ARCHIVIO EUROPEO DELLE MISCELE PERICOLOSE: PRINCIPALI ELEMENTI E CARATTERISTICHE NEL PERIODO TRANSITORIO

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ISS

ROMA

CLP – ANNEX VIII

- New Annex published in March 2017
- Obligation for **importers and downstream users** placing hazardous mixtures on the market to notify national appointed bodies
- Phased deadlines by 1 January
- 2020 for consumer use
- 2021 for professional use
- 2024 for industrial use
- 2025 marks end of transition period

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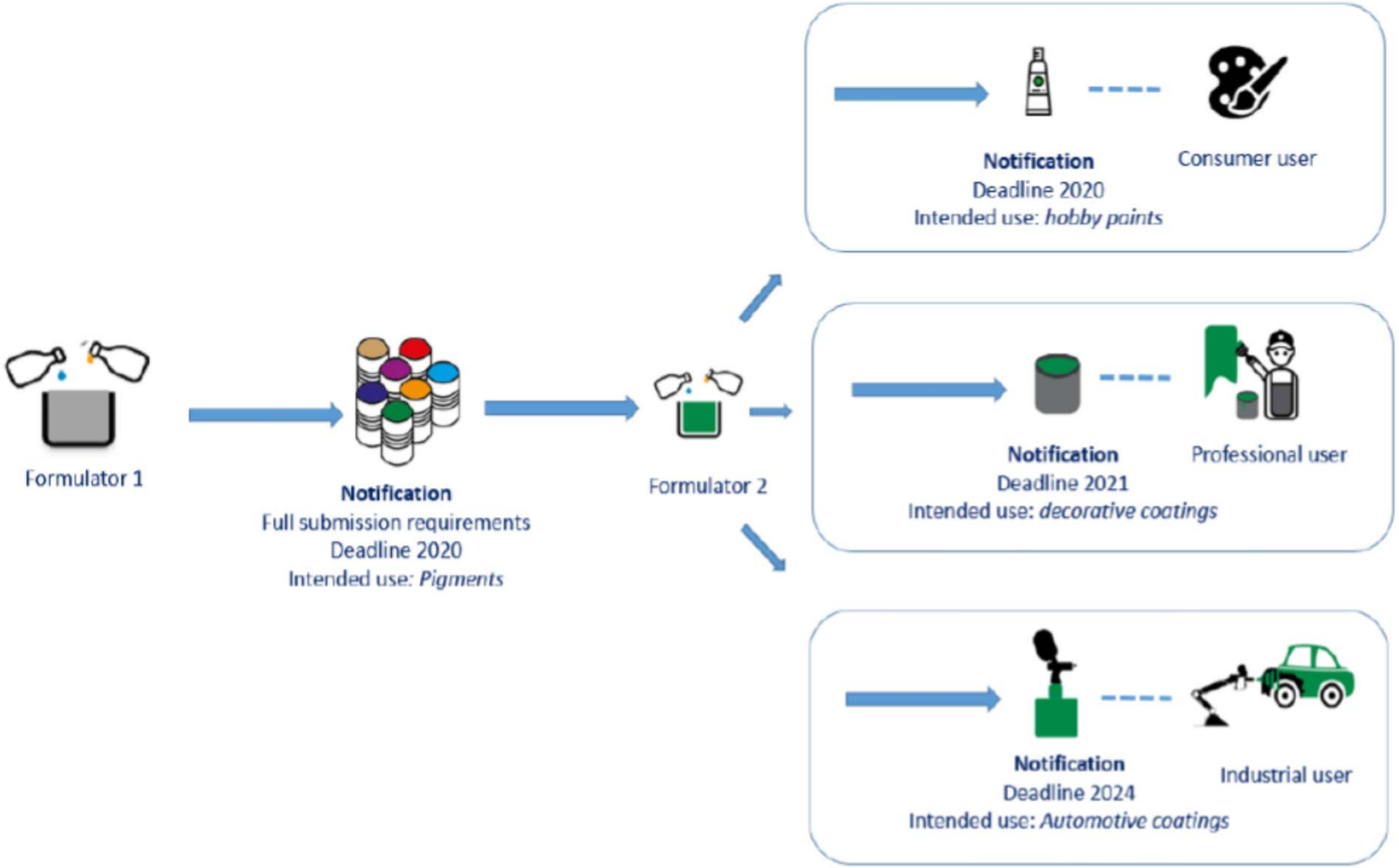
Intended use and end user



