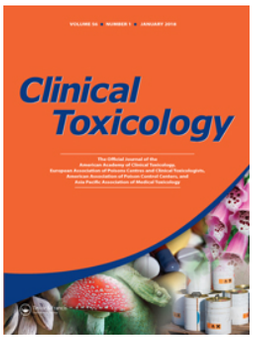

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COMMENTARY

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New legal requirements for submission of product information to poisons centres in EU member states

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ABSTRACT

Introduction: In the past eight years, the European Association of Poisons Centres and Clinical Toxicologists (EAPCCT) has been intensively involved in a European Commission led process to develop EU legislation on the information of hazardous products that companies have to notify to EU Poisons Centres (or equivalent "appointed bodies"). As a result of this process, the Commission adopted Regulation (EU) No 2017/542, amending the CLP Regulation by adding an Annex on harmonised product submission requirements.

Harmonised mixture information requirements: Detailed and consistent information on the composition of the hazardous product will become available to EU Poisons Centres (PC). The information will be submitted by companies to PCs (or equivalent "appointed bodies") using a web-based software application or in-house software. Two new important features are introduced. Firstly, to be able to rapidly identify the product formula, a Unique Formula Identifier (UFI) on the product label links to the submitted information. Secondly, for better comparability of reports on poisonings between EU member states, a harmonised Product Categorisation System will specify the intended use of a product. Rapid product identification and availability of detailed composition information will lead to timely and adequate medical intervention. This may lead to considerable reduction in healthcare costs.
Additionally, for companies trading across the EU, costs of submission of this information will be reduced significantly.

Next steps: From 2017, an implementation period has started, consisting of a three-year period for stakeholders to implement the new requirements, followed by a gradual applicability for consumer products (2020), professional products (2021) and industrial use-only products (2024). Technical tools to generate the electronic format and the UFI together with guidance documents are expected to be made available by the end of 2017 by the European Chemicals Agency (ECHA). Guidance on interpretation of legal text and ECHA helpdesk support are planned to be ready at the end of 2018.

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Introduction

Chemical products containing hazardous substances, like household products, are expected to be safe when used according to instructions. However, adverse health effects as a result of ingestion, inhalation, skin contact or eye contact occur due to accidents, inappropriate use or intentional misuse. The main task of Poisons Centres (PCs) is to inform medical personnel and/or the public about the poisoning risk of the exposure, symptoms and poisoning severity to be expected, about adequate first aid measures and the best medical treatment options. To perform this task adequately, it is crucial that PCs receive information on the composition and properties of products placed on the market. To ensure this, submission of information on hazardous mixtures by companies to PCs (or equivalent "appointed bodies") is a legal obligation according to Article 45 of the Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation) [1].

In 2009, the European Commission (EC) under the auspices of Directorate-General Internal Market, Industry, Entrepreneurship and SME's (small and medium-sized enterprises) started a three-year review period to assess the possibility to harmonise the current varying mixture information requirements and submission procedures in European Union (EU) Member States (MS), [2] as mandated by Article 45(4).

After a positive outcome of the review concerning harmonisation [3] and support from MS Competent Authorities for REACH and CLP (CARACAL) in 2012, the EC strived to reach consensus on harmonised mixture information requirements and submission procedures by gathering input from all relevant stakeholders, that is industries, MS competent authorities and the European Association of Poisons Centres and Clinical Toxicologists (EAPCCT) [4]. In September 2016,

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EU MS voted in favour of a legislative proposal and on 22 March 2017 the Commission adopted Regulation (EU) No 2017/542 [5], amending the CLP Regulation by adding an Annex VIII on "Harmonised information relating to emergency health response and preventative measures". The new requirements will apply from 2020.

This commentary presents the harmonised mixture information requirements, including the Unique Formula Identifier as a link between product label and submitted mixture information, and the harmonised Product Categorisation System to specify the intended use of a mixture. Furthermore, the scope of the submission obligation, as well as costs and benefits of harmonisation and next steps in the practical implementation are discussed.

Mixture information requirements

Table 1 gives an overview of all information items required to be submitted according to Regulation (EU) No 2017/542 [5]. Many items are already available on a Safety Data Sheet (SDS) according to REACH Annex II [6] and thus can easily be supplied by companies. Items not available on the SDS or requiring more detailed information are marked in Table 1 and discussed below.

