# 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)


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# Resumé

Les opinions exprimées dans ce document représentent les points de vue des auteurs et ne reflètent pas nécessairement ceux de la Commission de l'Union européenne. La Commission ne garantit pas l'exactitude des données présentées dans ce rapport. Ni la Commission, ni les personnes agissant au nom de la Commission ne peuvent être tenus pour responsables de l'utilisation faite des informations présentées dans ce rapport.

Ce rapport détaille les conclusions du projet réalisé par Amec Foster Wheeler et le National Chemical Emergency Centre UK (NCEC) pour la Commission européenne concernant une 'étude sur l'harmonisation de l'information à soumettre aux centres antipoison en accord avec l'article 45(4) du Règlement EC No.1272/2008 (Règlement CLP)'.

L'article 45 du Règlement européen relatif à la classification, à l'étiquetage et à l'emballage des substances et des mélanges (Règlement CLP) et l'article 17 de la Directive 1999/45/EC sur les substances dangereuses, requièrent que les Etats Membres désignent un ou plusieurs organismes chargés de la réception des informations sur la composition chimique des mélanges mis sur le marché et classés comme dangereux en raison de leurs effets sur la santé ou de leurs effets physiques.

Ces organismes, connus sous le nom de centres antipoison, sont un composant important des systèmes nationaux de santé publique. En cas d'urgence sanitaire ils peuvent transmettre des informations détaillées sur la composition chimique de certains produits et leurs effets.

Les centres antipoison jouent un rôle central dans la sécurité d'utilisation des substances et des mélanges. A la suite d'exposition à des produits chimiques dangereux les centres antipoison peuvent donner des conseils d'ordre médical pour assister le grand public et les professionnels de la santé. Il a été estimé que les centres antipoison reçoivent et traitent en moyenne 600,000 appels par an (environ 1,700 appels par jour, dont la majorité concerne des cas d'enfants exposés à des substances). De plus, plus de 400 décès par an sont recensés du fait d'expositions à des produits chimiques. Les centres antipoison évaluent la gravité de l'intoxication, donnent des indications sur les premiers soins et déterminent la nécessité d'une intervention médicale. Les centres antipoison contribuent également à la réduction de traitements médicaux et d'hospitalisation non nécessaires.

Bien que l'Article 45 requiert la désignation d'organismes chargés de la réception de la documentation, le Règlement CLP ne définit pas le détail de l'information à être rassemblée ni de procédé de notification spécifique à suivre. Cela a donc résulté en une mise en œuvre de façon différente dans les Etats membres. Les Etats membres ont défini des procédures et des outils spécifiques pour requérir les informations sur la composition et la concentration. Suite à l'évolution de ces outils il y a maintenant en Europe une diversité d'exigences et de conditions à satisfaire. Cela représente une charge administrative considérable pour les entreprises qui doivent être en conformité avec différents systèmes pour pouvoir conduire des échanges à travers l'Europe.

En accord avec le Règlement CLP, le processus de notification devait être revu avant 2012. Pendant cette révision et suite à des entretiens avec les Etats membres, un document de travail a été rédigé et inclut la possibilité d'harmoniser et de standardiser les informations visées par le Règlement. Ce document de travail a été discuté en 2014 lors de la 14ième réunion CARACAL. Ce document de travail propose l'établissement d'un format harmonisé pour l'information à communiquer ainsi que la création d'un identifiant de formule unique (IFU) qui serait ajouté aux obligations

d'étiquetage et utilisé afin d'assister l'identification des produits impliqués lors des incidents avec des produits chimiques.

Il est nécessaire d'évaluer les coûts et les bénéfices que ces changements proposés apporteraient aux entreprises et aux centres antipoison. Pour cela, le projet a effectué une enquête auprès des personnes intéressées. Un questionnaire a été développé et diffusé largement dans les Etats membres. Un nombre important de réponses a été reçu et inclut plus de 550 réponses d'entreprises et provenant de 17 des 28 centres antipoison nationaux des Etats membres. Ls responsables du projet ont également conduit des entretiens téléphoniques avec une sélection de centres antipoison afin de rassembler plus de détails. Les réponses fournies par les entreprises ont été utilisées afin d'estimer les coûts et bénéfices quantifiables dus aux changements proposés. Les autres coûts et bénéfices qui ne pouvaient être quantifiés ont été analysés de façon qualitative.

Les résultats de l'enquête ont permis d'identifier un éventail d'opinions. Globalement, les estimations de coûts suggèrent que, pour les entreprises, l'harmonisation de l'information se traduirait par des économies, en particulier pour les entreprises qui conduisent des échanges dans la plupart des Etats membres. Cependant la situation n'est pas uniforme pour toutes les entreprises. Pour les entreprises qui opèrent uniquement au niveau national et dont les Etats membres ont des systèmes de notification des informations qui requièrent un faible volume de données, l'adoption d'une procédure harmonisée engendrerait des coûts nets pour ces entreprises. Ce problème est exacerbé par le fait que ces entreprises, qui opèrent au niveau national uniquement, incluent une proportion plus importante de PME que celles qui opèrent au niveau international. Cela se traduit donc pour ces PME par des coûts proportionnellement plus élevés (par rapport à leurs revenus) et par conséquent une moindre capacité pour gérer les changements.

Dans l'ensemble, la meilleure estimation des coûts/économies qui a été dérivée dans cette étude est que l'harmonisation des systèmes de notification engendrerait des économies pouvant atteindre €890 millions par an pour les entreprises concernées. L'introduction de l'IFU représenterait un coût annuel total de €340 millions. Ainsi, les changements proposés se traduiraient par une économie annuelle nette de €550 million.

Il est important de noter que l'analyse des coûts a nécessité la formulation d'hypothèses, due principalement à la grande quantité d'entreprises concernées, l'éventail de systèmes de notifications existant dans les Etats membres et les différences de marché pour les produits concernés. La modification de certaines de ces hypothèses pourrait mener à des résultats et estimations considérablement différents et des tests de sensibilité basiques ont été menés. Cependant, bien que les hypothèses et les incertitudes affectent la magnitude des coûts et des économies estimées, il est considéré que la direction globale identifiée (pour l'harmonisation, l'adoption de l'IFU et globalement) est correcte.

En outre des économies de vies humaines et des bénéfices pour la santé pourraient également être pris en compte. Ces bénéfices seraient apportés par les améliorations de la rapidité et la précision des réponses des centres antipoison qui réduiraient les effets des incidents impliquant des produits chimiques. Bien que ces aspects ne soient pas quantifiés dans cette étude, les centres antipoison ont indiqué que l'harmonisation et l'adoption de l'IFU mèneraient à une identification plus rapide des substances et par conséquent à une réponse des professionnels de la santé plus rapide. Ces mesures aideraient également à améliorer les connaissances sur les concentrations des substances dans les produits ce qui permettrait de réduire les surmédicalisations qui sont estimées se produire dans environ 40% des cas. En effet, lorsqu'il est difficile

d'identifier un produit ou une composition de substances contenues dans un produit, des traitements médicaux sont ajoutés par précaution. L'amélioration des connaissances et des réponses réduiraient la fréquence à laquelle les cas de surmédicalisations se produisent.

Bien que l'adoption de l'IFU engendre des coûts nouveaux pour les entreprises, elle présente également des bénéfices certains pour les centres antipoison et les patients. Dans cette étude, les coûts estimés pour l'adoption de l'IFU sont moins importants que les économies estimés dues à l'harmonisation. Les conséquences dues à l'adoption de l' IFU seront réduites par l'introduction d'une phase transitoire. Ce rapport présente les économies qui pourraient être réalisées par l'adoption d'une telle phase. La possibilité d'adopter un IFU de groupe pour les cas où il y a de grandes gammes de produits avec des compositions similaires est également explorée dans ce rapport.

# Executive Summary

*The information and views set out in this study 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.*

This report details a project undertaken for the European Commission by Amec Foster Wheeler and the National Chemical Emergency Centre UK (NCEC) on a 'study on the harmonisation of the information to be submitted to Poison Centres, according to article 45 (4) of the EC regulation No. 1272/2008 (CLP Regulation)'.

Article 45 of the EU Regulation on the classification, labelling and packaging of chemicals (CLP) (EC) No. 1272/2008)) and Article 17 of Directive 1999/45/EC (Dangerous Preparations Directive) place a requirement on the EU Member States to appoint a body (or bodies) responsible for receiving information on preparations/mixtures considered dangerous/hazardous on the basis of their health or physical effects. These appointed bodies often known as 'Poison Centres', provide a valuable service as part of national health care systems; relaying detailed information on health effects of chemicals within specific products during emergency incidents.

Poison Centres play an instrumental role in the safe use of chemicals. In case of exposure to hazardous chemicals, they provide medical advice to general consumers and physicians. It has been estimated through contact with the EU Poison Centres that on average these services receive and treat 600,000 calls per year (almost 1700 calls per day, mostly related to child exposure) and the number of fatalities related to chemical exposure is more than 400 per year. Poison Centres also have a vital role early within an incident to critically assess the severity of the case and the appropriate medical treatment needed. In cases of low severity incidents the Poison Centres across the EU have therefore also contributed to reducing unnecessary medical treatment or hospitalisation of patients where otherwise they would have been referred.

While Article 45 of the CLP Regulation places a requirement to appoint bodies and gather information, it does not define how the information should be notified and has therefore resulted in different Member States implementing different procedures and requirements on composition/concentration data and notification formats and tools. The evolution of these systems has meant that the current EU position presents a diverse set of systems and requirements which now places a significant burden on industry to manage these differing requirements while trading across the EU.

The CLP Regulation also includes a requirement to review this issue by 2012. During this process and the subsequent meetings with Member States a working paper on a potential harmonisation and standardisation of data requirements was discussed (14th CARACAL meeting in 2014). This paper supported the establishment of a harmonised format, along with the creation of a 'unique formula identifier' (UFI) to be included as part of the labelling requirements to aid identification of products during chemical incidents.

As part of the proposed harmonisation of data submission formats and adoption of a UFI it has been necessary to assess what the costs and benefits of such a change might mean for industry and Poison Centres. This project carried out a detailed stakeholder consultation exercise with industry and Poison Centres through the use of questionnaires, which received a high level of response (over 550 responses from industry contacts and representation for 17 out of 28 Member States Poison Centres). The project also included telephone interviews with selected stakeholders from Poison

Centres to gather further information. The results of the questionnaire with EU industry were used to estimate the quantifiable costs and benefits of the proposed changes. Other costs and benefits that could not be quantified were also analysed, based on the survey responses, with information presented in qualitative terms in the current report.

The results of the study highlighted a broad range of opinions from stakeholders. Overall the cost estimates suggest that there would be net savings for industry across the EU with the greatest savings made by those companies that trade in the most EU states. However while for the EU overall there are predicted to be net savings, this result does mask a set of disparities for some companies. In particular, for companies that trade only domestically that are found within Member States that currently have simpler or less data-intensive notification systems, the move to the proposed harmonised system would represent net costs. This is an issue which is exacerbated by the fact that those companies that trade only domestically will also include a higher proportion of SME category companies than those that trade internationally, which generally means higher costs as a proportion of revenues, as well as less capacity to deal with the changes.

Overall, the best estimate of costs/savings derived in this study is that the harmonisation could overall lead to savings of perhaps €8990 million per year across all affected companies in the EU. The introduction of the UFI could lead to total costs of around €340 million per year, giving total net savings of around €550 million per year.

The cost analysis required a number of assumptions to be made, given the large number of companies involved and the range of different notification systems and range of different markets for the products concerned. Modification of some of these assumptions can lead to significantly different results, and some basic sensitivity testing has been undertaken for the current report. Whilst these uncertainties will affect the magnitude of the estimated costs and savings, the overall direction of the costs and savings (for each component and overall) is considered to be correct.

Additional to the quantified costs and savings highlighted within the current study there could also be 'life savings' or 'health savings', where improvements to speed and accuracy of response by Poison Centres further reduces health effects of chemical incidents. While not quantified in the study, the qualitative feedback from Poison Centres indicated that the harmonisation and UFI would lead to more rapid identification of products and response to medical professionals; it would also help to address the issue of overtreatment estimated to occur in approximately up to 40% of cases, through improved information on concentrations of components. This occurs where difficulty in identifying a product or specific breakdown of substances within a product means that a precautionary strategy is required using additional medical treatment. Improved response would reduce the frequency of which overtreatment occurs.

The adoption of the UFI represents new costs to industry, but a clear benefit to Poison Centres and patients. Under the estimated costs presented within this report, these costs are exceeded by the harmonisation savings. The impact of adopting the UFI will be reduced by using a transitional phase and again the cost savings for this element have been provided within the report. The possibility of adopting a group UFI for cases where there are large product ranges with similar compositions is also explored.

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# Contents

# 1 Introduction

## 1.1 Background

Article 45[1] of the EU Regulation on the classification, labelling and packaging of chemicals (CLP) (EC) No. 1272/2008) and Article 17 of Directive 1999/45/EC (Dangerous Preparations Directive) place a requirement on the EU Member States to appoint a body (or bodies) responsible for receiving information on mixtures/preparations considered hazardous/dangerous on the basis of their health or physical effects. These appointed bodies, often known as 'Poison Centres', provide a valuable service as part of national/regional health care systems, relaying detailed information on health effects of chemicals within specific products during emergency incidents. The Poison Centres also provide a valuable interface between industry and the general public/health care professionals in gathering and storing the necessary information to provide such a response.

The requirement detailed under Article 45 of the CLP Regulation makes clear that the information provided by industry should be kept confidential and may only be related to medical emergencies. However the Regulation does not define how the information should be notified and has therefore resulted in different Member States implementing different procedures and requirements on composition/concentration data and also adopting different notification formats and tools.

The variety of different requirements and systems currently adopted across Europe places a significant burden on business to remain compliant. The CLP Regulation stipulated that the Commission, by January 2012, should carry out a review to assess the possibilities of harmonising the information submitted to Poison Centres, including establishing a format for data submission. During these discussions there was a broad agreement that harmonisation was a positive step. A Commission Working paper containing a potential format was put forward during the 14th Meeting of the Competent Authorities for REACH and CLP (CARACAL, in April 2014[2]) and is repeated for reference in Appendix A. These discussions also identified, as part of this harmonisation process, that there was value in the creation of a Unique Formulation Identifier (UFI) to aid rapid identification of chemical goods during an incident.

This report will provide the findings of a cost-benefit study and stakeholder engagement with European industry and the Poison Centres on both the proposed harmonisation and the adoption of the UFI system. It has been developed by Amec Foster Wheeler in association with the National Chemical Emergency Centre.

## 1.2 Existing approach to data management at Poison Centres

Currently there are three main approaches that Poison Centres appear to be applying to data management on a state by state basis (as informed by a study by the Netherlands of centres in 14 Member States[3] and the National Chemical Emergency Centre UK (NCEC) and Chemical Watch's recent Poison Centre survey):

[1] *European Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures came into force on 20 January 2009 in all EU Member States.*

[2] *14th CARACAL meeting held on the 2/3 April 2014, Centre A. Borschette, Brussels, Belgium. See Annex C for suggested harmonised format.*

[3] *RIVM, 'Article 17 of the Preparations Directive 1999/45/EC is differently implemented in EU Member States A survey on how Poisons Information Centres become informed on dangerous preparations' RIVM report number 233900001/2007*

i. No data on submission of product-specific information (a small number of centres – assumed to be around four Member States did not provide information)

ii. Submission of Safety Data Sheets (SDS) as registration (the majority)

iii. Submission of SDS plus additional information registration (large number – around 10 Member States in total)

The reason that some Poison Centres appear to be asking for the third option is that SDS often contain percentage ranges for chemicals, rather than precise formulations. Exact composition data of hazardous mixtures is something that industry is often hesitant to provide as this information is frequently commercially sensitive. Since the main activity of Poison Centres is to provide emergency health advice following chemical exposure, exact composition data is considered greatly important by them for certain hazard classifications. On the other hand, it is more convenient, and less costly, for industry to provide the Poison Centres with only the SDS.

Table 1.1 provides an outline of the current arrangements of different Member States' bodies at the time of writing based on the Netherlands study and NCEC Chemical Watch survey, as well as documentation provided to the contractor by the European Commission and other information collected during this study. This highlights the range of requirements in place.

Table 1.1 Data submission requirements of the EU Poison Centres

| Country | Level of information & compositional data | Use of bespoke tools or software | Legislative requirements | Submission Fee |
|---|---|---|---|---|
| **Austria** | Requires submission of SDS. For Toxic, Very Toxic and Corrosive chemicals more exact information is required on composition | No software information provided. | Mandatory submission | Yes, variable depending on submission |
| **Belgium** | Requires submission of SDS, exact composition and product label | Data is submitted using an Excel sheet to format the index of submitted products and then emailed as a pdf. Poison Centre uses internal and external database sources. | Mandatory submission | Yes (€200 to Ministry of Health) |
| **Bulgaria** | Limited information is so far known about the Bulgarian Poison Centre despite efforts to engage with it | No software information provided. | Mandatory submission | No cost information provided |
| **Croatia** | SDS are accepted | No web portal or bespoke software for submission. | Voluntary submission | No cost information provided |
| **Cyprus** | There is no known operational emergency telephone number service in Cyprus. However product formulation must be sent by a form to the | Information submitted by email using a form. The country maintains a register similar to Norway's product register. | Mandatory submission | No fee |

| Country | Level of information & compositional data | Use of bespoke tools or software | Legislative requirements | Submission Fee |
|---|---|---|---|---|
| | Department of Labour Inspection. | | | |
| **Czech Republic** | Requires submission of Czech language SDS. Exact formulation is not required provided the SDS is sufficiently comprehensive | A national database of toxic agents, a database of SDS, Toxbase and Poisindex. | Mandatory submission | No cost information provided |
| **Denmark** | Requests that company SDS be made easily accessible by internet search. However, exact product formulation must be submitted to the Danish Product Registry | The Danish Poison Centre does not maintain a database of SDS due to limited resources. They request that company SDS be made easily accessible by internet search. | Voluntary submission to Poison Centre Mandatory submission to the Danish Product Registry. | No fee |
| **Estonia** | Requests that company SDS be made easily accessible by internet search | The Estonian Poison Centre does not maintain a database of SDS due to limited resources. Estonia requests that company SDS be made easily accessible by internet search. Databases used by the Poison Information Centre include practice-based data collected by the Poison Information Centre of Finland and adapted for Estonian conditions. | Voluntary submission to Poison Centre | No fee |
| **Finland** | Requires submission of SDS to the Finnish Safety and Chemicals Agency by e-mail | SDS submitted to Poison Centre by email | Mandatory submission | fee (38 Euros per product/per year – discounted for bulk submissions) |
| **France** | Requires submission of exact formulation but not SDS | France has an in-depth notification procedure using proprietary software. Data submitted via Déclaration-Synapse web portal and accessible by national Poison Centres. | Mandatory submission | No fee |
| **Germany** | Requires submission of exact formulation. SDS can be submitted to the ISI (Information for Safety Data Sheets) database | An Excel spreadsheet is provided to generate the correct format for upload to a dedicated web portal. The Poison Centre uses proprietary software, its internal database of SDS and has access to the ISI (Information for Safety Data Sheets) database. | Mandatory submission of formulation. Voluntary submission of SDS. | No fee |

| Country | Level of information & compositional data | Use of bespoke tools or software | Legislative requirements | Submission Fee |
|---|---|---|---|---|
| **Greece** | Requires submission of exact formulation but not SDS | Notification to the Greek Directorate of Environment is via dedicated software for formatting product data, which is then transmitted via email. | Mandatory submission | No cost information provided |
| **Hungary** | Requires submission of Hungarian SDS. | Product information is submitted via web portal (OSZIR). | Mandatory submission | Yes, Ft 9200 per submission |
| **Ireland** | Exact product formulation is preferred but SDS are accepted | Notifiers are required to contact the Poison Centre directly to arrange data submission. Use Toxbase database (see UK below) | Mandatory submission | Yes, unspecified |
| **Italy** | Requires submission of exact formulation but not SDS | Product information is submitted via bespoke software (ISSFormula). | Mandatory submission | No cost information provided |
| **Latvia** | Limited information is so far known about the Latvian Poison Centre despite efforts to engage with it | Information submitted via written form. | Unknown | No cost information provided |
| **Lithuania** | Requires submission of SDS for hazardous substances/mixtures sold to market at greater than1000 kg/yr, However for specific hazards a lower threshold is applied; Toxic, sensitising, Environmental hazardous >100kg/yr; Very Toxic >10kg/yr | SDS information is submitted via web portal to the AIVIKS (Lithuanian Environmental Protection Agency Environmental Information System). | Mandatory submission if over notification threshold | No fee |
| **Luxembourg** | There is no known operational emergency telephone number service in Luxembourg. | - | - | - |
| **Malta** | Malta has proposed that an Official Advisory Body should be set up, but it is work in progress | - | - | - |
| **Netherlands** | Requires submission of SDS with exact formulation or as two separate documents. | Information is submitted via web portal. Micromedex and Poisindex, with several other databases available for specific chemicals, drugs, plants and toxins | Mandatory submission | No fee |

| Country | Level of information & compositional data | Use of bespoke tools or software | Legislative requirements | Submission Fee |
|---|---|---|---|---|
| **Norway (observer at CARACAL meeting)[4]** | Requires submission of exact formulation and SDS | Notifiers may submit SDS via a publicly accessible, non-confidential web portal "The Product Register" (pib.no). Norway uses a combination of an internal database, the Product Register, Poisindex and other articles and library sources to provide advice on curative measures. | Submission is not legally enforced | No fee |
| **Poland** | Requires submission of SDS | There is an online portal for data submission however there is no bespoke software for online data submission. | Mandatory submission | No fee |
| **Portugal** | Requires submission of exact formulation, SDS, full product formulations and pictures of the Portuguese language product labels | Notifiers may submit information by emailing the Poison Centre. | Mandatory submission | No fee |
| **Romania** | SDS are accepted | No software information provided. | Voluntary submission | No fee |
| **Slovakia** | Requires submission of SDS | Numerous information sources are used to provide advice on curative measures, including an internal SDS database, an internal toxicological database, a national drug database, Poisindex and a database of antidotes. | Mandatory submission | No fee |
| **Slovenia** | Requires submission of SDS | Information may be submitted via the ISK web portal or via written form. | Mandatory submission | Fee for written submissions. No fee for online submissions and amendments |
| **Spain** | Requires submission of SDS and product labels plus full information | A special Product Information Form must be used, this can be generated using free software that is downloaded and generates an 'Export' file. In addition Product labels or photocopies of product labels must also be sent. | Mandatory submission | Yes, € 30 for new submissions (there is a discounted price for SMEs) |

[4] *Norway is not a member of the European Union; Norway is however a member of the European Economic Area. Norway attends the CARACAL meetings as an observer on the basis that they are outside of the EU's remit but has vested interests in the ongoing activities of the European Union.*

| Country | Level of information & compositional data | Use of bespoke tools or software | Legislative requirements | Submission Fee |
|---|---|---|---|---|
| | | ~~In addition there are two letters with predetermined layout, designed to communicate the list of notified products.~~ Information must be sent by postal mail or via secure FTP. | | |
| **Sweden** | Exact product formulation is preferred but SDS are accepted | Information submitted via email. | Mandatory submission | No fee |
| **United Kingdom** | SDS are accepted | The UK and Ireland use the Toxbase clinical toxicology database, which contains information on 17,000 products and substances and information on chemical incidents and specialist articles. | Voluntary submission | No fee |

## 1.3 Proposed harmonised approach to data management at Poison Centres

Harmonisation of the data submission requirements is mentioned in paragraph 4 of Article 45 of the CLP Regulation which states:

*"By 20 January 2012 the Commission shall carry out a review to assess the possibility of harmonising the information referred to in paragraph 1, including establishing a format for the submission of information by importers and downstream users to appointed bodies. On the basis of this review, and following consultation with relevant stakeholders such as the European Association of Poison Centres and Clinical Toxicologists (EAPCCT), the Commission may adopt a Regulation adding an Annex to this Regulation."*

During the discussions held at CARACAL (including consultation with EAPCCT) a number of options were suggested and put forward to assist in the harmonisation of the data submission requirements. These suggestions are intended to both help streamline the process and reduce burden on industry and Poison Centres as well as to aid the quality and speed of service provided by the Poison Centres. Broadly these suggested improvements from the 13th CARACAL meeting[5] included:

- A centralised database system;
- A unique company identifier (UCI);
- A unique formula identifier (UFI);
- Chemical composition of mixtures;
- Designation of ingredients;
- Establishment of a data set version identifier (DVI);
- A product categorisation system;
- Review of the type of information requested.

[5] *13th CARACAL meeting 26-28th November 2013, Centre A. Borschette, Brussels, Belgium*

The discussions from the 13th CARACAL meeting suggested a move towards creating a centralised repository for the EU with a single submission point. While proving attractive this also raised a number of issues. The Member States make use of a variety of data submission formats with differing levels of information gathered and stored internally within different IT architectures. Additionally the different registration requirements also means that some Member States require an administrative fee for submitting information to Poison Centres (and others do not), while the issue of retaining national languages for submitted information was also an important aspect.

Therefore the proposed move towards a harmonised data submission format was agreed to help address the issues related to different data submission requirements across the Union, with a key longer-term aim being the development of a central data repository.

The proposed harmonisation at this stage will therefore cover two aspects. Firstly, to solve the issue of different data requirements across the EU, an agreed data submission format is proposed, setting out specifically what kind of information should be submitted. Secondly the adoption of a Unique Formula Identifier (UFI) system to help the rapid identification of chemical products during an incident is proposed.

The Commission services paper on the harmonisation of the information to be submitted to Poison Centres – first raised at CARACAL 13 and discussed at CARACAL 14 – identifies specific issues linked to the requirements under the new harmonised system including:

- Use of concentration bands / ranges instead of exact concentration
- Coverage of hazardous substances at 0.1% w/w and 'identified' hazardous substances <0.1% w/w
- Identified non-hazardous substances covered at 1% w/w
- Substance nomenclature will follow CLP art 18. 'Generic' names are not acceptable other than 'perfumes', 'fragrances', 'colouring agents', or natural substances 'extracts of...'
- UFI - which will be free of charge using a freeware tool;
- Retain submission of information to national/regional centres for now, with a longer term aim to consider one centralised repository;
- Information should be notified before commercialisation takes place;
- The system should make use of an EU-wide standardised XML reporting format to submit information;
- A product categorisation code is yet to be agreed.

## 1.4 Objectives of the study

The objectives of the current project are to *develop "the required information which allows the European Commission to broadly estimate the positive and negative impacts of a harmonised notification system of data to be transmitted to Poison Centres"*. The objectives are to provide:

i. Typical cost of notification under the existing national notification systems;

ii. Standard cost of a notification under the planned harmonised reporting format;

iii. Estimation of key multiplication factors to allow a cost estimate at EU level;

iv. Extrapolation of costs and benefits (costs-savings) of obligatory provision of information under the proposed harmonised reporting format;

v. Assessing the additional costs for the unique formula identifier (UFI).

# 2 Project Approach

## 2.1 Brief description project approach

The project approach has been built around four key stages with a number of discrete steps under each stage. The overall approach is outlined within Figure 2.1. These stages cover:

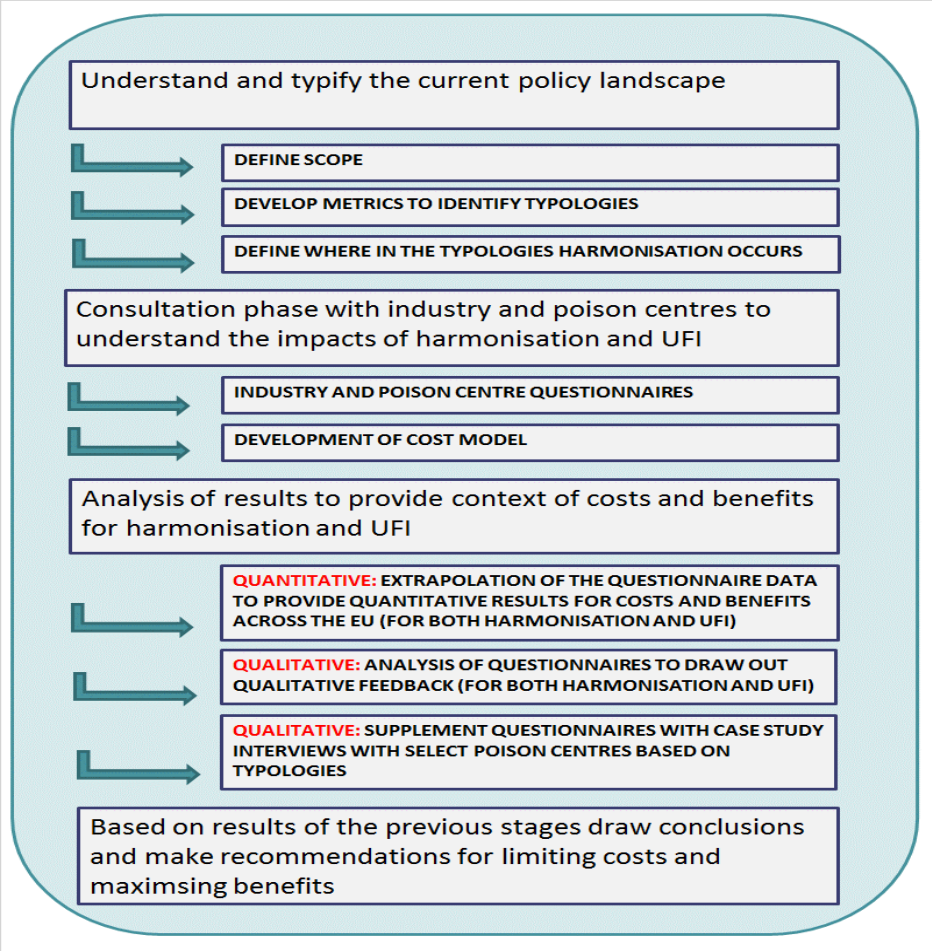
i. Developing a method to assess the current systems and data submission formats within the Member States and therefore the existing policy landscape in terms of how data is submitted to Poison Centres (Objective 1);

ii. To further fulfil the requirements of Objective 1 and link on to the next stages (Objectives 2 and 3) a cost model has been developed to understand the existing situation and the costs/savings under the proposed harmonisation. The variables within the cost model (including the UFI) have been defined through a consultation exercise with industry and Poison Centres to understand the pressures and costs of the existing landscape and what might be the benefits and costs of harmonisation. To extrapolate to the European Union level (Objective 3) information from on companies in different sectors has then been used;

iii. Analysis of the results of this consultation to draw out the data both in quantitative terms through the use of the cost model, but also in qualitative terms. This latter aspect is expected to provide a broad set of opinions within the different stakeholder groups as well as enriching the results of the cost model data. (Objective 4 and 5);

iv. Finally on completion of the preceding phases it should be possible to draw conclusions and highlight any recommendations to help minimise costs and maximise benefits (Objective 4 and 5).

