The background of the cover features a collage of laboratory glassware. In the top right corner, there is a cluster of various flasks and beakers containing liquids of different colors. The main part of the cover is dominated by a large, semi-transparent purple shape that contains the title text. Below this, several Erlenmeyer flasks and a beaker are visible, containing liquids in shades of orange, blue, and purple. The flasks have volume markings, with '0' and '500ml APPROX' visible on some. The overall aesthetic is clean and scientific.

Harmonisation of Information for Poison Centres

— **Stakeholder workshop report**



European Commission
Enterprise and Industry

Harmonisation of Information for Poison Centres

— **Stakeholder workshop report**

Article 45(4) of the CLP Regulation (EC) No 1272/2008

Brussels, 24 November 2010



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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. And to fulfil this task adequately, information about the product(s) involved is crucial, especially information about the composition and the concentration of the ingredients, as well as on appropriate emergency measures.

In 1988 the Dangerous Preparations Directives¹ created an obligation for Member States "to appoint bodies responsible for receiving information relating to

¹ 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,, which was replaced by Directive 1999/45/EC



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preparations" (now called mixtures according to the CLP Regulation)" that are considered hazardous due to their health effects and their physical-chemical properties".

At the time of adoption of that Directive, 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 burden for companies operating in several Member States as they often have to submit the same or similar information in different formats. 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.

These shortcomings of the Dangerous Preparations Directive have been addressed during the adoption of Regulation (EC) No 1272/2008 (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 adoption, Regulation (EC) No 1272/2008 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.

However, the submission of information to poison centres is not only foreseen under the CLP Regulation but also under the Biocidal Products Directive (Directive 1998/8/EC) and the Regulation on Cosmetic Products (Regulation (EC) No 1223/2009). Whilst Directive 1998/8/EC 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, some information to the Commission. 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 poison centres or similar bodies, where such centres or bodies have been established by Member States (for the purposes of medical treatment). In order to implement these requirements the Commission is setting up an electronic database, the so-called Cosmetic Products Notification Portal (CPNP), in close collaboration with

representatives from poison centres, competent authorities and industry. This database shall be operational as from 11 January 2012.

Taking into account that work under the Regulation on Cosmetic Products is already well advanced, solutions proposed for the CLP Regulation should aim at being compatible as far as possible in order to avoid duplication of work and to take advantage of what has already been accomplished.

In order to fulfil its obligations under Article 45 (4) of the CLP Regulation, the Commission organised two smaller expert meetings in 2010 involving representatives from poison centres in the Member States during which a number of specific proposals as well as questions were formulated with the recommendation to discuss them in a larger forum. This larger forum was convened in form of a workshop on 24 November 2010.

At the workshop, nearly 80 representatives from the European Association of Poison Centres and Clinical Toxicologists (EAPCCT), national poison centres, various Commission Services, competent authorities in the Member States, industry, industry associations, and other stakeholders were present.

This brochure contains the summaries of the presentations made at the workshop as well as the conclusions drawn and solutions proposed.

The full presentations are available on the website of DG Enterprise under the following link:

http://ec.europa.eu/enterprise/sectors/chemicals/classification/clp_workshop_en.htm.



Problems raised and solutions proposed

Background

Information needs of poison centres in the Europe Union are driven by the provisions in Article 45 (3) of the CLP Regulation which stipulates 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”

The scope of the tasks assigned to the poison centres in Member States varies due to the fact that the provisions in Article 45 (1) leave room for interpretation:

“Member States shall appoint a body or bodies responsible for receiving information relevant, in particular, for formulating preventative and curative measures, in particular in the event of emergency health response from importers and downstream users placing mixtures on the market. This information shall include the chemical composition of mixtures placed on the market and classified as hazardous on the basis of their health or physical effects, including the chemical identity of substances in mixtures for which a request for use of an alternative chemical name has been accepted by the Agency, in accordance with Article 24.”

As a consequence, ‘the information required by poison centres ... to carry out the tasks for which they are responsible’ varies amongst Member States, and sometimes also within a Member State itself.

Examples of currently existing diverging requirements in the Member States include:

- Different requirements for ingredients information
- Different requirements for composition information
- Different requirements for the format in which the information is submitted
- Different procedures (e.g. to whom must industry submit the requested information?)

This makes it a very challenging task for the Commission to fulfil the requirements in Article 45(4) of the CLP Regulation, namely to carry out a review to assess the possibility of harmonising the information referred to in paragraph 1, including establishing a format for the submission of information by importers and downstream users to appointed bodies and to possibly prepare a proposal to add an additional Annex to the CLP Regulation, which is realistic, acceptable by all stakeholders and will get the political support by the majority of the Member States.

The discussion at the workshop

The EAPCCT guidelines

The discussion at the workshop was based mainly on the EAPCCT guidelines² and the requirements and needs

² For further details about the origin of these guidelines and other information requirements mentioned there, please see the summary of the presentation of the “Draft EAPCCT guidelines – review of information requirements” in this brochure.

listed therein from the point of view of poison centres. These are in particular:

- to establish a unique identifier for the company which 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 poison centres unambiguously to the product involved in an incident
- 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 agree on the type of information which should be submitted to the poison centres
- to agree on a harmonised format in which information should be submitted to the poison centres in order to enable them to retrieve, compare and exchange information more easily
- to further develop product categorisation which exist already on a project level or in the context of specific legislation but should be extended to all products at 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 foreseen in Safety Data Sheets (SDS).

Establish a unique company identifier (UCI)

Reactions from industry representatives with regard to this proposal were somewhat divided. Whilst some did not consider this a problem, others questioned the added value of such an UCI compared to the information

which is already submitted to poison centres and available on the label of products, i.e. name, telephone number, and address of the company which places a mixture on the market). Whilst it was recognised that in a stressful situation like a call to a PIC numbers can be communicated more clearly than names, this is not necessarily true, when such numbers get too long. The argument that company names can change is equally valid for numbers.

Irrespective of the question on whether such a UCI is useful or not, it is not evident that agreement would easily be found on the format for such a number, and whether existing numbers like the EORI number³ or the EAN⁴ number or VAT numbers could be used. Administration of any new system of UCIs would also need further reflection – one idea was that – in case a European data base (see discussion further below) were to be established, a UCI could be generated like for registrants under REACH.

Establish a unique product identifier (UPI)

The main arguments brought forward in support of a UPI were that the trade names of products are often difficult to identify by consumers, that they are sometimes used for a group of products, and that the composition of products can be changed without changing the trade name, which can make it very difficult for the poison centres to link the product information in their data bases to the actual product involved in an incident. However, this is crucial in case of emergencies and of course for the right treatment.

Even if the trade name can be identified, mistakes occur when being communicated via telephone.

A proposal by EAPCCT is to use CEN Standard EN15178 for Product Identification, which uses the barcode together with a product identification element, which consists of a 5-digit company code, a 5-digit product code and a 2-digit GHS code which represents the hazard pictograms. In Germany, this system is used on

3 Economic Operators Registration and Identification

4 European Article Number

a voluntary basis for detergents, but there is no legal obligation for companies to follow this CEN standard.

Questions were raised whether the 5-digit company code, which seemed to work for one Member State would actually be sufficient if applied Europe wide (see also discussion on the unique company identifier above).

Industry representatives agreed that fast and correct product identification can be a problem for the poison centres. However, before being able to support or reject the solution proposed by EAPCCT, it would be necessary to carefully evaluate the implications and consult a broad range of companies. In addition, questions were raised whether all mixtures, meaning those used only by consumers and those only used by professional or industrial users, should be treated in the same way with regard to the additional requirements requested by EAPCCT. However, in practice such a distinction might be difficult because many products are used by consumers as well as by professional / industrial users and poison centres do not only have to reply to requests coming from consumers, but they receive such requests from professional / industrial users (or from medical staff treating such users) as well.

Harmonise the type and content of information which should be submitted

Currently, poison centres very often receive a paper copy of the SDS for a particular product. However, the information provided in an SDS is not always sufficient for the purpose and the tasks of the poison centres. They often need further information, like additional toxicological information or additional physical-chemical data (physical state, pH, total reserve acidity / alkalinity) in order to provide physicians with the advice necessary for the correct treatment of a patient.

In addition the information on ingredients in SDSs is limited to hazardous substances above a certain threshold. Substances not classified as hazardous do not need to be mentioned in an SDS but poison centres would like to receive this information as well.

“Versioning” of the information submitted to poison centres

Poison centres are in practice often confronted with difficulties to decide which information available at poison centres for a particular product is the one to use for the advice requested. As already mentioned above, the same product trade name is sometimes used even if the composition has changed over time, or different trade names are used for products with the same composition.

Poison centres also have to deal with the situation that at the same time different versions of a product (a new and an old one) are on the market in parallel (e.g. because ‘old’ versions of the product are still on the shelves of distributors, supermarkets etc), and they have to keep the information for both products, and not only the one for the latest version of the product.

Sometime industry also up-dates already submitted information, which does not necessarily concerns the composition of the product but other information (e.g. spelling errors), and the poison centres need to know which version they have to use when a product is involved in an incident.

According to EAPCCT, a so-called Product Formula Identifier (PFI) together with a Data Set Version Identifier (DVI) would solve the problems. The PFI would serve to identify different compositions of a product with the same trade name whereas the DVI would be used to identify the latest version of the product information. In reply to the question of whether these additional identifiers would still be necessary if in the end the Unique Product Identifier (as discussed above) was accepted, EAPCCT clarified that none of these identifiers will be requested on the label but only in the information submitted to the poison centres.

Industry representatives agreed that the concerns raised by EAPCCT regarding the need to identify the latest version of the product information for products with the same trade name were valid, and they were ready to consider the proposed PFI and DVI as possible solution. It would indeed be important that no additional labelling element will become mandatory, as the need to update labels creates additional costs for industry.

Developing a harmonised product categories system

The proposal from EAPCCT to further develop product categorisation, which already exists on a project level or in the context of specific legislation (e.g. cosmetics) and to establish a European harmonised categorisation system was well received by all stakeholders, as long as the product category does not have to appear on the product label but should only be communicated to the poison centres with the other product information.

It was clarified that a product category is not needed to give advice in emergency situations. However, it could be a useful tool to retrieve information on comparable products or to link for example the risk assessment for a particular group of products (e.g. dishwashing tablets) to the number of poisoning cases dealt with in poison centres.

