- The appointed bodies and poison centres also highlighted the importance of terminology, particularly for medical symptoms which may be interpreted and recorded differently by different poison centre personnel. Note that the MedDRA system was intended to help overcome this issue, by grouping terminology for symptoms into common categories to allow easier analysis.

5.5 Possible EU-wide toxicovigilance scheme

5.5.1 Challenges for an EU-wide toxicovigilance scheme

There are about 90 poison centres across the EU serving a population of 550 million people[121]. They would be amongst the first institutions that would become aware of emerging trends for potential poisoning events.

In a study to investigate the attitudes of poison centres in the EU to pooling data into an EU-wide database of poison centre enquiries[122], nearly 79% of respondents either agreed or strongly agreed that the database would yield useful public health data and 88% believed that it would be a valuable surveillance tool[123].

The main objectives of the ASHT research project were the design and testing of a rapid alert system for health threats caused by chemical agents, especially when chemicals have been deliberately released by terrorists (RASCHEM), and to assess the feasibility of a European case data collection system. The main partner for this project was the Health Protection Agency UK

[121] Giftinformationszentrum-Nord. (n.d.). ASHT Public Health Project Phase III. [online] Available at: https://www.giz-nord.de/cms/index.php/research-and-projects/411-asht-public-health-project-phase-iii.html [Accessed 8 May 2019].

[122] This study was a part of a feasibility study conducted for the EU Public Health Project 'Development of an Alerting System and Criteria for Development of a Health Surveillance System for the Deliberate Release of Chemicals by Terrorists' (ASHT)

[123] Tempowski, J., Sparrow, E., Schaper, A., O'Connell, S., Mockeviciute, J., Kupferschmidt, H., Edwards, N., R, D. and H, D. (2008). ASHT Project: Poisons Centre Attitudes to an EU-Wide Database of Enquiries. Journal of Clinical Toxicology, (46), p.370.

(now Public Health England)[124]. The project also acknowledged the need for Member States to be able to rapidly exchange and compare information on exposures and poisonings to toxic products, such as pesticides. A related work stream of this project was to automate the process of capturing and analysing poisons centre exposures case data (from Lille, Göttingen, Prague, Lithuania and Milan), as well as investigating the technical and logistical challenges faced in doing so[125]. The project identified a number of issues that make it difficult for different countries to compare information about exposures and poisonings to toxic products, such as different product names and different ways of recording relevant data in each country.

The 'Description of the Nature of Accidental Misuse of Chemicals and Chemical Products' (DeNaMiC) carried out by the Health Protection Agency in the UK between 2006 to 2009 sought to provide an overview of the nature and extent of accidental poisoning from chemicals in household chemical consumer products in the European region and to provide detailed information on the circumstances of where and why such exposures occur. Attempts to compare product categorisation schemes between poison centres within this study demonstrated that there was a good degree of compatibility and similarity in terms of matching product categorisations at the highest (and broadest) level, e.g. drain and oven cleaners. However, an analysis of more detailed sub-levels of product categorisation revealed that the scope of products encompassed by the higher levels of categorisation differed significantly between poison centres' individual schemes, e.g. fire products. Furthermore, the information contained within the annual reports published by European poison centres varied. These factors made product matching and mapping between poison centres difficult[126]. It should be noted that a standard format for case data record sheets and annual reports for European poison centres was proposed in 1990 in Annex I and Annex II of a European Council Resolution[127]. However, based on consultation with stakeholders, these standard formats did not provide fields for agent categorisation and specification. Under the current system, chemical products are categorised in different ways in different Member States, which makes cross-border toxicovigilance difficult, especially in circumstances where a product is purchased in one country but used in another country. Annex VIII standardises the information required to be collected from industry, and through the ECHA portal also standardises how this information is stored, which would help in toxicovigilance that spans Member States. Furthermore, the requirements under Annex VIII are broader than most current systems and require more detailed information about the composition of chemical products. This additional information would be useful for toxicovigilance as more data would be available to assess the risks posed by chemicals products. Poison centres also expect an improvement in information available[128].

The procedure for logging poison centre calls also varies across Member States, as does the data produced for emergency response. It was highlighted in some of the poison centre interviews that the categorisation systems for poison centre calls can differ: calls maybe categorised by intended use rather than by hazard or by the toxicological/chemical groups involved. In practice it may be necessary to analyse data in multiple different ways for surveillance of toxic risks.

For effective EU-wide toxicovigilance, there would need to be harmonisation of the following: format for logging in phone calls, follow up procedure, terminology, data segregation and product

[124] Giftinformationszentrum-Nord. (n.d.). ASHT Public Health Project. [online] Available at: https://www.giz-nord.de/cms/index.php/research-and-projects/108-asht-public-health-project-.html [Accessed 11 Dec. 2018].

[125] Public Health England (2014). Chemical Hazards and Poisons Report. [online] Available at: http://www.npis.org/PHE/CHaP_report_24_2.pdf [Accessed 11 Dec. 2018].

[126] Health Protection Agency (2008). Description of the Nature of Accidental Misuse of Chemicals and Chemical Products (DeNaMiC). [online] Available at: http://cefic-lri.org/wp-content/uploads/uploads/DeNaMiC%20poster%20(2008).pdf [Accessed 11 Dec. 2018].

[127] Council Resolution 90/C329/03 of 3 December 1990 on improving the prevention and treatment of of acute human poisoning [Online]. [Accessed 19 June 2019]. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C:1990:329:FULL&from=DE

[128] Personal communication from the Dutch poison centre, June 2019.

identification. There would also need to be collaboration with hospitals which receive and handle poisoning cases. Annex VIII would help to some extent to facilitate this harmonisation.

Furthermore, unlike for communicable diseases and the European Centre for Disease control, there is currently no equivalent authority responsible for the overall expert assessment and control of chemical public health events on EU level. This is partly due to the rarity of serious chemical health events[129].

A fragmented approach to emergency preparedness for chemical incidents poses a major obstacle to improving cross-border exposure assessment. There exist a number of different organisations and networks across Member States that are involved in chemical incident response, and as such the importance of informal communication channels and learning between Member States should be not be undervalued, and instead facilitated and encouraged through, for example, studies on how communication can be improved.[130]

5.5.2 Options for an EU-wide toxicovigilance scheme

Follow-up calls were made with the Spanish, Dutch and German national appointed bodies (noting that for the Netherlands and Spain the appointed body is also the poison centre) for toxicovigilance to gather more detailed information about their toxicovigilance systems and procedures, including information on the costs and resources involved, and to gauge whether there is potential to scale up their systems at an EU-wide level.

Although each has a sophisticated toxicovigilance system in place that works on a national level, discussions with these national appointed bodies led to the joint conclusion that none could be scaled up to successfully work on an EU-wide level. Spain and the Netherlands have only one poison centre each, so their systems are designed to analyse poison enquiries that are logged in only one format. They do not face the issues arising from the varying methods in which poison centre enquiries are logged, which would exist for an EU-wide toxicovigilance system.

Germany, on the other hand, has eight poison centres that provide selected call logs to the German Federal Institute for Risk Assessment (BfR) which carries out toxicovigilance. The different centres across Germany use their own approaches and systems to log calls, which differ from one another. This makes their data less comparable and presents a challenge for analysis by the BfR. Furthermore, if an unusual poisoning incident is noticed by a poison centre in Germany, it directly calls the local authority and the BfR to discuss it. This system would be difficult to replicate on an EU-wide level.

None of the interviewed national appointed bodies were able to provide specific cost data for their toxicovigilance activities. The BfR, however, provided information on the German "PiMont" pilot national data collection project running from May 2018 to June 2019, which aims to systematically collect information on all enquiries to German poison centres related to products such as pesticides, e-cigarettes (liquids), dietary supplements, dichloromethane-containing paint removers, etc. One objective of the "PiMont" pilot project is to analyse the time and resources needed by the BfR to conduct toxicovigilance analysis and by the poison centres to fulfil their reporting requirements. For the purpose of this project, the BfR provided poison centres with templates for data collection. The German poison centres and the BfR also estimated the costs incurred by poison centres for providing data of varying degrees of detail, acknowledging that the more detail provided, the more resource intensive it is for poison centres. These cost estimates are shown in Table 5.3.

[129] Orford, R., Crabbe, H., Hague, C., Schaper, A. and Duarte-Davidson, R. (2019). EU alerting and reporting systems for potential chemical public health threats and hazards. Environment International, 72(15-25).

[130] Stewart-Evans, J., Hall, L., Czerczak, S., Manley, K., Dobney, A., Hoffer, S., Pałaszewska-Tkacz, A. and Jankowska, A. (2014). Assessing and improving cross-border chemical incident preparedness and response across Europe. Environment International, [online] 72, pp.30-36. Available at: https://www.sciencedirect.com/science/article/pii/S0160412014000853 [Accessed 21 Jun. 2019].

Table 5.3 BfR cost estimates for poison centre data collection

Data set type	Estimated cost
Basic dataset This dataset includes basic patient information such as age, gender, date of call, route of exposure, name of toxic agent, aetiology	€ 20/case
Basic dataset and clinical data This dataset includes information from the basic dataset as well as the clinical effects using MedDRA terminology	€ 139/case
Basic data set, clinical data and follow-up This dataset includes information from the basic dataset and clinical data as well information from follow-up calls (including questions on circumstances of exposure, usually not asked by poison centres)	€ 218/case

It was noted in the interview with BfR that the costs presented in Table 6.3 are most likely underestimated, especially if quality checks (e.g. to check on consistency and completeness of dataset, elimination of double reporting, etc.) are performed, which would most likely be required. For more realistic estimation of costs, more information will be needed from poison centres.

Based on the information collected via literature review and the discussions with Member State appointed bodies for toxicovigilance, three options for an EU-wide toxicovigilance system were developed. These options seek to overcome the challenges identified for an EU-wide toxicovigilance system and take into account the potential time and financial resources that appointed bodies/poison centres would need to expend to support an EU wide scheme.

Option 1- Creation of a centralised EU database for all Member State poison centre enquiries and an EU network of expert toxicologists

Option 1 for an EU-wide toxicovigilance system is to create a centralised EU database for all Member State poison centre enquiries. This would be complimented by establishing an EU wide team of expert toxicologists to carry out the toxicovigilance.

Under this option, poison centres would be provided with a standardised template for logging poison centre enquiries and would be required to submit all enquires onto the centralised EU database. Given the variety of different systems and approaches in use both nationally, and in some cases at the sub-national level, it would likely reflect the highest cost burden and effort of the three proposed options. However, note that standardisation would also allow the highest level of consolidated data for analysis and allow design of a system which could have valuable compatibilities with other data-sets such as REACH and the CLP inventory. Specific cost impacts have not been calculated as they are likely to vary significantly across the EU.

The RASCHEM database developed under the first phase of the ASHT project could be a potential starting point for a centralised EU database. RASCHEM was developed for the notification, alerting and risk assessment of chemical incidents with potential cross border public health significance. It provides a platform for poison centre officials to share details with other poison centres in the EU on poisoning incidents with the potential for cross border health significance. For RASCHEM to be able to hold all poison centre enquiries, and not just the ones with potential cross border public health significance, its structure and technical capabilities would need to be developed further.

The RASCHEM database currently contains 19 fields for users to input data into, which can be classified into the following four groups[131]:

1. General information about the event
2. Data concerning the toxic agent
3. Exposure data
4. Clinical effects

The first part includes information on the data, time and country where the event occurred. The data concerning the toxic agent can include CAS-number, EC-number or a possible vehicle that was used, e.g. cyanide in beverages. Exposure data includes information on how contact was made with the toxic agent, e.g. a possible explosion, leakage or spillage of the toxic agent. The clinical effects field records the patients' symptoms such as coughing, gastrointestinal problems, etc. RASCHEM includes standardised clinical effect terminology based on the 'Medical Dictionary for Regulatory Activities' (MedDRA) symptom description terminology. The use of controlled terms in RASCHEM not only helps overcome the issue of different terminology used by poison centres to describe clinical effects, but also helps accommodate multiple languages and enables identification of similar cases[131].

Based on the information collected from the literature review as well as the poison centre interviews, follow-up calls appear to be an important component of toxicovigilance in many cases as they provide further details about a poisoning incident. RASCHEM's data input fields might therefore need to be developed further to include a section to provide information from follow-up calls. RASCHEM's data input fields could form the basis of a standardised template provided to poison centres across the EU for logging enquiries.

In addition to the establishment of a central database for harmonised poison centre enquires from across the EU, Option 1 would also see the establishment of an EU network of expert toxicologists to carry out EU-wide toxicovigilance. This proposition was discussed in the interview with Member State appointed bodies for toxicovigilance and some suggested that, instead of creating a new expert group, the expertise of existing groups could be relied upon, for e.g. the rapid risk assessment group of the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER).

Option 1 challenges

Although having a centralised database holding all poison centre enquiries from across the Member States in a harmonised format would facilitate thorough and in-depth EU-wide toxicovigilance, there are a number of challenges for Option 1.

Several Member States already have sophisticated toxicovigilance systems in place, with their own reporting formats and IT systems. Providing them with a standardised format for logging enquiries would require them to change their current processes, which could create a high financial burden. Furthermore, based on consultation with Member State poison centres, toxicovigilance is considered to be a national competence and therefore poison centres feel that it is up to them to decide how they manage their toxicovigilance activities. The primary responsibility of poison centres is to provide emergency health response, so they find it challenging to dedicate staff to other resource-intensive tasks.

Furthermore, there is little benefit in requesting poison centres to submit all the enquiries they receive into a centralised database because many of the enquiries that poison centres receive on a day to day basis are related to minor poisoning risks and are of limited benefit to toxicovigilance. Requesting poison centres to submit all their enquiries would result in a high administrative burden. Considering the cost estimates presented in Table 5.3 (from BfR) and the

[131] Schaper, A., Desel, H., Wyke, S., Orford, R., Griffiths, M., Edwards, N., Kupfershmidt, H., Mathieu, M., Pelclova, D. and Duarte-Davidson, R. (2012). Countering health threats by chemicals with a potential terrorist background — creating a rapid alert system for Europe. 23, e63-e66.

fact that poison centres in the EU receive an estimated 600,000 exposure-related calls a year from the general public or physicians[132], below are the potential annual costs for data collection under Option 1:

- Costs for basic dataset= 600,000 cases x €20/case= €12,000,000
- Costs for basic dataset and clinical data= 600,000 cases x €139/case= €83,400,000
- Costs for basic dataset, clinical data and follow-up= 600,000 cases x €218/case= €130,800,000

Furthermore, there would be significant costs associated with developing a centralised EU database, even if the RASCHEM is treated as a potential starting point.

Option 2- Creation of a centralised EU database for specific Member State poison centre enquiries

Option 2 for an EU-wide toxicovigilance system is similar to Option 1, however it can be expected to have a reduced overall burden. As indicated under option 1 poison centres receiving thousands of calls per annum which range from the very serious and life threatening or low-level incidents with minimal or no response required. Providing detailed reports of all calls received may represent a significant overburden to the poison centres.

Therefore option 2 would involve a set of criteria to be developed for when a call record needs to be forwarded on to the central EU repository. This would reduce the number of call records transmitted and likewise reduce the administrative burden for storing and managing records centrally.

It may be possible (through discussion with the poison centres) to further limit impact on poison centres as to how such a central EU database is developed. For example, if the number of records that need to be transmitted are lower it may be possible to retain the existing systems and create software to translate records into the required format for transmission.

Option 2 challenges

Although Option 2 is less financially burdensome compared to Option 1 due to fewer enquires being submitted on to the database, it would still require poison centres to adapt their current toxicovigilance systems and procedures to accommodate for the standardised template for logging poison centre enquiries. As mentioned under Option 1 challenges, Member State poison centres consider toxicovigilance to be a national competence

To an extent it may be possible to develop 'translation software', which re-shapes the data from pre-existing national/regional templates for submission to a central database. However, for some issues the nature of the call logs would require careful technical management manually. Additionally, it may also be the case that the central database included fields of information missing at national/regional level which would need to be incorporated.

Furthermore, there would be still be significant costs associated with developing a centralised EU database, even if the RASCHEM is treated as a potential starting point. It has not been possible to quantify these costs.

Option 3- EU level organisation or body to provide guidance and steer to existing national toxicovigilance schemes and the creation of an EU network of expert toxicologists

Instead of seeking to create a centralised EU database for poison centre enquiries and harmonising these enquiries, Option 3 acknowledges the different systems and procedures for toxicovigilance that are in place in Member States. Under this option, an EU level organisation or body such as the Commission would provide Member State appointed bodies with a clear steer

[132] European Commission. (n.d.). Poison centres - Internal Market, Industry, Entrepreneurship and SMEs - European Commission. [online] Available at: http://ec.europa.eu/growth/sectors/chemicals/poison-centres_en [Accessed 22 Mar. 2019].

and guidance on the consumer products that they should focus on in their national toxicovigilance activities, in a similar way to what is already in place today for biocidal products according to the Biocidal Products Regulation (EC) No. 528/2012, Article 65(3)b[133]

Option 3 would also see the establishment of an EU network of expert toxicologists to carry out the toxicovigilance. As discussed under Option 1, this does not necessarily need to be a new team but could potentially rely on the expertise of existing expert groups, for e.g. current national poison centre experts working on toxicovigilance, the rapid risk assessment group of the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER). This expert group could suggest the (consumer) products and topics of EU wide concern that national toxicovigilance systems should focus on based on regular communication with Member State appointed bodies.

Based on the interviews with appointed bodies/poison centres the respondents were keen to highlight that the role of informal communication networks and discussion through the EAPCCT should not be undervalued. Option 3 therefore could set in place clearer guidelines over what toxicovigilance is being planned annually and harmonisation of efforts at a national level to give the results of specific toxicovigilance studies more weight (i.e. for example the same study could be completed by multiple Member States at the same time with results aggregated for final conclusions).