Figure 2.1 Project approach




## 2.2 Defining the current policy landscape

### Background to approach

Under the CLP Regulation/DPD Directive, each Member State authority has defined what level of data is required and in which format it must be transmitted to the appointed body. This has resulted in a wide range of requirements at national level. From an industry perspective the variety of different options in a practical sense can be assumed to form a range or spectrum of data burden. At one end of the scale the burden on industry to submit data might be perceived as minimal (e.g. one-off submission of a Safety Data Sheet per product), while at the other end of the spectrum the level of effort required to remain compliant and ensure data submission may be much more significant (e.g. use of specialist free software which requires familiarisation time, as well as development of information going beyond that contained within a safety data sheet).

In developing an understanding of the policy landscape the project began with two key tasks, namely:

i) Identifying the project boundaries within which the current project would proceed

ii) Identifying suitable parameters from which to develop typologies (i.e. categorisation of the baseline requirements).

By developing a set of typologies which span the spectrum of effort needed to be compliant with the data requirements in different Member States, it should then be possible to use those metrics to place each Member State within suitable categories across the spectrum of effort. It should also be possible to assign a place on the spectrum for the proposed harmonisation. This in very broad terms would also allow for a suitable means of gauging what proportion of the Member States lay to the right of harmonisation (currently lower burden for companies that trade in that state) and what proportion of Member States lay to the left of harmonisation (currently greater burden for companies that trade in that state), noting that individual companies may supply products into multiple states across the scale.

### Scope of the current project

The first task within this stage of the project was to identify the boundaries within which the scope of the study was to be conducted. This should take into account that, across the EU 28 Member States, a range of national issues may be posed which influence the complexity in the way that data harmonisation is implemented. For example, the UK Poison Centres are only made available to medical health care professionals, while the French Poison Centres are also open to the general public. This affects how these different centres approach emergency response and therefore the perceived data that they request from industry to help achieve those tasks.

The broad boundaries of the project scope can be defined as follows:

Actors: Only those commercial entities which manufacture and retail goods in the EU are included within this study. This assumes that the project covers those corporate entities already obligated under CLP/DPD to provide information to Poison Centres. Any manufacture of goods within the EU which is then exported outside the EU and thus not requiring notification is excluded.

Poison Centres: These are assumed to mean those designated bodies providing advice during health emergency response cases. In the majority of cases the body collecting information from industry and providing response are one and the same. However a number of Member States, for example Italy and Denmark, have a division between the official body that receives the information and the Centre which provides a response. It is also possible for Member States to have more than one Poison Centre nationally providing such a response. In these cases we have aimed to canvass as many regional as well as national centres as possible.

Administrative fees: A number of Member States' Poison Centres require companies to pay an administrative fee along with submission of their data. These requirements on fees are made at national level and are not affected by the EU approach. The proposed harmonisation of data submission will therefore not affect this element. It is assumed that, where a Member State charges an administrative fee, it will continue to do so after harmonisation. Likewise where a Member State's Poison Centres do not currently charge an administrative fee, any change to this position will not be made or proposed at the EU level (but rather at the discretion of Member States) and as such administrative fees have been excluded from the scope of the current project.

Statistical data: In carrying out the study, we have consulted with industry through use of a questionnaire which included both quantitative and qualitative questions. In deriving the results of the study we have used the quantitative component as the basis for what is occurring at industry level from those that responded. In order to provide a full EU position we have used this information and then further made use of data from Eurostat to help extrapolate to all likely affected companies within the EU.

Identification of those companies that would likely be effected has been done on the basis of NACE codes[6], with further detail provided in Appendix B.

## 2.3 Developing parameters for typologies

The next task within this stage was to identify suitable parameters in order to accurately characterise the range of variables by type of Poison Centre regarding the burden for industry to submit the required data. As previously stated, the proposed harmonisation does not seek to change the existing systems regarding administrative fees and these are therefore excluded.

In identifying suitable parameters to help characterise the Poison Centre bodies around Europe, the starting point was a survey by RIVM[3] which included 15 Member States, responses being provided by 14 Member States. Again highlighted in section 1.2 and from the NCEC / Chemical Watch survey, the main differentiating factor lies around whether the submission can be made as a safety data sheet only or whether additional information is required. In some cases providing this additional information means making use of bespoke tools which can require the use of training for workers.

Based on the RIVM report and additional information from the European Commission on the characteristics of each centre, and consultation for the current study, the four metrics detailed in Table 2.1 were selected. For each metric there is a 'maximum data burden' and 'minimum data burden' to reflect the range in level of effort placed on companies operating within different typologies. So for example a number of Member States will accept a data submission in the form of an SDS only. A number of other Member States require an SDS plus an additional form with further toxicological data, and yet others require users to make use of bespoke software providing detailed chemical and toxicological information which would substantially exceed what is seen on a typical SDS.

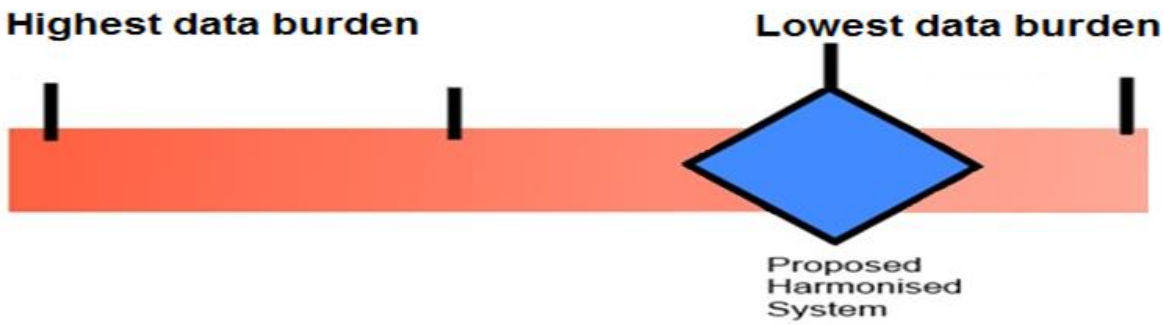
In using this approach to help demonstrate the range of different possibilities it is necessary to recognise some key caveats. Firstly, all Member States and industry would see a change to the data submission requirements as a result of the amended format detailed within the 14th CARACAL meeting. It should not be assumed that those countries with typologies at the same point on the sliding scale as 'harmonisation' are left untouched. Secondly when using a set of parameters to assign Member States to a category within the spectrum this is done by expert judgement and even for those countries in the same category there will remain differences between national requirements. Finally for multi-national companies that sell into multiple Member States spanning this spectrum it is not possible to use the sliding scale to assess what might be the cumulative effects. The sliding scale shown in Figure 2.2 is intended to act as a quick reference to identify the width and breadth of different typologies and at EU scale proportionally how these Member States fit within this overall spectrum.

[6] *The nomenclature des activites economiques (NACE) is an industry classification scheme used to identify and categorise different industry types based on a six digit code. The scheme has been adopted by the European Commission and is widely used across a variety of core industry statistics including Eurostat.*

Table 2.1 Metrics used for defining typologies.

| Typology criteria | Maximum data burden | Minimum data burden |
|---|---|---|
| **Level of information required** | More detailed than a SDS (e.g. provision of additional toxicology information) | SDS only |
| **Use of bespoke tools or software (likely requiring self-tutorial or training)** | Bespoke tools used | No Bespoke tools |
| **Legislative requirements** | Mandatory requirement to provide data | Voluntary to provide data |
| **Compositional data** | Requires exact formulation to be provided | Allowed to provide information on chemicals as concentration ranges |

Figure 2.2. Spectrum of data burden' based on defined metrics with harmonisation allocated




Based on the RIVM report and updated information from both RIVM[7] (2012) and the European Commission, it has been possible to place the majority of the EU Member States and Norway (as an observer) within the categories defined by the metrics. These are detailed within Table 2.2 with the full typology provided in Appendix C. It was not possible to place Luxembourg or Malta on the sliding scale due to a lack of data for these Member States. It is recognised that this categorisation is a simplification, but one necessary to build reasonable estimates within the constraints of an EU-wide analysis.

In Table 2.2 those countries in the far left hand column will have all of the 'maximum data burden' parameters from Table 2.1. Likewise it is assumed that all of the countries in the far right hand column will have all of the 'minimum data burden' parameters from Table 2.1. Those countries in the middle columns will have a mixture of maximum and minimum data burden parameters as defined in Table 2.1.

Broadly this would mean companies trading in the far right hand column would see an increase in costs linked to increase in data burden, while those in the far left and centre left would see a decrease in data costs. Again it is important to make clear all companies would see some change with the proposed format change. Those countries within the same column as "harmonisation" would still be required to make amendments. For example it is possible that countries at the same point in the sliding scale have similar data requirements to the proposed harmonisation but use a different format template or different means of upload portal. While the industry's cost

[7] *RIVM, 2012, 'Information sheet product notification', update to 2007 report*

linked to the submission of data would not increase, any automated system used to produce the required data would have to be updated to mirror the new format; equally the receiving database within the Poison Centre would need adjustment to receive the data in a new layout.

It is also important to make clear that, for those companies that trade in multiple countries, the cumulative effects are not taken into account. So for example it is possible that any given company trades into multiple Member States which span the width of the spectrum presented. The cumulative benefits of standardising into one system for all and any losses or gains across the spectrum are not captured within the scale but are captured within the cost/savings estimates derived during this study. It is intended instead to provide a simple guide on how the different Member States relate to the harmonised position in the table.

The use of the metrics and development of typologies is intended to provide an initial guide to how, relatively, the EU Centres compare. Greater examination of what the effects of harmonisation might be was obtained by reviews during the consultation stage with the industry and Poison Centre questionnaires.

Table 2.2 Assigning Member States to the spectrum based on typologies with extreme cases detailed at either end

| **More Detailed than SDS<br>Bespoke tools used<br>Mandatory submission<br>Exact composition required** | | | **SDS Only<br>No bespoke tools used<br>Voluntary submission<br>Concentration ranges** |
|---|---|---|---|
| France | Belgium | Austria | Croatia |
| Germany | Cyprus | Bulgaria | Denmark |
| Norway* (observer) | Greece | Czech Republic | Estonia |
| Portugal | Italy | Finland | Ireland |
| ~~Spain~~ | Lithuania | Latvia | Romania |
| | Spain | Hungary | Slovenia |
| | | Poland | United Kingdom |
| | | Slovakia | |
| | | Sweden | |
| | | Proposal for EU Harmonisation | |

## 2.4 Consultation phase

### Overview

The development of parameters and placing Member States within typologies across a spectrum of assumed data burden and related costs on industry allowed the project team to gain a useful understanding of how the different Member States varied proportionally. To further explore the current position and cost of data submission for industry and also what the costs and benefits of the proposed harmonisation might be, it was necessary to consult with industry. It was also important to seek the opinion of the Poison Centres.

The function and approach to emergency response practised by different Poison Centres across Europe was expected to differ. As Table 2.2 demonstrates, a number of Member States lie to the left or far left of the proposed harmonised position. A move towards harmonisation would therefore potentially reduce the cost of data submission requirements on companies operating in those countries but could also mean reduced levels of detail in the information provided to those Poison Centres. It was therefore important to seek the opinion of the different Poison Centres on how they operate and the perceived costs and benefits in maintaining or exceeding the current levels of service provided by those Poison Centres to the left of the harmonised position.

The consultation phase of the project was approached in two different ways, firstly through questionnaires aimed at industry and Poison Centres which had a mixture of quantitative and qualitative questions. The full questionnaires can be found within Appendix B of this report. Secondly, to help build on from the qualitative questions and enrich the understanding of the impact on Poison Centres, a selection of Poison Centres from different points in the spectrum of data burden were invited to take part in telephone interviews to discuss the study further. The details of these discussions are also provided in the results section of this report.

### Developing questionnaires

In developing the questionnaires for industry the project team aimed to strike a balance between quantitative cost data for the current position, post harmonisation and adoption of the UFI, as well as qualitative questions allowing companies taking part to express an opinion. The responses from the questionnaires were also used to examine whether the potential implications of the proposed harmonisation and UFI differed between different industry sectors and also between large sized companies and companies with small and medium size enterprise (SME) status. The project team made use of the NACE codes index system also used within Eurostat to identify a list of industry sectors. Those responding to the questionnaires were asked to indicate their main sector of operation, how many EU countries they traded within and their SME status.

The quantitative data derived from the industry questionnaires was used as the basis for a cost model to incorporate this information and then make use of Eurostat data to extrapolate to the EU level, with national level costs and benefits also included.

Similarly the questionnaire aimed at Poison Centres carried a mix of quantitative and qualitative questions, although in this case greater emphasis was given towards the qualitative elements. This was because it was expected to be difficult to fully quantify what the costs might be for processing individual data submissions. The Poison Centre questionnaire instead aimed to gain greater insight into the day-to-day activities of the Centres, what the benefits/impacts might be of harmonisation and the value to Poison Centres of having a UFI.

Both questionnaires were made available online via the "survey monkey" software program in October 2014 for a period of three weeks (extended from two weeks to allow respondents more time to provide their information). The duration of the survey window was planned in order to ensure that the results of the project would be ready for the next CARACAL meeting in March 2015. However, to help aid the shorter survey window and ensure a good level of response to the questionnaires a number of European trade associations were contacted in advance of the launch and again at the time of release to promote and encourage their membership to take part. The questionnaires were also advertised in a number of chemical industry publications, including through NCEC's newsletter.

Likewise the identified contacts at Poison Centres across Europe were contacted by e-mail to make them aware that the questionnaires were available for completion.

On closure of the survey window the data from the questionnaires was consolidated with spoiled and duplicate responses removed and the resulting data then used to help define the key variables within the cost model developed as part of the project.

## 2.5 Development of cost model

### Overview of the model

In order to quantify anticipated costs and benefits associated with the proposed harmonisation, a model has been built (in MS Excel). This has been developed to assess the changes for industry as a two tier approach; this includes firstly the proposed changes on data submission formats for consumer[8] and professional use products[9] as part of harmonisation, and then secondly for industrial mixtures[10], harmonisation of data format. This disaggregation was made as the requirements for industrial mixtures are supposed to be different compared to consumer and professional use goods including the proposed alternative solution of using the information contained in an SDS plus a 24/7 number telephone number instead of providing the full amount of data to Poison Centres. The proposed use of the UFI is assessed separately. Overall, changes to the reporting system (reporting format and content, mandatory or voluntary systems), and introduction of the UFI requirement within the scope of Poison Centre reporting will determine the extent of the costs and benefits.

The scope of the assessment and key elements of the model are set out in the table below. Note that this focuses primarily on (changes in) costs, with most of the benefits being less easily quantified, though still being of great importance to the changes.

Table 2.3 Model scope and key costing hypothesis

| Metric | Proposed Harmonised System - specific changes | Nature of the change | Cost assessment assumptions |
|---|---|---|---|
| **System design** | Mandatory<br>System design: consumer and professional use | Increased number of submissions in countries with | Costs under baseline - costs of submissions in required format (To individual MSs). |

[8] *'Consumer' goods are thosed assumed to be those directly available for purchase and use by the general public.*

[9] *'Professional' goods are thosed assumed to be used away from industrial facilities but not made directly available to the general public for sale.*

[10] *'Industrial' mixtures are assumed to be those goods used only at industrial facilities.*

| Metric | Proposed Harmonised System - specific changes | Nature of the change | Cost assessment assumptions |
|---|---|---|---|
| | | voluntary systems (especially from companies trading domestically only).<br><br>Companies trading in multiple MS could already be providing submissions under voluntary systems. | Costs under harmonisation - additional costs associated with increased number of submissions (due to shift from voluntary to mandatory submission system and potentially increased frequency of re-submissions). |
| **System design** | Mandatory<br>System design: industrial use | The responses from the industry consultation suggested that in voluntary systems for industrial mixtures companies may be less likely to submit data to Poison Centres instead making use of a range of other options including 24/7 numbers. Switch to mandatory systems will see number of submissions will increase. | Costs under the baseline: mixed – companies in some Member States will already provide data to Poison Centres. Others will be less likely to do so. Assumption within the model that for industrial mixtures within voluntary states for domestic only do not provide information to Poison Centres<br><br>Costs under harmonisation - for industry to industry reporting vary depending on sector, size, MS, number of companies affected (industry to industry sales), number of submissions (depending on number of products and frequency of change) and unit costs. |
| **Reporting format and content** | Reporting: consumer and professional uses<br><br>Use of an electronic submission (e.g. standardised XML template).<br><br>Content: SDS-like with more information on breakdown of substances<br><br>Ranges allowed with option of exact concentrations | Companies trading domestically: additional costs/ savings associated with the change in reporting format (potentially coupled with increased number of submissions (voluntary to mandatory change).<br><br>Companies trading in multiple MS: additional cost/ cost savings associated with the change in the system design. Potentially significant reduction in cost of reporting following harmonisation. | Costs under baseline - costs of submissions in required format (by individual MSs) for companies trading domestically and in multiple MS.<br><br>Costs under harmonisation (domestic trading) - additional costs associated with increased number of submissions (due to shift from voluntary to mandatory submission system, potentially increased frequency of re-submissions and relative change in format.<br><br>Costs under harmonisation (multiple MS trading) - additional costs associated with increased number of submissions and potentially frequency of re-submissions; but cost savings due to harmonised format and reduced cost per additional Member State. Costs/savings vary dependent on sector, size, MS, number of submissions, unit costs, domestic vs multiple MS trading. |

| Metric | Proposed Harmonised System - specific changes | Nature of the change | Cost assessment assumptions |
|---|---|---|---|
| | Reporting: industrial use | Industry to industry mixtures to be brought into the scope of reporting. SDS only plus additional data to be available on request. | Costs under the baseline: mixed – in some Member States companies already provide data to Poison Centres, in others do not<br>Costs of industry to industry reporting (SDS sheet) vary depending on sector, size, MS, number of companies affected (industry to industry sales), number of submissions (depending on umber of products and frequency of change) and unit costs. |
| **UFI** | UFI: new products (consumer and professional use) UFI to be added to all product labels (including existing stock) | UFI is to be displayed on the products Labelling, printing, software, administrative, marketing costs | Costs of UFI under baseline: none.<br><br>Costs of UFI under harmonisation: annual costs for companies producing consumer and professional products including labelling, printing, marketing and administrative costs to generate, display and report UFI. Costs vary depending on sector, size, MS, number of submissions and frequency of change. |
| | UFI: re-labelling stockpiles will have a transitional period to minimise impact on industry | Transitional phase will be used to implement the UFI. This will minimise the impact on industry. To assess the benefit of this aspect costs also have been calculated to demonstrate cost without transitional phase. | Costs of UFI under baseline - none.<br><br>Costs of UFI under harmonisation for stockpiles if transitional phase were not incorporated: costs per company (temporary) to re-label stockpiles/ existing stock. Costs vary depending on sector, size, MS and stockpiled volumes. |
| | UFI: new products (industrial use) | UFI is to be generated and submitted on SDS. Generating and reporting costs. | Costs of UFI under baseline - none.<br><br>Costs of UFI under harmonisation: annual costs for companies producing industrial products including costs to generate and report UFI. Costs vary depending on sector, size, MS, number of submissions and frequency of change. |

## Developing the base case cost model and other scenarios

Table 2.3 sets out the scope of the assessment covered by the cost model. The results of the consultation with industry have been used to help define the key variables within the model, such as unit price per submission, in order to provide the quantitative cost/savings estimates. As a further step to assess the sensitivity of the results and key assumptions made within the model, a sensitivity analysis has been carried out as a set of scenarios. All additional scenarios have been based on the

original version of the model which is referred to as the basecase (scenario A) with the following variations:

Scenario A – Base case

Scenario B – Reduction in the frequency of submissions (compared to base case)

Scenario C – Reduction in the number of internationally traded goods (i.e. not all products are sold to all Member States)

Scenario D – Standalone scenario to assess what the impact of the UFI would be without a transitional phase-in period.

Scenario E – Implementation of a group UFI for products with similar composition

Scenario F – Scenarios B, C and E combined.

The remainder of this section detail the methodology used to help derive the base case model, followed by further detail on the other scenarios.

## 2.6 Description of base case

### Number of companies and submissions

The model is based on consideration of the number of companies, products and submissions on one hand and unit costs associated with different aspects of the current and proposed harmonised reporting system on the other.

Assessment of the number of companies and submissions is vital to operating the model and calculating costs or savings.

The model uses published Eurostat data on the number of companies within each key sector, including by size and specific Member State. The model does not predict changes in the number of companies in the future, i.e. total number of companies per sector in each Member State is assumed to be static. A breakdown on the number of companies by sector is provided in Table 2.4 below.

Table 2.4 Number of companies by sector across the EU based on Eurostat data for companies in 2011 (most recent complete year).

| Sector | Large sized | Medium Sized | Small Sized | Micro Sized | Total |
|---|---|---|---|---|---|
| **Industrial Gases** | 22 | 51 | 118 | 257 | **448** |
| **Dyes and Pigments** | 30 | 75 | 151 | 358 | **614** |
| **Basic Inorganics** | 51 | 135 | 260 | 597 | **1043** |
| **Basic Organics** | 107 | 258 | 529 | 1139 | **2033** |
| **Fertilisers** | 63 | 155 | 311 | 764 | **1293** |
| **Pesticides and Agrochemicals** | 30 | 78 | 152 | 374 | **634** |
| **Paints and Varnishes** | 146 | 534 | 1181 | 2314 | **4175** |
| **Soaps and Detergents** | 78 | 299 | 707 | 2682 | **3766** |
| **Perfumes and Toiletries** | 95 | 353 | 828 | 3137 | **4413** |
| **Adhesives** | 31 | 79 | 155 | 359 | **624** |
| **Chemical production (Not Otherwise Covered)** | 92 | 470 | 1054 | 2797 | **4413** |
| **Total** | 745 | 2487 | 5446 | 14778 | **23456** |

In the case of consumer and professional use products, the total number of affected companies is estimated using the results of the consultation undertaken for this study which asked respondents to indicate whether they are submitting registrations to the PCs and to identify their production for 'industrial', 'consumer' and 'professional' products. This allowed the team to identify what proportion of the total number of companies manufacture only consumer and professional mixtures. To extrapolate this data to an EU level Eurostat data was taken for a number of companies as a whole. These companies were chosen from certain sectors (identified by NACE codes) where reporting to Poison Centres is expected to be relevant.

The results of the consultation with industry through the questionnaire indicated that between 5% and 25% of companies trading in the EU (varying for different size bands) manufacture mixtures for the consumer and professional market only. In contrast 75% to 95% of businesses manufacture and sell goods as industrial mixtures to other companies. Many companies will of course do both, and that is included in the latter figure

Following the assessment of the number of companies affected (by sector, size and Member State), the number of submissions to Poison Centres was estimated. The model calculates the total number of submissions by using the consultation responses that provided data on the average number of products and Poison Centre submissions per company, per year (by sector, size and MS). The larger the company, the higher the average number of products manufactured (in general, and on average).

Similarly, the average number of submissions for companies trading domestically only is lower than for companies trading in multiple Member States. Total number of submissions per company per year for those trading in multiple Member States (and hence the costs of reporting) was calculated by multiplying the average number of products within each company type (derived from consultation responses), frequency of reporting per year and average number of trading partners. For instance, if a company is trading 100 products in 5 Member States, total number of reporting submissions will be 500 per year[11]. As a final step, the model then allocates these submissions to all three reporting systems – simple (SDS only), SDS plus additional data or advanced (additional data to SDS and use of bespoke tools) – using the distribution of 40%, 30% and 30% respectively (see Table 2.2 for allocation of Member States to sliding scale). This is calculated based on the consultation responses.

In the case of industrial use products a similar method to consumer/professional has been used to calculate the total number of affected companies based on the consultation activities. The number of companies included in the estimates is then calculated by multiplying the total number of companies (based on Eurostat data) by the share of the companies affected.

In particular one key difference between the consumer/professional and industrial mixture category relates to the number of submissions provided to Poison Centres within Member States that have voluntary systems. As industry facilities already manage risk and safety on a daily basis the industry consultation suggested that submission of data to poison centres may be less likely to occur as companies use alternative approaches. The model has been developed therefore on the assumption that for those companies trading domestically with industrial mixtures in voluntary systems the assumption has been made that data is not submitted. For those companies with industrial mixtures trading internationally and submitting data under

[11] *Under the base case scenario. In practice, it is recognised that not all of a company's products will be sold into all Member States, and this aspect is explored in the other scenarios.*

both mandatory and voluntary systems they will submit data in 50% cases (in the case of SMEs) and 75% for large companies under the baseline. Under proposed harmonisation, these companies will submit data in all cases.

The model includes the functionality of changing the number of companies and submissions under the baseline and under the harmonised reporting system. This includes the potential increase in numbers of submissions for industrial use products with the switch from voluntary to mandatory reporting for companies trading domestically only. Similarly, in the case of consumer and professional use products, shift from voluntary to mandatory reporting system will affect companies trading domestically and will result in an increase in the number of submissions. While no quantitative estimate of such increase was provided by the consultation responses, the model assumes 50% increase in number of submissions after harmonisation by companies trading domestically only in Member States with voluntary reporting system at present.

### Harmonised reporting to Poison Centres

Introduction of the new harmonised reporting system will have different impacts on those companies trading internationally compared to those that trade domestically only.

For companies trading domestically only, the impact of the harmonised reporting format will depend on the current reporting system. Companies trading in those Member States with the simple, SDS-based reporting format will see additional costs due to a shift to more demanding reporting. Conversely, companies trading in Member States with advanced reporting systems might see a reduction of costs as a result of the simplified reporting.

For companies trading in multiple Member States, the impact of the proposed harmonised system will be driven by the balance between the changes from simple to harmonised reporting system in some Member States and from advanced to harmonised system in other Member States (and little change in other Member States which already have systems similar to the harmonised system).

More importantly, for those trading in multiple Member States, total costs or savings are driven by the reduced costs associated with having to produce different information, in different formats, for different Member States. These are calculated based on the number of companies and submissions, distribution of trade partners and reporting unit costs under the baseline and after harmonisation. The model assumes that the unit costs of submission under the harmonised reporting system are similar to the existing SDS plus additional data information format. The SDS plus additional information category covers those Member States that require (in addition to the SDS) further information which might include further breakdown of composition, additional toxicological information or other data not held within the safety data sheet. This reflects that the harmonised format requires the use of a bespoke template and potentially more information on composition than used for a typical SDS.

Calculation of the net costs or savings is sensitive to the changes in the number of submissions either due to significant changes to the number of companies covered by the Poison Centres reporting requirements under the harmonised system or due to increases in frequency of submissions (for instance due to frequent changes to product formulations). This is an issue which has been explored further within scenario B, discussed later in this chapter.

The model allows the number of companies and submissions under the current reporting requirements and under the proposed harmonised system to be differentiated. The unit costs used in the model are based on the analysis of the

consultation responses and presented in Appendix D along with other key assumptions.

In the case of industrial use products, the proposed harmonised system envisages introducing certain additional requirements. This could include the information contained in an SDS plus a 24 hour hot line number as an alternative to providing the full amount of information to Poison Centres. Overall, the switch from voluntary to mandatory systems will result in net additional costs as those companies are not reporting (or are less likely to) under the present system. Costs of harmonisation for industrial submissions are calculated by multiplying the number of submissions by sector, size and MS by unit cost of submissions per year (145 Euro/ per submission per year (calculated as an average of responses for Question 20 for companies producing industrial use products)). This value has been based on question 13 of the industry questionnaire relating to the information provided for those companies that only trade industrially and question 20 of the industry questionnaire on post harmonisation costs.

### Introduction of the UFI

Introduction of the UFI will have different impacts on the companies producing consumer and professional use products as compared to companies producing industrial use only products. This is because, for industrial mixtures, the UFI is expected to be only required on the SDS, not on the product label.

In the case of consumer and professional use products, introduction of the UFI will require generation and reporting of the UFI numbers as well as adding these to the product labels. The addition of the UFI will be implemented through a transitional phase to minimise the impact on industry for relabeling of products. The cost model has been designed to assess the benefit of this transitional phase and what additional costs might be faced if it is not used. First of all, the costs associated with the introduction of the UFI are estimated based on the number of companies and products affected per year and the unit costs per product per year (340 Euro/ product per year as suggested by the consultation responses (calculated as a sum of average estimates of responses for Question 24 (i, ii and iii) for companies producing consumer products)).

The use of a transitional phase will be used to minimise the impact on industry where it would be expected that re-labelling existing stockpiles would result in substantial albeit time-limited costs to companies. To explore the importance of this transition period, the hypothetical costs to industry without any phase-in have been calculated as a separate component. In order to calculate these costs, the total UFI costs associated with dealing with stockpiles are calculated based on the number of companies affected and average costs per company per year, differentiated by their size. The assumption used suggests that any company manufacturing consumer and professional use products and falling within the scope of the Poison Centre reporting is expected to have some quantity of stockpiled goods. The estimated unit costs per company are set out in Appendix D.

In the case of industrial use products, the proposed harmonised system envisages generation of a UFI and its inclusion within the SDS document. The costs associated with the UFI under the baseline are zero. UFI costs under the proposed harmonisation depend on the number of companies and products affected and unit costs of the UFI generation. Analysis of the consultation responses (those indicating industrial mixtures only) suggested average costs of about 60 Euro/product per year (calculated as a sum of average estimates of responses for Question 24 (i, ii) for companies producing industrial use products).

Overall, the model suggests that introduction of the UFI will result in additional costs to companies producing consumer, professional and industrial use products. Introduction of a transition period in relation to UFI generation and re-labelling of stockpiles in particular could alleviate the total UFI cost burden.

### Calculation of costs or benefits

The model then presents the results differentiated by:

- Member State
- Sectors (separately for (1) paints, varnishes and inks, (2) soaps and detergents and (3) other sectors). These 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. This would mean the burden on providing data to Poison Centres may impact on these sectors differently (more significantly) to the others under review, although it is recognised that there may be other sectors in similar positions.
- Industrial use products, differentiated between harmonised reporting costs and UFI.
- Consumer and professional use products, differentiated between harmonised reporting costs, UFI and stockpiles.

The costs are expressed in Euros on an annualised basis. Net present value is also calculated using a 10 year appraisal period and a 4% discount rate. To further aid understanding of the base case scenario, a set of worked examples has been provided in box 2.1 for a company trading within a hypothetical Member State with a similar typology to the proposed harmonisation as shown in the sliding scale (Figure 2.2).

## Box 2.1 Worked example of cost estimates

This worked example of how costs have been estimated has been based on a large company (>250 employees) manufacturing consumer and professional use products in a hypothetical Member State with a similar typology to the proposed harmonisation and operating in a sector other than varnishes, paints and inks or soaps and detergents which typically have largely product ranges. It is assumed that the hypothetical Member State features a voluntary registration system with a simple SDS submission format.