Product categorisation can be used in statistics and annual reports, but also, as demonstrated in the presentation on product categories, as a basis for evidence that can be used for example for classification purposes. It is clear that increasing refinement of a product categorisation system will allow more refined analyses. On the other hand there should not be too many categories or sub-categories to keep the categorisation system manageable.

Currently, different categorisation systems are used by poison centres in different Member States as well as by industry. Consequently, it is very difficult to produce for example product related reports or statistics across the EU or to compare findings between different Member States.

Various attempts have been made at a national and industry level or under specific legislation, which could be used as a starting point to develop an EU-wide system. Such a system should be developed in close cooperation between poison centres, Member States and industry associations. It should also build on what already exists. Industry for example uses product categories for marketing or data reporting purposes. The

Nordic countries have developed the SPIN⁵ database which is publicly available via the Internet, and which uses a product category code with some hundred different product categories. Under the Cosmetic Products Regulation around 300 categories have been developed, and France has about 570 categories in its national database on products and compositions.

The question arose whether the REACH system of categories of uses could serve as a starting point to develop a European product category system. However, this system might not be detailed enough for the purpose of the poison centres and their own needs. A European system would need more details but it might be possible to start from the REACH system of use categories and then refine them further as appropriate.

Level of detail with regard to chemical composition

This topic and the related proposals from EAPCCT created the most animated discussion. The possible options include:

- Obliging industry to provide information only on hazardous ingredients (as requested in the legislation), or on all substances regardless whether or not they are hazardous
- Requesting the exact concentration of the ingredients or only concentration ranges
- Requesting the exact concentration only for the most important hazard categories⁶, and allow concentration ranges for the remaining ingredients

5 SPIN is a database on the use of Substances in Products in the Nordic Countries. The database is based on data from the Product Registries of Norway, Sweden, Denmark and Finland

6 Under the current system (Dangerous Substance Directive 67/548/EEC and Dangerous Preparations Directive 1999/45/EC) this would refer to substances classified as very toxic, toxic and corrosive, under the CLP Regulation, this would according to the proposal of EAPCCT refer to substances classified as acute toxic, category 1, 2 and 3 for all exposure routes, STOT single and repeated exposure, category 1 and 2, for skin corrosion, category 1A, 1B and 1C, and for serious eye damage, category 1

Currently, the obligations for industry differ in the Member States.

The reason for the poison centres to receive the exact concentration of all ingredients of a mixture (or at least of its most hazardous ingredients) is the need to provide the right therapy advice to medical staff or private persons, when they are contacted. EAPCCT representatives explained that it is often difficult to quantify actual exposure in case of incidents, because the precise quantity of product involved is not known. Having exact substance concentrations will therefore help to provide advice that avoids insufficient or too aggressive therapy.

Industry representatives cautioned that requesting precise concentrations of all ingredients in products could not be workable – for example in certain sectors (e.g. paints) the numbers of products with almost identical composition are very high and companies are often not in the position to provide the exact composition of their mixtures / products for various reasons. The “composition” of their product is for example performance driven, meaning the final product is made according to specific requirements of the customer (e.g. changing viscosity of a specific batch by adding solvents) and not according to a specific formula or recipe. For other industries which for example work with natural ingredients and raw materials, delivering the exact composition of their products or specific batches is virtually impossible.

Another aspect to be taken into account is that many mixtures are composed of other mixtures. Upstream producers are often reluctant to disclose precise composition of mixtures to their downstream clients to protect their business interests. This means in practice that at least for downstream producers of mixtures made of mixtures it is not possible to provide the exact composition of the mixtures they produce, not even for all the hazardous ingredients, and not at all for the non-hazardous ingredients. In fact, in accordance with current legal requirements, downstream users of mixtures receive from their suppliers only certain information. For example, the information provided in SDSs is linked to the requirement of the REACH and the CLP Regulations which a) do not require complete

disclosure of composition, b) only refer to hazardous ingredients, c) apply only above certain legally foreseen thresholds and d) allow the use of concentration ranges.

This means that any additional legal requirement to submit precise information on concentration of either non-hazardous ingredients or hazardous ingredients below the threshold which leads to classification can only be introduced via a substantial change to the CLP Regulation.

Industry representatives also informed that for reasons of confidentiality the option to submit information on ingredients only in concentration ranges would be preferable. In fact, in the past there had unfortunately been cases, where confidential business information from poison centres had leaked outside. A compromise solution could be to use narrower concentration ranges than those currently for example foreseen in Table 1.2 of Annex I to the CLP Regulation. Concentration ranges/bands also require less frequent up-date of the information submitted to the poison centres.

On the other hand, there exists already a legal obligation for certain products (detergents) to submit the complete composition including non-hazardous substances on request to medical staff.

In order to have a better basis for further discussions on this topic, it was proposed that poison centres should develop some examples which would demonstrate that advice given to medical staff or the general public based on concentration ranges could have severe consequences which would be prevented by having the exact composition of a mixture, taking into account that the uncertainties around exposure would probably be much larger. That might help to decide why in certain cases the exact composition is necessary. However, it does not solve the problem that this information is not necessarily available.

In the end, a balanced solution needs to be found between what is desirable with regard to the best possible treatment of victims of poisoning incidents and the feasibility of providing the exact concentration of all ingredients in a mixture, as well as the workability of providing the necessary updates to the poison centres.

The IT-format of the information

There was a broad consensus that a common format should be used when submitting the information to poison centres and that the XML format should be used.

A common format would reduce the burden for both, industry and poison centres. Industry would profit because they could submit their information to all Member States in the same way. A common format would enable poison centres to process, compare, and retrieve data in a much more efficient way.

According to experts, the XML format is an internationally recognised and used Internet Standard for data exchange because it is very flexible, dynamic and allows automatic validation. It is already used world wide in many applications, but in particular also in the European Chemicals Agency (ECHA).

EAPCCT suggested establishing a permanent working group in the context of the CLP Regulation. Such a working group should be composed of IT experts and representatives from poison centres, Member States and industry. Industry representatives supported the proposal also because they have been involved very actively in the development for all IT tools for REACH, and they would consider it very helpful to be part of such a discussion from the very beginning.

The experience gathered under the Cosmetic Products Regulation when setting up the Cosmetics Product Notification Portal should be built on. In addition, developments in related areas need to be taken into account, e.g. a current industry initiative to establish a common XML format for the submission of safety data sheets under REACH.

Harmonise procedures to receive information

This is also a topic where solutions are not straight forward. Two alternative models exist: either a central European data base or a decentralised system of data bases in the Member States that allow full information exchange.

Establishment of a European database and portal via which industry could centrally submit its PIC notifications is not necessarily considered to be very useful by all stakeholders. Apart from the question who should manage such a data base (Commission / ECHA?), which means receiving, storing, and distributing the information, as well as maintenance, software updates etc, there is the need to finance such a database. This would require the approval by the Council and the European Parliament to provide the Commission with the adequate budget.

A central European database would have clear benefits at least for large companies which operate in several or all Member States and which currently have to adapt their notifications to the different procedures used in different Member States for the same product.

However, SMEs might consider this as an additional burden, in particular if they only market few products and operate only in one or two Member States.

There are also clear advantages for Member States and the poison centres, for example

- the possibility to exchange data between individual poison centres and / or Member States
- to generate better and in particular European wide statistics
- to have a better scientific justification in case European wide action on individual substances is prepared

On the other hand, Member States and poison centres have currently very well established procedures. They have access to the data they need for example for prevention or toxicovigilance. As a further draw back, a European database would require, due to the obligation to treat the data received as confidential, quite complex data-access rules as currently seen under REACH-IT. Again, the experience that is currently gained under the Cosmetic Products Regulation for setting up the centralised European Cosmetics Product Notification Portal will provide further insights for developing the best solution.

Names to be used for substances in the mixture

This was a topic briefly outlined during the presentation of the EAPCCT guidelines, but was not discussed further. EAPCCT proposed a type of hierarchy for names used for substances contained in a mixture, starting with the name used in Annex VI to the CLP Regulation, followed by names used in the C&L Inventory, IUPAC names and other international chemical names together with identification numbers like CAS number or EC number. In addition, EAPCCT considered it important to know whether a substance is in nano-form or not.

Summary and follow-up

- Broad consensus that it is possible and appropriate to harmonise the information to be submitted to poison centres
- Broad consensus on the need to develop a European product categorisation system
- Broad consensus to use a common IT format to submit the information and to use XML
- 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 and the possibility to establish a European database for submitting PIC notifications

As a general rule, solutions should be found that satisfy the needs of poison centres 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 REACH, CLP and the Cosmetic Products Regulation should be taken into account. This applies as well to other initiatives, projects, IT tools etc. developed at national or regional level.

The Commission intends to organise 2 follow-up meetings in 2011 with experts from poison centres,

industry, and all other relevant stakeholders in order to discuss further steps and legal possibilities.

The Commission will also set up a CIRCA interest group which will allow those who cannot participate in the meetings to follow the discussion and submit contributions and ideas.

By 20 January 2012, the Commission will provide an analysis of what has been discussed, not only at the workshop but including also the outcome of the forthcoming consultations. If the outcome of this analysis is that the Commission should present a legislative proposal, this will follow the normal legislative procedure – discussions in working groups and a vote by Member States in the relevant regulatory Committee.

Additional information

The presentations given at the workshop are available on the website of DG Enterprise and Industry website:

http://ec.europa.eu/enterprise/sectors/chemicals/classification/clp_workshop_en.htm.

On the same website, links to the web stream of the event will be available until at least 31 December 2011.





Summaries of presentations

1. **Notification of product information to poison centres: the road to harmonisation at EU level**

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Current EU legislation does not define the quality and format of information required to be notified to poison centres about hazardous mixtures. Consequently, companies are confronted with a broad variety of country specific rules, making notification a serious administrative burden. On the other hand, poison centres often do not receive the quality of information necessary to perform their tasks. With paragraph 4 of article 45 in the CLP Regulation (EG) No 1272/2008, the European Commission recognises the problem and so will carry out a review with all stakeholders to analyse if harmonisation of product notification to poison centres can be achieved. Poison centres took the first steps on this road that could lead to an annex of the CLP Regulation containing the requirements on the quality of information and format for product notification to poison centres.

Introduction

The main task of poison centres is to inform medical personnel and/or the general public about symptoms and treatment of acute intoxications. These mostly occur because consumers and professionals use products that are safe with regular use, in an inappropriate way, either intentionally or accidentally. There is a broad scope of

exposures ("Pretty much everything that one can imagine"), ranging from drug overdoses by adults to the accidental intake of household products by young children. In addition, poison centres are often involved in assisting the government with medical information in the case of larger incidents where the health of greater numbers is at stake. For example, when accidents occur at a production plant or during the transport of chemicals.

