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# A look into the PCN format, UFI generator and EU PCS

*Dijana Spasojevic, Principal consultant, and Philippe Boveroux, Project manager*

*7th BfR User conference*

*15 November, 2015*

# Who we are

## Dijana Spasojevic

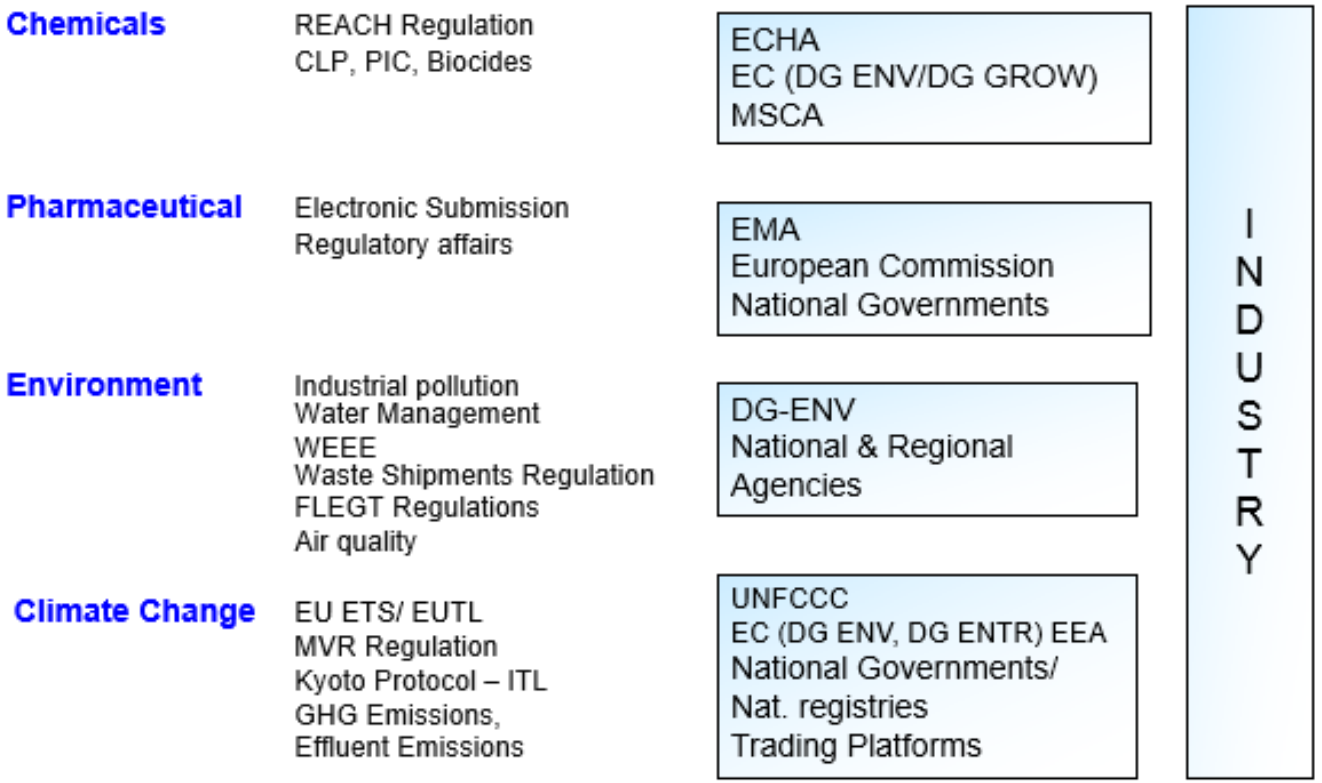
- Principal consultant at Trasys,
  Practice director, Sustainability and EHS
- Key projects in chemicals & EHS:
  - 2008-2010: FWC for providing services related to scientific, technical, health and environmental aspects of REACH regulation.
  - 2010-2013: Industry support for REACH and Global Chemicals regulations (Turkey, China)
  - 2014: Definition of EDI for Waste Shipments Regulation (WSR)
  - 2015: Harmonised format for poison centres
  - 2015: WEEE harmonised format for registration and reporting
  - 2016: Product Categorisation System

## Philippe Boveroux

- Project manager at Trasys
- Key projects in chemicals and environment sectors:
  - 2003-2007: Analysis REACH-IT and IUCLID
  - 2006-2010: Implementation REACH-IT
  - 2010-2013: EU Emission Trading System
  - 2014: EU ETS Electronic Reporting
  - 2015: Harmonised format for poison centres and editing application
  - 2016: UFI Generator

# Who we are

**TRASYS:** *Niche player for Sustainability and EHS information management*




1. Context and regulatory background
2. The Poison Centre Notification Format -(PCN) format
3. Unique Formula Identifier (UFI) generator
4. European Product Categorisation System (EU PCS)
5. Harmonised notification and formats: Towards an electronic submission scheme from industry to appointed bodies

# Context and regulatory background

- CLP Regulation Article 45: Obligation by importers and downstream users to submit information on hazardous chemical mixtures to appointed bodies (often called poison centres)
- That information allows poison centres to provide emergency health response based on evidence received on products
- Currently, each Member State has its own requirements/system
  - Different submission/format requirements throughout the EU for industry
  - Different degrees of (quality of) information available for emergency health response

# Context and regulatory background

*A brief history*

- 2008: CLP Regulation Article 45(4): “Assess the possibility of harmonising the information received by appointed bodies”
- 2010-2012: Stakeholders’ consultation
- 2012: Commission’s review concluding that “it is possible to harmonise the information to be submitted to poison centres and to establish a common format for the electronic submission of this information”
- 2012-2014: Several CARACAL meetings and workshops
- 2013: Decision that this harmonised submission format should be supported by a relevant PCN (XML) format
- 2015: PCN format and PCN editor (i.e. PC editor, basic application)
- 2016: UFI and EU PCS – must be integrated in the PCN editor

# Context and regulatory background

*New regulation framework*

- Regulation amending CLP and harmonising the information relating to emergency health response was voted in September 2016

  It lays down the obligations and information requirements for importers and downstream users

- Dates of applicability of this Regulation
  - **1st January 2020** for hazardous mixtures intended for **consumers**
  - 2021 and 2024 for professional and industrial uses, respectively

# The PCN (XML) format

... and the PC Editor

# The PCN format

*Why and objectives*

- PCN (XML) format is the de-facto standard for the definition of exchange formats
- Highly structured and aligned with regulatory provisions for harmonisation
- Cater for future automated submissions

