

Archivio Europeo delle miscele pericolose: aggiornamenti ed operatività

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Poison Centres Notification Format (PCN)

- The Poison Centres Notification (PCN) format structures the information on hazardous mixtures classified for health or physical hazards to be submitted to the Member States .
- This information has The format is XML based and defined by the requirements laid out in Annex VIII to the CLP Regulation.
- The information includes the full chemical composition, toxicological information, relevant product and mixture details including the intended use ([EuPCS](#)), in addition to the label elements such as the unique formula identifier ([UFI](#)).
- The PCN format aims to harmonise and ensure consistency of the information available to poison centres in cases of poisoning incidents in the EU.
- Version 1 of the PCN format is compatible with IUCLID,

The format is in XML

- PCN format (version 1.0, published on 30 April 2018): the format is made available as a set of XML schema definition files (XSDs).
- There is also a data model that shows all relevant fields and their interconnections to be downloaded at ECHA website.

<https://poisoncentres.echa.europa.eu/it/poison-centres-notification-format> offers some models:

- Part A - Preparing a PCN dossier: this document provides a technical background and offers a practical guide to the industry on how to encode, prepare and complete a dossier compliant with the PCN format. The XML content and the inner structure of the PCN format is explained in a simple manner avoiding technical details or jargons.
 - [Download Part A – Preparing a PCN dossier \(.pdf\)](#)
- Part B - Developers' guide to the IUCLID format: in IUCLID, the exchange of chemical information is facilitated via a zip/archive file with the extension .i6z (IUCLID 6 zip). The information can be exported from one IUCLID 6 installation and imported into another. This file contains information concerning all (inter)related IUCLID 6 entities (documents and attachments), in a well-defined and structured format. This guide explains the structure of the IUCLID file in order for developers to build other systems than IUCLID 6 which can generate this format.
 - [Download Part B – Developers' guide to the IUCLID format \(.pdf\)](#)

Examples of PCN files are also provided both for single and group notifications.

- Download a single notification example (197 KB | .i6z) and the corresponding IUCLID 6-generated report (132 KB | .pdf)
- Download a group notifications example (188 KB | .i6z) and the corresponding IUCLID 6-generated report (156 KB | .pdf)
- *Note: the PCN examples, provided in i6z format are compatible with a future release of IUCLID that will be made available in October 2018 on the IUCLID 6 website. It is currently not possible to import such examples in the current version of IUCLID.*

The Poison Centres Notification (PCN) portal.

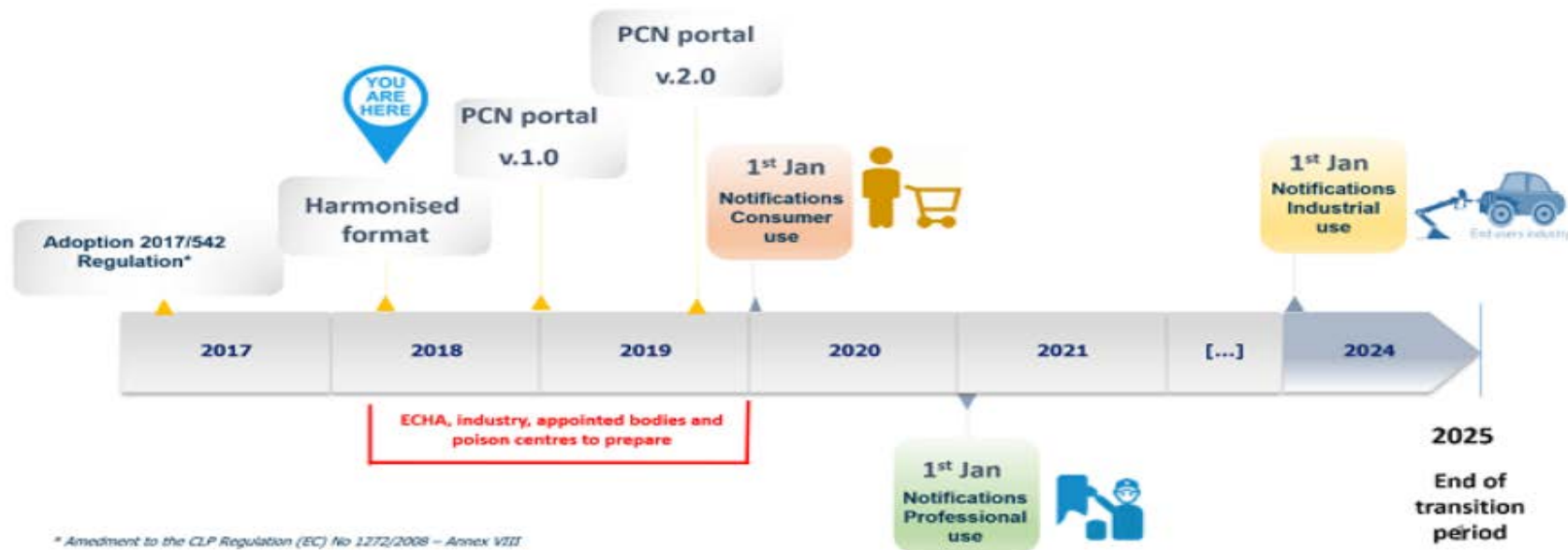
- ECHA has conducted a feasibility study during April-September 2017 to investigate this option.
- The outcome of the study was to recommend the collection and dispatching of notifications via a centralised portal managed by ECHA.
- Following the ECHA Management Board decision in December 2017, ECHA will develop an EU portal enabling submissions from companies, dispatching of submissions to the appointed bodies (and their designated poison centres), and central storage of the submissions for auditing purposes and possible retrieval by submitters.

