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ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Chemicals, metals, mechanical, electrical and construction industries; Raw materials
Chemicals - Classification & Labelling, Specific Products, Competitiveness

Harmonisation of Information for Poison Centres

**Review according to Article 45(4) of Regulation (EC) No 1272/2008 on classification,
labelling and packaging of substances and mixtures**

1. BACKGROUND AND INTRODUCTION

On a daily basis, consumers and workers come into contact with numerous chemicals, including sometimes hazardous substances and mixtures, be it in their private life when using for example paints or glues, or in their occupational environment while using for example industrial cleaners or solvents.

Although substances and mixtures placed on the market are expected to be safe when used according to their instructions, unintentional exposure to chemicals contained therein by ingestion, inhalation or through skin contact can occur, for example through accidents or the inappropriate use of products.

Once such an unintended exposure has occurred, it is crucial for medical staff to have immediate access to relevant information about the chemicals contained in the product in question in order to choose the right treatment and to avoid further damage to the exposed person.

Informing medical personnel (physicians, veterinarians, pharmacists) or the public about symptoms and treatment of acute intoxications is the main task of Poison Centres (PCs). To fulfil this task adequately, information about the product(s) involved is crucial, especially adequate information about the composition and the concentration of the ingredients, as well as on appropriate emergency measures.

In 1988 the Dangerous Preparations Directive¹ created in Article 12 an obligation for Member States to "appoint the body or bodies responsible for receiving information on dangerous preparations², including their chemical composition".

The Directive was repealed and replaced by Directive 1999/45/EC³. Article 17 of this Directive contained a very similar obligation by requiring that "Member States shall appoint the body or bodies responsible for receiving information, including chemical composition, relating to preparations placed on the market and considered dangerous on the basis of their health effects or on the basis of their physico-chemical effects."

Apart from specifying the type of effects, for which information should be received, the legislators did not establish clear and detailed rules on how these legal obligations should be fulfilled, either by Member State Competent Authorities or by Industry - which is obliged to provide the information.

As a result, a considerable variety of notification systems, data formats and country-specific requirements regarding the requested information have been developed in Member States. This leads to unnecessary burdens for companies operating in several Member States as they often have to submit the same or similar information in different formats or different information for the same mixture. It also leads to an uneven situation between Member States with regard to the information available to medical personnel and the general public in cases of poisoning incidents.

¹ Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

² now called "mixtures"

³ Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

These shortcomings of the Dangerous Preparations Directive and its predecessor were addressed during the adoption of Regulation (EC) No 1272/2008⁴ (the CLP Regulation), which aligns previous EU legislation on classification, labelling and packaging of chemicals to the UN Globally Harmonised System (GHS) and which will repeal the Dangerous Preparations Directive in June 2015.

Due to a lack of time for the necessary consultations to agree on all aspects of harmonisation at the time of adopting the CLP Regulation, a review procedure was included in the text. Article 45(4) of the CLP Regulation stipulates that the Commission, by 20 January 2012, "shall carry out a review to assess the possibilities of harmonising the information" submitted to poison centres, "including establishing a format for the submission of information". On the basis of this review, including the consultation of relevant stakeholders, the Commission may, if it is found appropriate, prepare a Regulation which would add an Annex to the CLP Regulation. As one "relevant" stakeholder, Article 45(4) explicitly mentions the European Association of Poison Centres and Clinical Toxicologists (EAPCCT).

2. REVIEW PROCESS AND STAKEHOLDER CONSULTATION

2.1. Expert meetings in 2010

In order to fulfil its obligations under Article 45 (4) of the CLP Regulation, the Commission services launched an extensive consultation process that started with two smaller expert meetings on 17 March and 28 May 2010. Representatives of national PCs in the Member States as well as representatives of EAPCCT were invited to participate. The minutes of the meetings are attached in Annex I and Annex II, respectively to this review.

As one result of these meetings, EAPCCT agreed to update its guidelines on product information needs and to discuss them in a wider forum with other stakeholders from industry, Member States, PCs and other interested parties.

2.2. Workshop in November 2010

This wider forum was convened in form of a workshop on 24 November 2010. Nearly 80 representatives of national PCs, EAPCCT, competent authorities of the Member States, industry associations, other stakeholders and various Commission services participated.

The discussion at the workshop was based on the EAPCCT guidelines, as endorsed by the EAPCCT Board on 18 September 2010 (attached in Annex III to this review), and the information requirements and needs listed therein from the point of view of PCs. These are in particular:

- to establish a unique identifier for the company that places a mixture on the market in order to know exactly whom to call in case of emergencies or questions;
- to establish a unique product identifier in order to be able to link the information available at the PCs **unambiguously** to the product involved in an incident;

⁴ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

- to receive the exact chemical composition of the product at least for the most hazardous ingredients (and in the form of concentration ranges for the less severe ones) in order to be able to perform a proper risk assessment and to provide the best possible advice to medical staff or consumers;
- to define the type of information which should be submitted to the PCs;
- to agree on a harmonised format in which information should be submitted to the PCs in order to enable them to retrieve, compare and exchange information more easily;
- to further develop product categorisation that exists already on a project level or in the context of specific legislation but should be extended to all products on the EU market. Such categories can be used, for example, in the context of toxicovigilance, which in turn can provide a basis for evidence that can be used for classification purposes;
- to receive additional information, for example on the toxicology of the mixture, which goes beyond the information currently required in Safety Data Sheets (SDSs).

Conclusions reached at the workshop in November 2010

At the end of the workshop, there was broad consensus:

- that it is possible and appropriate to harmonise the information to be submitted to PCs;
- on the need to develop a European product categorisation system;
- to use a common IT format to submit the information and to use XML;

and that further work needs to be done with regard to:

- the level of detail for the information concerning the composition of mixtures;
- the need for a unique company identifier and/or a unique product identifier;
- the need for, and the possibility to establish, a European database for submitting notifications to PCs.

There was also consensus, that, as a general rule, solutions should be found that satisfy the needs of PCs while creating a minimum of administrative burden for those who have to submit the information.

Experience gained in the context of other European legislation like REACH⁵ and the Cosmetic Products Regulation⁶, as well as other initiatives, projects, IT tools, developed at national or regional level, should be taken into account.

A brochure containing the summaries of the presentations made at the workshop, as well as the conclusions drawn and solutions proposed, was published in March 2011. This brochure is available on the website of DG Enterprise and Industry under the following link:

⁵ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

⁶ Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (Text with EEA relevance)

http://ec.europa.eu/enterprise/sectors/chemicals/files/clp/workshop_report_en.pdf

The web-streaming from the workshop as well as the presentation from the workshop are available on the following website of DG Enterprise and Industry:

http://ec.europa.eu/enterprise/sectors/chemicals/classification/poison-centres/index_en.htm

2.3. Expert meeting on 15 June 2011

As a follow-up to the workshop of November 2010, the Commission services convened a smaller expert meeting on 15 June 2011 with representatives of PCs, Member States' authorities, industry, and other relevant stakeholders in order to discuss further the topics for which no consensus could be reached at the workshop (see above). The minutes of the meeting are attached in Annex IV to this review.

The discussion mainly focussed on the following three topics:

- Is it necessary and feasible to submit to the PCs the exact composition for all types of mixtures, including non-hazardous ingredients? What are the legal constraints? What are the expected benefits compared to notification of concentration bands?
- Is there a need for / are there benefits from a unique company identifier (UCI) and /or a unique product identifier (UPI) and, if yes, what should they look like?
- Which different procedures are currently used in Member States to receive the requested information; and are Member States ready to harmonise these procedures? Would a more centralised system, like, for example, the one established under the Cosmetic Products Regulation, be a solution; and how should such a system be managed and financed?

The main conclusions of the discussion were the following:

- Several Member State authorities expressed flexibility with regard to the precise quantitative information for certain product types (e.g. paints) where it is difficult to get the exact composition. For these specific product types the EAPCCT could further discuss the use of ranges in small bands if the exact composition is not possible. The use of ranges for all ingredients, in particular those with the most severe hazards, was not supported by the EAPCCT.
- Several Member States hesitated to agree with the EAPCCT guidelines, especially those that currently legally require more precise information than in the EAPCCT guidelines. They would be reluctant to envisage a change of their national system for the sake of a harmonised European system that would require on a mandatory basis less information than currently collected in those Member States.
- More information on the type of data to be submitted at national level (mandatory and non-mandatory, exact composition yes /no, who has access, etc.) should be collected. The Commission services indicated that they would contact the Member States to obtain further information.
- Additional discussion was also required to assess possible different treatment of products for consumer/professional/industrial uses.

- Mandatory labelling of products with a UPI would be strongly appreciated by PCs and Member States, in particular in order to enable PCs to identify unambiguously the mixture involved in an emergency situation.
- Such an identifier would also facilitate the work of PCs when it comes to the identification of mixtures composed of other mixtures.
- Industry representatives considered a UPI to be useful additional information, but it should not be mandatory due to the additional costs involved in (re-)labelling and due to the increased space needed for mandatory labelling elements (e.g. from to the CLP-Regulation).
- For industry, it would be sufficient to harmonise the data requirements on the basis of the SDS (as specified in REACH Annex II). If additional data on composition would have to be notified in the future, use of INCI (International Nomenclature of Cosmetic Ingredients) names should be permitted, if appropriate and available.

2.4. Establishment of Newsgroups

After the meeting on 15 June 2011, the Commission services established 8 newsgroups within the relevant CIRCA Interest Group in order to allow those who could not participate in the meeting to follow the discussion and submit contributions and ideas on the following topics:

- Centralised versus decentralised system for submitting information;
- Chemical composition of mixtures;
- Designation of ingredients;
- Data Set Version Identifier (DVI);
- Type of information requested;
- Product Categorisation System (PCS);
- Unique Company Identifier (UCI);
- Unique Product Identifier (UPI).

Each topic was introduced by a thought-starter and key questions.

The Commission services informed the members of CARACAL, as well as the members of the CIRCA Interest Group "CLP Poison Centres", about the establishment of the newsgroups in order to ensure a wide participation in the discussions.

Statistical information about the participation in the newsgroups and a comprehensive evaluation of the contributions received is attached in Annex VI to this review.

2.5. Expert meeting on 7 November 2011

In order to conclude the stakeholder consultations, the Commission services organised a further expert group meeting on 7 November 2011 with representatives of Member States, PCs, EAPCCT and industry. The minutes of the meeting are attached in Annex V to this review.

This meeting was web-streamed and the web stream is available on the following website of DG Enterprise and Industry:

http://ec.europa.eu/enterprise/sectors/chemicals/classification/poison-centres/index_en.htm

The Commission services presented the outcome of the debate in the newsgroups for further discussion. The results and agreements reached are summarised in the following sections.

2.5.1. Information about the composition of mixtures

Throughout the review, the level of detail concerning the composition of mixtures to be notified to the PCs was one of the most controversial issues. Several Member States' authorities maintained that the precise composition of each mixture placed on the market should be notified to PCs. Other Member States' authorities and PCs themselves (in the EAPCCT guidelines) had called for the notification of precise concentrations only for substances classified for the most severe hazards, while accepting concentration ranges/bands for other substances. Industry representatives had contended that the notification of exact compositions is unnecessary and impractical due to frequent minor changes in mixture compositions, which would lead to very high numbers of notifications having to be made – therefore, appropriate concentration ranges/bands for all hazardous components in a mixture should be used.

Participants at the meeting on 7 November examined in detail the EAPCCT guidelines (see box), and it emerged that the notification of 'precise composition' in reality allows also certain tolerances corresponding to concentration range/bands: for example, if a mixture has been notified to PCs as containing a substance classified for Acute Toxicity, Cat. 1, a re-notification is required only if that concentration varies by more than 30% (i.e. between 0.7 % and 1.3%).

According to the latest version of the EAPCCT guidelines, the exact concentration is only required for substances in mixtures classified according to Regulation (EC) No 1272/2008 in the following hazard classes and hazard categories:

- acute toxicity (oral, dermal, inhalation), category 1, 2 and 3,
- STOT - single exposure, category 1 and 2,
- STOT - repeated exposure, category 1 and 2,
- skin corrosion, category 1A, 1B and 1C and
- serious eye damage, category 1.

For all other hazard classes, the following concentration bands are acceptable:

- >0 - ≤ 0,1%
- >0,1 - ≤ 1%
- >1 - ≤ 3%
- >3 - ≤ 10%
- >10 - ≤ 20%
- >20 - ≤ 30%
- >30 - ≤ 50%
- >50 - ≤ 75%
- >75%

In addition, the EAPCCT guidelines require a new notification inter alia:

- when a change in the initial concentration of one or more substances occurs for which the above mentioned concentration bands can be used and which as a consequence of the change of the concentration would fall into a different concentration band; and

- when a change in the initial concentration of one or more substances occurs for which the exact concentration is required. However, in such a case the EAPCCT guidelines only require a new notification according to the following table:

<i>Initial concentration range of the substance</i>	<i>Re-notification necessary if initial concentration changes by more than:</i>
concentration \leq 2,5%	30 %
2,5 < concentration \leq 10%	20 %
10 < concentration \leq 25%	10 %
25 < concentration \leq 100%	5 %

Authorities from Member States who currently require notification of precise composition also confirmed that updates are normally done only periodically (e.g. once per year) and not necessarily following each modification of the concentrations of components in a mixture.

Representatives of EAPCCT and PCs confirmed that notification of concentrations in ranges/bands could actually be acceptable for all substances, provided the ranges/bands were set appropriately narrow for the most relevant hazards. However, EAPCCT and PCs also wanted to receive information with regard to the presence of non-hazardous substances in mixtures.

Industry representatives reiterated their strong preference for notification of concentration in appropriate ranges/bands and confirmed that industry would be prepared to submit also information on non-hazardous ingredients present above a certain threshold, even if this information is not mandatory in SDSs.

The Commission services concluded that there was consensus among all participants that the concentration of substances being components of mixtures should be notified in appropriate ranges/bands and should include non-hazardous substances present above a minimum threshold. The Commission services will consult further with EAPCCT on the values to be set for the concentration ranges/bands.

2.5.2. Establishment of a centralised database versus maintaining the existing decentralised systems

This debate was influenced by the fact that the submission of information to PCs is not only provided for under the CLP Regulation but also under the Biocidal Products Directive⁷ and the Cosmetic Products Regulation.