# The PCN format

*Key principles*

- One submission includes the **mixture** description and the relevant **products**
  - Mixture part: physico-chemical properties, composition, classification & labelling
  - Products part (per product): identifiers, use, product category, packaging info, SDS
- The format support bulk submission, i.e. several submissions from the same company in a single document
- Allow multi-lingual submissions
- The submission document is linked to one Member State
- Mixtures must be identified: UFI is part of the format
- Products need to be categorised: EU PCS will be added to the format

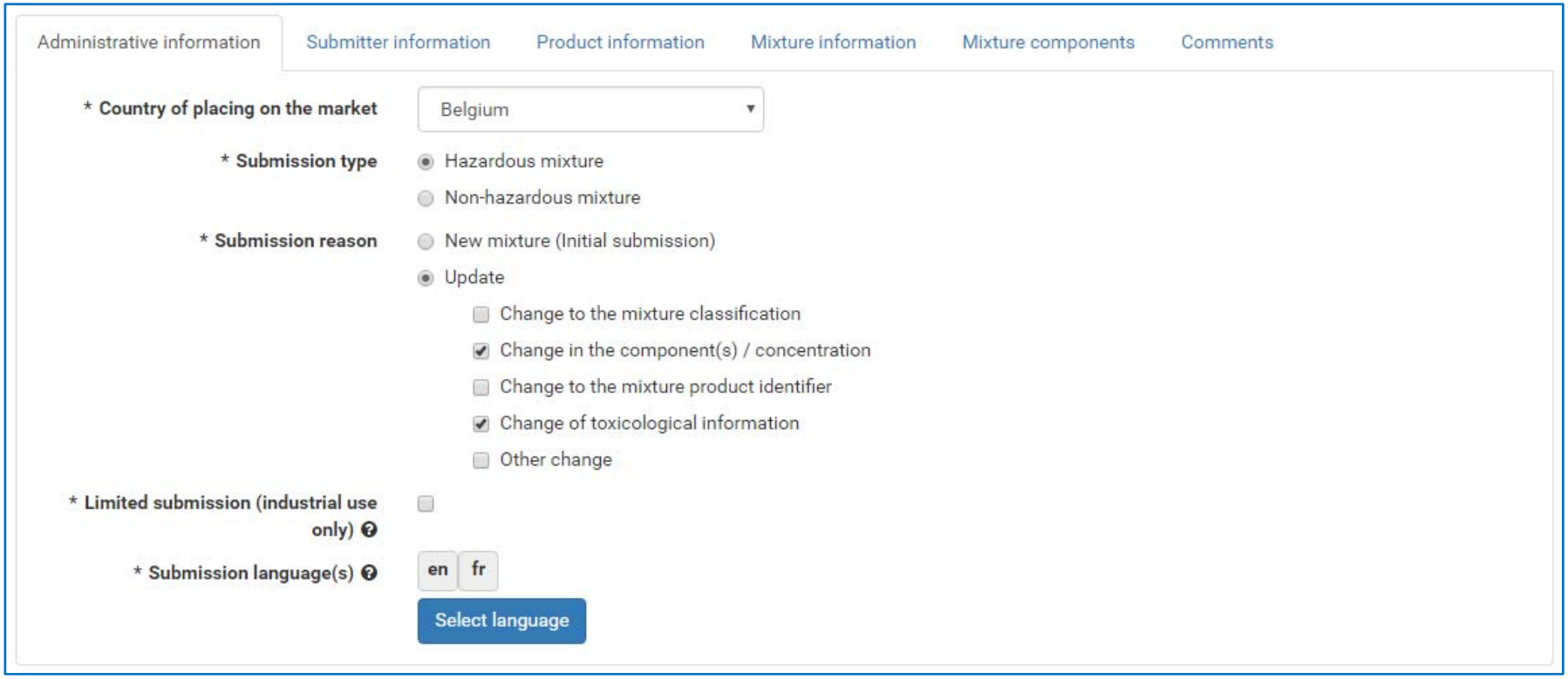
# The PCN format

*The PCN editor (basic application) - Key principles*

- An application allows encoding and saving a submission as an harmonised XML document
- Web application https://poisoncentres.echa.europa.eu/editor
- No submission of information
- No underlying database

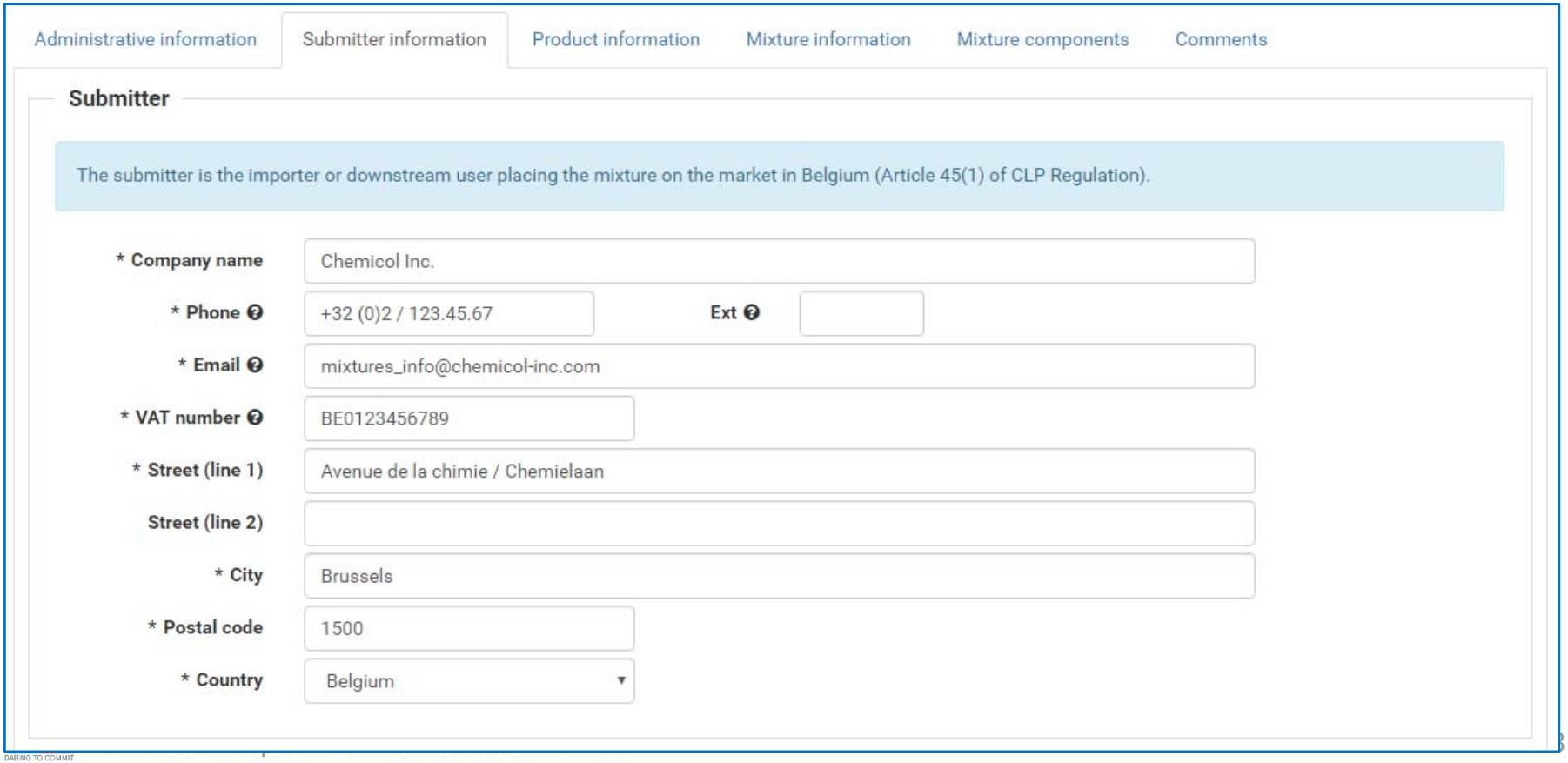
# The PCN editor (i.e. basic application)