Assuming that the company is only trading domestically the average number of products to register with the Poison Centre per year is 240 (derived based on the consultation results). In the case of the 'other sector' (i.e. non soaps, detergents or paints, varnishes and inks sectors), the assumed frequency of product submissions per year is one resulting in total number of product registrations per year of 240. Having regard to the simple submission format, the costs of product registrations under the baseline are 16,800 Euro per year (calculated as 240 (submissions) multiplied by 70 Euro (per submission per year)). Proposed harmonisation would result in a relatively more demanding reporting format and the total costs of 50,400 Euro per company per year (calculated as 240 (submissions) multiplied by 210 Euro (per submission per year)). Unit costs associated with different reporting formats are derived from the consultation results. In this example, introduction of a harmonised reporting format would result in net additional costs of 33,600 Euro per year. Furthermore, introduction of a harmonised system would entail generation and display of UFI codes on the product labels. Total annual costs associated with UFI generation are estimated at 81,600 Euro per company per year (calculated as 240 products multiplied by 340 Euro per product submission). Total ongoing net costs are calculated at 115,200 Euro per year. In this case, introduction of proposed harmonised system along with the additional UFI requirements would result in additional net costs to the company.

Now assume that the same company is trading in multiple Member States as opposed to domestically only. According to the consultation results, the average number of products in such a case is 1,274. The average number of trading partners is 21 (i.e. large companies trading to multiple Member States on average trade with 21 EU Member States). The resulting number of product submissions per year that such a company has to make is 26,754 (calculated by multiplying 1,274 products by 21 Member States submissions. This total number of annual submissions is distributed among Member States with different reporting systems – simple, medium, advanced ones. The unit costs of such Poison Centre submissions are 70 Euro, 300 Euro and 700 Euro per product submission per year, respectively. To derive total annual costs to such a company under the baseline, one needs to allocate the total number of Poison Centre submissions across 21 Member States to three different reporting formats that exist currently. Consultation results suggest the split of 40%, 30% and 30% between simple, medium and advanced reporting systems. This results in total annual cost per company of 8.8 million Euro per year. Introduction of a harmonised reporting system would result in an increase of submission costs in Member States where currently a simple reporting system is in place. However, such an increase in submission costs in some Member States would be compensated by a relative decrease in submission costs in countries with the advanced reporting system. The total annual costs per company under the harmonised system are calculated at 5.6 million Euro (derived by multiplying total number of annual submissions across all trading partners (26,754) with the unit submission costs of 210 Euro). In such case, introduction of a harmonised system would result in 3.2 million Euro annual savings.

Similarly, to the example above, introduction of a harmonised system would entail generation and display of UFI codes on the product labels. Total annual costs associated with UFI generation are estimated at 0.4 million Euro per company per year (calculated as 1,274 products multiplied by 340 Euro per product submission).

Total ongoing net cost savings for a company trading consumer and professional use products in multiple Member States are calculated at 2.8 million Euro per year.

## 2.7 Developing the sensitivity analysis – Scenarios B - F

### Overview

The industry consultation questionnaire was used to better understand the current systems and activities carried out by industry in submitting information to the Poison Centres around the EU. The results of the questionnaire have also been used to help define the key variables detailed earlier in this chapter which have been used within the cost model. These variables when combined with the data from Eurostat company information have been used to extrapolate costs and savings for the EU based on the current situation and effects of the proposed harmonisation and UFI.

In developing the basecase (scenario A) the project team were able to identify specific variables which would potentially have a significant effect on the final quantitative results provided by the cost model. On that basis as part of a sensitivity analysis using the basecase scenario as the blueprint additional scenarios were developed to vary specific variables, the specific detail of how they are varied is provided in Appendix D with a summary description provided below.

The additional scenarios explore alternative data/assumptions on which it was not feasible to collect data during the consultation exercise, but which may better reflect the real-world situation.

### Scenario B: Reduction in the frequency of submission

The cost model is based on a unit cost per submission per number of products per company to the different categories of system that exist (SDS only, SDS+, Advanced). Therefore the frequency of submissions by companies will have a direct bearing on the overall results. The frequency of submissions used within the basecase are based on the averaged results provided from the industry consultation. However in some cases the frequency of submission seemed high based on the project team's knowledge of how these industries function.

In particular, the consultation responses suggested, in some sectors that there would be multiple submissions per year, and that each of these could incur the same costs as the original submission. Clearly this is not realistic if only a minor amendment is made to a product, for example. The harmonised system should not lead to substantial new/resubmissions, except where not currently mandatory, although in some sectors there are very frequent resubmissions due to even small changes in composition (this is also affected by the concentration limits/bands chosen for the harmonised system). Resubmission would be much less resource-intensive than the first submission so e.g. if submitting 4x per year (this is an average figure), the additional resource associated with the 2nd, 3rd and 4th submission would be minor e.g. 10% of the original submission, hence the frequency in the model is adjusted to 1.3 per year.

To assess the issue of frequency Scenario B provides the costs/savings based on a revised frequency lower than in the basecase.

### Scenario C: Reduction in the number of internationally traded goods

The cost model is developed based on unit cost per submission per number of products per company. The industry consultation provided valuable information on the trading behaviour of companies and the numbers of Member States traded into for those trading internationally. However the market split for trading internationally was less clear. So for example if company A has an average of 100 products and trades into 5 Member States (based on the industry consultation results), information was not collected on how many individual submissions there were. The basecase scenario

assumes that all 100 products are traded to all 5 Member States, which would equate to 500 required submissions of data to Poison Centres, with associated overestimate in costs (both because the actual number of submissions will generally be lower, but also because some Member States already have similar systems). In reality the situation may be more complex and perhaps company A trades 60 products to one Member State only, and then 10 products each to the remaining 4 Member States, equating to 100 data submissions. Scenario C incorporates a number of assumptions to reduce the number of internationally traded goods (or more correctly reduce the number of submissions for internationally traded goods) on that basis. As a caveat to this scenario the reduction in the number of internationally traded goods is applied evenly across the EU, and no distinction has been made as to where specifically companies trade beyond what has been provided in the industry consultation.

### Scenario D – Impact of adopting the UFI without a transitional phase

The Commission Services has confirmed that it intends to propose, with adoption of the UFI, a transitional phase of between 2 and 3 years to minimise the impact on industry, including for relabeling of existing stockpiles. The Commission Services would also like to understand what the impact would be on industry if this transitional phase was not utilised. Scenario D provides the basecase scenario model with the addition of calculated costs for industry to implement the UFI immediately (i.e. with these relabelling costs).

### Scenario E – Implementation of a group UFI for products with similar composition

The responses from the industry consultation highlighted that, in some cases, the use of a 'group' UFI would reduce the burden on industry where product ranges had similar mixtures. A good example is a range of paint products where small incremental changes are used to change a shade of colour. Scenario D applies a reduction value to reduce the number of UFIs needed by industry on the basis that a group UFI could be implemented.

### Scenario F – Scenarios B, C and E combined

Scenario F provides the case where the variations quoted in Scenarios B, C and E have been implemented in combination.

# 3 Costs and Benefits for Industry

## 3.1 Industry survey

In October 2014 the two questionnaires, one aimed at industry and one aimed at Poison Centres, were launched and allowed to run open to responses for three weeks. To help encourage responses to the questionnaires (presented in full in Appendix B) prior notification was given through the European Commission to representative trade bodies for industry and through the CARACAL meetings for Poison Centres. Both groups were also notified by e-mail when the two questionnaires went live. Both sets of questionnaires received a high level of response with 554 responses from industry operators plus position papers from two international trade associations for the industry questionnaire.

## 3.2 Overview of survey responses

The industry questionnaire was designed to present both quantitative questions about the current policy landscape and proposed harmonisation and the UFI, as well as qualitative questions to allow respondents an opportunity to voice their opinion on the proposed changes. To help provide greater detail on the responses given and identify specific sensitivities to the proposed harmonisation, those taking part in the questionnaire were also asked to identify their main sector of business, their company size, location of head office and the number of EU Member States in which they trade.

In selecting industry sectors by which to categorise responses, the NACE industry code scheme was used. This is also used by Eurostat. Figure 3.1 indicates that the key sectors which responded to the questionnaire were the 'paints, varnishes and inks' and 'the soaps and detergents' sectors. There were also a large number of responses who selected the 'other' category. Closer examination of this sector and the comments box made available to respondents demonstrated that the majority of those that selected the 'other' category had production processes which spanned multiple NACE codes and as such it was difficult for the respondent to pick one 'main' industry sector. The responses within the comments box also highlighted one new industrial activity not included within the original set of choices: the manufacture of pharmaceutical products.

Figure 3.2 provides details on the location of the head office of those industry operators that responded. This demonstrated that the key countries were Germany, the Netherlands, Spain and the UK, with France and Italy making up smaller fractions. Those companies with head offices outside of the EU were largely situated either in the USA or Switzerland. It is important to recognise that head office does not always denote sites of production but does provide at least an indication of where respondents are based.

Figures 3.3 and 3.4 provide more detail on company size information and breakdown of company size by industry sector respectively. Company size definitions were based on those accepted under Commission Recommendation of 6 May 2003 and referenced within Article 3(36) of the REACH regulation for number of employees and company turnover. The pie chart in Figure 3.3 shows an even split between large size companies (>250 employees) and those with 'SME' status (<250 employees) with 42% of the responses from large sized and a further 42% from SMEs. A further 16% opted not to provide company size information. Within the SME companies that responded, the greatest fraction fell within the medium sized grouping (>50 employees, <250 employees) with micro sized (1 – 10 employees) companies making up the smallest fraction. Closer scrutiny of this information is provided in Figure 3.4 which provides a breakdown by industry sector. This graph demonstrates the highest

proportion of SME companies (60%) were within the 'paints, varnishes and inks' sector. Similarly the mineral construction products (55%) and soaps and detergents (50%) sectors also had high proportions of SME companies. In practice, there are often more SMEs than larger companies in many sectors, but as with many surveys of this type, the response rate from SMEs is typically lower.

Figure 3.5 provides a breakdown of industry sector of the number of Member States that operators trade into. This demonstrates that the 'alcohols, solvents and reagents' and 'mineral construction products' had the highest proportion of internationally-traded goods with 35% of the respondents stating that they traded into 21 Member States or more. Conversely the 'industrial gases' and 'water treatment chemicals' had the highest proportion of (only) domestically traded goods.

Figure 3.1 Number of replies by main business sector of operation

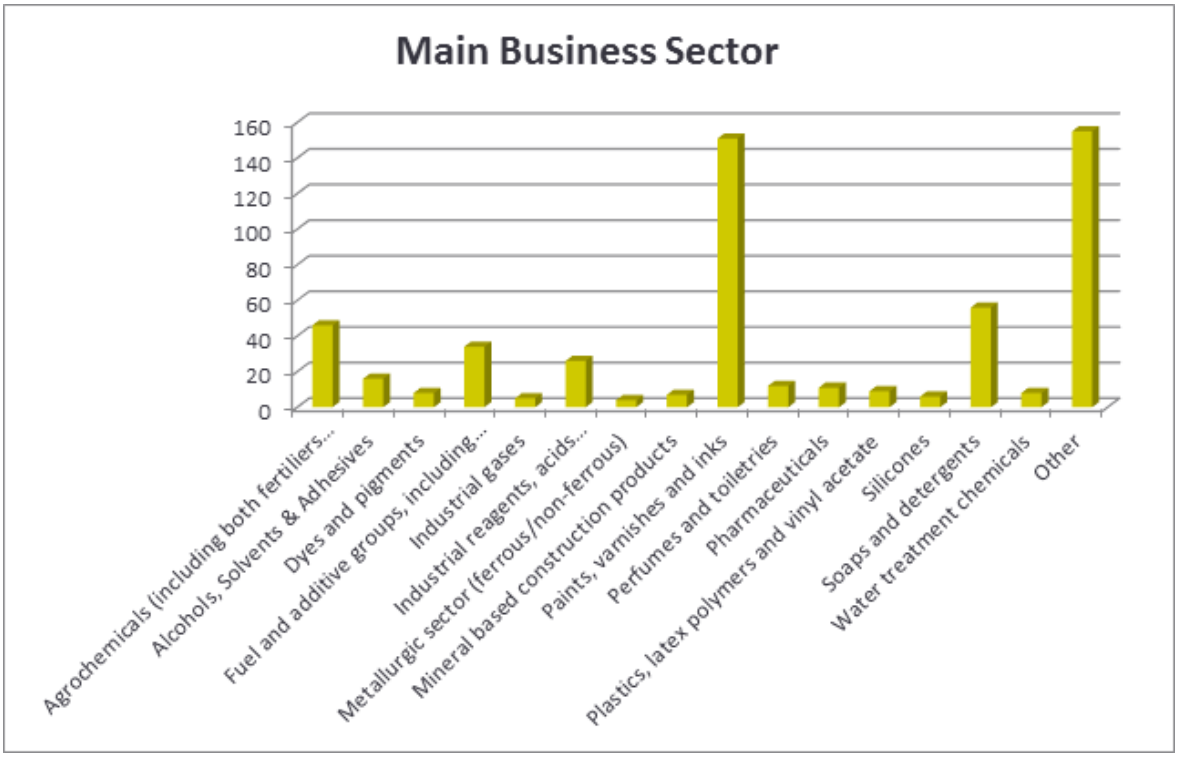


Figure 3.2 Number of replies by location of head office

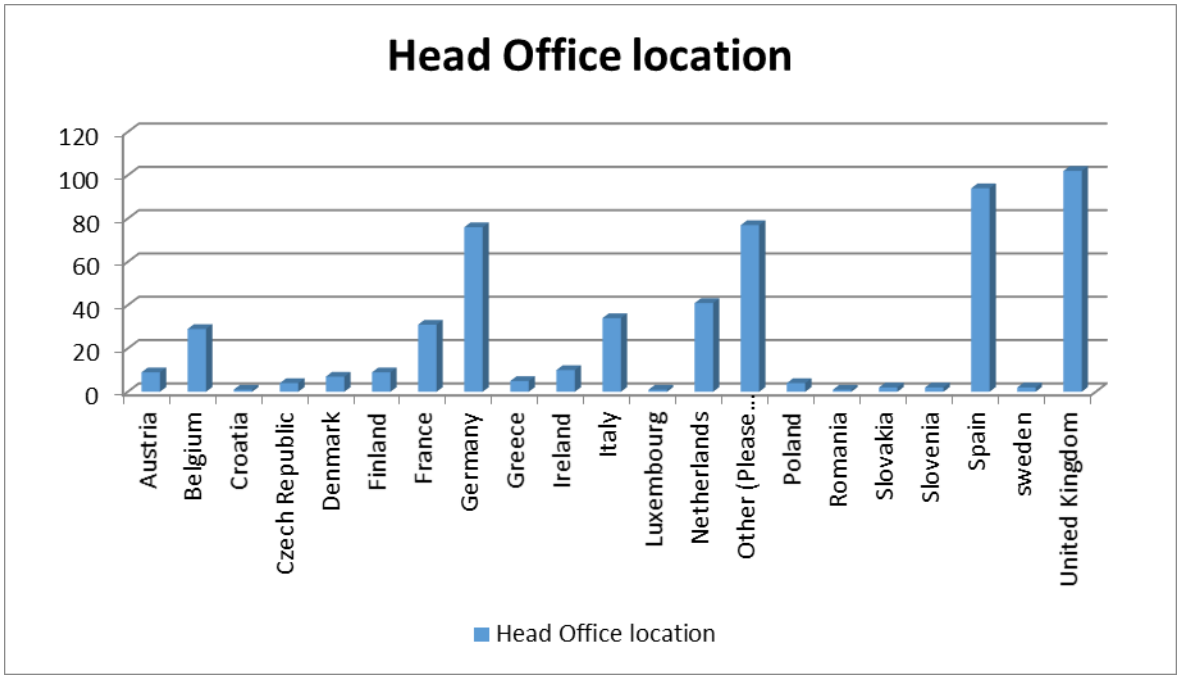



Figure 3.3 Number of replies by company size

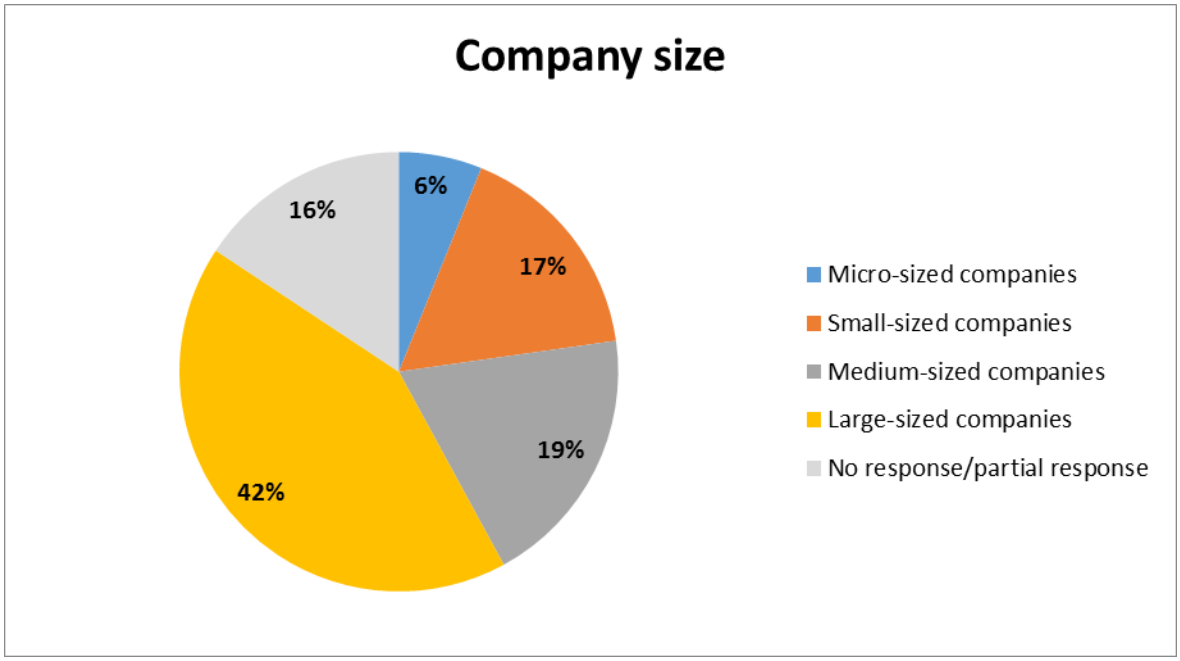


Figure 3.4 Breakdown of company size by industry sector

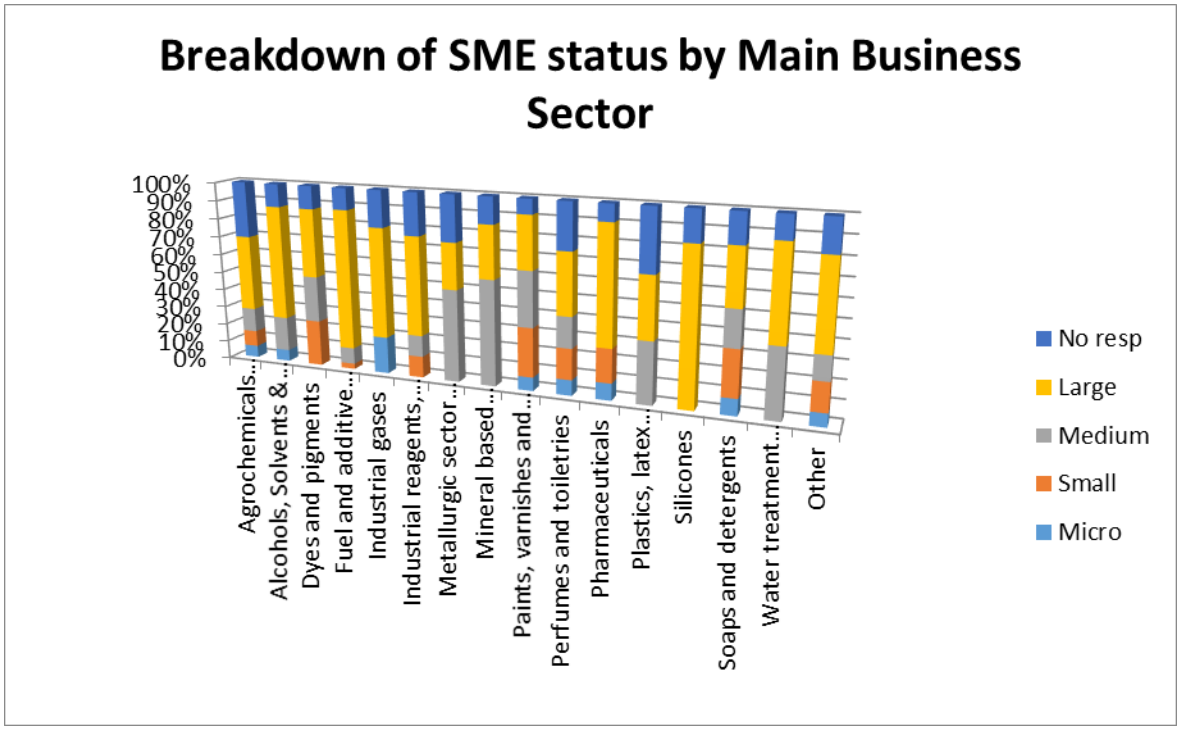
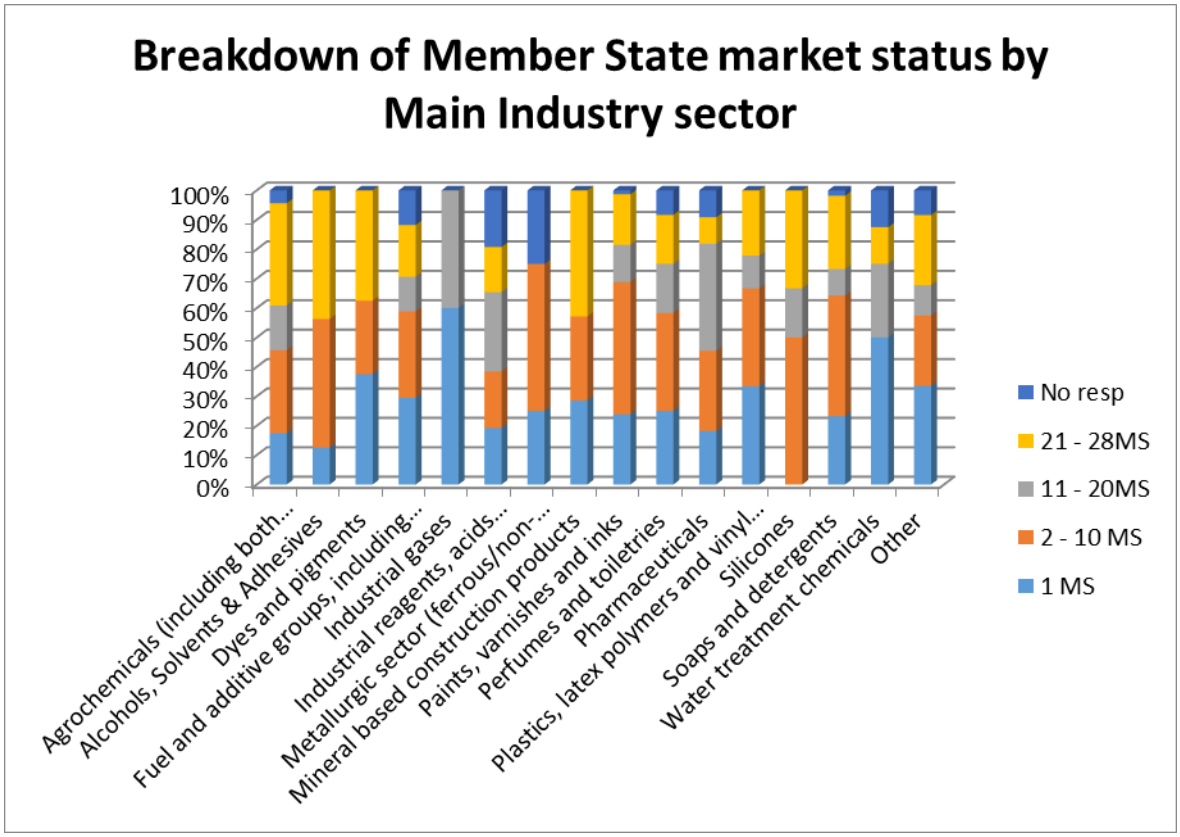



Figure 3.5 Breakdown of trading in multiple Member States by industry sector



## 3.2 Costs and benefits of harmonisation for industry

### Quantified benefits and costs

The quantitative results of the cost model for industry presented and discussed within this chapter cover the details from the basecase (Scenario A) unless otherwise indicated. A more complete discussion of the other scenarios and sensitivity analysis is provided in chapter 5.

Based on the results of the cost model the existing costs for those companies reporting data to Poison Centres depend on the level of detail required within the information provided, complexity of data submission format, and cumulative effective of submitting into multiple Member States. On that basis, the introduction of the harmonised reporting format for those companies submitting such information to Poison Centres at the EU scale would result in net savings.

These savings, however, depend on specific details of the proposed harmonisation format, such as ability of companies to report chemical substances within defined concentration ranges rather than the exact compositions. They also rely on the additional burdens beyond the harmonised format to be dropped in favour of harmonisation. For example some Member States require the provision of photographs of labels and packaging additional to the poisons information provided to Poison Centres. In this example harmonisation would replace all of the requirements, not only the data component of the submission. Harmonisation would also be expected to lead to an increase in the number of companies reporting in Member States with currently voluntary reporting systems (seven Member States of the EU28 have voluntary system with Spain currently in the process of moving to a mandatory system for the remaining specific conditions which are voluntary requirements), particularly those with industrial mixtures.

Furthermore, companies only trading domestically could face additional costs in some Member States where currently a simple reporting system is in place. In most cases, these Member States also have a voluntary rather than mandatory reporting system. Harmonisation will then result in additional costs associated with both a relative increase in unit submission costs due to more complex reporting requirements, and also an increase in the number of reporting companies / products reported upon.

Beyond these general principles at sector level, those sectors with large product ranges or more frequent need to submit information (e.g. due to frequent product changes) would feel the effects of harmonisation more strongly. The estimates for frequency of submission within the basecase scenario (Scenario A) have been taken from the averaged results provided from the industry consultation. During the consultation the reason for the frequency of submitting data multiple times a year related to the complexity of the substance mixture and potentially changing composition, particularly in batch processes. The use of SDS with concentration ranges allows for some variation of the product on the basic formula, while the use of exact composition or tight ranges may require more frequent updates and hence more frequent submissions. The distinction between the submissions of data for a 'new' product and resubmission of data for a minor change or variation in composition based on existing data was not clarified during the questionnaires provided.

For example the paints, varnishes and inks sector which includes large product ranges and potentially a need to submit data more frequently was estimated under the basecase to currently provide data on a per product basis three times per annum. Under harmonisation the survey results suggest that (on average) this would increase to four times per product per annum as the use of tighter concentration ranges would require more updates. However the move to harmonisation in this case would see greater benefits to this sector than others due to the overall costs (due to unit costs x

frequency) across a range of data format types, particularly the shift from submitting data in the 'advanced' format to 'harmonised' format. This is true particularly for companies selling into multiple Member States.

However those companies in the paints, varnishes and inks sector which trade only domestically, and which also fall within the Member States with current data burden lower than harmonisation may see net costs rather than savings. Again this would be due to the broader range of products produced and more frequent need to submit data compared to other sectors included in the study. This would potentially be of greatest concern for the SMEs in those countries with currently lower data burden.

Table 3.1 provides a breakdown of net savings in Euros per year at EU level. This has been based on the proportion of companies which produce mixtures for the consumer/professional market and industrial mixtures market separately. This disaggregation is due to the different requirements of harmonisation between these categories. When considering the estimated number of products per year subject to PC registration, consumer and professional use product account for about ¼ of the total number, while industrial mixtures account for the remaining ¾ of the total number.

Table 3.1 Benefits of harmonised reporting under scenario A (consumer and professional use products) for all EU Member States plus Norway.

| | **Savings, Euro per year (total EU) (annualised costs)** | | | | |
|---|---|---|---|---|---|
| | **Paints, varnishes and inks** | **Soaps and detergents** | **Other sectors** | **All sectors aggregated** | **NPV, Euro (10 yr)** |
| **Consumer products (PC submissions)** | -1,000,000,000 | -130,000,000 | -610,000,000 | -1,740,000,000 | -15,400,000,000 |
| **Industrial mixtures (PC submissions)** | -320,000,000 | -180,000,000 | -390,000,000 | -890,000,000 | -7,800,000,000 |
| **Overall Total Savings** | -1,320,000,000 | -310,000,000 | -1,000,000,000 | -2,630,000,000 | -23,200,000,000 |

The headline figures provided in Table 3.1 illustrates that at European level the harmonisation of data submission requirements presents significant cost savings under the base case for scenario A. However the base case scenario, which based on the responses from the industry questionnaire, makes certain necessary assumptions which may reflect an overestimate of such savings. For this reason, as part of a sensitivity analysis, additional scenarios (B – F) have been created to test the assumptions within the base case scenario. Based on these additional scenarios the authors believe that scenario F represents the best estimate for the overall costs/savings, with a net EU saving of around €550 million per year. Further discussion of the sensitivity analysis and other scenarios is provided in chapter 5.

In order to fully understand the complexity of the situation presented and range of data formats and business types it is necessary to look at the different cost elements in greater disaggregation. Table 3.2 provide a breakdown of information by Member State. Duplicate Tables for scenarios B – F can be found in Appendix E. Within this table the negative values (in black) represent cost savings to industry while positive values (in red) represent costs incurred. The table also indicates at Member State

level the difference between those companies that trade only domestically as well as those that trade to multiple Member States.

For those countries where the existing data submission requirements currently represent a lower burden than the proposed harmonisation, the harmonisation would represent an increase in effort (equated as staff time) to meet the requirements and thus greater cost. This would be offset in the case of companies trading with multiple Member States where both more advanced systems and more simple systems exist. However, inevitably for those trading only domestically in countries with systems of currently lower burden there would be net costs.

Returning to the worked example in box 2.1 looking at a 'large' sized company in hypothetical Member State within the consumer/professional sector. For those large sized companies within this typology on the sliding scale (other than varnishes, paints and inks or soaps and detergents sector) that trade only domestically, a net cost of 13,200 Euros is incurred by the move to harmonisation. At the same time those large companies in the hypothetical Member State that trade in multiple Member States could be expected to make a net saving of 9 million Euro. This would suggest that the overall rewards from harmonisation outweigh the costs, even when the adoption of the UFI (estimated to be a cost of 1.2million Euro) is factored into the equation.

