

Art. 45 Reg. CLP: implementazione e sviluppi del format europeo per le miscele pericolose.

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Scope of harmonised European PCS

- ▶ The system would cover mixtures self-classified as hazardous based on their health effects and physical properties (cfr. Article 45 of the CLP Regulation).
- ▶ In addition, the system would contain other categories of products (e.g. cosmetics, pharmaceuticals, etc.).
- ▶ These additional non-CLP categories are for accident tracking and reporting purposes within a poison centre.
- ▶ Information on products belonging to these additional categories is to be submitted on a voluntary bases only.

ANNEX

'ANNEX VIII

HARMONISED INFORMATION RELATING TO EMERGENCY HEALTH RESPONSE AND PREVENTATIVE MEASURES

PART A

GENERAL REQUIREMENTS

1. Application

- 1.1. Importers and downstream users placing on the market mixtures for consumer use, within the meaning of section 2.5 of Part A of this Annex, shall comply with this Annex from 1 July 2019.
- 1.2. Importers and downstream users placing on the market mixtures for professional use, within the meaning of section 2.5 of Part A of this Annex, shall comply with this Annex from 1 July 2020.
- 1.3. Importers and downstream users placing on the market mixtures for industrial use within the meaning of section 2.5 of Part A of this Annex, shall comply with this Annex from 1 July 2023.
- 1.4. Importers and downstream users having submitted information relating to hazardous mixtures to a body appointed in accordance with Article 45(1) of Regulation (EC) No 1272/2008 before the dates of applicability mentioned in sections 1.1, 1.2 and 1.3 and which are not in accordance with this Annex, shall not be required to comply with this Annex until 1 January 2025.



This Annex shall not apply to mixtures classified only for one or more of the following hazards:

- (1) Gases under pressure;
- (2) Explosives (Unstable explosives and Divisions 1.1 to 1.6)

2.3. In the case of mixtures placed on the market for industrial use only, submitters may opt for a limited submission, as an alternative to general submission requirements, in accordance with section 5.3 of this Part and section 3.1.1 of Part B, provided that a rapid access to additional detailed product information is available in accordance with section 1.3 of Part B.

2.4. For the purposes of this Annex the following definitions shall apply:

- (1) ‘Mixture for industrial use’ means a mixture intended to be used at industrial sites only;
- (2) ‘Mixture for consumer use’ means a mixture intended to be used by consumers;
- (3) ‘Mixture for professional use’ means a mixture intended to be used by professional users but not at industrial sites.

Where mixtures have more than one use, the following requirements for all relevant categories shall be met.

INFORMATION CONTAINED IN A SUBMISSION

1. Identification of the mixture and of the submitter

1.1. Product identifier of the mixture

The product identifier shall be provided in accordance with Article 17(2) and Article 18(3)(a).

The complete trade name or names of the mixture shall be provided, including, where relevant, brand name, name of the product and variant names as they appear on the label, without abbreviations and enabling its specific identification.

In addition, the UFI(s) shall be included in the submission.

1.1.1. Group submission

In the case of a group submission, all product identifiers for the relevant mixtures shall be provided according to the criteria listed in section 1.1.

1.2. Details of the submitter

The name, full address, telephone number and e-mail address of the submitter shall be provided. This information shall be consistent with the data provided on the label in accordance with Article 17(1)(a).

1.3. Telephone number for rapid access to additional product information

In the case of a limited submission as laid down in section 2.4 of Part A, a telephone number for rapid access to additional detailed product information services shall be provided. It shall consist of a telephone number accessible 24 hours per day, 7 days per week at which rapid access to detailed additional product information in the language provided in section 3.3 of part A is available for appointed bodies during emergencies.

INFORMATION CONTAINED IN A SUBMISSION

2. Hazards identification and additional information

This section sets out the health and physical hazards of the mixture and the appropriate warning information associated with those hazards, as well as the additional information to be included in a submission.

2.1. Classification of the mixture

The classification of the mixture for health and physical hazards (hazard class and category) shall be provided in accordance with the classification rules in Annex I.

2.2. Label elements

The following labelling elements required in accordance with Article 17 shall be provided, if applicable:

- hazard pictogram codes (Annex V);
- signal word;
- hazard statement codes (Annex III including supplemental hazard information);
- precautionary statement codes.

2.3. Toxicological information

The submission shall include the information on the toxicological effects of the mixture or its components contained in Section 11 of the Safety Data Sheet of the mixture, in accordance with Annex II to Regulation (EC) No 1907/2006.

2.4. Additional information

The following additional information shall be provided:

- the type(s) and size(s) of the packaging used to place the mixture on the market for consumer or professional use;
- the colours and the physical states of the mixture, as supplied;
- the pH of the mixture (where applicable the pH shall be indicated for an aqueous solution of the mixture; in that case the concentration shall be expressed in % w/w);
- product categorisation (see section 3.4 of Part A);
- use (consumer, professional, industrial).

INFORMATION CONTAINED IN A SUBMISSION

3. Information on mixture components

3.1. General requirements

The chemical identity and the concentrations of the components contained in the mixture shall be indicated in the submission in accordance with sections 3.2, 3.3 and 3.4.

3.1.1. Requirements for mixtures for industrial use

In the case of a limited submission as laid down in section 2.4 of Part A, the information to be submitted on the composition of a mixture for industrial use may be limited to the information contained in the Safety Data Sheet in accordance with Annex II to Regulation (EC) No 1907/2006, provided that additional information on the components is rapidly available on request in emergencies in accordance with section 1.3.



Use of German TSK + REACH Product Categories as a structure for EU PCS

- ▶ The main structure of the European PCS will be based on the German TDI-CSA/TKS system up to **three levels** of categories and cross-referenced to the corresponding REACH Product Categories.
- ▶ Further levels of product categories (e.g. the fourth and fifth level) will be based either on the categories already defined in the Commission legislations, such as for example Biocidal Products Regulation, or on the categories defined by the sector-specific industry associations.
- ▶ These detailed product categories will serve as a 'building blocs' of a European PCS.
- ▶ For some specific case products, such as biocides and pesticides, an indication of the presence of an active substance in the mixture could be included in the section on composition.



Structure and number of category levels

- ▶ Harmonised European PCS should have a hierarchical structure with 3-4 levels, but internationally recognised and used categorisation systems, such as WHO ATC, would be used even if they have more than 4 category levels.
- ▶ First category, coded with letter “**E**”, **Products**, includes “anything manufactured and traded including solutions ready for use and gases that develop through degassing /evaporation of parts of products or during processes of hardening (without combustion)”.
- ▶ Second category, coded with letter “**N**”, **Natural environment**, includes “anything from the environment taken and not processed or treated in any way”.
- ▶ Third category, coded with letter “**R**”, **Waste**, “means any substance or object which the holder discards or intends or is required to discard as defined in the EU Waste Framework Directive.”
- ▶ Fourth category, coded with letter “**U**”, **Unclassified/unknown items**, defined as “anything not identified from a composition perspective (unknown). Anything identified from the composition perspective, but no suitable category from intended use perspective (unclassified).”