To adequately perform a risk assessment in the event of exposure, poison centres need detailed information on products to which consumers and professional users can be exposed. Two important aspects are the quality of the product information and identification of the product. Good information quality means knowing what substances are present and which are hazardous, knowing their concentration and knowing the toxicological properties of the product and/or substances. However, having this good quality of product information is in itself not enough. It is also important that this product information can be unambiguously linked to the product causing the intoxication. In the experience of poison centres this means that in addition to the trade and company names, a unique formula specific product identification element should be present on the label.

Past

The notification of information on hazardous products by companies to a government authority (GA) and/or a poison centre in EU Member States is currently regulated by national legislation. This is based on article 17 of the Dangerous Preparations Directive 1999/45/EC. The article states that the appointed body (GA and/or poison centre) in each Member State is “responsible for receiving information, including chemical composition, relating to preparations placed on the market and considered hazardous on the basis of their health effects or on the basis of their physical/chemical effects”. The information is confidential and “may only be used to meet any medical demand by formulating preventive and curative measures, in particular in case of emergency”.

The Dutch Ministry of Health asked the Dutch poison centre to conduct a survey on the implementation of article 17 in EU Member States. In 2007, the results were published in a report that showed a considerable variety in country specific (electronic) notification procedures, formats and requirements on product composition and ingredient concentrations in the EU Member States that responded (1). The report’s general conclusion was that article 17 was the cause of the problem as it lacked specific guidelines on the quality and format of the information.

It is understandable that for companies placing products on the European market, to comply with all these different notification procedures is an administrative burden. Poison centres often do not receive the quality of information necessary to perform their tasks. It is not hard to imagine that the willingness to supply detailed product information will increase if the requirements are the same for all EU Member States. All stakeholders involved – poison centres, GAs and industry – would benefit from European harmonisation of notification of product information to the competent authorities. To reach that goal, three steps have to be taken. First, all stakeholders should agree on the quality of information required. Then, a data exchange format for notifying the product information should be developed. Finally, these requirements on the quality and format of information should be incorporated into EU legislation.

The Dutch report pointed out that the forthcoming CLP Regulation (referred to as “EU-GHS” at that time) replacing Directive 1999/45/EC and article 17, would give an opportunity to harmonise product notification within EU Member States. It was suggested that product notification requirements should be incorporated into the new regulation which was then under consideration.

One year later, through the joint efforts of industry, Member State representatives and the European Association of Poisons Centres and Clinical Toxicologists (EAPCCT), article 45 in the final version of the CLP Regulation was extended with a provision that the European Commission (EC) shall review the possibility of harmonising product notification to the appointed bodies. From the entry into force of the legislation on 20 January 2009, the EC has three years to consider this possibility, which also includes establishing a common format. The final result may be adopted by the EC and added as an annex to the CLP Regulation. The EAPCCT was recognised as an important stakeholder to be consulted to achieve this harmonisation.

Present

In order to respond to recent developments in European legislation, the EAPCCT Board reactivated the Working Group on Poison Centres Activities in 2009, now renamed the Working Group on Poison Centres Activities/ European Regulatory Issues. A sub-working group on CLP issues was established with representatives of several EU poison centres coordinating the discussion on the harmonisation of product notification.

In September 2009, the sub-working group and the EC discussed a procedure for the article 45(4) review process in 2010. The EC offered to organise two meetings of poison centres’ representatives to discuss requirements for the notification of product information. These meetings would be followed by a workshop, where all stakeholders would be invited and the poison centres’ points of view could be presented and discussed.

In these two meetings plus an additional third one, organised by the EAPCCT, the notification of product information was discussed in great detail with the

goal of reaching consensus on these requirements for poison centres. In the second meeting, representatives of national authorities took part in the discussions.

The starting point for the discussions was the EAPCCT guidelines document on product information requirements from 1989, created shortly after the publication of the first version of the Dangerous Preparations Directive 88/379/EEC in 1988. After three meetings, an updated 2010 version of the guidelines was established and, in September 2010, endorsed by the EAPCCT Board. These guidelines were discussed with other stakeholders in the workshop on 24 November.

An important part of the new EAPCCT guidelines are, of course, the requirements on the composition of a product and the concentration of its substances. In the old guidelines, these requirements consisted of the notification of the full composition (without the use of thresholds), exact concentrations for (very) toxic and corrosive substances and well defined concentration ranges for the other substances. However, with the new classification rules for substances and mixtures of the CLP regulation, which also include new terminology, it became necessary to redefine these 'old' requirements. The hazard classes and categories were individually discussed. Based on the poison centres' everyday practice of advising on how to treat acute intoxications, a selection was made for which hazard classes and categories of a substance an exact concentration is required. In addition, the old rules, on the notification of the full composition (without the use of thresholds) and on the use of defined concentration ranges for other substances, still apply. These are the minimum requirements for poison centres. Notification of exact concentrations for all substances in the mixture is preferred.

Similarly, other requirements on product and company information were addressed and integrated into the new EAPCCT guidelines.

In the workshop on 24 November, Ronald de Groot from the Dutch poison centre presented and explained the new EAPCCT guidelines in more detail.

In the meetings, it became clear that some subjects required more discussion. These, and their importance,

are mentioned and explained in the new EAPCCT guidelines, but a final view on them has not yet been reached. The problems are clear, as are possible solutions, but discussions with stakeholders, especially industry, are necessary to reach an agreement.

One major discussion concerned how the product (formula) information present in the poison centre can be unambiguously linked to the product (formula) that caused the intoxication. This is important because it is essential for the poison centre to determine the risk of the exposure to the product and advise on the treatment. In a poison centre's everyday practice, this is a problem.

For identification of a product, a poison centre is usually provided with only the trade name found on the label by the patient or physician. Uncertainty about the complete trade name as depicted on the label, which can include brand name, product line, name of the product and a variant name in different font styles and sizes, often hampers clear identification. Also, several formulae of a product, with different toxicological properties, can be on the market and often cannot be distinguished by the product name. Therefore, the presence of a unique formula specific 'product identification element' (PIE) on the label, identifying the product and its specific formula, is highly recommended. In addition, the creation of a product identification field on the label, according to CEN Norm EN 15178:2007-11, where all relevant product identifiers can be found, could possibly improve product identification.

In the workshop on 24 November, Axel Hahn from the German BfR reflected on the product identification problem and its possible solutions.

On the other side of the product identification problem is the documentation sent to poison centres by the company notifying its mixture. As product information can be regularly updated, it becomes important to keep track of the different notified data sets and the changes they contain. It is especially important for poison centres to know when the formula of a mixture has changed since various formulae of a mixture may be present on the market. This can be achieved if the documentation of the product carries an ID that only changes when the formula changes.

In the workshop on 24 November, Herbert Desel from the German poison centre in Göttingen further discussed versioning of the product information notified by companies.

Discussions also focused on product categorisation since a harmonised categorisation system could prove useful for all stakeholders. If accomplished, it will become possible to better combine all European poison centres' data in annual European reports on intoxications. It will enable comparison of exposure to products in certain categories between countries. The development of such a categorisation system requires collaboration between the EAPCCT and industry.

In the workshop on 24 November, Andreas Stürer from the Swiss poison centre further explained the advantages of harmonised product categorisation.

Poison centres also had their first discussions on how the required product information could be best notified to them. The Safety Data Sheet (SDS), a standard for product information exchange in the supply chain of companies, is often used to notify a poison centre. However, the SDS does not provide the required quality of information as it, for example, does not contain the complete composition and exact concentrations or well defined concentration ranges. Only a minor part of the poison centre's requirements is present on the SDS. In addition, the SDS is sent in PDF format, making it impossible to extract the relevant data for import into a poison centre database.

Therefore, in addition to an SDS, poison centres would like to receive all the important product information as one electronic dataset. In this way, the structured data can be easily imported into local databases and the quality of the information automatically analysed and validated. In addition, the data can be easily searched to answer information requests on intoxications or to respond to statistical inquiries by Member State authorities in conformity with article 45(2). The XML format, a general standard for data exchange, is already used in some Member States for the exchange of product information between poison centres and/or GAs. In the execution of REACH, the XML format is also used for the registration of substance information by companies in the ECHA databases.

Most of the poison centre representatives involved in the discussions come from centres that make use of information systems for storage of product information and/or intoxication case information. However, in the EU there are poison centres that do not yet have such information systems at their disposal. Here, a PDF is probably a preferable data exchange format.

It is evident from the above that discussions between poison centres, GAs and industry are necessary to establish a uniform electronic data exchange format.

In the workshop on 24 November, Christophe Dupriez from the Belgian poison centre focused on the use of electronic data exchange formats for notification.

Of interest for the developments of this CLP project is another one by the EC that is establishing a Cosmetic Products Notification Portal (CPNP). In the new Cosmetics Regulation No 1223/2009 article 13, companies are required to notify, by electronic means, product information to the EC, which shall make this available electronically to poison centres and competent authorities. The EC is, therefore, developing a central database to which cosmetic product information can be uploaded by companies. Poison centres and GAs can search, view and download the available product information. The EC CPNP working group contains, in addition to the European Commission's IT consultants, representatives of the cosmetic industry, GAs and poison centres. Current planning is to bring the CPNP into production at the beginning of 2012.

The poison centre representatives present in this EC CPNP working group are organised as a sub-working group on CPNP issues of the EAPCCT Working Group on Poison Centres Activities/European Regulatory Issues. In the CPNP project meetings, poison centre requirements on the quality and format of information are brought into the discussion and wherever possible into the design of the CPNP.

Both these EC projects are developing along different paths and different timeframes. The EAPCCT and poison centres do not favour the development of these projects into different electronic data exchange formats. For all stakeholders involved it would be best if only one

electronic data exchange format is established that suits the notification of all (hazardous) mixtures.

Future

In the workshop on 24 November, poison centres were, for the first time, able to present to a broader audience the importance of their requirements on product notification in respect of the tasks they have. They explained what article 45(3) summarises as *“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”*. Representatives of governmental authorities and industry had the opportunity to react, comment and present their own points of view. As a result, the positions of the main stakeholders became clear and helped identify important points for future discussion.