The submission shall be in the official language(s) of the MS where the mixture is placed on the market, unless the MS concerned provides otherwise (e.g., if submission in English is accepted).

Composition of the mixture

For PCs to make an optimal clinical (toxicological) risk assessment in case of exposure to a product, it is necessary to access detailed product information, especially on the composition. The EAPCCT initially requested a complete formula of the mixture while industry preferred to submit the Safety Data Sheet (SDS) only, thus not meeting these requirements. On the SDS, classified components below a concentration threshold (0.1% or 1%) and non-classified components regardless of concentration do not need to be mentioned [6]. PCs pointed out that non-classified components (e.g., sodium bromide, propylene glycol) may cause adverse health effects (poisoning, allergic reactions or by interaction with

Table 1. Overview of required information items (adapted from PART C of regulation (EU) no 2017/542 [5]).

Identification of the mixture and of the submitter	
Product identifier	Complete trade name of the product (in case of group submission, all product identifiers shall be listed)
	Other names, synonyms
	Unique Formula Identifier(s) (UFI)
	Other identifiers (authorisation number, company product codes)
Contact details of submitter	Name
	Full address
	Telephone number
	E-mail address
Contact details for rapid access to additional product information (24 h/7 days). Only for limited submission.	Name
	Telephone number (24 h per day, 7 days per week)
	E-mail address
Classification of the mixture, label elements and toxicology	
Classification of the mixture and label elements	Hazard class and category
	Hazard pictogram codes (according to Annex V to the CLP Regulation)
	Signal word
	Hazard statement codes, including supplemental hazard information codes (Annex III to the CLP Regulation)
	Precautionary statement codes (Annex IV to the CLP Regulation)
Toxicological information	Description of the toxicity of the mixture or its components (as required in section 11 of the Safety Data Sheet in accordance with Annex II to Regulation No 1907/2006)
Additional information on the mixture	Colour
	pH (where applicable)
	Physical state
	Packaging (type and size)
	Intended use (product categorisation code)
	Uses (consumer, professional, industrial)
Product identifiers of the mixture components	
Product identifiers of the mixture components (substances and mixtures in mixtures where applicable)	Chemical/trade name of the components
	CAS number (where applicable)
	EC number (where applicable)
	UFI (where applicable)
Concentration and concentration ranges of the mixture components (substances and MIM)	Exact concentration or concentration range
Classification of mixture components (substances and MIM)	Hazard classification (where applicable)
	Additional identifiers (where applicable and relevant for health response)

Items requiring new (or more detailed) information as compared to the safety data sheet according to Annex II to REACH [6] are marked with grey background.

food or drugs) and are therefore of concern in individual risk assessments.

As a compromise, for mixture components classified for a health hazard or a physical hazard, a concentration threshold of 0.1% was accepted. Below this threshold, identified components ("known" by the company) must also be indicated unless the submitter can demonstrate that those components are irrelevant for the purposes of emergency health response and preventative measures. In practice, it is expected to come down to a complete list of components classified as such with exclusion of e.g. impurities. All other components, classified for an environmental hazard only or non-classified, have to be indicated if identified and present in the mixture in concentrations equal to or greater than 1%.

Concentration of the components

For the SDS, there are no guidelines on how to indicate the concentration of components in the mixture [6]. In practice, wide concentration ranges are often used. Wide ranges hamper an adequate risk assessment by PCs: using the maximum concentration as a worst-case assumption could lead to an overestimation of the poisoning risk and could consequently lead to overtreatment. The submission of exact concentrations on the other hand, although preferred by PCs, would require frequent submission updates due to small composition changes. Consequently, this would increase costs and administrative burden for industry and the number of data sets PCs have to process.

As an appropriate balance, the use of narrow concentration ranges for all components was accepted (Table 2): instead of predefined concentration ranges with fixed minimum and maximum concentrations, the concept of flexible ranges was introduced. The maximum allowed width of a range depends on the classification of a component (higher hazard, narrower width) and its actual concentration in the mixture (lower concentration, narrower width). For example, a component classified for the highest acute toxicity category (category 1) with an exact concentration of 26% falls in the range of an allowed 5% maximum bandwidth (for situations in which more stringent rules apply, Table 2). The concentration of the component can thus be indicated as follows: 21–26%, 22–27%, …, or 26–31%. Smaller bandwidths or an exact concentration would be welcomed by PCs and can be submitted on a voluntary basis.