However, Member States may opt-out and develop their own national submission systems.

- Since the format and requirements for the notifications have been harmonised across the EU, any submission system (be it centralised or national) must ensure that it complies with these legal requirements.
- The first version of the portal will be launched in Q1 2019 with an additional release foreseen for Q3 in 2019.
- In April 2017, ECHA established an IT user group comprised of various stakeholders from Member States and industry to support the feasibility study and to review and assessed functional and non-functional requirements signalled by Member States and other stakeholders

Deadlines

You should notify your mixture BEFORE putting on the market and according to the following deadlines:



The Unique Formula Identifier (UFI)

- UFI establishes an unambiguous link between a mixture and the information submitted to Poison Centres about that mixture.
- It complements the other means used by Poison Centres to identify the source of poisoning as basis for clinical toxicological risk assessment and to propose the right medical treatment. E.g. the UFI will be used to distinguish two formulations sold under the same trade name.
- CLP ANNEX therefore requires to print or affix a UFI on the label of a product and mention the UFI in the submission of information to Poison Centres.
- The UFI shall be unique. Therefore, the same UFI can never be assigned to two different mixtures.
- Practically, this is achieved by constructing UFIs from two parameters:
 - A VAT number, as used in countries of the EEA;
 - A numerical formulation number between 0 and 268.435.455 (included).

https://poisoncentres.echa.europa.eu/documents/22284544/22295820/ufi_what_it_means_en.pdf/576a9a82-c352-b5b3-df73-e763da37e559



In brief

ECHA-18-B-02-EN

The UFI and what it means for your product labels

Key information to companies placing hazardous mixtures on the EEA¹ market

WHEN?

- A new label element will appear on product labels from 2020 – a 16-character code called the unique formula identifier (UFI).
- By 2025, the UFI will be mandatory on the label of all products classified for health or physical hazards.
- Importers and downstream users placing such products on the market, will have to provide specific product information, including the UFI, to poison centres.
- Tools and support to generate the UFI are available on ECHA's Poison Centres website.

WHAT DO YOU NEED TO CREATE A UFI?

- To create a UFI for your mixture, you need your company's VAT number (or 'company key', in specific cases) and a mixture-specific formulation number.
- Entering these two numbers into **ECHA's UFI Generator online tool** will provide you with your UFI code.
- The VAT number is a key element to ensure that your UFI is unique so that no overlap occurs between UFIs generated by different companies.

CAN YOU USE UFIS FOR NON- HAZARDOUS MIXTURES?