However, the workshop is not the end of the process, rather it is the starting point for the discussion between stakeholders to reach harmonised notification of product information in EU Member States. Given that the EC review ends at the beginning of 2012, there is still

one year left in which the first few meetings between all stakeholders can take place and the requirements on the quality and format of the information can be discussed. The review could then end with a clear perspective of what has to be done from 2012 onwards and of the role the EC will continue to play in reaching the harmonisation. This is expected to involve guiding the discussions with stakeholders to a final agreement on the requirements for the quality and format of information and integrating these into an annex of the CLP Regulation. Ideally, the cooperation will be extended and, like in the CPNP project, the EC will become involved with implementing the new annex by developing tools that support the notification process for all stakeholders.

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Available at:
<http://www.rivm.nl/bibliotheek/rapporten/233900001.html>



2. Draft EAPCCT guidelines – review of information requirements

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To perform a risk assessment adequately, poison centres need detailed information about the contents of mixtures. The first task of the EAPCCT sub-working group on CLP was to reach a consensus on the required product information, especially the necessary details of the product composition. To achieve this, the 1989 EAPCCT guidelines on product information requirements were updated. The new guidelines, endorsed by the EAPCCT Board in September 2010, will be the start of discussions with industry and EU Member State representatives. The guidelines contain the complete dataset that should be available for poison centres. They include some items from the Safety Data Sheet (SDS), but mainly more accurate additional information.

The sub-working group agreed that the SDS can be accepted as part of the notified mixture information, but noted that on its own it would not meet the needs of poison centres. The SDS is designed to inform professional and industrial users of the risks of a mixture. As such, it does not provide sufficient detail to make an accurate risk assessment in the event of acute intoxications. An important shortcoming of the SDS for poison centre use is that only hazardous substances above specified concentration thresholds have to be declared. More importantly, the absence of guidelines on the accuracy of the substance concentrations makes the use of wide concentration ranges general practice. Consequently it is very difficult for poison centres to inform healthcare personnel adequately in the event of acute intoxications. If an SDS states that the concentration of a substance is >25%, the range from a minimum of 25% to a maximum of 100% can be the difference between a mild and severe intoxication. The REACH Regulation that now contains the SDS guidelines has not changed their quality with respect to mixture composition and substance concentration.

In the text below, the new EAPCCT guidelines are explained; why specific information is needed; and what is still to be decided upon by the sub-working group in collaboration with industry. The headlines correspond to those of the EAPCCT guidelines document.

Company information

As explained in the 'note to industry' in the guidelines, the 'company placing the mixture on the market', that is responsible for the notification, is not always able to submit the required product information, such as a detailed composition. In this case, there can be a separate 'company submitting the mixture information'. In practice, the producer of the mixture often takes over responsibility for submitting adequate information for its 'private label clients'. The submitting company can also be a specialised agent that simply takes care of the notification procedure in different countries for a variety of firms. Information on both companies is important for poison centres. Naturally, contact details of the company actually submitting the information are necessary for poison centres to be able to discuss the procedure and to contact them in case of problems with the notification. The company placing the product on the market is mentioned on the label and/or packaging of the mixture and is an important additional identifier of the mixture. In general, the 'company placing the mixture on the market' and the 'company submitting the mixture information' are one and the same.

For companies, a unique company identifier should be provided, identifying the legal entity. This should be discussed with industry to determine a useful identifier that would also be available for small companies. Optimally, this would be a unique code within the EU. For this purpose, the use of the VAT number (which

is unique in Europe if extended by country code), enterprise identification number, EORI number from European Customs and the EAN company code number amongst others could be considered.

One outstanding point of discussion is the 'contact point(s) in case of emergency'. There may be situations, such as unusual exposures, when poison centres need rapid direct contact to acquire more specific product information. This 24/7 availability might present problems for companies and needs to be discussed. An 'emergency telephone number' should be provided on the SDS, but this 'may be the body responsible for receiving information' and will in most instances be the poison centre.

Identification of the mixture

After exposure it is crucial to identify unambiguously the mixture and its specific formulation. The complete trade name and any other useful identifier present on the label should be notified.

The importance of this will be further discussed in a separate item in this brochure.

Grouping of mixtures is allowed when variants of a product have essentially the same composition, but only differ in colour and/or fragrance, for example a paint in 100 different colours or a household cleaner in different fragrance variants. A grouped notification will reduce unnecessary workload for companies. The composition of these products will of course differ slightly. Grouping these variants is not allowed when hazardous substances, for which an exact concentration is required, differ, either in presence or concentration, between variants. These substances are the most important to make a risk assessment after exposure as will be explained in the section on 'composition'.

It can be confusing if totally different products (with different trade names) are grouped because the composition is almost equal. Although in practice this will probably not occur very often, this was the idea behind the rule that 'only mixtures with a common part in the trade name followed by an additional component

indicating the specific variant, may be grouped'. For example, variant names like 'All purpose cleaner spring' and 'All purpose cleaner summer'.

For some mixtures, like biocides and pesticides, national official registration/authorisation numbers can exist. If these mixtures are separately registered at a national authority, they should also be separately notified to the poison centres, i.e. they should not be grouped.

Composition

Substances in the mixture

All substances in a mixture, whatever their toxicity, impurities and stabilising additives must be mentioned. There is no concentration cut-off value below which substances in the mixture do not have to be mentioned as was the case in the old EAPCCT guidelines and is currently required in many EU countries (see the Dutch 2007 survey). This is in line with the complete list of ingredients of detergents that should be available for medical personnel according to article 8(3) of Regulation (EC) No 648/2004.

It should be noted that for the SDS, concentration thresholds of 0.1% and 1% are used according to the hazard classification of a substance. The SDS is designed to inform on the intended, occupational use of a mixture by adults and for that purpose the thresholds are relevant. Poison centres have to deal with unusual conditions of exposure or product misuse, such as accidental ingestion in children or deliberate ingestion in suicide attempts. In those cases, every ingredient in a mixture may be of concern.

As the term 'internationally accepted chemical name' is not very clear, a guideline was introduced that is based on article 18(2) of the CLP Regulation on 'the product identifier for a substance'. For practical reasons, it was decided to allow the names 'perfumes', 'fragrances' and 'colouring agents', and (derived from Annex I, 1.4.2 of the CLP Regulation) for substances occurring in nature, 'essential oil of ...' and 'extract of...'. In the case of perfumes, they are usually only present in the mixture in small amounts and can consist of more than 20 substances.

The CAS-number and EC numbers (EINECS/ELINCS) are required if they are available for a substance to facilitate its identification. Other information on 'functional group name' and hazard classification of the substance are voluntary and can help the poison centre to focus quickly on the most important substances in the mixture when making a risk assessment after exposure to the product. Poison centres would like to know if substances in the mixture are nanoformulated or not.

Mixtures with nanomaterials are relatively new and any health problems with these specific mixtures should be monitored closely.

Substance concentrations

On substance concentrations, the 1989 EAPCCT guidelines stated that the actual concentrations on very toxic (T⁺), toxic (T) and corrosive (C) substances and specified concentration ranges for the other substances should be mentioned. When comparing these guidelines with the various requirements in EU countries (as was done in the Dutch survey in 2007), the division between exact concentrations for substances with an important health hazard and ranges for other substances is still a reasonable compromise.

For the new EAPCCCT guidelines it was necessary to translate the requirements in terms of the new classification according to the CLP Regulation. See figure 1 for a comparison between the old and new classification.

It was most important for the working group to define for which CLP hazard classes and categories an exact concentration is required. It was decided to require actual concentrations of substances classified according to the CLP Regulation as:

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

These are the substances that can give the most severe acute effects after exposure and therefore are the most important for poison centres to be able to make an adequate risk assessment. For substances classified in the remaining categories (of lower toxicity) of the above-mentioned hazard classes, an exact concentration is of less importance. For substances in the remaining CLP health hazard classes – '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 exact concentration.

For all other substances, for which an exact concentration is not required, the following defined concentration bands are acceptable: 0-0.1%, 0.1-1%, 1-3%, 3-10%, 10-20%, 20-30%, 30-50%, 50-75%, >75%. When these ranges are used, it should be noted that as poison centres may be confronted with very unusual misuse, such as an injection, a complete and accurate composition should be given on request in exceptional cases.

Reformulation

The composition of a mixture can be changed, for example to improve the product or remove hazardous substances, without it being marketed as a different product. In other words, the product name stays the same, but some of the substances in the mixture will change. In such cases, it is important to renew notification to poison centres. This should be done for any substitution, addition or deletion of one or more substances in the mixture. If the concentration of a substance in a mixture changes so it falls in a different concentration band, this should also trigger renotification. Discussion in the EAPCCT working group focussed on which concentration changes in substances where an exact concentration is needed should require renewed notification. Instead of stating a simple rule like 'with any change in the concentration of a substance of 10% or more' it was decided it would be more practical for companies to use the limits in the change of the initial concentration of a substance as described in Table 1.2 of Part 1 of Annex I of the CLP Regulation. The limits in this table are used to define when a new evaluation of the hazard classification of a mixture is necessary. In this way, the necessity for companies to make a new evaluation

of the mixture would coincide with the need to submit new product information to the poison centre.

Categorisation

Categorisation will be further discussed in a separate item in this brochure.

Classification

The hazard classification and labelling of the mixture, as present on the Safety Data Sheet is requested.

Packaging

For a risk assessment after exposure, it is important to have information on the intake (usually the amount ingested). In addition to information such as 'one or two sips', it is often said that 'half a bottle' was swallowed or 'a complete bottle that was one-third full'. If the intake is unknown, the total amount of a package can be used for a worst case scenario. The package size is mentioned on the product label, but often a patient is brought to hospital without the package of the mixture. Therefore, it is important that this information is notified to the poison centre. There are also types of packages that could influence the outcome of an exposure. For instance, ingestion of a mixture in an aerosol package makes the probable intake low. The same applies to 'ready-to-use' cleaning wipes.

Providing the mixture's label as requested by poison centres, can be useful for cross checking where identification of the mixture is problematic.

Physical/chemical characteristics

The physical state and pH as present on the Safety Data Sheet are requested. If available, it is optional to also give the total reserve acidity/alkalinity where relevant. This can provide valuable extra insight into the corrosiveness of the mixture.

Toxicology

On the current SDS, information on the toxicology of the mixture is limited. With the new REACH Regulation, it is expected that the toxicological properties of the mixture will be incorporated in the SDS in the near future. REACH aims to improve the quality of the available toxicological information on the SDS, as producers and downstream users need to exchange more information on substances and products in the specific context of (the risks of) their use. This information either becomes an integral part of the SDS or has to be supplemented to the SDS as Chemical Safety Reports.

Other information

Other information that can be useful is the date of first marketing of the product and the date the product information form was completed. Under this topic, there is also room for any additional remarks.