EU PCS main categories

E_

Products

N_

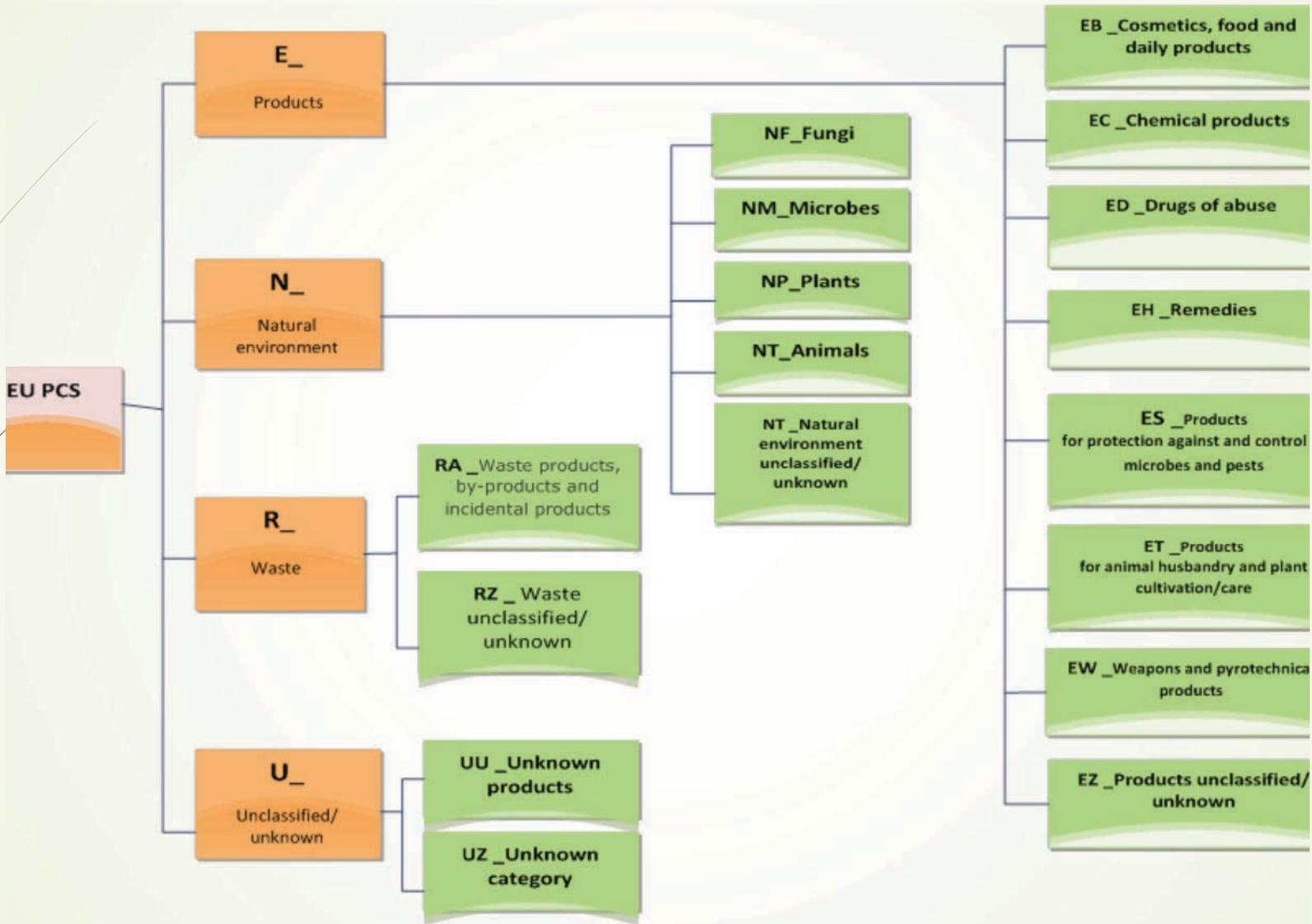
Natural environment

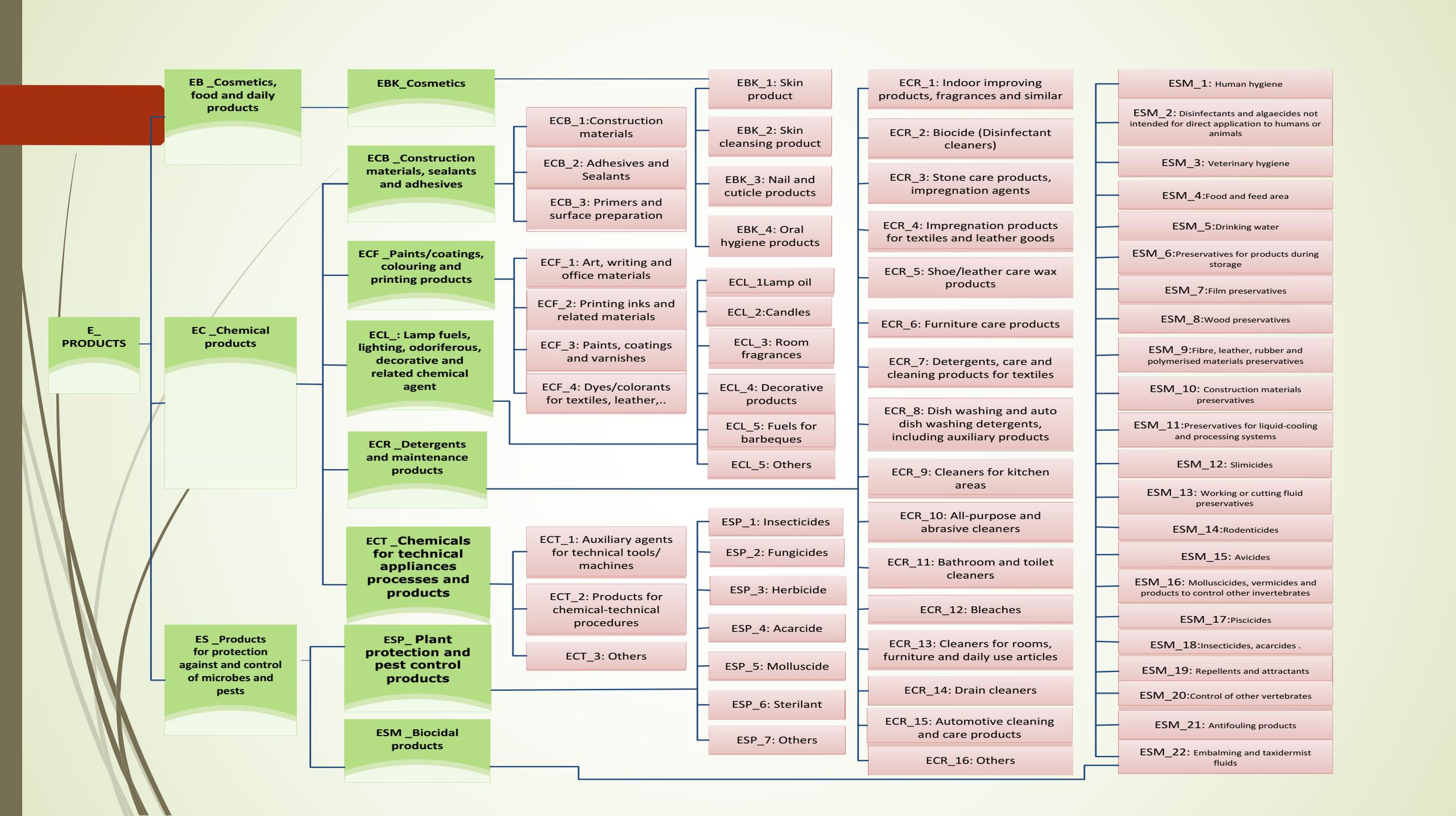
R_

Waste

U_

Unclassified/Unknown





6 different types of products

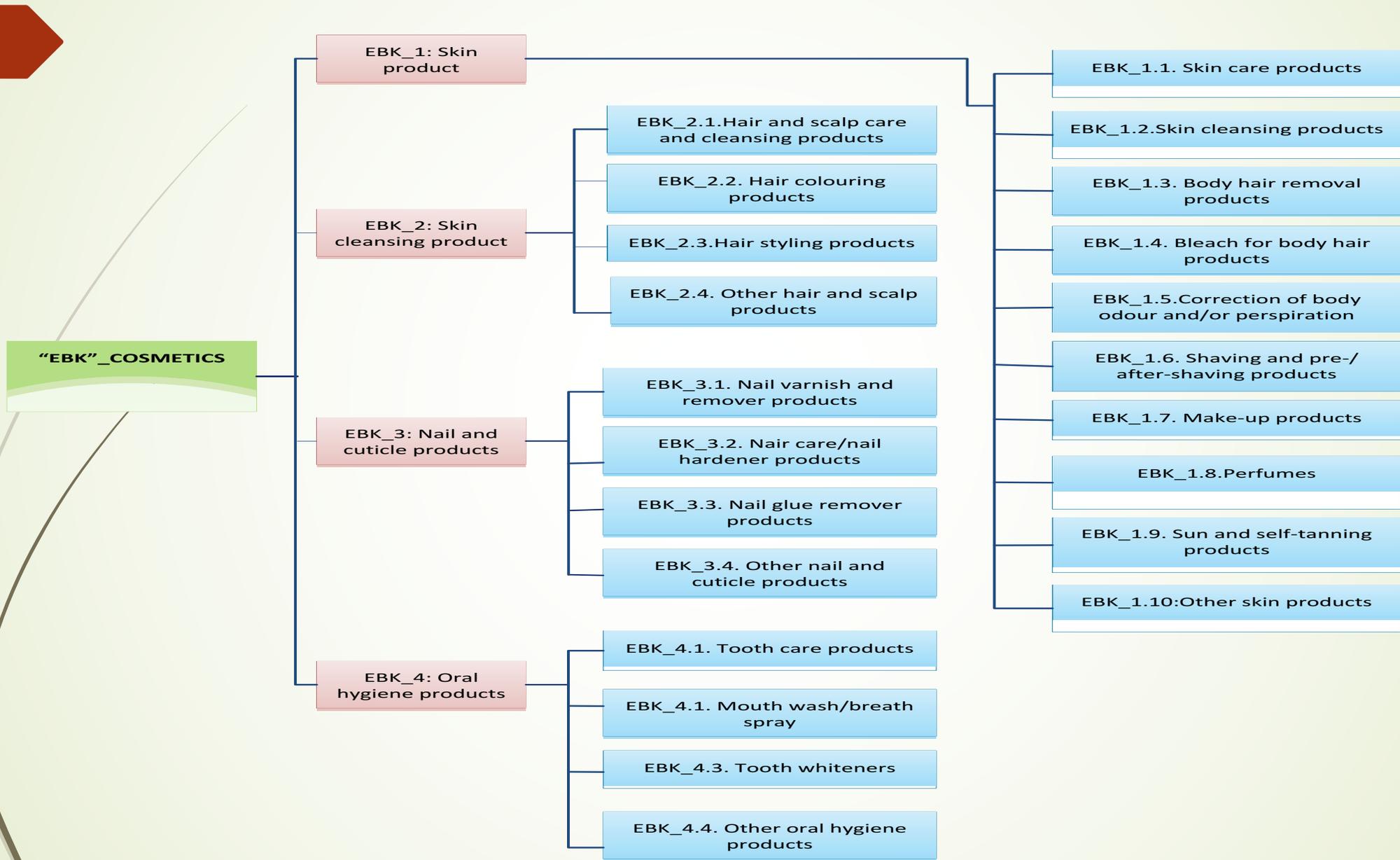
TKS code	TKS_name	TKS_definition	EUPCS code	EU PCS_name	EU PCS_definition (proposed)
E	Products		E	Products	
EC_	Chemical/physicochemical products	Products, whose chemical or physicochemical effects in their application are used.	EC_	Chemical products	Substances, mixtures, and mixtures-in-mixture, as defined in the REACH and CLP Regulations, and also other relevant EU legislation for construction chemicals, paints, etc.
ECB_	Construction materials, sealants and adhesives	Products for construction, adherence and protection of buildings (without biocides, but including fireproofing agents)	ECB_	Construction materials, sealants and adhesives	Products for construction, adherence and protection of buildings (without biocides, but including fireproofing agents)
ECF_	Paints, varnishes and dyes	Coats of paint including adjuvants (i.e. solvents, primers, additives), as well as painting, writing, drawing, office, printer and textile paints and dyes.	ECF_	Paints/coatings, colouring and printing products.	Coats of paint including adjuvants (i.e. solvents, primers, additives), as well as painting, writing, drawing, office, printer and textile paints and dyes.