Table 3.2 Scenario A - Further breakdown of extrapolated costs and benefits by Member State (using Eurostat data) – Values are presented as thousands of Euros.

| | AT | BE | BG | HR | CY | CZ | DK | EE | FI | FR | DE | EL | HU | IE |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Consumer, Professional and industrial mixtures** | | | | | | | | | | | | | | |
| **No. of Comps** | 107 | 214 | 170 | 90 | 69 | 284 | 83 | 29 | 89 | 789 | 1080 | 222 | 167 | 65 |
| **SME** | 98 | 196 | 165 | 88 | 69 | 266 | 80 | 29 | 80 | 733 | 999 | 211 | 157 | 57 |
| **Large** | 9 | 18 | 5 | 2 | 0 | 18 | 2 | 1 | 9 | 56 | 81 | 11 | 11 | 8 |
| **Costs Domestically trade only – Total** | -890 | 4,200 | -1,200 | 1,400 | -280 | 9,400 | -3,000 | 680 | 1,500 | -32,000 | -69,000 | -11,000 | 3,300 | 760 |
| **SME** | -500 | 3,100 | -820 | 1,300 | -280 | 7,000 | -2,900 | 680 | 930 | -26,000 | -43,000 | -7,700 | 2,300 | 660 |
| **Large** | -390 | 1,200 | -360 | 22 | 0 | 2,400 | -82 | 3 | 530 | -5,500 | -26,000 | -3,200 | 960 | 100 |
| **Costs Multiple MS traded** | -54,000 | -87,000 | -46,000 | -7,900 | -4,800 | -120,000 | -9,700 | -2,800 | -41,000 | -240,000 | -520,000 | -65,000 | -64,000 | -28,000 |
| **SME** | -4,700 | -7,800 | -5,700 | -2,400 | -4,800 | -10,000 | -3,400 | -1,200 | -3,300 | -36,000 | -56,000 | -5,900 | -8,300 | -3,600 |
| **Large** | -50,000 | -80,000 | -41,000 | -5,500 | 0 | -110,000 | -6,400 | -1,600 | -37,000 | -200,000 | -460,000 | -59,000 | -56,000 | -25,000 |
| **Cost of the UFI** | 27,000 | 48,000 | 30,000 | 12,000 | 13,000 | 100,000 | 12,000 | 8,000 | 16,000 | 140,000 | 290,000 | 44,000 | 38,000 | 7,900 |
| **SME** | 16,000 | 33,000 | 19,000 | 11,000 | 13,000 | 75,000 | 11,000 | 7,800 | 9,700 | 110,000 | 190,000 | 32,000 | 26,000 | 5,200 |
| **Large** | 11,000 | 15,000 | 10,000 | 550 | 0 | 26,000 | 560 | 140 | 6,800 | 28,000 | 100,000 | 13,000 | 12,000 | 2,700 |
| **Consumer/ professional/ industrial total** | -28,000 | -35,000 | -17,000 | 5,500 | 7,900 | -10,500 | -700 | 5,900 | -23,000 | -130,000 | -300,000 | -32,000 | -23,000 | -19,000 |

Country definition codes: Austria (AT), Belgium (BE), Bulgaria (BG), Croatia (HR), Cyprus (CY), Czech Republic (CZ), Denmark (DK), Estonia (EE), Finland (FI), France (FR), Germany (DE), Greece (EL), Hungary (HU), Ireland (IE)

Table 3.2 Scenario A - continued - Values in thousands of Euros

| | IT | LV | LT | LU | MT | NL | PL | PT | RO | SK | SI | ES | SE | UK |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Consumer, Professional and Industrial mixtures** | | | | | | | | | | | | | | |
| **No. of Comps** | 1520 | 53 | 44 | 11 | 71 | 228 | 586 | 220 | 262 | 95 | 51 | 1007 | 233 | 790 |
| **SME** | 1490 | 52 | 43 | 8 | 68 | 212 | 557 | 218 | 252 | 84 | 49 | 984 | 223 | 754 |
| **Large** | 30 | 1 | 1 | 3 | 3 | 15 | 29 | 2 | 10 | 10 | 2 | 23 | 9 | 35 |
| **Costs Domestically trade only** | -71,000 | -180 | -2,000 | -240 | -380 | -13,000 | 8,000 | -9,700 | 5,900 | 1,700 | 830 | -44,000 | 3,500 | 18,000 |
| **SME** | -60,000 | -170 | -1,900 | -37 | -260 | -10,000 | 6,400 | -8,900 | 4,900 | 550 | 580 | -37,000 | 2,600 | 14,000 |
| **Large** | -12,000 | -10 | -49 | -210 | -130 | -2,500 | 1,500 | -840 | 1,000 | 1,100 | 250 | -6,300 | 900 | 4,100 |
| **Costs Internationally traded** | -230,000 | -4,800 | -5,000 | -23,000 | -18,000 | -73,000 | -150,000 | -18,000 | -53,000 | -61,000 | -14,000 | -160,000 | -55,000 | -210,000 |
| **SME** | -40,000 | -2,400 | -1,200 | -510 | -2,900 | -9,700 | -22,000 | -5,400 | -6,200 | -4,500 | -2,400 | -37,000 | -7,700 | -31,000 |
| **Large** | -190,000 | -2,400 | -3,800 | -22,000 | -15,000 | -63,000 | -130,000 | -13,000 | -47,000 | -56,000 | -12,000 | -120,000 | -48,000 | -180,000 |
| **Cost of the UFI** | 260,000 | 6,200 | 7,100 | 7,500 | 7,600 | 55,000 | 93,000 | 35,000 | 48,000 | 18,000 | 9,700 | 170,000 | 41,000 | 160,000 |
| **SME** | 210,000 | 5,800 | 6,800 | 1,600 | 4,100 | 45,000 | 70,000 | 32,000 | 38,000 | 5,700 | 6,800 | 140,000 | 31,000 | 120,000 |
| **Large** | 45,000 | 330 | 330 | 5,900 | 3,500 | 11,000 | 23,000 | 3,200 | 9,400 | 12,000 | 2,800 | 26,000 | 10,000 | 37,000 |
| **Consumer/ Professional/ Industrial total** | -41,000 | 1,100 | 100 | -16,000 | -11,000 | -31,000 | -49,000 | 7,300 | 900 | -41,000 | -3,500 | -34,000 | -10,000 | -32,000 |

Country definition codes: Italy (IT), Latvia (LV), Lithuania (LT), Luxembourg (LU), Malta (MT), Netherlands (NL), Poland (PL), Portugal (PT), Romania (RO), Slovakia (SK), Slovenia (SI), Spain (ES), Sweden (SE) and United Kingdom (UK)

In the above table, numbers of companies affected was calculated by multiplying the total number of companies as reported in Eurostat (table 2.4) by the share of companies affected by the PC requirements within the total number of companies by sector and size as detailed in the Appendix D based on consultation results

The cost estimates provided above by Member States are intended to be indicative, representing analysis that was possible within the constraints of an EU-wide study, with in some cases limited actual data provided for specific Member States. Undoubtedly a more detailed study per Member State would allow for a more robust estimate to be provided at Member State level.

A key question posed by the disaggregated data within Table 3.2 is to identify any specific cases where the SME sector trading domestically are particularly adversely effected by the proposed harmonisation. Table 3.3 provides a greater breakdown of net costs by micro, small, and medium sized companies in those Member States from Table 3.2 where net costs are estimated.

The single biggest net cost to SMEs trading domestically (only) from the proposed harmonisation is found in the UK, the Czech Republic and Poland. These costs converted to a 'per company' basis represent around 67,000 Euros for UK based SMEs, 108,000 euros for Czech Republic SMEs and 40,000 euros for Polish SMEs. Overall net costs for the UK based on the cost model estimates are 8.9 million euro with the costs largely focussed on the 'medium' sized enterprises (>50 -<250 employees) and latterly small and micro sized companies. This reflects the Eurostat company data which demonstrates that the 'micro' sized companies make up the smallest proportion of the SME category. Along with the UK, the Czech Republic (5 million Euro) and Poland (4.5 million Euro) could also face significant net costs.. Total costs for each Member State are estimated taking into account the average number of manufactured products per company and submission frequency differentiated by size, sector and type of the products as well as current reporting system (as opposed to using same average per company unit costs).

As a counter-point to this position Table 3.4 provides a breakdown of net savings for those companies that trade only domestically based in Member States with systems having a data burden equal to or more advanced than the proposed harmonisation. In terms of those companies that trade domestically, Table 3.2 can also be used to help identify those types of companies that would (in aggregate) enjoy the biggest benefits of harmonisation. Typically these companies would be found trading in a Member State that currently has the 'advanced' data requirements detailed earlier in the report. Looking again at the SME market sector, those companies in Germany, France Spain and Italy gain the biggest net savings with 'per company' average savings of 149,000 Euros, 95,000 Euros, 90,000 Euros and 91,000 Euros respectively. Total savings for companies operating in these countries would be in the order of 23 million, 13 million, 17 million and 25 million Euros respectively. These savings are based on the assumption that the additional existing requirements above the harmonised system would not remain.

The overall savings presented in Table 3.2 include the net savings from trading in multiple Member States, minus the costs to those that trade domestically, minus the cost of adopting the UFI. Again the greatest net savings are seen by those companies based in countries with advanced systems. In these cases companies will benefit from the harmonisation, both those trading domestically only trading and those trading in multiple Member States. The biggest net-savings are seen in Germany, France and Italy. However even in the UK (net savings of 39 million Euro), Czech Republic (net savings of 9.5 million Euro) and Poland (net savings of 51 million Euro), which currently have less onerous systems, the position is the same, with no Member State having a position of overall net-costs from the proposed harmonisation.

Therefore, the overall quantitative results of the cost model shown in Table 3.1 and Table 3.2 demonstrate a net saving across the EU for industry. However these overall savings do mask a situation where costs will be felt by some companies where others see savings. In particular Table 3.2 highlights an issue for companies that only trade domestically in Member States where data burden is lower than the proposed harmonisation. This is particularly an issue for the SME sector in the UK, Czech Republic and Poland highlighted as facing the greatest net cost increases (in absolute terms).

Table 3.3 Further disaggregation of SME companies (consumer/professional) based in Member States where net costs are expected for those trading domestically only – costs expressed as thousands of euros

| | **BE** | **HR** | **CZ** | **EE** | **FI** | **HU** | **IE** | **PL** | **RO** | **SK** | **SI** | **SE** | **UK** | **Total** |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **No. of SME Companies affected (trading domestically only)** | 36 | 19 | 46 | 5 | 15 | 30 | 7 | 111 | 50 | 16 | 10 | 48 | 132 | **525** |
| **Costs** | | | | | | | | | | | | | | |
| **Micro** | 420 | 340 | 84 | 52 | 130 | 170 | 21 | 1,300 | 700 | 90 | 37 | 350 | 1,700 | **5,400** |
| **Small** | 490 | 100 | 1,400 | 56 | 220 | 300 | 180 | 860 | 880 | 180 | 68 | 190 | 2,000 | **6,900** |
| **Medium** | 1,200 | 420 | 3,500 | 420 | 260 | 1,300 | 140 | 2,400 | 1,300 | 31 | 170 | 780 | 5,100 | **17,000** |
| **Total costs for companies trading domestically only (SME)** | 2,200 | 860 | 5,000 | 530 | 600 | 1,700 | 340 | 4,500 | 2,900 | 300 | 280 | 1,300 | 8,900 | **29,4900** |

Table 3.4 Further disaggregation of SME companies (consumer/professional) based in Member States where net savings are expected for those trading domestically only – costs expressed as thousands of Euros

| | AT | BG | CY | DK | FR | DE | EL | IT | LV | LT | LU | MT | NL | PT | ES | **Total** |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **No. of SME Companies affected (trading domestically only)** | 17 | 33 | 6 | 13 | 136 | 154 | 46 | 273 | 11 | 8 | 2 | 13 | 38 | 44 | 187 | **981** |
| **Savings** | | | | | | | | | | | | | | | | |
| **Micro** | -13 | -28 | -1 | -310 | -1,800 | -2,200 | -1,400 | -5,900 | -10 | -170 | -2 | -11 | -640 | -950 | -3,200 | **-16,600** |
| **Small** | -10 | -18 | -7 | -340 | -2,900 | -4,300 | -480 | -9,500 | -3 | -330 | 0 | -8 | -1,000 | -1,400 | -5,000 | **-25,300** |
| **Medium** | -29 | -21 | -24 | -700 | -8,400 | -16,000 | -2,000 | -10,000 | -9 | -320 | -3 | -5 | -3,800 | -1,500 | -8,900 | **-51,700** |
| **Total savings for companies trading only domestically (SME)** | -52 | -67 | -32 | -1,400 | -13,000 | -23,000 | -3,900 | -25,000 | -22 | -820 | -6 | -24 | -5,500 | -3,800 | -17,000 | **-93,600** |

In developing the estimates for the base case (scenario A) it is also important to make clear that the key variables developed from the industry questionnaire have a direct impact on the estimates produced. There are a number of variables for which the results have greater sensitivity. In particular the frequency of submissions is of high importance. The cost model estimates are derived on a unit cost per submission based on an average number of products (which alters dependent on company size and industry sector) and set number of submissions per annum. For some sectors this can include multiple submissions per annum per product depending on the sensitivity of the product to change, in for example batch processes. To assess these sensitivities the cost model was developed with a number of scenarios to explore these elements. A more detailed discussion of these scenarios is provided in Chapter 5, but in the case of the predicted results for harmonisation. Reducing the frequency of submissions under scenario B (actually reflecting reduced costs for subsequent submissions for similar products) reduced the overall cost savings but not the trends described here, with overall net savings at EU level and net costs for those companies that trade only domestically in Member States where data burden is currently lower than the proposed harmonisation.

## Qualitative description of other benefits and costs

### Benefits

Alongside the quantitative component of the questionnaires, qualitative information was also gathered to better understand the opinions within the industry groups surveyed. This part of the questionnaire highlighted the broad range of opinion and expressed by the industry stakeholder group. One issue that was clear and apparent from this part of the survey was that for many respondents within industry there was still confusion over specifically what was meant by 'harmonisation'. For some respondents this lack of clarity caused increased anxiety over what the proposed future might mean for them.

More generally a large proportion of those that responded, particularly those that traded in many EU Member States, welcomed the opportunity for harmonisation. The key benefits of such harmonisation were quoted as:

- Savings in staff time and cost for compiling information.
- Clearer audit trail of information on products
- Reduced potential for clerical errors as the information requirements are standardised
- Opportunity to redeploy staff to other tasks such as R&D

Beyond these benefits there were a small number of respondents who made additional interesting comments worth including within this section of the report. In order to keep the identity of those that responded anonymous the specific source of the comment is not included. Additional comments included:

- For SMEs it can prove a struggle to remain compliant with the multitude of different systems in place due to the limited resources available. The opportunity for harmonisation was welcomed as it would mean a clearer understanding of what is expected from companies.
- For a large multi-national company the approach to remaining compliant meant the need for regional centres who could specialise in the requirements of that region. The opportunity for harmonisation would allow centralisation of these duties allowing greater coherence and efficiency between team members.

- A number of larger companies state that, to truly see benefits, there is a need for a central repository and called for a 'one product, one submission' approach. This would save a great deal of time/cost. It is unclear from these responses however whether the 'one product one submission' approach would also mean one language, although this would be a likely assumption.

### Costs

The qualitative part of the industry questionnaire provided a very wide range of opinions. A number of respondents highlighted concerns about increasing costs from additional demands to develop and provide submissions for Poison Centres. The responses from the industry consultation suggested that potentially within Member States which currently have voluntary systems, those companies with industrial mixtures may prefer to utilise other options such which would mean that data is not currently provided to the Poison Centre in those states. Where data submissions do not currently take place the respondents were concerned about significant costs which could be felt with the need for additional specialised staff and software.

The concerns surrounding harmonisation for these companies included:

- Need for additional staff to help develop the information to be submitted.
- Need for additional IT software to manage the information compiled and submitted.
- SME companies highlighted that the need for a 24/7 emergency number would prove challenging. This was because the companies themselves had limited resources to provide such a service internally and use of external providers could prove expensive, making it difficult for them to compete in the market place.

Aside from the specific issue with goods for industrial use, a number of companies supplying consumer and professional products wished to raise concerns. In particular for those companies based in countries which currently have reduced data requirements compared to the proposed harmonisation, there were concerns that the level of information required was more detailed and that costs to provide such information would be an issue. Additionally one industry sector (fragrances) highlighted that many of their raw goods are imported into the EU and that there is a complex supply network which works across EU and non-EU borders. This means that it can be difficult and time consuming to get the kind of detailed information that might be required under harmonisation. This would be due in part to commercial sensitivity issues as well as the complex supply chain, and is likely to also be true for other sectors.

Finally a number of domestically trading (only) companies stated that they would see no benefit from the proposed harmonisation and at worse increased costs from needing to gather more data.

## 3.3 Costs of the UFI to Industry

The questionnaires specifically included both quantitative and qualitative questions to get in depth knowledge on what issues the adoption of the UFI might pose to industry. Unlike harmonisation where there are both costs and benefits to industry, the UFI poses a straight cost to industry and benefits to Poison Centres and ultimately the patients receiving treatment.

The results of the industry questionnaire highlighted some important details which should be considered when developing the strategy for implementation of the UFI. In particular the timing and phase-in period of the UFI was a key element for industry. In

applying the UFI, industry faces both one-off costs to handle label design, software and processing of new systems and annual costs for managing the ongoing use of the UFI. A large number of respondents highlighted the issue that companies manufacturing consumer and professional goods often stockpile goods to manage supply and demand and these could require retrospective addition of the UFI.

As an illustration, one respondent from the pesticides sector noted that the level of detail required for their products meant that they used 'stick on booklets' which are produced using printing plates. Any amendment would require new printing plates to be developed at a cost of millions of euros for the full product range. The same respondent highlighted that over the course of their business there were often points where printing plates had to be amended or updated for a number of reasons. A phase in period of around two years would allow the manufacturers in this sector to time the adoption of the UFI at a point where such costs could be avoided.

Should the UFI be brought in with immediate effect this would require a re-labelling exercise which could represent significant costs to industry. However, the Commission Services envisages an appropriate transitional period of at least 2 years, and therefore the implementation of the UFI could be adopted in a fashion which would minimise the impact on industry. In applying a transitional phase, the Commission Services were also interested to understand the value of this transitional phase and the scale of the burden to industry if it is not incorporated. The development of the cost model included a specific standalone scenario (scenario D) to calculate the costs for industry if a transitional phase was not used. These net costs displayed in Table 3.5 would be for the relabeling of stockpiles and include largely consumables and redesign of software as opposed to staff costs. The overall net costs from the relabeling exercise could be around 550 million euros, spread across the EU Member States, as presented below.

Table 3.5 Estimated cost savings from using the transitional phase in period as thousands of Euros per year

| | AT | BE | BG | HR | CY | CZ | DK | EE | FI | FR | DE | EL | HU | IE |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Costs for relabeling of stock** | 9,400 | 18,000 | 8,500 | 3,200 | 3,100 | 22,000 | 4,300 | 1,400 | 8,000 | 62,000 | 96,000 | 12,000 | 13,000 | 7,300 |
| **SME** | 4,000 | 7,800 | 5,300 | 2,200 | 3,100 | 11,000 | 3,000 | 1,000 | 3,000 | 30,000 | 48,000 | 5,400 | 6,400 | 3,000 |
| **Large** | 5,300 | 11,000 | 3,200 | 1,000 | 0 | 10,000 | 1,300 | 330 | 5,000 | 32,000 | 48,000 | 6,300 | 6,300 | 4,300 |

| | IT | LV | LT | LU | MT | NL | PL | PT | RO | SK | SI | ES | SE | UK |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Costs for relabeling of stock** | 65,000 | 1,900 | 2,300 | 2,000 | 3,700 | 18,000 | 35,000 | 7,400 | 13,000 | 9,400 | 3,100 | 46,000 | 12,000 | 49,000 |
| **SME** | 48,000 | 1,500 | 1,600 | 350 | 2,200 | 9,100 | 18,000 | 6,300 | 7,100 | 3,200 | 1,900 | 33,000 | 6,700 | 28,000 |
| **Large** | 18,000 | 330 | 770 | 1,600 | 1,500 | 8,900 | 17,000 | 1,100 | 5,700 | 6,200 | 1,100 | 13,000 | 5,500 | 21,000 |

Again, please note that the results presented at Member State level are subject to greater uncertainty than the overall EU results.

Other issues raised by the respondents to the industry questionnaire related to the available space on labels, with one noting that, to make room for the UFI, other important information would have to be removed. Others questioned what supporting information would be needed along with the UFI to explain to the consumers what it was and how it should be used during a chemical incident.

It is also worth illustrating concern raised by one key sector – paints. The respondents from this sector noted that typically manufacturers within this sector have large product ranges based on small incremental changes to formulas, often the non-hazardous components. These small incremental changes allow paint manufacturers to produce the broad array of colours and shades demanded by consumers. The need for an individual UFI per product could lead to huge costs which, in their view, would be disproportionate for this sector. The respondents from this sector requested the possibility of a group UFI which would cover these small incremental changes on the same basic formula for the wide array of products.

In developing the cost model for the UFI these comments have been taken into account (please refer to the scenario E and set of assumptions in the Appendix D and Appendix E). Table 3.6 provides the cost model breakdown for industry costs associated with the UFI. This suggests that costs could be as high as €1.7 billion per year, but with more realistic assumptions, including use of the transitional period and use of a 'group UFI' for products with similar composition, these costs could be much lower. Scenario E which addresses the base case scenario (Scenario A) with the addition of a Group UFI would reduce overall net costs to around €875 Million per year, while Scenario F which includes the Group UFI but also the other measures to compensate for overestimate of submission frequency and internationally traded goods further reduces the net cost to around €340 million per year across the EU as a whole.

Table 3.6 Costs of UFI under scenario A for total EU Member States plus Norway

| | **Costs, Euro per year (total EU)** | | | | **NPV, Euro (10 yr)** |
|---|---|---|---|---|---|
| | **Paints, varnishes and inks** | **Soaps and detergents** | **Other sectors** | **All sectors aggregated** | **NPV (all requirements)** |
| **Industrial products (UFI)** | 200,000,000 | 14,000,000 | 26,000,000 | **240,000,000** | 2,100,000,000 |
| **Consumer products (UFI)** | 1,300,000,000 | 89,000,000 | 120,000,000 | **1,509,000,000** | 13,000,000,000 |
| **Total costs** | **1,320,000,000** | **103,000,000** | **146,000,000** | **1,749,000,000** | **15,100,000,000** |

# 4 Costs and Benefits for Poison Centres

## 4.1 Introduction to the work and role of Poison Centres

Poison Centres across Europe provide a first line response to relay detailed information on the properties and effects of chemicals during incidents that involve chemicals. Those making use of the service that Poison Centres provide will broadly fall into a small number of different types of caller which can be categorised as:

- Medical professionals
- Members of the public
- Professional or industrial users
- Emergency services

These caller types can be further categorised as between 'professionals', assuming this to mean those with a full working medical knowledge or professional industrial experience of chemicals, and 'non-professionals', which typically makes up the general public. While some Poison Centres such as the Netherlands and the UK are geared to providing response to medical professionals only, and Ireland has two services one for medical professionals (24/7) and one for general public (10am – 8pm), for those that receive calls from all caller types, there is a broadly a 50/50 split between professional and non-professional caller types. The kinds of calls that can be received in this case span a broad range of scenarios, from those calls received by doctors at hospitals where a patient has already been admitted and is in a serious condition at one end of the spectrum, to callers who are at home/place of business and do not require professional medical intervention but simply guidance and reassurance at the other end of the spectrum.

The nature of the calls received can also span a broad range of products but is largely dominated by consumer goods, particularly pharmaceuticals, with professional use goods making up a smaller proportion of the calls received. Typically in responding to the emergency calls received, Poison Centres are mainly providing advice around poisoning (deliberate or accidental) or exposure to substances which can include incorrect use (such as heating) or unexpected chemical reactions such as mixing different types of detergents.

The advice that Poison Centres provide will help ensure the safety of those who have been involved in an incident with chemical goods. Their advice may reassure the caller that action/no action is required and if, in doing so, they reassure the caller that there is no need to seek medical treatment then this provides a positive benefit in a reduction in cases arriving at hospital. Some centres, for example in France, also conduct remote monitoring of patients' conditions at home so they could ensure that medical advice is sought if the situation changes. This 'in situ' monitoring could also result in significant healthcare savings and reduced burden on hospitals. Each Member State's Poison Centre(s) have been setup in different ways, however advice from many centres is provided using a risk-based approach using the WHO/IPCS/EC/EAPCCT Poisoning Severity Score (PSS).

Based on the results of a questionnaire for the current study (spanning 17 of 28 Member States) Poison Centres across Europe respond to over 600,000 calls per annum (almost 1700 calls per day mostly related to exposure of children), which will have a large range of severities. Further breakdown of these calls to identify trends within specific products groups as well as the volume and nature of more serious incidents is also covered as part of the work of these centres. For example an indicative breakdown of call volume by severity includes:

- Germany - Poisoning cases related to chemicals exposure from one of the German Poison Centres were 11,470 in 2013 and they had 120 severe symptoms and 6 fatalities (this centre represents ~ 16% of Germany). Scaling this up assuming full proportionality and representativeness results in around 70,000 calls, 750 cases with severe symptoms and around 40 fatalities for the whole of Germany.
- Italy - The Milan Poison Centre reported 16,000 cases in 2009 including 6 fatalities. By extrapolation, this suggests there could be approximately 21,000 cases for the whole of Italy and 8 fatalities (the Milan Poison Centre covers around 75% of the country).
- France – The Nancy Poison Centre reported that for France as a whole the French Poison Centres attended to 85,000 call per annum. There were also around 300 fatalities per annum as a result of exposure to hazardous chemicals.
- The Netherlands received 43,334 calls in 2013, of which 2,882 (or 12%) concerned chemical products.
- The UK receives around 55,000 calls per annum, with the annual report for 2012/13 highlighting 11 fatalities linked to poisoning via pesticides and alcohol based products[12].
- Spain - In 2014 the Spanish PC (INTCF) received about 71,000 calls for actual exposure (other consultations are excluded; e.g. preventive measures). Accidental exposure to chemicals: accounted for about 29,000 calls.

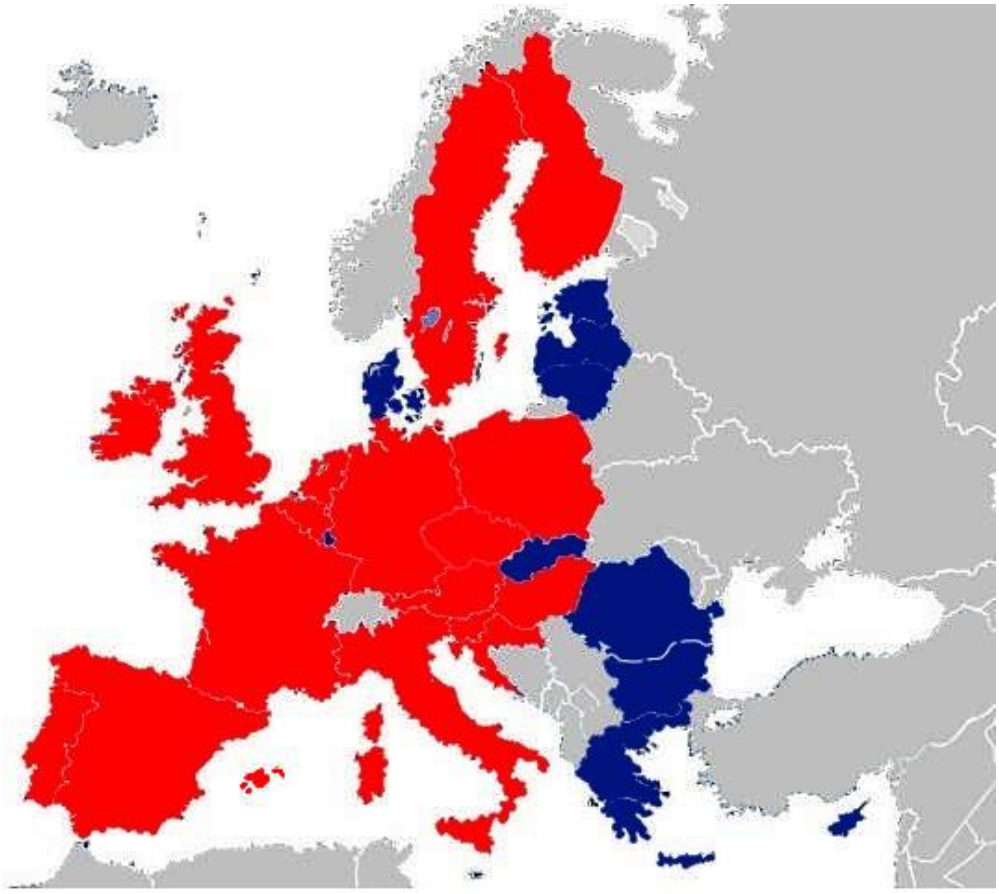
## 4.2 Overview of survey responses

The questionnaire developed for Poison Centres had a more qualitative angle than the industry questionnaire with the focus being on building an understanding of current operations and what benefit/impact harmonisation and the adoption of the UFI might have. Further discussion of the results is provided later in this section, but the level of response from the Poison Centres was rather good, with 17 out of 28 Member States represented, equivalent to 90% of the EU population. Figure 4.1 provides a breakdown of which countries were represented in the response, coloured in red. Non-responding countries are shown in blue and non-EU countries in grey.

A number of Member States, notably France, Germany, Italy and the UK have more than one Poison Centre providing response on a regional basis. During the questionnaire phase all regional Poison Centres were contacted by e-mail and invited to take part. For all four of the above countries, more than one regional centre responded with the centres covering the majority of the population in France, Germany, Italy and the UK covered by the responses provided. Additional more detailed consultation was held with four Member States' poison centres, as outlined below.

[12] *NPIS, 2013, 'National Poisons Information Service Report 2012/13'.*

Figure 4.1 Member State Poison Centres who responded within the EU



## 4.3 Costs and benefits of harmonisation

### Benefits

The Poison Centre questionnaires focussed on both the proposed harmonisation as well as the adoption of the UFI, both of which were welcomed. For harmonisation of the data requirements the chief benefit of those Poison Centre staff that took part was concluded to be an improvement in the consistency of the detail in the data provided. It was believed that this improvement in consistency would aid the Poison Centre staff by providing a more accurate and appropriate response during incidents.

A number of respondents also said that harmonisation may have beneficial effects on the speed of response which would have obvious benefits for the patient.

### Costs

The main concern highlighted by the Poison Centre questionnaire responses was the increase in the number of documents submitted to Poison Centres. All respondents to the questionnaire expected the number of submissions to increase under harmonisation with many highlighting the fact that Poison Centres often operate with limited resources and that significant increases in the number of submissions could prove challenging. In practice however it was difficult for the respondents to estimate what scale the increase might be, although the move to mandatory requirements in

Member States where the system is currently voluntary would be part of the reason for such an increase.