- You may find it helpful to assign a UFI to a nonhazardous mixture or to mixtures that are classified as hazardous to the environment only.
- **Voluntarily including the UFI on the label of end products** containing such mixtures would assist poison centres, as knowledge of any product communicated in a poison centre call, classified or not, allows health responders to give more informed advice.



UFI Developers Manual

July 2018

CLEANING PRODUCT



WARNING

Lorem ipsum dolor sit amet, consectetur adipiscing elit. Aliquam dapibus nisi interdum semper elementum. Etiam venenatis lacus at neque varius, vel varius arcu laoreet.

COMPANY

PO Box XXX
Street and number
Postal code, City
Country

INSTRUCTIONS FOR USE

Integer tempus neque ac posuere tincidunt. Sed vehicula facilisis auctor. Suspendisse molestie nunc sit amet velit hendrerit scelerisque. Quisque volutpat euismod leo et feugiat. Quisque sagittis, lectus quis dictum gravida, mauris libero sollicitudin velit, eget elementum libero felis et velit. Duis fringilla aliquam varius. Donec faucibus et felis et tincidunt. Etiam eget felis porta est blandit fermentum in vel enim. Aliquam mattis magna mauris, sit amet mollis ipsum tincidunt sed. Ut sed libero mauris. Ut et urna tempus nisi laoreet fringilla.

UFI: H563-L905-R783-J823



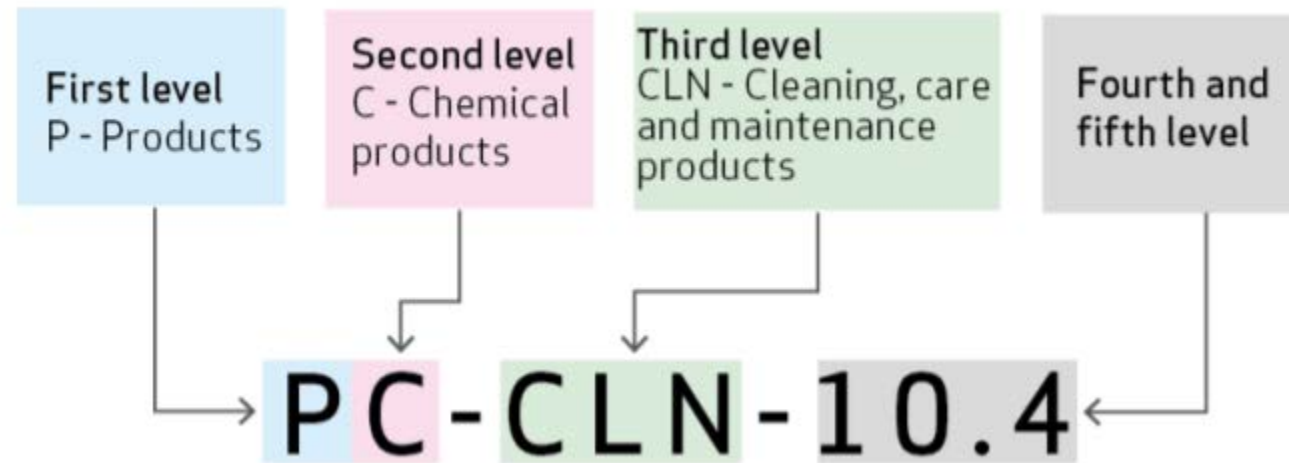
Product categorisation system

- The **intended use of a mixture** shall be described in accordance with a harmonised product categorisation system
- When preparing a submission of information for a hazardous mixture, the submitter must assign a product category which best defines the intended use of that mixture which will be placed on the market.
- The EuPCS categories may also be used for the voluntary submission of information for mixtures not obliged to notification, e.g. detergents that are not classified as hazardous, or hazardous for the environment only