Combined, the final outcome of discussions on components in the mixture and their concentration has led to an acceptable compromise between different stakeholder views. It also represents a good compromise in the perspective of current variable requirements on submitted mixture composition details in EU MS (some less, some more stringent).

Generic identifiers for mixture components

Substances in the mixture must be indicated with their chemical name. By derogation of this requirement the generic identifiers "perfumes", "fragrances" and "colouring agents" are allowed if the component (1) qualifies as such, (2) is not classified for any health hazard and (3) to the extent that the concentration of mixture components identified with a given generic product identifier does not exceed a total 5% for the sum of perfumes and fragrances and 25% for the sum of colouring agents.

Table 2. Legislative text on concentration requirements (adapted from regulation (EU) no 2017/542 [5]).

Requirements on concentrations for hazardous components of major concern for emergency health response and preventative measures

When mixture components are classified in accordance with this Regulation for at least one of the hazard categories listed below, their concentration in a mixture shall be expressed as exact percentages, in descending order by mass or volume:

- Acute toxicity, Category 1, 2 or 3;
- Specific target organ toxicity - Single exposure, Category 1 or 2;
- Specific target organ toxicity - Repeated exposure, Category 1 or 2;
- Skin corrosion, category 1, 1A, 1B or 1C;
- Serious eye damage, Category 1;

As an alternative to providing concentrations as exact percentages, a range of percentages may be submitted in accordance with [the table below].

Concentration range of the hazardous component contained in the mixture (%)	Maximum width of the concentration range to be used in the submission
≥25 to <100	5% units
≥10 to <25	3% units
≥1 to <10	1% units
≥0.1 to <1	0.3% units
>0 to <0.1	0.1% units

Requirements on concentrations for other hazardous components and components not classified as hazardous

The concentrations of the hazardous components in a mixture not classified for any of the hazard categories listed [above] and of the identified components not classified as hazardous shall be expressed, in accordance with [the table below], as ranges of percentages in descending order by mass or volume. As an alternative, exact percentages may be provided.

Concentration range of the component contained in the mixture (%)	Maximum width of the concentration range to be used in the submission
≥25 to <100	20% units
≥10 to <25	10% units
≥1 to <10	3% units
>0 to <1	1% units

Unique formula identifier

After exposure, correct identification of the involved product is often problematic. Patients or medical experts have difficulties recognising the correct/complete trade name on the label. As a result, PCs frequently experience problems linking a trade name reported on the phone to the corresponding mixture dataset in the PC product database [7]. To solve this problem, the Unique Formula Identifier (UFI) was proposed [8]. A UFI, both present on the label of a hazardous product placed on the EU market and in the submitted mixture information, will substantially improve product identification. Moreover, with the UFI being formula specific, composition changes over time under the same trade name, can now be distinguished.

Another benefit is the use of the UFI for the identification of "mixtures in mixtures". When a mixture is used as a component in another mixture, the first mixture is referred to as

a "mixture in mixture" (MIM). When a MIM composition is not made available to the submitting company due to confidentiality reasons, the MIM can be indicated with its UFI, trade name and concentration in the mixture. In this case, the MIM composition must be submitted separately (by another party) allowing PCs to deduce the complete composition.

The UFI is a 16-digit alphanumeric code presented in four blocks of four characters. This code is preceded by "UFI" (e.g., "UFI 18CV – C4HJ – P000 – DSFN"). The UFI excludes the letters "L", "I", "B", "Z" and "O" to prevent confusion when read and communicated ("spell-by-phone-friendly") and contains a check digit in order to verify whether the UFI is built correctly. Based on company, VAT number and arbitrary company formulation code, companies can create over 268 million codes per VAT number by use of an algorithm. This high number was deemed necessary for large companies formulating (industrial) mixtures.

An online UFI generator application was developed to allow companies to create UFI's either single or in bulk. Alternatively, the UFI algorithm can be implemented by companies in their own IT system.