Option 3 challenges

Although this option is less resource intensive in terms of capital costs compared to Options 1 and 2, as it does not require the development of a centralised EU database or modification of existing Member State toxicovigilance systems, the toxicovigilance conducted under this option would require other kinds of input.

The current study has highlighted that the levels of ongoing toxicovigilance across the EU vary, with some Member States being more proactive than others, and some Member States being more resource constrained. Option 3 would allow toxicovigilance to continue at national level but there being more streamlining of what is expected by whom and by when, in order to build up more effective and comparable toxicovigilance at EU level.

Therefore to limit impact it may be necessary to manage resources accordingly (for example under other related legislation REACH the community rolling action plan reflects an agreement as to what are the key topics of interest for evaluation and then assigns tasks based on the available resources of different Member States). However, note that this approach to toxicovigilance may miss issues which are Member State specific, particularly if resources are constrained.

As mentioned under the challenges for Options 1 and 2, Member State poison centres consider toxicovigilance to be a national competence.

[133] Commission Regulation (EC) No. 528/2012 of 22 May 2012 concerning the making available on the market and use of biocidal products. [Online]. [Accessed 19 June 2017]. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0528&from=EN

6. Assessment of solutions proposed by stakeholders

6.1 Summary of workability issues and possible solutions

Section 3.11 provided a summary and analysis of the workability issues identified within Task 1 of the study. This included consideration of workability issues which are genuinely sector-specific and workability issues which may have broader cross-cutting implications across multiple sectors. For the workability issues identified and reported by industry it was also recognised (within section 3.11) in many cases that there may be commonalities. For example the petroleum sector and cements sector (including mortars, gypsum and readymix concrete) are based on continuous production using natural feedstocks which may vary[134] leading to the workability issues for those sectors.

Where commonalities exist it also means that the possible solutions raised under one sector may also have merit for other sectors. Therefore as part of the study approach it was important to consider all of the workability issues and possible solutions together to look at potential groupings and synergies. This formed the focus of a study workshop with the European Commission, industry representatives, and representatives for competent authorities, appointed bodies and poison centres.

This section therefore provides a further analysis and summary of the workability issues and possible solutions, including commonalities which allow grouping, and consideration of the synergies for possible solutions as a possible way forward. Table 6.1 provides details of the workability issues and possible options as a reference point for the further analysis and discussion.

As well as input from industry and poison centres / appointed bodies sought before and during the project workshop, written inputs were provided on the workability issues and possible solutions by appointed bodies and poison centres. This feedback is provided in Appendix C and includes feedback from Belgium, Croatia, Germany, Ireland and the Netherlands. Appendix C also includes further suggestions made by Germany on 26 June 2019, in advance of the CARACAL meeting on 2 July 2019.

[134] Note, however, the way that different industry sectors work, including infrastructure and distribution networks mean that the workability issues may manifest in different ways meaning that they are still somewhat sector specific.

Table 6.1 Summary of workability issues and options

Sector	Workability issue	Description	Possible solution	Description
Petroleum	PP1	"Product variation in continuous blending process" Petroleum products are manufactured from feedstocks that use natural mixture components (crude oil) as part of a continuous blending process. This means that there can be frequent variations in mixture components triggering many notification (and UFI) updates.	PP-A	"Generic UFI" Proposal for a group submission (and single UFI) to cover mixtures of similar (but not exactly the same) composition with the same hazards. A new UFI would be needed when there was a change in hazard for the mixture. This would address PP1 and the issue of variability in natural mixture components. This would need to be limited to small variations in continuous blending processes, as some mixture components can have different hazards/effects while having the same hazard classification (e.g. aliphatic vs aromatic hydrocarbons).
	PP2	"Long supply chains with reprocessing at many stages" The petroleum network has a long distribution chain with reprocessing, (including addition of further mixture components) and blending at different stages. This means the specific composition changes across the supply chain while the hazard classification will remain unchanged. Maintaining an audit trail for compositional changes across the entire supply chain is expected to be very challenging.	PP-B	"Compositional ranges in Tables 1 and 2 superseded by pre-existing technical standards" Proposal to widen the concentration ranges in Tables 1 and 2 where a pre-existing standard already exists. For example where the Fuel Quality Directive already dictates concentration ranges for mixture components this could supersede the concentration ranges quoted in Annex VIII. This would address PP1 and PP2, and to a lesser degree PP3.

Sector	Workability issue	Description	Possible solution	Description
	PP3	"Multiple batches stored within the same bunkers" It is common practice to store fuels within bunkers (e.g. at fuel stations). These bunkers are constantly replenished, and rarely run completely empty. This means that different batches (with different UFIs) are stored together allowing further mixing that will change the composition and trigger updates and issues in identifying the composition at any given time.		Both PP-A and PP-B may also be applicable to resolve workability issue PP3.
Industrial Gases	IG1	"Bespoke on-demand mixtures based on incremental changes to same mixture components" Industrial gases are often produced on-demand using a base-set of mixture components blended to produce a final mixture. The industry survey suggested that potentially up to 300 mixture components can be used (although the average for all products is five mixture components). In reality the potential different mixtures produced are based on small incremental changes in composition to meet technical specifications, mean that a wide product range is available using this base-set. Compliance with Annex VIII would generate many mixtures requiring their own UFI and notification, while the hazards of many of those mixtures would be the same. Industry also question how beneficial the data would be for industrial gases with only physical hazards (i.e.(flammable and/or oxidising), given that medical health advice for such hazards is less likely to be needed and considering other physical hazards are exempt ('gases under pressure' and 'explosive gases').	IG-A	"Grouping approach for gases with only physical hazards" Proposal for gases classified only for physical hazards to deviate from the concentration ranges in Table 2 of Annex VIII. This would allow a single UFI and notification for the composition provided that there was no change in classification. So for example all hydrogen and nitrogen mixtures classified as flammable would be covered by one UFI and notification. Alternate suggestion would be to exempt flammable and oxidising classes in line with other physical hazard classifications.

Sector	Workability issue	Description	Possible solution	Description
Cement	CM1	"Product variation in continuous blending process" "Cements" are taken here to also include mortar, gypsum and readymix concrete. Cements are manufactured as part of a continuous blending process using naturally occurring mixture components that can vary frequently. Furthermore cement is manufactured to a technical specification and the chemical mixture composition can be altered mid-process for technical reasons. This will create a challenge to monitor chemical composition, which in effect could be impossible and lead to the need for many notification and UFI updates.	-	It has been suggested by industry that the solution PP-A (see petroleum) may also work for cements. EU and national associations and companies have suggested that a generic UFI for cement, based on the cement standard EN 197-1, could be a solution.
	CM2	"Multiple suppliers of same mixture components" To maintain business continuity manufacturers will make use of multiple suppliers for the same mixture component. The different product identifiers would lead to many updates despite there being no technical change in composition or hazard classification. Cement, consisting of clinker and other inorganic constituents (e.g. limestone, fly ash, blast furnace slag, gypsum and natural pozzolans, iron sulfate) is a MIM in products such as mortars or readymix concretes.	CM-A	"Comparable MIMs" The cement industry note that many of the mixture components in use (including cement itself) are themselves mixtures. This means that cement-based products will contain MIMs (mixture in mixture) as mixture components. The proposed solution is a "comparable MIM" approach meaning that where different suppliers for the same technical function mixture component are used, changes in composition would not trigger an update. This would address CM2, and to a lesser degree CM1.

Sector	Workability issue	Description	Possible solution	Description
Construction (exc. Cement)	OC1	"Use of pigment pastes as only variable in broad product ranges" Many construction products contain mixture components to add colour. Annex VIII allows the use of a generic product identifier (GPI) for mixture components that add colour provided they are not classified for human health hazards. The construction industry comment that pigment pastes are the primary colourant used and that the paste itself will normally be classified. This means that the GPI cannot be used and therefore a UFI and notification may be needed for each and every colour shade of construction product, while the rest of the product's composition is unchanged.	-	No solution identified. An approach similar to solution P-A below might be possible. ""
	OC2	"Multiple suppliers of same mixture component" Construction companies will use many suppliers for each type of mixture component to maintain business continuity. The products from different suppliers will have different product identifiers (e.g. CAS No for substances, UFI for MIMs) even if they are technically the same and have the same hazards. Interchanging these mixture components (which is common practice) would trigger an update each and every time a different supplier was used, despite there being no change to technical composition or hazard classification.	OC-A	"Comparable MIMs" As for cements, the industry proposes the use of "comparable MIMs" for where different suppliers are used for the same technical function mixture component. This would avoid the need for updates when changing suppliers for what are considered technically equivalent mixture components with the same hazard classification. This addresses OC2.

Sector	Workability issue	Description	Possible solution	Description
Paints	P1	"Paint tints classified as hazardous for human health*" Industry highlight that they are unable to make use of the GPI for colourants as many of the tints in use do have human health hazard classifications. This means that the full composition of the tint must be provided. This represents a significant burden to industry.	P-A	"Refinement of generic product identifier criteria for 'colouring agents" The GPI for colourants could be modified to allow components classified for human health hazards, provided the classification was unchanged across the group of components covered by that GPI, i.e. for all paint pigments classified as e.g. skin sensitisers the same GPI – Colourants classified as skin sensitisers - could be used. This would allow greater application of the GPI and reduce the number of notifications without loss of information. It has been suggested by one PC that this should not be allowed for colourants classified for one of the hazardous components of major concern (Section 3.4.1 of Part B) as different components with the same hazard classification may have different hazards.
	P2	"Bespoke on-demand mixtures based on incremental changes to same mixture components*" Paints can be produced on demand as 'point-of-sale' products. This means that potential customers can select any possible colour they desire. Point-of-sale paints are produced by using a generic base paint mixture plus addition of tints as MIMs. Up to 99 different tints exist which can be used in any combination. In practice, this can mean large product ranges based on small incremental changes to composition. This would lead to many UFIs and notifications for very similar products, both from a chemical and hazard point of view.	P-B	"Use UFIs for the base paint and colourants in colour mixing systems on demand" P-B proposes to assign the UFI for the base paint and tints separately. At the time of tinting, a sticker would be printed containing the UFI for the base paint plus each additional tint that is added. The label could also contain information for what proportion of the final mixture each UFI makes up (though industry has noted that there would be intellectual property concerns with providing the exact composition).

Sector	Workability issue	Description	Possible solution	Description
	P3	"Multiple suppliers of same mixture component" Industry makes use of multiple suppliers for their mixture components to help ensure business continuity. Many of the substances used within the tints can be naturally occurring, meaning that the composition can vary from supplier to supplier. Such changes would trigger an update (despite there being no change in technical properties or hazard classification), which when combined with P1 could lead to millions of updates.	P-C	"Supply chain information sharing and use of comparable mixture components approach*" The use of a comparable MIM approach for suppliers of the same mixture component, but varying composition. This is the same approach documented under CM-A and OC-A
Perfumes	FR1	"Industrial mixtures treated as mixtures for consumer/professional use" Fragrances are manufactured as mixtures within industrial settings. However, these mixtures (as MIMs) can be found in the final mixtures of professional and consumer use items. This means that the fragrance produced within industrial settings has to be treated as a professional /consumer mixture and the full requirements of Annex VIII apply, including earlier deadlines and not being able to make use of the limited notification. As the final use is often unknown or cannot be controlled the fragrance sector will assume that all fragrance mixtures are for consumer use, which will create significant burden. The industry notes the diluting effect of MIMs within a final mixture may mean the information provided does not affect the hazard classification of the final mixture.	FR-A	"Limited submission for mixtures where data requirements are comparable to SDS in final consumer/professional mixture" The proposal from industry is that fragrances should be allowed to make use of the industrial settings requirements, including the limited notification. Industry asserts that this is on the basis that the diluting effect of the final mixture means that the information collected from a downstream user on the composition of the fragrance in the final mixture would be comparable to the information held by a SDS for the original fragrance mixture. Therefore, there would be no loss of information for poison centres, while the administrative burden on industry would be greatly eased.

Sector	Workability issue	Description	Possible solution	Description
Soaps and Detergents	SD1	"Fragrances classified as hazardous for human health" Industry comment that they are not able to make use of the GPI for fragrances as many of the fragrances in use will carry human health hazard classifications. Fragrances are complex mixtures with many mixture components (albeit at low concentrations in the final mixture), and therefore this represents a significant challenge. The issue relates both to tracking the complete composition but also to making multiple notifications, particularly where composition is expected to vary frequently.	SD-A	"Amendment of GPI to exclude use for only severely hazardous human health classes" Industry notes that, during the original discussions on Annex VIII, the GPI was permissible except for severely hazardous classifications (Acute toxicity 1,2,3, STOT 1 or 2, Skin Corrosion 1,1A,1B or 1C, serious eye damage, and CMR 1A or 1B), but the exclusions were later broadened to all human health hazard classifications. Industry proposes that the GPI could be amended, so that use of the GPI was allowed provided a severely hazardous classification was not included (e.g. to allow sensitisers to be covered by the GPI). This would allow far greater application of the GPI, limit the number of notifications and mean only a small loss of information for poison centres.
	SD2	"Multiple suppliers of same mixture component" Many suppliers are used for the same mixture components for business continuity reasons. These can vary from supplier to supplier (in terms of e.g. CAS No, UFI for MIMs) despite them being technically equivalent and having the same hazard classification to their function in soaps and detergents. This will lead to many updates for soap and detergent final mixtures whenever a supplier for a given mixture component is changed.	SD-B	"Single notification for mixture components with technical equivalence and same hazard classification from different suppliers" Industry proposes an approach of allowing a single submission where mixture components which are technically equivalent and have the same hazard classification are used from different suppliers. The process would work by the formulator identifying and including the UFIs for all suppliers of the same mixture component in the final mixture. This would allow the formulator to use any of these suppliers without the need for updating the notification.

Based on the descriptions from Table 6.1 the following comments can be made:

- A distinction is made that some of the workability issues identified are genuinely sector specific, while others have broader cross-cutting implications affecting many sectors (see section 3.11). In particular the workability issues related to the use of multiple suppliers for the same mixture component / component with same technical function are broader than a single sector issue. These are the issues documented for cement (CM2); other construction (OC2); paints (P3); and soaps and detergents (SD2). All four sectors have suggested a similar approach using 'comparable MIMs', or 'technically equivalent mixtures' (see options CM-A, OC-A, P-C, and SD-B). The application of the options however is slightly different amongst the industry suggestions.

  CM-A, OC-A, and P-C suggest an approach where a mixture component is named linking back to the UFIs of different suppliers and an automated check completed by the ECHA portal (based on parameters to be agreed) to confirm comparability, which would mean an update is not needed.

  SD-B suggests that all suppliers should be named within the original notification as supplying technically equivalent mixture components. After this point the formulator could use any of the named suppliers without needing to update.

- A number of the workability issues relate to the use of generic product identifiers (GPIs), including options to create new GPIs or amend existing GPIs. The focus in this case relates to hazard classifications[135] and how they are used. So for example:

  - SD-A for perfumes within soaps and detergents suggests that the GPI could be amended to exclude its use only for severely hazardous classified substances (Acute toxicity 1,2,3, STOT cat 1 or 2, Skin corrosion 1, 1A,1B or 1C, serious damage to eyes, and CMR cat 1A or 1B)[136].

  - P-A (paints industry) for colourants suggests that the GPI could be allowed where mixture components were classified for human health, provided the classification does not change across the group of colourants covered by the GPI e.g. all colourants classified as skin sensitisers.

Further issues relate to grouping approaches for mixtures, including:

- IG-A suggests that, for industrial gases, with mixture components classified for only physical hazards, a grouping approach (including a single UFI) could be used provided that the classification does not change, e.g. all hydrogen/nitrogen mixtures classified as flammable *und*er one UFI and notification.

- PP-A (petroleum products) suggests the possibility of single notifications for comparable mixtures where natural mixture components are used. This would be particularly the case where the mixture component is produced from natural materials with possible variation.

These suggested approaches would solve some of the workability issues for industry but there is also the question of which information is of highest importance to poison centres and what flexibility exists in how GPIs might be implemented in practice.

- FR-A further highlights the importance of MIMs and ultimate placing on the market of final mixtures, particularly for professional or consumer use. FR-A argues that the level of information obtained for the final mixture would be comparable to a SDS and therefore

[135] Recognising that the feedback from poison centres that hazard classification alone is not sufficient to provide an emergency response, because the different named chemicals with the same hazard classification can have different treatment options. Instead, information on factors such as toxicological mode of action and potency have been highlighted as important in determining treatment options. Indeed, these were included in some of the suggestions from industry on possible solutions (e.g. from the soaps and detergents industry, AISE 27/11/2018).

[136] Although note the use of GPIs was discussed and agreed during the development and implementation of Annex VIII and does therefore not constitute a new or unforeseen workability issue.

the original mixture should be allowed to make use of the industrial settings requirements. This issue is also covered under Task 2.

- P-B provides a solution for large product ranges based on small incremental changes to composition of the same base components. This would see the use of multiple UFIs on the product packaging. This would reduce the number of notifications for this sector. However, feedback from poison centres highlights that there could be practical issues for providing emergency response if a given product has multiple UFIs, and implications for collection of the data, identification of composition, analysis of data across multiple documents and formulating a response. A limitation on the number of UFIs included might therefore be needed[137]. Such an approach could also potentially have wider applications to other sectors with similar issues (i.e. petroleum and to a lesser degree industrial gases)
- PP-A and PP-B provide options to the petroleum sector, notably PP-B proposes the options to deviate away from the concentration ranges used in Tables 1 and 2 where a pre-existing technical standard exists (PP-A was discussed above). This could also be used in the cement sector. However, this would mean a loss of accuracy in the data provided and again poses the question of what information is critical to poison centres.