The CLP Regulation introduces new hazard classes that are subdivided into hazard categories. For example, the hazard class 'acute toxicity oral' is subdivided into the categories 1, 2, 3, and 4 of decreasing toxicity. The corresponding old classifications that fall in this hazard class are T⁺ with R28 (Very toxic if swallowed), T with R25 (Toxic if swallowed), and Xn with R22 (Harmful if swallowed). For each hazard category specific hazard communication elements are introduced consisting of new pictograms, signal words, hazard statements and precautionary sentences.

FIGURE 1

CLP Regulation (EC) No 1272/2008		Directive 67/548/EEC
Health hazard classes	Categories	Classification
Acute toxicity Oral	1 2 3 4	T* R28 / T R25 / Xn R22
Acute toxicity Dermal	1 2 3 4	T* R27 / T R24 / Xn R21
Acute toxicity Inhalation	1 2 3 4	T* R26 / T R23 / Xn R20
STOT* - single exposure	1 2 3	T* R39 / T R39 / Xn R68 / R37 / R67
STOT* - repeated exposure	1 2	T R48 / Xn R48
Aspiration hazard	1	Xn R65
Skin corrosion/irritation	1ABC 2	C R35 / C R34 / Xi R38
Eye damage/irritation	1 2	Xi R41 / Xi R36
Respiratory sensitisation	1	Xn R42
Skin sensitisation	1	Xi R43
Carcinogenicity	1AB 2	cat.1/2 (T R45/R49) / cat.3 (Xn R40)
Germ cell mutagenicity	1AB 2	cat.1/2 (T R46) / cat. 3 (Xn R68)
Reproductive toxicity	1AB 2	cat.1/2 (T R60/R61) / cat.3 (Xn R62/R63)
Effects on or via lactation		R64

* Specific Target Organ Toxicity

Signal words

Danger **Warning**

T* (Very toxic), T (Toxic), Xn (Harmful), Xi (Irritation), C (Corrosion), R20 Harmful by inhalation, R21 Harmful in contact with skin, R22 Harmful if swallowed, R23 Toxic by inhalation, R24 Toxic in contact with skin, R25 Toxic if swallowed, R26 Very toxic by inhalation, R27 Very toxic in contact with skin, R28 Very toxic if swallowed, R34 Causes burns, R35 Causes severe burns, R36 Irritating to eyes, R37 Irritating to respiratory system, R38 Irritating to skin, R39 Danger of very serious irreversible effects, R40 Limited evidence of a carcinogenic effect, R41 Risk of serious damage to eyes, R42 May cause sensitisation by inhalation, R43 May cause sensitisation by skin contact, R45 May cause cancer, R46 May cause heritable genetic damage, R48 Danger of serious damage to health by prolonged exposure, R49 May cause cancer by inhalation, R60 May impair fertility, R61 May cause harm to the unborn child, R62 Possible risk of impaired fertility, R63 Possible risk of

Health hazard classification of substances and mixtures according to the CLP Regulation (EC) No 1272/2008 (entered into force on 20 January 2009) compared with the classification according to Directive 67/548/EEC.

Reproduced from Clinical Toxicology (2010) 48, 28-33 'The changes in hazard classification and product notification procedures of the new European CLP and Cosmetics Regulation'. R. de Groot, PJAM Brekelmans, J. Meulenbelt. Link to article:

<http://informahealthcare.com/doi/full/10.3109/15563650903376097>

3. Product Identification: A Need For Poison Centres

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Every day, numerous accidents occur in European households due to ingestion of products. In 1995, data from the European Commission indicated that European poison centres (PCs) handle at least 800,000 – 900,000 poison calls per year. Recent data from PCs came to about one million calls. These were inquiries on products used in households, do-it-yourself activities, agriculture, plant protection etc.

The appropriate treatment requires predominantly a precise knowledge of the substances contained in the product, their percentage and their toxic relevance. In emergency situations especially, it is of particular importance to find the exact composition of a product immediately to provide the patient with tailor-made medical treatment in time. Any delay in identifying the product's exact composition will involve the risk of inadequate medical treatment possibly followed by long-term effects or late sequelae or damage for the patient.

Today, the usual product identification is based on the product's trade name, which often leads to considerable time consuming problems for PCs. In Germany, it is estimated that approximately 20-40% of inquiries addressed to PCs cause problems with identification of products. These primarily arise for the following reasons:

- 1) The formulation of the product is not available.
- 2) The formulation is available but the means for electronic research in the database must be improved.
- 3) While having the packaging to hand, doctors, lay persons and others cannot find and pass on the right name of the product on the label or packaging (BfR Survey 2003). To address this last reason, a joint improvement process has been started, based on the experience of the German Poison Committee and the

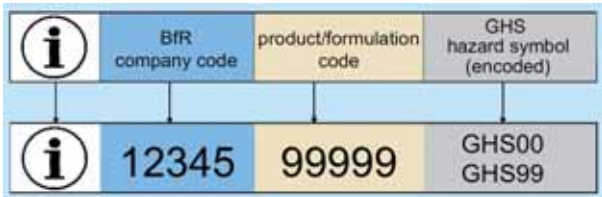
good results of product identification with the former German UBA-Number for detergents.

After initial proposals for a distinct product identification (PI)-area on product labels at the 20th EAPCCT Congress in Amsterdam (2000), a German standardisation committee DIN 'Product Identification' was founded in April 2001 consisting of representatives of the industry, associations, public authorities, science and research, poison centres and consumers. The project was initiated by the Federal Institute for Risk Assessment (BfR) and supported by the German Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) and later by the German Industrial Association (VCI). The aim of the project was to find a graphical and verbal solution that allows simple identification of product names for the consumer.

The first result of this standardisation work was a draft of a German DIN document. This was submitted to the European Committee for Standardisation (CEN) as a proposal for a European standardisation project. From November 2003 onwards, a CEN working group started to design a European standardised product identification project for fast identification of products in the event of an emergency. A graphical symbol ('I' in a circle) has been decided on followed by an unambiguous element of product identification. This element may consist of the product/brand name (possibly abbreviated), the corresponding number of product, registration number (i. e. UBA (Federal Environmental Agency)-number) and/or official registration numbers.

In any case, the identification element shall refer unambiguously to the registered formulations. The graphical symbol together with the identification element will form the area of product identification. This should be located close to the barcode whenever possible, in order to facilitate identification. The CEN standardisation EN 15178 came into force in late 2007.

FIG.X: BfR-PROPOSAL FOR A PRODUCT IDENTIFICATION ELEMENT FOR PRODUCTS



Based on this CEN standard, the BfR has proposed, for better identification in the future, a uniform identification element starting with the i symbol followed by a five digit BfR company code, a five digit formulation code to be assigned by the manufacturer and the official hazard symbol.

In the interest of consumers and worried parents, the BfR hopes that manufacturers and distributors will implement these proposals without delay so that the PI labelling can soon be used as better identification in the future.

However, this standardisation project for elements to identify products on labels and packaging and its design is an international activity to improve consumer protection in cases of suspected poisoning and also in monitoring adverse effects from products.

4. Product Information Versioning

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Need for Product Information Versioning

Poison centres (PC) in Europe respond to several thousand telephone calls on exposure to commercially distributed mixtures (chemical products) every day. Most exposures are assessed for the risk of poisoning and handled in a single phone call within three to five minutes. Fast and reliable access to good product information is a prerequisite for this work.

Therefore, the product entity plays an important role in PC daily work. Typically, exposure to a product raising poisoning concerns is notified to a poison centre. As an important step in the consultation process the product name – and in most cases only the name – is communicated by telephone. In rare cases, selected additional data from the label is communicated orally or a copy or photograph of a product label is sent to the PC.

In an ideal situation, the product name can be easily identified on the label and there is one single formula (one chemical composition) of the product on the market – or more formulae of the product are on the market and a (formula specific) product identification element is provided on the label. One single product information document describes all product formula related data.

In poison centres' daily experience, access to correct product information varies in most cases. Often the product name cannot be reliably identified on a busy label, several formulae of the product are, or have been recently, on the market, no product identification element can be found on the label and a series of product data documents with identical (or very similar) product names are available in the PC database.

Chemical products change in formula, in names, and – last but not least – in safety data. These changes must be

reflected in the product information notified to poison centres. Multiple notifications related to one product may be necessary for many products.

When receiving notifications of product information, it is of great importance for a PC to differentiate between new data and data either updating or amending existing data sets.

Reasons for re-notifying data of a product may be either:

1. A change in submitted data without a change in the product formula or,
2. A change in the formula (chemical composition).

In the first instance, re-notification may be to correct data errors, such as spellings, or to update names or information related to product safety or marketing (e.g. out-of-market date). At the PC, the new data must replace old data, i. e. the correctly identified old data set is deleted by an overwrite procedure or labelled as invalid (i. e. disabled for routine access).

In the second case, if a product formula is changed, while the name on the label is not, the re-notified data must not replace the original data set, although the older dataset may be labelled as outdated by new formula. Both data sets have to be kept visible for the PC officer to be able to differentiate between exposures to both formulae.

Notification of product versions

To enable a PC to differentiate between the different types of product information updates, two identifiers are needed for correct data processing.

1. Product Formula Identifier (PFI)
2. Data Set Version Identifier (DVI)

The Product Formula Identifier (PFI) facilitates identification of a specific product formula on a technical level for controlling data exchange, i. e. to enable recognition whether a new data set may replace an outdated data set:

If a product is notified

- With no PFI in the PC database, then the product is registered as a new product formula entry.
- With a PFI already in the PC database, then the new product data is registered as an update and the new data set replaces the old data set.

It is important to understand that notification of any change in formula has to lead to a change in the Product Formula Identifier (PFI).

Although PC experience shows that this is a critical point, following the criteria in the EAPCCT guidelines (chapter 'Reformulation') it is simple to decide whether a new PFI has to be created or an existing PFI be reused.

The Product Formula Identifier (PFI) and the product identification element on the label as described elsewhere in the brochure have a similar meaning, but on different levels of product identification. The product identification element on the label will become an important voluntary item for product identification and is visible on the label and visible for the PC officer on duty. On the other hand, the PFI will be a technically important mandatory item of the product data format (and for the notification procedure). The PFI will not be visible on the label or for the PC officer. Nevertheless, if there is a product identification element on the label there should usually be a link between the PFI for product information versioning and the product identification element.

The Data Version Identifier (DVI) is used to identify the most recent version of a product formula data set (with identical PFI). As temporal hierarchy must be recorded unambiguously, supplying the date of re-notification is important for data handling protocol.