OBBLIGHI DI NOTIFICA

Chi deve notificare:

- Importatori o Downstream User (chi immette sul mercato)

Quali miscele classificare:

- Miscele classificate per le proprietà chimico fisiche o la salute umana
- Esclusione per miscele classificate solo per l'ambiente, gas sotto pressione o esplosivi

La notifica va fatta prima dell'immissione in commercio entro:

- Miscele consumer use: 1.1.2020
- Miscele professional use: 1.1.2021
- Miscele industrial use: 1.1.2024

Dove notificare:

- Direttamente all'appointed body nazionale
- Attraverso il portale ECHA

COSA NOTIFICARE

- Categoria di prodotto
- Identificatori (e.g. CAS, EC number…) dei componenti la miscela e loro concentrazioni
- Unique Formula Identifier (UFI)
- Identità del notificante
- Classificazione della miscela
- Informazioni tossicologiche

COSA NOTIFICARE

Informazioni

- Componenti della miscela e loro concentrazione, anche quei componenti non classificati come pericolosi.
- Le concentrazioni possono essere espresse come percentuali esatte o come un range di percentuali.

COSA NOTIFICARE

Informazioni aggiuntive

- Tipologia e dimensioni dell'imballaggio
- Colore
- Stato fisico
- pH
- Categoria di prodotto in accordo col Product Categorisation System (lista in preparazione ad ECHA)
- Tipologia di uso (consumer, professional, industrial)