Whilst Directive 1998/8/EC on biocidal products contains no further details in this regard, Regulation (EC) No 1223/2009 on cosmetic products requires that, prior to placing a cosmetic product on the market, the responsible person shall submit, by electronic means, a set of information to the Commission. The Regulation also lays down that the Commission shall make some of this information available electronically to all competent authorities (for the purposes of market surveillance, market analysis, evaluation, and consumer information) and to PCs or similar bodies, where such centres or bodies have been established by Member States (for the purposes of medical treatment).

⁷ Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market

In order to implement these requirements, the Commission has launched the so-called Cosmetic Products Notification Portal (CPNP) on 11 January 2012. This is the result of a close collaboration between the Commission services and the representatives of PCs, competent authorities and industry.

This database is planned in such a way that it can comprise information on nearly 1 million products, which is about half the number of products that are expected to be notified to PCs in the context of Article 45 of the CLP Regulation. The notifications to CPNP are possible in all official languages of the EU, and are highly standardised by mainly providing boxes to tick or terms to be selected from drop-down menus for the information requested. The Cosmetic Products Regulation provides for notification in the form of frame formulations for most products and more detailed concentration information is only required for a limited number of products and ingredients.

DG Health and Consumer Protection considered that there are many advantages linked to a centralised system, including:

- all information is available in standardised form;
- the information is available for all products Europe-wide even if a certain product is only placed on the market in one or a limited number of EU Member States. Consumers can nonetheless buy them when travelling and take them back to their Member State of residence, even if the particular product is not placed on the market there;
- companies would only need one notification instead of 27 different notifications in a worst-case scenario.

Some Member States and PC representatives present at the meeting on 7 November 2011 reiterated their scepticism with regard to a centralised database. They would prefer a decentralised system – with the possibility to exchange information – as this would increase the quality of the data records and PCs would have a better overview of the products that are actually on the market in their territories. On the other hand, industry representatives expressed their clear preference for a centralised data base as it would reduce administrative burdens and costs linked to multiple notifications. The database should be hosted by ECHA, which has extensive experience in operating large databases for chemicals and can guarantee sufficient security and confidentiality for the information notified. One Member State proposed in addition that REACH IT could be extended to collect this information and also to disseminate the information to the PCs via REACH IT. PCs should be given access to REACH IT that exists already in the MSCAs, with the same level of confidentiality assured.

The Commission services concluded that opinions among stakeholders still remained divided and further analysis will be required with regard to costs and workability. The Commission services invited Member States to provide information on the costs they incur in operating national databases (both financial and human resources), which could then be compared to estimates for a centralised database.

The desire from PC's to have a more direct overview on products on the market in their territories could be satisfied also in a centralised database by including a data field that would indicate in which Member States a given product is placed on the market (*nota bene*: this is not possible in the CPNP).

Whatever solution will be chosen also needs to take into account potential language problems as the product information to be provided in the context of Article 45 of the CLP Regulation will be less standardised than for cosmetic products, which operate mainly with frame formulations and INCI nomenclature for ingredients. For example, SMEs operating only in one or a few Member States might strongly prefer to make notifications in their languages (in particular the names of substances) rather than in English. PCs and most Member States would actually accept to have the names of substances indicated in English only. The C&L Inventory and Annex VI translations to be published on ECHA's website might actually help to overcome such language issues⁸.

In any case, work under the Cosmetic Products Regulation is already well advanced and the actual experience to be gained as of January 2012 will be valuable for the further work in the context of the CLP Regulation. If a centralised database were to be envisaged, it should aim at being compatible as far as possible with CPNP and with other existing formats used for the submission of regulatory information on substances (cf. IUCLID) in order to avoid duplication of work and to take advantage of what has already been accomplished. However, this can only be a long-term project, which requires for example sufficient funding and additional human resources at the Commission (or ECHA) level, which need approval by the European Parliament and the Council.

Finally, the Commission services recalled that the harmonisation of the data-sets to be provided and of the electronic format for notifications are the most important issues. If that is achieved, the question whether there should be a centralised database or a decentralised system of interconnected databases that would allow full exchange of information is rendered somewhat less significant.

2.5.3. Type of information to be submitted

Currently, if there are no different national requirements, companies often submit the Safety Data Sheets to PCs in order to fulfil their notification obligations. However, EAPCCT considered that, in the past, the information in the SDS was rather scarce, in particular with regard to the toxicological information, and, therefore not sufficient for the purposes of PCs.

The information required in Section 11 of the "new" version of the SDS according to Annex II to the REACH Regulation ("Toxicological information") is expected to close this gap and PCs agreed that this information is sufficient provided that the following elements are submitted as well (not necessarily as part of the SDS):

- Information about the composition of mixtures;
- Information on the product category;
- Information on the size and type of packaging, and
- Information on whether the product is used by consumers and / or by industrial users.

⁸ It has to be noted that only the names of substances in Annex VI to the CLP Regulation (in English and their translations) have been verified. Names of substances in the C&L Inventory submitted during the notification process (either in English or in other languages) have not been verified by ECHA and are therefore less reliable.

Industry representatives repeated their position that the information contained in (well-drafted) SDS in accordance with Annex II of REACH should suffice, in particular for products placed on the market for professional or industrial use.

The Commission services took the view that on this particular issue, the requests from EAPCCT should be carefully considered as PCs are best placed to know what kind of information they need. The Commission services asked industry how it would deal with notifications for consumer products for which SDS are normally not provided. Industry confirmed that most companies are able to establish SDS also for consumer products.

The Commission services recalled that any harmonised notification system for electronic submission of information would most likely not enable companies just to send copies of their SDS to PCs, as these would then have to enter the information themselves into their databases. Instead companies would have to prepare notifications in the agreed format. Most SDS today are generated by specific computer software, which could probably be modified to also establish PC notifications in XML format with the same information elements and companies would then 'only' have to add the additional elements requested by EAPCCT, which would be rather limited (4 additional items as detailed above). There is broad agreement among all stakeholders with regard to the details concerning the composition (as discussed in section 2.5.1) and to add information on the product categories, once such a system has been developed. Categorisation could be developed in such a way that it would distinguish between professional and consumer use. The information on the size and type of the packaging could probably be linked to the Unique Product Identifier (UPI) – see section 2.5.5 below.

2.5.4. Designation of ingredients

All stakeholders agreed that a number of nomenclatures used in various pieces of legislation (CLP Regulation, REACH Regulation, and Detergents Regulation) are well-established and should be used for designating the ingredients when notifying the composition of mixtures to the PCs. The hierarchy for choosing their names (e.g. Annex VI of CLP, IUPAC) and their internationally-accepted identification numbers (e.g. CAS) as outlined in Article 18 of the CLP Regulation should be followed, where possible.

Regarding the language of the notification, there is agreement that it should always be possible to submit the notification in the official language of the Member State where a company is marketing its products. However, as already mentioned in section 2.5.2, PCs and competent authorities are willing to accept also notifications in English, in particular with regard to the name of the ingredients. With the help of the CAS number or other identification numbers that are normally part of the notification (e.g. the EC number), it should be possible in the future for PCs and companies alike to retrieve the name of ingredients in different languages in Annex VI and/or the C&L Inventory published on the website of ECHA⁹.

2.5.5. Unique Product Identifier (UPI)

At the meeting on 7 November 2011, EAPCCT representatives repeated their strong desire to establish and use a numeric UPI on the packaging of products. Currently in approximately 20

⁹ See the previous comment on the reliability of names of substances submitted to the C&L Inventory during the notification process.

to 40% of the cases there are difficulties in finding the right data record in PC databases due to the fact that those calling for information have difficulties in the correct identification of the product. Industry representatives repeated their concerns about additional burdens and costs from adding further elements to product labels. The potential impact of UPI on parallel trade was also mentioned. If a UPI were to be foreseen, companies should then be allowed to assign themselves the UPI to their products and printing on labels should be simple laser-printing (to be added in a similar way as the batch number).

Representatives of the PCs in France presented a tool developed by the PC of Nancy, which is available on-line free of charge and allows combining a company's VAT number plus a company internal product code to establish a rather short UPI. As every company has one (or several) VAT numbers already, there is no need to develop any further administrative structures for such a system¹⁰.

After some further discussion, a broad agreement emerged that such a UPI would be a useful tool that would actually solve a number of problems identified by PCs or by industry itself, e.g.

- to identify unambiguously the product involved in an incident;
- to determine the composition of mixtures composed of mixtures when suppliers do not want to disclose all information to downstream users.

The system developed by the PC of Nancy would be a good starting point.

This UPI system would also be able to convey information on the size and type of the packaging as different packaging size or type of the same mixture could receive different UPIs. Furthermore, this UPI system would render obsolete the need for developing an additional Unique Company Identifier (UCI) and a Data set Version Identifier (DVI) as originally requested by EAPCCT (see sections 2.5.7 and 2.5.8).

However, additional labelling costs for companies should be kept in mind when establishing such a number. The Commission services would also have to examine how the labelling rules in the CLP Regulation should be modified if a UPI was to become mandatory, since this would require an amendment of existing provision in the CLP Regulation.

2.5.6. *Product Categorisation System (PCS)*

There was broad consensus among all stakeholders that a European Product Categorisation System would be very useful. Among other benefits this would be helpful for statistical analysis of poisoning incidents and would ensure comparability of statistics among all Member States. The German *Toxicological Documentation and Information Networks Project (TDI)* could serve as a template for the development of a European PCS, taking into account further use descriptions as being developed by ECHA in the framework of REACH.

When developing such a system, one could also foresee the possibility not only to identify the product category as such, but also to indicate whether the product is used either exclusively by consumers or exclusively by professional / industrial users.

¹⁰ <http://upi.toxalert.fr>

2.5.7. *Data Set Version Identifier (DVI)*

Following further discussion on the need for / benefits of a DVI, all stakeholders agreed that such a DVI is not necessary if a Unique Product Identifier (UPI) as discussed in section 2.5.5 is developed and used for labelling products and submitting notifications to PCs.

2.5.8. *Unique Company Identifier (UCI)*

All stakeholders agreed that such a UCI is not necessary if a Unique Product Identifier (UPI) as discussed in section 2.5.5 is developed and used for labelling products and submitting notifications to PCs as this UPI would also contain a company-identifier component.

3. CONCLUSIONS AND RECOMMENDATIONS

As a result of the comprehensive consultations with all stakeholders, it is possible to harmonise the information to be submitted to PCs and to establish a common format for the electronic submission of this information based on the following principles:

- The information on the ingredients in a mixture can be notified in concentration ranges/bands. The width of such ranges/bands should be defined as a function of the hazards of the substances.
- Non-hazardous ingredients should be notified as well, if they are present above a certain threshold that still needs to be defined.
- A Unique Product Identifier (UPI), which includes a company-identifier component should be printed on labels and used for PC notifications in order to facilitate identification of products involved in poisoning incidents and the retrieval of the correct data records in PCs. A UPI would also facilitate the identification of mixtures in mixtures and guarantee at the same time that confidential business information does not have to be revealed to downstream users of mixtures. Further analysis is still required on how the labelling rules in the CLP Regulation should be modified to accommodate a mandatory UPI and the implications this would have on the potential legislative procedure to be followed to implement the outcome of this review.
- The designation of ingredients in mixtures should, where possible, follow the hierarchy as outlined in Article 18 of the CLP Regulation.
- The information contained in the extended SDS in line with Annex II to the REACH Regulation is considered to be sufficient for PC notifications, if some additional information will be provided as well (e.g. composition details as described above, including also non-hazardous ingredients), product category (as described below) and size and type of the packaging (which can be linked to the UPI).
- Notifications should be possible in all official languages of the country in which a company is marketing its product and/or alternatively in English.
- A European Product Categorisation System should be developed, using the German *TDI* as a template and taking into account further use descriptions as being developed by ECHA in the framework of REACH.
- PC notifications should be submitted electronically in a harmonised XML format.

- Further analysis is still required to decide whether PC notifications should be submitted to a centralised European database (with access possibilities for all PCs) or rather to databases in the Member States that would be interconnected and could exchange information between them. The analysis should include cost / benefit considerations for authorities at European level and in Member States, PCs, and industry, as well as aspects such as security, quality of data records, effects on SMEs, languages, who would host a central database, etc. Experience to be gained with the European Cosmetic Products Notification Portal (CPNP) as of January 2012 will provide valuable input for the analysis. A centralised database would require additional resources at EU level, which need approval by the European Parliament and the Council.

The Commission services will seek reactions from authorities and stakeholders in CARACAL on these conclusions and recommendations. Provided that there is sufficient support, the Commission services will continue to analyse the remaining issues outlined above and start the development of a Regulation to add an Annex to the CLP Regulation in accordance with Article 45 (4) of the CLP Regulation or, alternatively, prepare an amendment to the CLP Regulation if the labelling provisions of CLP are to be adapted.

ANNEX I

Minutes of the meeting of the representatives of the Poison Centres

17 March 2010

CLP Article 45(4) - emergency health response

Assessment of possibility of harmonising information

Introduction and presentations at the start of the meeting

- The chairman of the EAPCCT ‘Working Group on Poisons Centres activities / European Regulatory Issues’ started the meeting with an overview of the working group activities on ASHT/RAS-CHEM, CPNP and the CLP Regulation article 45(4).
- All participants agreed on the proposal that the Dutch National Poisons Information Centre will take the lead as EAPCCT Working Group coordinator within the CLP-process.
- COM gave a presentation on CLP Regulation article 45. Art. 45 (4) contains a review clause: ‘By Jan. 2012, the Commission shall carry out a review to assess the possibility of harmonising the information..., including establishing a format for the submission of information by importers and downstream users to appointed bodies. On the basis of this review ... the Commission may adopt a Regulation.’ It was stressed that the Article does not include an obligation for setting up a database on EU level (unlike e.g. the Cosmetics Regulation). The proposed way forward was described: Any proposed Commission Regulation to adapt CLP to technical progress to cover Article 45(4) would be adopted in accordance with the "*regulatory procedure with scrutiny*" (Comitology). According to this procedure, the Commission submits a draft Regulation to the existing MS Committee responsible for matters under the CLP and REACH Regulations – the REACH Committee. REACH Committee members cannot formally amend the Commission proposal but discuss it. After the vote in the Committee, the proposal will subsequently be submitted to the Council and the European Parliament. These two co-legislators can approve or reject the Regulation, but cannot introduce amendments. If adopted, the proposal is intended to provide for a transitional period of around 18 months after which the new requirements will replace all national legislation in Member States on the required product information to be sent to the appointed body. The presentation was distributed by e-mail on 18-03-2010.
- A representative of EAPCCT presented the discussion points for the EAPCCT Working Group to be addressed during the meeting and on the translation of the EAPCCT guidelines on composition in the new CLP classification. This is also described in the working document ‘CLP Regulation article 45 –harmonisation of PIC requirements on product notification’ that was distributed before the meeting and acted as a guideline in the discussions. The presentation was distributed by e-mail on 18-03-2010.
- In reaction to the involvement of governmental institutes in some countries, a representative of a French PC gave an overview of the electronic notification to PCs and the governmental institute INRS in France by the website: www.declaration-synapse.fr. Especially interesting was the possibility of a bulk upload of product information in a structured XML-format.