Product Categorisation System

A Product Categorisation System is often a hierarchical system with wide product groups on the top level such as "detergents", branching into specific mixture types, such as "dishwashing products" at a lower level. PCs use such systems (1) to retrieve comparable products in case of missing product information, (2) to retrieve case series of specific product type exposures for scientific evaluations and (3) to group exposure cases for statistics, toxicosurveillance and presentation in annual reports.

There was broad consensus between stakeholders to develop a harmonised EU Product Categorisation System in order to improve comparability of PCs' statistics among EU MS, to facilitate European multicentre case studies and to improve rapid identification of cross-border poisoning risks. Furthermore, with such an international Product Categorisation System, it is easier to share information with industry for product stewardship purposes.

In order to develop a harmonised system, stakeholders were consulted and existing categorisation systems used by appointed bodies and industry or present in EU legislation were analysed. The main structure of the resulting harmonised Product Categorisation System is based on the German TDI categorisation system with further levels defined by sector-specific industry associations [9]. Mixtures are categorised according to their intended use only and not on toxicological properties or chemical agent (class) in the lower levels as in some PC systems.

User identification

In the harmonised mixture information, it is a requirement to indicate the intended user: "consumer use", "professional use" (i.e., professional use outside industrial sites) and/or industrial use (i.e., professional use at industrial sites only). This will better enable PCs to provide data on exposure incidence based on user identification in the near future.

Packaging type and size

Type and size of the packaging of a mixture placed on the market is not required on an SDS but is valuable information for PCs. The size of a packaging can give a worst-case estimate of exposure if detailed dose information is lacking and it is only indicated that, for example, "half a bottle" was ingested. Type of packaging can also influence the poisoning risk, for example, ingestion of large amounts is less likely with a spray can where inhalation of aerosol is to be expected. Indication of packaging type will also facilitate studies on poisoning risks related to packaging type as has been performed with detergents contained in a water-soluble film (e.g., "liquid laundry capsules") [10].

Scope of the submission requirements

According to article 45 of the CLP Regulation, companies placing mixtures on the market shall submit information on mixtures classified as hazardous on the basis of their health or physical effects. Submission of information is required for consumer, professional and industrial products alike.

Regardless of current practice, the costs and administrative burden to submit information on professional and industrial mixtures were seen by industry as disproportionate to the limited number of exposure cases, especially for the huge number of industrial mixtures on the EU market ("millions" as estimated by industry).

The majority of PC consultations involve mixtures for consumer use, but PCs are expected to give advice irrespective of product group or exposure setting. Besides, products labelled as "professional" are often generally available, may be used in the domestic setting by professional users and are brought home from the workplace by personnel. The EAPCCT pointed out in stakeholder discussions that mixtures are often more hazardous and poisonings are more severe for professional and industrial products with higher risk for multiple exposed persons after an incident.

As a final outcome of all stakeholder views, it was decided that for consumer mixtures and professional mixtures complete product information must be submitted. For "mixtures for industrial use only" reduced requirements will apply: relevant information contained in the SDS will be submitted, provided that additional information (e.g., a detailed composition) is available on request (24h/7d telephone number).

Further reducing the submission scope, the obligation will not apply to (1) mixtures for scientific research and development (RD), (2) mixtures for product and process oriented research and development (PPORD) and (3) mixtures classified only for one or both of the physical hazards "gases under pressure" and "(unstable) explosives".

Although these exemptions and the limited requirements for industrial mixtures are seen as a reasonable compromise from a cost-benefit perspective, PCs are reluctant to reduce the submission scope. If mixture information is not available,

this hampers rapid and appropriate Poisons Centres' advice. Instead of reducing the scope, PCs would rather receive product information on all mixtures, even if not classified according to the CLP Regulation. It is important to note that "non-classified" does not mean "non-hazardous", especially in case of exposure routes (e.g., ingestion) or suicidal doses that PCs are frequently consulted for. It is interesting in this regard, that REACH[6] Annex II (paragraph 3.2) does require that an SDS should also be available for non-classified mixtures if these contain specified substances of concern, e.g. substances classified as hazardous to health present above 1% (0,2% for gaseous mixtures). Many companies already comply with the request for voluntary submission out of responsible product stewardship, especially when it concerns consumer products.