ECL_	Lamp fuels, lighting odoriferous, decorative and related chemical agent.	Lamp oil, candles, room fragrances, decoration products/fuels for barbeques, camping and fire-eating/igniters.	ECL_	Lamp fuels, lighting, odoriferous, decorative and related chemical agent.	Lamp oil, candles, room fragrances, decoration products/fuels for barbeques, camping and fire-igniters.
ECR_	Detergents, cleaning and maintenance products	Not provided	ECR_	Detergents and maintenance products	Products as defined by the EU Regulation on Detergents.
ECT_	Chemicals for technical appliances processes and products	Products of a chemical-technical nature (lamps, batteries, thermometers...), auxiliary agents for technical tools/machines (lubricants, refrigerants, frost protection agents, hydraulics, fuels,...), and products for chemical-technical procedures (photography, electroplating, welding, soldering...)	ECT_	Chemicals for technical appliances, processes and products	Products of a chemical-technical nature mainly for professional use (lamps, batteries, thermometers...), auxiliary agents for technical tools/machines (lubricants, refrigerants, frost protection agents, hydraulics, fuels,...), products for chemical-technical procedures (photography, electroplating, welding, soldering...)
ECZ_	Chemical/physicochemical products-others/unknown	Not provided	ECZ_	Chemical products-unclassified/unknown	Products not identified from composition perspective (unknown products). Products identified from the composition perspective, but no suitable category from intended use perspective.