Discussion

- The participants agreed that the Safety Data Sheet (SDS) can be used as part of the product information in combination with a document containing the composition and information necessary for PIC but missing on the SDS.
- The required information essential for medical purposes, especially on the required quality of the composition, was discussed by the participants. Decisions made and proposals for the new EAPCCT guidelines are incorporated in the working document ‘CLP Regulation article 45 – harmonisation of PIC requirements on product notification’.

Steps to be taken

- An updated working document with the results of the meeting discussions and a first draft ‘EAPCCT guidelines 2010’ will be distributed by the Dutch PIC. Further comments will be gathered by e-mail to refine the guideline.
- There will be a second meeting of the representatives of the PCs organised by the EC at the end of May (26,27 or 28 May as possible options) to further discuss the PIC requirements on product information and especially the format/versioning.
- Representatives of Member States will be informed by an announcement and a request for proposed participants at the CARACAL meeting on 17th of June 2010. It has yet to be decided who will represent the EAPCCT Working Group to present the draft proposal at the meeting. The EAPCCT President would be ideal.
- The workshop with industry, Member State authorities, PIC and interested stakeholders will be organised in November 2010. It is expected that a maximum of 80-100 participants will attend the meeting. The workshop will consist of presentations and questions/answer sessions. This will result in a workshop report that can be the basis for the review prepared by the Commission and to be presented for voting.

ANNEX II

Minutes of the meeting of representatives of Poison Centres and Governmental authorities

28 May 2010

CLP Article 45(4) - emergency health response

Assessment of possibility of harmonising information

Introduction and presentations at the start of the meeting

- COM opened the meeting. After including additional presentations by some participants the agenda was adopted.
- A representative of EAPCCT started the meeting with a presentation on the identification of products. It would be useful for Poisons Centres if a product label contains a unique product identification number that identifies the product to its specific formula. Such a number could contain several components to identify successively: country, company, product and formula.
- Representatives of ECHA presented (by webinar and conference call) an overview of IUCLID5 (see: <http://iuclid.echa.europa.eu/>) IUCLID5 is an IT application to store, organise and report on hazardous properties of chemicals. By industry it is used to prepare the technical dossier for registration of substances. Interestingly, besides dossiers of substances it is possible to create a dossier for mixtures (no legal requirement). Interesting for Poisons Centres is also the company code (UUID) that is given to manufacturers, as a unique company code is also part of the product identification number as presented by EAPCCT (see above).
- Representatives of ECHA also demonstrated the use of the ECHA website to retrieve substance information (section 7, toxicological information, as an example). The substance information is found on the ECHA website by choosing 'ECHA CHEM' in the left menu and than 'Registered substances' (URL: <http://apps.echa.europa.eu/registered/registered-sub.aspx>). Not all available substance information will be published. See article 119(1) of the REACH Regulation for the information that will always be publicly available and article 119(2) for the information that will be publicly available unless a confidentiality claim of a company is granted. For example, the results of toxicological studies will always be published but a study summary can remain confidential.
- In addition to the poster on the topic that was distributed before the meeting, a representative of the German PC presented an overview of the product notification in Germany and the role of the BfR in this process. The BfR is currently developing a uniform standardized electronic data set for product data to be submitted by companies. Also interesting is the development of a MS-Excel Macro writer that produces the required XML-format. An analysis conducted by the BfR showed that due to the new CLP Regulation, a notification of 40.000-50.000 mixtures (excluding cosmetics) is expected every year.
- A representative of the Dutch PC presented an overview of the current state of the discussions on the required product information, the format and versioning as discussed by the EAPCCT Working Group.

The items currently included in the guideline were presented, as well as those left out of the former EAPCCT guideline of 1989, and an overview of the remaining discussion points in the current draft was given (as also described in the 'second draft with comments' that was distributed before the meeting). It was stated that the involvement of governmental authorities is very important as in some EU countries these governmental authorities receive the product information to make it available to Poisons Centres. Changes in requirements and format will also affect their

procedures.

Discussion

- On IUCLID5
The participants agree that the substance information that can be retrieved from the ECHA website can be useful for Poisons Centres although the demonstration by ECHA showed that information is possibly not always found very quickly (seen the amount of available fields). It could be interesting for Poisons Centres to also have access to the confidential information. Future access of Poisons Centres as official bodies should be explored. Besides, IUCLID5 can give ideas on the format for product information.
- On product identification:
The participants agree that a unique product identifier on the label identifying the product and its specific formula would be very useful for Poisons Centres but a legal requirement will not be easily achieved in a short period of time. The EAPCCT guidelines could contain a request for and an explanation of the structure of such a unique product identifier, so companies using it on a voluntary basis can notify it on the product information sheet. A representative of EAPCCT will prepare a draft text on this topic to include in the guideline. In this way the need of clear product identification (up to its specific formula) and a proposal for a solution is communicated to industry. This can possibly be a first step to a future European product identification number.
- On the ‘draft EAPCCT guideline 2010’:
The most important discussion was on the necessary dataset for notification to Poisons Centres. Until now discussions focussed on the additional information that is necessary besides the information already present on the Safety Data Sheet (SDS). It is necessary though, to define the complete dataset which will also include some information as present on the SDS. For example information on the hazard classification of a mixture is present on the SDS but should be included in the dataset because it will then be electronically available in the Poisons Centres database (if the dataset is notified in an XML format). The Dutch PIC will propose the items from the SDS to include in the dataset (mainly the hazard classification and selected physical characteristics like pH) in the next draft EAPCCT guidelines. The other information on the SDS (like the toxicological information that is expected to improve due to the REACH Regulation) will probably be notified in PDF-format. Discussion points on the current draft were discussed by the participants. All comments will be gathered in the draft EAPCCT guideline that will be distributed shortly by the Dutch PIC.
- For PIC, validation of the notified electronic data is very important. With all relevant data in the electronic dataset, PCs have the means to automatically perform validation tests, instead of the manual checks now performed.

Steps to be taken

- An updated draft EAPCCT guideline including the comments and the changes according to the meeting discussions will be distributed by the Dutch PIC shortly. Further comments on this draft will be gathered by e-mail to refine this guideline into a third draft. The distribution of this third ‘official’ draft and also an updated working document (‘CLP Regulation article 45 –harmonisation of PIC requirements on product notification’) with an overview of all discussions, is planned for August 2010.
- Another meeting of the EAPCCT Working Group is necessary and will be planned at the end of August or beginning of September 2010 to further discuss the PIC requirements, especially the format/versioning.
- Representatives of Member States will be informed on the progress of the working group at the CARACAL meeting on 17th of June 2010. A representative of EAPCCT will attend the meeting to give a presentation.

- The workshop with industry, Member State authorities, Poisons Centres and interested stakeholders is scheduled for 25th November 2010 (information provided after the meeting). The CPNP meeting is moved to the 26th November to save travel time/expense for participants attending both meetings. It is expected that around 120 participants will attend the stakeholder workshop.
The workshop will consist of presentations by some CLP Working Group members about the history and current state of the project and by industry. COM will sent round a first proposal for a programme to comment.
It is intended to prepare a report about the workshop summarising the current state of the project.

ANNEX III

EAPCCT guidelines 2010 Guidelines for the completion of a product information form, additional to the use of the Safety Data Sheet. This version was endorsed by the EAPCCT Board on the 18th of September 2010.	
COMPANY INFORMATION	
- Company placing the mixture on the market - Company submitting the mixture information	Name and address of the company placing the mixture on the market (and mentioned on the label and/or packaging of the mixture). A unique company identifier should be provided, identifying the legal entity. name, address, telephone number, e-mail address and, if available, fax number of the company submitting the mixture information. A unique company identifier should be provided, identifying the legal entity. <u>Note to industry:</u> According to article 45 of Regulation (EC) No 1272/2008 the appointed body will receive information from importers and downstream users placing mixtures on the market (also mentioned on the label and/or packaging of the mixture as the supplier). In the experience of Poison Centres, this 'company placing the mixture on the market' is not always able to submit the required mixture information such as a detailed composition. In this case there can be a separate 'company submitting the mixture information'. Otherwise the 'company placing the mixture on the market' and the 'company submitting the mixture information' are one and the same company.
- Contact Point(s) in case of emergency	For additional information, Poison Centres need a name of a department with telephone number/e-mail address for rapid direct contact. Companies should set up internal procedures to cope with contacts with Poison Centres which may be needed in emergency situations.

IDENTIFICATION OF THE MIXTURE	
- Mixture identifiers	<p>Mention the complete trade name(s) of the mixture as present on the label (if relevant including brand name, product line, name of the product and variant name) without abbreviations, enabling its specific identification. Other names or synonyms by which the mixture is labelled or commonly known, such as alternative names shall also be provided.</p> <p>Where the mixture is marketed under different names in the same country (e.g. different languages), list all these names <u>on the same product information form</u>.</p> <p>If available, also mention other mixture identifiers present on the label. The type of identifier should be specified (registration/authorization number, article number e.g.).</p> <p><u>On the grouping of mixtures:</u></p> <p>Under special circumstances the product information sheet can cover more than one mixture. Grouping of mixtures is allowed when variants of a product have essentially the same composition but only differ in colour and/or fragrance. Grouping is not allowed if substances (in the mixture), that are classified according to Regulation (EC) No 1272/2008 as</p> <ul style="list-style-type: none"> - acute toxicity (oral, dermal, inhalation), category 1, 2 and 3, - STOT - single exposure, category 1 and 2, - STOT - repeated exposure, category 1 and 2, - skin corrosion, category 1A, 1B and 1C and - serious eye damage, category 1, <p>differ, either in presence or concentration, between mixture variants. When a National official registration/authorization number exists for some mixture categories (pesticides, biocides e.g.) it is not allowed to group notifications for separately registered/authorized mixtures.</p>

	<p>When mixture variants are grouped, all relevant mixture identifiers as described above must be mentioned on the same product information form, including all trade names indicating the different product variants. Only mixtures with a common part in the trade name followed by an additional component indicating the specific variant, may be grouped.</p>
<p>COMPOSITION</p>	
<p>- Substances in the mixture</p>	<p>Mention all substances (whatever their toxicity), impurities and stabilising additives, by internationally accepted chemical names, present in the mixture when placed on the market.</p> <p>Guideline on the use of internationally accepted chemical names, in descending order of preference:</p> <ul style="list-style-type: none"> - the name as given in Part 3 of Annex VI of Regulation (EC) No 1272/2008, - the name as given in the classification and labelling inventory (mentioned in Article 18(2) of Regulation (EC) No. 1272/2008), - the name set out in the nomenclature provided by the IUPAC or - another international chemical name. <p>The names ‘perfumes’, ‘fragrances’ and/or ‘colouring agents’ can be used.</p> <p>In the case of substances occurring in nature, a chemical name or chemical names of the type "essential oil of ..." or "extract of ..." may be used instead of the chemical names of the components of that essential oil or extract.</p> <p>If available for a substance, the Chemical Abstracts Service (CAS) and EC numbers (EINECS/ELINCS) are required. Optional is mentioning the ‘functional group name’, hazard classification (hazard class(es) and category code(s)) according to Regulation (EC) No 1272/2008 with H-statements (their codes shall be sufficient) for every single substance in</p>

	the mixture. Optional is also to mention if the substances in the mixture are nanoformulated or not (yes/no).
- Substance concentrations	<p>Give actual concentrations of substances in the mixture classified as:</p> <ul style="list-style-type: none"> - acute toxicity (oral, dermal, inhalation), category 1, 2 and 3, - STOT - single exposure, category 1 and 2, - STOT - repeated exposure, category 1 and 2, - skin corrosion, category 1A, 1B and 1C and - serious eye damage, category 1, <p>according to Regulation (EC) No 1272/2008. Give concentrations of all other substances in the mixture in the following concentration bands: >0 - ≤ 0,1%, >0,1 - ≤ 1%, >1 - ≤3%, >3 - ≤10%, >10 - ≤20%, >20 - ≤30%, >30 - ≤50%, >50 - ≤75%, >75%</p> <p><u>Note to industry:</u> detailed information on the composition of a mixture is essential to perform an adequate risk assessment in case of an intoxication with the mixture. Especially important are exact concentrations of the substances classified as described above. The notification of exact concentrations for all substances in a mixture is preferred but for substances classified for the health hazards ‘Aspiration hazard’, ‘Respiratory sensitisation’, ‘Skin sensitisation’, ‘Carcinogenicity’, ‘Mutagenicity’ and ‘Reproductive toxicity’, to know the presence in a mixture is more important than to know the actual concentration. As Poison Centres may be confronted with very unusual misuse (injection e.g.) a complete accurate composition should be given on request in exceptional cases.</p>
- Reformulation	<p>If the mixture is reformulated and the name is unchanged, it is necessary to renew the notification to Poison Centres in case of:</p> <ul style="list-style-type: none"> - the substitution or addition of one or more substances

	<ul style="list-style-type: none"> - a change in the initial concentration of one or more existing substances (for which concentration bands can be used) that will therefore fall into a different concentration band - a change in the initial concentration of one or more substances for which an exact concentration is required at or above the limits in the table below - the deletion of one or more substances <p>If the name of the product is changed it will be a new notification.</p> <table border="0" style="width: 100%; margin-top: 20px;"> <thead> <tr> <th style="text-align: left; width: 50%;"><u>Initial concentration range of the substance:</u></th> <th style="text-align: left; width: 50%;"><u>Renotification necessary if initial concentration of the substance changes by more than:</u></th> </tr> </thead> <tbody> <tr> <td>concentration \leq 2,5 %</td> <td>30 %</td> </tr> <tr> <td>2,5 < concentration \leq 10 %</td> <td>20 %</td> </tr> <tr> <td>10 < concentration \leq 25 %</td> <td>10 %</td> </tr> <tr> <td>25 < concentration \leq 100 %</td> <td>5 %</td> </tr> </tbody> </table>	<u>Initial concentration range of the substance:</u>	<u>Renotification necessary if initial concentration of the substance changes by more than:</u>	concentration \leq 2,5 %	30 %	2,5 < concentration \leq 10 %	20 %	10 < concentration \leq 25 %	10 %	25 < concentration \leq 100 %	5 %
<u>Initial concentration range of the substance:</u>	<u>Renotification necessary if initial concentration of the substance changes by more than:</u>										
concentration \leq 2,5 %	30 %										
2,5 < concentration \leq 10 %	20 %										
10 < concentration \leq 25 %	10 %										
25 < concentration \leq 100 %	5 %										
CATEGORISATION											
<p>- Product Category</p>	<p>Describe the intended use of the mixture.</p> <p>Ideally a harmonised categorisation system should be developed by the EAPCCT in collaboration with industry.</p>										