Based on the commonalities identified across different industry sectors it possible to identify groupings for the different workability issues:

1. Continuous production with natural/incremental changes.
2. Complex supply chain with inability to know exact composition.
3. Multiple suppliers of the "same" mixture component (which includes both cases where the same mixture component is provided by different suppliers as well as different mixture components from different suppliers that serve the same technical function).
4. Limitations on use of group submissions
5. Industrial vs professional/consumer use of MIMs

An elaboration of the issues as grouped above is provided within Table 6.2. Further discussion on the possible way forward has been based on these groupings.

Table 6.2 Overview of issues

Sector	Issue	Possible solution	Possible groupings	Comments
Petroleum	PP1 "Product variation in continuous blending process"	PP-A "Generic UFI"	1 Continuous production with natural/incremental changes	The Generic UFI is similar to IG-A, and could be used to help address workability issue CM1 for cements.
	PP2 "Long supply chains with reprocessing at many stages"	PP-B "Compositional ranges in Tables 1 and 2 superseded by pre-existing technical standards"	2 Complex supply chain with inability to know exact composition	PP-B would provide a solution to both PP2 and PP3 workability issues

[137] For example, this might include limiting the number of UFIs stated on the label to those mixture components present at above a certain concentration, or limiting the number of mixture components for which variable UFIs are allowed.

Sector	Issue	Possible solution	Possible groupings	Comments
	PP3 "Multiple batches stored within the same bunkers"	Refer to PP-A and/or PP-B.	2 Complex supply chain with inability to know exact composition	See PP-A and/or PP-B
Industrial Gases	IG1 "Bespoke on-demand mixtures based on incremental changes to same mixture components"	IG-A "Grouping approach for gases with only physical hazards"	1 Continuous production with natural/incremental changes	Similar to PP-A
Cements (including mortar, gypsum and readymix concrete)	CM1 "Product variation in continuous blending process"	Generic UFI (similar to solution PP-A) could be appropriate for cements e.g. based on the cement standard EN 197-1	1 Continuous production with natural/incremental changes	See option PP-A
	CM2 "Multiple suppliers of same mixture components"	CM-A "Comparable MIMs"	3 Multiple suppliers of the "same" mixture component	The use of comparable MIMs is similar to 'interchangeable technical mixture components'. See options: CM-A; OC-A; P-C; SD-B
Construction (exc. Cement)	OC1 "Use of pigment pastes as only variable in broad product ranges"	No solution identified.	4 Limitations on use of group submissions	Possible solution outlined by P-A.
	OC2 "Multiple suppliers of same mixture component"	OC-A "Comparable MIMs"	3 Multiple suppliers of the "same" mixture component	Similar or the same as CM-A; P-C; and SD-B
Paints	P1 "Paint tints classified as hazardous for human health"	P-A "Refinement of generic product identifier criteria for 'colouring agents ”"	4 Limitations on use of group submissions	P-A may act as a solution to the workability issue for both P1 and OC1.
	P2 "Bespoke on-demand mixtures based on incremental changes to same mixture components"	P-B " Use UFIs for the base paint and colourants in colour mixing systems on demand "	1 Continuous production with natural/incremental changes	Similar or the same as SD-A

Sector	Issue	Possible solution	Possible groupings	Comments
	P3 "Multiple suppliers of same mixture component"	P-C " Supply chain information sharing and use of comparable mixture components approach s"	3 Multiple suppliers of the "same" mixture component	Similar or the same as CM-A, OC-A and SD-B
Perfumes	FR1 " Industrial mixtures treated as mixtures for consumer/profess ional use "	FR-A "Limited submission for industrial mixtures where data requirements are comparable to SDS in final consumer/professiona l mixture"	5 industrial vs professional/consume r use of MIMs	This workability issue relates to Task 2.
Soaps and Detergents	SD1 "Fragrances classified as hazardous for human health"	SD-A "Amendment of GPI to exclude use for only severely hazardous human health classes"	4 Limitations on use of group submissions	Similar or the same as P-B
	SD2 "Multiple suppliers of same mixture component"	SD-B " Single notification for mixture components with technical equivalence from different suppliers "	3 Multiple suppliers of the "same" mixture component	Similar or the same as CM-A; OC-A and P-C

6.2 Conclusions on solutions suggested by stakeholders

6.2.1 Overview

Representatives from industry, competent authorities, appointed bodies and poison centres have been open to discuss the potential issues identified by industry and find solutions that work for all parties. However, key to these discussions has been the need to limit burden on industry without the loss of key information needed to provide emergency health response. It is evident from Section 3 that, while industry has proposed a number of possible solutions to address the workability issues raised, the competent authorities, appointed bodies and poison centres that have taken part in the study have expressed some concerns about potential loss of information needed for emergency health response and toxicovigilance, if those options were to be implemented.

Nonetheless, a number of potential refinements to the industry-proposed solutions have been raised by competent authorities, appointed bodies and poison centres. It is foreseeable that these could be used as a basis for further investigation of possible amendment of Annex VIII in order to address the workability issues when considered sufficiently significant while not compromising the ability to provide emergency health response and toxicovigilance.

The following sections provide a summary of the feedback from authorities on the industry-proposed solutions, and conclusions as per the groupings indicated in Table 6.2 on a possible way forward. Information on the benefits and avoided costs of the possible solutions is provided, where possible.

It should be noted that some Member States have already been working with industry to develop solutions to the workability issues raised. At the time of writing, this work was ongoing[138]. For example, in France, possible approaches have been developed to address cases of complex mixtures and also cases where there are a large number of mixture variants with incremental changes to mixture components. These are described in the relevant sections below.

Furthermore, Germany provided some additional suggestions, on 26 June 2019, which would involve extension of the group submission rules for perfume and fragrance components to other types of components which would involve replacing the indication of all possible variable components in a group submission with the general indication of a toxicologically pertinent indicator (GHI – General Hazardous Components Identifier). A proposal was also made to allow reference to standard formulas for variable mixtures, such as petroleum products or cement (see descriptions in Appendix C).

6.2.2 Product variation due to natural/incremental change in mixture components

Table 6.3 summarises the main workability issues linked to product variation due to natural or incremental changes in mixture components. Further details on the issues and the solutions proposed are set out in Table 6.1.

[138] Personal communication, French Ministry of Health, 6 June 2019.

Table 6.3 Possible solutions for issues related to product variation due to natural/incremental changes

Workability issue	Industry proposed solution	Feedback from authorities
Petroleum, PP1 "Product variation in continuous blending process"	PP-A "Generic UFI"	Recognition that this is an issue for industry, and also that relatively few calls to PCs (around 1% of the total) are received for fuel products. PCs expressed concern regarding reduced levels of data availability. However, an alternative proposal was made by the German authority that would involve a set of additional GPIs that represent predefined Group formulations (GFs) (which may be linked to existing technical standards), with wider concentration ranges and/or variable, but similar substances.
Industrial gases, IG1 "Bespoke on-demand mixtures based on incremental changes to same mixture components"	IG-A "Grouping approach for gases with only physical hazards"	There was recognition from the majority of CAs, ABs and PCs that took part that there is limited additional benefit for emergency health response through detailed information on physical hazards. However, concern regarding potential loss of information. Potential for further grouping, wider concentration limits or exemptions might have merit for gases with only physical hazards.
Cement, CM1 "Product variation in continuous blending process"	Generic UFI (similar to solution PP-A) could be appropriate for cements e.g. based on the cement standard EN 197-1	See comments on PP1 and CM1 in Table 6.1 above.
Paints, P2 "Bespoke on-demand mixtures based on incremental changes to same mixture components"	P-B " Use UFIs for the base paint and colourants in colour mixing systems on demand "	Solution appears to have merit based on PC feedback. However, there is a concern that having too many UFIs on a paint tin would make the solution unworkable.

In order to address issue PP1, poison centres expressed concern that use of a generic UFI would lead to an unacceptable loss of data. Data from poison centres suggests the volume of calls associated with petroleum products is relatively low (e.g. 1% in Ireland, and 0.2% in Germany), however, it is unclear what severity of incidents are witnessed for petroleum products and therefore the issue should be treated of moderate concern for emergency health response. The German authority (BfR) proposed a solution to address this issue, which could also apply to other sectors with natural changes in composition, such as construction products and fragrances. This approach, understood to be based on experiences under the Cosmetic Products Regulation, would involve:

- Defining a set of additional generic product identifiers representing predefined Group Formulations (GF) with wider concentrations and/or variable but similar substances.
- Existing technical specifications (e.g. for cements, petroleum products) could be used to define those Group Formulations.
- They suggest that substances with specific concern for emergency health response (e.g. very toxic substances or those with specific medical treatment options available) should

not be contained in those Group Formulations and should be notified according to Table 1 of Annex VIII.

For the petroleum products sector, this would allow the potential costs of strict compliance to be largely offset e.g. costs for notification every time the composition in a fuel tank at a service station changes (estimated €7 billion per year for analysis alone, and assumed to be practically very challenging (impossible in the industry's opinion) given the lack of laboratory capacity and disruption to fuel suppliers). For the construction products sectors, it is assumed that the possible costs of several hundred million Euro per year could be significantly offset, though the extent of this is unknown.

In order to address issue IG1, there seems to be support from the industry sector but also from poison centres to considering the possibility for single submissions with wider concentration ranges for gases that are classified only for physical hazards. It is expected that this could significantly reduce the total number of submissions required (from an estimated 57,000) and the associated cost (from an industry estimate of €6.7 million per year[139]. Specifically, EIGA estimate that only 30% of their members' products will be classified for health hazards, but the majority (70%) will be classified for physical hazards only.

One poison centre highlighted that it would need to be clarified whether the product variation is mainly due to change in components, natural variation in concentrations or both, and also that where reference is made to 'technical standards', these are an appropriate basis for new groupings (GF or GPI).

In order to address issue P2, the industry-proposed solution to allow separate UFIs for the base paint and the colourants (where colour mixing systems are used at point of sale) appears to be recognised as feasible. However, authorities have highlighted that including very large numbers of UFIs on paint tins would cause problems for emergency health response. This option therefore warrants further consideration, including the potential need to limit the number of UFIs that could be applied. The theoretical costs to the paint industry could be €13-27 billion per year if all possible products had to be notified, and this solution could substantially reduce those costs. It is understood that the French authorities have developed a solution to this issue in conjunction with industry.

At a recent CARACAL meeting (20 March 2019), the French authorities offered to provide further elaboration on this. France reports[140] having reached an agreement to address cases of complex mixtures as follows:

- A generic UFI is created for families of products e.g. for each cement and petroleum product defined by a European standard or an international standard.
- Every complex mixture put on the market, identified by its UFI, is declared with a composition that includes: (a) the generic UFI corresponding to the product family concerned; (b) each of the intentionally added ingredients designated by its CAS or ECN number if applicable or the UFI of the MIM used.
- Representative samples are required to undergo chemical analysis on a periodic (e.g. annual basis), representative of the variability of the mixtures concerned.
- If other ingredients are intentionally added by the manufacturer to mixtures placed on the market, this information must be made available to the health authorities, in the declaration.

In the case of mixtures with a very large number of varieties (such as in the case of paint mixing at point-of-sale), the proposed approach is:

[139] Further review is needed for the industrial gas sector to determine how significant the impact of the identified workability issues may be in reality, particularly as greater understanding on the presented cost estimates is needed.

[140] Personal communication, French Ministry of Health, 6 June 2019 and 27 June 2019.

- A notification is made on the basis of a UFI range, incorporating all the mixture ingredients that may be in the range (for example, for a paint, the different bases and dyestuffs that can be used). The company must ensure that all the variable elements of the final mixture are declared, each with its own UFI. On the label of the mixture (which is produced by a tinting machine in the case of a paint), there is a list of the UFIs of the ingredients actually used. For a paint this includes a base and up to 6 pigment pastes.
- The packaging will have a matrix code (QR code) integrating in particular the generic UFI of the range and the specific UFIs of the actual MIMs that are included.
- If adopted, these provisions would require an amendment to Annex VIII of the CLP Regulation introducing the possibility of identification by a matrix code and also the ability to designate a mixture by a set of UFIs.

These approaches are also taken into account in the latter parts of this report.

6.2.3 Inability to know exact composition in complex supply chains / with mixing at multiple stages

The second grouping related to workability issues associated with complex supply chains where there may be an inability to know the exact composition of mixtures. This group of issues affected the petroleum sector in particular (PP2 and PP3). A summary of the main workability issues is provided in the table below. Further details on the issues and the solutions proposed is set out in Table 6.4.

Table 6.4 Possible solutions for issues related to inability to know exact composition in complex supply chains / with mixing at multiple stages

Workability issue	Industry proposed solution	Feedback from authorities
Petroleum, PP2 "Complex distribution network"	PP-B "Compositional ranges in Tables 1 and 2 superseded by pre-existing technical standards"	There was recognition from PCs that the petroleum supply chain is particularly complex, and that furthermore it is equally undesirable for appointed bodies to receive many (potentially millions) of notifications for very similar mixtures.
Petroleum, PP3 "Continuous mixing of different batches of petroleum products in storage tanks"	PP-B "Compositional ranges in Tables 1 and 2 superseded by pre-existing technical standards"	While the PCs had concerns over the potential loss of key information under proposed solution PP-A; solution PP-B may be more acceptable, particularly if there are pre-existing technical standards that could be used. However, some PCs were less familiar with these technical standards and stated that more needed to be known before a final comment could be made.

The review of the workability issues for the petroleum sector identified three discrete issues, which cumulatively create a significant logistical challenge for the industry to track the specific composition from the original production to the product that is sold to consumers. The first of these three workability issues relating to the continuous production of petroleum products using natural mixture components was discussed in the previous section (product variation due to natural/incremental change in mixture components, PP1). The remaining two workability issues relate to the extended supply chain with possibility for further mixing and additions at each step, as well as the issue relating to storage of final mixtures in the same tank allowing further mixing.

The petroleum sector has highlighted that the only certain way to confirm the specific composition of the final mixture would be sampling and analysis of the final mixture at each stage of the value chain, right up to fuel stations. New deliveries are typically received every other day and this would also equate to the need for sampling and analysis every other day. For

Germany alone (15,000 fuel stations) this would equate to 11 million samples per annum, which in kind would mean the same number of notifications per annum. Extrapolated to EU (based on number of fuel stations) this would be 57 million annually.

The sector proposed two possible solutions (detailed in this report as PP-A and PP-B, see table above). As detailed in the previous sub-section PCs raised concerns that the proposed generic UFI covered by PP-A would likely result in a loss of key information which would be unacceptable. The proposed solution PP-B suggests that wider concentration ranges could be used, possibly as a derogation to Tables 1 and 2 of Annex VIII where pre-existing technical standards are in place.

The PCs commented that it is equally undesirable for appointed bodies to receive millions of notifications for very similar mixtures as it would create a significant administrative burden without any tangible benefits. Therefore the proposed solution PP-B could be acceptable as a solution to limit the burden on industry and appointed bodies without such a loss of information as PP-A.

One appointed body did highlight that they were less familiar with the specific technical standards and would therefore need to know more before they could agree. However, an alternate solution was also suggested by BfR termed 'G6' in their response, which suggests a series of groupings could be used for typical compositions; this reportedly draws on a similar approach that is used within the cosmetics sector (see Appendix C).

6.2.4 Multiple suppliers of mixture components with "same" technical properties and hazards

The table below summarises the main workability issues linked to cases where there are multiple suppliers of mixture components that are technically equivalent and which have the same hazards. Further details on the issues and the solutions proposed is set out in Table 6.5.

Table 6.5 Possible solutions for issues related to multiple suppliers of "the same" mixture components

Workability issue	Industry proposed solution	Feedback from authorities
Cement, CM2 "Multiple suppliers of same mixture components"	CM-A "Comparable MIMs"	Agreement that this represents a significant workability issue. Concerns were raised that a long list of interchangeable MIMs/mixture components would be impractical during an emergency. An automatic evaluation procedure would be needed in determining technical equivalence and toxicological equivalence should extend wider than hazard classification to include e.g. toxicological mode of action. The potential solution could depend on whether the interchangeable mixture components are actually the same, or are similar (see e.g. BfR suggestions on options G2 and G3 in Appendix C).
Other construction, OC2 "Multiple suppliers of same mixture component"	OC-A "Comparable MIMs"	Same feedback raised as for CM-A.

Workability issue	Industry proposed solution	Feedback from authorities
Paints, P3 "Multiple suppliers of same mixture component"	P-C "Supply chain information sharing and use of comparable mixture components approaches"	Same feedback raised as for CM-A.
Soaps and detergents, SD2 "Multiple suppliers of same mixture component"	SD-B "Single notification for mixture components with technical equivalence from different suppliers "	Same feedback raised as for CM-A.

The issues described here are essentially the same for all four of the sectors, and the feedback received from poison centres and appointed bodies is also essentially the same.

Further suggestions made by industry (reproduced in Appendix B) which proposed the following solution to the workability issues:

> *"In their submission, the notifier identifies component substance(s)/mixture(s) which are subject to variation.*

- For these components, the notifier identifies all alternative components that may be present due to variation, creating a limit of variation. All components subject to variation and their alternatives must be reported and:
    - Be identified according to Section 3, Part B of Annex VIII information requirements (as potentially amended) or using the UFI or SDS/supplier (for notified MiMs as per Part B 3.2.2)
    - Serve the same technical function within the mixture
    - Carry the same health and physical hazard classification
- Validity of the submission with respect to the above criteria could be determined electronically during submission (e.g. IT check via validation assistant during submission).
- Following submission, appointed bodies or ECHA would be entitled (as per Part A 3.2) to review/assess the submitted limit of variation and conduct follow up if deemed appropriate.
- Assuming the notifier places formulations on the market that are within the notified limits of variation, no new UFI or submission update are required."