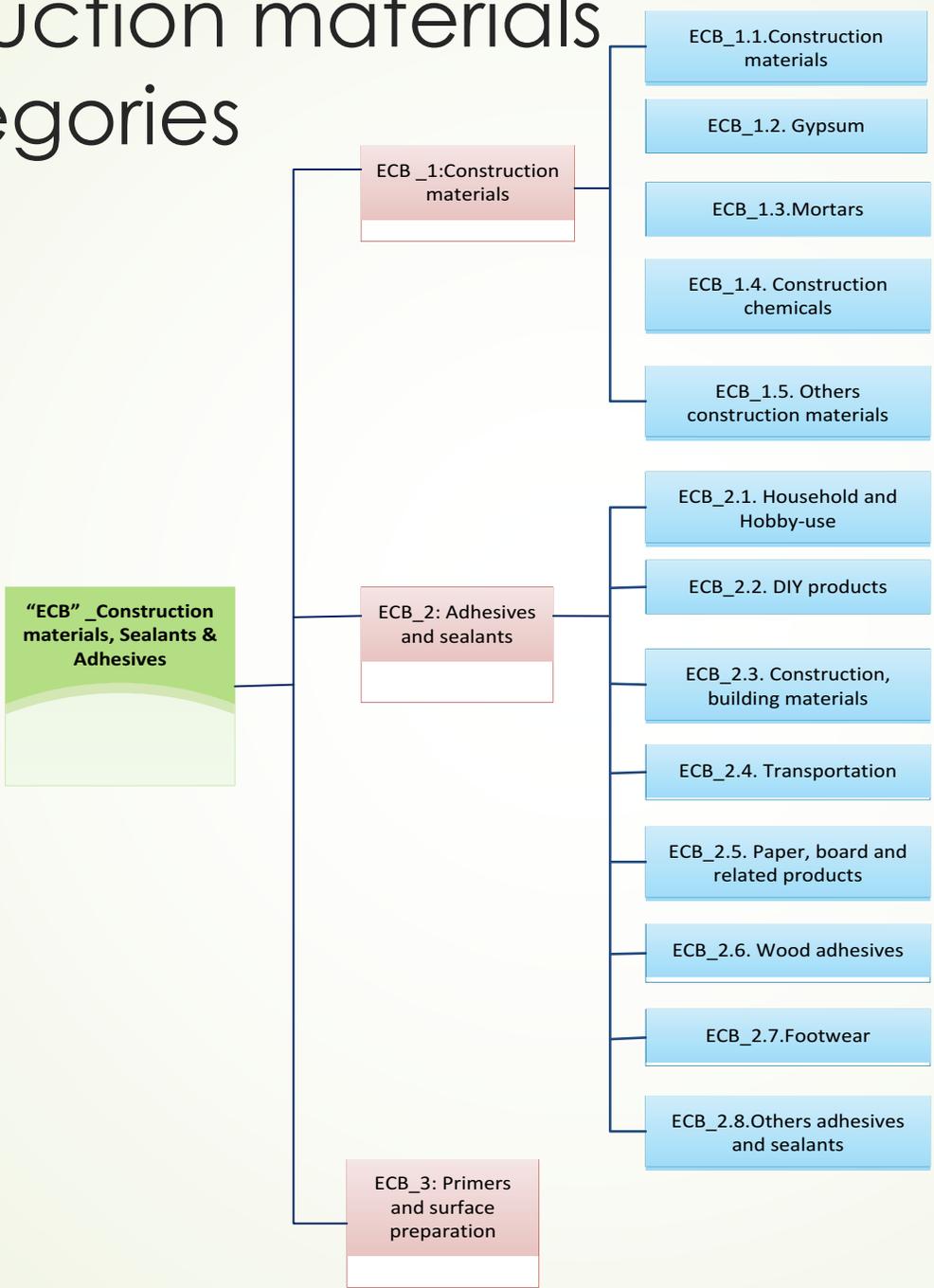
The fourth and fifth level categories for selected product categories of harmonised EU PCS

- ▶ The fourth and fifth level categories of the European PCS are based on the categories that are already harmonised (e.g. Cosmetics) or are defined in the relevant EU legislations (e.g. Biocidal Products Regulation, Regulation on pesticides statistics) or they are proposed from the sector-specific industry associations (e.g. International Association for Soaps, Detergents and maintenance products (A.I.S.E.)).