<p>- Consumer/ Professional use</p>	<p>Specify if the mixture is for consumer and/or professional use.</p>
<p>CLASSIFICATION</p>	
<p>- Classification</p>	<p>The classification (hazard class and category) of the mixture as provided in Section 2.1 of the SDS according to Regulation (EC) No 1907/2006.</p> <p>When both the classification according to Directive 1999/45/EC and Regulation (EC) No 1272/2008 is provided on the SDS, the classification according to Regulation (EC) No 1272/2008 can be provided on the product information form.</p>
<p>- Label elements</p>	<p>The label elements of the mixture as provided in Section 2.2. of the SDS according to Regulation (EC) No 1907/2006.</p> <p>Label elements according to Directive 1999/45/EC: symbol(s), indication(s) of danger, risk phrase(s) and safety advice. Label elements according to Regulation (EC) No 1272/2008: hazard pictogram(s), signal word(s), hazard statement(s) and precautionary statement(s).</p>
<p>PACKAGING</p>	
<p>- Type(s) - Size(s)</p>	<p>Mention the type and size of packaging.</p> <p>The type and size may influence toxic hazard.</p>
<p>- Labels</p>	<p>Providing labels is preferred, particularly for products with a health hazard classification according to Regulation (EC) No 1272/2008.</p>
<p>PHYSICAL/CHEMICAL CHARACTERISTICS</p>	
<p>- Physical state</p>	<p>The physical state of the mixture as provided in Section 9.1 (a) of the SDS according to Regulation (EC) No 1907/2006.</p>

	<p>The physical state (solid (including appropriate and available safety information on granulometry and specific surface area if not already specified elsewhere in this safety data sheet), liquid, gas) and the colour of the substance or mixture as supplied shall be indicated.</p>
- pH	<p>The pH of the mixture as provided in Section 9.1 (d) of the SDS according to Regulation (EC) No 1907/2006.</p> <p>The pH shall be indicated of the substance or mixture as supplied or of an aqueous solution; in the latter case, the concentration shall be indicated.</p>
- total reserve acidity/alkalinity	<p>If available, give total reserve acidity/alkalinity of product where relevant.</p> <p>For acidic mixtures, this is the amount (g) of sodium hydroxide/100 g of mixture required to produce a specified pH. For alkaline mixtures, it is the amount (g) of sodium hydroxide equivalent to the g sulphuric acid/100 g of mixture required to produce a specified pH.</p> <p>Acid/alkali reserve measurement. For powders/solids and liquids the acid/alkali reserve is determined by titration (e.g. with 2 N-sodium hydroxide or 2 N-sulphuric acid) for acid substances/mixtures up to a pH of 4 and for alkaline substances/mixtures down to a pH of 10. Acid/alkali reserve is expressed as g sodium hydroxide (equivalent)/100 g powder/solid or liquid required to adjust the pH to the appropriate value.</p>
TOXICOLOGY	<p><u>Note to industry</u>: relevant information on the toxicity of the mixture is important for Poison Centres and should be provided according to the Regulation 1907/2006 on the Safety Data Sheet.</p>

OTHER INFORMATION	
	Date of first marketing. Date product information form completed. Remarks

TO BE FURTHER DISCUSSED BY EAPCCT CLP WG MEMBERS / INDUSTRY
<p>For an adequate risk assessment in case of an intoxication with a mixture, it is very important for Poison Centres to know the exact formula of a mixture. Since various formulas of a mixture may be present on the market, it is essential that Poison Centres are able to identify these different formulas of a mixture.</p> <p>A unique mixture identifier on the label (and also in the SDS or other notification document) that allows formula identification would be an important improvement. In addition, it should be clear from the notification (update) of the product information that a formula has changed. Poison Centres would like to discuss with industry how this problem of uniquely identifying a formula of a mixture can be solved.</p>

ANNEX IV

Minutes

Meeting of stakeholder representatives on Art. 45(4) CLP Regulation

Brussels 15 June 2011

BELLIARD building, rue Belliard 100, 1040 Brussels, room 09/SDR

1. Opening and adoption of the agenda

COM welcomed the participants.

The draft agenda was adopted without requests for additional items.

2. Introduction by the Commission

COM summarised the main outcome of the workshop held on 24 November 2010, the results of which have been published in a brochure which can be downloaded from the following website:

http://ec.europa.eu/enterprise/sectors/chemicals/files/clp/workshop_report_en.pdf

COM highlighted the main points of consensus and the remaining aspects where further discussion is needed to explore the potential for a more harmonised system. Those remaining aspects are the following:

- Is it necessary and feasible to submit to the PCs the exact composition for all types of mixtures, including non-hazardous ingredients? What are the legal constraints? What are the expected benefits compared to notification of concentration bands?
- Is there a need for / are there benefits from a unique company identifier and /or a unique product identifier and if yes, what should they look like?
- Which different procedures are currently used in Member States to receive the requested information and are Member States ready to harmonise these procedures? Would a more centralised system like for example the one established under the Cosmetic Products Regulation be a solution and how should such a system be managed and financed?

COM recalled that the CIRCA interest group is the main tool to share information and documents linked to this debate. Participants were reminded to request access to CIRCA and to encourage other potential interested stakeholders to contact COM to register (an e-mail should be sent to the following functional mailbox: Entr-Chemicals@ec.europa.eu).

COM will launch several discussion fora via newsgroups on this CIRCA interest group which will give all stakeholders interested in the debate the possibility to submit ideas and comments. Those newsgroups will cover both the topics discussed at this meeting but also other topics discussed at the November workshop and for which a general support for harmonisation was already reached then, but for which more concrete ideas are necessary.

COM also announced that a 2nd meeting with stakeholders will be organised towards the end of September / beginning of October 2011, aiming at presenting initial ideas on aspects that could be harmonised based on Member States and stakeholders reactions collected via CIRCA. The exact date will be communicated at a later stage.

COM stressed that future harmonisation will take into account work already being done under the Cosmetic Products Regulation.

3. Discussion on the information to be submitted regarding the (exact) composition of mixtures and possible solutions

COM invited participants to present which information is currently required by the different national legal systems.

In Germany, according to information provided by BfR and AISE, two databases contain information on detergents, cosmetics, biocides and hazardous mixtures. For hazardous mixtures, information is required for those classified as sensitizers, corrosive, toxic, very toxic or CMR which are placed on the market for consumers and for biocidal products (both for consumers and professional use). It is allowed to provide ranges which are narrower for ingredients with a high hazard potential. Furthermore, for ingredients with low hazard potential, agent group names (e.g. “anionic surfactants” or “vegetable oils”) are allowed.

NL PC presented an overview of the legal systems in EU-15 regarding legal requirements to provide information on composition and concentration. The information presented did not specify whether the obligations applied to professional and/or consumer uses. Many EU Member States (The Netherlands, Belgium, France, Portugal, Spain, Sweden, Norway, and Ireland in this review) currently require a complete list of ingredients without the use of thresholds as is also required in the 2010 EAPCCT guidelines. Besides, for detergents the complete list of ingredients should already be available for medical personnel according to article 9(3) of Regulation (EC) No 648/2004. □For cosmetic products containing ingredients of concern and cosmetic products not fitting a Frame Formulation a more detailed formula declaration will be necessary (notification from 2012 by use of the CPNP portal according to Regulation (EC) No 1223/2009). Many EU Member States require either an exact concentration for all substances (The Netherlands, Portugal, Norway, Denmark in this review) or a combination of exact concentration for selected substances and defined concentration ranges for the others (The Netherlands, Belgium, France, Germany, Austria, Spain, Sweden, Ireland in this review) as in the 2010 EAPCCT guidelines. For the notification of cosmetic products an exact concentration is also required for some ingredients of concerns (based on Poisons Centre experience and hazard classification according to the CLP Regulation). It was stressed that the EAPCCT guidelines already are a compromise (especially on the required concentration of the ingredients) between the different requirements in EU Member States.

IT indicated that in their national system there is no distinction between professional and consumer uses. The obligation to provide the information applies to both product groups in the same manner. It is required to provide the composition of all ingredients but the concentration of ingredients is submitted in ranges, the specific concentration is never required.

CEFIC expressed concerns about requiring the exact composition, rather than ranges, for all hazardous properties of mixtures.

EAPCCT indicated that PCs have to deal with uncertainties regularly and work on the basis of worst case assumptions (e.g. regarding quantity ingested). In order to avoid unnecessary and potentially dangerous medical treatment it is necessary to obtain more precise data.

CEPE added that formulation of products such as paints is based in ranges due to current legal obligations on communication of hazardous substance information in the supply chain. There are technical and operational reasons for variations within the ranges. The exact formulation should also be kept confidential to protect legitimate business interests.

DK provided some details of the legal framework in the Nordic region. The specific concentration above a certain minimum concentration limit is provided for all ingredients and the full composition has to be supplied to the national product register which provides information relevant not only to PC but also for market surveillance purposes. In Sweden, it is compulsory to provide information on mixtures both for professional / consumer uses. However PC does not have direct access to the information. In Norway registration is required for all hazardous products (above a certain threshold). There is no difference between professional and private use. In Denmark, it is compulsory to provide the information for professional uses for those mixtures where a SDS is required.

LV indicated that the national database does not contain information on plant protection products, medicinal and veterinary products and medical devices, all other chemicals are included. The obligation to provide information applies to every company placing or introducing substances/mixtures on the LV market above 100 kg/year or labelled as T or T+, and CMR cat. 1 and 2 above 10 kg/year. Group names are not allowed. Qualitative data should be provided as well as quantitative, except for paints where frame formulations with ranges are allowed. For all the other products the exact concentrations of substances are required. The information is provided to a central database which contains more information than required by Article 45 for different purposes. Access to the information in the central database varies depending on the user. National PCs have access to the composition of mixtures including the exact concentration of ingredients, but not to the quantity of chemicals on the market. Other authorities (Health Inspectorate, State Labour Inspectorate, State Environmental Service and State Fire and Rescue Service) do neither receive the exact composition nor the concentration. New legislation is under development to facilitate submission of information in electronic format

PL indicated that manufacturers and importers of dangerous mixtures are obliged to submit the SDS to the competent authority. The PC has access to the national database which only contains SDSs. A new system is under development requiring information on the composition of mixtures but not the exact quantitative composition; ranges would be enough. Alternative chemical names given under Article 15 DPD or 24 CLP when there are requests for confidentiality would be accepted. For mixtures in mixtures, Poland is of the opinion that it should not be a problem as the supplier would provide the SDS where the composition is already provided (at least the substances required by REACH Annex II, point 3 with their exact or ranges of concentrations). Thus, the producer of a “new” mixture using other mixture as a component should have sufficient information to give composition of his mixture in section 3 of the SDS. Of course, this will not work if exact qualitative and quantitative composition is required.

FR stated that EAPCCT guidelines could be supported. Discussions with industry on perfumes were ongoing regarding the disclosure of all ingredients.

BE informed that manufacturers have to provide authorities with the information that PCs would need to fulfil their obligations. Therefore there is some flexibility embedded in the legal system to ask for more information. Regarding consumer products, it is required to provide the exact concentration of hazardous substances and submit ranges for the non-hazardous ones. For plant protection products, information on the full quantitative composition is required.

AISE expressed concerns with regard to the appropriate level of information that should be required for chemicals only used in laboratories (such as perfume oils) or in industrial facilities. It should not be necessary to disclose ingredients for mixtures used only in laboratories, while for consumer products more information would be appropriate. AISE's position was not far from the EAPCCT proposal, with some changes, in particular, ranges should be provided for all ingredients, not only for the less hazardous ones (even if narrow ranges could be accepted for very hazardous substances).“

COM summarised the main conclusions of the discussion:

- Several MS expressed flexibility with regard to the precise quantitative information for certain product types (paints e.g.) where it is difficult to get the exact composition. For these specific product types the EAPCCT can further discuss the use of ranges in small bands if the exact composition is not possible. The use of ranges for all ingredients is not supported by the EAPCCT.
- It is necessary to collect more information on the data required by national legal systems. COM will contact MS to obtain detailed data.
- Additional discussion is necessary to consider MS readiness to agree with the EAPCCT guidelines, especially for those MS that currently legally require more exact information than in the EAPCCT guidelines.

Additional discussion is also required to assess possible different treatment of products for consumer/professional/industrial uses.

4. Discussion on the need for a unique company identifier (UCI) and /or unique product identifier (UPI) and possible solutions

COM invited the PC representatives to explain in more detail why unique identifiers are considered necessary and which added value would emerge compared to the information currently already provided on the label and in SDSs.

According to the PC representatives, it is a daily challenge in case of a request for poisoning advice to identify the right product in the database. It is often very difficult to identify the brand name of the product (20-40% of PCs' inquiries have problems with the product identification).

Once the brand name has been identified and communicated, this information has to be associated with a specific notification available in the database of the PC. Often small differences (spelling, abbreviation, punctuation, etc.) may drive to false positives or to a list of different notifications (so different products and formulations).

In order to assure the right medical treatment it is absolutely necessary to identify the correct product. Consequently, a certain degree of redundancy in the information available on the label has been considered as necessary.

The UPI could be located on the label next to the already affixed bar code (an approach used in Germany for detergents, where a related CEN standard has been developed, see below).

A UPI offers an additional advantage with regard to the problem of determining the components of mixtures, which have been prepared by adding mixtures to mixtures for which the exact composition is not known by the formulator. A UPI would enable the PCs to identify the composition of such a mixture, because they could refer to the notifications of the original mixtures used in the mixtures for which a request is made.

A technical product formula identifier (PFI), as presentation at the November workshop, is another possible tool to facilitate the identification of the mixture in question. PFI is especially needed for PCs if no UPI would be available. (On the other hand, the data set version identifier (DVI) is needed - on a technical level - to correctly process corrections and updates of a notified data set related to the same mixture).

COM raised some concerns regarding the added value of a UCI, if a **unique** UPI would be available. Information to identify the company which places the mixture on the market is already available on the label and in SDSs and the most important information is the composition of the mixture in case of emergencies.