Electronic submission format

In addition to the product information requirements, article 45(4) also mentions that if harmonisation is possible, the commission should provide a format for the submission of information. In 2015, a prototype of the "Poison Centres Notification (PCN)" format was defined as eXtensible Markup Language Scheme (XML Scheme). XML is a general modern standard for electronic data exchange. Specifically for small and medium-sized enterprises (SMEs) an online software application, "the PCN editor", was developed. After manual input of all relevant product and company information the harmonised format is generated. On the other hand, it is expected that large companies and software companies offering SDS creating software will adapt their IT systems to export the mixture information into the harmonised format.

Submission of mixture information in an electronic format allows appointed bodies to check completeness and quality of information automatically before import. After import, search capabilities could be improved and the information can be presented in the format of the IT system.

Study on costs and benefits

On request by stakeholders, the EC launched a study to assess the costs and benefits of harmonising the EU product submission procedures, as well as introducing the UFI as a labelling requirement [11]. This study concluded that EU harmonisation of mixture submission procedures despite costs for adopting the UFI could overall lead to a net savings for industry of around 550 million euros per year. However, it was noted that companies can be differently affected. The benefit of harmonisation will be greatest for companies trading in multiple countries. At the moment, these companies have to comply with a multitude of mixture information requirements and procedures as adopted in EU MS, which is a significant burden. For companies that only trade domestically within a MS with less stringent mixture information requirements as compared to the harmonised procedure, harmonisation could represent a net increase in costs.

Application of the UFI will both increase the speed of identification and the number of cases where the mixture formula can be unambiguously identified. Together with the availability of detailed composition information this will consequently result in more rapid and accurate medical advice. These improvements can avoid hospitalisation and overtreatment as a precautionary strategy on the one hand and allow more rapid treatment where actually necessary (and thus minimising injury) on the other hand. Preventing overtreatment and timely providing the appropriate treatment when needed may lead to a considerable reduction in healthcare costs.

Adaptation of databases to process the PCN format are one-off costs for PCs. Depending on current procedures for receiving, checking and storing product information, processing the new PCN format could reduce costs, despite an expected increase in product submissions.

Next steps

The new requirements will apply in 2020 for mixtures for consumer use, followed by mixtures for professional and industrial use in 2021 and 2024, respectively. Importers and downstream users placing hazardous mixtures on the market should start preparing for the implementation of the new submission procedure and for the use of the UFI on product labels. Final versions of the PCN format, technical tools to create the format (PCN editor) and UFI together with guidance documents are planned to be ready at the end of 2017. These will be made available by the European Chemicals Agency (ECHA) on the "Poison Centres" website [12]. ECHA Helpdesk support and guidance documents on issues of scope or interpretation arising from publication of Regulation (EU) No 2017/542 [5] are expected to be ready end 2018. Furthermore, the possibility of an online portal at ECHA for centralised submission of product information and further distribution to PC and other national appointed bodies will be explored in 2017.

In the upcoming three years, appointed bodies have to prepare to receive and process information in the new format. Best practice would be to develop an import module for their IT system to automatically process the new information into their database. A complicating matter for appointed bodies is the need to keep existing product information in the old format at least until 2025. The new requirements will gradually apply for products newly introduced on the market and for submission of updated mixture information. If information was submitted before the dates of applicability, it is not necessary to comply with Regulation (EU) No 2017/542 [5] until 1 January 2025. Only from 2025, information on all hazardous mixtures on the market needs to be available to PCs in the new format.

Conclusions

The adoption of Regulation (EU) No 2017/542 [5] on product submission marks the end of a period of extensive stakeholder discussions that started in 2009 and is an important milestone in the harmonisation project.

As a result of this project, detailed and consistent information on hazardous mixtures will become available to all EU Poisons Centres and the mixture formula can be rapidly identified by use of the UFI, leading to better and more appropriate medical response after exposure to hazardous products. At the same time, administrative burden and costs of submission for industry trading across the EU will reduce significantly. Stakeholders should prepare to be ready for the new submission procedure which will gradually replace current national information requirements from 2020.

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Disclosure statement

The authors are affiliated with a Poisons Centre or an "Appointed Body" and are active members of the EAPCCT Working Group on European Regulatory Issues. They participated in the Commission stakeholder discussions as Member State representatives and partially as EAPCCT representatives.

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