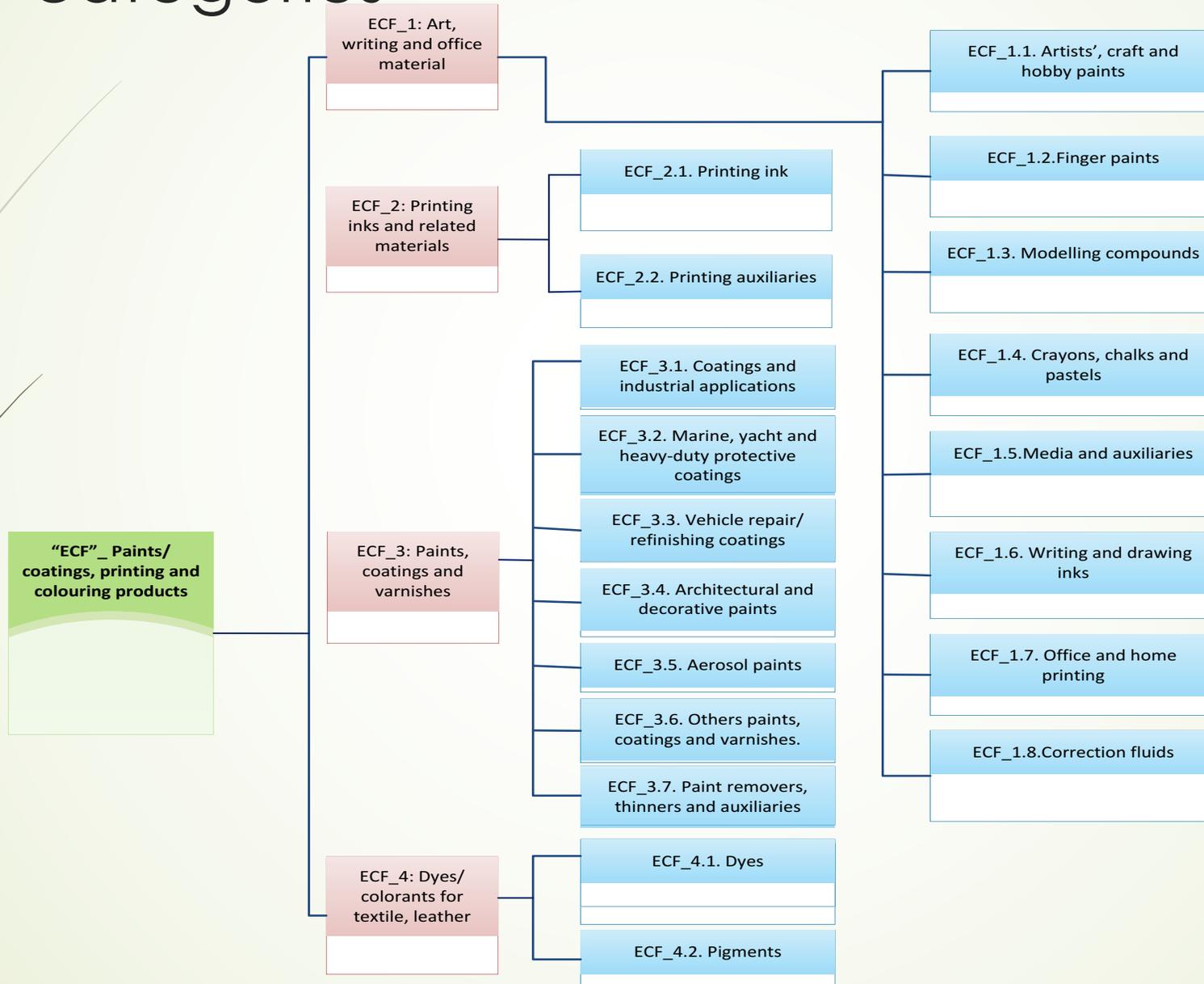
EBK Cosmetics subcategories



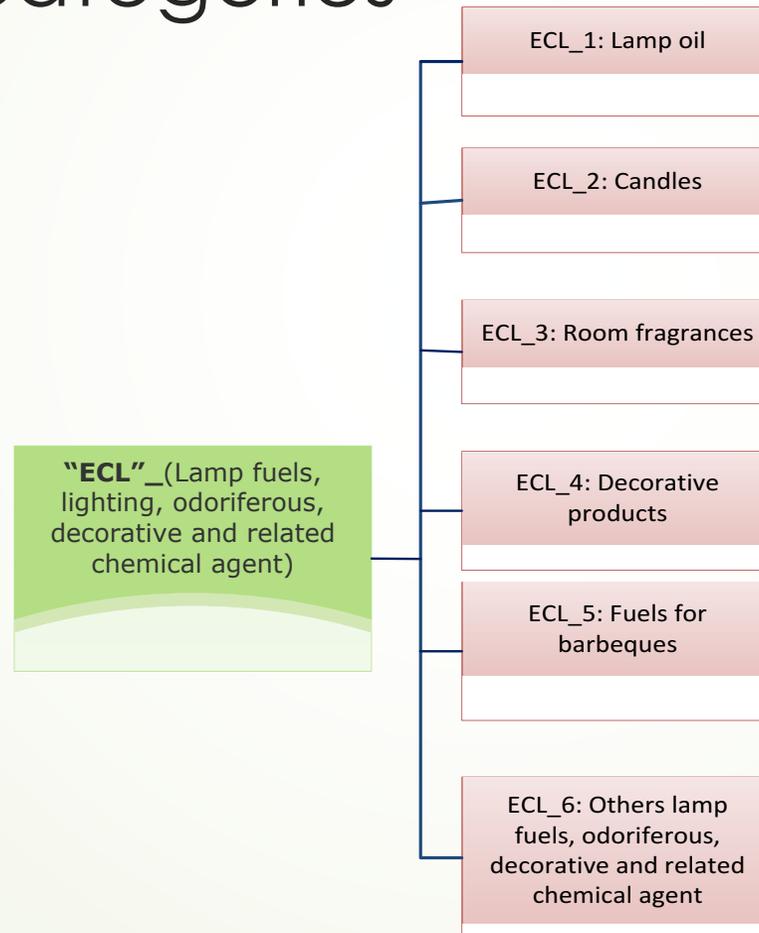
ECB Construction materials subcategories



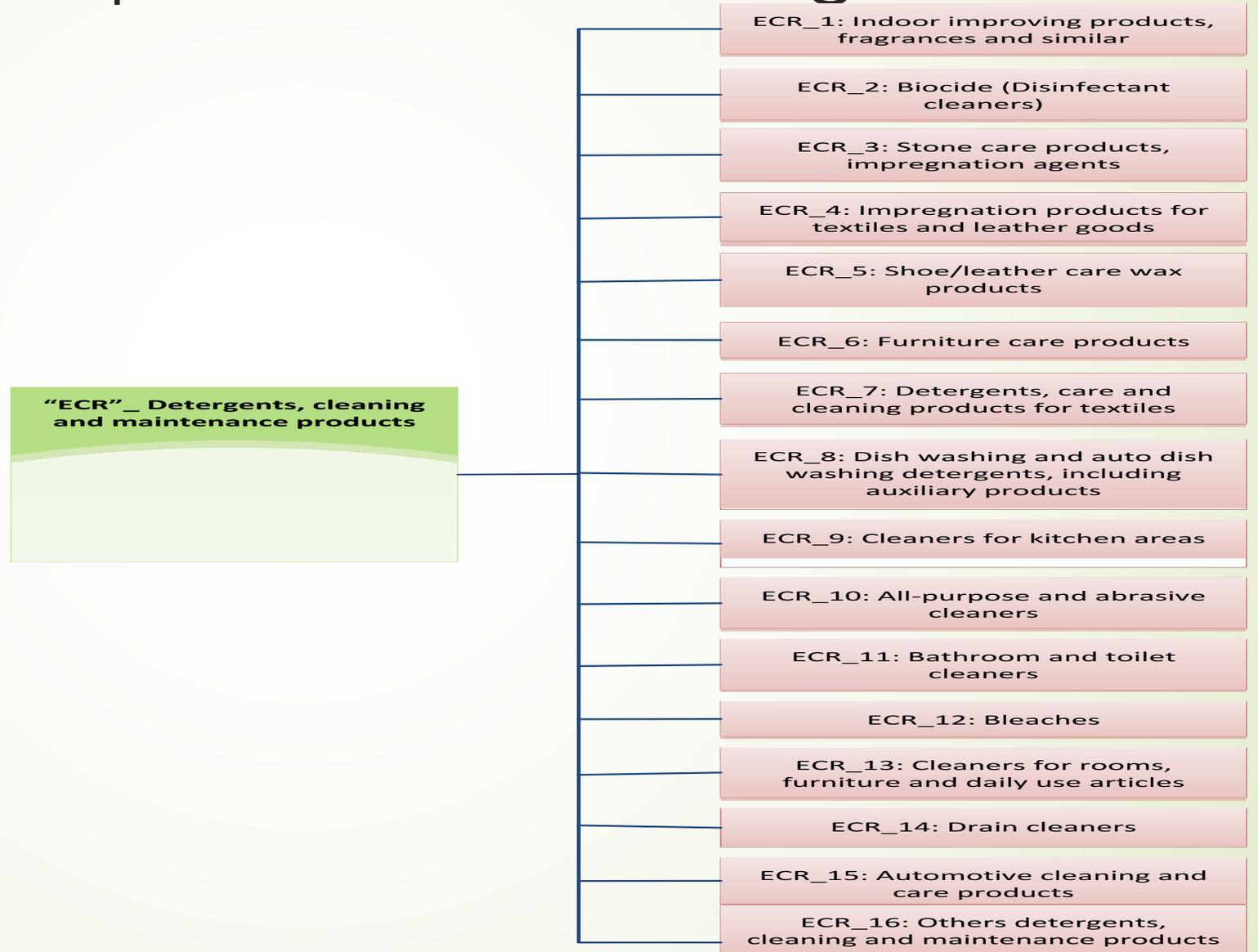
ECF Paints/coatings, printing and colouring products sub-categories