AISE provided some comments on previous experience carried out in Germany for detergents where on a voluntary basis the producers have been invited to adopt a common product formula identifier system (ie. UPI, about 60% of the detergents bear such an identifier, for about 40% of the detergents this voluntary system is not applied). AISE favours a voluntary approach at EU level, conversely mandatory labelling with a UPI should not be considered unless really necessary.

COM stressed the fact that the mandate provided under Article 45 CLP is to evaluate possibilities for harmonising information. A voluntary approach would not suit such a purpose unless it was universally applied by all economic operators.

FR presented a code which would fulfil the requirements of a UPI developed by the PC of Nancy, and stressed the usefulness of this system for the cases of "mixtures in mixtures".

Industry representatives raised concerns regarding the additional administrative burden and economic impact linked to an additional labelling requirement, as well as the challenge of fitting this onto labels along with other mandatory labelling elements, and the potential for confusion among users caused by adding another number. They also stressed the need to ensure the confidentiality of the data submitted.

Harmonisation is considered as a shared goal also for industry but this approach should as well consider the potential impacts of the stakeholders.

COM summarised the main conclusions of the discussion:

- Mandatory labelling of products with a UPI is a tool which at least from the perspective of PCs and Member States would be appreciated, in particular in order to enable PCs to identify unambiguously the mixture involved in an emergency situation.
- Such an identifier would also facilitate the work of PCs when it comes to the identification of mixtures composed of other mixtures.
- Industry considers this also to be useful additional information. However, it should not be mandatory due to the additional costs involved for the re-labelling and due to the increasing space needed for mandatory labelling elements (e.g. due to the CLP-Regulation).

5. Discussion on the different procedures currently used in Member States to receive the information and possibilities to harmonise these procedures

Currently, the kind of information required by individual Member States, in order to guarantee preventative and curative measures, differ significantly. Those differences are caused by different tasks assigned to PCs at Member State level, e.g. use of the information also for market surveillance, enforcement, professional diseases etc.

Member States representatives were invited to provide a short overview of the main purposes of their national system of notification, in particular to provide information on which data is mandatory and which is submitted on a voluntary basis.

IT reported that the national database has been implemented mainly for preventative and curative measures. So far, C&L and pH data are not required as compulsory information to be transmitted to the Competent Authority (ISS). It is under discussion, to request this information as well in the future on a mandatory basis.

DK confirmed that its database has been developed also for others purposes than purely emergency responses and prevention (e.g. market surveillance). No commitment for a change in the national system for the sake of a harmonised European system can be made, because this would be subject to the approval by the parliament.

FR reported that the full composition of all substances (dangerous and not dangerous) is required. For France, it would be currently necessary to request the submission of the full composition of all mixtures to the PCs and to establish a UPI on a mandatory basis. The date of 2015 for CLP replacing finally the 'old' system would according to France be a good point in time to establish these two obligations Europe wide.

LV – The national database has been developed also for other purposes. Customers are for example the Health Inspectorate, the State Labour Inspectorate, the State Fire and Rescue Services and the State Environmental Inspectorate. Access rights to the information in the central database vary depending on the user. National PCs have access to the composition and the exact concentration, but not to the quantity of chemicals on the market. The database contains information on both mixtures and substances, as well as for environmental hazards.

NL – The main source of the information are SDSs and the composition of mixtures. Different uses are foreseen for the database in the future.

PL – The only source of information are SDSs. No additional information is requested from companies. The information in the database is available for toxicological centres as well as for enforcement authorities. PL also collects information on all mixtures that are classified as hazardous in at least one category (including physical and environmental hazards).

DE – The full composition is only required for certain mixtures (e.g. detergents, corrosive consumer products, biocides) and information foreseen in the above mentioned CEN standard is required on a voluntary basis. Due to a lack of sanctions there are doubts regarding the completeness of the notifications (according to some non-representative trials 20% of declarations may be not complete, incorrect or missing).

SE – Before entry into force of CLP it was not compulsory to send information to the PCs. Data has been collected directly by the Competent Authority. The national register contains only information for chemicals placed on the market in quantities above 100 kg. The exact composition of ingredients is required except from those which are not classified if they are below 5 %.

CEFIC - Information requirements should be harmonised based on the information submitted in SDSs. Due to additional requirements for SDSs according to REACH, the information contained therein should be sufficient to fulfil the tasks of PCs. Harmonisation at the level of those countries requesting most information is not supported.

CEPE - The potential harmonisation of national requirements should be balanced with the additional administrative burden for industry, in particular with regard to SMEs.

AISE - Harmonization is in the interest of industry but the amount of information to be submitted should be first defined according to the real needs of the PCs to be able to recommend emergency measures.

A proposal to harmonise the minimum information requirements at EU level and to 'add' country specific requirements as annexes to the minimum information requirements is rejected by industry, because this would cause only additional costs without having the benefit to submit the same information to all Member States.

COM summarised the main conclusions of the discussion:

- More information is needed from all Member States regarding the type of information collected (mandatory and non-mandatory, exact composition yes /no, who has access etc) at national level.
- Those Member States present at the meeting which currently demand very detailed information are very reluctant to envisage a change of their national system for the sake of a harmonised European system which would require on a mandatory basis less information than currently collected in those Member States.
- For industry it would be sufficient to harmonise the data requirements on the basis of the SDS (as specified in REACH Annex II) requirements. If additional data on composition will have to be notified in the future INCI (International Nomenclature of Cosmetic Ingredients) names should be allowed to be used, if appropriate and available.

7. Follow-up

COM will prepare draft minutes of the meeting which will be circulated for comments to the participants. After approval, they will be published on CIRCA.

COM will establish on CIRCA newsgroups to collect further comments on the three topics discussed at the meeting and other, less controversial issues, discussed at the workshop in November 2010.

COM will send a questionnaire to Member States in order to receive further information on the national systems, in particular with regard to the type of information collected.

The next meeting is envisaged to take place at the beginning of October 2011. At that meeting, the outcome of the CIRCA discussion fora will be presented, as well as preliminary conclusions drawn by COM.

ANNEX V

DRAFT MINUTES

2ND STAKEHOLDER MEETING ON THE

HARMONISATION OF INFORMATION FOR POISON CENTRES

Brussels, 7th November 2011, 9h30 – 17h

The web streaming of the meeting can be found under the following link:

<http://scic.ec.europa.eu/str/index.php?sessionno=370bfb31abd222b582245b977ea5f25a>

Preliminary evaluation of the contributions to the Newsgroups is provided under the following link:

http://circa.europa.eu/Members/irc/enterprise/clp-poison-centres/library?l=/november_stakeholder&vm=detailed&sb=Title

1. Opening and adoption of the agenda

The Chair (Klaus Berend) welcomed the participants and presented also the possibility to send comments during the meeting via the functional mail box of DG ENTR.

The draft agenda (see Annex I) was adopted without changes.

2. Introduction by the Commission

The chair briefly recalled the context in which this meeting took place (Article 45(4) of the CLP Regulation).

He then summarised the activities performed within the last two years to fulfil the duties of the Commission with regard to Article 45(4) of the CLP Regulation.

After two preparatory meeting with experts in 2010, intensive consultations with experts and stakeholders at a workshop held on 24th November 2010, and a smaller expert meeting held on 15th June 2011, the Commission established eight newsgroups on the following website to further support the debate on how to harmonise the information to be submitted to poison centres (PCs):

<http://circa.europa.eu/Members/irc/enterprise/clp-poison-centres/newsgroups>.

The purpose of this meeting was to report on the outcome of the discussion in the newsgroups, as well as to come if possible to an agreement on the diverging issues, which will enable the Commission to prepare its review on the possibilities of harmonising information submitted to PCs by 20th January 2012. How to present that review is not yet fully decided, and needs further reflection.

COM then summarised in a more general way the contributions to the various newsgroups before presenting the outcome per topic in more detail. COM noted that the summary document circulated in preparation of the meeting did not indicate all commenting organisations or reflect their input (e.g. DUCC).

3. Presentation of the outcome of the newsgroups and discussion

3a) Chemical Composition of Mixtures

COM presented the main outcome of the stakeholder consultation on questions related to the chemical composition of mixtures, which remained one of the key issues to be resolved, and opened the discussion (see link to the preliminary evaluation of the Newsgroups on page 1).

The Unilever representative raised the point that some of the key ingredients of their products including surfactants would need to be reported with the exact composition according to the EAPCCT guidelines when the new criteria adopted in the 2nd ATP to the CLP Regulation (e.g. eye irritation) will enter into force. He also expressed his concern that for these ingredients, every small formulation change would trigger a new notification. Therefore, he said, his industry is strongly in favour of concentration ranges rather than exact concentrations for these ingredients. He agreed, however, that tighter concentration ranges than those currently used could be accepted for these ingredients in the future. One of the main concerns is to be forced to submit a re-notification for the smallest change in the composition. That is something that should be avoided.

According to an EAPCCT representative, concentration ranges are already foreseen for some hazard categories. However, for the most severe hazard categories, detailed information is necessary. For those hazard categories, the EAPCCT guidelines require the notification of exact concentrations.

He explained that according to the EAPCCT guidelines, there would be no need for a re-notification at every small change in the composition of the mixture. A re-notification would only be required if the concentration of a hazardous ingredient (for which the EAPCCT guidelines require the notification of the exact concentration) would change beyond a certain percentage (a change of more than 5%, 10%, 20% or 30% depending on the initial concentration of the ingredient).

According to COM, such a tolerance would actually be equivalent to concentration ranges because a change within a concentration band around the notified value is allowed. COM asked if it would then not be possible to accept concentration ranges altogether.

The EAPCCT representative anticipated that according to the re-formulation rules as presented in the EAPCCT guidelines, the 'exact concentration with allowed percentage of change' could also be expressed as small concentration bands. An option could be to have two sets of concentration bands: small concentration bands for the ingredients with the most severe hazard classification and the concentration bands already described in the guidelines for all other ingredients.

COM invited participants to specify how accurate companies are in notifying changes.

The Latvian representative explained that any change in concentration that leads to a change in classification requires an update. However, small changes do not have to be notified but are updated in an annual report.

The German representative said that a similar procedure is in place in Germany.

The Polish representative explained that a database was under construction in Poland and that formulation updates were made every year. Following the discussion in the framework of the review, PL will work with concentration bands rather than the exact concentration.

The French representative agreed using concentration ranges. He stressed that the priority was to have a full qualitative list of ingredients rather than their exact concentrations.

The German representative added that in Germany a list with ranges and 100% formulation is required.

COM invited participants to comment on the need of providing information on non-hazardous ingredients in mixtures.

An EAPCCT representative explained that non-hazardous ingredients are not classified, but can nevertheless be harmful if they are ingested in large amounts.

COM concluded that PC and government representatives agreed to use concentration ranges. Based on this compromise, COM asked industry representatives whether they would be ready to include information of non-hazardous ingredients (*i.e.* in ranges), and if present in the mixture above a certain minimum concentration.

The CEPE representative asked to keep in mind that many downstream formulators do not have the information required by PCs, as their upstream suppliers are not obliged to communicate the identity of non-hazardous ingredients. A lot of mixtures are made from other mixtures, and the downstream formulator will receive a SDS for which there is no obligation to communicate the identity of a non-classified component.

COM reminded the SDS does not exclude that this information is provided, and that the Unique Product Identifier (UPI - to be discussed later) could offer a solution for this.

The CEFIC representative suggested using cut-off concentrations for non-hazardous ingredients in mixtures. However, this information should only be notified to PCs and not be revealed in the SDSs.

COM summarised the main conclusions of the discussion:

- **PC and government representatives accepted using concentration ranges. However, the precise details still need to be defined starting from the EAPCCT guidelines.**
- **Industry representatives agreed notifying also non-hazardous ingredients in mixtures**
- **Cut-off concentrations should be used for non-hazardous ingredients in mixtures**
- **Mixtures in mixtures may be identified via a Unique Product Identifier (UPI)**

3b) Designation of Ingredients

COM presented the main outcome of the stakeholder consultation on the designation of ingredients (see link to the preliminary evaluation of the Newsgroups on page 1), before opening the discussion.

It was noted by an EAPCCT representative that PCs could also accept INCI names for detergents. He expressed his expectation that they will be included in the next version of the EAPCCT guidelines.

COM invited participants (in particular PCs) to explain how important it is to submit/receive information in their own language.

The Polish representative clarified that any legal act has to be in a country's national language. However, he suggested allowing companies to submit information in English to avoid translation.

English names were also accepted by an EAPCCT representative.

The German representative agreed using English names for substances, stressing that it might facilitate the spread of information across countries.

COM recalled that small and medium enterprises (SMEs) might be disadvantaged if they had to submit information in a foreign language (*i.e.* English).

It was pointed out by an EAPCCT representative that if submitting information in English is a problem for SMEs, then the ingredient's English name could always be retrieved automatically based on the registration number or CAS number (affirming the need of these numbers).

COM summarised the main conclusions of the discussion:

- **The hierarchy for choosing their names and their internationally accepted identification numbers as outlined in Article 18 of the CLP Regulation should be followed, where possible**
- **INCI names should be possible, as well**
- **Annex VI of the CLP Regulation can be used to retrieve English names of ingredients of mixtures**
- **Submitting information in English might represent a problem for SMEs**
- **English names might be retrieved automatically using the information provided very soon in the ECHA C&L Inventory**

3c) Data Set Version Identifier (DVI)

COM presented the outcome of the stakeholder consultation on questions related to the data set version identifier and opened the discussion (see link to the preliminary evaluation of the Newsgroups on page 1)

COM invited stakeholders to explain why a DVI is important.

According to the EAPCCT concept DVI is created by the notifier when the product dataset is exported from the company's database for upload to the PC (or to a central database). The main advantage of a DVI is, according to an EAPCCT representative, to be able to identify quickly the newest version of a dataset record for a product of the same composition, and to be able to disregard outdated versions for this product. This facilitates communication between PC and industry in case of data inconsistency. It is a technical tool which should be in the format of a date/time-stamp. He also stressed that this is not a tool to identify products with for example the same name but a different composition. For this purpose, EAPCCT has proposed the so-called Product Formula Identifier, which was not further discussed.

COM recalled that the use of an electronic system for notification (either centralised or de-centralised) would offer the possibility to register the date and time of submission automatically. Working with the UPI and updating that for example in case there is a change in the composition of the product, would offer a more appropriate solution to identify unambiguously the product in question and the related information present at the PCs.

The EAPCCT representative agreed that if there is an electronic centralised system (national or EU-wide), the necessary information can be created automatically. Such an automatically created date / time stamp could also be used by the notifying company in its communication with a PC in case of data inconsistency.