*Some screen fragments – Administrative section*



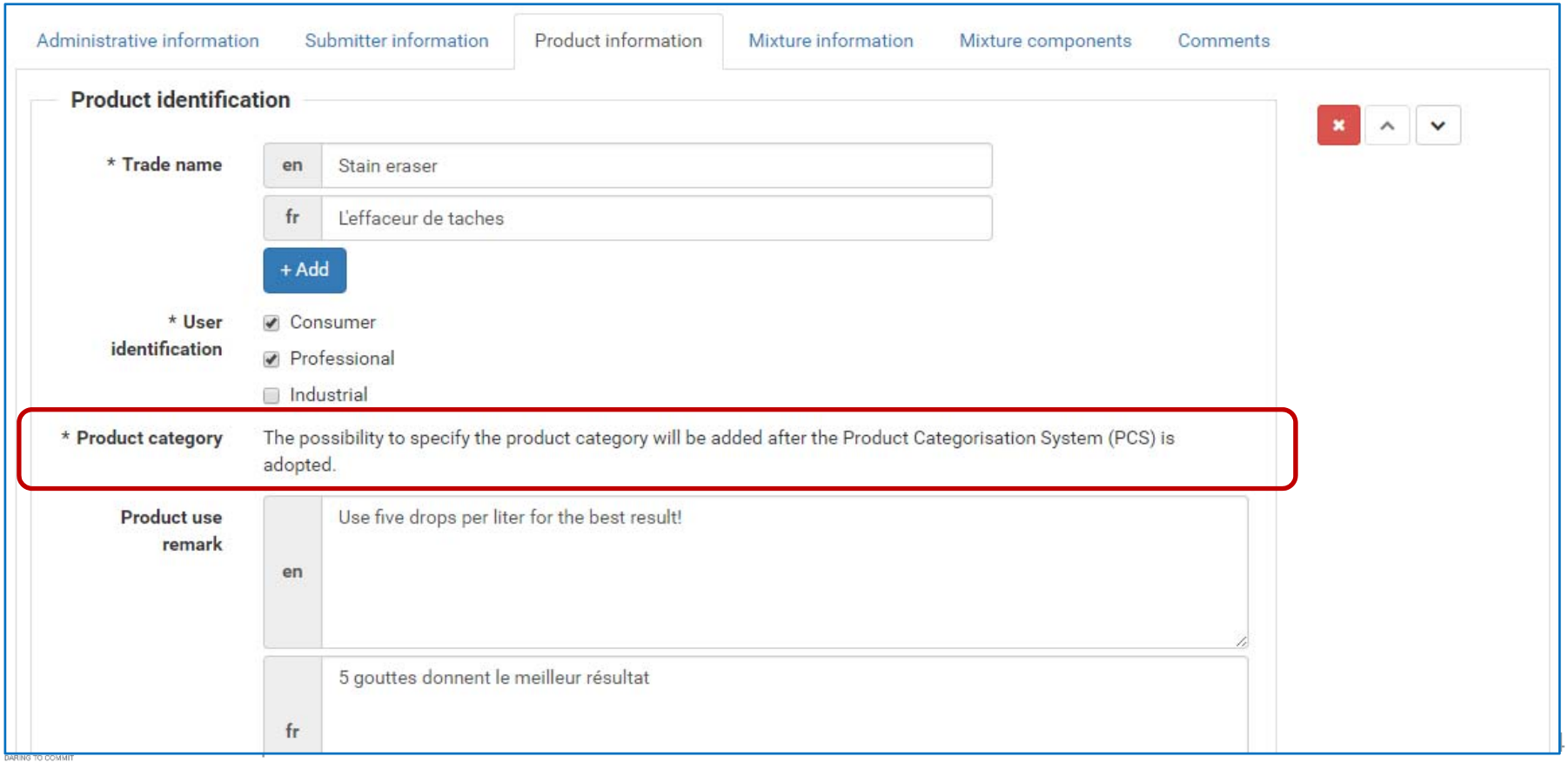
# The PCN editor

*Some screen fragments – Submitter section*



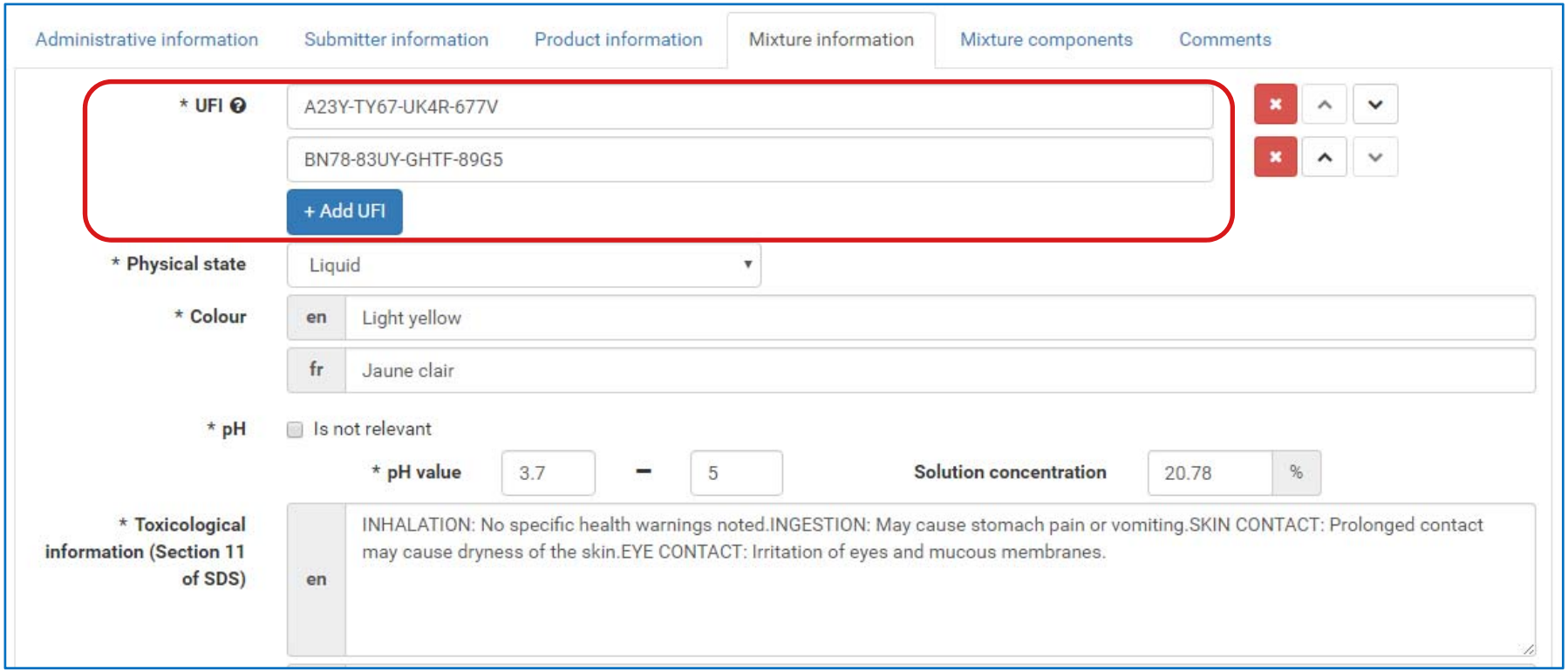
# The PCN editor

*Some screen fragments – Product section*



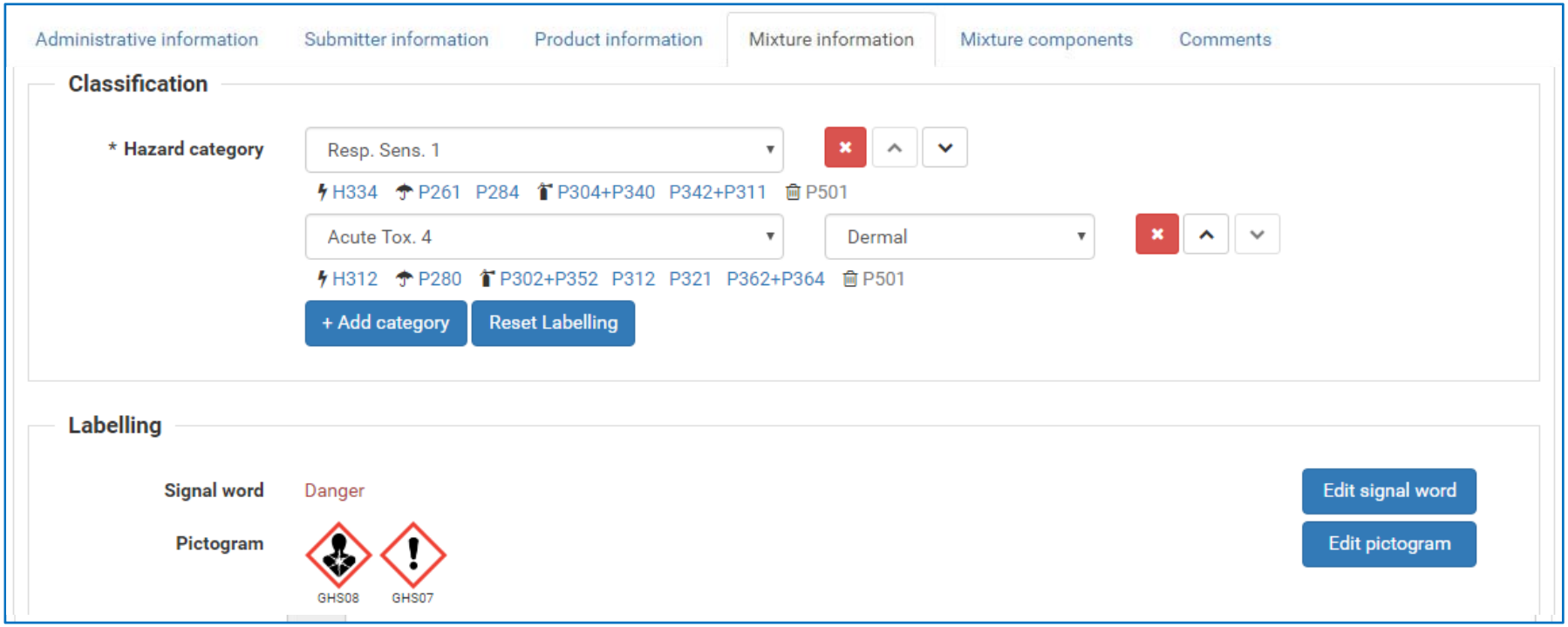
# The PCN editor

*Some screen fragments – Mixture information*



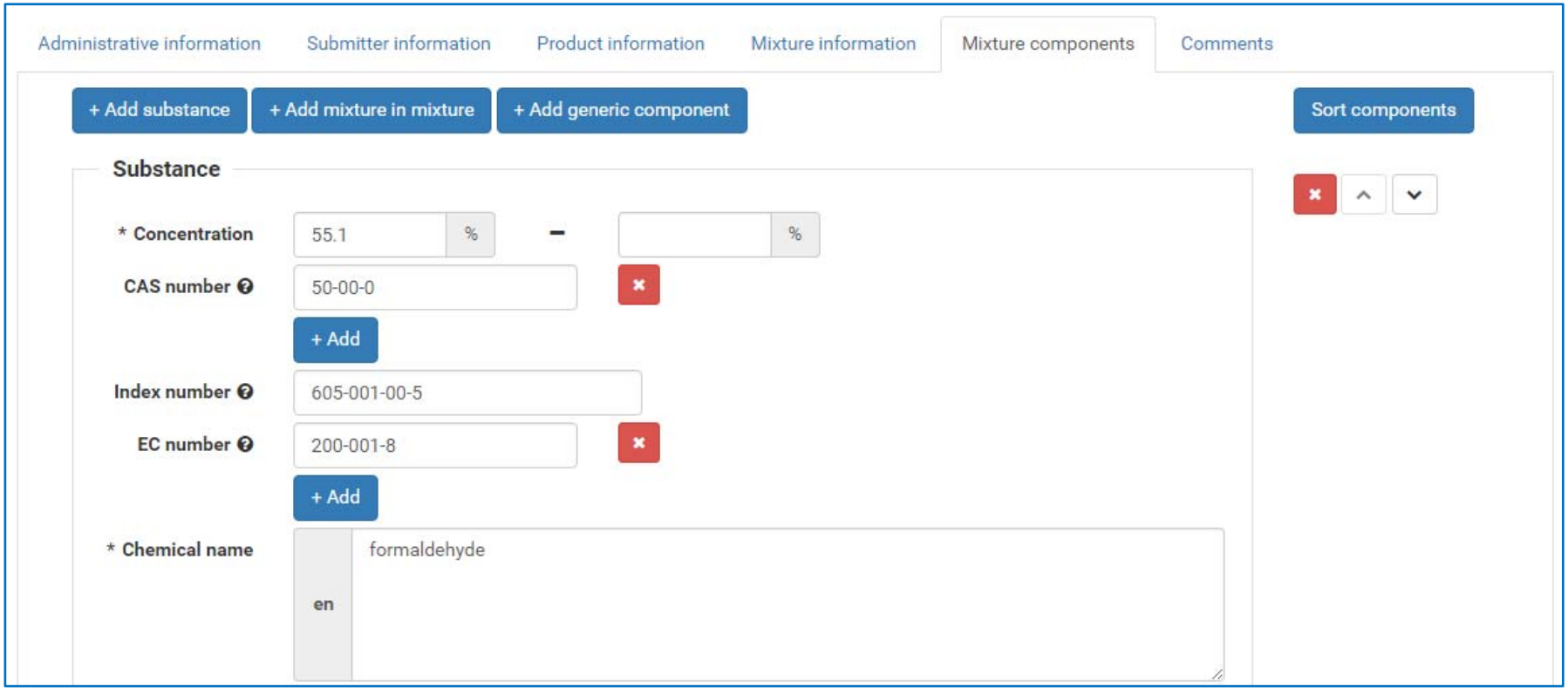
# The PCN editor

*Some screen fragments – Mixture information*



# The PCN editor

*Some screen fragments – Mixture composition*



# The PCN format

*Responsibilities - Industry*

- Prepare and submit information to Appointed Bodies / Poison centres in the harmonised format and in accordance to the regulatory deadlines; i.e. as of January 2020 for hazardous mixtures intended for consumers
- Prepare and submit updates to Appointed Bodies / Poison centres in accordance to regulatory provisions:
  - When the mixture product identifier (including the UFI) has changed
  - When the mixture classification for health or physical hazards has changed
  - When relevant new toxicological information that is required in section 11 of the Safety Data Sheet becomes available on the hazardous properties of the mixture or its components
  - For any “major” change in the composition of the mixture
- Submission format is harmonised yet a submission remains necessary to each Member State where the mixture is placed on the market

# The PCN format

*Responsibilities - Appointed bodies / Poison centres*

- Accept submissions and updates in the harmonised format from industry in accordance to the regulatory deadlines

# Unique Formula Identifier (UFI)

... and the UFI Generator

# Unique Formula Identifier

*Context and key principles*

- Poison centres experience problems with the correct identification of the mixture concerned in poisoning cases in up to 40 percent of the calls they receive
- As part of the harmonisation of the information, it is mandated to provide the identification of a mixture by a Unique Formula Identifier
- Objectives of the Unique Formula Identifier
  - Establish an unambiguous link between mixture and information submitted to appointed bodies
  - Placed on the product label for reference during emergency calls

# Unique Formula Identifier

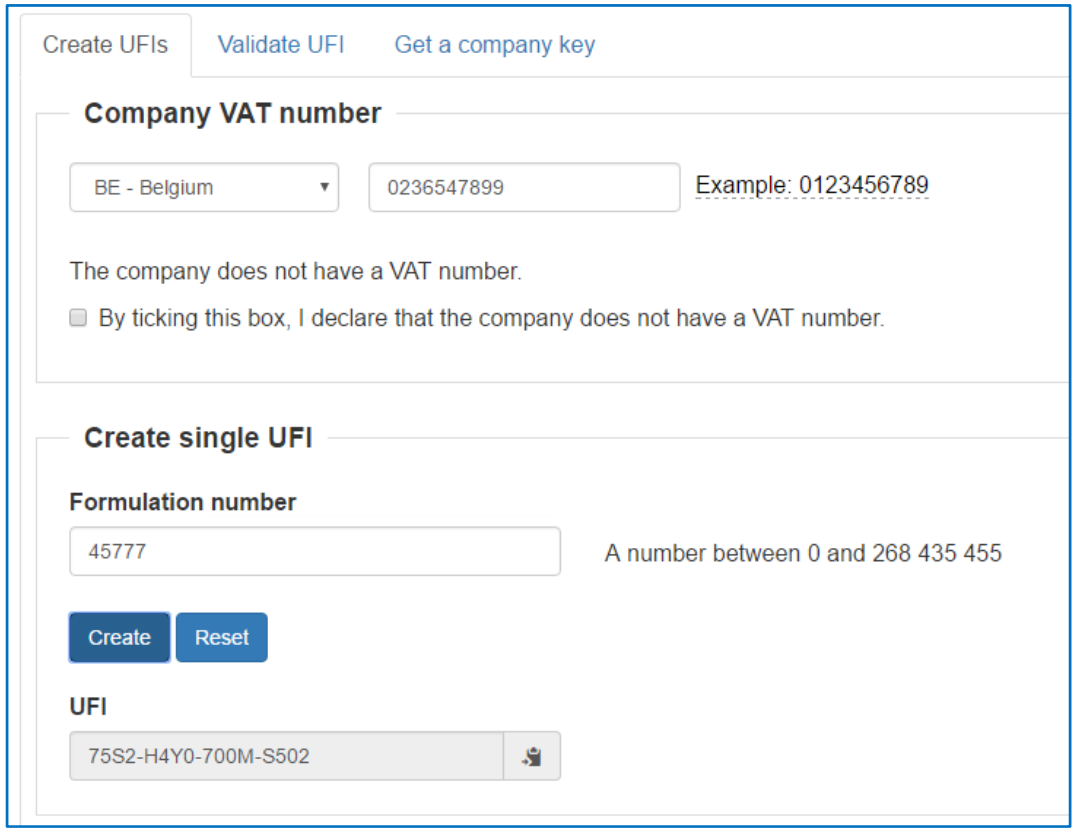
*Main requirements*

- Unique and based on VAT and formulation number
  - Company manages the formulation numbers
  - VAT used as company-specific element to avoid collisions (between companies). Support for company without VAT exists
- Easy to read: 16-character alphanumeric code in 4 blocks
  - Example: A300-N06Y-N00U-G73S
- Checksum to detect errors
- Very large pool of formulation numbers (268+ million per VAT)
- Support for more countries in the future