It is important to understand that notification of a change in product information without a change of formula does not lead to a change in Product Formula Identifier (PFI), but to a change in Data Version Identifier (DVI).

Conclusion

The Product Formula Identifier (PFI) and the Data Set Version Identifier (DVI) should become a mandatory item of the European Harmonised Product Data Exchange Format.

Open discussion points in the EAPCCT working group on CLP Art 45

The Universally Unique Identifier (**UUID**, 1) may be a good technical solution for the Product Formula Identifier (PFI).

Furthermore, a date-time stamp (e.g. YYYYMMDDHHMM) may be a good technical solution for the Data Set Version Identifier (DVI).

Both proposals have to be discussed further within the working group and with other stakeholders.

Reference

1. RFC4122: Leach P, Mealling M, Salz R. "A Universally Unique Identifier (UUID) URN Namespace", July 2005, <http://www.ietf.org/rfc/rfc4122.txt>

5. Product Categorisation

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1 Necessity and usage of categories in poison

Poison centres (PCs) have to handle a huge amount of documents:

- Between 100,000 and 1,000,000 records linked to information on products and other agents in PCs' data bases,
- Between 10,000 and 100,000 cases per year.

To quickly consult documents in an emergency, PCs need Categorisation Systems for Agents (CSA) in their daily work. The CSA is a hierarchical system linked to the index of names for products and agents. With this structure, a scale from complete product groups, such as cosmetics, detergents and maintenance products, to specific product types, like after shave lotions and automatic dishwashing products, is feasible.

PCs use the CSA to:

- Categorise the product to which the exposure occurs during case recording,
- Process and store incoming product information from industry,
- Retrieve comparable products in case of missing product information for the exposed product,
- Retrieve case series in the frame of scientific evaluations, and
- Group cases in annual reports.

2 Does industry need categories? – Lessons we learned from the MAGAM Study

PCs could not judge whether industry benefits by using categories in their work. But in the interaction between industry and PCs, particularly in reply to questions from the former about human exposure to their products, the CSA has shown to be of valuable assistance.

Within the MAGAM study (1) we detected the importance of a CSA to identify human exposure cases (1.8 million cases were checked for six product groups like automatic dishwashing products and drain cleaners). Without a CSA the complete list of product names has to be checked.

3 Process of categorisation within European PCs

The process of product categorisation is mostly done by each individual PC by obtaining product information from the inquirer (physician or exposed person) or by receiving the information before or after consulting with industry. This resulted in a different categorisation of products among PCs.

As industry does not use common harmonised categories in the notification of product information, the categorisation of these products is also not uniform. In this situation, product identification for specific product types within European multicentre case studies is very difficult and time-consuming or not feasible.

4 Experience of the TDI project and the Klinitox working group V

From 1999 to 2006, ten German PCs in cooperation with the Federal Institute for Risk assessment (BfR, Berlin) carried out the research project TDI (Toxicological

Documentation and Information Network) and developed a harmonised CSA for PCs. A first version with 15,000 categories became available in 2006. After finishing the project, a working group of Klinitox (Society of Clinical Toxicology of the German speaking PCs in Austria, Germany and Switzerland) continued further development of the TDI CSA and provided a second version of the system available via the Klinitox website (2). In this way, the system spread to Austria and Switzerland.

The common CSA is now fully accepted by the 11 PCs in the three countries. Meanwhile, some PCs have completely integrated the system into their own data bases and other PCs have built interfaces to their local categorisation systems. In October 2010, Klinitox and the 11 PCs started a data pooling of human exposure cases from the year 2009 according to the common CSA as a first step to a common annual report of German speaking PCs. In March 2011, the Klinitox working group will provide the third version of the CSA as a first complete version with some 23,000 categories and English terms for the three top levels of the system.

5 CPNP: joint venture COLIPA – PCs – example of harmonised product categories

Due to the new European cosmetics regulation a central data base, the Cosmetics Products Notification Portal (CPNP), is under development by the European Commission. Within this project, European PCs and COLIPA, the European Cosmetics Association, devised a draft proposal for common cosmetics products categories – there are 301 – during the last 12 months within a Commission working group. The project will be finalised in 2011 due to the revision of the frame formulations. As of 2012, the European cosmetics industry will classify all products with the common categorisation system during the notification process. Subsequently, all European PCs will receive structured electronically transmitted data on cosmetic products with uniform categories. This will make it easy to do multicentre studies on such products.

6 MAGAM group: first draft version of harmonised detergents categories

As a result of the MAGAM study, the Klinitox working group decided to continue the fruitful cooperation with the industry and started harmonising categories for detergents and maintenance products in January 2010. Active members in the MAGAM group are:

- IKW (German Cosmetic, Toiletry, Perfumery and Detergent Association; Frankfurt/Main
=> domestic products),
- IHO (German Association for Hygiene and Surface Protection; Frankfurt/Main
=> industrial products),
- BfR (Federal Institute for Risk assessment, Berlin), and
- Klinitox (Society of Clinical Toxicology of the German speaking PCs).

During three meetings and four conference calls, the group developed a draft version for detergents and maintenance products categories on the basis of the corresponding sector in the TDI CSA. This draft version is available on the Klinitox website (3).

7 Conclusions

- Poison centres crucially need categories for their daily work,
- Industry and PCs should use uniform product categories,
- Categorisation of products should be performed by the manufacturer/notifier,
- Categories should be transmitted electronically in a structured manner together with other product information,
- With the above conditions, quality of patient care will improve and European multicentre studies will be easier to perform,

- Categorisation systems should be harmonised by the EAPCCT in cooperation with the industrial associations, such as AISE for detergents products and European Coatings for coatings products,
- The draft version of detergents products categories from the MAGAM group could serve as a basis for harmonisation in Europe, and
- The European Commission should ensure appropriate conditions for the harmonisation process.

References

- 1) MAGAM Study: www.klinitox.de/263.0.html
- 2) TDI Categorisation System for Agents in PCs: www.klinitox.de/142.0.html
(see table "TKS Versionen" "Version 2.0", German language)
- 3) Detergents and maintenance products categories (draft proposal of the MAGAM working group): www.klinitox.de/175.0.html



6. Data Exchange Formats for Industry Submitting Mixtures Information to Poison Centres and National Authorities

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Introduction

The workshop on the harmonisation of information for poison centres was organised to foster collaboration between industry, poison centres and national authorities. It aimed to improve existing processes for creating and transmitting information about mixtures placed on the market by industry so that poison centres can successfully manage the potentially toxic exposures that arise. This contribution outlines the IT developments proposed to reach these goals and hopes it will motivate stakeholders to collaborate further on these developments.

Designing a data exchange format

Effective

Effectiveness could be defined as reaching a 'timely delivery of adequate information allowing poison centre specialists to manage exposures to the different mixtures on the market'. The EAPCCT guidelines have been designed to define what the adequate information is.

Checking compliance with current EAPCCT guidelines = checking effectiveness

Efficient

Producing information incurs costs for industry: its sustainability calls for close attention to be paid to efficiency by all stakeholders. We must consider:

- Being 'future proof', by adhering to international standards to lower implementation and maintenance costs. Those standards are designed to be extensive and also flexible to accommodate different industries, such as paint, pesticides and households, for good easy integration into existing processes.
- Reusing existing procedures whenever stakeholders are already satisfied.
- Easing production of data by industry to keep associated costs as low as possible.
- Creating automatic validations for EAPCCT guidelines' compliance in order to detect and correct errors as early as possible.

From past to future

Currently, the main medium to communicate mixtures safety information is Safety Data Sheet (SDS). The SDS production and distribution by companies and their collection by poison centres is already very well organised in many countries. SDS are PDF documents. PDF enables documents to be printed from any computer. This is why PDF content is for human reading only and is not suitable for further processing.

Flexible and future proof

To exchange information, we, therefore, propose to use XML (eXtensible Markup Language) and its schema

definition languages. XML is the worldwide internet standard for that purpose. XML makes possible:

- Additional fields whenever necessary without making previous files obsolete.
- Dynamic reformatting: the information can be presented in different ways using either CSS (Cascading Style Sheets) or XSL (eXtensible Stylesheet Language) to suit readers' needs. PDF files with different presentations can be produced automatically starting from an XML file.
- Automated validation: rules can be applied to validate the individual fields but also ensure coherence between different data fields. Most EAPCCT guidelines could be enforced.

XML basic principles are very simple:

1. XML files are sequences of information elements.
2. Each element of information is 'tagged' to indicate its nature.

Tags surround information and have a beginning <tag> and an end </tag>.

3. Sub-elements can be defined to refine information provided for any element.

For instance:

```
<submission>
  <date>2010-11-24</date>
  <market>be</market>
  <submitter>
    <name>Industrial Detergents Company</name>
    ...
  </submitter>
  <mixture>
    <product-id>...</product-id>
    <trade-name>Industrial Detergent XYZ</trade-name>
    ...
    <composition>
      <ingredient>
```

```
      <cas>7601-54-9</cas>
      <min>3</min>
      <max>10</max>
      <unit>percent</unit>
    </ingredient>
    ...
  </composition>
</mixture>
...
</submission>
```

XML files are not typed by hand. They are produced by software programmes simplifying data entry, collection and transmission. XML is already used by the European Chemicals Agency and in the exchange of product information between poison centres and/or governmental authorities in Germany (TDI project, Rosetta XML) and France (Synapse). It is also employed in many industry applications. We will examine the existing XML applications to see which one could be extended with maximum global benefits in terms of functions, available software and field implementation.

Semantic Web standards (RDF) are not ignored and may be considered by the working group even if today the related tools are not as mature as those for XML.

Improving rather than reinventing

Currently, the submission process varies from one European country to another. The aim of this project is to ensure that:

- A common European format exists to submit mixture data in all countries using similar files. This will simplify life for companies of any size dealing with multiple countries in Europe (efficiency).
- All content submitted in the future complies with the new EAPCCT guidelines (effectiveness). Industry and poison centres will, therefore, move gradually from different national procedures to a common European one.

Different approaches may suit industry:

- Adaptation of the current SDS management software products to also produce mixtures data submission files.
- Open source project to develop modules to be integrated within companies' in-house applications.

Poison centres will also have to invest to support the new common format and benefit from its advantages:

- During a transitional period, some poison centres may translate automatically XML submissions into readable PDF.
- Local database applications will need some adjustments to display ergonomically XML files to poison centre specialists.
- Validation programmes could be developed by a community of computer scientists working for different stakeholders.