Updating Eu PCS

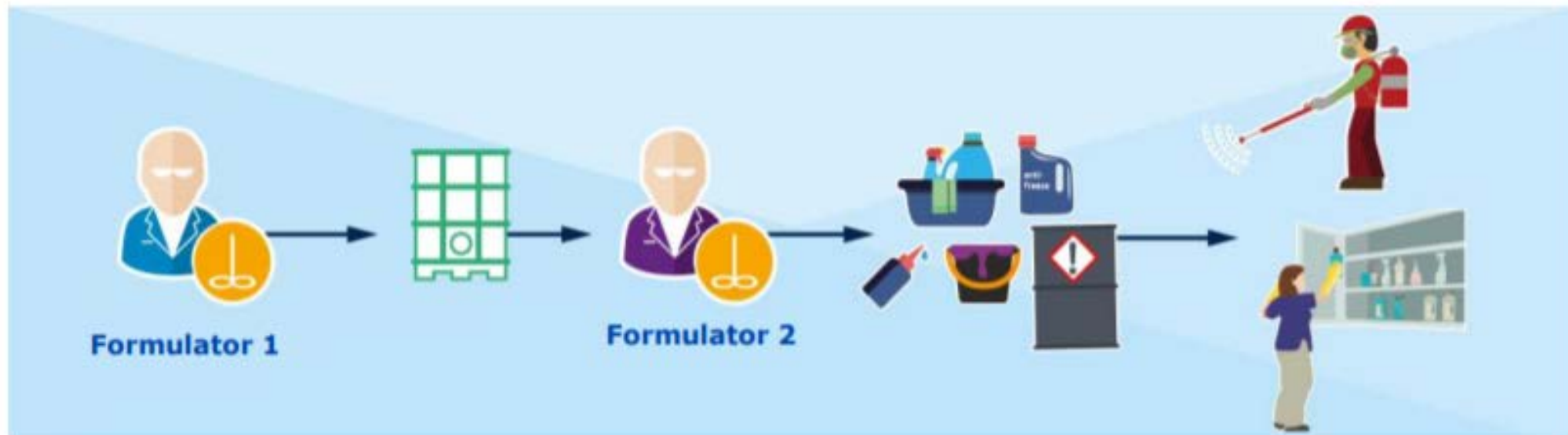
- The **EuPCS is a dynamic system** that needs to reflect legislative changes, industry needs and the requirements for Member States' poison centres and appointed bodies, and as such must accommodate changes that may be considered desirable or necessary.
- A process is currently being established for this purpose and will be made available in the EuPCS section of ECHA's Poison Centres website. An important function of the EuPCS is to maintain a stable system for identifying product categories.
- For this reason, a compelling justification is needed for changing the EuPCS, as the procedure aims to ensure the highest stability possible for the system.
- In cases where an update need is identified, contact your industry association for further advice or clarification.

Individuate your PC



Relationship in the supply chain concerning mixtures for further formulation as well as end use products (e.g. cleaning products, biocides, adhesives, paints, fuels).

Mixtures for further formulation are only used by formulators (e.g. a perfume/fragrance mixture used to formulate cleaning products), whereas end use products (e.g. a detergent) may be for consumer, professional and/or industrial end users.