The majority of those that responded stated that, wherever possible, they would manage such an increase in submissions through automated processes and aim to limit the burden on staff time. In addition to these concerns, one centre which currently operates with a format more detailed than the proposed harmonisation, wished to highlight concerns with a loss of information. In this case the loss of detailed information to aide response would likely have to be countered through the recruitment of additional experienced toxicologists to interpret data which would be a direct cost to the Poison Centre.

## 4.4 Poison Centre case studies

### Approach

Based on responses to the Poison Centre questionnaire described in Section 2.4 and the typology of Poison Centres described in Section 2.3, four representative Poison Centres were selected from which additional insight was sought. The selected Poison Centres were: France, Italy, Czech Republic and UK. Detailed conversations were held with senior representatives of each Poison Centre from which the following insights were obtained.

### French Poison Centre – Nancy

The French Poison Centres operate on a regional basis with 10 antipoison and toxicovigilance centres (Centre Antipoison et de Toxicovigilance, CAPTV) and 3 toxicovigilance centres (Centre de Toxicovigilance, CTV) included in 10 Hospitals. This includes the national database on products and compositions (Base Nationale des Produits et Compositions – BNPC) held at the Centre in Nancy. The Poison Centre receives the majority of its calls from consumers (70%) with around 25% calls being received from medical professionals. In total 24% of calls require hospital admission with 15% of total calls requiring admission for at least 24 hours. In many cases the intervention of the Poison Centre prevents hospital admissions.

The French Poison Centre adopts a risk-based approach towards incident response and management. In cases where there is doubt as to the product formulation, the Poison Centre is more likely to recommend hospital treatment for the affected person(s). Additional information about product composition is seen as useful in allowing the Poison Centre to downgrade the response to a chemical exposure and reduce healthcare costs.

Industry in France supplies chemical data to the French Poison Centre through an online portal or in hard copy (by post). As is common for many Poison Centres, administrative employees check and register chemical data. The database which is used in France has the potential to include the proposed XML/UFI data and to include audit functionality which allows enquiries to be tracked and monitored.

An issue for the French Poison Centre is product identification. Quite often a lack of useful or reliable data will result in unnecessary hospitalisation or testing of a casualty. As a result of these problems in particular, the French Poison Centre has a positive disposition towards precise formulation data being available, and towards the UFI, since together, these would provide additional information about chemical identity and composition and assist the Poison Centre in making a risk based judgement about required medical intervention.

### Italian Poison Centre – Milan

The Italian Poison Centres operate on a regional basis and are organised by the Istituto Superiore di Sanità, National Centre for Chemicals. Of the 60,000 calls the Poison Centre receives each year, around 50% are received from consumers and around 50% from medical professionals. Of all chemical exposures notified to the Poison Centre, around 40% involve children. The majority of calls relate to pharmaceutical (drug) or cleaning products.

The Poison Centre takes a risk based approach towards its response to chemical exposures. As with other Poison Centres, its objective is to avoid unnecessary medical care and related healthcare cost impacts. Again, the availability of chemical information is critical in order to assess risk and successfully meet this core objective.

Italy has a central database of chemical products organised by the government. In the case of the Poison Centre, a separate database is also maintained. Data on chemical products is provided on a mandatory basis to the government and on a voluntary basis to the Poison Centre. It is felt that the proposed harmonisation offers the potential to create a more unified, harmonised and user-friendly system for product data storage and access which can improve the performance of the Poison Centre.

The Italian Poison Centre reports a challenge relating to availability of pH data. Without knowing the pH of a chemical product the Poison Centre finds it difficult to adopt a risk based approach and is therefore unable to prevent the exposed person being directed to hospital. In other cases, it is not possible to identify the product to which exposure has occurred, and again this results in a higher proportion of hospital admissions than would otherwise be hoped for.

The proposed harmonisation project is welcomed by the Italian Poison Centre due to the benefits of a well-designed database and the improvement in product identification which is expected as a result of the UFI. There is a feeling that the UFI should be of a designated and sufficient size when printed on the product packaging in order to be easily identifiable by Poison Centre callers.

### The Czech Republic Poison Centre - Prague

The Czech Republic Poison Centre is placed within the General University Hospital in Prague and is operated by a core team of five doctors / clinical toxicologists and five part-time occupational toxicologists who provide the consultations needed. The Unit is also responsible within the Czech Republic for providing guidance on pharmacology and toxicology with the hospital also housing the national stockpile of unregistered antidotes, antitoxins, and other drugs needed for specialist intervention.

The Czech centre serves a population of around 10 million people receiving around 17,000 calls annually on a 24/7 basis. 54% of these calls come from healthcare professionals, 43% from consumers or industry and around 3% come from veterinary professionals. Typically the vast majority of calls relate to consumer products; professional use calls make up a much smaller fraction at around 5% of total calls. The majority of calls received relate to drug-related incidents (40%) with consumer goods such as detergents (25%) and botanical substances such as mushrooms and toadstools (14%) making up secondary fractions. The Centre also receives calls on professional pesticidal products (4%) and corrosive materials (1-2%). A high percentage (53%) of all calls relate to children, and this is a core focus for the centre.

The team at the centre uses two strategies to managing the calls they receive based on the caller type. For calls received from consumers or industry/professional users a risk based approach is used to firstly identify the product and then assess the seriousness of the incident. Based on this approach it is possible to treat 60-70% of calls from the consumers by management at home without the need to refer to a

hospital. However the need to refer a caller to hospital depends on the nature of the incident and symptoms exhibited. Where calls come from medical professionals the patient may have already been admitted to hospital or require intervention. For example, for around 72% of drug related cases, callers are either already admitted or are required to attend hospital.

For calls received from medical professionals or hospitals the incidents are likely to be more serious. In these cases again product identification is the first step but more detailed information is often required on the toxicokinetics of the product and medical management. Response can be particularly challenging for products that are reactive or behave in a way not prescribed by the use, such as heating or antagonistic effects between multiple chemicals/products.

The Czech centre primarily accepts information in the form of safety data sheets. Provided these documents carry a high level of breakdown on composition and correct information they are sufficient for the centre to be able to provide a good service. In carrying out their duties one aspect that can prove problematic is the varying quality of SDS.

Based on the calls received (c.50 per day) approximately 2-3 calls per day relate to incidents where the safety data sheet is either incomplete or incorrect making an appropriate response more difficult.

The work of the centre includes quality checking and review of documents. Where information looks incorrect they will contact the company and ask them to verify whether information is correct. Documentation is provided to the centre through a variety of pathways; electronic submission is preferable but hardcopy is accepted. In these cases the documents are reviewed and added to their database, with hardcopies being scanned.

Additionally industry also has the option to make use of software such as CHES[13] to provide additional information on their products and this software is expected to be easy to use.

Confidentiality of the information provided is also of a high priority. As the Czech centre is based in a hospital they treat the information provided with the same level of security as patient records. This strict control system ensures that data is managed and treated with suitable care.

The Czech centre strongly supports the use of a UFI and can see the intrinsic value to response in at least 25% of the calls received. The main problem regarding identification of a product can span multiple issues, but for consumer products a key problem is brand name products, where a large range of goods exist with similar names but varying composition. This can make the spectrum of effects from irritant to corrosive possible for products with the same brand name. For professional/industrial products, chemical goods sometimes have unusual names or use additional characters or symbols within the name. This can complicate taking information over the telephone and again rapid identification of the product. A UFI would help alleviate some of these issues.

### The UK Poison Centre – Birmingham

Similarly to the Italian Poison Centre, the UK Poison Centre is spread over a number of regional bases. It is provided by the National Poison Information Service which is part of Public Health England. The UK Poison Centre receives approximately 56,000 calls

[13] *CHES is a free software package provided by the Czech Republic Ministry of Health to allow manufacturers to characterise chemical information and health data for submission to the Poison Centre. The website for this software is: https://snzr.ksrzis.cz/snzr/ozn/*

per year of which all were received from medical professionals as the telephone number is not available to consumers. The majority of calls relate to drug exposure although approximately 30% relate to exposure to chemicals. Of calls received in 2013/14 2,900 related to exposure during pregnancy.

As with other Poison Centres, the UK follows a risk based approach, which in this case is based on the WHO/IPCS/EC/EAPCCT Poisoning Severity Score. Of the telephone enquiries received 34% were from other telephone-based medical support services such as the UK's NHS 111 service, meaning the Poison Centre was able to prevent unnecessary hospital referrals through provision of its advice. Other benefits of the Poison Centre advice included being able to shorten hospital stay and improve quality of treatment for admitted patients through provision of poisons advice to hospital-based medical staff.

SDS are collected from UK industry on a voluntary basis. The attempt to encourage voluntary submission of chemical data is perceived by the UK Poison Centre to be highly effective and data is used to increase or update around 17,000 entries on the Toxbase database. Precise product formulations are not preferred over concentration ranges which are felt to provide sufficient clinical benefit. However, the naming of only active ingredients on an SDS is felt to be insufficient since it is not necessarily the active ingredient which may form the toxic component of the product. The UK centre gathers information on a voluntary basis from those companies selling in the UK. They state that the main reasons for the success in gathering a large amount of information is down to the following key steps;

- Personal letters written by the Director of the NPIS to senior company managers / leaders when first contact is established;
- A separate Database of named company individuals who are contacted regularly by NPIS staff to ensure that all SDS are up-to-date;
- Gaining the trust of individuals and companies for the secure management of data;
- A network of company toxicologists who have links to NPIS staff;
- Close contacts with professional organisations;
- Close working arrangements with commercial SDS providers who have contracts for almost all supermarket product SDS;
- Data confidentiality

A key challenge for the UK Poison Centre is product identification. In some cases the product name is not known or the product information or name is not in the possession of the caller at the time of the enquiry. For this reason it was felt that the UFI, while providing some benefit in product identification, might not help in all cases.

The UK Poison Centre anticipates that the proposed harmonisation will result in a significant increase in the number of data submissions being made to the Poison Centre, with a resultant increase in administrative workload and cost.

## 4.5 Benefits and Costs of the UFI to Poison Centres

The Unique Formula Identifier (UFI) to be put on the label of chemical products (or in the case of industrial mixtures on SDS) would allow a better identification of products. This would allow further improvement of the care received by those affected during chemical incidents. To help characterise what these benefits might be provided by the UFI, questions were included within the Poison Centre questionnaires to specifically cover this aspect.

The response from the questionnaire and the case study interviews highlighted issues with identification of chemical goods for a large proportion of incidents. This can be explained by a number of reasons, including where brand name products are used across a range to cover a wide selection of goods with similar names but varying formulations. The composition of mixtures for industrial use with unusual names can be incorrectly relayed to the Poison Centre, particularly if there are multiple parties involved in incidents passing on transcribed information given over the phone. These difficulties can delay the response provided by Poison Centres or in the cases where substances cannot be identified, precautionary hospitalisation can take place, to carry out tests for identification of substances. The questionnaire to Poison Centres highlighted that those consulted believed that in 5-40% of cases patients were over-treated due to difficulties with diagnosis.

The response to the questionnaires showed that 15 of the 19 respondents endorsed the UFI and felt that it would have benefit. Two replies stated that they felt it would have no benefit and a further two were unsure. The main benefits highlighted by the replies were:

- Speed of response
- Being able to accurately identify the product
- Reducing over-treatment of patients

The two centres that stated they felt the UFI would not provide benefits stated that this was because the UFI would only be of benefit alongside detailed information needed to provide a response and this could only be the case with the proposed harmonised format (i.e. the responses seem to suggest that the UFI alone would not be sufficient, but that with harmonisation it would be beneficial). Furthermore, in many cases the issues with identification of a given product are related to the fact that the patient does not have the product with them / has not taken note of the name of the product. In these cases it is necessary to try and respond based on the type of product involved. The UFI would not be able to resolve this issue.

# 5 Summary of overall costs and benefits of the proposals

## 5.1 Overview

The project objectives set out within section 1.4 have been used to define the overall project approach. This chapter begins by providing the answers to the objectives listed in section 1.4 based on the results of the industry and Poison Centre questionnaires and cost model. The chapter then moves on to provide a more detailed discussion of the overall results and sensitivity analysis covered through the use of scenarios B to E described within section 2.5 and Appendix E.

## 5.2 Typical costs of notification

This section provides details of the estimates and assumptions used to estimate:

- Objective 1 Typical cost of notification under the existing national notification systems;
- Objective 2 Standard cost of a notification under the planned harmonised reporting format.

The first and second objectives of the project aimed to provide information to help assess what the current cost of notification would be under existing notifications and then for objective 2 what the cost would be under the proposed harmonisation.

In answering the first objective it was recognised that multiple systems exist with variations at national level across the EU. These variations were grouped into three core categories of 'SDS Only', 'SDS +' and 'Advanced' with increasing levels of detail and effort required to complete submission. The industry consultation sought to quantify both the existing costs and those under the proposed harmonisation, linked largely to costs as staff time. Table 5.1 provides the averaged values from the industry consultation for both existing costs and the proposed harmonisation, in terms of cost per submission. Proportionally the data submitted across the EU is split 3:3:4 between the three categories for existing systems.

Table 5.1 Estimates costs of the existing systems

| Cost per submission for SDS only | Cost per submission SDS + | Cost per submission Advanced | Cost per submission for harmonised system |
|---|---|---|---|
| €70 | €300 | €700 | €220 |

These data are based on the questionnaire responses, but it is important to note that costs under the existing and harmonised systems will vary significantly, according to factors such as hourly staff costs, complexity of formulations, availability of data (including also during resubmissions), as well as various other factors. The values presented above are therefore to be taken as indicative only, and were derived for use in setting up estimates of overall EU costs.

## 5.3 Scaling factors to estimate costs at EU level

Various data and assumptions were needed in order to address the following objective:

- Objective 3 Estimation of key multiplication factors to allow a cost estimate at EU level

The industry questionnaire provided valuable insights into the current activities of industry in developing and submitting data to the Poison Centres across the EU. The responses from the industry consultation were used to help define key variables within the cost model such as unit price per submission. In order to extrapolate the variables within the cost model to full EU level it was necessary to identify additional data to help populate full EU level results with sufficient level of disaggregation as to make the results meaningful.

Eurostat company data provides a breakdown by industry sector using NACE indexing to identify the number of companies by size, sector and Member State in operation. However these are often incomplete at national level providing instead EU totals for numbers of companies and Member State and company size data for the majority but not all EU Member States. The ratios between company size and distribution within the known states were used to help fill gaps for the missing states in order to provide comprehensive data on EU company information (albeit with inherent uncertainties).

The company information from Eurostat was then used in combination with the defined variables in the cost model to generate full EU level results, including breakdown by key sectors, national totals and company size information.

Details of the numbers of companies per sector are set out in the table 2.4 and Appendix D. There were also a number of data and assumptions used to derive EU-level estimates such as:

- Assumed frequency of submission in different sectors.
- Numbers of products sold per company in different size ranges.
- Numbers of Member States into which products are sold (average per company).
- Share of companies selling to consumer/professional use and to industrial use.

Details of some of the key assumptions around these parameters are provided in Appendix D

## 5.4 EU level estimates of quantified costs and benefits

The remaining two objectives related to providing estimates of costs and savings of the proposals, at EU level, specifically:

- Objective 4 Extrapolation of costs and benefits (costs-savings) of obligatory provision of information under the proposed harmonised reporting format;
- Objective 5 Assessing the additional costs for the unique formula identifier (UFI).

The quantitative results of the cost model developed from the industry questionnaires and Eurostat company data provide extrapolated results for the EU. As stated within chapter 3 these results show an overall net saving for industry, which is expected to more than offset the net costs for the adoption of the UFI. These savings do however mask some specific disparities, particularly for those companies that trade only domestically within Member States that currently have less data intensive systems than the proposed harmonisation. This issue can further be exacerbated in those Member States where submission of data is voluntary. The switch to a mandatory system proposed under the harmonised format would likely also increase the number of companies having to submit data to Poison Centres.

Table 5.2 provides the overall costs (highlighted in red) and savings (black) for the EU disaggregated by the core industry sectors identified within the industry consultation. This recognises that the paints, varnishes and dyes sector, along with the soaps and detergents sector may have broader product ranges than other sectors and thus need to make more data submissions (although the same may be true for some other sectors, the data was not available to assess these from the consultation results).

In the case of the UFI the reason that the paints, varnishes and dyes sector sees a bigger net cost (1.3 billion Euro) is due to the significantly larger product range size compared to other sectors. Likewise based on the cost model assumptions the frequency of data submissions to Poison Centres reflects submissions upon a change in formulation, which would also mean the need for an update to the UFI and packaging. This represents a significant cost for companies in the paints, varnishes and inks sector under scenario A. However the use of a Group UFI highlighted under scenarios E and F shows that much of this cost can be eliminated. Under Scenario F total EU costs for the UFI per annum would be around 343 Million Euro.

The costs and savings highlighted within Table 5.2 also reflect the differences between consumer/professional goods and industrial mixtures. The results from the industry questionnaire used to develop the cost model highlighted differences in the size of product range and also frequency of data submission between consumer/professional and industrial mixtures. The industry questionnaire also identified a broad split in company business with a quarter of the affected companies producing consumer/professional goods and three quarters of the affected companies producing industrial mixtures.

In the case of the UFI for industrial mixtures, companies would only need to display this information on the SDS which is expected to be a less complex and costly process than relabeling of product packaging.

These estimates are based on a number of assumptions and simplifications. There is thus a degree of uncertainty regarding the magnitude of the different cost elements.

In developing the base case scenario (scenario A) the project team used the data provided from the industry consultation to develop the key variables within the cost model that drive the results presented in Table 5.2 (without modification). However in deriving these calculations, specific sensitivities around some of the core variables were identified.

There were a number of issues that it was not feasible to pick up in the industry questionnaire such as the fact that not all products sold by a company are sold to all of the Member States into which that companies sells across their range, that the cost of resubmission for a reformulated product is expected to be lower than the cost of the original submission, and that the incremental costs of submission to additional Member States are expected to be less (under the baseline) than the costs of the most substantive submission.

Table 5.2 Summary of total costs and benefits (Base case – Scenario A)

| | | **Costs, Millions of Euro per year (total EU plus Norway)** | | | |
|---|---|---|---|---|---|
| | | Paints, varnishes and inks | Soaps and detergents | Other sectors | **All sectors aggregated** |
| **All sectors** | Consumer and professional products (PC submissions) | -1,000 | -130 | -610 | -1,740 |
| | Consumer and professional products (UFI) | 1,300 | 90 | 120 | **1,510** |
| | **Total consumer and professional products** | **300** | **-40** | **-490** | **-230** |
| | Industrial products (PC submissions) | -320 | -185 | -390 | -895 |
| | Industrial products (UFI) | 200 | 14 | 26 | **240** |
| | **Total industrial products** | **-120** | **-171** | **-364** | **-655** |
| | Total Savings from Harmonisation (Consumer/professional + Industrial Mixtures) | **-1320** | **-315** | **-1000** | **-2635** |
| | Total costs from UFI (Consumer/professional + Industrial Mixtures) | **1500** | **104** | **146** | **1750** |
| | **Overall Total costs/ savings** | **180** | **-211** | **-854** | **-885** |

To test the sensitivity of these results an additional set of scenarios were developed to adjust the frequency of submission (Scenario B) (as a proxy for the incremental costs of re-submission), number of international sales (Scenario C), use of a group UFI for product ranges with similar composition (Scenario E) and also the combination of these scenarios (Scenario F).

In addition, the cost model had one standalone scenario to assess the cost impact of implementing the UFI without a transitional phase. In practice the adoption of the UFI would include a planned transitional phase which could be around 2 to 3 years, to limit the impact on industry, for example related to relabeling existing stockpiles. In developing the cost estimates the Commission Services wanted to understand the impact if such a transitional phase were not used.

Table 5.3 provides an overall set of costs (highlighted in red) and savings (black) for each of the different scenarios. For scenario D in particular the relabeling costs for the UFI could amount to around 550 million euros, which would represent a significant reduction in any net saving and could present a challenge to SME companies in

particular. As stated above, adoption of the UFI is expected in practice to include a transitional phase, but scenario D provides a useful indication of the value of such a transitional phase.

Scenarios B and C see a reduction in the overall savings as a result of fewer submissions (Scenario B) and fewer products + submissions (Scenario C). In developing the costs and savings for the EU the key driver is the unit price cost per submission. This would see the greatest savings recognised in the move from advanced data systems to the harmonised position. The industry consultation provided information on the frequency of submission which for some sectors included multiple submissions per product per year. In reality the project team would expect these successive submissions to account for changes in composition which would affect the specific reported breakdown. In the case where narrow concentration ranges are used this could mean a need to report more often, particularly for mixtures produced using batch processes (with minor ingredient changes) or with frequently changing compositions. Given the broad diversity of the chemicals industry it is unclear whether the frequency quoted in the base case scenario is suitable to represent the broad range of industry accounted for.

Table 5.3 Sensitivity analysis and scenarios for all EU Member States plus Norway– costs/savings in millions of euros

| | Scenario A | Scenario B | Scenario C | Scenario D | Scenario E | Scenario F |
|---|---|---|---|---|---|---|
| **Costs (savings) of harmonisation – total** | **-2,635** | **-2,670** | **-930** | **-2,645** | **-2,645** | **-893** |
| Costs (savings) of UFI | 1,750 | 690 | 1,750 | 1,750 | 875 | 343 |
| Costs of relabeling stock for UFI if transitional phase not used | - | - | - | 555 | - | - |
| **Costs of UFI – total** | **1,750** | **690** | **1,750** | **2,305** | **875** | **343** |
| **Total costs (savings)** | **-885** | **-1,980** | **820** | **-340** | **-1,770** | **-550** |

Scenario A (basecase); Scenario B (reduced frequency of submissions); Scenario C (reduced international trade); Scenario D (re-establish labelling costs); Scenario E (use of a Group UFI); Scenario F (Scenarios B, C and E combined)

Equally the information gathered for international sales developed an average number of products and markets based on company size. It was however not practicable within the questionnaire to estimate whether there was any specific disaggregation to project ranges to specific geographies. The base case scenario assumes for example that if company A sells 100 products within 5 Member States it sells all 100 to all 5 Member States, equating to 500 data submissions to Poison Centres. In reality companies may tailor their goods for specific geographic regions, so the number of internationally traded goods in Scenario A may represent an overestimate. Likewise the incremental costs of supplying to additional Member States may be less than the original submission.

Finally Scenario E is intended to explore the possibility of adopting a 'group UFI' in specific cases where companies have large product ranges based on a basic formula that has only small incremental changes between products. This issue would largely affect companies marketing consumer and professional goods noting that for industrial mixtures the adoption of the UFI would appear on the SDS only. The results of

scenario E, perhaps as expected, show a reduction in costs for the UFI to industry and therefore an increase in the overall net savings using this approach.

Scenario F represents the combination of scenarios B, C and E. However it is still important to make clear that Scenario F still represents net overall savings which more than offset the costs of adopting the UFI.

Scenario A represents a case where:

- It is assumed that all products sold by a company are sold into all of the Member States with which that company trades, across its entire product range.
- The costs of a resubmission following a formulation change are as much as the costs of the original submission.
- There is no potential for a group UFI and even minor formulation differences (e.g. slight colour differences) would need a different UFI.

Overall, Scenario A is considered to represent an overestimate of the costs under the baseline, and hence an overestimate of the potential savings through harmonisation. Scenario F may represent a better estimate of the actual costs and savings, as it incorporates:

- An assumed lower incremental cost under the baseline for resubmission following minor reformulations of existing products (accounted for in the model by reducing the submission frequency, which is used as a multiplication factor).
- A reduced multiplication factor to account for the fact that not all products produced by a company will be sold to all Member States with which that company trades across its product range, and that the incremental costs of submission to each additional Member State will not necessarily be the same as the costs of submission to the first (most data-intensive) Member State.
- A group UFI.

The suggested variations to the key variables used within Scenario F likely represent the best estimate of what the overall costs and benefits would be for companies in the EU as a result of harmonisation and the UFI.

Table 5.4 presents the Scenario F overall net savings breakdown as a contrast to the net savings presented for Scenario A within Table 5.2. As with the Scenario A calculations, the paints, varnishes and inks sector and the soaps and detergents sector would see the greatest savings, based on broader product ranges and more frequent need to provide information to Poison Centres. Table 5.4 suggests the associated costs for the UFI could be around 340 million euros across EU businesses. This cost is offset by the harmonisation of data formats to provide an overall net saving of around 550 million euros.

Table 5.4 Summary of total costs and benefits (Combined options – Scenario F)

| | | **Costs, Millions of Euro per year (total EU plus Norway)** | | | |
|---|---|---|---|---|---|
| | | Paints, varnishes and inks | Soaps and detergents | Other sectors | **All sectors aggregated** |
| **All sectors** | Consumer and professional products (PC submissions) | -450 | -43 | -185 | -678 |
| | Consumer and professional products (UFI) | 210 | 15 | 59 | 284 |
| | **Total consumer and professional products** | **-240** | **-28** | **-126** | **-394** |
| | Industrial products (PC submissions) | -64 | -26 | -125 | -215 |
| | Industrial products (UFI) | 43 | 3 | 13 | 59 |
| | **Total industrial products** | **-21** | **-23** | **-112** | **-156** |
| | Total Savings from Harmonisation (Consumer/professional + Industrial Mixtures) | **-514** | **-69** | **-310** | **-893** |
| | Total costs from UFI (Consumer/professional + Industrial Mixtures) | **253** | **18** | **72** | **343** |
| | **Overall Total costs/ savings** | **-261** | **-51** | **-238** | **-550** |

Overall, the introduction of harmonisation is expected to result in substantial savings to EU industry as a whole, amounting to around €550 million under scenario F, or on average around €40,000 per company per year[14]. However, this masks the fact that some companies would incur significant additional (net) costs, such as companies based in Member States with systems that are currently voluntary, and which trade in only a small number of Member States. These companies (i.e. those trading domestically only) are more likely to be SMEs. Companies that benefit most would be those that sell their products to multiple Member States, as there would be a substantial reduction in burden of having to submit tailored information for each Member State.

The UFI represents a net cost to industry, and under scenario F this accounts for around €340 million per year.

In contrast, both the harmonisation (taken as a whole) and the UFI would provide substantial benefits to poison centres and ultimately to the treatment of people who

[14] Derived from an estimate of around 23,500 companies in the sectors covered based on the Eurostat data.

have been poisoned by these products, as illustrated by the responses to the questionnaire and more detailed consultation with selected Member States' centres. These benefits include increased speed and quality of response, and reduced likelihood of over-treatment (including reduced hospitalisation), which should ultimately save lives and reduce negative health effects. While it has not been possible to quantify such effects, they are likely to be significant.

# 6 Conclusions and Recommendations

## 6.1 Summary of findings

Article 45 of the EU Regulation on the classification, labelling and packaging of chemicals (CLP) (EC) No. 1272/2008)) and Article 17 of the Dangerous Preparations Directive (Directive 1999/45/EC) place a requirement on the EU Member States to appoint a body (or bodies) responsible for receiving information on mixtures/preparations considered hazardous/dangerous on the basis of their health or physical effects. However the evolution of different typologies of such bodies in the Member States across the EU has created a diverse and complex system of data requirements which places a substantial burden on industry, particularly where trading into multiple Member States.

The Commission Working paper on the harmonisation of data requirements discussed at the 14th CARACAL meeting attempts to address this issue. The results of a stakeholder consultation with industry and Poison Centres via questionnaires (for the current study) has highlighted the broad range of opinions and concerns that both industry and Poison Centres have regarding harmonisation of the data submission format and the adoption of the UFI.

Overall, the quantitative estimates of costs and savings under the proposed harmonised system suggest net savings across the EU, particularly for those products for which industry is already required to provide data to the Poison Centres (consumer and professional products). However there may be net costs for those companies that trade domestically only. In particular this would affect SMEs operating in Member States were the current data burden is less than the proposed harmonisation. However, the results are very sensitive to certain assumptions, particularly the frequency of submission to PCs, but also a number of others (such as the average number of products per Member State where companies supply to multiple Member States).

For goods for industrial use, there would be net costs to meet the new requirements under the harmonised system in cases where companies do not currently provide information to Poison Centres other than via the SDS Consultation with Poison Centres highlighted that the majority of calls received related to consumer goods, particularly pharmaceuticals. Based on the volume and type of calls received, this would suggest the current primary focus on consumer and professional use mixtures is the correct approach.

Based on the responses of the Poison Centre questionnaire, the UFI has been largely welcomed, with a number of obvious potential benefits highlighted. In particular responses noted the benefit that the UFI would have to aid response times and identification of products. The costs to industry of adopting the UFI are expected to be offset by harmonisation costs (when looking at total EU costs), with net overall savings for harmonisation including the UFI (notwithstanding the above points on sensitivity of results). However the net costs could be reduced by careful consideration of how the UFI is adopted, such as including a phase in period (which is already envisaged) and group UFI for specific product types/sectors.

Table 6.1 provides a summary of the main results and issues discussed within the earlier chapters of this report.