However, based on the previously-described feedback from poison centres and appointed bodies, it is unlikely that this proposed solution would be considered acceptable to all. In particular, authorities highlighted that, if such an approach were to be applied, there would be a need for greater certainty on sameness, especially as regards toxicological mode of action (not just hazard classification). In fact, the solution originally proposed by the soaps and detergents industry (SD-B) suggested that such interchangeable mixture components should also be required to have the same use concentration (± a defined concentration limit), be of comparable potency, and have the same toxicological mode of action.

If such additional criteria were taken into account, it is expected that there would still be a significant reduction in the number of notifications and updates required, but that the reduction

would not be as great as if only the technical function and hazard classification were required to be the same.

The German authorities proposed (see Appendix C) an approach for toxicologically comparable substances (known chemical identity) or mixtures (full composition and chemical identity may be unknown). This would be a form of modified group submission and would involve:

- One or a few components being exchangeable by similar components, while all other components, their concentrations, hazard classification of the variable components and hazard classification of the final mixture are shared between all members of the group.
- All substances or mixtures that are exchanged would need to share the same mode of action, leading to a common or very similar clinical risk assessment and poisoning advice. For mixtures, this could be assumed if all the MIMs included share all components and all components are within the same narrow concentration ranges (Tables 1 and 2 of Annex VIII).
- This would require the generation of new generic product identifiers (GPI).
- All substances or mixtures (MIMs) that could be exchanged would need to be listed with product identifiers (and UFIs for mixtures) as described for fragrances (Parts A4.4 and B3.1).

This approach is similar to the "comparable mixture components" approaches suggested by industry but would require a GPI to be defined for the group of interchangeable mixture components.

This is clearly a significant issue for multiple sectors, as highlighted in Chapter 3. In particular costs expected to be faced by the sectors in question (related in part at least to this workability issue) include costs of several hundred million Euro for the cements and other construction sectors; €13-27 billion for the paints sector and €4 billion (or more) capital costs for the soaps and detergents sector, based on industry's estimates[141]).

6.2.5 Limitations on use of group submission approaches

The table below summarises the main workability issues linked to limitations on use of group submission approaches. Further details on the issues and the solutions proposed is set out in Section 3.7.

141 Note that these are estimates from the industry sectors themselves. Furthermore, costs relate to Annex VIII as agreed, but relate to multiple workability issues in some cases (i.e. costs cannot be estimated separately for each of the workability issues based on the data available).

Table 6.6 Possible solutions for issues related to limitations on use of group submission approaches

Workability issue	Industry proposed solution	Feedback from authorities
Other construction, OC1 "Use of colourants and the generic product identifier"	See P-A and SD-A	See P-A and SD-A (below)
Paint, P1 "Inability to use the product identifier for 'colouring agents"	P-A "Refinement of generic product identifier for 'colouring agents'	P-A suggests that the GPI could be amended to allow a disaggregation based on hazard class – i.e. colourants classified as irritant. The response from PCs were mixed. While some thought that the proposed solution could be acceptable and warranted further exploration, others felt that in practice it would be overly complex and that hazard class alone does not indicate mode of action. Overall the majority of PCs suggested that this proposed solution would not be acceptable as it would likely result in a loss of key information needed for emergency health response.
Soaps and Detergents, SD1 "	SD-A "Refinement of general product identifier criteria"	SD-A suggests that the GPI could be amended to only exclude severely hazardous substances. Some PCs commented that this proposed solution was the original starting point for the GPI in the Commission's original proposal, but the list was extended during negotiation of the regulation. While some PCs thought that this was an acceptable solution, others did not, largely due to the need for data to serve toxicovigilance. Adopting the proposed solution would therefore mean reversing what had already been agreed which is considered unacceptable to some authorities. However, one PC highlighted that the original discussions had involved many options for GPIs which had been concluded quickly. Therefore, it may be necessary to re-open the debate, particularly where the main issue relates to the role of emergency health response and toxicovigilance. There is clearly a difference between authorities required to provide emergency response (PCs) and those responsible for toxicovigilance (ABs, CAs), though some organisations fulfil both AB and PC roles.

The main concerns raised by the PCs to the proposed solutions for P-A and SD-A were two-fold, firstly that in order to develop a response for emergency health calls it is necessary to know the mode of action for given substances. The solutions proposed would result in a loss of key information needed to help determine this aspect and therefore the proposed solutions are unacceptable to them. Secondly, the PCs highlighted that the data submitted to appointed bodies serves two functions, the first being emergency health response and the second being toxicovigilance. In order to conduct the later it is necessary to know the full composition, particularly named components that have human health hazard classifications. Again the proposed solutions would result in a critical loss of this information.

The survey results for the paint sector highlighted that on average 54% of product portfolios would not be able to use the GPI for colourants as one or more of the mixture components would be classified for human health. CEPE commented that for paints very wide product ranges exist, potentially equating to thousands or even millions of products. The survey responses highlighted that for one company the different between using and not using the GPI for paints would result in a difference of a few hundred notifications and 80,000 notifications. Another company highlighted that their full product range would equate to around 40 million different possible combinations.

During the discussions between industry, competent authorities, appointed bodies and poison centres it was commented that it is undesirable for the appointed bodies to receive many (millions) of notifications for similar mixtures as it would represent a significant administrative burden and would slow down systems, which is equally undesirable. Therefore a compromise is needed. Feedback from the Dutch PC commented that during the original discussions around GPIs that many different options had been proposed with only a short discussion. It may be necessary therefore to re-open this debate to further explore the needs around emergency health response and toxicovigilance to see whether solution SD-A could be acceptable. The approach to be taken (and information provided) for toxicovigilance purposes could be different to that for emergency health response e.g. the former could be collected in a more targeted manner.

Furthermore during the workshop it was suggested as a compromise that if SD-A could be adopted, the UFI for the original mixture component classified for human health could be provided. This would allow a full audit trail for toxicovigilance purposes while allowing the GPI to still be used.

Overall, the view from PCs seems to be that proposed solution P-A seemed overly complicated for practical implementation with concerns again raised about loss of key information. Proposed solution SD-A was more mixed with reservations over loss of information and differing needs for emergency health response and toxicovigilance, but also that very high numbers of notifications for similar mixtures to appointed bodies was highly undesirable and should be avoided.

6.2.6 Mixtures in mixtures – Industrial vs professional/consumer use

The table below summarises the main workability issues linked to the treatment of MIM as being for consumer/professional use although they are initially used in industrial settings. Further details on the issues and the solutions proposed is set out in Section 3.7.

Table 6.7 Possible solutions for issues related to industrial vs professional/consumer use of MIMs

Workability issue	Industry proposed solution	Feedback from authorities
Fragrances FR1: Industrial mixtures treated as mixtures for consumer/professional use	FR-A: Limited submission for mixtures where data requirements are comparable to SDS in final consumer/professional mixture	Limited submission (but with potential for Abs to request information) would not appear to cause problems, provided that concentration of fragrances is low e.g. 5%.
Chemical suppliers: Raised same concern as analysed under Task 2	Suggestions for reliance on SDS and/or delay of deadline for compliance to 2024 instead of 2020/21	Suggestion that the proposed solution (with a limitation on concentration) need not be limited to the fragrances sector.

It is clear from the analysis for Task 2 that there are a significant number of mixtures on the market, across multiple sectors, that are initially used in industrial settings but which are subsequently incorporated into consumer or professional products. Feedback from chemical suppliers in general, as well as from the fragrances and animal feed additives sectors, have highlighted that the earlier compliance deadline for industrial mixtures, as well as the inability to benefit from the provisions for reduced submissions, would cause significant additional costs.

In contrast, poison centres have raised concerns that having only a reduced level of information on concentrations of hazardous substances and lack of information on non-hazardous substances (as would be available through an SDS) could cause problems in terms of emergency health response and toxicovigilance.

Nonetheless, the feedback received during and after the workshop from authorities suggests that the limited information submission should not cause significant problems provided that the concentration of the hazardous substances (fragrances but also potentially other substances) is below a certain level. As set out in Section 4 the cut-off values or dilution factors above and below which the information on the presence of hazardous substances included in SDS would be required as well as an Annex VIII notification, are largely determined by the concentration limits for listing of a substance in an SDS under Annex II to the REACH regulation (typically 0.1% or 1.0%). However, based on the feedback from some poison centres, supply of a reduced submission (based on SDS) rather than a full notification could be possible without interfering with emergency health response at a higher concentration (e.g. 5%), provided that authorities could request information from mixture providers if needed. It has also been pointed out that the issue of allowing a reduced submission is separate from that of the compliance deadlines.

7. Identification of options to take forward

7.1 Scope

One of the tasks of this study was to identify options to address the confirmed workability issues without losing benefits due to better and more detailed information for emergency health response and preventative action (including possible modifications of Annex VIII).

This section identifies a number of options that are proposed to be taken forward for further consideration by the Commission and concerned stakeholders. It is understood that the Commission will set up a sub-group under the CARACAL expert group with this remit.

The information in this section builds on the information presented in sections 3 (Task 1) and 4 (Task 2), as well as the synthesis provided in Sections 6.1 and 6.2. Three possible solutions to address the confirmed workability issues (see Section 3.11) are put forward:

- Option A: Ability to use limited submission for certain MIMs that are ultimately used in consumer and professional products
- Option B: Allow use of multiple UFIs for bespoke point-of-sale consumer and professional products
- Option C: Allow deviation from concentration limits for inherently variable or technically interchangeable mixture components

The pros and cons of the possible options are described, primarily in qualitative terms. Where feasible, an assessment of the costs and benefits of the options is provided, as compared to those calculated in the costs and benefits study and Annex VIII. The options could be applied individually or in combination.

7.2 Approach to development of options

The options set out in this section are based on the various study inputs and activities described elsewhere in this report, including:

- The workability issues identified by industry and the appraisal of their significance.
- The potential solutions put forward by industry to address the workability issues during the initial consultation phase. These potential solutions were sector-specific.
- Poison centres' and appointed bodies' views on the workability issues and on industry's proposed solutions identified during the initial consultation phase.
- Discussions at the study workshop, including suggestions put forward by industry and the views of authorities on those suggestions.
- Feedback from poison centres, authorities and industry after the study workshop (February/March 2019) and also on the draft report (May/June 2019), including new and/or modified suggestions to address the workability issues.

These options have been developed with a view to finding solutions that limit the costs on industry without compromising the ability to provide emergency health response. The options are also intended to be non-sector-specific where possible, in order that other sectors with similar workability issues (but which may not yet have vocalised a concern) should not be disadvantaged. Another criterion was the need for a simple and easy-to-apply solution that can be readily translated into a legal text.

Section 6 of this report grouped the workability issues into five main topic areas. In reality there remains a degree of overlap between those groups of workability issues, and in possible solutions

within each of those groups. The intention here has therefore been to systematically consider those groupings and solutions and to further consolidate the options to address those workability issues, into a practical form for possible amendment to Annex VIII.

7.3 Options put forward for further consideration

7.3.1 Option A: Ability to use limited submission for certain MIMs that are ultimately used in consumer and professional products

Description of the option

This option is intended to address the issue whereby original mixtures that are initially used (for formulation) in industrial settings cannot benefit from the limited submission provisions because the original mixtures are used as MIMs in final mixture products sold to consumers or professionals.

This option would involve the possibility, for cases where a mixture is supplied initially for use (in formulation) in industrial settings, to apply the limited submission requirements, provided that it can be demonstrated that the mixture is never used in final mixtures for consumer or professional use at concentrations above a certain level (threshold to be determined e.g. 5%). This could be included by the notifier/supplier as a precondition of supply of the original mixture to their customer.

This approach is a modification of the industry (fragrances/Cefic) suggestions. The industry suggestions incorporated a complete exemption from the need for full notification for such mixtures, but authorities (e.g. Germany, Spain) considered the option to be acceptable only if there were some associated concentration threshold in the final mixture. A complete exemption would indeed appear inappropriate e.g. in the case of fragrances used in air fresheners, where the concentration in the final product may be very high (e.g. 30-100% for liquid air fresheners).

How industry and poison centre workability issues and proposed solutions are addressed

This option would address the issue for chemicals (mixtures) suppliers that reportedly often do not know the exact final use of all of the mixtures that they supply. While they may know the majority of uses, possible use in consumer/professional products cannot be ruled out, so the suppliers would currently need to make a full notification of composition for all such products.

Benefits that could be realised

This issue has been highlighted by the chemicals supply industry (through Cefic member companies) and also more specifically for the fragrances sector. As illustrated in Table 4.4, many fragrance compounds (which are MIMs) are used in very low concentrations in final products, and the concentrations of hazardous substances will be lower still in most cases (recognising that fragrance compounds may contain e.g. up to 200 individual mixture components). Therefore, a significant number of mixtures are likely to be able to benefit from being able to use the limited submission requirements.

In the case of poisoning incidents, poison centres would still have access to the information on composition from the safety data sheets of the MIMs concerned.

Potential drawbacks

This option would require the derivation of an appropriate threshold concentration below which the mixture could be used in mixtures for consumer/professional use. As the work on Task 2 of this study (Section 3.1) highlights, it is not straightforward to define dilution factors below which the information on composition in a full notification is equivalent to that contained in an SDS (so such an approach is not recommended). Instead, it would appear to make sense to link a threshold to the concentration limits for listing of a substance in an SDS.

In addition, it may not always be feasible for suppliers to include such a threshold condition in their sales contracts. Where this is not possible, they would have to revert to supply chain communication to identify the mixture concentration in their customers' final products.

Furthermore, if following the initial limited submission by the mixture supplier, the industrial user of the original mixture decides to use the mixture at above the concentration limit in consumer/professional products, poison centres would presumably need access to the full composition (through a full notification and provision of the appropriate UFI to the industrial user). This would create additional time and effort.

7.3.2 Option B: Use of multiple UFIs for bespoke point-of-sale consumer and professional products

Description of the option

This option is intended to address the issue whereby, for mixing of paints at point-of-sale, potentially millions of individual notifications would need to be either generated and submitted in advance, or would need to be generated each time a new colour is mixed and sold (e.g. at a home improvement store) to a consumer or professional. This is workability issue P2 in the previous chapters of this report, and the proposed solution is P-B. Whilst the issue has been identified specifically for paints, a non-sector-specific approach is considered appropriate given that other sectors might face the same issue.

The option would be to allow the use of a single UFI for the base product (e.g. base paint) and additional, separate UFIs for individual colourants where mixtures are produced on-demand at point-of-sale for consumers and professionals. The concentration range of the components would also need to be specified.

Such an approach is based on an industry proposal and seems to be supported by feedback from poison centres.

Furthermore, as noted in Section 6.2.2, a variant on this option is already being considered in France (with the authorities and industry), whereby a notification is made on the basis of the different bases and pigments that may be included within a paint. In this case, the packaging would include a QR code incorporating the generic UFI of the base paint and the specific UFIs of the interchangeable pigment components in that particular product. Note that the use of a QR code is not (currently) compatible with Annex VIII which requires that the UFI itself be included on the label or the packaging in proximity to the other label elements.

How industry and poison centre workability issues and proposed solutions are addressed

This option would primarily address workability issue P2 for the paints sector i.e. where paints are mixed with colourants to create bespoke colours and products at the point-of-sale. The solution is essentially based on the industry proposal for a solution P-B, as well as the approach being applied in France.

While other sectors with the same issue have not been identified, it appears appropriate not to limit this option to the paints sector within any guidance or amendment to Annex VIII.

Benefits that could be realised

The theoretical costs to the paint industry of compliance with Annex VIII were indicated by the industry to be in the order of €13-27 billion per year if all possible products (estimated 44.5 million (see Section 3.7.3)) had to be notified. This solution could significantly reduce those costs, as a large proportion is understood to be related to paints mixed at point-of-sale. The proportion by which those costs could be reduced is not known but is likely to be substantial.

Poison centres appeared to be largely supportive of this option, and it would reduce the volume of notifications that they would need to deal with. This is assumed to be of particular benefit in those Member States not using the ECHA searchable database.

Potential drawbacks

The main drawback identified with this option is that there would potentially be either very large numbers of UFIs included on paint tins, which would cause problems for emergency health response; or very large numbers of UFIs included in a possible overall notification, making it more difficult to identify the specific emergency response needed.

Specifically, it would be challenging for a patient in an emergency situation to decide which number to pass on. It would also be time-consuming. Furthermore, if the approach of using a QR code were applied (noting that this is not allowed under CLP), the patient would often be using their mobile phone to call the poison centre, which would make scanning the QR code challenging.

7.3.3 Option C: Deviation from concentration limits for inherently variable or technically interchangeable mixture components

Description of the option

This option would be designed to address cases where mixture components (e.g. from multiple suppliers) are considered technically equivalent and are interchangeable (and where they have equivalent hazard), as well as where mixture components are inherently variable due for example to natural variations in concentrations of mixture components.

Deviation from the concentration limits in Tables 1 and 2 would be allowed, by a specified percentage, for such mixture components. In such cases, there would be no need for re-notification when such a mixture component changes, provided that certain conditions are fulfilled, such as:

- Where mixture components are interchangeable or inherently variable within this group, all such mixture components (substances/MIMs) would need to be listed (with product identifiers / UFIs) as part of the notification[142].
- All other mixture components would need to remain the same, and in the same concentration [ranges].
- The notifier would need to be able to demonstrate, on demand, that there is no difference in toxicological mode of action, potency, hazard classification, etc. of the interchanged mixture components, and no difference in treatment in the event of poisoning, as well as no change in hazard classification of the final mixture[143].
- This option could be limited to mixture components that are not classified for certain hazards (e.g. hazardous components of major concern for emergency health response as per 3.4.1 of Part B of Annex VIII would not be able to benefit from this option).
- A single UFI covering the mixture and all its expected variants would then be created.

It may be appropriate for the notifier to be able to demonstrate, if requested by the authorities, that the different mixtures within the group are technically equivalent e.g. through reference to internationally-recognised standards.