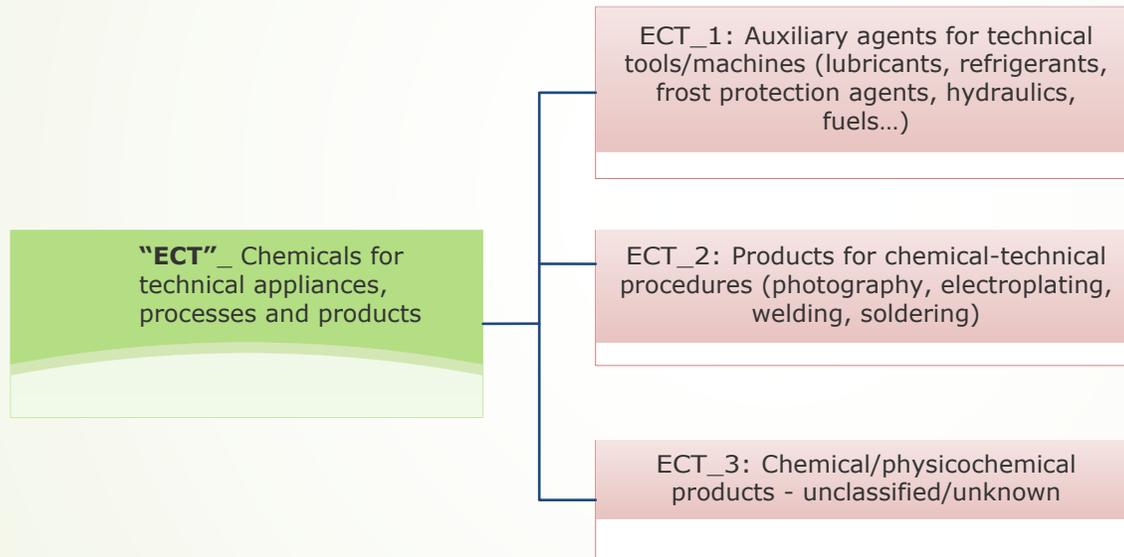
ECL Lamp fuels, lighting, odoriferous, decorative and related chemical agent sub-categories



ECR Detergents, cleaning and maintenance products sub-categories



ECT Chemicals for technical appliances, processes and products subcategories



ESM Biocides (subcategories= 22 PTs)

"ESM"_ Biocidal products

ESM_1: Human hygiene

ESM_2: Disinfectants and algaecides not intended for direct application to humans or animals

ESM_3: Veterinary hygiene

ESM_4: Food and feed area

ESM_5: Drinking water

ESM_6: Preservatives for products during storage

ESM_7: Film preservatives

ESM_8: Wood preservatives

ESM_9: Fibre, leather, rubber and polymerised materials preservatives

ESM_10: Construction materials preservatives

ESM_11: Preservatives for liquid-cooling and processing systems

ESM_12: Slimecides

ESM_13: Working or cutting fluid preservatives

ESM_14: Rodenticides

ESM_15: Avicides

ESM_16: Molluscicides, vermicides and products to control other invertebrates

ESM_17: Piscicides

ESM_18: Insecticides, acaricides

ESM_19: Repellent and attractants

ESM_20: Control of other vertebrates

ESM_21: Antifouling products

ESM_22: Embalming and taxidermist fluids

ESP PPPs subcategories

**"ESP" _Plant
protection and pest
control**

ESP_1:
Insecticides

ESP_2:
Fungicides

ESP_3:
Herbicide

ESP_4: Acaricide

ESP_5:
Molluscide

ESP_6: Sterilant

ESP_7: Others
plant protection
and pest control



Group submission



4. Group submission

- 4.1. A single submission, hereinafter 'group submission', may be provided for more than one mixture where all the mixtures in a group have the same classification for health and physical hazards and the information in that submission covers all the composition variants of the mixtures in a group in accordance with section 1.1.1 of Part B for each of those mixtures.
- 4.2. A group submission shall only be permitted when the concentration of a component (substance or mixture in mixture) present in the group of mixtures lies within the concentration range, as provided in section 3.4 of Part B.



Ranges



- Declarations will be made according to defined ranges
- Currently proposed ranges have been subject to a request of derogations by the following sectors:
 - Fragrances and perfumes (AISE)
 - Petroleum producers (CONCAWE)
 - Concrete producers (CEMBUREAU)
 - Varnishes, paints and dyeing producers (CEPE)

UFI (Unique Formula identifier)

- ▶ The UFI is a unique alphanumeric code that unambiguously links the submitted information on the composition of a mixture to a specific mixture.
- ▶ It is meant to complement the other means used by PC 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 or confirm that the formulation was correctly identified based on the information present on the label of the product.
- ▶ The UFI is part of the information submitted to the appointed body in the XML file format



UFI



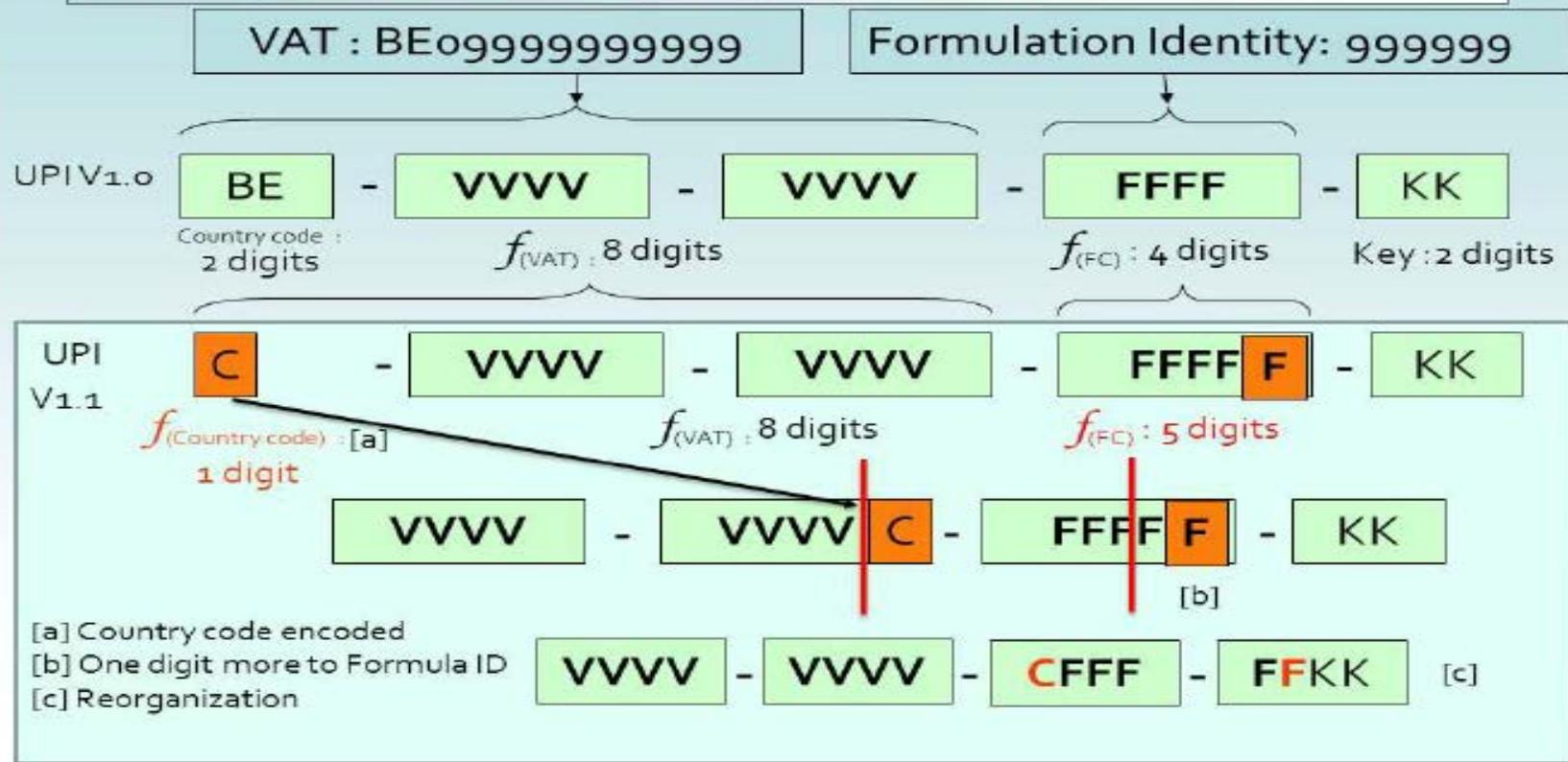
- 5.1. The submitter shall create a Unique Formula Identifier, hereinafter UFI, by electronic means made available by the Agency. The UFI is a unique alphanumeric code that unambiguously links the submitted information on the composition of a mixture or a group of mixtures to a specific mixture or group of mixtures. The assignment of a UFI is free of charge and it shall be provided in the format set out in Part C.