EuPCS

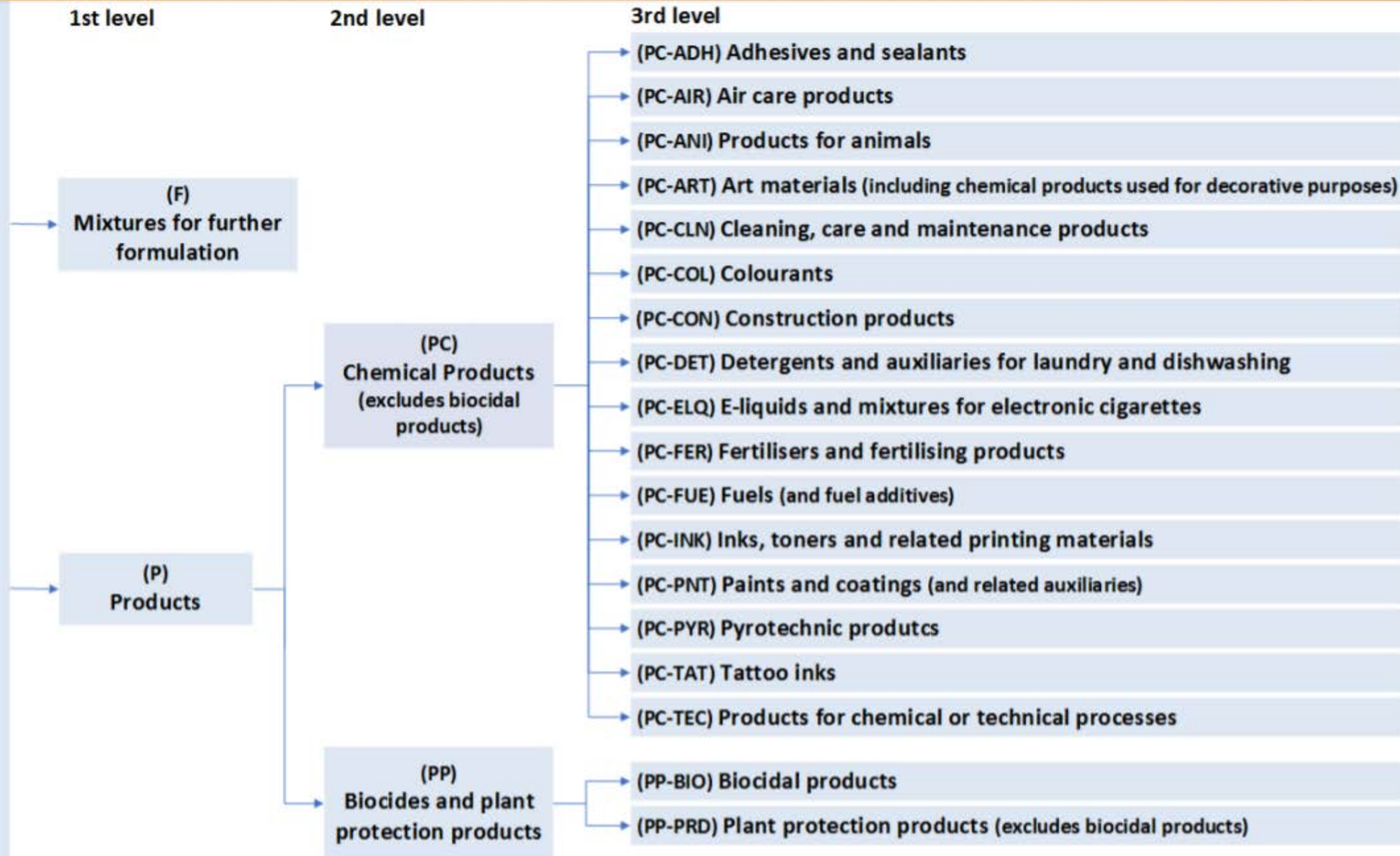


Figure 3: Categorisation of products in the EuPCS to the third level.

BPR and PPR products

- For example, if a disinfecting cleaner for kitchen areas was granted a product authorisation according to the BPR and the product could fit in the category 'PC-CLN-10.1 – Cleaners for kitchen areas' as well as in the category 'PP-BIO-2 – Disinfectants and algacides not intended for direct application to humans or animals', according to the general rule above, the appropriate biocidal product category is to be reflected as the main intended use of the disinfecting cleaner.
- In the case of a product that contains an active substance but does not require an authorisation according to the BPR (i.e. a treated article according to Article 3 of the BPR, that does not have a primary biocidal function itself, such as a decorative paint containing an in-can preservative) or the PPPR, the submitter should determine the main intended use

When no suitable category exists

- In some cases, a suitable product category to describe the intended use may not exist at the lowest level, and the description of the category at the previous level may be better suited to the product, as the concept is wider, for example:
- At the fourth or fifth level: It is possible to select one of the ‘Other...’ categories. The categorisation as ‘Other...’ is always made referencing the higher category under which the product can be placed (e.g. ‘PC-CLN-OTH – Other cleaning, care and maintenance products’).
- At the third level: Where the intended use of the product cannot be linked to the main product group areas (e.g. adhesives, detergents, paints), selecting the category ‘Chemical products - uncategorised’ (category code PC-UNC) may be an option.
- In general, the categories ‘Other...’ or ‘Chemical products – uncategorised’ should be used in exceptional cases and only after the submitter has carefully assessed that none of the more specific categories (including those contained in other third-level categories) can describe the intended use of the product.
- When the selection of ‘Other...’ has been made, it is not possible for the submitter to indicate their own specific product category as free text in the submission.