[142] It could also be appropriate to allow a single notification (no need for re-notification) in cases where the change in mixture components only relates to components classified for physical hazards.

[143] It would need to be determined to what extent 'proof' of toxicological equivalence should be included in the submission. The default position assumes that the burden would lie with industry to provide this, if required; only the identity of the potentially interchangeable or variable mixture components would be included in the submission.

It may also be appropriate to limit the number of mixture components that are interchangeable within a given notification, and/or the number of alternatives for each interchangeable mixture component, in order to make submission and review of notifications by poison centres practicable.

It would also be appropriate for the notifier to be able to demonstrate (e.g. on demand or at regular intervals) that mixtures produced and sold using the UFI in question are indeed representative of the original notification.

It is assumed that the burden of proof/effort should not be on the PCs or ECHA to either define any groups[144] or to systematically check toxicological equivalence. However, they would have the opportunity to check (and request additional information) and to reject the notification if appropriate.

How industry and poison centre workability issues and proposed solutions are addressed

This option would address, at least in part, the following workability issues (amongst the five listed in Section 6of this report):

- Product variation due to natural / incremental changes in mixture components
- Inability to know exact composition in complex supply chains / with mixing at multiple stages
- Multiple suppliers of mixture components with 'the same' technical properties and hazards

The burden would be on industry to ensure that there should be no difference in treatment in the event of poisoning if exposure occurs to any of the variants within the ranges of concentrations/components specified.

There should be no need for the definition of additional generic product identifiers (GPIs) or group formulas (GFs) by authorities.

This option also takes into account the inputs from industry that products produced to certain existing technical standards often also have the same associated hazards.

It is important to note that, under this option, it would not be sufficient to simply demonstrate no change in hazard classification, but to demonstrate that there would be no significant change in toxicological effects or treatment.

Benefits that could be realised

This option would serve to reduce the overall number of submissions by allowing a modified form of grouping.

There would be benefits to poison centres through reduced numbers of essentially equivalent notifications being received and needing to be processed. Several poison centres have mentioned that there would be little value in receiving large numbers of notifications when only minor components vary and there is no change in treatment required.

As set out in Section 6 of this report, this option would help with the following:

- For sectors, with issues related to natural variability in mixture components and complex supply chains with multiple mixing stages, to:
    - offset some of e.g. the industry-estimated €7 billion per year for analysis in the petroleum sector and avoidance of distribution to the fuel supply system (e.g. frequent notifications at each fuel station); and

[144] Some of the options suggested by stakeholders to address workability issues involved the definition of new groups.

  - offset some of the several hundred million € per year costs to the construction products sectors associated with multiple notifications.

- For cases where there are multiple suppliers of mixture components with "same" technical properties and hazards, the need for additional infrastructure (e.g. silos) claimed by the paints and the soaps and detergents industries would be substantially avoided (€13-27 billion for paints and €4 billion or more for detergents).
- A number of other sectors facing similar issues (including industrial gases but also various other sectors) could also benefit from reduced numbers of notifications.

This option would also address, at least in part, the issues addressed by Options A and B. Depending on the exact scope and wording of the option in the legal text, additional cases, in particular those covered by Option B, could be addressed as well.

Potential drawbacks

In theory, there should be no difference in treatment recommended for different variants of the same mixture under such an approach. However, there is greater potential for variation (unintentional or otherwise) in the toxicity of the mixture concerned than with individual notifications for each variant. However, the obligation to ensure toxicological and treatment equivalence (and associated liability) would rest with industry and hence provide an incentive to avoid such a situation.

Again, whilst there should be no difference in treatment recommended, the submissions would inevitably be at least slightly more complex than a single individual notification. This could potentially affect the ability to review and provide emergency health response in a timely manner.

Furthermore, while the variable mixture components should have the same toxicity/hazard, there would be a reduction in the level of information available on which specific individual substances are contained within a given mixture. This is likely more of a concern in terms of toxicovigilance rather than for emergency health response. It is therefore important that legal provisions allowing more detailed information on composition to be provided are considered, if requested by the authorities.

7.4 Comparison against costs and benefits study and Annex VIII

7.4.1 Overview

This section is intended to provide context in terms of how the above options might change the conclusions on the balance of costs and benefits as originally identified in (a) the 2015 costs and benefits study, and (b) in Annex VIII itself. Note that the underlying assumptions in the costs and benefits study did not correspond in all cases to the provisions finally included in Annex VIII.

7.4.2 Summary of costs and benefits identified in the 2015 costs and benefits study

The table below summarises the main cost / savings elements identified in the 2015 study:

Table 7.1 Summary of quantified EU annual costs and savings in the 2015 costs and benefits study

Cost element	Cost (saving)
Costs (savings) through harmonisation	(€893 million)
Cost of UFI requirements	€343 million
Total costs (savings)	(€550 million)

Source: Study on the harmonisation of the information to be submitted to Poison Centres, according to article 45 (4) of the regulation (EC) No. 1272/2008 (CLP Regulation), 18/11/2015. Based on Scenario F as the most likely option / best estimate.

In the 2015 study, it was highlighted that the cost analysis required a number of assumptions to be made, given the large number of companies involved and the range of different exiting notification systems in different Member States and range of different markets for the products concerned. Modification of some of these assumptions would lead to significantly different results.

The study also identified, in addition to the quantified costs and savings, benefits in terms of 'life savings' or 'health savings', where improvements to speed and accuracy of response by poison centres further reduces health effects of chemical incidents.

Importantly, the study highlighted that "the compliance costs associated with harmonisation are highly dependent on whether submission to PCs would be required even in the event of minor formulation changes (e.g. slight changes to raw material sources) or would be limited to only more substantive changes. This could make a difference between the overall harmonisation having net costs or net benefits for the EU as a whole. This should be considered in the overall system design."

In the 2015 study, the costs and benefits were estimated separately for (1) paints, varnishes and inks; (2) soaps and detergents; and (3) other sectors. The first two sectors were separated on the basis that the responses to the industry questionnaire suggested that they have wider product ranges and more frequently changing formulations.

It is clear from the present study that both of the two named sectors ((1) and (2) above) have highlighted significant limitations in the ability to reduce numbers of submissions to PCs in the event of only minor formulation changes (e.g. through grouping). Whilst it has not been feasible to re-run the original costs and benefits study within the scope of the current work, it is clear that many if not all of the net savings through harmonisation and grouping could be lost for these sectors. As set out in Sections 3.7.4 and3.11, there is the potential for many if not all of the net benefits identified in the 2015 study to be not realised due to the currently expected costs of multiple submissions with only minor formulation changes.

7.4.3 Summary of costs and benefits of Annex VIII as adopted

The provisions of Annex VIII as finally adopted were not exactly the same as those assumed in the 2015 costs and benefits study, as highlighted above. However, the main costs and benefits following from implementation of the Annex, were considered to be consistent with those in the costs and benefits study, including:

- Annex VIII highlights that the costs and benefits study confirmed that, in addition to improved health response, the harmonisation of information to be provided to appointed bodies would lead overall to significant cost savings.
- It highlights that poison centres and other appointed bodies have reported experiencing problems with the correct identification of the mixture concerned in up to 40% of the calls they receive. This could lead to unnecessary overtreatment of patients and hospitalisation for precautionary reasons. Therefore, it was deemed appropriate, as part of the harmonisation of the information, to require identification of a mixture by a UFI.
- It was recognised in the Annex VIII text that, in order to ensure a smooth transition and avoid disproportionate costs, the submissions provided to appointed bodies before the date of application of the Annex should remain valid for a certain time after it starts to apply. However, if significant changes in the formulation, product identifier or toxicology of the mixture occur in the meantime, a submission update should be required.

Whilst the benefits of having the information in the UFI, as well as the harmonisation of requirements, are not questioned, the key issue here seems to be that many more notifications and updates will be required under Annex VIII as currently drafted than was originally envisaged.

Because updates will be required in practice after only minor changes in formulation in several sectors, there will not only be more notifications than originally expected, but also companies may not be able to take advantage of the extended validity (to 2025) under the third bullet point above (and as reflected in Sections 1.4 and 1.5 of Part A of Annex VIII). Even where a mixture has already been notified before the data of applicability of the Annex, an update to the notification could be required in accordance with the format specified in Annex VIII where formulations change outside the parameters of the original notification as specified by the Member State concerned (i.e. in practice, companies may not be able to take advantage of the extended 2025 deadline in cases where their mixtures change composition frequently – which in many cases is several times a year).

7.4.4 Impact of the proposed options on the balance of costs and benefits

The options set out in this section would largely reduce the number of notifications and updates (options B and C) with the aim of reducing the burden (costs) for industry, and without compromising emergency health response. They would also (option A) reduce the complexity of submissions in certain cases where mixtures are sold for initial use in industrial settings but which may (in part) ultimately end up in consumer uses.

Whilst it has not been possible to quantify the change in costs for the individual sectors, associated with either Annex VIII as finally agreed[145], or with the proposed options, it is possible to conclude the following:

- In terms of quantified costs and benefits, the 2015 study concluded that a net saving associated with the harmonisation of information submitted to PCs as well as introduction of the UFI could be around €550 million per year for the EU as a whole.
- Based on the information on the workability issues raised by industry, the provisions of Annex VIII as finally agreed, mean that many more notifications and updates than were originally envisaged would be required. The costs associated with these notifications and updates could be sufficient to significantly reduce, or even reverse, the net benefits identified in the 2015 study[146].
- The proposed options to address the workability issues would reduce the numbers of notifications and updates, while not compromising the benefits achieved in terms of emergency health response through harmonisation[147]. This makes it more likely that the balance of benefits to costs would remain positive. Moreover, and arguably more importantly, some of the practical difficulties associated with compliance (i.e. technical challenges leading to significant supply chain disruption or major infrastructure changes) would be removed.
- Nonetheless, the options would entail some loss of information that might otherwise be available for toxicovigilance purposes.

[145] Indeed this was not within the scope of the study.

[146] It is noted that the cost estimates are subject to uncertainty as they are necessarily based on forecasts as practical implementation has not yet started.

[147] Note that, under option 2, if the number of UFIs on the packaging or label were not limited, the benefits of harmonisation for emergency health response might not be fully realised.

Appendix A
Copy of project terms of reference

1. TECHNICAL SPECIFICATIONS

1.1. DESCRIPTION OF TASKS

Objective of the study

The objectives of this study are (i) to analyse the workability of certain provisions of Annex VIII to Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures (Regulation (EU) 2017/542 on harmonised information relating to emergency health response, hereinafter "Annex VIII"[1]) in relation to certain industries with complex material inputs and supply chains and (ii) to investigate and propose options to address the workability issues raised by some stakeholders if they are confirmed, without losing necessary information for appointed bodies/poison centres to perform their duties in accordance with Article 45 of the Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures ('CLP Regulation').

Task 1: Assessment of workability issues of certain provisions of Annex VIII

For the sectors and issues mentioned below, the contractor shall:

- Assess the correctness of the claims described below under the section on "specific workability issues". This will require a legal analysis, a technical analysis of the product and supply chain characteristics, and a discussion with the Commission services, the concerned stakeholders and national authorities, as well as a comparison with experiences from existing national notification systems which currently require detailed information also for product categories and mixtures covered by this task.

  Calculate the annual number of notifications to be expected under the provisions of Annex VIII, and compare this number with the assumptions taken in the costs and benefits study[2].
- Estimate the related costs for concerned businesses under the adopted Annex VIII compared to the costs estimated in the costs and benefit study.
- Evaluate the benefits related to better and more detailed information for emergency health response and preventative action, and the impact of the changes on the overall costs and benefits of Annex VIII compared to the assumptions of the costs and benefit study.
- For each of the product groups listed below, compile one or several case studies for a representative mixture, including a mock notification, a description of challenges that notifiers may encounter and an estimation of the costs and benefits of the notification.

[1] OJ L 78/1; http://data.europa.eu/eli/reg/2017/542/oj

[2] http://ec.europa.eu/DocsRoom/documents/14006/attachments/1/translations; note that this study was based on an early draft of provisions, which were partially modified until the adoption of Annex VIII.

- In co-operation with the Commission, identify options to address the confirmed workability issues without losing benefits due to better and more detailed information for emergency health response and preventative action (including possible modifications of Annex VIII).
- Assess the costs and benefits of those options compared to those calculated in the costs and benefits study and Annex VIII.

For the analysis of the workability issues the contractor shall use input previously provided by Member States, appointed bodies and industry stakeholders. This input, including the position papers relevant for the issues mentioned below, are available on: Annex VIII to CLP – workability study. In addition, the contractor shall liaise with relevant stakeholders, such as specific industry sector organisations and Member State authorities and appointed bodies.

In particular, the contractor shall assess the following specific workability issues claimed by the respective industrial sectors:

Petroleum products

Concentration ranges to be reported according to Annex VIII (specified in Tables 1 and 2 of part B of the Annex) are claimed to be unrealistic for petroleum products, as these are usually made by blending different petroleum substances. Depending on the supply chain, batches are different, and blending can be done in many stages. According to industry sources, a separate submission would be needed for each batch, while the product specifications and hazard profile remain the same.

Industrial gases

Similar to the petroleum products industry, the industrial gases sector claims that due to the narrowness of concentration ranges specified in Annex VIII, several different notifications need to be done for products with essentially the same (physical) hazards. The industry questions the need for such multiplication of work and the value added of the differentiation of the information for appointed bodies.

Construction products

- Common cements for construction are standardised via the European harmonised standard EN 197-1. Industry claims that depending on the availability of raw materials, the variation of the chemical/mineralogical composition of the main constituents and the required technical performances, the final formulation of the cements can vary considerably and frequently. Because of this variation, under Annex VIII, frequent submission updates would be required, each update resulting in a new unique formula identifier (UFI).
- The interpretation of the term 'colouring agent' for which specific rules are foreseen in Annex VIII could allegedly lead to difficulties in the implementation of Annex VIII in the area of pigmented construction products.

Commodity chemicals formulation

Chemical formulators in most cases have more than one supplier for their commodity chemicals. Traditionally, the management implies buying from different suppliers, storing in the same tank, diluting, blending and finally filling, repacking and relabeling to be sold to other industries that will further manipulate these chemicals. With the new legislative requirements under the new Annex VIII to CLP the management of the traceability of the mixtures is claimed to become difficult for formulators due to the management of UFI numbers. This problem is relevant for various industrial sectors; it has also been claimed to be problematic by the construction products industry *inter alia*.

Paints

The ability to use group submissions for point-of-sale paint mixing systems is questioned. For technical reasons the compositions of tinting pastes (other than the pigments) vary, and these will contain some hazardous substances which are by definition excluded from aggregation within the generic identifier. Every final tinted paint will therefore have a slightly different composition. The prohibition in Part B, 3.1 of Annex VIII to notify components not present in the mixture implies that group submission might be impossible, and several million individual submissions are claimed to possibly be required to cover a complete range according to the rules.

Perfumes

For mixtures containing perfumes, Annex VIII foresees specific possibilities to allow group submission, even when perfume components are varying (including part A, sections 4.3 and 5.1, third paragraph, part B sections 3.1 last paragraph, 3.4.2 second paragraph and 4.1 last paragraph). Those provisions have been added compared to the set of provisions analysed in the costs and benefits study. The consultant shall assess the differences in costs and benefits compared to the provisions assessed in that study.

Task 2: Mixtures in mixtures

Mixtures produced in an industrial setting ('original mixture') and integrated by a downstream formulator into a mixture for consumer/professional use ('final mixture')

The Commission has taken the view that mixtures produced in an industrial setting ('original mixture') and integrated by a downstream formulator into a mixture for consumer/professional use ('final mixture') are to be considered as mixtures for consumer/professional use[3]. Nevertheless, in certain cases, due to the dilution of the 'original mixture' in the 'final mixture' the information contained in the Safety Data Sheet, if any, could be sufficient to provide the necessary information on the relevant mixture components. Moreover, some of these original mixtures may end up

[3] CA 47 2017 rev1 RCOM new Annex VIII to CLP, available on circa-bc: Annex VIII to CLP – workability study

exclusively in final mixtures which are subject to notification to appointed bodies under other legislations than the CLP and therefore their notification under CLP may be unnecessary.

The contractor shall:

- describe the main supply chains in which mixtures produced in an industrial setting are integrated into a mixture for consumer/professional use, including the concentrations in which the original mixtures are typically used in the final mixture.
- analyse the information on the composition of mixtures to be provided in the safety data sheet, and compare it with full information that would be available if the composition of the original mixture were notified as part of the final mixture without having recourse to the 'mixture in mixture' provisions in Annex VIII, taking into account the dilution of the original mixture in the final mixture.
- calculate dilution factors above which the information in the safety data sheet of the original mixture would be at least as detailed as the full information that would be available if the composition of the original mixture were notified as part of the final mixture without having recourse to the 'mixture in mixture' provisions in Annex VIII.
- give an overview of the supply chains in which the information in the safety data sheets of the original mixture would typically be at least as detailed as the full information that would be available if the composition of the original mixture were notified as part of the final mixture without having recourse to the 'mixture in mixture' provisions in Annex VIII.
- give an overview of the supply chains in which the information in the safety data sheets of the original mixture would typically be less detailed than the full information that would be available if the composition of the original mixture were notified as part of the final mixture without having recourse to the 'mixture in mixture' provisions in Annex VIII. For those mixtures, analyse the difference of information requirements between information in safety data sheets of original mixtures and full information that would be available if the composition of the original mixture were notified as part of the final mixture without having recourse to the 'mixture in mixture' provisions in Annex VIII, and analyse the value added of the more detailed information for emergency health response and preventative action.
- analyse experiences from existing national notification systems which currently require detailed information also for product categories and mixtures covered by this task.
- identify the main supply chains for which original mixtures typically end up exclusively in consumer/professional mixtures exempt from notification obligations under Annex VIII. Analyse the obligation to notify to appointed bodies under the respective legislations (e.g. cosmetics, pharmaceuticals, food products, phytopharmaceuticals, etc)

Task 3: Investigate possibilities to establish an EU toxicovigilance system

The contractor shall:

- Prepare a comparative overview of existing national toxicovigilance systems with regard to *inter alia* types of products covered, parallels and/or links with other toxicovigilance systems (e.g. pharmacovigilance, cosmetovigilance, …) and frequency of analysis and reporting.
- Provide examples of specific actions undertaken at national level as a result of the application of toxicovigilance and their impact on subsequent incident numbers and severity.
- Develop options for the establishment of an EU toxicovigilance system, and estimate related costs and benefits. Options shall describe the possible sources of information – taking into account, inter alia, the possible development of a central notification portal and database at the European Chemicals Agency (ECHA) and national databases, data on incidents gathered by poison centres, other databases and scientific literature etc. The contractor shall give estimates on the amount and type of information to be analysed, as well as opportunities and obstacles to be addressed, and make an analysis of actors that could be involved in a possible EU toxicovigilance system.