COM summarised the main conclusions of the discussion:

- **A date/time stamp to identify a certain product can be generated in any electronic system**

3d) Centralised versus Decentralised System

COM presented the main outcome of the stakeholder consultation on questions related to a centralised versus a decentralised system and opened the discussion (see link to the preliminary evaluation of the Newsgroups on page 1)

COM invited a representative of DG SANCO to present their experience on the establishment of the Cosmetic Products Notification Portal (CPNP).

DG SANCO explained that the database will be running from 11th January 2012. It is expected that the database will comprise about 1 Mio products, which will be added progressively during an 18-month transitional period. Users will be able to use the database in their own language. No problems were encountered in the development of a multi-language database, as most parameters to be entered were standardised. Formulations include INCI names and Frame Formulations (in all languages). DG SANCO explained that the cost of developing this database was manageable at European Commission level, although no precise figures were available at the meeting. The German TDI System was used as template for the development of a product categorisation system in the Cosmetic Products database. It was stressed that the main priority in establishing the database was to standardise the information entered into the database as much as possible (*e.g.* selecting the information requested from a list of standardised options rather than providing for the possibility to enter the information in free text format). In addition to the standard online access to the database, the database allows bulk upload/download of information in the near future, so that PCs have access to the information at all times (*i.e.* even when the database is inaccessible for some reason).

Concerns were raised by the German representative regarding the maintenance cost of such a database. He explained that in Germany, a cosmetics database comprising 250 000 products is maintained by as many as 5 people.

DG SANCO clarified that the use of the database was free of charge. DG SANCO will provide information on the cost of developing and maintaining that database which are covered by the EU budget.

COM recalled the need to protect confidential business information (CBI) in a system which is accessible to many users.

The Cosmetic Products database is accessible only to specified persons (including competent authorities and PCs). The safety of the database itself (*e.g.* hacking attacks) is provided by adequate IT measures. PCs deal with sensitive information as they have done in the past, thus no problems should be associated with the downloading of information. Finally, competitors will not have access to each other's data and accounts may be closed if there is a breach of confidentiality.

COM highlighted that no case of leaking of CBI from PCs has been reported in the past.

The representative from ECPA explained that it is almost impossible to track down the source of a CBI leak. For this reason only, no examples of leaking of CBI from PCs might have been found.

The CEFIC representative suggested discussing with ECHA how to protect large databases from hacker attacks, as ECHA has experience with large databases. He also raised concerns regarding possible requests of NGOs to access the data.

COM recalled that the CLP Regulation clearly defines what can be done with the information submitted to PCs.

According to the German representative, in Germany, a good co-operation is in place between industry and PCs, without complaints or concerns. Furthermore, he explained that he supports a decentralised system, which ensures better quality data, the control and maintenance of all records, as well as the direct contact between industry and PCs. This would not be possible at a European level.

COM referred to the transitional period foreseen under the Regulations on Cosmetic Products to populate the database, and emphasized that such a transitional period should also be considered for a new system conceived under the CLP Regulation in order to avoid serious problems for companies but also to avoid the overload of a centralised or decentralised database by requiring the notification of all products which are already on the market within a very short time frame.

DG SANCO confirmed that after the 18-months transitional period foreseen under the Regulation on Cosmetic Products all products on the European market should be included in the database, so that PCs can fully rely on the information contained therein. A re-notification is also necessary to avoid, that different levels of details are available for existing and new cosmetic products, because the Regulation requires more information than what was requested before.

With regard to the resubmission of existing records, the representative from CEPE reminded the meeting that existing databases currently only contain information on consumer products, while a database as discussed now would also include industrial products, resulting in a very large number of additional notifications for companies.

COM replied that already today, some Member States also require notification on professional products.

The representative of the French PC mentioned that in case a centralised database was to be created, it would be important to be able to extract information on the products placed on the market in France.

DG SANCO mentioned the limitations of their centralised database, as there are certain legal limits. For example, companies do not have to disclose in which countries their products are sold

The Latvian representative expressed his concerns on the additional costs that a centralised database would entail if it was operated by ECHA (e.g. fees).

COM concluded that financing a centralised database is still an issue, with the possibilities of fees, and that the European Council and European Parliament would have to approve the budget. The target is to have a single product notification system in all European countries, whether in a centralised or decentralised system. Moreover, Member States would like to be informed about the products that are sold in their country. COM asked Member States to provide information about costs for national databases.

DG SANCO stressed that as products are circulating in Europe, a centralised database is necessary to have information on all products sold in Europe, not only in specific countries. Consumers can travel and buy products in other Member States.

An EAPCCT representative mentioned that in Germany the national authority appointed for product data collection supports notifiers. The question was raised how sufficient help for notifiers, especially SMEs, could be ensured in a centralised system.

COM reminded that ECHA has experience with helpdesks, and that a centralised system would not exclude such a helpdesk.

A Dutch representative stressed the starting point should be the harmonisation of the information, whether in a centralised or decentralised system.

COM summarised the discussion:

- **Financing/Budgetary as well as legal issues remain**
- **Information must be harmonised**
- **Confidentiality is an important issue for which experience exist in ECHA and in Member States**
- **MS are keen to know what products are on “their market”**
- **Appropriate transition periods must be allowed to fill any new system of database(s)**
- **Support for notifiers must be ensured (e.g. helpdesk in notifier’s own language)**

3e) Type of Information to be submitted to Poison Centres

COM presented the main outcome of the stakeholder consultation on questions related to the type of information to be submitted to PCs and opened the discussion (see link to the preliminary evaluation of the Newsgroups on page 1).

An EAPCCT representative mentioned four points that should be added to the information contained in safety datasheets (SDSs), including the composition of the mixture, the product category, an indication on consumer/professional use, and the type/size of the packaging.

Regarding the discussion on consumer and non-consumer products, the CEFIC representative suggested awaiting the outcome of the discussion currently performed in ECHA with Member States and other stakeholders on the further development use description system designed and used for the REACH registration to adopt it to the needs of the authorisation system. The new system of product categories should be more suitable for the needs of PCs, which might be included in SDSs in the future.

COM mentioned that there is not always a clear distinction between consumer/professional products. In case of an accident, a very small company will call a PC because there is normally not a doctor on-site. However, this aspect will be kept in mind and could perhaps be addressed through a better product categorisation system.

The representative from ECPA suggested building on existing systems, in particular to use the SDSs and expand them if necessary. Importantly, the system should be kept as simple as possible.

COM summarised the main conclusions of the discussion:

- Stakeholders agreed to provide in addition to the information contained in SDSs some information in the notification on the composition of the mixture (as discussed earlier), the product category, an indication on consumer/professional use, and the type/size of the packaging, as requested by the EAPCCT
- It might be possible to encode some of this additional information (for example the size of the packaging) in the UPI

3f) Product Categorisation System

COM presented the main outcome of the stakeholder consultation on questions related to the Product Categorisation System and opened the discussion (see link to the preliminary evaluation of the Newsgroups on page 1)

All participants agreed that it would be very useful to further develop existing product categorisation systems, starting with those product categories which are of main concern for PCs (e.g. due to the number and severity of the incidents registered, the amount of products used etc).

A number of industry and / or national initiatives are already fairly advanced. However, they cover only a limited number of product categories and need to be further developed in order to fulfil the needs of PCs, MS CAs and industry alike. Analyses of exposures and poisonings are facilitated on the basis of product categories and incidents registered at PCs. Such analyses can and will be used by all stakeholders in the future.

Further work needs to be done with regard to get an overview on which systems have been developed already or are being developed, which products types are covered, and which product types needs to be added in order to fulfil the needs of PCs, MS CAs and industry.

COM suggested developing a product categorisation system starting in particular from the German TDI project as a template and taking into account further use descriptions as being developed by ECHA in the framework of REACH

3g) Unique Company Identifier (UCI) and Unique Product Identifier (UPI)

COM presented the main outcome of the stakeholder consultation on questions related to the Unique Company Identifier (UCI) and the Unique Product Identifier (UPI) and opened the discussion (see link to the preliminary evaluation of the Newsgroups on page 1)

COM stressed that the main concern is to have a system in which a product involved in a poisoning incident can be unequivocally identified in a database. A UPI (visible on the label and contained in the notified product dataset) may fulfil this purpose. The UPI should be a manageable number, easily identifiable. A good starting point for the development of a UPI may be a system proposed by the Nancy PC. This UPI contains both unique company identifier and product identifier, combined in a single 16 digit alphanumeric code. The identifier can easily be generated by the notifying company without involvement of a controlling authority. A French PC representative demonstrated how the UPI generator works. The UPI generator uses, the VAT identification number of a company (including the official EU two letter country code) and a company-chosen product (formulation) code to generate a UPI. The UPI ends with a checksum-control-

key. The UPI generator is available online, freely accessible, and easy to use (a free-test generator is available on: <http://upi.toxalert.fr>).

An industry representative raised concerns regarding companies having several VAT numbers for different countries.

COM replied that a company may have several VAT numbers without problem, as long as the UPI is based on one of them.

COM reflected on the costs that might be generated if an additional number needs to be added on a package. Furthermore, COM highlighted that a UPI might solve the problem of mixtures in mixtures.

An industry representative suggested that companies should be able to design their own in-house UPI. COM replied that some companies might generate accidentally the same UPI: A company identifier included into UPI guarantees the no “risk of collision” between two “own in-house UPI”. Therefore a link with a company identifier is necessary.

The AISE representative mentioned that the use of the Company VAT number may be an issue for private label manufacturers where the same formulation may be marketed under different company names (e.g. various supermarkets) and product names.

It was explained that such products could be notified once (with all names and one UPI in one dataset and on all labels) or several times (one notification for each name with different UPIs).

The PPG representative expressed his concern about linking a manufacturer to a certain product. Separate notifications and UPIs would be necessary from both manufacturer and distributor/retailer; a 100% mixture-in-mixture composition would enable the formulation to be traced in the database with no visible link on the product label.

COM asked whether the UPI could be reconverted (*e.g.* in cases where a retailer does not want to disclose the manufacturer). It was explained that this problem could be solved by another notification of the product by the concerned retailer (using a UPI generated by himself using his own VAT number).

The representative from ECPA mentioned the problem of parallel trading (*i.e.* when the same product is sold in a different packaging). It was explained that such products could also be notified once (with all names and one UPI in one dataset and on all labels) or several times (one notification for each name with different UPIs).

COM said that in the end a judgement has to be made whether the additional benefit of a UPI for PCs would justify the additional labelling costs for companies.

An industry representative replied costs would mainly depend on re-notifications (*i.e.* for ranges, single changes would not have to be re-notified), and whether a new artwork needs to be designed or a simple laser-print on pack (*i.e.* in-line printing) is enough for the UPI. Flexibility regarding UPI location will help.

COM asked companies to provide information on actual costs.

COM summarised the discussion as follows:

- **A UPI number could be printed on the label or stamped on primary packaging, *for example* near the barcode**
- **A UPI might help solve the problem of mixtures in mixtures**

- **The question remains on whether the benefits of a UPI for PCs would outweigh the relabeling costs for Industry**

4. Summary of the meeting and follow-up

Chemical composition of mixtures

- Concentration ranges for hazardous ingredients - details to be defined starting from EAPCCT guidelines
- Cut-off concentration for non-hazardous mixtures
- Mixtures in mixtures identified via Unique Product Identifier (UPI)

Designation of ingredients

- Follow the hierarchy of names as outlined in Article 18 of the CLP Regulation, where possible – INCI names could be used
- Need to be mindful of language problems
- Submitting information in English might be a problem for SMEs
- C&L inventory from ECHA and Annex VI to the CLP Regulation can help
- Registration number/CAS number/ EC number may be used to retrieve English name

Data Set Version Identifier

- Use date/time stamp (identify newest versus outdated dataset version) – It can be generated automatically in any electronic notification system
- UPI might be better solution than DVI generated by the notifier without UPI.

Centralised versus decentralised system

- Build on IT experience with DG SANCO Cosmetic Products Notification Portal
- Including all specific contents with regard to Article 45 of the CLP Regulation.
- Budget issues
- Legal issues
- Language issues
- Confidential business information protection
- Target is to submit only one notification for all EU MS
- Need to know in which countries products are marketed
- Help for notifiers should be available (helpdesk)
- Need for an appropriate transition period to fill new database(s)

Type of information

- Complete composition (hazardous and non-hazardous components)
- Type/size of packaging - could become part of an UPI
- Product category
- Consumer/professional use
- Work ongoing under REACH (ECHA) to further develop use descriptors
- Inspired by TDI project

Unique Product Identifier

- May use Nancy PC UPI generator as basis for EU UPI
- Nancy PC UPI would combine UPI and UCI
- UPI could help solve problem of mixtures in mixtures
- Would the benefits for PCs justify the additional labelling/packaging costs for Industry
- Problem of parallel trading can easily be solved
- Number printed near barcode

Follow-up:

- By 30th November submit information on national systems
- Also by 30th November, industry to submit examples for estimated costs of UPI implementation
- By 20th January finalise report

ANNEX VI

STAKEHOLDER CONSULTATION ON THE HARMONIZATION OF INFORMATION FOR POISON CENTRES

Evaluation of Stakeholder Replies

Background

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation) aligns previous European Union (EU) legislation to the United Nations (UN) Globally Harmonised System (GHS).

The new CLP Regulation entered into force on 20 January 2009, and will replace the current rules on classification, labelling and packaging of substances (Directive 67/548/EEC) and mixtures (Directive 1999/45/EC) by 1 December 2010 and 1 June 2015, respectively.

One particular provision of the CLP Regulation – Article 45 (4) calls on the European Commission to assess the possibility to harmonise the information submitted to PCs. Information about hazardous product(s) (*e.g.* composition, concentration of ingredients, appropriate emergency measures) is necessary for PCs to inform medical personnel (physicians, veterinarians, pharmacists) or the public about symptoms and treatment of acute intoxications. To date, the information submitted to PCs varies widely among Member States (*e.g.* different requirements for information about ingredients and composition, for the format, and for the procedures).

The Consultation

In this context, the Commission organized several consultations with relevant stakeholders from Member States (competent authorities and PCs) and the industry. Following the last meeting of stakeholder representatives on 15 June 2011 in Brussels, the Commission launched from 29 August 2011 to 1 October 2011 several discussion fora via newsgroups in the dedicated CIRCA interest group. This gave all stakeholders who were interested in the debate the possibility to submit ideas and comments.