Table 6.1 Summary of costs and benefits

| Element | Costs | Benefits |
|---|---|---|
| **Harmonisation of data to be submitted – preparing and submitting data to Poison Centres** | Companies submitting: Additional costs of preparing submissions for Member States with less extensive existing requirements.<br><br>Companies submitting: Additional costs for preparing submissions in Member States where submission is currently voluntary<br><br>Companies submitting: Additional costs for preparing submissions in companies that trade only domestically in Member States where data burden is currently lower than proposed harmonisation.<br><br>Poison Centres: Additional costs associated with processing a greater number of submissions, particularly for countries that switch from voluntary to mandatory.<br><br>Poison Centres: Additional costs for more trained staff at those Poison Centres where the existing data requirements are more extensive. This would be required to provide additional interpretation where there is a loss of data. | Companies submitting: Reduced costs through being able to submit the same information to all Member States where products are marketed. Overall net saving at EU level of €550 Million Euro (based on scenario F). (but note sensitivity of results to key parameters<br><br>Companies submitting domestically only: In those Member States with currently more advanced systems with greater burden, for those companies there would still be a net-saving.<br><br>Poison Centres: Increased consistency of information provided and improved level of detail for Member States with less extensive existing systems. More rapid response and effective medical advice. The indirect benefit of improved diagnostic ability would potentially lead to a reduction in over treatment as well as the potential to avoid referral of some cases to hospital unnecessarily. The Poison Centre surveys highlighted that up to 40% of calls result in over treatment due to difficulties with diagnosis |
| **Submission of data on mixtures for industrial use** | Companies submitting: New costs of preparing submissions for all companies across all Member States, estimated at 782 Million Euro.<br><br>Companies submitting: SMEs highlight the adoption of a 24/7 emergency response number for SDS could proving challenging with limited internal resource and costs of third parties prohibitive | Poison Centres: Additional information would allow for more complete databases and possibility to respond in case of incidents involving hazardous mixtures for industrial use.<br><br>Harmonisation benefits for those companies who already notify Poison Centres, with estimated savings of €215 Million Euro (Scenario F) |
| **Harmonisation of data to be submitted – health effects** | Poison Centres: Possible reduced level of diagnosis if Member States with more extensive existing systems reduce the information requirements to the harmonised level | Poison Centres: Expected increased diagnostic ability leading to improved treatment of poisoning cases.<br><br>Poison Centres: The indirect benefit of improved diagnostic ability would potentially lead to a reduction in over treatment as well as the potential to save referral of some cases to hospital unnecessarily. The |

| Element | Costs | Benefits |
|---|---|---|
| | | Poison Centre surveys highlighted that up to 40% of calls result in over treatment from difficulties with diagnosis. |
| **UFI for new products:** | Companies adopting UFI: Costs to adopt UFI which would include both one-off costs for label redesigns, new software, training, but also annual running costs to maintain the system. Expected costs based on Scenario F are around €343 Million Euro per annum. | Poison Centres: Improved response time to rapidly identify products. Improved diagnostic ability to identify products where currently other issues make this difficult such as products with similar names.<br><br>Poison Centres: The indirect benefit of speeding identification and response in case of incidents would be to avoid over treatment, allow more rapid treatment and thus minimise injury and reduce the need for referral of patients to hospital in cases where this is not necessary. |
| **UFI for mixtures for industrial use** | Companies adopting UFI: Costs to adopt UFI which would include both one-off costs for label redesigns, new software, training, but also annual running costs to maintain the system. | Poison Centres: Improved response time to rapidly identify products. Improved diagnostic ability to identify products where currently other issues make this difficult such as products with similar names.<br><br>Poison Centres: The indirect benefit of speeding identification and response in incidents would be to avoid over treatment, allow more rapid treatment and thus minimise injury and reduce the need for referral of patients to hospital in cases where this is not necessary. |

## 6.2 Recommendations

Based on the stakeholder engagement with industry and Poison Centres and the results of the cost analysis the following recommendations are made:

- **Raising awareness** - The stakeholder engagement with industry highlighted that there are still a significant number of stakeholders who are confused to what specifically is included within the harmonisation of data submission requirements. For a number of respondents this confusion caused some anxiety. These potentially unfounded concerns and fears could be mitigated by more widespread communication with industry.
- **Minimize impacts** - The overall results of the proposed harmonisation, for those companies reporting to Poison Centres show that the EU as a whole could see net savings. However for companies that trade only domestically, particularly in countries with currently lower burden than harmonisation, there would be net costs. Within this group there are likely to be a large proportion of SMEs which might be affected. On this basis there could be an option to engage with those Member States specifically to assess what further options could be utilised to help minimise cost impacts (e.g. transitional periods)..

- **UFI benefits -**Based on information from those that took part in the Poison Centre questionnaire and telephone interviews the UFI has been largely welcomed by Poison Centres with the potential benefit of speeding up rates of response and rapid identification of products highlighted. The Commission Services have indicated that the adoption of the UFI would be accompanied by a transitional phase to limit the impact on industry for relabeling existing stockpiles. Without such a transitional phase additional costs of around 550 million euro could be borne by companies in the EU.
- **Grouping UFI** - The industry consultation has also highlighted a specific issue for adopting the UFI within sectors which have broad ranges of products based on a basic formula with small incremental changes to the formula to provide subtly different products. In these incidences, a group UFI could be considered in order to limit the burden on these sectors. Given the basic formula adopted by these sectors, the use of a group UFI could limit the cost impacts with minimal loss of benefit to identification of goods.
- **Use of ranges** - Similarly, 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.
- **Transitional period** - The differences in impacts of harmonisation amongst Member States and companies are significant. Inevitably some companies will benefit while others will incur net costs with the proposed changes. For those companies that are more likely to incur increased costs (e.g. where they currently only sell domestically in Member States with relatively simple systems), it may be appropriate to consider how the cost burden could be softened, such as through the timing of the introduction of the harmonisation measures.

# Appendix A: Suggested Harmonised Format based on the 14th Meeting of the Competent Authorities for REACH and CLP (CARACAL). Held on the 2-3 April 2014 at Centre A. Borschette, Brussels, Belgium

# PART C

## 5 Submission format

This part sets out the format of the submission to be submitted, in accordance with Art. 45 of this Regulation.

### 5.1 Submission Format for Part B Section 1

This section sets out the format of the submission for Part B Sections 1.1, 1.1.1., 1.2. and 1.3.

**Identification of the mixture**

| | |
|---|---|
| Complete trade name of the product<br>*(in case of group submission list all product identifiers)* | |
| Other Names, Synonyms | |
| Unique Formula Identifier (UFI) | |
| Other identifiers (registration number, authorization number, company product codes) | |

**Product categorisation**

| | |
|---|---|
| Intended use (Product categorization Code) | |
| User identification (indicate all uses) | □ consumer use<br>□ professional use<br>□ industrial use |

| **Contact details of the submitter** | |
|---|---|
| Company name | |
| Company address (street, city, postal code, country) | |
| Company telephone number | |
| Company e-mail | |

| **Contact details for rapid access to additional product information (24 hours/7 days)** | |
|---|---|
| Company (department) name | |
| Company telephone number (24 hours per day/ 7 days per week) | |

### 5.2 Submission Format for Part B Section 2

This section sets out the format of the submission for Part B Sections 2.1, 2.2, 2.3 and 2.4.

| **Classification of the mixture and label elements** | |
|---|---|
| Hazard class and category | |
| Hazard pictograms | |
| Signal word | |
| Hazard statements | |
| Precautionary statements | |
| **Toxicological information** | |
| Description of the toxicity of the mixture (as specified on Section 11 Safety Data Sheet Annex II of Regulation No 1907/2006 (REACH) | |
| **Additional Information on the mixture** | |
| Colour | |
| pH (if not supplied as an aqueous solution, indicate the pH of an aqueous solution containing a concentration of 10% of the mixture) | |
| Physical state | □ solid<br>□ liquid<br>□ gas |
| Packaging (type and size) | |

### 5.3 Submission Format for Part B Section 3

This section sets out the format of the submission for Part B Sections 3.0.1, 3.1, 3.2 and 3.3.

**Product identifiers of the mixture components (substances and mixtures in mixtures if applicable)**

| Chemical name of the substance or product identifier of MIM | CAS number (if applicable) | EC number (if applicable) | UFI (if applicable) | Exact concentration | Minimum concentration | Maximum concentration |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

# Appendix B: Questionnaires

## Survey Questions for Poison Centres

**A. Administrative Details**

1. Name of Poison Centre
2. Main contact person
3. Contact details – E-mail
4. Contact details – phone number including international dialling code
5. Member State represented
6. Languages used for submissions received.
7. Approximate number of calls received per annum

**B. Harmonised data for Poison Centres – Benefits**

8. What do you perceive as the key benefits of a harmonised data submission for your Poison Centre (Drop down with the following options 'More appropriate response', 'more timely response', 'Gain of useful resources' or 'Other' – Allow comments box for Other answers
9. Will implementation of a UFI (unique formulation identifier) help you to ensure you a faster and more reliable identification of the product of interest?
10. Currently, for what proportion of calls can no product be clearly identified? Please provide a percentage
11. Do you think non-identification of a product has ever led to over treatment? If yes, please provide an estimation in percentage
12. Please provide an estimation of the number of calls related to mixtures for industrial use only (exposure to products in an industrial context only), mixtures for professional use only and mixtures for general consumer (see table below)

| | All calls | Calls related to general consumer products | Calls related to products for professional use only | Calls related to products for industrial use only |
|---|---|---|---|---|
| Estimation N° of calls per year | | | | |

**C. Harmonised data for Poison Centres – Costs**

13. Based on the extended scope of the harmonised data submission, do you predict any increase or decrease in the volume of submissions?
14. If there is such a change in the volume of submissions, what would be the difference in costs per annum in Euros?
15. If there is such a change in the volume of submissions, what would be your approach to tackle the cost increase of handling additional data?

**D. Data handling details**

16. What are the national requirements for data submission in your country? I.e. is submission of hazardous mixtures a mandatory requirement or voluntary system? (should be a simple tick box / drop down with either 'Mandatory' or 'Voluntary').
17. Do you make use of any online web portal for submitting data? (Same as above simple tick box/drop down with 'yes' / 'no'). Can add a comments box underneath if that helps.
18. Do you make use of bespoke software to help applicants detail their product? (Same as above simple tick box/drop down with 'yes' / 'no'). Can add a comments box underneath if that helps.

19. If the answer to Q18 was yes please can you provide the following details of costs:
    a. One-off / non-recurring costs for further development / upgrade of the software
    b. Breakdown of running costs (operational expenditure) to maintain the existing system including total operational costs, which should break down into overhead costs and staff costs per annum.
20. Does your organisation charge any fee for the submission of data to the national Poison Centre/s? If so, what fees are charged?

**E. Data handling details**

21. Does the centre require pre-registration?
22. What pre-registration data do you require? Please list
23. What do you use this for?
24. Please describe the data requirements for submission of data to the national Poison Centre? i.e. SDS only, SDS + additional data on toxicity, more advanced system requiring further details on the nature of the product? (Same as with earlier questions simple tick box/drop down with 'SDS only' / 'SDS + additional data' 'more advanced system'). Can add a comments box underneath if that helps.
25. Do you require exact composition or composition ranges? (same as above tick box/drop down with 'yes' and 'no')
26. What do you use the data for – just advice or Member State reporting
27. Number of SDS / products registered in total to date since the Centre opened?
28. How many additional products/SDS are being registered per annum?
29. Number of companies registered to date
30. How many new companies are being registered per annum?
31. What is the average number of submissions per company per annum?

## Survey Questions for Industry

**A. Company details**

1. Company name
2. Contact name
3. Job title
4. Contact E-mail address
5. Contact Telephone number with international dialling code
6. In which country is your head quarters office registered
7. Which Member State(s) does your company operate in
8. What is your company SME status? (see Figure 1.3)
9. Main industry sector of business (drop down by categories listed in Figure 1.3)

**B. Harmonised data for Poison Centres – Benefits**

10. If your company completes registrations in multiple Member State countries please can you provide an estimate (in Euros per annum) of the potential savings from harmonising the data submission requirements for Poison Centres.

11. If your company completes registrations in multiple Member State countries please can you explain what the qualitative benefits would be? e.g. additional staff time for other duties, cost savings on deriving data, etc.

**C. Harmonised data for Poison Centres – Costs**

12. Have you submitted hazardous mixture registrations to Poison Centres in the last 3 years? (Y – go to Q11/ N – go to Q20)

13. Please provide an estimation of the registered mixtures (products) for industrial use only, for professional use only and for general consumer (see table below)

| | All products | General consumer products | Products for professional use only | Products for industrial use only |
|---|---|---|---|---|
| Estimation N° of products placed on the market per year | | | | |

14. What is the total annual ongoing/operational costs spent on Poison Centre registrations for your company (based on the last full year)?

15. Please provide percentage breakdown by:

    Training, data handling, supply chain liaison, data input, collation and submission, maintaining audit systems.

16. What are the one-off / non-recurring costs (e.g. equipment costs) spent on Poison Centre registrations for your company (expressed BOTH as one-off expenditure and, if possible, on an annual basis, i.e. as equivalent annual costs)

17. Please provide a percentage breakdown for these one off costs by:

    New equipment costs, equipment maintenance (non-staff), analytical requirements, systems changes.

18. Please provide a percentage breakdown for these annual costs by:

    New equipment costs, equipment maintenance (non-staff), analytical requirements, systems changes.

19. Please provide a breakdown of costs for each country to which you submit registrations based on the product types described below (where applicable). This should be estimated as € per registration.

| | Simple product – Stable | Simple product – Stable | Simple product – Stable | Simple product – Stable |
|---|---|---|---|---|
| List of countries on vertical axis | | | | |

Simple product – A product with four or fewer substances in the mixture which can be easily identified e.g. cleaning products

Complex product – a product with more than four substances or where substances are complex family of chemicals e.g. coal tars

Stable product – A product where the formulation rarely changes, this would suggest only 1 data submission per Member State per year is needed for the product. e.g. paints

Frequently variable product – The composition of the product is open to change and may mean that multiple updates of data submissions are required per year. e.g. industrial gases

20. Based on the proposed harmonised registration system please estimate what you think would be the likely costs per product for registration in Euro against the following product types:

| | Harmonised System |
|---|---|
| Simple product – Stable | |
| Simple product – frequently variable | |
| Complex product – stable | |
| Complex product – frequently variable | |

21. Given the info in Q20. What is the estimated overall CHANGE to the total ongoing/operational costs spent on Poison Centre registrations for your company per annum under the new system as Euro/per registration

22. Given the info in Q20. What is the estimated overall CHANGE to the one-off / non-recurring costs (e.g. equipment costs) (expressed BOTH as one-off expenditure and, if possible, on an annual basis, i.e. as equivalent annual costs)

23. Please give an explanation of the main reasons why the costs are expected to change, for your business, under the proposed harmonised system.

**D. Costs associated with adoption of UFI system**

24. Please provide details of the predicted costs per annum in Euros for your company for adopting the UFI system based on:

i) Marketing cost to add to the label and other documentation

ii) Administrative cost associated with the Unique Formula Identifier (UFI)

iii) Development of internal company product inventory software to include UFI

Taking account of the timescales for implementation – cost of replacing existing product labels (potentially where stock has been stockpiled)

# Appendix C: Member States Metrics

| **Austria** | | **Croatia** | |
|---|---|---|---|
| ***Level of information required*** | More detailed than SDS | *Level of information required* | SDS Only |
| ***Use of Bespoke tools or software (likely requiring self-tutorial or training)*** | No bespoke tools used | *Use of Bespoke tools or software (likely requiring self-tutorial or training)* | No Bespoke tools used |
| ***Legislative requirements*** | Mandatory | *Legislative requirements* | Voluntary to provide information |
| ***Compositional data*** | Can use concentration ranges | *Compositional data* | Can use concentration ranges |
| **Belgium** | | **Cyprus** | |
| ***Level of information required*** | SDS only | *Level of information required* | More detailed than SDS |
| ***Use of Bespoke tools or software (likely requiring self-tutorial or training)*** | No Bespoke tools used | *Use of Bespoke tools or software (likely requiring self-tutorial or training)* | No Bespoke tools used |
| ***Legislative requirements*** | Mandatory | *Legislative requirements* | Mandatory |
| ***Compositional data*** | Requires exact formula | *Compositional data* | Requires exact formula |
| **Bulgaria** | | **Czech Republic** | |
| ***Level of information required*** | More detailed than SDS | *Level of information required* | SDS Only |
| ***Use of Bespoke tools or software (likely requiring self-tutorial or training)*** | No bespoke tools used | *Use of Bespoke tools or software (likely requiring self-tutorial or training)* | SDS is accepted but Bespoke tools are also available to provide additional data such as CHES |
| ***Legislative requirements*** | Mandatory | *Legislative requirements* | Mandatory |
| ***Compositional data*** | Unknown – assume ranges can be used | *Compositional data* | Can use concentration ranges |
| **Denmark** | | **France** | |
| ***Level of information required*** | SDS Only | *Level of information required* | More detailed than SDS |
| ***Use of Bespoke tools or software (likely requiring self-tutorial or training)*** | No bespoke tools used | *Use of Bespoke tools or software (likely requiring self-tutorial or training)* | Bespoke software used |
| ***Legislative requirements*** | Voluntary | *Legislative requirements* | Mandatory |
| ***Compositional data*** | Can use concentration ranges | *Compositional data* | Requires exact formula |

| **Estonia** | | **Germany** | |
|---|---|---|---|
| ***Level of information required*** | SDS Only | *Level of information required* | More detailed than SDS |
| ***Use of Bespoke tools or software (likely requiring self-tutorial or training)*** | No bespoke tools used | *Use of Bespoke tools or software (likely requiring self-tutorial or training)* | Bespoke software used |
| ***Legislative requirements*** | Assumed to be voluntary | *Legislative requirements* | Mandatory |
| ***Compositional data*** | Concentration ranges can be used | *Compositional data* | Requires exact formula |
| **Finland** | | **Greece** | |
| ***Level of information required*** | SDS Onlu | *Level of information required* | More detailed than SDS |
| ***Use of Bespoke tools or software (likely requiring self-tutorial or training)*** | No bespoke tools used | *Use of Bespoke tools or software (likely requiring self-tutorial or training)* | Uses bespoke software |
| ***Legislative requirements*** | Mandatory | *Legislative requirements* | Unknown |
| ***Compositional data*** | Concentration ranges can be used | *Compositional data* | Unknown |
| **Hungary** | | **Latvia** | |
| ***Level of information required*** | SDS only | *Level of information required* | More detailed than SDS |
| ***Use of Bespoke tools or software (likely requiring self-tutorial or training)*** | No bespoke tools used | *Use of Bespoke tools or software (likely requiring self-tutorial or training)* | No bespoke tools used |
| ***Legislative requirements*** | Mandatory | *Legislative requirements* | Mandatory |
| ***Compositional data*** | Requires exact formula | *Compositional data* | Unknown |
| **Ireland** | | **Lithuania** | |
| ***Level of information required*** | SDS Only | *Level of information required* | More detailed than SDS |
| ***Use of Bespoke tools or software (likely requiring self-tutorial or training)*** | No bespoke tools used | *Use of Bespoke tools or software (likely requiring self-tutorial or training)* | Bespoke software used |
| ***Legislative requirements*** | Voluntary | *Legislative requirements* | Mandatory |
| ***Compositional data*** | Concentration ranges can be used | *Compositional data* | Unknown |

| **Italy** | | **Netherlands** | |
|---|---|---|---|
| ***Level of information required*** | More detailed than SDS | *Level of information required* | More detailed than SDS |
| ***Use of Bespoke tools or software (likely requiring self-tutorial or training)*** | Bespoke software used | *Use of Bespoke tools or software (likely requiring self-tutorial or training)* | Bespoke software used |
| ***Legislative requirements*** | Mandatory | *Legislative requirements* | Mandatory |
| ***Compositional data*** | Can use concentration ranges | *Compositional data* | Exact concentration but UVCB products can use ranges |

Unable to assign a position on the metrics for Luxembourg and Malta due to lack of information

| **Norway (as observer)** | | **Romania** | |
|---|---|---|---|
| ***Level of information required*** | More detailed than SDS | *Level of information required* | SDS Only |
| ***Use of Bespoke tools or software (likely requiring self-tutorial or training)*** | Bespoke software used | *Use of Bespoke tools or software (likely requiring self-tutorial or training)* | No bespoke tools used |
| ***Legislative requirements*** | Mandatory | *Legislative requirements* | Voluntary |
| ***Compositional data*** | Requires exact formula | *Compositional data* | Concentration ranges can be used |
| **Poland** | | **Slovakia** | |
| ***Level of information required*** | SDS Only | *Level of information required* | SDS Only |
| ***Use of Bespoke tools or software (likely requiring self-tutorial or training)*** | No bespoke tools used | *Use of Bespoke tools or software (likely requiring self-tutorial or training)* | No bespoke tools used |
| ***Legislative requirements*** | Mandatory | *Legislative requirements* | Mandatory |
| ***Compositional data*** | Concentration ranges can be used | *Compositional data* | Concentration ranges can be used |
| **Portugal** | | Slovenia | |
| ***Level of information required*** | More detailed than SDS | *Level of information required* | More detailed than SDS |
| ***Use of Bespoke tools or software (likely requiring self-tutorial or training)*** | Bespoke software used | *Use of Bespoke tools or software (likely requiring self-tutorial or training)* | No bespoke tools used |

| **Norway (as observer)** | | **Romania** | |
|---|---|---|---|
| ***Legislative requirements*** | Mandatory | *Legislative requirements* | Voluntary |
| ***Compositional data*** | Requires exact formula | *Compositional data* | Concentration ranges can be used |
| **Spain** | | **United Kingdom** | |
| ***Level of information required*** | More detailed than SDS | *Level of information required* | SDS Only |
| ***Use of Bespoke tools or software (likely requiring self-tutorial or training)*** | Bespoke software used | *Use of Bespoke tools or software (likely requiring self-tutorial or training)* | No bespoke tools used |
| ***Legislative requirements*** | Mandatory | *Legislative requirements* | Voluntary |
| ***Compositional data*** | Can use concentration ranges~~Requires exact formula~~ | *Compositional data* | Can use concentration ranges |
| **Sweden** | | | |
| ***Level of information required*** | More detailed than SDS | | |
| ***Use of Bespoke tools or software (likely requiring self-tutorial or training)*** | No bespoke tools used | | |
| ***Legislative requirements*** | Voluntary | | |
| ***Compositional data*** | Requires exact formula | | |

# Appendix D: Cost model assumptions

Scenario A

## Consumer and professional use products

| | | Value: baseline (other sectors) | Value: baseline (paints and varnishes) | Value: baseline (soaps and detergents) | Value: harmonisation (other sectors) | Value: harmonisation (paints, varnishes) | Value: harmonisation (soaps and detergents) | Unit/ notes |
|---|---|---|---|---|---|---|---|---|
| Share of companies manufacturing chemicals for consumer and professional use within the total number of companies by sector covered by PC requirements | Share of companies manufacturing chemicals for consumer and professional use within the total number of companies by sector | 0.2 | 0.4 | 0.2 | 0.2 | 0.4 | 0.2 | per cent<br>to be used if no data by company size |
| | Share of companies manufacturing chemicals for consumer and professional use within the total number of companies by sector -SMEs (<10) | 0.1 | 0.4 | 0.1 | 0.1 | 0.4 | 0.1 | per cent;<br>estimated based on industry data and consultation responses; expected to increase as a result of system design changes (shifting from voluntary to mandatory). Can be manually adjusted to be MS specific after harmonisation |
| | Share of companies manufacturing chemicals for consumer and professional use within the total number of companies by sector SMEs (<50) | 0.3 | 0.5 | 0.3 | 0.3 | 0.5 | 0.3 | |
| | Share of companies manufacturing chemicals for consumer and professional use within the total number of companies by sector only SMEs (<250) | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | |

| | | Value: baseline (other sectors) | Value: baseline (paints and varnishes) | Value: baseline (soaps and detergents) | Value: harmonisation (other sectors) | Value: harmonisation (paints, varnishes) | Value: harmonisation (soaps and detergents) | Unit/ notes |
|---|---|---|---|---|---|---|---|---|
| Share of companies manufacturing chemicals for consumer and professional use within the total number of companies by sector trading domestically only | Share of companies manufacturing chemicals for consumer and professional use within the total number of companies by sector only non SMEs (>250) | 0.2 | 0.5 | 0.2 | 0.2 | 0.5 | 0.2 | |
| | Share of companies manufacturing chemicals for consumer and professional use within the total number of companies by sector trading domestically only | 0.15 | 0.2 | 0.15 | 0.15 | 0.2 | 0.15 | per cent; to be used if no data by company size |
| | Share of companies manufacturing chemicals for consumer and professional use within the total number of companies by sector trading domestically only-SMEs (<10) | 0.5 | 0.33 | 0.5 | 0.5 | 0.33 | 0.5 | per cent; estimated based on industry data and consultation responses; trading patterns assumed to be unaffected as a result of system design changes (shifting from voluntary to mandatory). |
| | Share of companies manufacturing chemicals for consumer and professional use within the total number of companies by sector trading domestically only SMEs (<50) | 0.13 | 0.35 | 0.13 | 0.13 | 0.35 | 0.13 | |
| | Share of companies manufacturing chemicals for consumer and professional use within the total number of companies by sector trading domestically only SMEs (<250) | 0.19 | 0.16 | 0.19 | 0.19 | 0.16 | 0.19 | |

| | | Value: baseline (other sectors) | Value: baseline (paints and varnishes) | Value: baseline (soaps and detergents) | Value: harmonisation (other sectors) | Value: harmonisation (paints, varnishes) | Value: harmonisation (soaps and detergents) | Unit/ notes |
|---|---|---|---|---|---|---|---|---|
| | Share of companies manufacturing chemicals for consumer and professional use within the total number of companies by sector trading domestically only non SMEs (>250) | 0.1 | 0.16 | 0.1 | 0.1 | 0.16 | 0.1 | |
| Number of submissions per company (consumer and professional use) per year - trading domestically only | number of submissions per company (consumer and professional use) trading domestically only | | | | | | | number; to be used if no data by company size |
| | number of submissions per company - SMEs (<10) | 14 | 190 | 42 | 14 | 253 | 56 | number; estimated based on consultation responses (depend on the number of products and frequency of submissions). Number of submissions per company under harmonisation could increase due to increased frequency of submissions but number of products manufactured won't be affected (increase from shifting from voluntary to mandatory will be captured via number of companies affected) |
| | number of submissions per company - SMEs (<50) | 14 | 492 | 42 | 14 | 656 | 56 | |
| | number of submissions per company - SMEs (<250) | 77 | 8192 | 231 | 77 | 10923 | 308 | |
| | number of submissions per company - non-SMEs (>250) | 240 | 8287 | 719 | 240 | 11049 | 959 | |
| Number of submissions per company (consumer and professional use) per year | number of submissions per company (consumer and professional use) trading in multiple MSs | | | | | | | number; to be used if no data by company size |
| | number of submissions per company - SMEs (<10) | | 1846 | 2784 | 928 | 2461 | 3713 | number; estimated based on consultation responses |

| | | Value: baseline (other sectors) | Value: baseline (paints and varnishes) | Value: baseline (soaps and detergents) | Value: harmonisation (other sectors) | Value: harmonisation (paints, varnishes) | Value: harmonisation (soaps and detergents) | Unit/ notes |
|---|---|---|---|---|---|---|---|---|
| - trading in multiple MSs | number of submissions per company - SMEs (<50) | 844 | 8642 | 2531 | 844 | 11522 | 3375 | (depend on the number of products, number of trading partners and frequency of submissions). Number of submissions per company under harmonisation could increase due to increased frequency of submissions but number of products manufactured and number of trading partners won't be affected (increase from shifting from voluntary to mandatory will be captured via number of companies affected) |
| | number of submissions per company - SMEs (<250) | 2161 | 90112 | 6483 | 2161 | 120149 | 8644 | |
| | number of submissions per company - non-SMEs (>250) | 26749 | 171150 | 80246 | 26749 | 228200 | 106995 | |
| UFI | Consumer/professional use: costs per product, Euro/per product) | 0 | 0 | 0 | 340 | 340 | 340 | Euro/ product per year [annual]; |
| | Consumer/professional use: costs per product, Euro/per product) SMEs (<10) | 0 | 0 | 0 | 340 | 340 | 340 | Euro/ product per year [annual]; estimated based on consultation responses - driven by the number of companies affected per sector, number of products and frequency of submissions (potentially size of companies) |
| | Consumer/professional use: costs per product, Euro/per product) -SMEs (<50) | 0 | 0 | 0 | 340 | 340 | 340 | |
| | Consumer/professional use: costs per product, Euro/per product) -SMEs (<250) | 0 | 0 | 0 | 340 | 340 | 340 | |
| | Consumer/professional use: costs per product, Euro/per product) -non-SMEs (>250) | 0 | 0 | 0 | 340 | 340 | 340 | |

| | | Value: baseline (other sectors) | Value: baseline (paints and varnishes) | Value: baseline (soaps and detergents) | Value: harmonisation (other sectors) | Value: harmonisation (paints, varnishes) | Value: harmonisation (soaps and detergents) | Unit/ notes |
|---|---|---|---|---|---|---|---|---|
| UFI: stockpiles | share of companies per sector with stockpiles subject to UFI requirements | 0 | 0 | 0 | 0% | 0% | 0% | per cent; to be used if no data by company size |
| | share of companies per sector with stockpiles subject to UFI requirements -SMEs (<10) | 0 | 0 | 0 | 0% | 0% | 0% | per cent; estimated based on industry data and consultation responses; Scenarios A, B, C, E and F assume transition period is given to avoid re-labelling of existing stock. Scenario D assumes 100% to consider avoided costs of stock re-labelling |
| | share of companies per sector with stockpiles subject to UFI requirements-SMEs (<50) | 0 | 0 | 0 | 0% | 0% | 0% | |
| | share of companies per sector with stockpiles subject to UFI requirements -SMEs (<250) | 0 | 0 | 0 | 0% | 0% | 0% | |
| | share of companies per sector with stockpiles subject to UFI requirements -non-SMEs (>250) | 0 | 0 | 0 | 0% | 0% | 0% | |
| | Stockpiles: costs per company, Euro/per company (consumer and professional use) | | | | | | | Euro/ company per year [annual]; estimated based on consultation responses - driven by the number of companies affected per sector, number of products and (potentially size of companies) |
| | Stockpiles: costs per company, Euro/per company-SMEs (<10) | 0 | 0 | 0 | 17,700 | 17,700 | 17,700 | |
| | Stockpiles: costs per company, Euro/per company-SMEs (<50) | 0 | 0 | 0 | 55,900 | 55,900 | 55,900 | |
| | Stockpiles: costs per company, Euro/per company-SMEs (<250) | 0 | 0 | 0 | 237,800 | 237,800 | 237,800 | |

| | | Value: baseline (other sectors) | Value: baseline (paints and varnishes) | Value: baseline (soaps and detergents) | Value: harmonisation (other sectors) | Value: harmonisation (paints, varnishes) | Value: harmonisation (soaps and detergents) | Unit/ notes |
|---|---|---|---|---|---|---|---|---|
| | Stockpiles: costs per company, Euro/per company-non-SMEs (>250) | 0 | 0 | 0 | 1,126,000 | 1,126,000 | 1,126,000 | |

## Unit costs of submissions under different reporting formats: consumer and professional use

| | SDS only (other sectors, soaps and detergents) | SDS only (paints, varnishes) | SDS + additional (other sectors, soaps and detergents) | SDS + additional (paints, varnishes) | Advanced submission format (other sectors, soaps and detergents) | Advanced submission format (paints, varnishes) | Unit/ notes |
|---|---|---|---|---|---|---|---|
| Consumer, professional use: costs per submission, Euro/per submission - trading domestically only - baseline | 70 | 70 | 300 | 300 | 700 | 700 | Euro/ submission per year [annual] |
| Consumer and professional use: costs per submission, Euro/per submission - trading domestically only -after harmonization | 0 | 0 | 210 | 220 | 0 | 0 | Euro/ submission per year [annual] |
| Consumer, professional use: costs per submission, Euro/per submission - trading in multiple MS – baseline | 70 | 70 | 300 | 300 | 700 | 700 | Euro/ submission per year [annual] |

| | SDS only (other sectors, soaps and detergents) | SDS only (paints, varnishes) | SDS + additional (other sectors, soaps and detergents) | SDS + additional (paints, varnishes) | Advanced submission format (other sectors, soaps and detergents) | Advanced submission format (paints, varnishes) | Unit/ notes |
|---|---|---|---|---|---|---|---|
| Consumer and professional use: costs per submission, Euro/per submission - trading in multiple MS - after harmonisation | 0 | 0 | 210 | 220 | 0 | 0 | Euro/ submission per year [annual] |