Group submission

Submission type	Mixture composition	Number of products	Product categories per submission	Remarks
Standard – single product	1	1	1	-
Standard – multiple products	1	Multiple	Multiple – each product can be assigned its own product category	If products within the submission are assigned different product categories, it is recommended that they are linked to a different UFI.
Group submission	Multiple 'similar' compositions (excluding perfumes and fragrances)	Multiple, at least one per mixture composition in the group	1	All mixtures must belong to the same product category

Products fitting multiple categories

- The selection of a product category is based on the intended use of a product. Selecting multiple product categories for a single product is not possible. In some cases, products may correspond to multiple intended uses. In such cases, the categorisation shall be made according to a single main intended use.
- For products that may fit within a subcategory of 'P – Products' (i.e. have an end use) as well as of 'F – Mixtures for further formulation', the main intended use should reflect the end use category which provides more information for the purposes of providing an emergency health response.

REACH product categories		EuPCS product categories
Code	Category label	Category code (and label)
PC1	Adhesives, sealants	PC-ADH – Adhesives and sealants*
PC2	Adsorbents	PC-TEC-1 – Adsorbents
PC3	Air care products	PC-AIR – Air care products*
PC4	Anti-freeze and de-icing products	PC-TEC-2 – Anti-freeze and de-icing products
PC7	Base metals and alloys	1
PC8	Biocidal products	PP-BIO – Biocidal products*
PC9a	Coatings and paints, thinners, paint removers	For example: PC-PNT – Paints and coatings (and related auxiliaries)* PC-ART – Art materials (including chemical products used for decorative purposes)*
PC9b	Fillers, putties, plasters, modelling clay	Including, but not limited to: PC-ADH – Adhesives and sealants* PC-ART-5 – Modelling compounds PC-CON-3 – Gypsum PC-CON-4 – Mortars
PC9c	Finger paints	PC-ART-2 – Finger paints
PC11	Explosives	PC-PYR – Pyrotechnics ²
PC12	Fertilisers	PC-FER – Fertilisers and fertilising products*
PC13	Fuels	PC-FUE – Fuels (and fuel additives)*
PC14	Metal surface treatment products	PC-TEC-12 – Metal surface treatment products
PC15	Non-metal surface treatment products	For example: PC-CON-5 – Construction chemicals PC-PNT – Paints and coatings (and related auxiliaries)*
PC16	Heat transfer fluids	PC-TEC-7 – Heat transfer fluids
PC17	Hydraulic fluids	PC-TEC-8 – Hydraulic fluids, including brake and transmission fluids
PC18	Ink and toners	PC-INK – Inks, toners and related printing materials*
PC20	Processing aids such as pH-regulators, flocculants, precipitants, neutralisation agents	PC-TEC-17 – Processing aids
PC21	Laboratory chemicals	PC-TEC-19 – Reagents and laboratory chemicals
PC23	Leather treatment products	Including, but not limited to: PC-COL – Colourants* PC-TEC-10 – Leather treatment products (excludes dyes and pigments) PC-CLN-16.5 – Impregnation products for finished textiles and leather goods

PC24	Lubricants, greases, release products	PC-TEC-11 – Lubricants, greases, release agents
PC25	Metal working fluids	PC-TEC-13 – Metal working fluids
PC26	Paper and board treatment products	Including, but not limited to: PC-TEC-14 – Paper and board treatment products (excluding dyes) PC-COL – Colourants*
PC27	Plant protection products	PP-PRD – Plant protection products (excluding biocidal products)*
PC28	Perfumes, fragrances	PC-TEC-6 – Fragrances
PC29	Pharmaceuticals	1
PC30	Photochemicals	PC-TEC-15 – Photochemicals
PC31	Polishes and wax blends	PC-CLN – Cleaning, care and maintenance products (excluding biocidal products)*
PC32	Polymer preparations and compounds	PC-TEC-16 – Polymer preparations and compounds
PC33	Semiconductors	1