A new UFI shall be created when a change in the composition of components in the mixture fulfils one or more of the conditions foreseen in points (a), (b) and (c) of the third indent of section 4.1. [of Part B.](#)

A new UFI shall not be required for mixtures containing perfumes or fragrances provided that the change in the composition only concerns those perfumes or fragrances.

- 5.2. The submitter shall print or affix the UFI on the label or on the packaging of a hazardous mixture supplied for consumer and/or professional use. The UFI shall be preceded by the acronym "UFI" in capital letters and it shall be clearly visible, legible and indelibly marked.
- 5.3. In the case of a limited submission referred to in section 2.4, the UFI shall be indicated only in the Safety Data Sheet.

UPI generation : proposition for V1.1



Placing the UFI on the mixture label

- The submitter shall print or affix the UFI on the label of a hazardous mixture supplied for consumer and/or professional use.
- The UFI shall be preceded by the acronym "UFI" in capital letters and it shall be clearly visible, legible and indelibly marked.
- The UFI should remain clearly visible and legible when the package is opened in the recommended way.
- The UFI should be placed, by order of preference, depending on what information present on the product, near
 - a) The phone number of the poison centre,
 - b) The product identification under norm [DIN EN 15178],
 - c) The CLP pictograms,
 - d) The bar code,
 - e) The company address,
 - f) Black is the preferred colour, fonts and character sizes are not imposed.



UFI: an added value

- ▶ The UFI will certainly be a useful search criteria when it comes to narrowing down a search and disambiguating first search results based on the mixture name for instance.
- ▶ Poison Centre's applications must thus be completed with adequate search feature integrating the UFI as an important criterion.
- ▶ Additionally, Poison Centre's applications may benefit from error detection provided by the UFI checksum digit and possibly automatically highlight close matches in case of error.



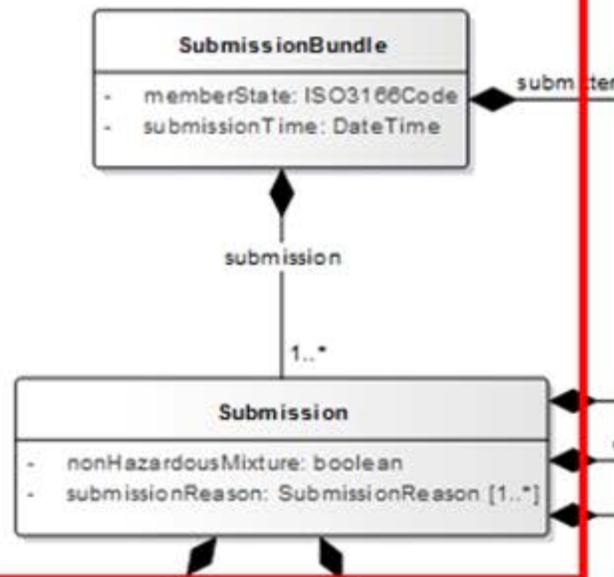
IT tools



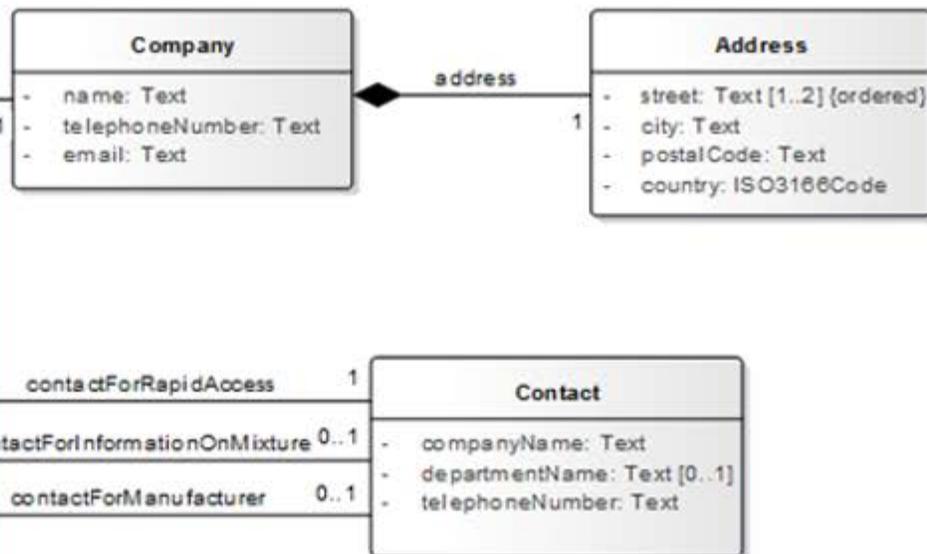
6. Formats and technical support for submission of information

- 6.1. The Agency shall specify, maintain and update the UFI generator, the XML formats for submissions and a harmonised product categorisation system and make them available free of charge on its website.
- 6.2. The Agency shall provide technical and scientific guidance, technical support and tools facilitating the submission of information.