# Unique Formula Identifier

*UFI Generator*

- Simple generation tool
- Will be hosted at ECHA
- Allows single and bulk generation
- Also allows validating an existing UFI



# Unique Formula Identifier

*Responsibilities - Industry*

- Generate UFIs, using the provided generator or one's own implementation
- Maintain correct association between mixture, formulation number(s) and UFI(s)
- Place UFI on the product label
- Include UFI(s) in the information submitted to appointed bodies about the mixture (using the harmonised format)

# Unique Formula Identifier

*Responsibilities - Appointed bodies / Poison centres*

- Store UFI along with mixture information in product database
- Consider improving search tools to retrieve products by UFI
  - Incremental searches: show matching values after first characters are entered
  - Highlight close matches when a checksum error is detected

# EU Product Categorisation System (EU PCS)

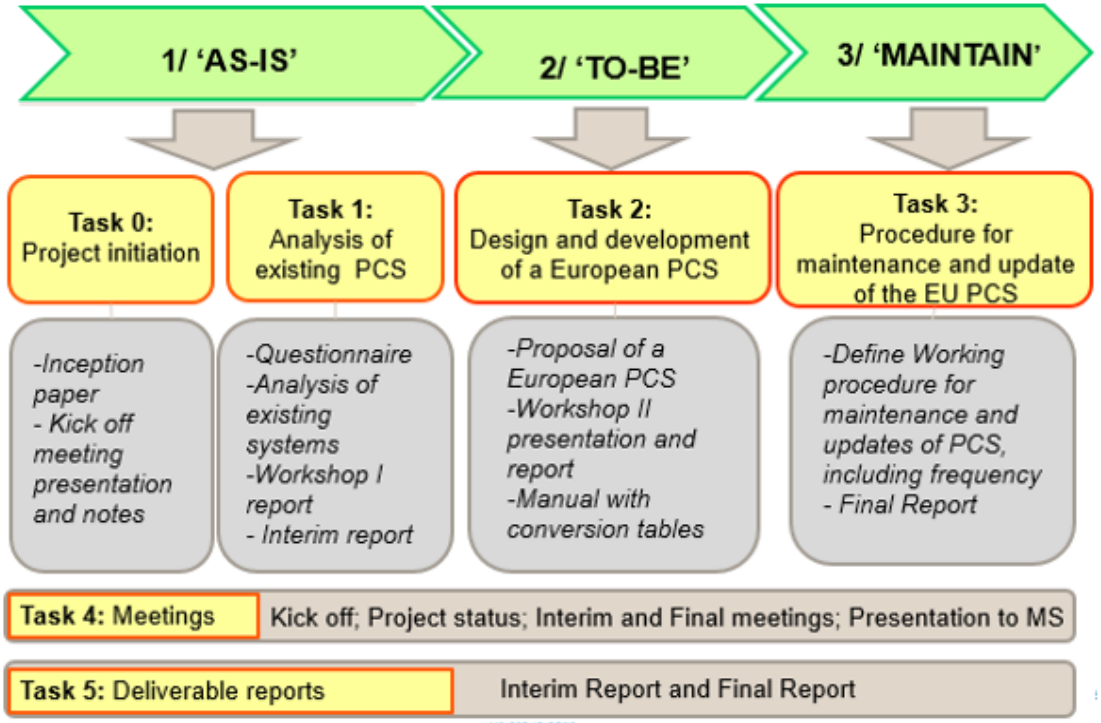
# EU Product Categorisation System

*Context*

- MS Appointed Bodies/Poison Centres need EU PCS
  - Recording of cases linked to the exposed products
  - Reporting and retrieval of comparable products
  - Statistical analysis and exchange of information between MS
- Industry need EU PCS
  - Submission of information to MS Appointed Bodies/Poison Centres using a harmonised system of categories throughout the EU and Norway
- EU PCS is a harmonised system which will allow case statistics to be done for the whole of the EU and exchange of information between MS

# EU Product Categorisation System

- Objective
  - Provide the European Commission with the tools to support establishment of a harmonised EU Product Categorisation System to be used by industry for submission of information and by MS appointed bodies/poison centres for statistical analysis and exchange of information.



# EU Product Categorisation System

*Authorities experience*

- 12 out of 27 countries have in place a system for products subject to Art. 45 of the CLP Regulation. However, only 6 countries have a PCS that is used by industry for submission of information
- Main issues with existing situation:
  - Identification of products; Multidimensional categorisation problems;
  - Statistical and comparative analysis of product groups;
  - Reporting issues and incoherence between the existing national PCS and categories required for preparation of specific reports or analysis.
- 25 out of 27 countries (or 93%) support and confirm a need for development of a harmonised EU PCS

# EU Product Categorisation System

*Industry experience*

- Industry experience and issues with existing situation
  - Existence of different categorisation systems (25 out of 63 respondents or 40%)
  - High number of product categories and sub-categories (24 out of 63 respondents or 38%)
  - Lack of coherence with product categorisation under other legislations, such as REACH, Biocides, etc. (21 out of 63 respondents or 34%)
- 45 out of 63 industry respondents (or 71%) indicated a need for development of a harmonised European PCS

# EU Product Categorisation System

*Requirements and design principles*

- EU PCS is a system of product categories to be used by all MS appointed bodies/poison centres and industry
- Industry > submission requirement to describe intended use of their products in accordance with the harmonised EU PCS
- Appointed bodies > need to integrate the harmonised EU PCS in their systems
- System is designed based on the five principles with regard to
  - Scope of the system
  - Backbone structure of the system
  - Dimensions for categorisation of products
  - Organisational structure of the system
  - Maintenance and update procedure for EU PCS

# EU Product Categorisation System

*Key principles*

1. *Scope of the EU PCS.* The system covers mixtures self-classified as hazardous on their health effects and physical properties in accordance to Article 45 of the CLP Regulation and other categories of products (e.g. cosmetics, pharmaceuticals, human medicine etc.)