## Consumer, professional and industrial use – multiple country trading

| Multiple MS trading | EU | Unit/ notes |
|---|---|---|
| Submission format: SDS only | 0.4 | Share; estimated based on consultation responses (depend on trading partners). Under harmonisation all submissions will be in SDS+ format. |
| Submission format: SDS plus additional data | 0.3 | |
| Submission format: advanced submission format | 0.3 | |

## Average number of trading partners and frequency (consumer and professional use)

| | Other sectors: number of trading partners | Frequency of submissions year: baseline | Frequency of submissions per year: harmonisation | Paints, varnishes number of trading partners | Frequency of submissions year: baseline | Frequency of submissions per year: harmonisation | Soaps and detergents number of trading partners | Frequency of submissions year: baseline | Frequency of submissions per year: harmonisation |
|---|---|---|---|---|---|---|---|---|---|
| number of submissions per company - SMEs (<10) | 11 | 1 | 1 | 4 | 3 | 4 | 11 | 3 | 4 |
| number of submissions per company - SMEs (<50) | 10 | 1 | 1 | 6 | 3 | 4 | 10 | 3 | 4 |
| number of submissions per company - SMEs (<250) | 15 | 1 | 1 | 11 | 3 | 4 | 15 | 3 | 4 |
| number of submissions per company - non-SMEs (>250) | 21 | 1 | 1 | 20 | 3 | 4 | 21 | 3 | 4 |

## Average number of products (consumer and professional use)

| | Other sectors: Domestic trade – average number of products | Other sectors: International trade – average number of products | Paints, varnishes and inks: Domestic trade – average number of products | Paints, varnishes and inks: International trade – average number of products | Soaps and detergents: Domestic trade – average number of products | Soaps and detergents: International trade – average number of products |
|---|---|---|---|---|---|---|
| number of submissions per company - SMEs (<10) | 14 | 84 | 63 | 154 | 14 | 84 |
| number of submissions per company - SMEs (<50) | 14 | 84 | 164 | 480 | 14 | 84 |
| number of submissions per company - SMEs (<250) | 77 | 144 | 2731 | 2731 | 77 | 144 |

| | Other sectors: Domestic trade – average number of products | Other sectors: International trade – average number of products | Paints, varnishes and inks: Domestic trade – average number of products | Paints, varnishes and inks: International trade – average number of products | Soaps and detergents: Domestic trade – average number of products | Soaps and detergents: International trade – average number of products |
|---|---|---|---|---|---|---|
| number of submissions per company - non-SMEs (>250) | 240 | 1274 | 2762 | 2853 | 240 | 1274 |

## Industrial use products

| | Variable | Value: baseline (other sectors) | Value: baseline (paints and varnishes) | Value: baseline (soaps and detergents | Value: harmonisation (other sectors) | Value: harmonisation (paints, varnishes) | Value: harmonisation (soaps and detergents | Unit/ notes |
|---|---|---|---|---|---|---|---|---|
| Share of companies manufacturing chemicals for industrial use within the total number of companies | Share of companies manufacturing chemicals for industrial use within the total number of companies by sector | | | | | | | estimated based on consultation responses - share of companies reporting industrial use products within total number of companies participating in the consultation |
| | Share of companies manufacturing chemicals for industrial use within the total number of companies by sector -SMEs (<10) | 0.1 | 0.2 | 0.1 | 0.1 | 0.2 | 0.1 | per cent; estimated based on consultation responses - share of companies reporting industrial use products (Q13) |
| | Share of companies manufacturing chemicals for industrial use within the total number of companies by sector SMEs (<50) | 0.2 | 0.4 | 0.2 | 0.2 | 0.4 | 0.2 | |

| | Variable | Value: baseline (other sectors) | Value: baseline (paints and varnishes) | Value: baseline (soaps and detergents | Value: harmonisation (other sectors) | Value: harmonisation (paints, varnishes) | Value: harmonisation (soaps and detergents | Unit/ notes |
|---|---|---|---|---|---|---|---|---|
| | Share of companies manufacturing chemicals for industrial use within the total number of companies by sector SMEs (<250) | 0.3 | 0.4 | 0.3 | 0.3 | 0.4 | 0.3 | within total number of companies responding to consultation - as a share within total responses by company size (all sectors excluding paints& varnishes) |
| | Share of companies manufacturing chemicals for industrial use within the total number of companies by sector non SMEs (>250) | 0.2 | 0.4 | 0.2 | 0.2 | 0.4 | 0.2 | |
| Share of companies manufacturing chemicals for industrial use within the total number of companies by sector trading domesticallly only | Share of companies manufacturing chemicals for industrial use within the total number of companies by sector trading domestically only | | | | | | | |
| | Share of companies manufacturing chemicals for industrial use within the total number of companies by sector trading domesticallly only-SMEs (<10) | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | |
| | Share of companies manufacturing chemicals for industrial use within the total number of companies by sector trading domestically only SMEs (<50) | 0.32 | 0.32 | 0.32 | 0.32 | 0.32 | 0.32 | |
| | Share of companies manufacturing chemicals for industrial use within the total number of companies by sector trading domesticallly only SMEs (<250) | 0.15 | 0.15 | 0.15 | 0.15 | 0.15 | 0.15 | |

| | Variable | Value: baseline (other sectors) | Value: baseline (paints and varnishes) | Value: baseline (soaps and detergents | Value: harmonisation (other sectors) | Value: harmonisation (paints, varnishes) | Value: harmonisation (soaps and detergents | Unit/ notes |
|---|---|---|---|---|---|---|---|---|
| | Share of companies manufacturing chemicals for industrial use within the total number of companies by sector trading domesticallly only non SMEs (>250) | 0.15 | 0.15 | 0.15 | 0.15 | 0.15 | 0.15 | |
| Number of submissions per company (industrial use) per year - trading domestically only | number of submissions per company (industrial use) trading domestically only | | | | | | | number; to be used if no data by company size |
| | number of submissions per company - SMEs (<10) | 41 | 243 | 123 | 41 | 243 | 123 | number; estimated based on consultation responses; no MS specific - driven by sector (nature of the product) and company size (rounded to '0) (all sectors minus paints&varnishes) |
| | number of submissions per company - SMEs (<50) | 61 | 1053 | 183 | 61 | 1053 | 183 | |
| | number of submissions per company - SMEs (<250) | 131 | 1734 | 393 | 131 | 1734 | 393 | |
| | number of submissions per company - non-SMEs (>250) | 751 | 11016 | 2253 | 751 | 11016 | 2253 | |
| Number of submissions per company (industrial use) per year - trading in multiple MSs | number of submissions per company (industriall use) trading in multiple MSs | | | | | | | number; to be used if no data by company size |
| | number of submissions per company - SMEs (<10) | 164 | 4200 | 492 | 328 | 8400 | 984 | number; no MS specific- driven by sector and nature of the product - stable/ frequently |
| | number of submissions per company - SMEs (<50) | 668 | 9792 | 2004 | 1336 | 19584 | 4008 | |

| | Variable | Value: baseline (other sectors) | Value: baseline (paints and varnishes) | Value: baseline (soaps and detergents | Value: harmonisation (other sectors) | Value: harmonisation (paints, varnishes) | Value: harmonisation (soaps and detergents | Unit/ notes |
|---|---|---|---|---|---|---|---|---|
| | number of submissions per company - SMEs (<250) | 2093 | 38850 | 6279 | 4186 | 77700 | 12558 | changing composition |
| | number of submissions per company - non-SMEs (>250) | 24624 | 213964 | 73872 | 32832 | 285285 | 98496 | |
| UFI | Industrial use: costs per submission (UFI generation), Euro/per submission | 0 | 0 | 0 | 60 | 60 | 60 | Euro/ submission per year<br>to be used if no data by company size |
| | Industrial use: costs per submission (UFI generation), Euro/per submission SMEs (<10) | 0 | 0 | 0 | 60 | 60 | 60 | Euro/ submission per year [annual]; estimated based on consultation responses - driven by the number of companies affected per sector, number of products and frequency of submissions (potentially size of companies) |
| | Industrial use: costs per submission (UFI generation), Euro/per submission -SMEs (<50) | 0 | 0 | 0 | 60 | 60 | 60 | |
| | Industrial use: costs per submission (UFI generation), Euro/per submission -SMEs (<250) | 0 | 0 | 0 | 60 | 60 | 60 | |
| | Industrial use: costs per submission (UFI generation), Euro/per submission -non-SMEs (>250) | 0 | 0 | 0 | 60 | 60 | 60 | |

## Unit costs of submissions under different reporting formats: industrial use

| | SDS only (other sectors, soaps and detergents) | SDS only (paints, varnishes) | SDS + additional (other sectors, soaps and detergents) | SDS + additional (paints, varnishes) | Advanced submission format (other sectors, soaps and detergents) | Advanced submission format (paints, varnishes) | Unit/ notes |
|---|---|---|---|---|---|---|---|
| Industrial use: costs per submission, Euro/per submission - trading domestically only - baseline | 70 | 70 | 300 | 300 | 700 | 700 | Euro/ submission per year [annual] |
| Industrial use: costs per submission, Euro/per submission - trading domestically only -after harmonization | 0 | 0 | 145 | 190 | 0 | 0 | Euro/ submission per year [annual] |
| Industrial use: costs per submission, Euro/per submission - trading in multiple MS – baseline | 70 | 70 | 300 | 300 | 700 | 700 | Euro/ submission per year [annual] |
| Industrial use: costs per submission, Euro/per submission - trading in multiple MS - after harmonisation | 0 | 0 | 145 | 190 | 0 | 0 | Euro/ submission per year [annual] |

### Average number of trading partners and frequency (industrial use) – other sectors

| | Domestic trade – average number of products | Domestic trade – frequency of submissions (baseline) | Domestic trade – frequency of submissions (harmonisation) | International trade – average number of products | International trade – average number of trading partners | International trade – frequency of submissions (baseline) - nominal | International trade – frequency of submissions (baseline) – adjustment* | International trade – frequency of submissions (baseline) | International trade – frequency of submissions (harmonisation) |
|---|---|---|---|---|---|---|---|---|---|
| number of submissions per company - SMEs (<10) | 41 | 1 | 1 | 41 | 8 | 1 | 50% | 0.5 | 1 |

| | Domestic trade – average number of products | Domestic trade – frequency of submissions (baseline) | Domestic trade – frequency of submissions (harmonisation) | International trade – average number of products | International trade – average number of trading partners | International trade – frequency of submissions (baseline) - nominal | International trade – frequency of submissions (baseline) – adjustment* | International trade – frequency of submissions (baseline) | International trade – frequency of submissions (harmonisation) |
|---|---|---|---|---|---|---|---|---|---|
| number of submissions per company - SMEs (<50) | 61 | 1 | 1 | 167 | 8 | 1 | 50% | 0.5 | 1 |
| number of submissions per company - SMEs (<250) | 131 | 1 | 1 | 299 | 14 | 1 | 50% | 0.5 | 1 |
| number of submissions per company - non-SMEs (>250) | 751 | 1 | 1 | 1728 | 19 | 1 | 75% | 0.75 | 1 |

Note: * share of companies trading internationally submitting fully to all MS PCs

## Average number of trading partners and frequency (industrial use) – paints, varnishes and inks sector

| | Domestic trade – average number of products | Domestic trade – frequency of submissions (baseline) | Domestic trade – frequency of submissions (harmonisation) | International trade – average number of products | International trade – average number of trading partners | International trade – frequency of submissions (baseline) - nominal | International trade – frequency of submissions (baseline) – adjustment* | International trade – frequency of submissions (baseline) | International trade – frequency of submissions (harmonisation) |
|---|---|---|---|---|---|---|---|---|---|
| number of submissions per company - SMEs (<10) | 81 | 3 | 3 | 350 | 8 | 3 | 50% | 1.5 | 3 |
| number of submissions per company - SMEs (<50) | 351 | 3 | 3 | 816 | 8 | 3 | 50% | 1.5 | 3 |
| number of submissions per company - SMEs (<250) | 578 | 3 | 3 | 1850 | 14 | 3 | 50% | 1.5 | 3 |
| number of submissions per company - non-SMEs (>250) | 3672 | 3 | 3 | 5005 | 19 | 3 | 75% | 2.3 | 3 |

Note: * share of companies trading internationally submitting fully to all MS PCs

Average number of trading partners and frequency (industrial use) – soaps and detergents sector

| | Domestic trade – average number of products | Domestic trade – frequency of submissions (baseline) | Domestic trade – frequency of submissions (harmonisation) | International trade – average number of products | International trade – average number of trading partners | International trade – frequency of submissions (baseline) - nominal | International trade – frequency of submissions (baseline) – adjustment* | International trade – frequency of submissions (baseline) | International trade – frequency of submissions (harmonisation) |
|---|---|---|---|---|---|---|---|---|---|
| number of submissions per company - SMEs (<10) | 41 | 3 | 3 | 41 | 8 | 3 | 50% | 1.5 | 3 |
| number of submissions per company - SMEs (<50) | 61 | 3 | 3 | 167 | 8 | 3 | 50% | 1.5 | 3 |
| number of submissions per company - SMEs (<250) | 131 | 3 | 3 | 299 | 14 | 3 | 50% | 1.5 | 3 |
| number of submissions per company - non-SMEs (>250) | 751 | 3 | 3 | 1728 | 19 | 3 | 75% | 2.3 | 3 |

Note: * share of companies trading internationally submitting fully to all MS PCs

## Specific assumptions for Scenario A – F

| Assumption | Basecase Scenario | Sensitivity Analysis |
|---|---|---|
| Frequency of submission | Current Baseline: 1/yr other sectors<br>3/yr paints/soaps<br>Harmonised: 1/yr other<br>4/yr paints/soaps<br>(Scenario A)<br>e.g. Company A (paints sector) with 100 products x 4 submissions per annum = 400 data submissions per annum. | Baseline: 1/yr other<br>1.3/yr paints/soaps<br>Harmonised: 1/yr other<br>1.3/yr paints/soaps<br>Justification: The harmonised system should not lead to substantial new/resubmissions, except where it's not mandatory. Resubmission would be much less resource-intensive so e.g. if submitting 4x per year (this is an average figure), the additional resource associated with the 2nd,3rd and 4th submission would be minor e.g. 10% of the original submission, hence 1.3/yr.<br>e.g. Company A (paints sector) with 100 products x 1.3 submissions per annum = 130 data submissions per annum.<br>(Scenario B) |
| No of MS submitted into for internationally-traded | Currently assume that no. of average trading countries is (for Micro, Small, Medium, and Large):<br>11, 10, 15, 21 for soaps and other sectors<br>4, 6, 11, 20 for paints<br>And assume that all products are sold into all Member States with associated costs incurred for all.<br>e.g. Company A (large size – paints sector) with 100 products x 20 (MS) = 2000 data submissions across EU.<br>(Scenario A) | Apply scaling factors to Member States as follows:<br>Submission for first Member State = 1<br>Submission for each subsequent Member State = 0.25x first Member State. Thus as an example for paints:<br>Micro = 1.75<br>Small = 2.25<br>Medium = 3.5<br>Large = 5.75<br>e.g. Company A (large size) with 100 products x 5.75 scaling factor = 575 data submissions across EU.<br>(Scenario C) |
| UFI Stockpiles | Assumption that there would be a transition period as envisaged by the Commission Services. No costs for relabelling of stockpiles.<br>(Scenario A) | Assumption that stockpiles would need relabelling.<br>(Scenario D) |

| Assumption | Basecase Scenario | Sensitivity Analysis |
|---|---|---|
| UFI grouping | No assumed grouping so UFI required for all products<br><br>(Scenario A)<br><br>e.g. Company A with 100 products x €340 (estimated cost per product per annum) = €34,000 per annum | Assume grouping is allowed, and on average only half the number of UFI for products is required.<br><br>(Scenario E)<br><br>e.g. Company A with 100 products x €340 (estimated cost per product per annum) /2 = €17,000 per annum |
| Combined sensitivity scenario | (Scenario A) | Combined changes as per scenario B, C, and E<br><br>(Scenario F) |

# Appendix E: Table 3.2 – Scenarios B - E

Scenario B - Further breakdown of extrapolated costs and benefits by Member State (using Eurostat data) – Values are presented as thousands of Euros.

| | AT | BE | BG | HR | CY | CZ | DK | EE | FI | FR | DE | EL | HU | IE |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Consumer, Professional and industrial mixtures** | | | | | | | | | | | | | | |
| **No. of Comps** | 107 | 214 | 170 | 90 | 69 | 284 | 83 | 29 | 89 | 789 | 1080 | 222 | 167 | 65 |
| **SME** | 98 | 196 | 165 | 88 | 69 | 266 | 80 | 29 | 80 | 733 | 999 | 211 | 157 | 57 |
| **Large** | 9 | 18 | 5 | 2 | 0 | 18 | 2 | 1 | 9 | 56 | 81 | 11 | 11 | 8 |
| **Costs Domestically trade only – Total** | -700 | 1,500 | -830 | 540 | -270 | 3,200 | -1,600 | 230 | 560 | -17,000 | -36,000 | -5,400 | 1,200 | 370 |
| **SME** | -410 | 1,100 | -590 | 520 | -270 | 2,400 | -1,500 | 230 | 350 | -14,000 | -23,000 | -3,800 | 830 | 290 |
| **Large** | -280 | 450 | -250 | 19 | 0 | 860 | -82 | 3 | 210 | -3,500 | -13,000 | -1,600 | 350 | 80 |
| **Costs Multiple MS traded** | -51,000 | -88,000 | -41,000 | -12,000 | -10,000 | -130,000 | -14,000 | -6,500 | -38,000 | -260,000 | -500,000 | -64,000 | -64,000 | -28,000 |
| **SME** | -12,000 | -21,000 | -12,000 | -6,700 | -10,000 | -45,000 | -7,700 | -4,900 | -6,900 | -81,000 | -140,000 | -18,000 | -20,000 | -5,300 |
| **Large** | -39,000 | -67,000 | -29,000 | -5,200 | 0 | -83,000 | -6,400 | -1,600 | -32,000 | -180,000 | -360,000 | -46,000 | -44,000 | -22,000 |
| **Cost of the UFI** | 11,000 | 20,000 | 11,000 | 4,700 | 4,900 | 37,000 | 5,000 | 2,900 | 7,200 | 60,000 | 110,000 | 17,000 | 15,000 | 4,300 |
| **SME** | 6,300 | 12,000 | 7,500 | 4,200 | 4,900 | 27,000 | 4,400 | 2,800 | 3,900 | 42,000 | 72,000 | 11,000 | 10,000 | 2,400 |
| **Large** | 4,600 | 7,100 | 3,700 | 460 | 0 | 10,000 | 560 | 140 | 3,400 | 17,000 | 42,000 | 5,300 | 4,900 | 2,000 |
| **Consumer/ professional/ industrial total** | -41,000 | -67,000 | -31,000 | -6,700 | -5,700 | -88,000 | -11,000 | -3,400 | -31,000 | -220,000 | -420,000 | -53,000 | -48,000 | -23,000 |

Country definition codes: Austria (AT), Belgium (BE), Bulgaria (BG), Croatia (HR), Cyprus (CY), Czech Republic (CZ), Denmark (DK), Estonia (EE), Finland (FI), France (FR), Germany (DE), Greece (EL), Hungary (HU), Ireland (IE)

Scenario B - continued - Values in thousands of Euros

| | IT | LV | LT | LU | MT | NL | PL | PT | RO | SK | SI | ES | SE | UK |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Consumer, Professional and Industrial mixtures** | | | | | | | | | | | | | | |
| **No. of Comps** | 1520 | 53 | 44 | 11 | 71 | 228 | 586 | 220 | 262 | 95 | 51 | 1007 | 233 | 790 |
| **SME** | 1490 | 52 | 43 | 8 | 68 | 212 | 557 | 218 | 252 | 84 | 49 | 984 | 223 | 754 |
| **Large** | 30 | 1 | 1 | 3 | 3 | 15 | 29 | 2 | 10 | 10 | 2 | 23 | 9 | 35 |
| **Costs Domestically trade only** | -36,000 | -160 | -1,000 | -180 | -270 | -6,700 | 2,900 | -4,900 | 2,300 | 640 | 300 | -22,000 | 1,300 | 7,100 |
| **SME** | -30,000 | -150 | -960 | -35 | -180 | -5,300 | 2,300 | -4,400 | 1,900 | 230 | 210 | -19,000 | 920 | 5,500 |
| **Large** | -5,600 | -6 | -49 | -140 | -91 | -1,400 | 600 | -410 | 420 | 410 | 90 | -3,200 | 340 | 1,600 |
| **Costs Internationally traded** | -270,000 | -6,600 | -7,600 | -17,000 | -16,000 | -84,000 | -150,000 | -27,000 | -60,000 | -51,000 | -14,000 | -190,000 | -59,000 | -220,000 |
| **SME** | -120,000 | -4,700 | -3,800 | -1,200 | -4,100 | -30,000 | -49,000 | -18,000 | -21,000 | -5,600 | -5,200 | -94,000 | -21,000 | -79,000 |
| **Large** | -140,000 | -1,900 | -3,800 | -16,000 | -12,000 | -54,000 | -100,000 | -9,700 | -38,000 | -45,000 | -9,000 | -96,000 | -39,000 | -140,000 |
| **Cost of the UFI** | 99,000 | 2,500 | 2,900 | 2,600 | 3,400 | 22,000 | 38,000 | 13,000 | 18,000 | 7,800 | 3,800 | 66,000 | 16,000 | 61,000 |
| **SME** | 82,000 | 2,300 | 2,600 | 590 | 2,000 | 17,000 | 27,000 | 12,000 | 14,000 | 2,600 | 2,700 | 55,000 | 12,000 | 45,000 |

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Large** | 17,000 | 160 | 330 | 2,100 | 1,400 | 5,700 | 11,000 | 1,200 | 4,200 | 5,300 | 1,100 | 11,000 | 4,400 | 16,000 |
| **Consumer/ Professional/ Industrial total** | -200,000 | -4,200 | -5,700 | -15,000 | -13,000 | -69,000 | -110,000 | -19,000 | -39,000 | -42,000 | -10,000 | -150,000 | -42,000 | -150,000 |

Country definition codes: Italy (IT), Latvia (LV), Lithuania (LT), Luxembourg (LU), Malta (MT), Netherlands (NL), Poland (PL), Portugal (PT), Romania (RO), Slovakia (SK), Slovenia (SI), Spain (ES), Sweden (SE) and United Kingdom (UK)

Scenario Ci - Further breakdown of extrapolated costs and benefits by Member State (using Eurostat data) – Values are presented as thousands of Euros.

| | **AT** | **BE** | **BG** | **HR** | **CY** | **CZ** | **DK** | **EE** | **FI** | **FR** | **DE** | **EL** | **HU** | **IE** |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Consumer, Professional and industrial mixtures** | | | | | | | | | | | | | | |
| **No. of Comps** | 107 | 214 | 170 | 90 | 69 | 284 | 83 | 29 | 89 | 789 | 1080 | 222 | 167 | 65 |
| **SME** | 98 | 196 | 165 | 88 | 69 | 266 | 80 | 29 | 80 | 733 | 999 | 211 | 157 | 57 |
| **Large** | 9 | 18 | 5 | 2 | 0 | 18 | 2 | 1 | 9 | 56 | 81 | 11 | 11 | 8 |
| **Costs Domestically trade only – Total** | -890 | 4,200 | -1,200 | 1,400 | -280 | 9,400 | -3,000 | 680 | 1,500 | -32,000 | -69,000 | -11,000 | 3,300 | 760 |
| **SME** | -500 | 3,100 | -820 | 1,300 | -280 | 7,000 | -2,900 | 680 | 930 | -26,000 | -43,000 | -7,700 | 2,300 | 660 |
| **Large** | -390 | 1,200 | -360 | 22 | 0 | 2,400 | -82 | 3 | 530 | -5,500 | -26,000 | -3,200 | 960 | 100 |
| **Costs Multiple MS traded** | -16,000 | -26,000 | -14,000 | -2,500 | -1,600 | -36,000 | -3,000 | -900 | -12,000 | -70,000 | -150,000 | -19,000 | -19,000 | -8,300 |
| **SME** | -1,600 | -2,700 | -1,900 | -870 | -1,600 | -3,800 | -1,100 | -440 | -1,100 | -12,000 | -19,000 | -2,200 | -2,800 | -1,100 |
| **Large** | -14,000 | -23,000 | -12,000 | -1,600 | 0 | -32,000 | -1,800 | -460 | -11,000 | -58,000 | -130,000 | -17,000 | -16,000 | -7,200 |
| **Cost of the UFI** | 27,000 | 48,000 | 30,000 | 12,000 | 13,000 | 100,000 | 12,000 | 8,000 | 16,000 | 140,000 | 290,000 | 44,000 | 38,000 | 7,900 |
| **SME** | 16,000 | 33,000 | 19,000 | 11,000 | 13,000 | 75,000 | 11,000 | 7,800 | 9,700 | 110,000 | 190,000 | 32,000 | 26,000 | 5,200 |

| | AT | BE | BG | HR | CY | CZ | DK | EE | FI | FR | DE | EL | HU | IE |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Large** | 11,000 | 15,000 | 10,000 | 550 | 0 | 26,000 | 560 | 140 | 6,800 | 28,000 | 100,000 | 13,000 | 12,000 | 2,700 |
| **Consumer/ professional/ industrial total** | 11,000 | 26,000 | 15,000 | 11,000 | 11,000 | 75,000 | 6,000 | 7,800 | 6,000 | 35,000 | 71,000 | 14,000 | 22,000 | 370 |

Country definition codes: Austria (AT), Belgium (BE), Bulgaria (BG), Croatia (HR), Cyprus (CY), Czech Republic (CZ), Denmark (DK), Estonia (EE), Finland (FI), France (FR), Germany (DE), Greece (EL), Hungary (HU), Ireland (IE)

Scenario Ci - continued - Values in thousands of Euros

| | IT | LV | LT | LU | MT | NL | PL | PT | RO | SK | SI | ES | SE | UK |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Consumer, Professional and Industrial mixtures** | | | | | | | | | | | | | | |
| **No. of Comps** | 1520 | 53 | 44 | 11 | 71 | 228 | 586 | 220 | 262 | 95 | 51 | 1007 | 233 | 790 |
| **SME** | 1490 | 52 | 43 | 8 | 68 | 212 | 557 | 218 | 252 | 84 | 49 | 984 | 223 | 754 |
| **Large** | 30 | 1 | 1 | 3 | 3 | 15 | 29 | 2 | 10 | 10 | 2 | 23 | 9 | 35 |
| **Costs Domestically trade only** | -71,000 | -180 | -2,000 | -240 | -380 | -13,000 | 8,000 | -9,700 | 5,900 | 1,700 | 830 | -44,000 | 3,500 | 18,000 |
| **SME** | -60,000 | -170 | -1,900 | -37 | -260 | -10,000 | 6,400 | -8,900 | 4,900 | 550 | 580 | -37,000 | 2,600 | 14,000 |
| **Large** | -12,000 | -10 | -49 | -210 | -130 | -2,500 | 1,500 | -840 | 1,000 | 1,100 | 250 | -6,300 | 900 | 4,100 |
| **Costs Internationally traded** | -69,000 | -1,500 | -1,500 | -6,500 | -5,300 | -22,000 | -45,000 | -5,600 | -16,000 | -18,000 | -4,300 | -48,000 | -16,000 | -63,000 |
| **SME** | -14,000 | -810 | -420 | -170 | -930 | -3,400 | -7,600 | -2,000 | -2,300 | -1,400 | -800 | -13,000 | -2,700 | -11,000 |
| **Large** | -54,000 | -700 | -1,100 | -6,400 | -4,300 | -18,000 | -37,000 | -3,700 | -14,000 | -16,000 | -3,500 | -36,000 | -14,000 | -53,000 |

| | IT | LV | LT | LU | MT | NL | PL | PT | RO | SK | SI | ES | SE | UK |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Cost of the UFI** | 260,000 | 6,200 | 7,100 | 7,500 | 7,600 | 55,000 | 93,000 | 35,000 | 48,000 | 18,000 | 9,700 | 170,000 | 41,000 | 160,000 |
| **SME** | 210,000 | 5,800 | 6,800 | 1,600 | 4,100 | 45,000 | 70,000 | 32,000 | 38,000 | 5,700 | 6,800 | 140,000 | 31,000 | 120,000 |
| **Large** | 45,000 | 330 | 330 | 5,900 | 3,500 | 11,000 | 23,000 | 3,200 | 9,400 | 12,000 | 2,800 | 26,000 | 10,000 | 37,000 |
| **Consumer/ Professional/ Industrial total** | 120,000 | 4,500 | 3,700 | 700 | 2,000 | 21,000 | 56,000 | 20,000 | 38,000 | 2,200 | 6,200 | 79,000 | 28,000 | 110,000 |

Country definition codes: Italy (IT), Latvia (LV), Lithuania (LT), Luxembourg (LU), Malta (MT), Netherlands (NL), Poland (PL), Portugal (PT), Romania (RO), Slovakia (SK), Slovenia (SI), Spain (ES), Sweden (SE) and United Kingdom (UK)

Scenario Cii - Further breakdown of extrapolated costs and benefits by Member State (using Eurostat data) – Values are presented as thousands of Euros.

| | AT | BE | BG | HR | CY | CZ | DK | EE | FI | FR | DE | EL | HU | IE |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Consumer, Professional and industrial mixtures** | | | | | | | | | | | | | | |
| **No. of Comps** | 107 | 214 | 170 | 90 | 69 | 284 | 83 | 29 | 89 | 789 | 1080 | 222 | 167 | 65 |
| **SME** | 98 | 196 | 165 | 88 | 69 | 266 | 80 | 29 | 80 | 733 | 999 | 211 | 157 | 57 |
| **Large** | 9 | 18 | 5 | 2 | 0 | 18 | 2 | 1 | 9 | 56 | 81 | 11 | 11 | 8 |
| **Costs Domestically trade only – Total** | -890 | 4,200 | -1,200 | 1,400 | -280 | 9,400 | -3,000 | 680 | 1,500 | -32,000 | -69,000 | -11,000 | 3,300 | 760 |
| **SME** | -500 | 3,100 | -820 | 1,300 | -280 | 7,000 | -2,900 | 680 | 930 | -26,000 | -43,000 | -7,700 | 2,300 | 660 |
| **Large** | -390 | 1,200 | -360 | 22 | 0 | 2,400 | -82 | 3 | 530 | -5,500 | -26,000 | -3,200 | 960 | 100 |