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

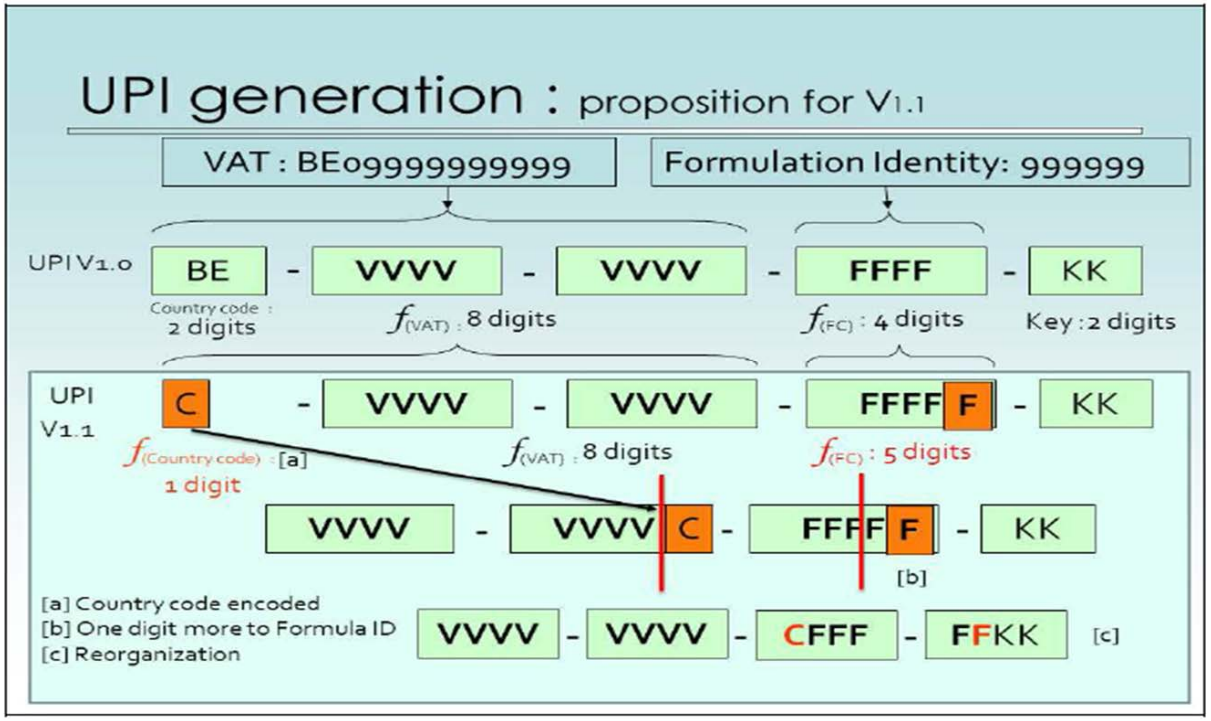
Unique Formula Identifier

New notification requirement for product label

Unique 16 character code in 4 blocks

UFI code links the notified mixture information to a specific product on the market

UFI


UPI generation : proposition for V1.1
VAT : BE0999999999
Formulation Identity: 999999
UPI V1.0
BE - VVVV - VVVV - FFFF - KK
Country code : 2 digits
f(VAT) : 8 digits
f(FC) : 4 digits
Key : 2 digits
UPI V1.1
C - VVVV - VVVV - FFFF F - KK
f(Country code) : [a] 1 digit
f(VAT) : 8 digits
f(FC) : 5 digits
VVVV - VVVV C - FFFF F - KK
[b]
[a] Country code encoded
[b] One digit more to Formula ID
[c] Reorganization
VVVV - VVVV - CFFF - FFKK
[c]

UFI

- 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 center,

b) The product identification under norm [DIN EN 15178],

c) The CLP pictograms,

d) The bar code,

e) The company address,

f) Black preferred colour, fonts and character sizes are not imposed.

UFI: AN ADDED VALUE

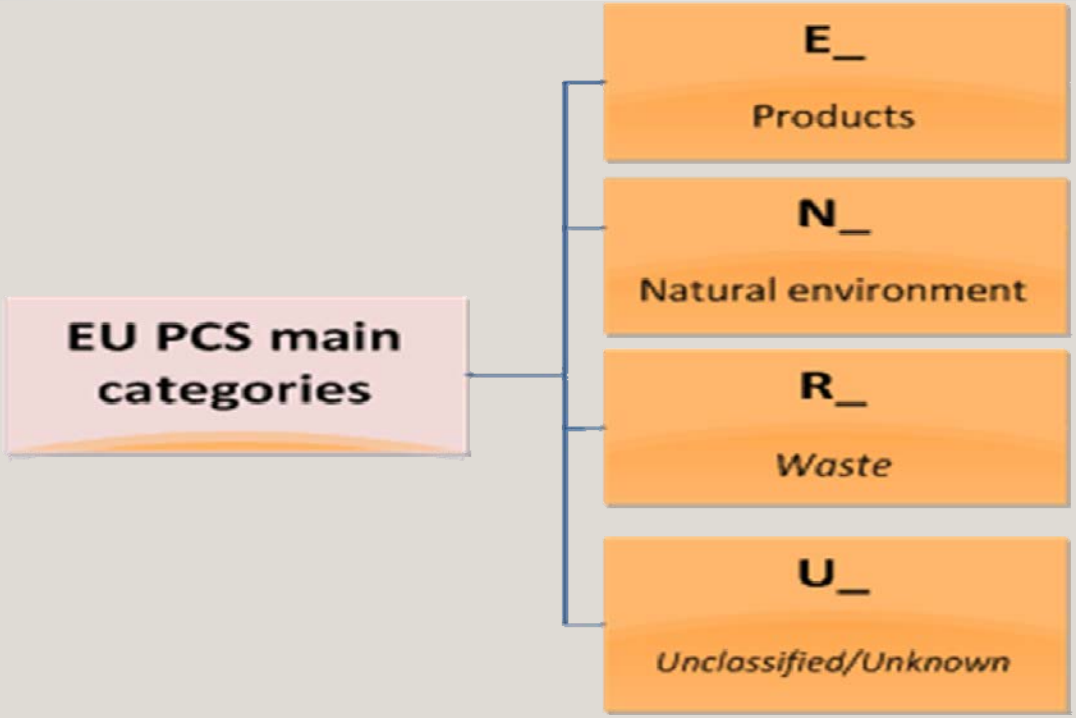
- The UFI will certainly be a useful search criteria when it comes to narrowing down a search and disambiguating first search results based on the mixture name for instance.
-
- Poison Centre's applications must thus be completed with adequate search feature integrating the UFI as an important criterion.
- 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.
- Same code in all EU (transporting goods)