The newsgroup covered topics discussed at the stakeholder meeting on 15 June 2011, as well as other topics discussed at the earlier workshop in November 2010. The following topics were covered:

- Centralised versus decentralised system for submitting information
- Chemical composition of mixtures
- Designation of ingredients
- Establishment of a data set version identifier (DVI)
- Type of information requested
- Product categorisation system (PCS)
- Unique company identifier (UCI)
- Unique product identifier (UPI)

Summary of the Consultation

59 stakeholder contributions were received in total, 61% were sent by industry representatives, 30% by poison information centres, and 7% by government authorities (**Figure 1**). The majority (56%) of responses were sent by European or international associations (*e.g.* CEPE, AISE, FECC, *etc.*), by organisations based in Germany (19%), Italy (8%), Slovenia (7%), as well as from other European countries (**Figure 2**). A list of all contributors is provided in **Table 1**.

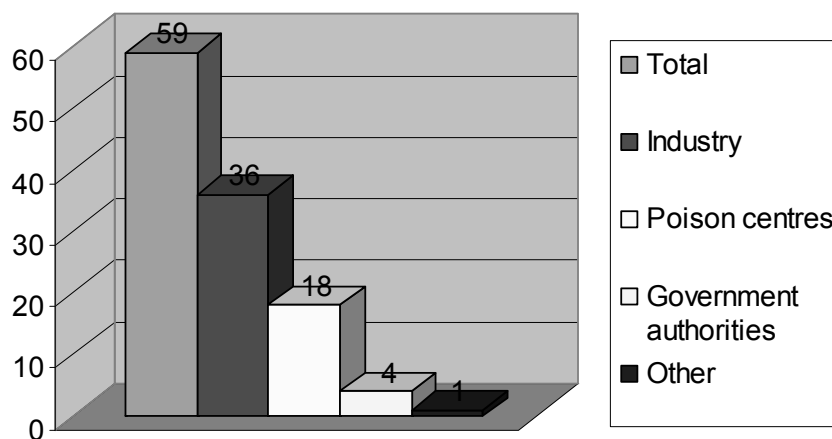


Figure 1. Distribution of stakeholder contributions by type of organisation

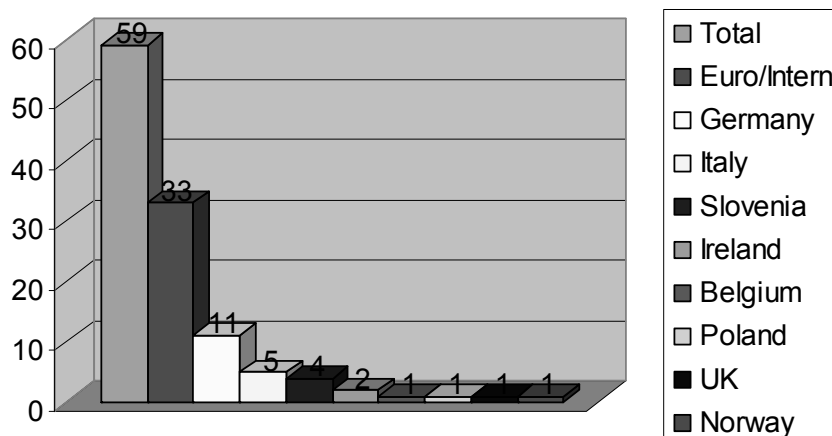


Figure 2. Distribution of stakeholder contributions by origin

Table 1. List of contributors

Acronym	Full Name	Type of Organisation	Origin
VCI	Verband der Chemischen Industrie e.V.	Industry	Germany
CEPE	European Council of the Paint, Printing Ink and Artists' Colours Industry	Industry	European
FEICA	Association of European Adhesive and Sealant Industry	Industry	European
EAPCCT	European Association of Poison Centers and Clinical Toxicologists	PCs, Clinical	European
EFFA	European Flavour Association	Industry	European
Thor GmbH	Multinational manufacturer and distributor of biocides, flame retardants, personal care ingredients and other speciality chemicals.	Industry	Germany
IFRA	International Fragrance Industry	Industry	International
Bureau for Chemical Substances	Bureau for Chemical Substances	Government authority	Poland
FECC	European Association of Chemical Distributors	Industry	European
A.I.S.E.	International Association for Soaps, Detergents and Maintenance Products	Industry	European
Milano Poison Control Centre	Milano Poison Control Centre	PC	Italy
ECPA	European Crop Protection Association	Industry	European
National Poison Info Centre Dublin, Ireland	National Poison Info Centre Dublin, Ireland	National PC	Ireland
DUCC	Downstream Users of Chemicals Coordination Group (A.I.S.E., CEPE, COLIPA, EFCC, FEA, FECC, FEICA,	Industry	European

	I&P Europe, IFRA)		
NHS	National Health System	Government authority	United Kingdom
PCC Slovenia	National PC Slovenia	PC	Slovenia
MAIS NRW	Ministerium für Arbeit, Integration, und Soziales Nordrhein Westphalen	Government authority	Germany
Norwegian Poison Info Centre	Norwegian Poison Info centre	PC	Norway
Health and Safety Authority	Health and Safety Authority	Government authority	Ireland
WHO	United Nations World Health Organisation		International

3.1.1. Centralised versus Decentralised System for submitting Information

General feedback

Of the 11 contributions that were received in total on questions relating to the *centralised or decentralised system for submitting information to poison centres*, 8 were sent by industry (72%), 2 by poison information centres (18%), and 1 by a government authority (9%). The replies came from 6 European/International associations (54%), 2 companies based in Germany (18%), 1 Belgian company (9%), 1 Italian PC (9%), and 1 Polish government authority (9%).

Questions

Thought starter "**Centralised vs decentralised system for submitting information**"

Key questions:

1. Which is your preferred option and why?
2. If a centralised European database is the preferred option,
 - a. Who should administer the database?
 - b. Who should have access to the database?
 - c. In what language should the information be submitted?
 - d. How can the security and the confidentiality of the data be guaranteed?
3. If a de-centralised European database is the preferred option,
 - a. Do you already use the XML format for submitting / receiving information?
 - b. If XML is not the format currently used, would you be prepared to use it in the future?

Stakeholder Answers

Among the 11 stakeholder replies, 7 supported a *centralised system* for submitting information to PCs (64%), whereas 3 were in favour of a *decentralised system* (27%) (**Fig. 3**). One stakeholder had *no opinion* on the subject (9%). The contributions that were in favour of a centralised system came predominantly from industry (*i.e.* companies or associations of companies) (86%), with a single approval from a PC (14%) (**Fig. 3**). In contrast, the decentralised system was supported by a government authority (33%), an industry representative (33%), and a PC (33%) (**Fig. 3**).

Several stakeholders emphasized the *benefits of a centralised system* for submitting information to PCs, including the reduced administrative burden from one single notification of a product which is placed on the market in several Member States, the easier access for PCs to the data, and the reduction in data management work.

Stakeholders that were not supporting a centralised database stressed the *constraints* of such a system: the large number of product notifications to a European portal may complicate and extend the retrieval process in the PCs in emergency cases, small and medium sized enterprises (SMEs) may be disadvantaged if they have to translate documents into English (or into the other 23 languages of the EU). Moreover, with at least 2 million mixtures on the European market, a centralised database would be too large to maintain. Finally, the costs of maintaining such a database would be enormous.

Alternative solutions were proposed:

- the EAPCCT recommended starting with a European product data collection for only a few important product categories in order to avoid the difficulties in handling a European ‘all product database’ in emergency situations.
- A representative of a Polish government authority suggested that national databases be harmonised in a way enabling multi-search via a portal giving access to all Member State databases of dangerous mixtures (e.g. similar to the eChemPortal of the OECD).
- A representative of the FECC (European Association of Chemical Distributors) pointed out that a much more efficient and cost effective solution to a single centralised/unified database would be to develop a better search engine or portals with access to several data bases.

In general, all stakeholders strongly supported the development of a harmonised electronic format for submitting information to PCs, whether at a centralised or national level.

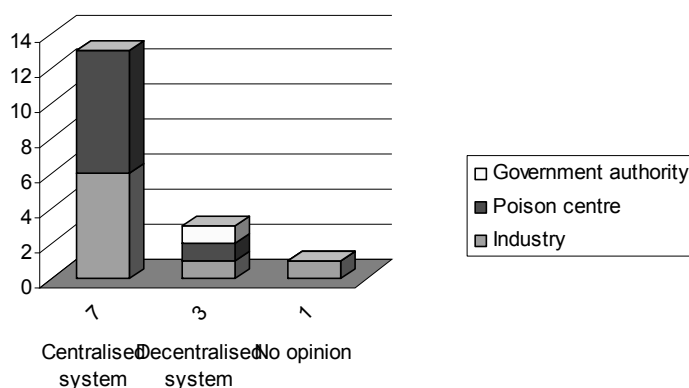


Figure 3. Number and distribution of stakeholder contributions in favour of a centralised or decentralised system for submitting information to PCs

Only 3 stakeholders addressed the issue of database administration (27%), with 2 of them suggesting ECHA as administrator for a centralised database (18%), and 1 proposing further investigation of this issue (9%).

Regarding the question of who should have access to the database, the majority of the participants of this consultation did not comment on this issue (64%). It was suggested that in addition to PCs, government authorities (57%) and industry (14%) should have access to the database.

Concerning the language in which information should be submitted to PCs, 36% of comments proposed that information should be submitted in any language of the Member States of the European Union. 63% of stakeholders did not give their opinion about this subject.

Industry representatives and a member of a Polish government authority stressed that SMEs would be disadvantaged should they not be able to submit information in their own language. A representative of A.I.S.E. suggested that information should be given preferentially in standard phrases which can be easily translated into other languages.

As much as 63% of stakeholders expressed their concern regarding the security and confidentiality of sensitive data stored in a centralised database. 27% estimated that it would be easier to protect a single database from disruptions (e.g. Hacker attacks).

A representative of A.I.S.E. specifically proposed that "technical aspects of security for the centralised system have to be discussed by experts in information technology security. The need for high level system security provisions will be lower if the amount of confidential business information to be notified is kept to an absolute minimum. Thus, notification requirements should be defined in a way to meet the needs of Poisons Information Centres without compromising the protection of confidential business information of the companies. For instance, it should not be mandatory to give actual percentage values for ingredients and it should be possible to give generic or group names for ingredients with similar toxicity (e.g. colorants, perfume, anionic surfactants). Restrictions on people accessing the system plus tracking/recording of people accessing data".

Among the stakeholder replies, 27% confirmed that they were already using the *XML format* to submit information to PCs, while 63% did not comment on this question. 45% confirmed that they would be ready to use the XML format in the future.

Several stakeholders commented on the fact that XML is already the preferred format for notifications to ECHA for REACH and SDS related activities. For CEPE/FEICA members the first choice would be to submit (upload) the SDS for each product, as REACH, and the amendments to Annex II in Regulation 453/2010, are increasing the quantity and quality of data provided in the SDS, so added value is seen in submitting the SDS itself instead of a different set of information parameters.

In general, what appeared to be most important for all stakeholders was that the data to be notified and the (electronic) reporting format should be the same in all EU Member States, to facilitate the export, submission, and exchange of mixture information and optimize the use of resources.

3.1.2. Chemical Composition of Mixtures

General feedback

In total, 12 stakeholder replies were received for questions concerning the *chemical composition of mixtures*, of which 6 were sent by industry (50%), 4 by poison information centres (33%), and 2 by government authorities (17%). The comments came from 5 European/international associations (42%), 3 replies were sent from Germany (25%), while single replies came from the United Kingdom, Ireland, Italy, and Slovenia (8% each).

Questions

Thought starter "**Chemical composition of mixtures**"

Key questions:

1. Which information on the chemical composition is currently requested in each Member State?
2. What other purposes than emergency health responses can the information requested serve and how?
3. What are the legal / technical limits to also providing information on non-hazardous ingredients of mixtures?
4. Would concentration ranges fulfil the needs of PCs?
 - a. If yes, would the concentration ranges proposed in the EAPCCT guidelines 2010 be sufficient?
 - b. If not, why and how is this problem currently dealt with?
5. How can the problem of "mixtures in mixtures" be solved?

6. Do you have concrete examples from the past where confidential business information had leaked outside a PC?

Stakeholder Answers

The following European legislation requires economic operators to submit information on the chemical composition of products:

- CLP Regulation
→ Article 45(1): the chemical composition of mixtures placed on the market and classified as hazardous on the basis of their health or physical effects
- Detergent Regulation (EC) No 648/2004
→ Article 9(3) in connection with annex VII: All ingredients shall be listed in order of decreasing abundance by weight, and the list shall be sub-divided in weight percentage ranges;
- Cosmetic Products Regulation (EC) No 1223/2009
→ Article 13: requests among others the notification of the presence of substances in the form of nanomaterials, the name and the CAS or EC number of substances classified as CMRs according to Annex VI to the CLP Regulation, and the frame formulation. For selected cosmetic products a more detailed formula declaration is necessary;
- REACH Regulation
→ Annex II , Safety Data Sheets (SDSs): Requires extensive information on hazardous (hazardous according to CLP) and under certain conditions on other ingredients.

In addition, in most Member States more precise information than what is required by EU legislations has to be communicated to competent authorities (*i.e.* the exact chemical composition of products). A review of Product notification requirements in EU Member States has been performed in 2007 (RIVM 2007 Report).

5 stakeholders (42%) commented on the purposes, other than emergency health responses, that the information requested may serve. They recalled that article 45(2) of the CLP Regulation specifies the purposes for which the information can be used. In particular, medical staff may access the information in order to formulate *preventative and curative measures*. Similarly, competent authorities appointed by Member States may undertake *statistical analysis* to identify where improved *risk management* measures may be needed. Several comments stressed the importance of risk assessments for PCs. Indeed, based on this information, PCs decide whether a patient needs to be hospitalised after a poisoning incident (unnecessary hospitalisation of patients may lead to increased costs for health services).

9 stakeholders (75%) commented on the issue of providing information on non-hazardous ingredients of mixtures. 25% of the replies (all from PCs) were in favour of the idea, while 42% rejected it (80% from industry). Many industry representatives highlighted the *additional administrative burden* that such a product notification extension would entail (*e.g.* in the flavour sector, SMEs may develop as many as 4000 new recipes per year). One PC representative mentioned that providing information on the exact composition of all ingredients can be sometimes '*misleading*'. He referred in particular to household products and anionic, non-ionic and amphoteric surfactants for which the actual chemical names can be very long. On the other hand, knowing the composition of all ingredients in a mixture may be useful in cases of *incidents involving a combination of two or more chemicals*.