Automated validations

Companies are responsible for the mixture information they submit. The quality of the information provided is essential for sound advice from poison centre specialists. Imprecise data generate advice on the 'safe side' often involving unnecessary medical procedures for patients. Today, if a poison centre wishes to implement a validation process, it is manual and very costly. Pre-validated XML data will save workforce hours, stress and delays.

What can be validated automatically?

- Structured data that a machine can analyse following precise syntax rules and numerical ranges.
 - Images or simple textual documents like PDFs cannot be validated efficiently.
- Code or name of the ingredients in the mixtures: look up in controlled vocabularies ingredients with hazard categorisation for each. For instance, CAS 7601-54-9 can be double-checked as being

TRISODIUM PHOSPHATE and, conversely, TRISODIUM ORTHOPHOSPHATE" and be normalised as CAS 7601-54-9.

- Usages for the mixtures (sectoral standardisation of 'normal uses' to be done)
- Accepted values or ranges for each field of information:
 - Compliance with EAPCCT guidelines,
 - Ranges based on classification of ingredients hazards,
 - Knowing the normal usage of a mixture, usual ranges for pH or other quantities.

Examples of support tools

- Web shared service to gather vocabularies (ingredients, usages) and make them easy to integrate within local applications.
- Composition Data Writer:
 - Starting from a cut/paste of ingredients on product labels, or other existing texts, list potential names from vocabularies, such as IUCLID, CAS, INCI, and ask for concentration ranges,
 - Control with EAPCCT rules on concentration ranges,
 - Arrange ingredients according to their concentration, function or hazard category.
- Usage Selection Helper: Starting from existing codes (e.g. Intrastat) or words about a mixture usage, reduced list of usage codes (vocabulary still to be normalised).
- Conversion of every linked document (DOC, Excel, JPG, GIF, TIFF) to a common format like PDF.
- Conversion of a file in the XML mixture data exchange format into a PDF file suitable for human reading (poison centres still without XML processing facilities).

Lowering costs by sharing

A lot already exists with big potential reuse: TDI+Rosetta in Germany, SYNAPSE in France, ECHA IUCLID-5 and

other approaches that have not yet been assessed. We advocate the creation of a permanent working group of people involved in the CLP

Mixtures Information Submission process (poison information and informatics specialists from poison centres, national authorities and industry) to:

- Specify and develop IT tools,
- Publish reference information,
- Maintain and assess the submission process.



7. View of the Italian Competent Authority

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The Italian competent authority decided at the end of the 1990s to apply the principle, included in the Dangerous Preparations Directive (DPD, at that time Dir 88/379/EC, then modified by the Dir 99/45/EC) to create a centralised national database on dangerous preparations for the benefit of the national poison centres to enable them to adopt the appropriate first aid measures with immediate access to the full chemical composition of a preparation in the event of accidental poisoning. The central unit for the implementation of the project was identified in the National Institute for Health (Istituto Superiore di Sanità, ISS), Laboratory of Applied Toxicology. Now this task is managed by the National Centre for Chemical Substances, also in the ISS.

Work on this began in 2000: a fully electronic system was established, based on a client/server platform managed by a dedicated webpage (www.preparatipericolosi.iss.it). Since the project was national, but applicable also to foreign companies selling their products in Italy, everything was also conducted in English. The aim of the project is not only to support the national poison centres, but also to provide a new tool for the central and regional bodies responsible for the protection of public health, including at the workplace.

The main information to provide when registering products is the full chemical composition. Since this data is clearly covered by confidentiality, the database is not open to the general public. Online access is granted only to those poison centres certified by the Ministry of Health as meeting several criteria. The first is the presence of internal facilities to guarantee confidential treatment of the information accessed by consulting the database. Any other requests for data contained in the database from other central or regional bodies have to be checked by the ISS on a case by case basis. The database is operational

24/7. Currently, nine national poison centres have been granted direct online access to the database.

Registration is mandatory in Italy for all dangerous preparations falling within the scope of DPD, and for detergents covered by Regulation 648/2004, irrespective of whether they are classified as dangerous or not. We have experienced a number of practical problems, particularly in the case of preparations containing other preparations as ingredients, where the company responsible for the marketing of the final preparation is usually unaware of the chemical composition of the 'ingredient preparation'. This leads to another difficulty: how to involve in the process foreign companies, many of them outside the EU, guaranteeing them confidentiality of the chemical composition of those 'ingredient preparations' even vis-à-vis the final producer. Another difficulty is the exact identification of the company responsible for marketing the preparation in Italy, particularly in the case of traders. Our interpretation has always been that traders are responsible when they buy the product in Europe and change the original label (e.g. putting their name on it), but they are not responsible when they buy the product in Europe and sell it in Italy without changing the original label.

The electronic forms contain essential information on each preparation. Some of them are mandatory, such as the full chemical composition, while others are optional (e.g. the C&L). Once a new preparation is put on sale, registration in the database has to be made within 30 days from the date it was introduced onto the Italian market. A complete informatics system is in place. Through the a.m. webpage it is possible to register the company in the database, download the client programme (ISS Formula), install it in the PC, use it for preparing the different records (one for each preparation), creating at the end of the process a zip

file which can be uploaded into the central database. Up to now a total of 4,691 companies are registered in the database. The majority are Italian (3,925), other EU (726) and non-EU (40).

The total number of records (preparations) stored in the database is around 1.5 million. With such a huge amount of data any manual intervention is critical. At present, we usually perform complete checks of the data on a random basis, apart of course for the uploads which are automatically rejected by the system. We are investigating possible ways to perform more effective checks, but this requires human resources. We are also working on a new platform which should increase the speed of a search, which is essential in the event of serious poisoning. When such a platform is fully operational, it will be possible to skip the client/server procedure, filling in the forms directly online. This will be a useful tool, particularly for those companies registering very few preparations, while for those with many preparations to register the possibility to work offline will remain available.

We are also working on enforcement. The aim is to provide local inspectors with essential information,

not the chemical composition, to allow them to check whether or not a company has fulfilled all national legislative requirements concerning the national database.

For the future, according to article 45 (4) of the CLP, we welcome any initiative from the Commission aimed at harmonising as far as possible different national measures. The first step could be identification of a core set of data considered essential by the European Association of Poison Centres and Clinical Toxicologists for the work of the European poison centres. On the basis of such a core set of data, a common format in an electronic platform compatible with all Member State systems should be developed.

This common format could be formally adopted to satisfy the requirements of all national databases. This would save industry having to fill in different forms for different databases. A second more ambitious step in the future could be the possible connection of different national databases into a European Network. This would not necessarily adopt a strictly common format and platform, but aim at electronic compatibility between different systems.

8. French organisation of toxicovigilance – Application of article 45 CLP

C. PAUL

French Ministry of Health – November 2010

I. National organisation of toxicovigilance

Current situation

Toxicovigilance is defined as the surveillance of acute or chronic human toxic effects of a substance, a mixture or a pollution leading to alerts, prevention, training or information activities. Toxicovigilance includes analysis of the consequences of human exposure to xenobiotics, detecting risk situations, known or unknown, and evaluating the health impact.

In France, there are ten poison and toxicovigilance centres (Centre Antipoison et de Toxicovigilance – CAPTV or poison control centres) and three toxicovigilance centres (Centres de Toxicovigilance – CTV), located throughout the country under the responsibility of the Ministry of Health. Both types of centre are usually called “CAPTV”. They have two responsibilities as defined by the public health code (article D. 6141-37): to answer 24h/7 the public and health professionals on toxicological risk, whether acute or chronic (the CTV, however, only respond to health professionals during business hours), and to ensure toxicological vigilance (TV). To fulfil their task of risk evaluation of acute or chronic exposure to xenobiotics, CAPTV should have immediate access to data on compositions of chemical products. Data from CAPTV are pooled in a national information system, the SICAP (Système d’Information des Centres AntiPoison), and used to assist telephonic replies and for toxicological and epidemiological studies.

Objectives and challenges

The French toxicovigilance system is intended to alert, prevent and provide accurate and reactive information on the occurrence or consequences of toxic events to national and regional public authorities and to the public. Toxicovigilance, drawing on toxicological and epidemiological assessment, is deeply involved in

surveillance, vigilance and issuing alerts on environmental health. It is essentially based on the activities of the 13 CAPTVs, whose information system is their major resource. Since 2005, coordination of toxicovigilance has been provided by the French Institute for Public Health Surveillance (InVS). It is in charge of organising the National Coordination Committee for Toxicovigilance (CCTV). This committee, including all the CAPTVs, the Ministry of Health – Health General Directorate (DGS) – and other French health safety agencies (AFSSAPS on health products safety, ANSES on environmental and professional risk and food safety), identifies risks and helps assess the health impact of a given situation. The toxicovigilance system includes specialised working groups (medicines, phytopharmaceutical products, chemicals, household accidents, quality and methods) and an operational unit (COTV) for toxicological alerts.

Evolution of French legislation and outlook

French legislation from July 2009 officially establishes national coordination of toxicovigilance by the French Institute for Public Health Surveillance (InVS). The law requires health professionals and industry to declare intoxication cases to the CAPTV, in order to collect information and enable toxicovigilance and detection of toxicological alerts. It also requires industry to declare qualitative and quantitative compositions of dangerous mixtures to the CAPTV. Decrees will spell out these legal obligations and describe the organisation of the national toxicovigilance system. A national commission will be created to develop and evaluate toxicovigilance programmes, while a committee will target expertise. Efforts will be made to improve the ability to detect or respond to alert signals. They include procedures for the national and regional organisations; quality control measures to evaluate the consistency and flexibility of the information system; and studies to identify early warning signals or monitor specific poisons, such as mushrooms, jellyfish or severe injuries. The involvement

of all health safety agencies and adequate funding remain the keystone of the organisation.

II. French information systems: national poison centres' information system SICAP, INRS database SEPIA and DECLARATION SYNAPSE portal

The national poison centres' information system (SICAP) has been collecting in real time for ten years all the information on products and toxic exposure recorded by CAPTV. The SICAP consists of:

- A national database on intoxication cases (Base Nationale des Cas d'Intoxication – BNCI) located in a Paris hospital. It includes data on intoxication cases (1.6 million as recorded in patients' files) registered during telephonic responses by poison centres to toxicological emergencies (RTU).
- A national database on products and compositions (Base Nationale des Produits et Compositions – BNPC) located in a Nancy hospital. It includes validated information on the composition of 200,000 agents, such as substances, mixtures and drugs, essential to CAPTV physicians to carry out their public health mission (RTU, toxicovigilance, expertise, surveillance and alerts).