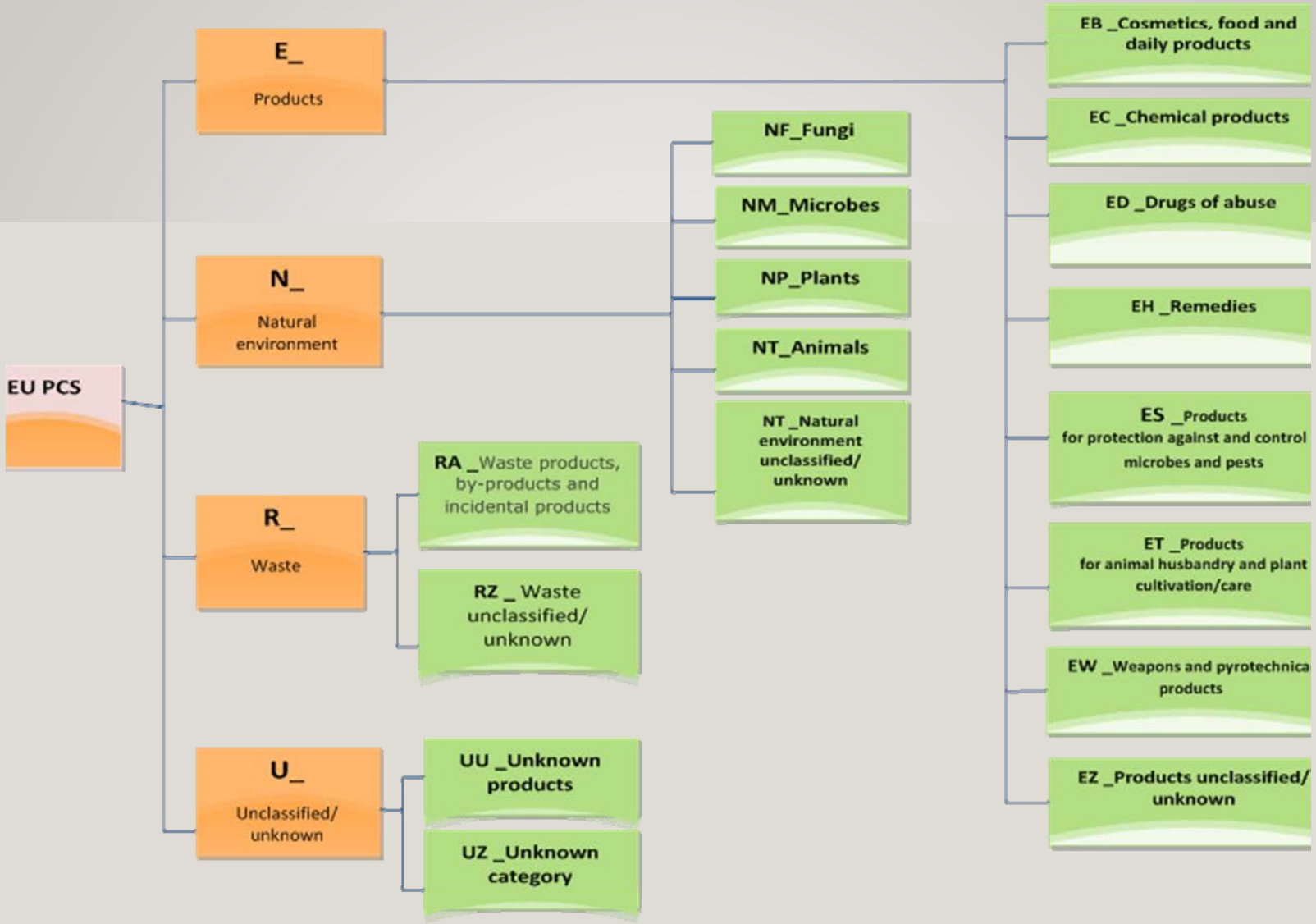
Relevance of UFI for poison centres

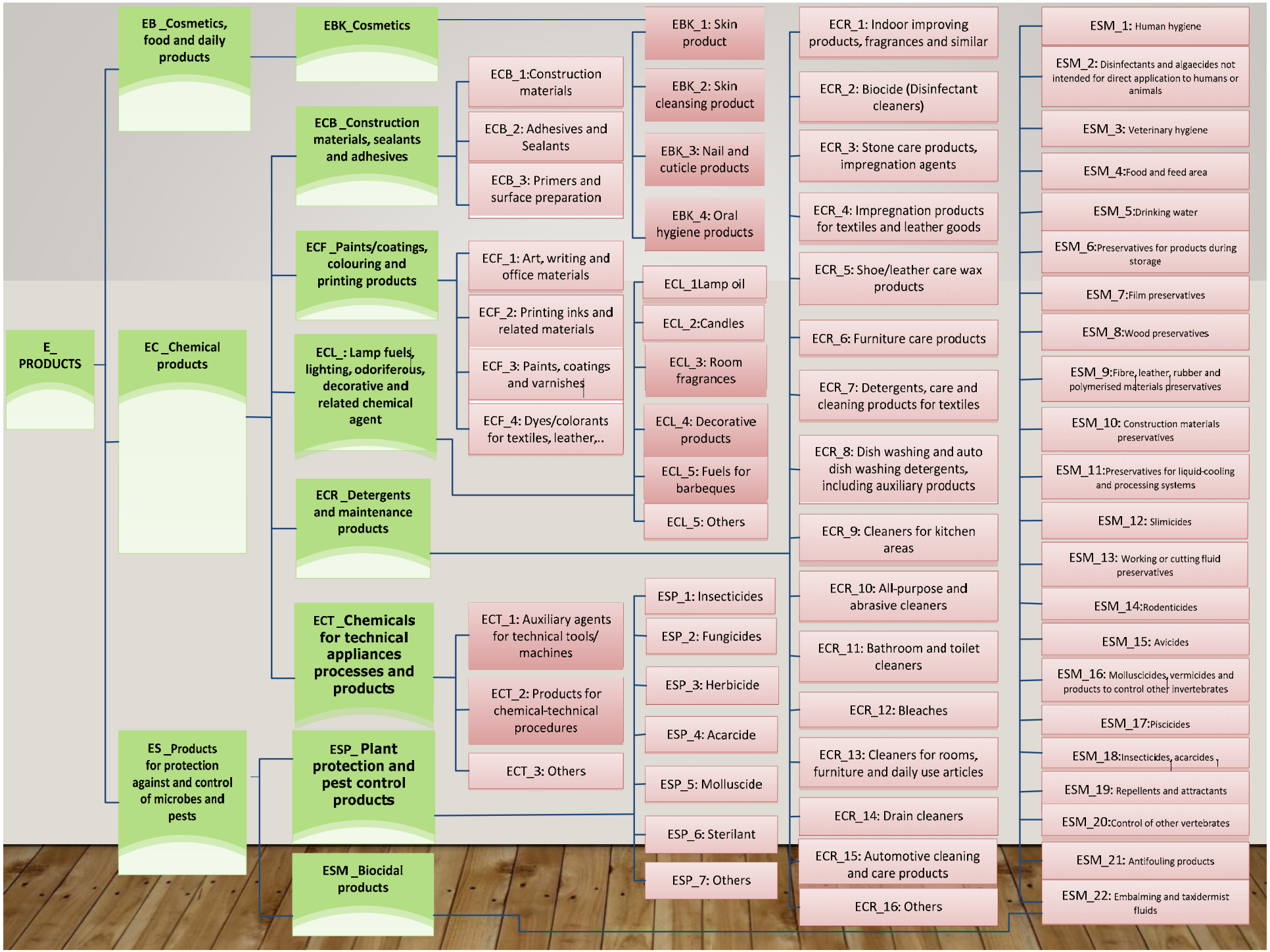
PRODUCT CATEGORIZATION

- Product category mandatory in industry notifications
- Single selection based on main intended use
- Supports appointed bodies at EU level
  - reporting/statistical analysis of poisoning incidents
  - identification of risks & proposing risk management measures
- Used by poison centres e.g. for registering cases in incidents

PRODUCT CATEGORIES




EU PCS
E_
Products
N_
Natural environment
R_
Waste
U_
Unclassified/ unknown
NF_Fungi
NM_Microbes
NP_Plants
NT_Animals
NT _Natural environment unclassified/ unknown
RA _Waste products, by-products and incidental products
RZ _ Waste unclassified/ unknown
UU _Unknown products
UZ _Unknown category
EB _Cosmetics, food and daily products
EC _Chemical products
ED _Drugs of abuse
EH _Remedies
ES _Products for protection against and control microbes and pests
ET _Products for animal husbandry and plant cultivation/care
EW _Weapons and pyrotechnica products
EZ _Products unclassified/ unknown


E_ PRODUCTS