50% of stakeholders (mainly from industry) considered that concentration ranges would fulfil the needs of poison information centres. In contrast, 33% of stakeholders (mainly from poison information centres) estimated that providing concentration ranges is not sufficient. Industry

representatives argued that poison information centres *base their estimates on worst-case scenarios* (i.e. there is usually a degree of uncertainty regarding the quantity of the mixture involved in the poisoning incident, thus exact concentrations are unnecessary), and that *additional information could be provided on request*. However, PCs highlighted the need of exact concentrations for all ingredients (*particularly important for the treatment of allergies*), in order to *perform adequate risk assessments* and thus *avoid unnecessary treatment*, distress, and significant costs to health services. Furthermore, concentration ranges provided to date are considered *too wide*. In addition, PCs disapproved the idea of obtaining additional information on request, as in emergency situations *decisions need to be taken fast*. Finally, it was noted that although substances not classified as hazardous 'in normal use' do not need to be mentioned in an SDS, whereas the scenarios that PCs are confronted with are usually not "normal use".

All stakeholders who agreed that concentration ranges would fulfil the needs of poison information centres also judged that the *concentration ranges listed in the EAPCCT 2010 guidelines* were precise enough. In particular, it was noted that the *implementation of the REACH Regulation 1907/2006 substantially improved the quantity and quality of information required in a modern Safety Data Sheet*. An EAPCCT representative recalled that the EAPCCT guidelines recommend to *'mention all substances (...) present in the mixture when placed on the market'*, and that article 45(3) of the CLP Regulation states that *'the appointed bodies shall have at their disposal all the information required from the importers and downstream users responsible for marketing to carry out the tasks for which they are responsible'*. Thus, it is for the appointed bodies to decide what information is necessary.

Concerning the *problem of 'mixtures in mixtures'*, an EAPCCT representative mentioned that an elegant solution is proposed by the Nancy PC and makes use of the *unique product identifier (UPI)*. For product groups for which notifying an exact concentration can be difficult (e.g. natural ingredients and raw materials) it is possible, according to EAPCCT guidelines 2010, to use the *name of groups of substances* and, in the case of substances occurring in nature, a chemical name or *chemical names of the type "essential oil of ..." or "extract of ..."* may be used instead of the chemical names of the components of that essential oil or extract. Regarding raw materials, CAS or other Official Registration Numbers already exist to identify "natural" ingredients. An industry representative proposed that the problem of 'mixtures within mixtures' could be solved by reference to the *trade name* of the mixture used (this should be possible if a centralised database is established).

No concrete examples were given regarding the *leaking of confidential business information from a PC*. An EAPCCT representative stressed that the information submitted to poisons centres and government authorities is treated as confidential, thus there *should not be a 'compromise solution' with ranges for all ingredients because of confidentiality concerns*. A representative of the European Flavour Association (EFFA) highlighted that food flavours are *not protected by patents* of intellectual property. Therefore, no protection is available in case of breach of confidential business information.

3.1.3. Designation of Ingredients

General feedback

Of the 7 stakeholder contributions that were received in total relating to the *designation of ingredients*, 4 were sent by industry (57%) and 3 by poison information centres (43%) (**Fig. 6**). The replies came from 4 European/international associations (57%), 1 association based in Germany (14%), 1 Slovenian PC (14%), and 1 Italian PC (14%) (**Fig. 7**).

Questions

Thought starter "**Designation of ingredients**"

Key questions:

1. Which systems exist already and what do they look like?
2. What is the added value of such a hierarchical system?

Stakeholders Answers

Several stakeholders commented on the systems that are already in place for the designation of ingredients, and the added value of such a hierarchical system.

These include:

- CLP Regulation (EC) 1272/2008 (Article 18(2) and Part 3 of Annex VI)
→ the product identifier for a substance
- Detergents Regulation (EC) No. 648/2004
→ use of INCI (International Nomenclature for Cosmetic Ingredients) names
- IUPAC nomenclature

3 industry representatives (43%) suggested that ingredients should be designated according to the official rules stated in *Article 18 of the CLP Regulation 1272/2008*. For detergents, the use of *INCI (International Nomenclature for Cosmetic Ingredients) names* is prescribed for certain ingredients by the *Detergents Regulation (EC) No. 648/2004*. In addition, other chemical identifiers are typically used under *REACH, SDS and CLP*, thus *consistency* is needed. A PC representative recommended using *IUPAC names, names used in Annex VI of the CLP Regulation*, as well as *CAS and EC numbers*. The EAPPCT representative listed in order of preference the use of internationally accepted chemical names:

1. the name as given in Part 3 of Annex VI of Regulation (EC) No 1272/2008,
2. the name as given in the classification and labelling inventory
(mentioned in Article 18(2) of Regulation (EC) No. 1272/2008),
3. the name set out in the nomenclature provided by the IUPAC,
4. another international chemical name.

Finally, the EAPCCT representative informed that the use of the INCI name as a possibility is currently discussed and is expected to be incorporated in the EAPCCT guidelines, and that mentioning if the substance in a mixture is nano-formulated or not is voluntary.

3.1.4. Establishment of a Data Set version Identifier (DVI)

General feedback

Of the 5 stakeholder contributions that were received on questions concerning the establishment of a data set version identifier (DVI), 4 were sent by industry (80%) while a single reply was sent by a PC (20%). The replies were mainly sent by European/international associations (80%), as well as one association based in Germany (20%).

Questions

Thought starter "**Establishment of a Data Set Version Identifier (DVI)**"

Key questions:

1. Under the assumption, that a UPI would be established, what is the added value of a DVI?
2. What should a DVI look like (format / length / ...)?
3. Do you have already experience in your country with such a system? If yes, could you please provide a description?

Stakeholder Answers

The idea of introducing a *data set version identifier (DVI)* was supported by only one stakeholder (EAPCCT representative) (20%), while 3 representatives from industry rejected the idea of introducing a DVI (60%). Several industry representatives expressed their *doubts regarding the added value of a DVI*. In particular, they highlighted that any formulation change significant enough to lead to a modification of the emergency medical advice would typically also prompt a change in the product name or code, suggesting that the *current system for product identification is sufficient*. Moreover, industry representatives proposed that detailed information could be provided to PCs *on request*. In addition, the introduction of a DVI might have a potential negative *commercial impact* on products (e.g. inability to sell or potential rejection of 'old' units, without technical or quality justification). Replying to these comments an EAPCCT representative clarified that a DVI is not designed as additional product formula identifier for minor product formula changes but is designed to *identify the most recent data set on a technical level*.

According to the EAPCCT representative, a DVI could/should be in the *format* of a *date/time-stamp* (as proposed in the November 2010 workshop).

The EAPCCT representative further commented on its *experience with a DVI-based system*. For example, DVIs are useful in cases where *notifications of changes in the dataset are occurring without change in the formula*. The *system would automatically recognize one dataset as outdated* (as the DIV indicates the older time stamp). Consequently, the *outdated dataset is not shown anymore* (and evaluation of this dataset is not needed by the PC officer, thus saving time in emergency situations). According to the EAPCCT representative, DVIs provide an important additional benefit when errors occur during the transmission of a dataset (e.g. due to technical problems, an outdated version reaches the PC later than a more recent version, but cannot be identified as 'out dated' due to the missing DVI).

3.1.5. Type of Information Requested

General feedback

10 contributions were received in total for questions relating to the *type of information requested*, 5 of which were sent by industry (50%), 4 by PCs (40%), and 1 by a government authority (10%). Contributions came from 5 European/international associations (50%), as well as from Germany, Norway, Slovenia, Ireland, and Italy (10% each).

Questions

Thought starter "Type of information requested"

Key questions:

1. Is there a need to provide additional information on top of those already contained in SDSs to PIC?
2. If yes, which information and why?

Stakeholder Answers

Stakeholders had mixed opinions regarding the need to provide additional information on top of those already contained in SDSs. Indeed, while 50% of stakeholders (all from industry) rejected the idea, 50% of stakeholders approved it (40% from PCs, 10% from a government authority). Industry representatives held the view that the information contained in the revised SDS (compliant with REACH requirements) is sufficient to meet the needs of poison information centres. EFA (the European Flavour Association) proposed that *full composition details may be provided to PCs on request*. On the other hand, PC representatives stated that SDSs do not provide enough information for the purpose of PCs. The EAPCCT guideline describes the complete dataset that should be available to Poison Centres. Some information is not present on the SDS, some information is voluntary to notify and some information can be copied from the SDS:

- Required information not present on the SDS:
 - composition of the mixture
 - product category (to be developed)
 - indication of consumer/professional use
 - type/size of packaging
- Voluntary information not present on the SDS:
 - labels (a picture of the label can be useful for cross checking where identification of the mixture is problematic).
 - total reserve acidity/alkalinity (if available)
 - mentioning with every ingredient of the mixture the 'functional group name' (non-ionic surfactant etc.), hazard classification and if the ingredient is nano-formulated or not.
- Information that is present on the SDS and can be copied from it:
 - classification of the mixture (section 2.1 of SDS)
 - label elements (section 2.2 of the SDS)
 - physical state (section 9.1(a) of the SDS)
 - pH (section 9.1(d) of the SDS)

3.1.6. Product Categorisation System (PCS)

General feedback

5 stakeholder contributions were received on questions relating to the development of a product categorisation system (PCS), with 2 replies from industry (40%), 2 from PCs (40%), and 1 reply from the United Nations World Health Organisation (WHO) (20%). Contributions came from 3 European/international associations (60%), as well as from Germany and Slovenia (20% each).

Questions

Thought starter "**Product Categorisation System (PCS)**"

Key questions:

1. Which systems exist already and what do they look like?
How detailed should a PCS be (categories / sub-categories) in order to fulfil its purpose?

Stakeholder Answers

3 stakeholders (60%) commented on *existing categorisation systems*. These include the *WHO INTOX project* (a product classification scheme including definitions of product categories (excluding pharmaceuticals)), the German Toxicological Documentation and Information Networks (*TDI project*), as well as *systems already in place in the UK, Italy and the Nordic countries*.

The EAPCCT representative proposed to use the *TDI project (Toxicological Documentation and Information Network)* as a template for the development of a European product categorisation system (i.e. the TDI already formed the basis for the development of the Cosmetic Products Notification Portal (CPNP)). A.I.S.E. suggested 'that PCS should be *sufficiently detailed* so that products can be easily differentiated/assigned thereby facilitating the provision of more refined analyses/reporting, and targeted preventive action, if needed. It would also allow generating 'human experience' data that could be useful for classification under CLP. This requires *unambiguous definitions of product categories*.' Finally, A.I.S.E. stressed that it would like to participate in the development of a PCS for detergents and cleaning products.

3.1.7. Unique Company Identifier (UCI)

General feedback

Only a single contribution was received on questions regarding the *establishment of a unique company identifier (UCI)*. The contribution was sent by a representative of the German chemicals industry.

Questions

Thought starter "**Establishment of a Unique Company Identifier (UCI)**"

Key questions:

1. What is the added value of such an UCI compared to the information which is already submitted to PCs and available on the label of products, i.e. name, telephone number, and address of the company which places a mixture on the market?
2. What should a UCI look like (format / length / ...)?
3. Do you have already experience in your country with such a system? If yes, could you please provide a description?
4. If such an UCI is established, how can we ensure
 - a. that it is easily identifiable amongst other information elements on a label? and
 - b. that it does not causes confusion for the users and an information overload on the label?

Stakeholder Answers

The stakeholder commented that the establishment of a UCI was *not necessary for hazardous mixtures*, and suggested that a substance or mixture classified as hazardous and contained in packaging shall bear a label including the desired elements concerning the identification of the company responsible.

3.1.8. Unique Product Identifier (UPI)

General feedback

8 stakeholder contributions were received on questions relating to the *establishment of a unique product identifier (UPI)*, with 6 contributions from industry (75%) and 2 from PCs (25%). The replies were sent by 6 European/international associations (75%), as well as by an association based in Germany (12%) and an Italian PC (12%).

Questions

Thought starter "**Establishment of a Unique Product Identifier (UPI)**"

Key questions:

1. If an UPI is established, should it be mandatory for all mixtures (meaning mixtures used either by consumers and / or by professional / industrial users) or only for mixtures used by consumers?
2. What should a UPI look like (format / length / ...)?
3. Do you have already experience in your country with such a system? If yes, could you please provide a description?
4. If such an UPI is established, how can we ensure
 - a. that it is easily identifiable amongst other information elements on a label? and
 - b. that it does not causes confusion for the users and an information overload on the label?

Stakeholder Answers

6 contributions (50%) commented on the issue of *establishing a UPI for all mixtures or only for mixtures used by consumers*. In general, industry representatives held the view that UPIs should be *restricted to hazardous mixtures made available to the general public (i.e. consumer products)*. The arguments supporting this view were as follows: millions of mixtures on the European market are supplied only to industrial/professional users, only a very small proportion of poisoning incidents involve non-consumer products, establishing a UPI for all products would represent a large additional burden for both industry and PCs, the safety data sheet is enough to give advice in the case of a poisoning incident. In support of this view, an Italian PC representative mentioned that it is very important to differentiate industrial products from household products, as the latter ones are at the origin of the largest number of calls to poison control centres. Thus, a detailed identification system for household product would be required. The EAPCCT representative requested that the UPI should be a mandatory element on the label.

Regarding the *format of the UPI*, 2 stakeholders (25%) suggested that the format should be *as described in CEN Standard (EN) 15178*. The EAPCCT representative stressed that the CEN Standard EN15178 for Product Identification does not contain a proposal for a product identification element. It proposes to place such a UPI together with a graphical symbol ('I' in a circle) close to the barcode so it can be found easily by the user.

A number of *forms of identification already exist* which can uniquely identify a product. These include the *trade name* and/or *product code*, but also other *voluntary systems* already in use for consumer products (e.g. European standard (EN) 15178:2007). A.I.S.E. mentioned that in Germany, product identification elements are used on a *voluntary basis* on a number of detergents. The identification element (mostly an *8- or 10-digit number*) is printed on the *label close to the barcode*, after the letter 'I' in a circle. Moreover, a UPI should *not require frequent label artwork change* and it *should be fit for its intended purpose* (in case of accident, quickly correlate a certain product package with the corresponding chemical composition). In general, stakeholders recommend continuing to use the existing product codes and identifiers already in place.

Concerning the *UPI labelling* on a product, several stakeholders expressed their concern about the extensive list of information that is required to be mentioned on product labels. Adding another piece of information would make it difficult to fit everything onto labels.