PC34	Textile dyes, and impregnating products	Including, but not limited to: PC-COL – Colourants* PC-TEC-23 – Textile treatment products (excluding dyes and pigments) PC-CLN-16.5 – Impregnation products for finished textiles and leather goods
PC35	Washing and cleaning products	PC-CLN – Cleaning, care and maintenance products (excluding biocidal products)* PC-DET – Detergents and auxiliaries for laundry and dishwashing (excluding biocidal products)*
PC36	Water softeners	Including, but not limited to: PC-DET-2.1 – Detergency boosters and in-wash stain removers PC-TEC – Processing aids
PC37	Water treatment chemicals	Including, but not limited to: PC-TEC-17 – Processing aids
PC38	Welding and soldering products, flux products	PC-TEC-24 – Welding, soldering and flux products
PC39	Cosmetics, personal care products	¹
PC40	Extraction agents	PC-TEC-21 – Solvents and extraction agents
PC41	Oil and gas exploration or production products	PC-TEC-18 – Products used in mining, oil or gas exploration processes
PC42	Electrolytes for batteries	PC-TEC-4 – Electrolytes for batteries
PC0	Other	For example: ...-OTH ³ – Other... PC-UNC – Chemical products – uncategorised

PCS Guideline



The European product categorisation system: A practical guide

June 2018

Special cases raised by Industry

- Colour mixing systems and group submissions
- Petroleum mixtures
- Perfumes and fragrances
- Klinker/concrete

Colour mixing systems and group submissions

- Many paints, printing inks etc. comprise ranges of similar mixtures, with the same properties, performance and hazards but in different colours
- Some ranges can number many thousands of discrete mixtures, particularly in the case of mixing systems – Tinting on demand/at point of sale: standard colours and/or custom colour matches
- Such ranges are obvious candidates for group submission
- This should be supported by the ability to use the generic identifier ‘colouring agents’ (up to a maximum of 25% total)

Petroleum derivatives

- Petroleum products are mixtures and made according to technical specifications but composition of mixtures vary in the supply chain.
- Changes in composition of mixtures do not change hazard classification, because the most severe hazard classification and labelling is recommended as default for all possible mixtures of components listed in the SDS.
- The proposed maximum widths of concentration ranges in Annex 1 will result to high number of submissions for the same product.

Perfumes/fragrances

- Use of the generic name “perfume” severely restricted in the final text adopted
- Unclear provisions and wording used in the text, e.g. “perfumes and fragrances” vs “perfume or fragrance components”
- High number of updates expected for minor changes in perfume variants;

Notification of “perfume” in a detergent mixture: practical example

Fabric Conditioning Liquid

Classification:

Non-classified;
EUH208 for BIT

Current way of reporting

Substances	Concentration range
Aqua	≥ 10%
Ditallowylethyl Hydroxyethylmonium Methosulfate	≥ 10%
Isopropyl alcohol	≥ 1%, < 10%
Dimethicone	< 0.1%
Benzisothiazolinone	< 0.1%
Etidronic Acid	< 0.1%
Calcium chloride	< 0.1%
Glyceryl stearate	< 0.1%
Polysorbate 60	< 0.1%
Cellulose Gum	< 0.1%
Silica	< 0.1%
Parfum	≥ 0.1%, < 1%