EB _Cosmetics, food and daily products
EC _Chemical products
ES _Products for protection against and control of microbes and pests
EBK_Cosmetics
ECB _Construction materials, sealants and adhesives
ECF _Paints/coatings, colouring and printing products
ECL_: Lamp fuels, lighting, odoriferous, decorative and related chemical agent
ECR _Detergents and maintenance products
ECT _Chemicals for technical appliances processes and products
ESP_ Plant protection and pest control products
ESM _Biocidal products
ECB_1:Construction materials
ECB_2: Adhesives and Sealants
ECB_3: Primers and surface preparation
ECF_1: Art, writing and office materials
ECF_2: Printing inks and related materials
ECF_3: Paints, coatings and varnishes
ECF_4: Dyes/colorants for textiles, leather,..
ECT_1: Auxiliary agents for technical tools/ machines
ECT_2: Products for chemical-technical procedures
ECT_3: Others
EBK_1: Skin product
EBK_2: Skin cleansing product
EBK_3: Nail and cuticle products
EBK_4: Oral hygiene products
ECL_1Lamp oil
ECL_2:Candles
ECL_3: Room fragrances
ECL_4: Decorative products
ECL_5: Fuels for barbeques
ECL_5: Others
ESP_1: Insecticides
ESP_2: Fungicides
ESP_3: Herbicide
ESP_4: Acarcide
ESP_5: Molluscide
ESP_6: Sterilant
ESP_7: Others
ECR_1: Indoor improving products, fragrances and similar
ECR_2: Biocide (Disinfectant cleaners)
ECR_3: Stone care products, impregnation agents
ECR_4: Impregnation products for textiles and leather goods
ECR_5: Shoe/leather care wax products
ECR_6: Furniture care products
ECR_7: Detergents, care and cleaning products for textiles
ECR_8: Dish washing and auto dish washing detergents, including auxiliary products
ECR_9: Cleaners for kitchen areas
ECR_10: All-purpose and abrasive cleaners
ECR_11: Bathroom and toilet cleaners
ECR_12: Bleaches
ECR_13: Cleaners for rooms, furniture and daily use articles
ECR_14: Drain cleaners
ECR_15: Automotive cleaning and care products
ECR_16: Others
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: Slimicides
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, acarcides
ESM_19: Repellents and attractants
ESM_20:Control of other vertebrates
ESM_21: Antifouling products
ESM_22: Embalming and taxidermist fluids