Task 4: Organisation of a workshop

The contractor will organise a one-day workshop at around month 6 of the contract to discuss the second interim report of the study with Member State appointed bodies and interested stakeholders. The workshop shall serve to present and validate draft conclusions in the reports submitted by that time, and shall be integrated into the study work in a way to allow revising conclusions and doing some additional study work if appropriate to integrate comments at the workshop. The contractor will be responsible for the workshop (draft) agenda, the administrative preparations (registration, invitation, secretariat, technical support and meeting materials, including participant badges), presentations during the workshop, contributions to the discussion under the overall chairmanship of the Commission and a workshop report. The Commission will make available a location for the workshop.

Task 5: Reserve for unexpected developments

The issues addressed in task 1 and 2 have been raised by concerned stakeholders only at the very last stage prior to the vote in the REACH Committee and partly only after the adoption of the Annex. Therefore, it cannot be excluded that further issues may arise that would require analysis under this contract. Therefore, 10% of the resources for the contract shall be reserved for additional issues arising during the contract, to be defined in agreement between the Commission and the contractor at the latest by the end of month 7 of the contract. If this is not used, this shall go into more work on the previous tasks upon prior agreement of the Commission.

The tender must comply with applicable environmental, social and labour law obligations established by Union law, national legislation, collective agreements or the international environmental, social and labour conventions listed in Annex X to the Directive 2014/24/EU.

1.2. BACKGROUND

Context

Following Art. 45(1) of the CLP Regulation importers and downstream users placing on the market hazardous chemical mixtures shall submit to Member State appointed bodies information relating to those mixtures for emergency health response. Art. 45(4) furthermore required the Commission to carry out a review to assess the possibility of harmonising the information to be submitted. As a result of this review, the Commission proposed an amendment to CLP specifying harmonised information requirements as well as a harmonised format for submission of information.

During the discussions on the legal proposal stakeholders signalled potential workability issues for their specific sectors. For the paints and perfumes sector specific provisions were taken up in the proposal, notably on the generic product identifier and specific exemptions from updating and composition reporting requirements. Only in a very late stage concerns regarding workability were raised by the petroleum, construction products and industrial gases sector. Given the time constraints, it was agreed in the regulatory committee to vote on the legal proposal provided that the Commission committed to studying those workability issues and amending the Regulation if deemed necessary.

On 22 March 2017, Regulation (EU) 2017/542 was adopted[4]. The Regulation amends CLP by adding an Annex (Annex VIII to CLP) and specifies the following among others:

- Information to be provided on the chemical mixture (product identifier, classification, toxicological information, composition *inter alia*)
- Requirement to generate a Unique Formula Identifier and to include it in the notification as well as affix it on the mixture's label
- Possibility for group submissions and the use of a generic product identifier for more efficient notification submission
- Format in which the information is to be provided[5]

[4] Commission Regulation (EU) 2017/542 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures by adding an Annex on harmonised information relating to emergency health response.

[5] The XML format is available on ECHA's poison centres website: https://poisoncentres.echa.europa.eu/poison-centres-notification-format

The Regulation has phased dates of applicability, depending on the intended use of the mixture concerned, as follows:

- Mixtures for consumer use: 1 January 2020
- Mixtures for professional use: 1 January 2021
- Mixtures for industrial use: 1 January 2024
- Mixtures already on the market and notified to the relevant appointed bodies do not need to be notified in the new format until 1 January 2025 (regardless of the intended use)

Relevant background information

- Legal text: Annex VIII to CLP – workability study.
- Position papers: Annex VIII to CLP – workability study
- Studies[6]
    - Review of the Commission services according to Article 45(4) of CLP Regulation
    - Study on costs and benefits of the harmonisation of information to be submitted to poison centres
    - Study on interlinked databases (XML) between poison centres
    - Study on analysis, development and testing of the Unique Formula Identifier (UFI) for information to be submitted to poison centres
    - Study on a Product Categorisation System for information to be submitted to poison centres
- Several IT tools for notification preparation and/or submission were developed or are under development[7]:
    - Poison Centres notification format and editor
    - UFI generator
    - Poison Centres notification portal (development subject to outcome of feasibility study conducted by the ECHA in the course of 2017).
- On 23 January, the Commission organised a workshop on the implementation of the new Annex VIII to CLP. Presentations of the workshop, including from stakeholders presenting their concerns, are available at http://ec.europa.eu/growth/sectors/chemicals/poison-centres_en

[6] All study reports can be consulted at http://ec.europa.eu/growth/sectors/chemicals/poison-centres_en

[7] All tools are available on ECHA's website: https://poisoncentres.echa.europa.eu/tools

1.3. REPORTS AND DOCUMENTS

The Contractor is to provide the required reports and documents in accordance with the conditions of the standard service contract appended in Annex **Error! Reference source not found.**.

The contractor shall provide the required reports and documents in accordance with the conditions of the standard service contract appended in Annex **Error! Reference source not found.**.
All documents must be provided in electronically editable format and written in English.

- **Meeting minutes –** for each meeting of the steering group (see further below in this section under 'Commission Steering Group and Stakeholder Advisory Group') the contractor will provide written minutes within 5 calendar days. The steering group will provide its comments within 10 calendar days. The contractor will address the received comments within the following 5 calendar days.
- **Inception Paper** – will be delivered 1 week before the kick-off meeting, which will take place within 4 weeks after the date of start of contract execution. The inception paper shall include a detailed work plan for the tasks mentioned above. The steering group shall provide comments either at the kick-off meeting or in written within 2 weeks after delivery of the inception paper. The comments shall be taken into account in a final revised version of the inception report within one week. The contractor will provide a tabular response to comments, indicating how each comment has been addressed.
- **Interim Reports** – Two interim reports shall be delivered at the latest 3 and 5 months after the date of start of contract execution. The second interim report will be an early draft of the draft final report and provide a first version of the assessment of all tasks but allow for further work if necessary, including issues arising from the stakeholder workshop. The steering group shall provide comments on both reports, at the first interim meeting or in written within four weeks after delivery of the first interim report and at the workshop or in written within four weeks after delivery of the second interim report. Member States and identified stakeholders shall be invited by the contractor to provide comments at the same time. The comments on the first interim report shall be taken into account in a final revised version within two weeks. The comments on the second interim report as well as input received during the workshop shall be taken into account in a final revised version within three weeks. The contractor will provide a tabular response to comments, indicating how each comment has been addressed.
- **Draft Final Report** – This report shall be delivered at the latest 8 months after the date of start of contract execution. The report shall address all tasks, take into account the comments received on the second interim report as well as the workshop results and contain a response to comments table on the comments received. The steering group shall provide comments within four weeks after delivery of the draft final report. Member States and

identified stakeholders shall be invited by the contractor to provide comments at the same time. The responsible Commission service shall have five weeks to accept this report as final report or issue further comments to the contractor. If applicable, those comments shall be integrated by the contractor within two weeks. Once accepted, the final version of the report, in publishable quality, respecting the below format shall be submitted electronically in PDF and Word format as well as in paper (three copies) as a pre-condition for final payment.

The final report shall include:

- an abstract of no more than 200 words and a publishable executive summary of maximum 6 pages in both English and French;

- the final report and the executive summary shall include the following standard disclaimer:

"The information and views set out in this study/summary are those of the author(s) and do not necessarily reflect the official opinion of the Commission. The Commission does not guarantee the accuracy of the data included in this study. Neither the Commission nor any person acting on the Commission's behalf may be held responsible for the use which may be made of the information contained therein."

- specific identifiers which shall be incorporated on the cover page and will be provided by the contracting authority.

The accuracy of the data produced and published will be under full responsibility of the contractor. The sources of the data must always be clearly identified. Assumptions and calculations should be made fully transparent. The data underpinning the assessment of costs and benefits shall be provided to Commission upon request.

For **graphic requirements**, please refer to the template provided in a separate document.

The contractor must deliver the study and all publishable deliverables in full compliance with the corporate visual identity of the European Commission, by applying the graphic rules set out in the European Commission's Visual Identity Manual, including its logo. The graphic rules, the Manual and further information are available at:
http://ec.europa.eu/dgs/communication/services/visual_identity/index_en.htm

A simple Word template will be provided to the contractor after contract signature. The contractor must fill in the cover page in accordance with the instructions provided in the template. The use of templates for studies is exclusive to European Commission's contractors. No template will be provided to tenderers while preparing their tenders.

Commission Steering Group and Stakeholder Advisory Group

The project will be supervised and managed by a Commission Steering Group, led by DG GROW. It will be assisted by a Stakeholder Advisory Group appointed by the Commission. For this Stakeholder Advisory Group, the Commission will invite participants from Member States authorities, appointed bodies/poison centres, concerned industry associations and civil society organisations.

Meetings

The contractor is expected to attend four meetings with the Commission, including 2 presentations to make to Member States, and a workshop, as specified below. The contractor shall cover his own travel and subsistence costs (see Section 4.2.5). The timing of the meetings may be modified in agreement with the Commission. Interim telephone conferences may be organised at the request of the Commission or the contractor.

- **Kick-off meeting** - The contractor is expected to attend a half day kick-off meeting within 4 weeks after the date of start of contract execution with the Commission's Steering Group.
- **Interim meeting -** The contractor is expected to attend a half day interim meeting, two weeks after the delivery of the first interim report with the Commission's Steering Group and the Stakeholder Advisory Group (first part of the meeting in joint session, second part with the Steering Group alone).
- **Workshop -** The contractor is expected to organise a workshop around 3 weeks after the submission of the second interim report. The contractor shall be responsible for and cover the costs of the technical preparations (draft agenda, invitations, presentation of study results etc. The workshop shall take place in the premises of the Commission (a room will be offered by the Commission).
- **Final meeting -** A last half-day meeting shall be held two weeks after the delivery of the draft final report to discuss the draft final report with the Steering Group and the Stakeholder Advisory Group (first part of the meeting in joint session, second part with the Steering Group alone).
- **Presentation to Member States –** <u>in addition to the above meetings</u>, the contractor shall be available to present the results at two meetings of a Commission expert group (e.g. CARACAL or one of its subgroups) taking place in Brussels. The contractor shall cover his own travel and subsistence costs.

The project team leader and at least one senior member of his/her team shall attend each of the above meetings.

Requirements relating to the drafting of the tender

The tender must include a description of the proposed team, its composition, its expertise and the work effort planned for each member in terms of man/days for each phase of the project, taking into account the below indicative time-framework.

Time-line	Meetings	Reports	Approval of reports	Payments
Date of start of contract execution				
1st month	Kick-off meeting	Inception paper		Pre-financing 30%
2nd month			X	
3rd month		Interim report no. 1		
4th month	Interim meeting no. 1		X	
5th month		Interim report no. 2		
6th month	Workshop		X	
7th month				Interim payment 30%
8th month		Draft final report		
9th month	Final meeting		X	
10th month		Final report		
11th month				
12th month			X	Payment of the balance

Appendix B
Proposed Room paper for workshop co-ordinated by AISE

Appendix 3 – Cross Sectoral Alignment Thought Starter on Regular Product Variation

Summary:

The inherent variability of raw materials and final product was of concern for 6 sectors (Oil, Cement, Construction, Paints/Inks, Perfumes and Detergents). Across these sectors it is reported that final product variation covers:

- Components that are either substances or mixtures
- Intentional (e.g. multi-source supply chains) or unintentional (e.g. storage conditions) variation.
- Driven by upstream (e.g. MiM suppliers) or downstream (e.g. bespoke customer requirements) factors.

Proposed Solution:

To address the concerns above, an inclusive solution is proposed. A merger of the CM-A ("Comparable MiM") and SD-B ("Technically Equivalent Components") solutions identified in the workability study draft interim report is proposed. Specifically:

- ***In their submission, the notifier identifies component substance(s)/mixture(s) which are subject to variation.***
- ***For these components, the notifier identifies all alternative components that may be present due to variation, creating a limit of variation. All components subject to variation and their alternatives must be reported and:***
    - ***Be identified according to Section 3, Part B of Annex VIII information requirements (as potentially amended) or using the UFI or SDS/supplier (for notified MiM's as per Part B 3.2.2)***
    - ***Serve the same technical function within the mixture***
    - ***Carry the same health and physical hazard classification***
- ***Validity of the submission with respect to the above criteria could be determined electronically during submission (e.g. IT check via validation assistant during submission).***
- ***Following submission, appointed bodies or ECHA would be entitled (as per Part A 3.2) to review/assess the submitted limit of variation and conduct follow up if deemed appropriate.***
- ***Assuming the notifier places formulations on the market that are within the notified limits of variation, no new UFI or submission update are required.***

Appendix 4 – Cross Sectoral Alignment Thought Starter on Generic Product Identifiers

Summary:

The overly narrow scope of generic product identifiers is of concern for certain sectors (Paints/Inks, Construction and Soaps/Detergents). Across these sectors current criteria for generic product identifiers are too restrictive, as they:

- Prevent the use of group submissions in a majority of submissions containing a colour or fragrance mixture, due to MiM classification
- Significantly increase the complexity of submissions due to additional disclosure of MiM components regardless of concentration in the bulk final mixture
- Increase the number of (non-value added) submission updates due to extensive ingredient disclosure and low threshold for update.

Proposed Solution:

To address some of the needs of the above sectors, it is proposed that for the generic product identifiers "perfumes", "fragrances" or "colouring agents", the following classifications of major concern would not be permitted (original proposal covered in the costs and benefits study). Specifically:

- ***acute toxicity, Category 1, 2 or 3,***
- ***specific target organ toxicity single exposure, Category 1 or 2,***
- ***specific target organ toxicity repeated exposure, Category 1 or 2,***
- ***skin corrosion, Category 1, 1A, 1B or 1C,***
- ***serious eye damage, Category 1.***

Note: this alone will not solve all issues for some sectors, and additional solutions may also be needed for specific cases e.g. point-of-sale colour mixing/tinting.

Appendix C
Feedback from appointed bodies and poison centres following workshop

Presentation slides from the workshop on 13/2/2019
Remarks Belgian Poison Centre (Dr Martine Mostin, Mr. François Wuyts)

1. Background slides

Slide 3: soap and detergents are not mentioned

Slide 5 : how can we provide additional input to the progress report if concerns expressed during the interview need some clarification or supplementation?

2. Initial study results

Slide 5: how is the problem of Poison Centre notification of industrial gasses currently handled?

Slide 11: assessment is not a task for the appointed bodies. Moreover in case of notification using the ECHA portal there is no central appointed body to carry on the task

We understand our French colleagues already developed a proposal to address cement declaration. Please provide us with the proposal and reactions of the sector.

Slide 13: how is the problem currently handled ? Our French colleagues already developed a proposals for paints. Can a similar solution be applicable for colorants in adhesives and sealants?

As a general remark Poison Centres are not interested in receiving updates triggered by the supplier of a component. Using substances based declaration is much more relevant for Poison Centre and avoid waste of time during a call.

A solution is needed to address the declaration of multiple component products.

Slide 18: how is the problem of Poison Centre notification of petroleum products currently handled? At least at the level of the Belgian Poison Centre we are not aware of a problem with those notifications. We feel no need to receive the exact composition of fuels in storage tanks at retail filling stations.

Poison centers are not used to work with technical standards. As a general remark it sounds logical to directly involve Poison Centers in developing solutions. Do our French colleagues already developed a proposal?

Slide 31: does this solution have consequences on structure of the data format?

Slide 35: our Poison Centre currently receives full composition data form major companies manufacturing detergents using CAS to describe ingredients including surfactants. The perfume, dye, and fragrance concentration are far much lower than 5% and mentioned using GPI (max 1% of the detergent formula). We are not interested in receiving detailed compositions of ingredients present in minute amounts in the formula. Using CAS instead of MIM is far more practical for Poison centers

Additional comment: the sector put multiple compartments product on the market, there is a need to develop a solution for these kind of notification.

Slide 38: About similar components carrying the same health classification: for most of the substances there is no harmonized classification available.

It not clear to what " comparable potency " means

3. Task 2 slides

No comment

4. Feedback from BOGs

Poisons Centre need clear and comprehensive information. Receiving UFI's of multiple MIM is totally unpractical for emergency response. Originally the principal use of an UFI was to provide a link between a mixture (for consumer use) and its formulation in the Poison Centre database.

Receiving a formula with many ingredients listed as MIM's will considerably complicate the emergency response.

Slide 9: key message 1: Toxicovigilance is more exacting and needs details on specific named chemicals *where a health hazard classification exists.* Regardless of the existence of a health hazard classification, Poison centers need clear and comprehensive information on the composition when available to perform their tasks of emergency health response and toxicovigilance.