Proposed way of reporting

Substances	Classification (health or phys/chem hazards)	Concentration range
Aqua		75-95%
Ditallowylethyl Hydroxyethylmonium Methosulfate	Skin cat 2, Eye cat 2 Flam liq 2, Eye cat 2, STOT SE 3	5-15%
Isopropyl alcohol	Flam liq 2, Acute tox 3, Skin cat 2 Eye cat 2, STOT SE 3	0-3%
Dimethicone	Acute tox 4 Skin cat 2 Skin sens 1	0-0.1%
Benzisothiazolinone	Eye cat 1 Acute tox 4 Metal corr 1	0-0.1%
Etidronic Acid	Eye cat 1	0-0.1%
Calcium chloride	Eye cat 2	0-1%
Glyceryl stearate		0-1%
Polysorbate 60		0-1%
Cellulose Gum		0-1%
Silica		0-1%
Perfume	Skin cat 2, Eye cat 2, Skin sens 1	0.5-0.8%
Perfume Ingredient 1	Skin sens 1B Skin cat 2, Eye cat 2,	0-0.1%
Perfume Ingredient 2	Skin sens 1	0-0.1%
Perfume Ingredient 3	Eye cat 2	0-1%
Perfume Ingredient 4	Skin cat 2	0-1%
Perfume Ingredient 5	Skin cat 2, Skin sens 1B	0-0.1%
Perfume Ingredient 6	Skin sens 1B Skin cat 2,	0-0.1%
Perfume Ingredient 7	Eye cat 2 Acute tox 4,	0-1%
Perfume Ingredient 8	Eye cat 2	0-1%
Perfume Ingredient 9	Skin sens 1B	0-0.1%
Perfume Ingredient 10	Eye cat 1 Acute tox 4, STOT RE 2	0-0.1%
Perfume Ingredient 11	Skin cat 2, Eye cat 2	0-1%
Perfume Ingredient 12	Acute tox 4	0-1%
Perfume Ingredient 13	Eye cat 2, Skin sens 1B	0-0.1%
Perfume Ingredient 14	Acute tox 4, Skin cat 2, Skin sens 1,	0-0.1%
Perfume Ingredient 15	Repr tox 2	0-0.1%
Perfume Ingredient 16	Skin sens 1B	0-0.1%
Perfume Ingredient 17	Eye cat 2 Acute tox 4, Acute tox 3,	0-1%
Perfume Ingredient 18	Skin sens 1	0-0.1%
Perfume Ingredient 19	Skin cat 2	0-1%
Perfume Ingredient 20	Acute tox 3 Skin cat 2, Eye cat 2,	0-0.1%
Perfume Ingredient 21	Repr tox 2 Acute tox 4, Skin cat 2,	0-1%
Perfume Ingredient 22	Eye cat 2, Repr tox 2	0-1%
Perfume Ingredient 23	Skin cat 2, Eye cat 2	0-1%
Perfume Ingredient 24	Eye cat 2	0-1%

Source:
AISE

Klinker/concrete producers position:

- Every cement manufacturer should make more than 90 registrations for its product (and therefore UFI) to the Poison Center.
- Cement has a single classification under CLP / REACH (which is not linked to the % of its components but depends only on the presence of clinker – notified as dangerous substance).
- The number of registrations would be the consequence of the extreme narrowness of the ranges that identify the components of the mixtures.
- The UFI must be reported on the cement bag and on the delivery documents.
- The cement industry consumes two million bags a year and therefore orders must be managed many months in advance.
- The increased diversification of products in relation to the UFI would increase costs and would complicate the management of the bags with very high waste.
- A valid solution could be to adopt the "single group submission" for all cements, according to the hazard classification, adopting larger concentration ranges (25% - 100%) for the components (clinker).

Klinker/concrete producers position:

To provide Appointed bodies with single SDS and single UFI for each company at MS level will generate additional burden with no additional added value for PCs

Concentration ranges applicable to hazardous components of major concern for emergency health response (substances or MIM)

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

Width of concentration range of clinker $\gg 5\%$

Width of concentration range of SnCl $> 0.3\%$

Width of concentration range of flue dust $> 1\%$

Cefic concern over IT delays and Commission's 2020 cut-off

It will be "impossible" for the European Commission to deliver the IT tools needed for the 1 January 2020 deadline for harmonised information relating to emergency health response (poison centres), according to Cefic, the European chemical industry body.

This is because of delays and unresolved issues, it says.

The deadline falls under [Annex VIII](#) of the classification, labelling and packaging (CLP) Regulation.

It will require importers and downstream users to notify national appointed bodies if they are placing hazardous substances on the market, specifically for consumer use, by this date.

Trade associations and member states have been commenting on the requirements at recent meetings of the competent authorities for REACH and CLP (Caracal).

In a paper published after the 12 June meeting, Cefic said that with 18 months to go, the Commission would be unable to "deliver results for a quality workability study" and solve "highly important issues".

Grazie

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