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Costs Multiple MS traded** | -8,200 | -13,000 | -7,100 | -1,400 | -980 | -19,000 | -1,600 | -530 | -6,100 | -37,000 | -79,000 | -10,000 | -9,900 | -4,300 |
| **SME** | -970 | -1,700 | -1,200 | -560 | -980 | -2,500 | -700 | -290 | -670 | -7,300 | -12,000 | -1,400 | -1,700 | -660 |
| **Large** | -7,300 | -12,000 | -6,000 | -800 | 0 | -16,000 | -920 | -230 | -5,500 | -29,000 | -68,000 | -8,600 | -8,200 | -3,600 |
| **Cost of the UFI** | 27,000 | 48,000 | 30,000 | 12,000 | 13,000 | 100,000 | 12,000 | 8,000 | 16,000 | 140,000 | 290,000 | 44,000 | 38,000 | 7,900 |
| **SME** | 16,000 | 33,000 | 19,000 | 11,000 | 13,000 | 75,000 | 11,000 | 7,800 | 9,700 | 110,000 | 190,000 | 32,000 | 26,000 | 5,200 |
| **Large** | 11,000 | 15,000 | 10,000 | 550 | 0 | 26,000 | 560 | 140 | 6,800 | 28,000 | 100,000 | 13,000 | 12,000 | 2,700 |
| **Consumer/ professional/ industrial total** | 18,000 | 39,000 | 21,000 | 12,000 | 11,000 | 92,000 | 7,400 | 8,100 | 12,000 | 68,000 | 140,000 | 24,000 | 31,000 | 4,400 |

Country definition codes: Austria (AT), Belgium (BE), Bulgaria (BG), Croatia (HR), Cyprus (CY), Czech Republic (CZ), Denmark (DK), Estonia (EE), Finland (FI), France (FR), Germany (DE), Greece (EL), Hungary (HU), Ireland (IE)

Scenario Cii - continued - Values in thousands of Euros

| | IT | LV | LT | LU | MT | NL | PL | PT | RO | SK | SI | ES | SE | UK |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Consumer, Professional and Industrial mixtures** | | | | | | | | | | | | | | |
| **No. of Comps** | 1520 | 53 | 44 | 11 | 71 | 228 | 586 | 220 | 262 | 95 | 51 | 1007 | 233 | 790 |
| **SME** | 1490 | 52 | 43 | 8 | 68 | 212 | 557 | 218 | 252 | 84 | 49 | 984 | 223 | 754 |
| **Large** | 30 | 1 | 1 | 3 | 3 | 15 | 29 | 2 | 10 | 10 | 2 | 23 | 9 | 35 |
| **Costs Domestically trade only** | -71,000 | -180 | -2,000 | -240 | -380 | -13,000 | 8,000 | -9,700 | 5,900 | 1,700 | 830 | -44,000 | 3,500 | 18,000 |
| **SME** | -60,000 | -170 | -1,900 | -37 | -260 | -10,000 | 6,400 | -8,900 | 4,900 | 550 | 580 | -37,000 | 2,600 | 14,000 |

| | IT | LV | LT | LU | MT | NL | PL | PT | RO | SK | SI | ES | SE | UK |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Large** | -12,000 | -10 | -49 | -210 | -130 | -2,500 | 1,500 | -840 | 1,000 | 1,100 | 250 | -6,300 | 900 | 4,100 |
| **Costs Internationally traded** | -37,000 | -850 | -810 | -3,300 | -2,700 | -11,000 | -23,000 | -3,100 | -8,400 | -9,000 | -2,200 | -26,000 | -8,600 | -33,000 |
| **SME** | -9,300 | -490 | -260 | -100 | -540 | -2,100 | -4,600 | -1,300 | -1,500 | -820 | -480 | -8,000 | -1,700 | -6,600 |
| **Large** | -28,000 | -350 | -550 | -3,200 | -2,200 | -9,200 | -19,000 | -1,900 | -6,900 | -8,200 | -1,800 | -18,000 | -7,000 | -27,000 |
| **Cost of the UFI** | 260,000 | 6,200 | 7,100 | 7,500 | 7,600 | 55,000 | 93,000 | 35,000 | 48,000 | 18,000 | 9,700 | 170,000 | 41,000 | 160,000 |
| **SME** | 210,000 | 5,800 | 6,800 | 1,600 | 4,100 | 45,000 | 70,000 | 32,000 | 38,000 | 5,700 | 6,800 | 140,000 | 31,000 | 120,000 |
| **Large** | 45,000 | 330 | 330 | 5,900 | 3,500 | 11,000 | 23,000 | 3,200 | 9,400 | 12,000 | 2,800 | 26,000 | 10,000 | 37,000 |
| **Consumer/ Professional/ Industrial total** | 150,000 | 5,100 | 4,400 | 3,900 | 4,500 | 31,000 | 77,000 | 22,000 | 45,000 | 11,000 | 8,300 | 100,000 | 36,000 | 140,000 |

Country definition codes: Italy (IT), Latvia (LV), Lithuania (LT), Luxembourg (LU), Malta (MT), Netherlands (NL), Poland (PL), Portugal (PT), Romania (RO), Slovakia (SK), Slovenia (SI), Spain (ES), Sweden (SE) and United Kingdom (UK)

Scenario D - Further breakdown of extrapolated costs and benefits by Member State (using Eurostat data) – Values are presented as thousands of Euros.

| | AT | BE | BG | HR | CY | CZ | DK | EE | FI | FR | DE | EL | HU | IE |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Consumer, Professional and industrial mixtures** | | | | | | | | | | | | | | |
| **No. of Comps** | 107 | 214 | 170 | 90 | 69 | 284 | 83 | 29 | 89 | 789 | 1080 | 222 | 167 | 65 |
| **SME** | 98 | 196 | 165 | 88 | 69 | 266 | 80 | 29 | 80 | 733 | 999 | 211 | 157 | 57 |
| **Large** | 9 | 18 | 5 | 2 | 0 | 18 | 2 | 1 | 9 | 56 | 81 | 11 | 11 | 8 |
| **Costs Domestically trade only – Total** | -890 | 4,200 | -1,200 | 1,400 | -280 | 9,400 | -3,000 | 680 | 1,500 | -32,000 | -69,000 | -11,000 | 3,300 | 760 |

| | AT | BE | BG | HR | CY | CZ | DK | EE | FI | FR | DE | EL | HU | IE |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **SME** | -500 | 3,100 | -820 | 1,300 | -280 | 7,000 | -2,900 | 680 | 930 | -26,000 | -43,000 | -7,700 | 2,300 | 660 |
| **Large** | -390 | 1,200 | -360 | 22 | 0 | 2,400 | -82 | 3 | 530 | -5,500 | -26,000 | -3,200 | 960 | 100 |
| **Costs Multiple MS traded** | -54,000 | -87,000 | -46,000 | -7,900 | -4,800 | -120,000 | -9,700 | -2,800 | -41,000 | -240,000 | -520,000 | -65,000 | -64,000 | -28,000 |
| **SME** | -4,700 | -7,800 | -5,700 | -2,400 | -4,800 | -10,000 | -3,400 | -1,200 | -3,300 | -36,000 | -56,000 | -5,900 | -8,300 | -3,600 |
| **Large** | -50,000 | -80,000 | -41,000 | -5,500 | 0 | -110,000 | -6,400 | -1,600 | -37,000 | -200,000 | -460,000 | -59,000 | -56,000 | -25,000 |
| **Cost of the UFI** | 27,000 | 48,000 | 30,000 | 12,000 | 13,000 | 100,000 | 12,000 | 8,000 | 16,000 | 140,000 | 290,000 | 44,000 | 38,000 | 7,900 |
| **SME** | 16,000 | 33,000 | 19,000 | 11,000 | 13,000 | 75,000 | 11,000 | 7,800 | 9,700 | 110,000 | 190,000 | 32,000 | 26,000 | 5,200 |
| **Large** | 11,000 | 15,000 | 10,000 | 550 | 0 | 26,000 | 560 | 140 | 6,800 | 28,000 | 100,000 | 13,000 | 12,000 | 2,700 |
| **Consumer/ professional/ industrial total** | -28,000 | -36,000 | -18,000 | 5,100 | 7,500 | -9,500 | -700 | 5,900 | -23,000 | -130,000 | -300,000 | -31,000 | -23,000 | -20,000 |
| **UFI- stockpiles** | 9,400 | 18,000 | 8,500 | 3,200 | 3,100 | 22,000 | 4,300 | 1,400 | 8,000 | 62,000 | 96,000 | 12,000 | 13,000 | 7,300 |

Country definition codes: Austria (AT), Belgium (BE), Bulgaria (BG), Croatia (HR), Cyprus (CY), Czech Republic (CZ), Denmark (DK), Estonia (EE), Finland (FI), France (FR), Germany (DE), Greece (EL), Hungary (HU), Ireland (IE)

Scenario D - continued - Values in thousands of Euros

| | IT | LV | LT | LU | MT | NL | PL | PT | RO | SK | SI | ES | SE | UK |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Consumer, Professional and Industrial mixtures** | | | | | | | | | | | | | | |
| **No. of Comps** | 1520 | 53 | 44 | 11 | 71 | 228 | 586 | 220 | 262 | 95 | 51 | 1007 | 233 | 790 |
| **SME** | 1490 | 52 | 43 | 8 | 68 | 212 | 557 | 218 | 252 | 84 | 49 | 984 | 223 | 754 |
| **Large** | 30 | 1 | 1 | 3 | 3 | 15 | 29 | 2 | 10 | 10 | 2 | 23 | 9 | 35 |
| **Costs Domestically trade only** | -71,000 | -180 | -2,000 | -240 | -380 | -13,000 | 8,000 | - | 5,900 | 1,700 | 830 | -44,000 | 3,500 | 18,000 |

| | IT | LV | LT | LU | MT | NL | PL | PT | RO | SK | SI | ES | SE | UK |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | 9,700 | | | | | | |
| **SME** | -60,000 | -170 | -1,900 | -37 | -260 | -10,000 | 6,400 | -8,900 | 4,900 | 550 | 580 | -37,000 | 2,600 | 14,000 |
| **Large** | -12,000 | -10 | -49 | -210 | -130 | -2,500 | 1,500 | -840 | 1,000 | 1,100 | 250 | -6,300 | 900 | 4,100 |
| **Costs Internationally traded** | -230,000 | -4,800 | -5,000 | -23,000 | -18,000 | -73,000 | -150,000 | -18,000 | -53,000 | -61,000 | -14,000 | -160,000 | -55,000 | -210,000 |
| **SME** | -40,000 | -2,400 | -1,200 | -510 | -2,900 | -9,700 | -22,000 | -5,400 | -6,200 | -4,500 | -2,400 | -37,000 | -7,700 | -31,000 |
| **Large** | -190,000 | -2,400 | -3,800 | -22,000 | -15,000 | -63,000 | -130,000 | -13,000 | -47,000 | -56,000 | -12,000 | -120,000 | -48,000 | -180,000 |
| **Cost of the UFI** | 260,000 | 6,200 | 7,100 | 7,500 | 7,600 | 55,000 | 93,000 | 35,000 | 48,000 | 18,000 | 9,700 | 170,000 | 41,000 | 160,000 |
| **SME** | 210,000 | 5,800 | 6,800 | 1,600 | 4,100 | 45,000 | 70,000 | 32,000 | 38,000 | 5,700 | 6,800 | 140,000 | 31,000 | 120,000 |
| **Large** | 45,000 | 330 | 330 | 5,900 | 3,500 | 11,000 | 23,000 | 3,200 | 9,400 | 12,000 | 2,800 | 26,000 | 10,000 | 37,000 |
| **Consumer/ Professional/ Industrial total** | -41,000 | 1,200 | 200 | -15,000 | -11,000 | -30,000 | -51,000 | 7,300 | 240 | -41,000 | -4,000 | -34,000 | -10,000 | -39,000 |
| **UFI- stockpiles** | 65,000 | 1,900 | 2,300 | 2,000 | 3,700 | 18,000 | 35,000 | 7,400 | 13,000 | 9,400 | 3,100 | 46,000 | 12,000 | 49,000 |

Country definition codes: Italy (IT), Latvia (LV), Lithuania (LT), Luxembourg (LU), Malta (MT), Netherlands (NL), Poland (PL), Portugal (PT), Romania (RO), Slovakia (SK), Slovenia (SI), Spain (ES), Sweden (SE) and United Kingdom (UK)

Scenario E - Further breakdown of extrapolated costs and benefits by Member State (using Eurostat data) – Values are presented as thousands of Euros.

| | AT | BE | BG | HR | CY | CZ | DK | EE | FI | FR | DE | EL | HU | IE |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Consumer, Professional and industrial mixtures** | | | | | | | | | | | | | | |
| **No. of Comps** | 107 | 214 | 170 | 90 | 69 | 284 | 83 | 29 | 89 | 789 | 1080 | 222 | 167 | 65 |
| **SME** | 98 | 196 | 165 | 88 | 69 | 266 | 80 | 29 | 80 | 733 | 999 | 211 | 157 | 57 |
| **Large** | 9 | 18 | 5 | 2 | 0 | 18 | 2 | 1 | 9 | 56 | 81 | 11 | 11 | 8 |
| **Costs Domestically trade only – Total** | -890 | 4,200 | -1,200 | 1,400 | -280 | 9,400 | -3,000 | 680 | 1,500 | -32,000 | -69,000 | -11,000 | 3,300 | 760 |
| **SME** | -500 | 3,100 | -820 | 1,300 | -280 | 7,000 | -2,900 | 680 | 930 | -26,000 | -43,000 | -7,700 | 2,300 | 660 |
| **Large** | -390 | 1,200 | -360 | 22 | 0 | 2,400 | -82 | 3 | 530 | -5,500 | -26,000 | -3,200 | 960 | 100 |
| **Costs Multiple MS traded** | -54,000 | -87,000 | -46,000 | -7,900 | -4,800 | -120,000 | -9,700 | -2,800 | -41,000 | -240,000 | -520,000 | -65,000 | -64,000 | -28,000 |
| **SME** | -4,700 | -7,800 | -5,700 | -2,400 | -4,800 | -10,000 | -3,400 | -1,200 | -3,300 | -36,000 | -56,000 | -5,900 | -8,300 | -3,600 |
| **Large** | -50,000 | -80,000 | -41,000 | -5,500 | 0 | -110,000 | -6,400 | -1,600 | -37,000 | -200,000 | -460,000 | -59,000 | -56,000 | -25,000 |
| **Cost of the UFI** | 14,000 | 24,000 | 15,000 | 5,800 | 6,300 | 51,000 | 6,000 | 4,000 | 8,200 | 68,000 | 150,000 | 22,000 | 19,000 | 4,000 |
| **SME** | 8,200 | 16,000 | 9,600 | 5,600 | 6,300 | 38,000 | 5,700 | 3,900 | 4,800 | 54,000 | 95,000 | 16,000 | 13,000 | 2,600 |
| **Large** | 5,500 | 7,400 | 5,200 | 280 | 0 | 13,000 | 280 | 71 | 3,400 | 14,000 | 52,000 | 6,400 | 5,800 | 1,400 |
| **Consumer/ professional/ industrial total** | -41,000 | -59,000 | -33,000 | -740 | 1,200 | -60,000 | -6,700 | 1,900 | -31,000 | -200,000 | -440,000 | -53,000 | -42,000 | -24,000 |

Country definition codes: Austria (AT), Belgium (BE), Bulgaria (BG), Croatia (HR), Cyprus (CY), Czech Republic (CZ), Denmark (DK), Estonia (EE), Finland (FI), France (FR), Germany (DE), Greece (EL), Hungary (HU), Ireland (IE)

Scenario E - continued - Values in thousands of Euros

| | IT | LV | LT | LU | MT | NL | PL | PT | RO | SK | SI | ES | SE | UK |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Consumer, Professional and Industrial mixtures** | | | | | | | | | | | | | | |
| **No. of Comps** | 1520 | 53 | 44 | 11 | 71 | 228 | 586 | 220 | 262 | 95 | 51 | 1007 | 233 | 790 |
| **SME** | 1490 | 52 | 43 | 8 | 68 | 212 | 557 | 218 | 252 | 84 | 49 | 984 | 223 | 754 |
| **Large** | 30 | 1 | 1 | 3 | 3 | 15 | 29 | 2 | 10 | 10 | 2 | 23 | 9 | 35 |
| **Costs Domestically trade only** | -71,000 | -180 | -2,000 | -240 | -380 | -13,000 | 8,000 | -9,700 | 5,900 | 1,700 | 830 | -44,000 | 3,500 | 18,000 |
| **SME** | -60,000 | -170 | -1,900 | -37 | -260 | -10,000 | 6,400 | -8,900 | 4,900 | 550 | 580 | -37,000 | 2,600 | 14,000 |
| **Large** | -12,000 | -10 | -49 | -210 | -130 | -2,500 | 1,500 | -840 | 1,000 | 1,100 | 250 | -6,300 | 900 | 4,100 |
| **Costs Internationally traded** | -230,000 | -4,800 | -5,000 | -23,000 | -18,000 | -73,000 | -150,000 | -18,000 | -53,000 | -61,000 | -14,000 | -160,000 | -55,000 | -210,000 |
| **SME** | -40,000 | -2,400 | -1,200 | -510 | -2,900 | -9,700 | -22,000 | -5,400 | -6,200 | -4,500 | -2,400 | -37,000 | -7,700 | -31,000 |
| **Large** | -190,000 | -2,400 | -3,800 | -22,000 | -15,000 | -63,000 | -130,000 | -13,000 | -47,000 | -56,000 | -12,000 | -120,000 | -48,000 | -180,000 |
| **Cost of the UFI** | 130,000 | 3,100 | 3,600 | 3,700 | 3,800 | 28,000 | 46,000 | 18,000 | 24,000 | 9,100 | 4,800 | 85,000 | 21,000 | 78,000 |
| **SME** | 110,000 | 2,900 | 3,400 | 790 | 2,000 | 22,000 | 35,000 | 16,000 | 19,000 | 2,800 | 3,400 | 72,000 | 16,000 | 59,000 |
| **Large** | 23,000 | 160 | 170 | 2,900 | 1,800 | 5,500 | 11,000 | 1,600 | 4,700 | 6,200 | 1,400 | 13,000 | 5,100 | 19,000 |
| **Consumer/ Professional/ Industrial total** | -170,000 | -1,900 | -3,400 | -19,000 | -15,000 | -58,000 | -97,000 | -10,000 | -24,000 | -50,000 | -8,800 | -120,000 | -31,000 | -120,000 |

Country definition codes: Italy (IT), Latvia (LV), Lithuania (LT), Luxembourg (LU), Malta (MT), Netherlands (NL), Poland (PL), Portugal (PT), Romania (RO), Slovakia (SK), Slovenia (SI), Spain (ES), Sweden (SE) and United Kingdom (UK)

Scenario Fi - Further breakdown of extrapolated costs and benefits by Member State (using Eurostat data) – Values are presented as thousands of Euros.

| | AT | BE | BG | HR | CY | CZ | DK | EE | FI | FR | DE | EL | HU | IE |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Consumer, Professional and industrial mixtures** | | | | | | | | | | | | | | |
| **No. of Comps** | 107 | 214 | 170 | 90 | 69 | 284 | 83 | 29 | 89 | 789 | 1080 | 222 | 167 | 65 |
| **SME** | 98 | 196 | 165 | 88 | 69 | 266 | 80 | 29 | 80 | 733 | 999 | 211 | 157 | 57 |
| **Large** | 9 | 18 | 5 | 2 | 0 | 18 | 2 | 1 | 9 | 56 | 81 | 11 | 11 | 8 |
| **Costs Domestically trade only – Total** | -700 | 1,500 | -830 | 540 | -270 | 3,200 | -1,600 | 230 | 560 | -17,000 | -36,000 | -5,400 | 1,200 | 370 |
| **SME** | -410 | 1,100 | -590 | 520 | -270 | 2,400 | -1,500 | 230 | 350 | -14,000 | -23,000 | -3,800 | 830 | 290 |
| **Large** | -280 | 450 | -250 | 19 | 0 | 860 | -82 | 3 | 210 | -3,500 | -13,000 | -1,600 | 350 | 80 |
| **Costs Multiple MS traded** | -15,000 | -26,000 | -13,000 | -3,800 | -3,400 | -39,000 | -4,400 | -2,100 | -11,000 | -78,000 | -150,000 | -19,000 | -19,000 | -8,100 |
| **SME** | -3,900 | -7,100 | -4,200 | -2,300 | -3,400 | -15,000 | -2,600 | -1,600 | -2,300 | -27,000 | -45,000 | -6,200 | -6,400 | -1,700 |
| **Large** | -11,000 | -19,000 | -8,400 | -1,500 | 0 | -24,000 | -1,800 | -460 | -9,100 | -52,000 | -100,000 | -13,000 | -13,000 | -6,400 |
| **Cost of the UFI** | 5,400 | 9,800 | 5,600 | 2,300 | 2,400 | 19,000 | 2,500 | 1,500 | 3,600 | 30,000 | 57,000 | 8,400 | 7,500 | 2,200 |
| **SME** | 3,200 | 6,200 | 3,700 | 2,100 | 2,400 | 14,000 | 2,200 | 1,400 | 1,900 | 21,000 | 36,000 | 5,700 | 5,100 | 1,200 |
| **Large** | 2,300 | 3,600 | 1,800 | 230 | 0 | 5,100 | 280 | 71 | 1,700 | 8,600 | 21,000 | 2,600 | 2,500 | 980 |
| **Consumer/ professional/ industrial total** | -10,000 | -15,000 | -7,800 | -910 | -1,200 | -17,000 | -3,500 | -390 | -7,200 | -66,000 | -130,000 | -16,000 | -10,000 | -5,600 |

Country definition codes: Austria (AT), Belgium (BE), Bulgaria (BG), Croatia (HR), Cyprus (CY), Czech Republic (CZ), Denmark (DK), Estonia (EE), Finland (FI), France (FR), Germany (DE), Greece (EL), Hungary (HU), Ireland (IE)

Scenario Fi - continued - Values in thousands of Euros

| | IT | LV | LT | LU | MT | NL | PL | PT | RO | SK | SI | ES | SE | UK |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Consumer, Professional and Industrial mixtures** | | | | | | | | | | | | | | |
| **No. of Comps** | 1520 | 53 | 44 | 11 | 71 | 228 | 586 | 220 | 262 | 95 | 51 | 1007 | 233 | 790 |
| **SME** | 1490 | 52 | 43 | 8 | 68 | 212 | 557 | 218 | 252 | 84 | 49 | 984 | 223 | 754 |
| **Large** | 30 | 1 | 1 | 3 | 3 | 15 | 29 | 2 | 10 | 10 | 2 | 23 | 9 | 35 |
| **Costs Domestically trade only** | -36,000 | -160 | -1,000 | -180 | -270 | -6,700 | 2,900 | -4,900 | 2,300 | 640 | 300 | -22,000 | 1,300 | 7,100 |
| **SME** | -30,000 | -150 | -960 | -35 | -180 | -5,300 | 2,300 | -4,400 | 1,900 | 230 | 210 | -19,000 | 920 | 5,500 |
| **Large** | -5,600 | -6 | -49 | -140 | -91 | -1,400 | 600 | -410 | 420 | 410 | 90 | -3,200 | 340 | 1,600 |
| **Costs Internationally traded** | -83,000 | -2,100 | -2,400 | -4,900 | -4,700 | -25,000 | -46,000 | -8,900 | -18,000 | -15,000 | -4,300 | -59,000 | -18,000 | -68,000 |
| **SME** | -42,000 | -1,500 | -1,300 | -390 | -1,400 | -9,800 | -16,000 | -6,100 | -7,300 | -1,800 | -1,700 | -31,000 | -6,900 | -26,000 |
| **Large** | -41,000 | -530 | -1,100 | -4,500 | -3,400 | -16,000 | -30,000 | -2,800 | -11,000 | -13,000 | -2,600 | -28,000 | -11,000 | -41,000 |
| **Cost of the UFI** | 50,000 | 1,300 | 1,400 | 1,300 | 1,700 | 11,000 | 19,000 | 6,600 | 9,200 | 3,900 | 1,900 | 33,000 | 8,200 | 31,000 |
| **SME** | 41,000 | 1,200 | 1,300 | 300 | 1,000 | 8,300 | 14,000 | 6,000 | 7,100 | 1,300 | 1,300 | 27,000 | 6,000 | 23,000 |
| **Large** | 8,600 | 82 | 170 | 1,000 | 710 | 2,800 | 5,400 | 600 | 2,100 | 2,600 | 540 | 5,400 | 2,200 | 8,000 |
| **Consumer/ Professional/ Industrial total** | -70,000 | -990 | -2,000 | -3,800 | -3,300 | -21,000 | -24,000 | -7,100 | -6,800 | -10,000 | -2,100 | -48,000 | -8,600 | -30,000 |

Country definition codes: Italy (IT), Latvia (LV), Lithuania (LT), Luxembourg (LU), Malta (MT), Netherlands (NL), Poland (PL), Portugal (PT), Romania (RO), Slovakia (SK), Slovenia (SI), Spain (ES), Sweden (SE) and United Kingdom (UK)

Scenario Fii - Further breakdown of extrapolated costs and benefits by Member State (using Eurostat data) – Values are presented as thousands of Euros.

| | AT | BE | BG | HR | CY | CZ | DK | EE | FI | FR | DE | EL | HU | IE |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Consumer, Professional and industrial mixtures** | | | | | | | | | | | | | | |
| **No. of Comps** | 107 | 214 | 170 | 90 | 69 | 284 | 83 | 29 | 89 | 789 | 1080 | 222 | 167 | 65 |
| **SME** | 98 | 196 | 165 | 88 | 69 | 266 | 80 | 29 | 80 | 733 | 999 | 211 | 157 | 57 |
| **Large** | 9 | 18 | 5 | 2 | 0 | 18 | 2 | 1 | 9 | 56 | 81 | 11 | 11 | 8 |
| **Costs Domestically trade only – Total** | -700 | 1,500 | -830 | 540 | -270 | 3,200 | -1,600 | 230 | 560 | -17,000 | -36,000 | -5,400 | 1,200 | 370 |
| **SME** | -410 | 1,100 | -590 | 520 | -270 | 2,400 | -1,500 | 230 | 350 | -14,000 | -23,000 | -3,800 | 830 | 290 |
| **Large** | -280 | 450 | -250 | 19 | 0 | 860 | -82 | 3 | 210 | -3,500 | -13,000 | -1,600 | 350 | 80 |
| **Costs Multiple MS traded** | -8,000 | -14,000 | -6,800 | -2,200 | -2,000 | -21,000 | -2,500 | -1,200 | -6,000 | -42,000 | -79,000 | -10,000 | -10,000 | -4,200 |
| **SME** | -2,300 | -4,300 | -2,500 | -1,400 | -2,000 | -8,900 | -1,500 | -970 | -1,400 | -16,000 | -27,000 | -3,800 | -3,800 | -1,000 |
| **Large** | -5,700 | -9,700 | -4,300 | -750 | 0 | -12,000 | -920 | -230 | -4,600 | -26,000 | -52,000 | -6,700 | -6,400 | -3,200 |
| **Cost of the UFI** | 5,400 | 9,800 | 5,600 | 2,300 | 2,400 | 19,000 | 2,500 | 1,500 | 3,600 | 30,000 | 57,000 | 8,400 | 7,500 | 2,200 |
| **SME** | 3,200 | 6,200 | 3,700 | 2,100 | 2,400 | 14,000 | 2,200 | 1,400 | 1,900 | 21,000 | 36,000 | 5,700 | 5,100 | 1,200 |
| **Large** | 2,300 | 3,600 | 1,800 | 230 | 0 | 5,100 | 280 | 71 | 1,700 | 8,600 | 21,000 | 2,600 | 2,500 | 980 |
| **Consumer/ professional/ industrial total** | -3,200 | -2,600 | -2,000 | 720 | 210 | 760 | -1,600 | 500 | -1,800 | -29,000 | -57,000 | -7,500 | -1,500 | -1,700 |

Country definition codes: Austria (AT), Belgium (BE), Bulgaria (BG), Croatia (HR), Cyprus (CY), Czech Republic (CZ), Denmark (DK), Estonia (EE), Finland (FI), France (FR), Germany (DE), Greece (EL), Hungary (HU), Ireland (IE)

Scenario Fii - continued - Values in thousands of Euros

| | IT | LV | LT | LU | MT | NL | PL | PT | RO | SK | SI | ES | SE | UK |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Consumer, Professional and Industrial mixtures** | | | | | | | | | | | | | | |
| **No. of Comps** | 1520 | 53 | 44 | 11 | 71 | 228 | 586 | 220 | 262 | 95 | 51 | 1007 | 233 | 790 |
| **SME** | 1490 | 52 | 43 | 8 | 68 | 212 | 557 | 218 | 252 | 84 | 49 | 984 | 223 | 754 |
| **Large** | 30 | 1 | 1 | 3 | 3 | 15 | 29 | 2 | 10 | 10 | 2 | 23 | 9 | 35 |
| **Costs Domestically trade only** | -36,000 | -160 | -1,000 | -180 | -270 | -6,700 | 2,900 | -4,900 | 2,300 | 640 | 300 | -22,000 | 1,300 | 7,100 |
| **SME** | -30,000 | -150 | -960 | -35 | -180 | -5,300 | 2,300 | -4,400 | 1,900 | 230 | 210 | -19,000 | 920 | 5,500 |
| **Large** | -5,600 | -6 | -49 | -140 | -91 | -1,400 | 600 | -410 | 420 | 410 | 90 | -3,200 | 340 | 1,600 |
| **Costs Internationally traded** | -47,000 | -1,200 | -1,300 | -2,500 | -2,500 | -14,000 | -25,000 | -5,100 | -10,000 | -7,600 | -2,300 | -33,000 | -9,800 | -37,000 |
| **SME** | -26,000 | -920 | -800 | -230 | -810 | -5,800 | -9,700 | -3,700 | -4,500 | -1,100 | -1,000 | -19,000 | -4,100 | -16,000 |
| **Large** | -21,000 | -270 | -550 | -2,300 | -1,700 | -7,900 | -15,000 | -1,400 | -5,600 | -6,600 | -1,300 | -14,000 | -5,600 | -21,000 |
| **Cost of the UFI** | 50,000 | 1,300 | 1,400 | 1,300 | 1,700 | 11,000 | 19,000 | 6,600 | 9,200 | 3,900 | 1,900 | 33,000 | 8,200 | 31,000 |
| **SME** | 41,000 | 1,200 | 1,300 | 300 | 1,000 | 8,300 | 14,000 | 6,000 | 7,100 | 1,300 | 1,300 | 27,000 | 6,000 | 23,000 |
| **Large** | 8,600 | 82 | 170 | 1,000 | 710 | 2,800 | 5,400 | 600 | 2,100 | 2,600 | 540 | 5,400 | 2,200 | 8,000 |
| **Consumer/** | -33,000 | -92 | -910 | -1,400 | -1,100 | -9,200 | -2,900 | - | 1,400 | -3,100 | -130 | -22,000 | -350 | 960 |

| | |
|---|---|
| **Professional/ Industrial total** | 3,400 |

Country definition codes: Italy (IT), Latvia (LV), Lithuania (LT), Luxembourg (LU), Malta (MT), Netherlands (NL), Poland (PL), Portugal (PT), Romania (RO), Slovakia (SK), Slovenia (SI), Spain (ES), Sweden (SE) and United Kingdom (UK)