5. Overview of breakout groups

No comment

6. Plenary discussion

A point was raised by Belgium at the end of the plenary: it is of paramount importance both for the industry and the Poison Centers to wait for a final version of the format, considering the adopted solutions and the pending problem of multiple components mixtures. The modifications currently under discussion and the lack of support for multiple component products will imply significant changes on the structure of the database in the future when starting with the currently defined PCN format. It would not only be a waste of time and money to build a database which is based on a data model that is not final, but beside that, the possible significant changes of the database structure will imply a migration of the already notified mixtures on a later date towards the new database structure. Considering the limitations of the currently developed format, that migration process will probably be rather complex. Not only the data will have to be migrated, but also the visualization of mixtures on the screen will have to be redesigned. Such a migration/redesign process will possibly involve undefined downtime for the Poison Centers of their existing system. This could be minimalized by asking the industry to resubmit everything in the new format.

Nevertheless, it should be much more logical not to go in production until the above adaptations are implemented. By doing that, adjustments in the format would not be subject to any restrictions. This will also imply important cost-savings for all stakeholders in the future. In worst case, the format can be redefined from scratch, considering all the experience gained by designing the current format.

Moreover, there is need to allow Poison Centers at least a one-year period from the availability of the final version of the format to adapt their software/infrastructure. There is also an urgent need to obtain realistic and documented figures on the actual number of declarations to be expected. This information is needed to draft specification and launch tendering procedures in case of outsourcing the design of the database and the visualization of the data in their existing systems. The volume of data will also have financial implications for the Poison Centers in term of hardware (servers, backup systems, internet connection …). Figures are needed to allow budget planning.

Comment German Federal Institute for Risk Assessment (BfR) on CLP Annex VIII Workability Issues

(2nd Interim Report and Workshop of Workability Study 2019-02-13)

2019-02-27

Several challenges were identified in the

> 2nd Interim Report of the "Study on workbility issues concerning the implementation of Annex VIII of Regulation (EC) No 1272/2008 on harmonised information relating to emergency health response and preventive measures" and at the related Workshop on 13 February 2019.

While the report describes the challenges of the different industry sectors surveyed the workshop was seeking for more general descriptions. This was facilitated by a "thought starter" provided by some industry associations and presented by A.I.S.E:

> Thought Starter: Cross sectorial alignment on common solutions – inherent variability (12 February 2019)

I. Preface

The workability study has shown that there are workability issues for a number of sectors. While some difficulties for industry are justifiable through benefit for emergency health response, for some sectors requirements seem to be unfeasible.

By evaluating the extent of data requirements it needs to be minded that besides the emergency health response another (no less important) aim of Article 45 CLP is to facilitate 'statistical analysis for improved risk management measures' (Article 45 (2) b CLP). To that end regulatory bodies need to be aware of which substances may be included in a mixture to be able to make a risk assessment for regulatory purposes (for example restrictions under REACH). While the study has worked out workability issues, which in our view should be addressed, we have to strike a balance between the two aims of Article 45 on the one hand and the burden for the industry on the other hand.

In our comments, we first refer to the solutions proposed in the study (chapter II). In chapter III we make considerations as to whether the number of approaches could be narrowed down in order to reduce complexity.

II. Comments on possible solutions outlined in the report

In the Report a list of issues is compiled in Table 7.1, providing potential solutions in the right hand column. These solution are summaried and commented

solution code by Wood	short name of solution to facilitate discussion	description	BfR evaluation and position
PP-A	UCI	group submission extended to all mixtures with the same health classification (so called "similar mixtures") UFI only changes if hazard classification changes, i.e. UFI does not link to a formula but to a classification	This is a wide extension of the Group Submission concept. It would mean a maximal flexibility: any component may change and any concentration of any component may change. The only restriction is same classification It is not described how the formula would look like when using this solution. UFI would become a unique classification identifier ("UCI"), what seems to be a redundant information. Not clear whether hazard class of component or hazard class of mixture is criterion for new UFI This solution is generally not acceptable, but may be acceptable, if only a single component (substance or MIM) is replaced by a similar component (see below)

PP-B	WiderConcR	Use pre-existing "technical standard" concentration ranges to describe formulas, i.e. allow wider ranges for defined product types	Not possible to evaluate without knowledge of the standards that is referred to in detail. May be acceptable. Not clear whether this would lead to notifications with different classifications. This would not be acceptable.
IG-A(1)	UCIAppr	like UCI / PP-A	*see above (UCI / PP-A)*
IG-A(2)	Exempt	Exempt from notification requirement	Not acceptable as lack of information would increase knowledge gap substantially.
Unnamed („CM-Z")	TchnFncUFI	mixture components with same technical function and same hazards make use of "Generic UFI"	Not clear how component name would look like – not acceptable without more detailed description (see comments below).
CM-A	CompMIMs	Comparable MIMs. The concept means that instead of one MIM (with one UFI) a set of MIMs can be notified as one component, if these MIMs are very similar in their formulas, i.e. contain the same components in similar concentrations. A data user (e.g. Appointed Body, PC, ECHA) shall check the similarity: In brief, c omparable MIM notification would only be accepted if all comparable MIMs share all chemical components and concentration range of all MIM components would fulfill the criteria of Annex VIII tables.	Seems generally acceptable, but would need an automatic evaluation procedure

OC-A	-	Very similar to CompMIMs	*see above (CompMIMs, CM-A)*
P-A	GUFIforAll	"refinement of generic product identifier criteria"; "UCI" for all tints classified for health hazards	Similar to UCI, but for selected components only. This means one notification for all products with colouring agents with the same health hazards (with health hazards to be indicated). A restriction to hazardous components of major concern (B 3.4.1) is not mentioned in this proposal. A notification hiding the chemical identity of components classified for health (or physical hazard) was discussed in preparation of Annex VIII in CARACAL/REACH Committee. It was not accepted by some MS at that time. Propably not acceptable in a general way
P-B	+UFIforCol	Provide more than one UFI on the label: one UFI for base paint and additional UFIs for each tint, UFI and percentage indicated on 2nd label	might be acceptable - but more than 3 UFIs on the label - potentially leading to agents with different hazards - could hardly be handled in emergencies
P-C	-	identical to CompMIMs	*see above (CompMIMs, CM-A)*

FR-A	LimSubm	Limited submission for product that are only used at industrial sites, but might be used as component in non-industrial product	This was discussed earlier. Solution not generally acceptable. The solution might be acceptable if the industrial product is only used in concentration up to 5 % of final solution. No need to restrict this solution to fragrances.
SD-A	GPIforAAll	GPI for all fragrance components classified for minor-concern health hazards or no health hazards only	Similar to PP-a/UCI and P-A/G_UFIforAll. This means one notification for all products with fragrances with the same health hazards. Health hazards to be indicated when using GPI. Hazardous components of major concern are excluded in this proposal (in contrast to P-A/G_UFIforAll) A notification hiding the chemical identity of components classified for health (or physical hazard) was discussed in preparation of Annex VIII in CARACAL/REACH Committee. It was not accepted by some MS at that time.
SD-B	-	identical to CompMIMs	*see above (CM-A / CompMIMs)*

III. Proposal for more comprehensive approaches

From the BfR's point of view, the following general issues were identified (with proposal for related problem not discussed comprehensively in the bottom, i.e. G4):

General Issue ID (in brackets: sector-specific Issue IDs of Interim Report, list may be not compre-hensive)	Challenge: There is a group of similar mixtures that would need multiple notifications with multiple Unique Formula Identifiers (UFIs). Industry would like to facilitate notification by making only **one notification** with **one UFI.** According to Annex VIII this does not work because ...	Solution discussed	DE Comment
G1 (IG1)	all components are identical, but the concentration ranges of components in the group of mixtures is wider than the ranges indicated in Table 1 or Table 2 of the Annex	Single submission with wider concen-tration ranges	Acceptable for a selected product group • Gases classified for physical hazards only

G2 (many, including thought starter)	one or few components are exchanged by similar components with known chemical identity (**toxicologically comparable substances TComS**) while • all other components, • their concentrations, • hazard classification of the variable components • hazard classification of the (final) mixture are shared between all mixtures in the group	Amended Group Submission, e.g. see problem description SD-1 of Report	Acceptable if substances that are exchanged within the grouped mixtures not only share the same health classification, but are also similar with respect to their mode of action, leading to a common or very similar clinical risk assessment and poisoning advice (toxicologically comparable substances). New Generic Product Identifiers shall be defined. For each group notification, all substances that could be interchanged must be listed with product identifier as described for fragrances in the Annex (Parts A 4.4, B 3.1). This facilitating option shall only be used for TComS that are described by a GPI

G3 (many, including thought starter)	one or few components are exchanged by similar components with un-known chemical identity and full composition **(toxicologically compa-rable mixtures-in-mixtures, TCoMIMs)** while • all other components, • their concentrations, • hazard classification of the variable components • hazard classification of the (final) mixture are shared between all mixtures in the group	Amended Group Submission	Acceptable if MIMs that are exchanged within the grouped mixtures not only share the same health classification, but are also similar with respect to their mode of action, leading to a common or very similar clinical risk assessment and poisoning advice (toxicologically comparable substances). This could generally be assumed if all the MIMs included share all components and all components are within the same narrow concentration ranges, according to Table 1 or Table 2 of the Annex, respectively (to be verified on submission). New Generic Product Identifiers shall be created. For each group notification, all MIMs that could be interchanged must be listed with product identifiers and UFIs as described for fragrances in the Annex (Parts A 4.4, B 3.1). This facilitating option shall only be used for TCoMIMs that are described by a GPI [1].

[1] The G3 proposal is similar, but not identical to the Comparable MIMs Concept proposed by the construction industry. G3 would also work if not all components of the comparable MIMs were identical, but G3 would only work if a GPI for the group of comparable MIMs had been agreed on.

G4	a component is added to one mixture of the group in less than 10 % final concentration but all other components remain the same (i.e. their concentrations will decrease less than 10 %)	Not discussed at workshop, but similar to G2 and G3	Modified type of Group Submission: acceptable, if added substance or MIM is of minor toxicological concern (i.e. new component concentration to be reported according to Table 2 of Annex) and if addition did not change the hazard classification of the final mixture This facilitating option can only be used for components that can be described by a GPI.
G5	Very variable composition of paints and other products that are prepared with different tints or colourants	Single notifications of base paint and all possible tints, the label of the final product contains (product identifiers and) UFIs for every component used in a given mixture	Acceptable, could be technically handled like multi-component products

Variable Formulas ("G6")

At the Workshop the issues of some non-industrial use product groups that are characterised by very variable composition of mixtures containing raw material of natural original (e.g. petrol, cement, fragrances, with or without complex supply chains) were generally addressed, but solutions were not discussed in great detail.

For these product groups many notifications (and many UFIs) would be needed to comply with Annex VIII with little or for some product groups even no additional value for emergency health response.

We propose a modified type of Group Submission for these products taking into account the technical tools developed so far by ECHA and experience from cosmetics products notification:

- A set of additional GPIs may be defined that represent predefined Group Formulations (GFs) with wider concentration ranges and/or variable, but similar substances. Existing technical specifications might be applicable for the definition of these GFs, if appropriate for decision making in emergency health responses.

Mixtures containing substances with specific concern for emergency health response (typically very toxic substances and substances with specific medical treatment option available) shall not contained in FFs and shall, if present, be notified with narrow concentration ranges according to Table 1 in addition.

Example:
"YSON Diesel Fuel (UFI: WWWW-XXXX-YYYY-ZZZZ)":
98 % Standard Diesel Formula (approved GF)
2 % Methanol

General remark 1:
The facilitating options described above may be combined.

General remark 2:
The notification of the reduced information set for mixtures used in formulation of consumer or professional use products (e.g. fragrances) is not supported as the reduced formula information is not precise and complete enough for emergency health responses in many cases, especially if the MIM is used in the final mixture in high percentage (e.g. 80 to 100 %, see chapter II, solution FR-A/LimSubm).

Comments of Dutch Poisons Center / Appointed body on Workability issues
February 2019

The comments are grouped according to the topics of the breakout sessions during the workshop on February 13th 2019 and as described in the 'Workshop background paper'.
Reference is also made to the BfR document:
- Comment Germany on CLP Annex VIII Workability Issues.docx
Please find Dutch PC/AB comments on BfR proposals in a separate paragraph at the end.

The comments concern the opinion of the Dutch PC/AB. If a more general Poisons Center view could help in the discussions, items could be discussed within the 'EAPCCT working group on regulatory issues' which could result in a position document from the European Association of Poisons Centers and Clinical Toxicologists (EAPCCT).

General comment:

- In some Member States, appointed bodies might already have specific solutions for current workability issues. An overview in the Workability report would be very useful.

1. Product variation due to natural/incremental change in mixture components
Concerns problem/solution: PP1/PP-A, IG1/IG-A, CM1/PP-A, P2/P-B.
Problem: components can differ in concentration or specific substances due to continuous blending. UFI and notification necessary for each composition. Industry branches: petroleum, industrial gases, cement, paints.
Variety of industry proposed solutions: grouping of similar mixtures with same hazard classification, use of wider ranges (deviate from Annex VIII table 2), general exemption from Annex VIII for certain product groups/classifications, for 'point of sale' (POS) blended paints indicate base component UFI and added tints (colourant) UFI's on the label.

Comments on solution PP-A:
PP-A = group similar mixtures with same hazard classification under one UFI (proposed for cement (CM1) and petroleum (PP1)).

- Not acceptable. Grouping according to the same hazard classification is not sufficient for an adequate risk assessment and to decide on treatment options: two mixtures both classified for e.g. 'acute toxicity' can have an entirely different toxicological profile, diagnostics and treatment. Difficult to set up general criteria on when grouping is possible.
- Possible solutions for petroleum products to explore:
  - use wider concentration ranges according to industry standards (solution PP-B).
  - BfR proposal ('Variable Formulas'; G6): set of Group Formulations.

- Possible solutions for cement to explore:
  - BfR proposal ('Variable Formulas'; G6): set of Group Formulations.
    For example based on the 27 different products in the technical standard EN-197-1.
  - 'New Generic Product Identifiers' (as proposed by BfR) to group cement components with natural variation.

Comments on solution IG-A:
IG-A = use of wider concentration ranges for industrial gases classified for physical hazards (deviate from Table 2) and grouping under one UFI as long as hazard classification is the same. Alternative: exempt gases classified for a physical hazard from Annex VIII requirements.

- Wider concentration ranges:
  Could be acceptable. Industry standards should be reviewed.
- Exemption:
  An exemption for gases with only a physical hazard classification could be further discussed with Poisons Centres. 'Gases under pressure' and 'explosives' in general are already exempted from Annex VIII although CLP article 45 requires notification for all mixtures with a physical hazard.

Comments on solution P-B:
P-B = for 'point of sale' (POS) blending of paints, UFI's of the base paint and the added tints could be added to the label on a sticker. Industry branch: paint.

- It is not practical to communicate a lot of UFI's after an exposure. Three or four might just be possible but with 15 UFI's on a label this is not feasible.
- CEPE indicated that around 90% would be the 'base paint'. A limit could be set of 5% or 10% for the added tints ('colourants'). Most of the composition would be know and for the last 5-10%, extra effort would be necessary in exceptional cases. This could be discussed with Poisons Centers. Problematic could be if some tints have a health hazard classification of major concern, if so, all UFI's should be communicated and all tints assessed if the concentration is significant. Examples from industry are welcomed.
- There just not seems to be a practical alternative for this POS blending.

2. Inability to know exact composition in complex supply chains
Concerns problem/solution: PP2/PP-B, PP3/PP-B
Problem: changes in composition due to reprocessing in the supply chain and storing of multiple batches in the same storage bunkers (which are rarely completely empty). Industry branch: petroleum.

Comment on solution PP-B:
PP-B = use of wider ranges for components (deviate from Annex VIII table 2).

- For reprocessing of petroleum products in the supply chain: if components/MiMs are added, products mixed etc. to create a new product, these products should be notified. Reference to MiM with UFI is possible.
- Wider concentration ranges:
  Could be acceptable for petroleum products. Industry standards are interesting and should be reviewed.
- For these problems it would be best to explore the BfR proposal ('Variable Formulas'; G6): set of Group Formulations. These could for example be based on the 27 different products in the technical standard EN-197-1.

3. Multiple suppliers of mixture components with 'same' technical properties and hazards
Concerns problem/solution: CM-2/CM-A, OC2/OC-A, P3/P-C, SD2/SD-B.
Problem: components can differ in concentration or specific substances due to different suppliers. UFI necessary for each composition.
Industry proposed solution: grouping of similar mixtures with same hazard classification.
Solutions can be grouped as 'Comparable MiM/substances solution'.

Comments on solution 'Comparable MiM/substances solution':

- It is important that 'comparable MiMs/substances' have similar toxicological properties and same diagnostics/treatment options after exposure. The same hazard classification is not enough: two substances both classified for e.g. Acute Toxicity can have an entirely different toxicological profile.
  Companies do know when substances/MiM are technically interchangeable but it would be hard for them to assess when these are toxicologically interchangeable. It is difficult to set up general criteria.
  Probably not acceptable for MS appointed bodies that require a detailed composition for 'toxicovigilance/monitoring' tasks (see also discussion under 4 for GPI).
- Solution presented by BfR could be explored: creating 'New Generic Product Identifiers' with a list as described in Annex VIII A4.4 and B3.1.
- It would help if industry provides examples. For a 'technically interchangeable' MiM: what is the difference in substances, what is the concentration (range) of these differing substances, what is the difference in concentration of the other substance (within Annex VIII table 1 and 2?).

4. Limitations on the use of group submission approaches

Concerns problems/solution: OC1/'maybe P-A', P1/P-A, SD1/SD-A.
Problem: GPI's cannot be used in practise due to exclusion of components classified for a health hazard'. Industry proposed solution: refinement/amendment of the GPI rules.

Comments on solution P-A:
P-A = for GPI 'colouring agent' allow a classification for a human health hazard where this GPI classification applies to all mixtures in the group, e.g. all mixtures contain a 'sensitising colouring agent'.