2. *Backbone structure for European PCS -use of German TDI-CSA/TKS + REACH Product Categories.* Use of TDI-CSA/TKS system up to three levels with cross-reference to REACH PC. 'Building blocks' of sector-specific product categories based on already regulated categorisation systems and on categorisation of products as defined by respective industry-associations.

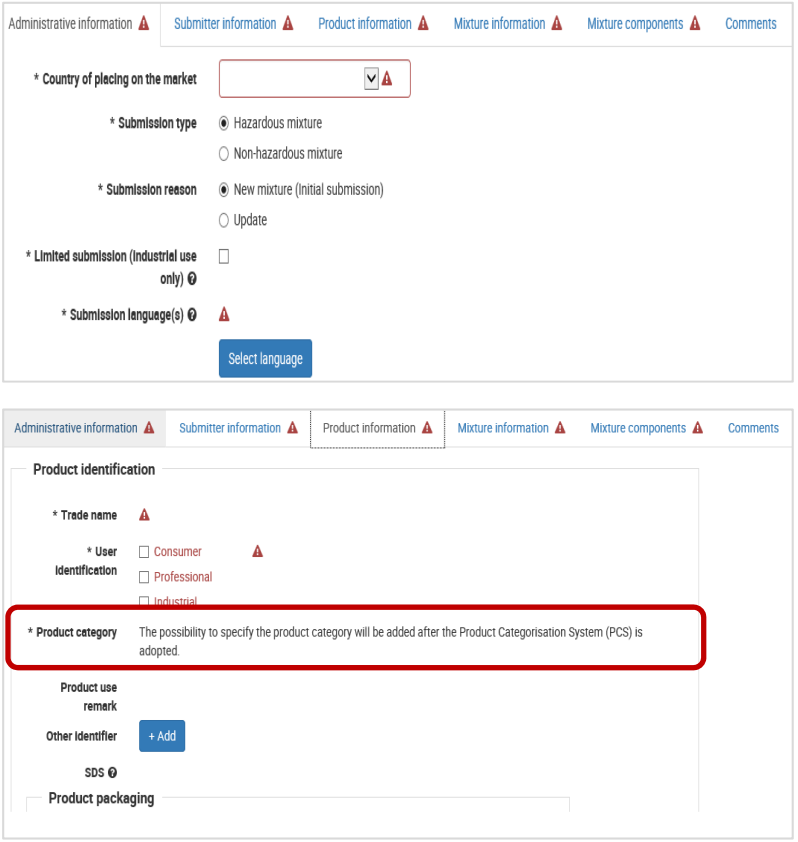
# EU Product Categorisation System

*Key principles*

3. *Dimension for categorisation of products in EU PCS*. Products are categorised on the intended use since the properties of a mixture (e.g. composition, physical state, etc.) are already part of the harmonised format for submission of information.

4. *Organisational structure*. Harmonised European PCS has hierarchical structure.

5. *Procedure and frequency for update and maintenance of EU PCS*. An assessment of a need for update of the EU PCS and its implementation would be carried out on a need basis.

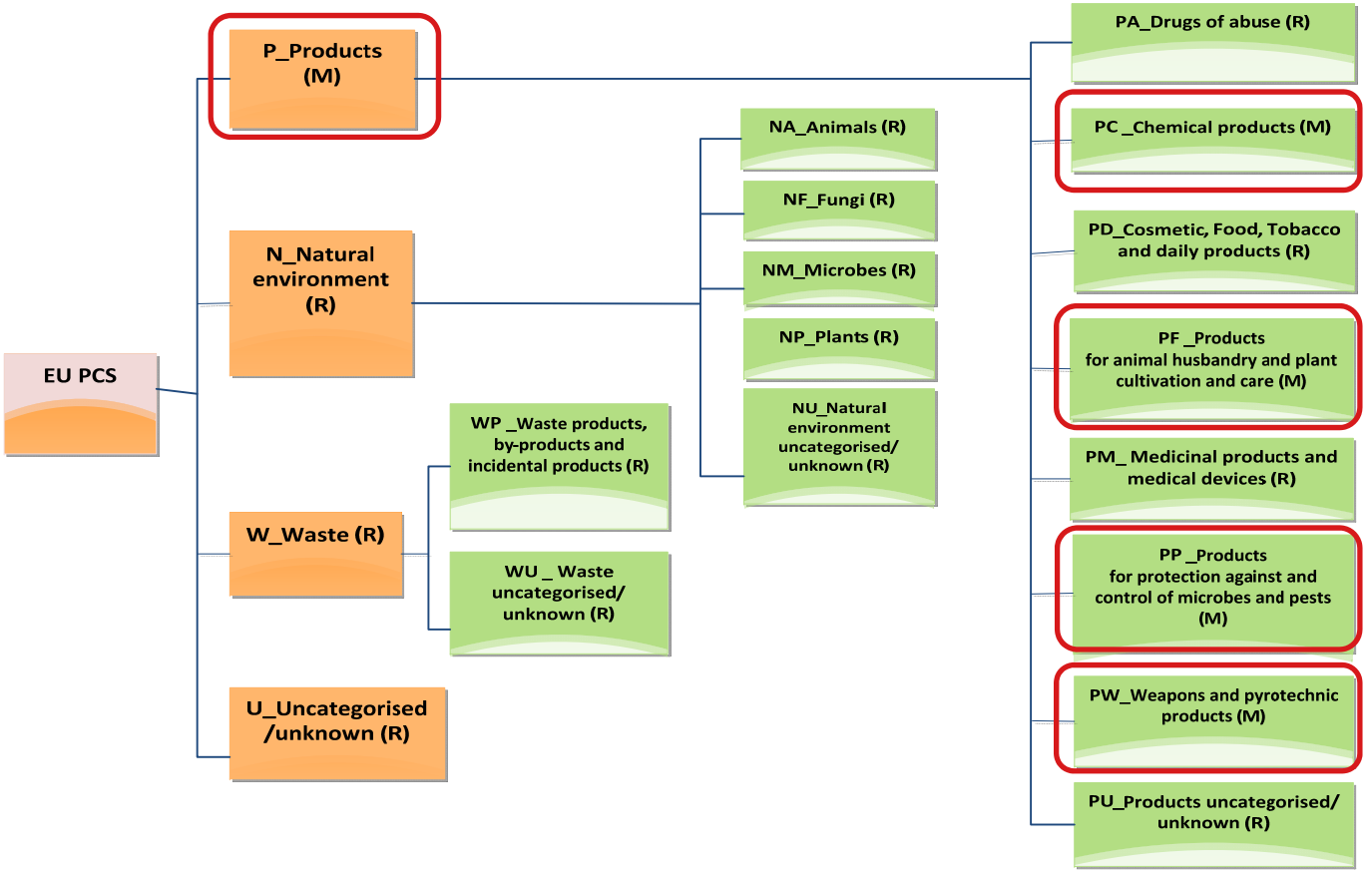


# EU Product Categorisation System

*Broad stakeholders consultation process*

- Stakeholders consultation period using structured questionnaire and in-depth interviews run from 10th February-4th March 2016
- 1st workshop held on 13th April 2016
- 2nd workshop held on 28th June 2016
- Another round of stakeholders consultation run from 4th October-28th October 2016
  - 42 institutions from 27 MS and Norway
  - 34 industry associations (e.g. A.I.S.E., CEPE, CEMBUREAU, EMO,ETAD, FEICA,ETRM, I&P Europe, IKW, VCI, etc.)