The BNPC is linked to the BNCI (a case is usually linked to one or more product registers in the BNPC). The CAPTV consults this base to assess risks to a patient when giving an emergency response. The SICAP is the overall essential tool for toxicovigilance. A Decision Information System provides complete and easy ways to analyse the full database, except for personal data. It is updated daily. This makes it possible to establish activity reports, multicriteria queries, studies on products associated with poisoning cases and toxicovigilance surveys. An early detection alert system is planned based on statistical analyses of the number of intoxication cases by class of product or by item, similar to the TESS database in the USA.

In France, data on chemicals products are integrated in two databases: SEPIA for products for professional use in the health and safety research institute (Institut National de Recherche et de Sécurité - INRS) and BNPC (SICAP) for all products concerning consumers and the public. INRS and CAPTV require data on products, in particular compositions, to fulfil their mission to assess and prevent toxicological risk. According to French legislation, confidential information on the composition of products is transmitted following an intoxication, in which case the CAPTV asks the company, or via a voluntary declaration by a company to the CAPTV. Industry is obliged to transmit to INRS information on chemicals classified as very toxic, toxic or corrosive, including CMR categories 1 or 2, within 30 calendar days after being placed on the market.

A portal called DECLARATION SYNAPSE⁷, developed jointly by INRS and CAPTV, allows all manufacturers, importers and distributors responsible for placing products on the market to make easy, quick, unique, secure and reliable product composition declarations. A prerequisite to any declaration is registration with the DECLARATION SYNAPSE service. Registration depends on providing a level 3, PRIS V1 electronic certificate. After registering, each registrant is provided with a personal space entitled 'My declarations'. In this account, they can view previous declarations and update or complete them.

III. Interest in developing a system with exhaustive and precise information

- For public health: to better know the chemicals market to better assess exposure. For studies on a particular substance included in several products, it is possible to assess the number of persons exposed and, as the products are linked to the intoxication cases, to estimate the risk for the population. In France, CCTV studies can be consulted via this link: <http://www.centres-antipoison.net/CCTV/index.html>
- For companies which provide exhaustive and precise information to CAPTV: They are not obliged to be

7 www.declaration-synapse.fr

on call 24h/7 to supply information. This is a quality approach which strengthens the safety of their products for consumers. They can also be informed about poisoning cases in which their products are involved.

IV. Application of article 45 CLP regulation

French legislation requires companies to transmit information to CAPTV and/or INRS – the information is validated and collected in BNPC and SEPIA databases – notably on:

- Composition of chemicals, exhaustive and precise qualitative and quantitative data, including designation name and identification number (CAS, ENEICS);
- Previous uses (categories of use): the list of uses is the same in both BNPC and SEPIA databases;
- Designation of included products in the mixture (composition of included products if known).

With the aim of being more efficient, in the event of intoxication, and when it is necessary to know the exposure of the population to dangerous substances, it seems appropriate to strengthen databases and obtain more data from companies. France is developing the following approach:

- Making it a statutory obligation to give information on all mixtures classified as dangerous by the CLP regulation;

- Helping enterprises, through information and training, to declare correctly the composition and type of use;
- Providing information from other databases (phytopharmaceutical products, biocides, drugs, cosmetics);
- Trying to ensure good correspondence between the composition and the commercial name, using an identification number (in draft, to be discussed with other Members States).

On the harmonisation of PIC requirements on product information for CLP regulation article 45, French authorities are in favour of:

- Qualitative and quantitative information;
- Versioning of submitted product information;
- A unique identification number for each product place on the market. This will also enable identification of each included mixture (more and more products are composed of included mixture of unknown composition);
- An XML exchange format, which is essential to analyse and share data;
- A need to categorise uses (to class each product under one or several uses),
- A need to know the presence of known and classified impurities.

To be able to reach consensus on these PIC requirements, the French authorities call upon the European Commission to set up a working group on the harmonisation of PIC requirements on chemicals information containing representatives designated by each Member State involved.

9. Why poison centres?

Niek Wetser for CEPE

The PIC is appointed by the CA in each country. They give medical advice in the event of emergencies where dangerous chemicals and human health are involved. They are available to give this information 24/7. For this purpose, the PIC needs to have information on which dangerous substances are present in the used products.

Views of the paint industry

We support the PIC concept. This will enable the provision of immediate medical advice on curative measures in the event of emergency health responses, which we as industry cannot provide.

At the moment, we have problems with notifications by country. Every Member State has a different interpretation of the information needed for this task. It takes from one to 15 minutes to notify one formulation. In addition, they all have their own way of receiving the data, such as via a website to be filled per formulation, a CD-ROM or PDF form. The information has to be maintained in all these places. It takes a lot of work to update any formulation change, or change in safety data after any legislative change.

The paint industry is not happy about disclosing all its formulations, as these are our intellectual property. They are the soul of our existence. Up to now, these have been guaranteed in CLP article 45 (2a and b).

We do not have the complete breakdown of all the raw materials. We have to work with the SDS from our raw material suppliers (section 3, with dangerous components.)

With colour mixing systems at the point of sale, we are not able to provide data for every colour on the market. Therefore, we need the possibility of a grouping concept.

Proposal

The data the industry has to deliver should not increase the administrative burden. So, in an emergency, the SDS should give all the information needed to react properly. More and more data on substances are available because of REACH, so the substances mentioned in section 3 are well known after registration and how they should be handled in case of an emergency.

If a physician needs to know more about the formulation for a non-emergency situation he can contact the producer or importer (whose contact data is on the SDS). This contact person can then give the complete chemical breakdown as far as it is known.

The creation of one data base at the European Chemicals Agency will bring many advantages. It knows how to handle large amounts of data, has the organisation already in place and the substance knowledge is available. The PICs have to log in via a secure data line to retrieve the data they need.

CEPE would like to continue to be an active participant in the discussion of the process. This must lead to an effective, accurate PIC database. CEPE knows how and what the paint industry can deliver without raising the administrative burden.



10. A.I.S.E. Welcomes Harmonisation of the Information to be Submitted to Poison Centres

Danielle van Corven-Kloosterman

Dutch Soap Association

A.I.S.E. fully supports the undertaking of the Commission to harmonise the information to be submitted to Poison Centres (PCs), according to Article 45 of CLP and in line with internal market considerations. This initiative offers the potential to harmonise both the product information to be provided to PCs and the means of providing it. This is all the more important given the same products are placed on the market in many different Member States.

The information on composition and properties of substances and mixtures must be sufficient and adequate for the PCs to provide first aid in an emergency. On the other hand, the workload for companies providing such data should remain manageable. Balancing the two needs is essential to deliver a working and workable process, for industry and PCs alike.

Harmonising dataset

In the fast changing world of chemical legislation that includes among others REACH (including SDS), CLP, Biocidal Products Directive and the Detergent Regulation, the workload for industry is high. It is a must to have a dataset consistent with current legal obligations like the SDS and the datasheet for medical personnel.

The use of concentration ranges helps minimise the submission of new information for minor formulation changes which have no added value in an emergency. For A.I.S.E., confidentiality of composition is not a problem so long as the dataset is in line with current legal obligations.

Harmonising provision of data

The development of one European submission platform is fully supported by A.I.S.E. as it would reduce the workload for companies in the mid- to long-term, and ensure that the same data are consistently accessible to PCs in all Member States. In addition, it would be possible to incorporate this obligation into existing SDS and labelling software.

Next steps

The draft EAPCCT guidelines are a good starting point for harmonisation. A.I.S.E. stresses that EAPCCT, the Commission and industry should work together to build a system which is beneficial for all parties involved. **A.I.S.E. would like to participate in working out the details for optimal harmonisation.**

A.I.S.E.

A.I.S.E., the international Association for Soaps, Detergents and Maintenance Products is the official representative body of this industry in Europe. Its membership totals 37 national associations in 42 countries, covering about 900 companies ranging from small and medium-sized enterprises to large multinationals active both in the consumer goods market and the industrial & institutional (I&I) domains. The industry mission is to benefit society by contributing to the sustainable improvement of the quality and comfort of life through hygiene and cleanliness, in a free, competitive and innovative way.

A.I.S.E. industry activities are driven by the Agenda for Responsible Sustainable Cleaning which has as its core objective sustainable development. This agenda is supported by two pillars of activities: developing and promoting voluntary actions and cooperating with stakeholders at EU and local level to achieve a balanced and better regulatory framework.

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Annex I

EAPCCT guidelines 2010

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	<p>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.</p> <p><u>Note to industry:</u></p> <p>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.</p>
– Contact Point(s) in case of emergency	<p>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.</p>

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>
COMPOSITION	
– Substances in the mixture	<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 the mixture. Optional is also to mention if the substances in the mixture are nanoformulated or not (yes/no).</p>

<p>– Substance concentrations</p>	<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>														
<p>– Reformulation</p>	<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 - 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: 10px;"> <tr> <td style="text-align: left;"><u>Initial concentration range</u></td> <td style="text-align: left;"><u>Renotification necessary if initial</u></td> </tr> <tr> <td style="text-align: left;"><u>of the substance:</u></td> <td style="text-align: left;"><u>concentration of the substance</u></td> </tr> <tr> <td></td> <td style="text-align: left;"><u>changes by more than:</u></td> </tr> <tr> <td>concentration ≤ 2,5%</td> <td>30%</td> </tr> <tr> <td>2,5 < concentration ≤ 10%</td> <td>20%</td> </tr> <tr> <td>10 < concentration ≤ 25%</td> <td>10%</td> </tr> <tr> <td>25 < concentration ≤ 100%</td> <td>5%</td> </tr> </table>	<u>Initial concentration range</u>	<u>Renotification necessary if initial</u>	<u>of the substance:</u>	<u>concentration of the substance</u>		<u>changes by more than:</u>	concentration ≤ 2,5%	30%	2,5 < concentration ≤ 10%	20%	10 < concentration ≤ 25%	10%	25 < concentration ≤ 100%	5%
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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>														
CLASSIFICATION															
<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. 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>
<p>- pH</p>	<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>
<p>- total reserve acidity/alkalinity</p>	<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>
<p>TOXICOLOGY</p>	<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>
<p>OTHER INFORMATION</p>	
	<p>Date of first marketing. Date product information form completed. Remarks</p>

<p>TO BE FURTHER DISCUSSED BY EAPCCT CLP WG MEMBERS / INDUSTRY</p>
<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>

European Commission

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