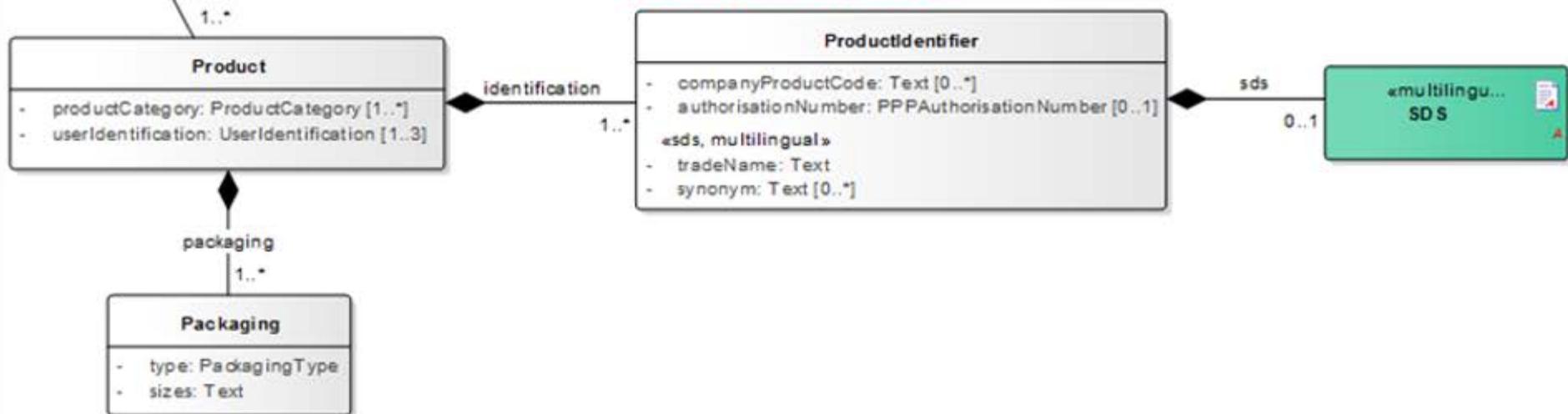
Administrative information



Submitter information

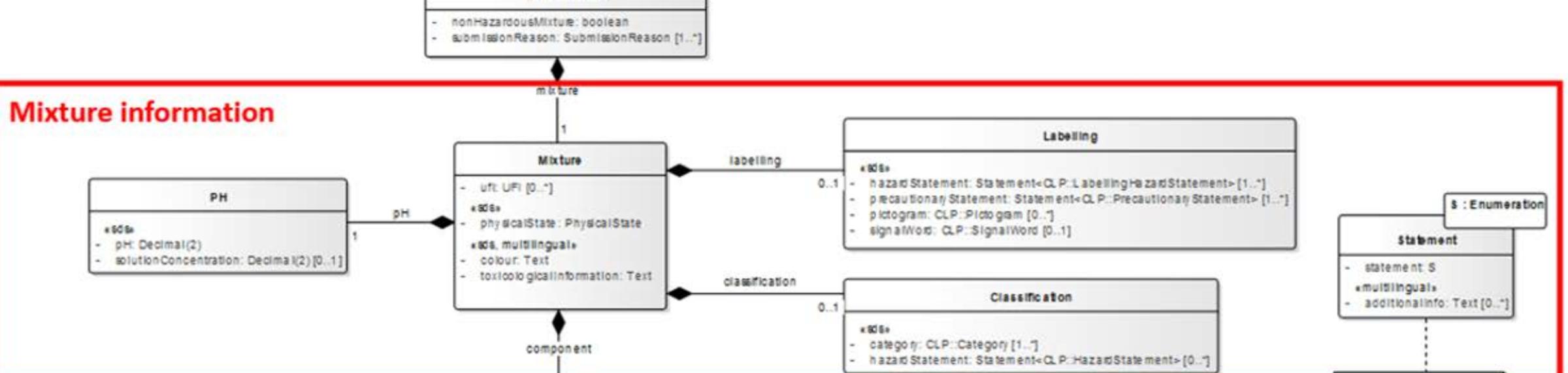


Product information

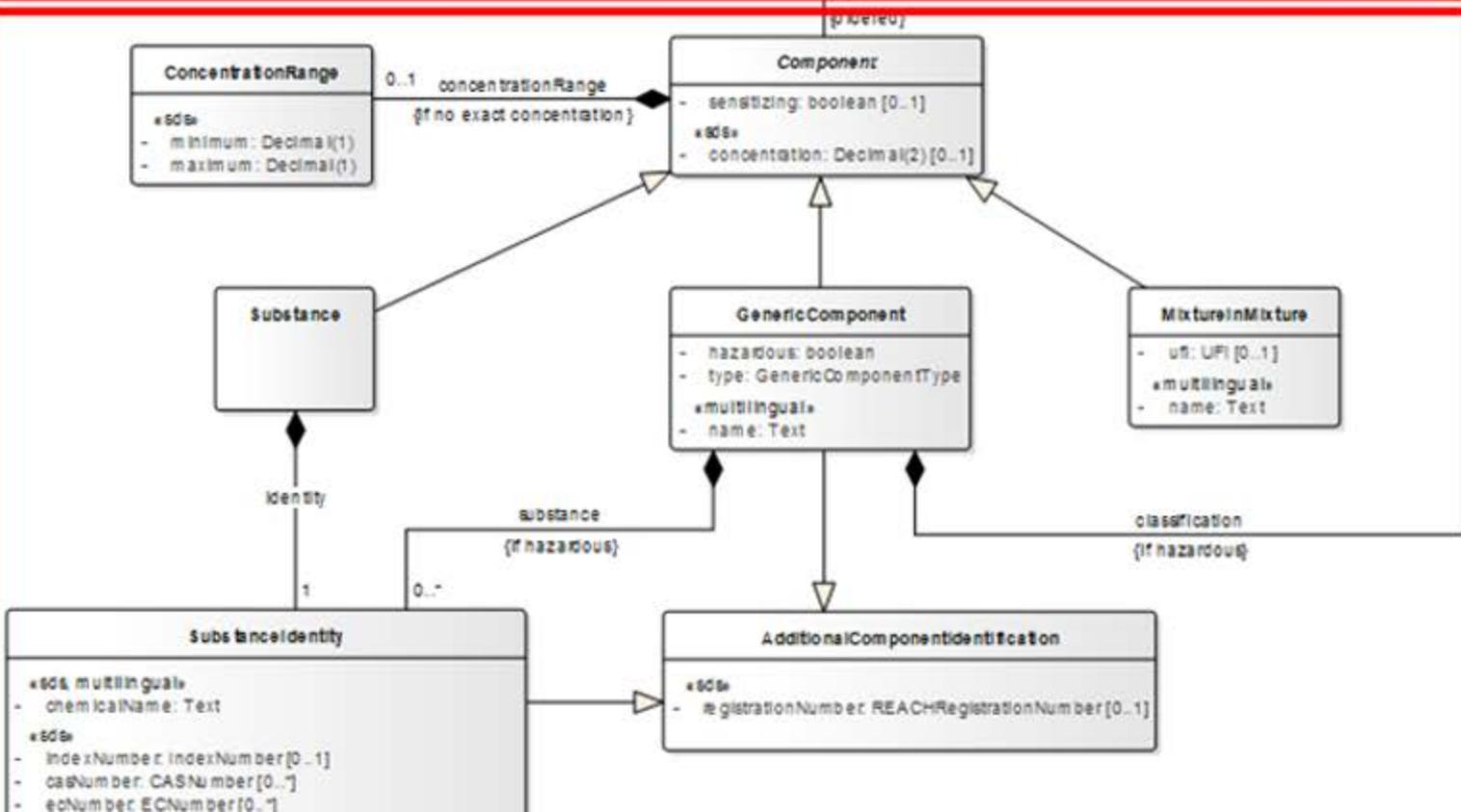


See diagram
Mixture details.

Mixture information



Placeholders need to be replaced with additional information in some statements.



Component information



Timing

- Approved at REACH Committee ,
Brussels, 20-21 September 2016
- Published probably by the end of
2016
- A specific WG will take care of
derogations



Grazie per l'attenzione