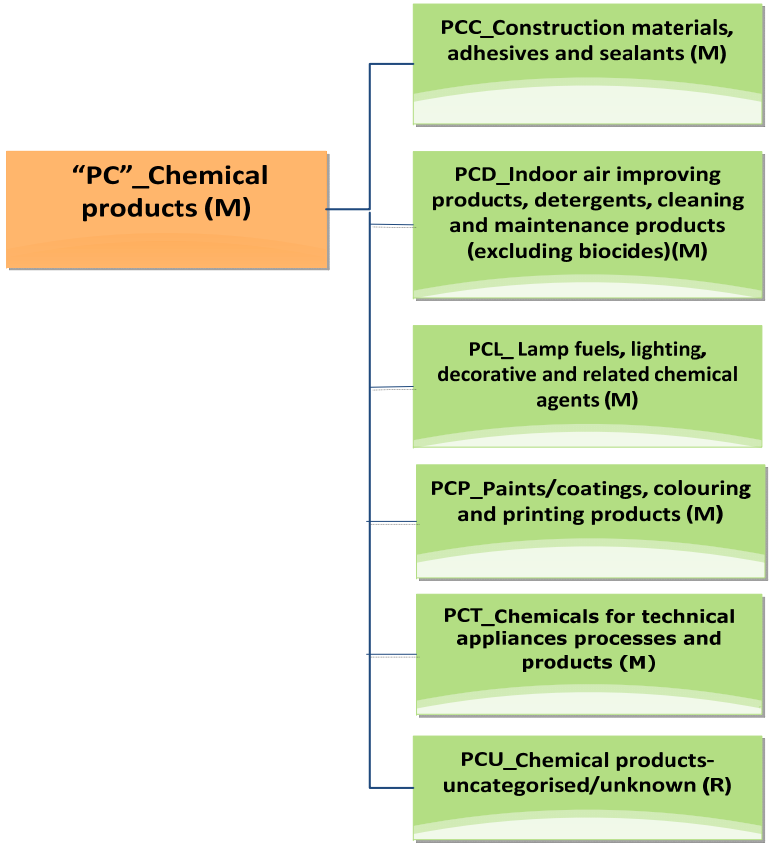
# EU Product Categorisation System



# EU Product Categorisation System

*Focus on product categories subject to submission of information*

| Code | Industry associations input |
|---|---|
| PCC | EFCC, FEICA, CEMBUREAU, EROGYPSUM, EMO, ERMA |
| PCD | A.I.S.E., IKW |
| PCP | CEPE, ETAD, I&P Europe, |
| PCT | CEFIC, ECMA, EDANA, ERMA, ETRM, VCI, ATIEL |



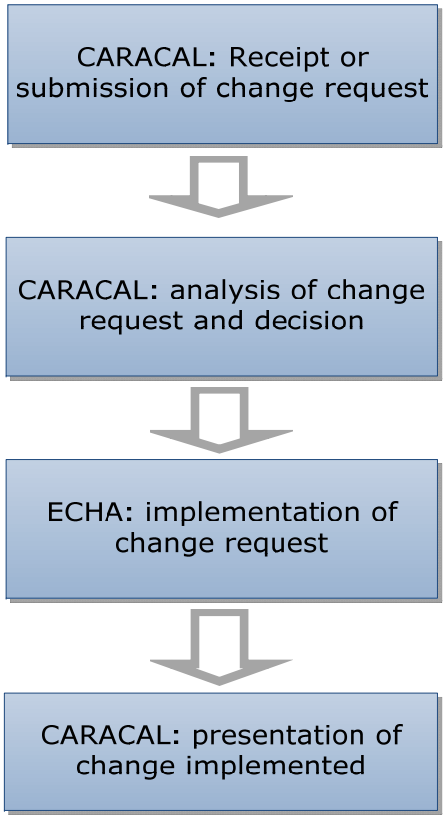
# EU Product Categorisation System

*Proposed procedure for maintenance and update of the harmonised EU PCS*

- *CARACAL*- will have the following responsibilities in the context of the EU PCS governance mechanism:
  - Submit change, maintenance or update requests relating to the EU PCS
  - Analyse change requests from stakeholders
  - Endorse updates and new releases of the EU PCS.

- *ECHA*- will be responsible for update and maintenance of the EU PCS and consequently changes of the harmonised (XML) format and release management of the basic application (PC editor)

- *Working Group* - stakeholders and invited experts



# Harmonised notification and formats: Towards an electronic submission scheme

# Towards an electronic submission scheme

*Key enablers are prepared and will be available*

- Key enablers for the electronic submission of information between industry and appointed bodies are in preparation
  - Harmonised PCN format and the PCN editor
  - UFI and UFI Generator
  - EU PCS (and its future XML representation in PCN format)
- All tools will be hosted by ECHA and made available for free. Visit ECHA's poison centre web site at https://poisoncentres.echa.europa.eu/
- The tools currently available are not in their final state, yet can be used for preparatory purposes or practice. All tools will be updated and the definitive versions will only be available in the course of 2017
- There remains a long way to go to achieve complete automation

# Towards an electronic submission scheme

*What needs to be added?*

- Appointed bodies
  - Develop software to process and store PCN (XML) harmonised format submissions
    - Notification mechanism: manual (web form) vs. automated (web service)
    - Database to store and query harmonised submissions
    - Migration of existing data vs. keeping two databases (until the old is phased out)
    - Address security
- Industry
  - Develop software to generate XML harmonised submissions
  - Develop software to submit the data (if automated at appointed bodies)
- Remember the deadline: 1st January 2020 for consumer products!

# Thank you for your attention

Do you have questions?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