- Solution P-A is not acceptable for emergency health response. Such grouping should at least not be allowed for 'hazardous components of major concern for emergency health response'. This solution of grouping by classification is also proposed for other problems (e.g. PP1) but it is important to realise that only to know that a mixture contains for example '25% of an unknown component classified for Acute Toxicity', is not useful for risk assessment and to decide on treatment options. 'Toxic' will not say anything on what toxicity to expect.

Comments on solution SD-A:
SD-A = for GPI 'perfumes/fragrances' only exclude components with severely hazardous human health classes. During the breakout session, AISE presented a proposal to exclude the following classifications of major concern: acute tox (1,2,3), STOT SE (1,2), STOT RE (1,2), skin cor (1,1A,1B,1C), serious eye damage (1). Note: sensitising would be included, so these components could be 'hidden' in the GPI.

- The proposed solution is not feasible. The AISE proposal resembles the GPI rules as they were at the start of the REACH committee discussions in 2016. Although acceptable for most Poisons Centers for 'emergency health response (but to a limited concentration; not 25% for colouring agents'; at that time max. 10%), these where not acceptable to some MS appointed bodies. If discussions on GPI is reopened a more realistic compromise between needs for 'emergency health response' and 'toxicovigilance/monitoring' should be the starting point (see below).

Alternatives for solution P-A and SD-A:
It must be noted that the rules on GPI have been a major topic of discussion during the REACH committee phase in 2016 with the current rules as a result. On the other hand, a lot of alternative GPI rules where discussed in a very short time period and in two occasions support was sought for two very differing variants. There mainly is a difference in requirements from an 'emergency health response' perspective and a 'toxicovigilance/monitoring' perspective.
Two alternative options could be explored if discussions on this item can be reopened.

1. It could be worthwhile to look at all presented options in the past and see if a compromise is possible that suits both needs and is less stringent on the ability to group mixtures. For emergency health response the exclusion of 'health hazards of major concern' is important (industry solution SD-1). Since colouring agents has a maximum of 25%, the AISE proposal can be extended with Acute toxicity cat. 4 and STOT SE cat. 3 (as expressed in an earlier 'EAPCCT position'). For 'toxicovigilance/monitoring' it appeared especially important to know if sensitising agents are present in a mixture. This was addressed in industry solution P-A. If a chemical name of e.g. a sensitising agent is necessary use could be made of the 'reasoned request' option. So a combination of SD-1 and P-A could be feasible.
2. If some MS appointed bodies would like to know exactly which classified component is present in which mixture, the solution as presented by the BfR should be explored: creating 'New Generic Product Identifiers' with a list as described in Annex VIII A4.4 and B3.1. See comment on this proposal in a separate paragraph.

5. Mixtures in mixtures – Industrial vs professional/consumer use

Concerns problems/solution: FR1/FR-A, Task 2

No further comments since proposal is in preliminary phase.

Comments on BfR proposals for 'New Generic Product Identifiers' and 'Variable Formula's

The BfR has proposed some interesting solutions to the 'variable components problem in document: **'**Comment Germany on CLP Annex VIII Workability Issues.docx'

1. <u>New Generic Product Identifiers</u>.
   New Generic Product Identifiers shall be created and agreed on by an expert panel including PCs (e.g. EAPCCT). For each group notification, all substances that could be interchanged must be listed with product identifier as described for fragrances in the Annex (Parts A 4.4, B 3.1).
   Acceptable if substances/MiMs that are exchanged within the grouped mixtures not only share the same health classification, but are also similar with respect to their mode of action, leading to a common or very similar clinical risk assessment and poisoning advice (toxicologically comparable substances/MiMs).

Dutch PC/AB comments:

- Probably acceptable for industry because it resembles the industry proposal in the 'Thought Starter' document 'Cross sectorial alignment on common solutions – Inherent variability' which was distributed during the workshop.

- 'Functional GPI' could also be an advantage for 'emergency health response' if the toxicology for a specific functional group is very similar and assessment of individual substances/MiMs is not necessary.
- Depending on how similar the toxicology/PC advise for the substances/MiMs in the group is, maybe there should be a maximum concentration for GPI use within a notified composition.
- To create an agree upon these new GPI is a lot of work… use of multiple suppliers and resulting small changes in component/MiM composition seems commonplace. Important to prioritise the requests for new GPI's.
- ECHA could set up a 'focus group' and an annual assessment cycle, as is done for PCS issues.

2. A set of additional GPIs may be defined that represent predefined Group Formulations (GFs) with wider concentration ranges and/or variable, but similar substances. Existing technical specifications might be applicable for the definition of these GFs, if appropriate for decision making in emergency health responses.
   In any case, GFs shall be agreed by a panel including PCs (e.g. EAPCCT).

Dutch PC/AB comments:

- Again, creating such GFs is a lot of work and it should be restricted to specific product groups with serious workability issues. For cement and petroleum products it could be an option.
- ECHA could set up a 'focus group' to assess industry proposed GFs in specific product categories.

Beaumont Hospital, PO Box 1297
Beaumont Road, Dublin 9.

Telephone:	01 8092566 / 8379964
Email:	npicdublin@beaumont.ie
Website:	www.poisons.ie
Facebook:	@NPICIreland
Clinical Director:	Dr Edel Duggan

25 February 2019

Comments from the National Poisons Information Centre of Ireland on the Study on workability issues concerning the implementation of Annex VIII of Regulation (EC) No 1272/2008 on harmonised information relating to emergency health response and preventative measures Second Interim Progress Report

1. General comments

a. **Mixtures in mixtures (MIMs)**
It is important that the information on composition of mixtures is displayed to poisons centre staff in a useful format. In particular, a list of MIMs names and UFIs will not be helpful when dealing with urgent cases. Rather, the IT tool should utilise the information submitted on the composition of the MIMs and generate a list of the substances present in the final mixture and their final concentrations.

b. **Hazard classification**
The limitations of the hazard classification of a mixture should be recognised. The hazard classification is usually based on animal data and may be even be derived from data on similar chemicals rather than the substances present in the mixture. A broad hazard classification such as Acute toxicity 1, 2 or 3 does not help poisons centres provide detailed advice for human cases of poisoning. Poisons Centres need to know which substances are in the mixture and their concentrations to answer questions such as;
   - Is the mixture hazardous by this route of exposure?
   - How much is a toxic dose if ingested?
   - What symptoms will it cause?
   - How long will it be before symptoms appear?
   - Does the patient need to go to hospital immediately?
   - How long should they be observed in hospital?
   - Are blood tests or other investigations required?
   - Should the patient be admitted to a specialised ward e.g. for cardiac monitoring?

- What treatment will they need, other than supportive care?
- Will the patient need follow-up after discharge from hospital? / Are there any potential long-term effects?

c. Cross sectoral alignment on common solutions

Papers on Cross sectoral alignment on common solutions were tabled at the Workability workshop on 13th February. These proposals aim to reduce the burden of making notifications for industry but would result in loss of information on the components in mixtures. For certain types of products it may be necessary to accept such loss of information, to avoid placing demands on industry which are disproportionate to the number of poisoning incidents involving these products. However, when poisons centres receive frequent calls about a product category the balance is shifted and the burden of making notifications becomes justified.

2. Soaps and detergents

A substantial proportion of calls to the National Poisons Information Centre of Ireland (NPIC) involve detergent products (12.5% of cases in 2017). Fabric cleaning products (particularly liquid detergent capsules), dishwasher products, general purpose cleaners, bleach and toilet cleaners/fresheners were the most common.

Workability issue: SD1 – Fragrances classified as hazardous for human health

The use of a GPI for fragrances classified as skin sensitisers which are used in soaps and detergents should be permitted (possible solution SD-A). However, since the sensitising substances are listed on the product label and/or SDS, could these also be listed in the notification? For example, a component might be listed as “Fragrances classified as skin sensitisers – contains (DL)-Limolene, Linalool, Geraniol”.

Workability issue: SD2 – Multiple suppliers of same mixture component

The proposed solution SD-B would make it impossible for poisons centres to formulate advice quickly. For example, if a mixture contains 10 components and each component has 3 suppliers, and therefore 3 UFIs, the poisons centre staff would have to search for information on at least 30 substances, compared to 10 if the actual mixture components were listed.

Furthermore, we shouldn’t assume that mixture components which are technically equivalent and have the same hazard classification will always cause the same acute toxic effects. For example, laundry detergent capsules were expected to have the same toxicity as traditional liquid laundry detergents, but experience in many countries has shown that this is not the case. In addition, the hazard classification doesn’t provide enough information for poisons centres to answer callers questions, as explained in General Comments b.

3. Petroleum products: Workability issues PP1, PP2 and PP3

Less than 1% of calls to the NPIC concern exposure to ground fuels or aviation fuels. Therefore, the burden on industry to make many notifications and frequent updates seems disproportionate. The possible solution PP-A of a group

submission, and single UFI, for each semi-finished base petroleum product (for which there is a standard) has merit.

4. **Industrial gases: Workability issue IG1**
   For gases with only physical hazards the need for a poison centre response is very limited. The possible solution IG-A "Grouping approach" would seem to provide enough information for poisons centres to formulate medical advice in an emergency.

5. **Cement**
   Workability issue CM1 "Product variation in a continuous blending process"
   The NPIC receives very few calls about cement and these usually involve skin contact and the resultant corrosive injury. As with fuels, the burden on industry of making many notifications and frequent updates seems disproportionate. The possible solution PP-A of a group submission, and single UFI, for each cement for which there is a standard has merit.

   Workability issue CM2 "Multiple suppliers for mixture components"
   The proposed solution CM-A "Comparable MIMs" seems rather complex and it would be a large project to decide what mixtures could be considered 'comparable' and to develop an automated comparability check. This seems disproportionate to the scale of the problem. Solution PP-A would possibly eliminate the need for this.

6. **Construction products exc. Cement: Workability issue OC1**
   The NPIC receives only a small number of calls about adhesives, sealants and other construction chemicals. Solution PP-A could be used for products where standards exist. If no standards exist, the limited submission requirements for industrial products, could be extended to other construction products.

7. **Paints**
   Workability issue: P1 - Paint tints classified as hazardous for human health
   The possible solution P-A has merit. Using a GPI of "Colourants classified as skin sensitisers" would reduce the number of notifications without loss of the information needed for emergency health response. A GPI should not be used for components which can cause systemic toxic effects – see General comments b.

   Workability issue: P3 – Multiple suppliers of same mixture component
   The proposed solution P-C "Comparable MIMs" seems rather complex and it would be a large project to decide what mixtures could be considered 'comparable' and to develop an automated comparability check.

8. **Perfumes**
   Workability issue: FR1 – Fragrances/Industrial mixtures treated as mixtures for consumer/professional use
   Possible solution FR-A proposes that fragrances should be allowed to make use of the industrial settings requirements, including the limited notification. For many final mixtures this would not cause difficulties for poisons centres because the

concentration of fragrances in the final mixture is low. However, it could be problematic for mixtures where the final concentration of the fragrance remains high, such as air fresheners.

Limited notification could be permitted for fragrances, with the requirement to make a full notification if requested by ECHA or an appointed body, for example if the fragrance mixture was present at a high concentration in a final mixture for consumer or professional use. Could the IT tool automatically make a request for a full notification in these circumstances?

Workshop related to the study of workability issues regarding the implementation of Annex VIII to CLP

13 February 2019

Commission building MERODE, Avenue de Tervuren 41, Brussels

In the following text are comments of Department for Toxicology of Croatian Institute of Public Health (appointed body of Croatia) compiled with comments of Institute for Medical Research and Occupational Health (Poison Centre of Croatia) to certain points on the study of workability issues and/or foreseen changes of the Annex VIII to CLP.

Since year 2006, we have been collecting SDS's of all mixtures that fall under the scope of Article 31. of REACH Regulation. So far, we have collected around 77 500 SDS's. Those SDS's, together with other kind of databases, have been used by Croatian Poison Control Centre.

With all those SDS's and different kind of databases, there were difficulties because it was hard to get the exact name of the chemical, and the label was usually unreachable at the moment of the call. Hopefully this will change in the future and people will realise the importance of the labels/packages of chemicals and of the UFI number stated there. The right kind of UFI campaigns at Union, but also at national level, might help.

When it comes to UFI numbers, the same UFI might be used for different but similar mixtures, as far as classification of the mixture(s) has not changed. If UFI stays the same, there's no need to make or receive new notification. When it comes to mixtures intended for consumer use, our Poison Control Centre feels that more stringent requirements are needed when there is a composition change which needs to be updated even if no change in classification as it might result in different approach in the treatment of poisoning, especially when allergic reactions may be envisaged.

As it was said during the workshop, French colleagues have developed a proposal for paint mixtures. What kind of proposal is it? And can it be used for petroleum products, cements, adhesives and sealants, fragrances and similar kind of mixtures which were part of the study?

Mixture in mixture (MiM) – rather than receiving the full composition of MIM's component in mixtures (imagine mixture with 2 essential oils in composition, and each of essential oil has 10 components in its composition), we see no problem if SDS for MIM(s) is/are part of notification.

24/06/2019

German Proposals for solving the workability issues for variable mixtures

We propose two solutions to the problem of notifying mixtures with variable composition. The solutions can be applied in parallel. We expect both proposals to require only minor changes to the legal text and the PCN format.

I. Proposal on extending the provisions on group submissions for perfume or fragrance components (Annex VIII, Part A, point 4.3) to include other components

1. Current situation under Annex VIII:

Group submissions under Section 4 of Part A of Annex VIII are currently permitted when
- all mixtures have the same classification and
- contain the same components.

A group submission is also permitted where the difference in the composition only concerns **perfumes or fragrances**, provided that their total concentration **does not exceed 5 %** (Annex VIII, Part A, point 4.3 of of). All perfumes and fragrances that are potential components of the mixtures included in the group submission are to be indicated in the PCN format. A supporting list specifies the individual components contained in each product (Part B, point 3.1). This rule also applies to classified perfume and fragrance components.[1]

2. Proposal: Extension of the submission rules for perfume and fragrance components to other types of components

- Based on the model of group submissions for perfume and fragrance components, **additional cases** should be introduced for group submissions of mixtures containing other types of **highly variable** components.
- Currently, group submissions for perfume and fragrance components **require the indication of all components contained in at least one mixture in the PCN format**; the supporting list specifies which products contain these components.
- In order to make submissions more workable for poison centres, we propose replacing the indication of all possible variable components in a group submission with the general **indication of a toxicologically pertinent indicator** (suggested abbreviation: GHI – General Hazardous Components Identifier)[2].
- The GHI is to be specified in the PCN format (cf. item (a)). Supporting information is given in the list (cf. item (b)).

[1] This proposal does not affect the GPI (Generic Product Identifiers) concept applicable to non-classified perfume or fragrance and colourant components.

[2] The wording has been chosen in contrast to the GPI concept, which basically does not apply to components classified as hazardous.

a) GHI in the PCN format:

- The GHI is indicated in the PCN format with its concentration and classification (cf. below in bold type).

Example:

Components	Percentage	Classification
Chemical name component A	60 – 80 %	not classified
Chemical name component B	12 – 20 %	not classified
"Anionic Surfactant (GHI)"	**10 – 12 %**	**Eye Cat 1**

- **Possible GHIs** must be **stipulated in the regulation text itself**. They should be as informative as possible for poison centres.
- **Additional requirements** should be laid down in the text of the regulation to ensure that the variable components grouped into a GHI are toxicologically comparable. We propose the following minimum criteria:
  - **same classification** (with regard to health hazards) and
  - **same functioning/mechanism of action**

b) Representation in the list:

- The supporting list should specify possible replacement components as well as their GHI and classification.

Example:

GHI	Component (substance or MIM)	Identifiers	Percentage
Anionic Surfactant	Component chemical name C	EC XXX-XXX-X	10 – 11 %
Anionic Surfactant	Component chemical name D	UFI YYYY- … + Manuf.	12 %

3. Summary and need for adjusting the text of the regulation

- The proposal is based on the group submission for perfume and fragrance components (group submission + list).
- In the group submission a general indicator (GHI) is required, which is then further specified in the list with regards to all components (substances and MIMs) possibly contained.
- Legal changes will likely be limited to the provision on group submissions (Part A, point 3.1); it would be necessary to slightly adjust / extend the list format to include the concentration of components.

II. Proposal for variable mixtures with reference to standard formulas

- There is a limited number of mixture groups for which the procedure presented so far is not suitable because of their highly variable composition (for example petroleum products or cement). We propose to accept a reference to standard formulas for these mixtures.

Example (indications in PCN format):

Components	Percentage	Classification
Cement (standard formula 1)	100 %	Skin Sens 1 Eye Irrit. 2 STOT SE3

- The standard formulas would have to be specified in Annex VIII:

Example/proposal: cement (standard formula 1)

Component	EC number	Concentration	Classification
Portland cement clinker	66-043-4	80 – 100 %	Skin Irrit. 2 Skin Sens. 1B Eye Damage 1 STOT SE3
Fly ash	70-659-9	0 – 10 %	Skin Irrit. 2 Skin Sens. 1B Eye Damage 1 STOT SE3
Calcium hydroxide	215-137-3	0 – 10 %	Skin Irrit. 2 Eye Damage 1 STOT SE3

- Before standard formulas are specified in Annex VIII, CARACAL experts should consulted to review their suitability for emergency health response. EAPCCT should also be involved.

<u>Summary:</u>

- Standard formulas should only be used where the proposal described in the first part is not effective because possible components are too variable; this approach should be limited to a small number of problematic cases (e.g. cement, petroleum products).
- The standard formulas should be laid down in Annex VIII; it would be possible for the Commission to continuously add new standard formulas following the procedure under Article 290 TFEU (adoption of delegated acts).

[Catalogue number]

Publications Office

doi:10.2873/574339