RANGES

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

- Generic identifiers:
- "Perfumes", "Fragances" : concentration does not exceed 5% in total

  "Colouring agents": Concentration does not exceed 25% in total

INDUSTRY ACTIONS

- Identify mixtures that require submission of information (affected by Annex VIII of CLP)
- Identify the use of your mixture (consumers, professionals or industrial) : for industrial mixtures: possible limited submission of information
- Identify the use to determine the deadline (Consumer, professional or industrial use)
- Identify the category
- Check your composition and define ranges
- Update your data
- Monitor and manage changes
- Start assigning UFI to your mixtures.
- Consider your budget
- Companies should provide a telephone number with a 24/7 on call service and an email address for rapid access to additional information.

INDUSTRY ACTIONS

Group submission:

- all mixtures in the group contain the same components, the reported concentration range is the same for all mixtures.

Mixtures in mixtures (MiM):

- Contact the supplier for further information on the exact composition of the MiM
  - Provide information on known mixture components, the product identifier of the MiM together with its concentration and the UFI.
  - When the UFI is not available, information on known mixture components, the product identifier and concentration of the MiM together and the SDS, name, email address and telephone number of the MiM supplier should be provided.

CONSIDER THE FOLLOWING :

- The mixture classification for health and physical hazards has changed
- Relevant new toxicological information are available
- Consider if a new notification or an update is
- required
- The composition of the mixture has changed
- The mixture product identifier (including UFI) has changed
- Notifier data are changed

WORK IN PROGRESS

- Commission, ECHA, Industry and Appointed Bodies are working towards:
  - Creating a workable system
  - Achieving harmonization throughout Europe to provide information for emergency response
  - Collecting data in a useful manner
  - Providing all the stakeholders support and guidance.

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imelines

2017

Finalising tools (Q1 2018)
- PCN format
- UFI generator
- EU PCS

Preparation of support material started

Feasibility study on notification portal

2018

Development of central portal starts, according to feasibility study outcome

Completion of guidance and support material

2019

Formats, to guidance, helpdesks a support mat in place

Central port ready, first version

- ECHA/Stakeholder working groups in operation

Guidance	EU product categorisation system	IT tools

Guidance phase 1

Phase 1: drafting (on-going)

- Active involvement of authorities and industry via working group

  poisoncentres.echa.europa.eu/guidance

- Workshop planned early December

- First draft by end 2017

8 Guidance on harmonised information relating to emergency health responses
Draft (Internal) version 1.0 – Month 201x

1. Introduction

1.1 General introduction

A large number of chemical mixtures are used in the EU on a daily basis. The general public and workers regularly come into contact with them, both in their private life and in the occupational environments.

Chemical products are in general considered to be safe when they are used properly. Nevertheless, unintentional exposure to chemicals can occur, for example due to inappropriate use or accidents. When this happens, immediate access to relevant information on the chemical product is crucial to medical staff and those who provide emergency response.

1.2 Legal background

Already since 1988, Council Directive 88/379/EEC required Member States to appoint a body for receiving information on dangerous preparations ry to meet any medical demand by formulating preventative and curative mea ective was repealed by 1999/45/EC, which provided for a similar obligation. Already ba hat obligation, many Member States had in place a system for collecting mation fro mpanies placing chemical products on the market. This informatio s accessible to the Poison Centres, the bodies established in the Member States to pr me l advice on health emergencies. Depending on the Member State, physicians en edical staff, workers and the general public are able to contact the Poison Centres to ge mendations on medical treatment.

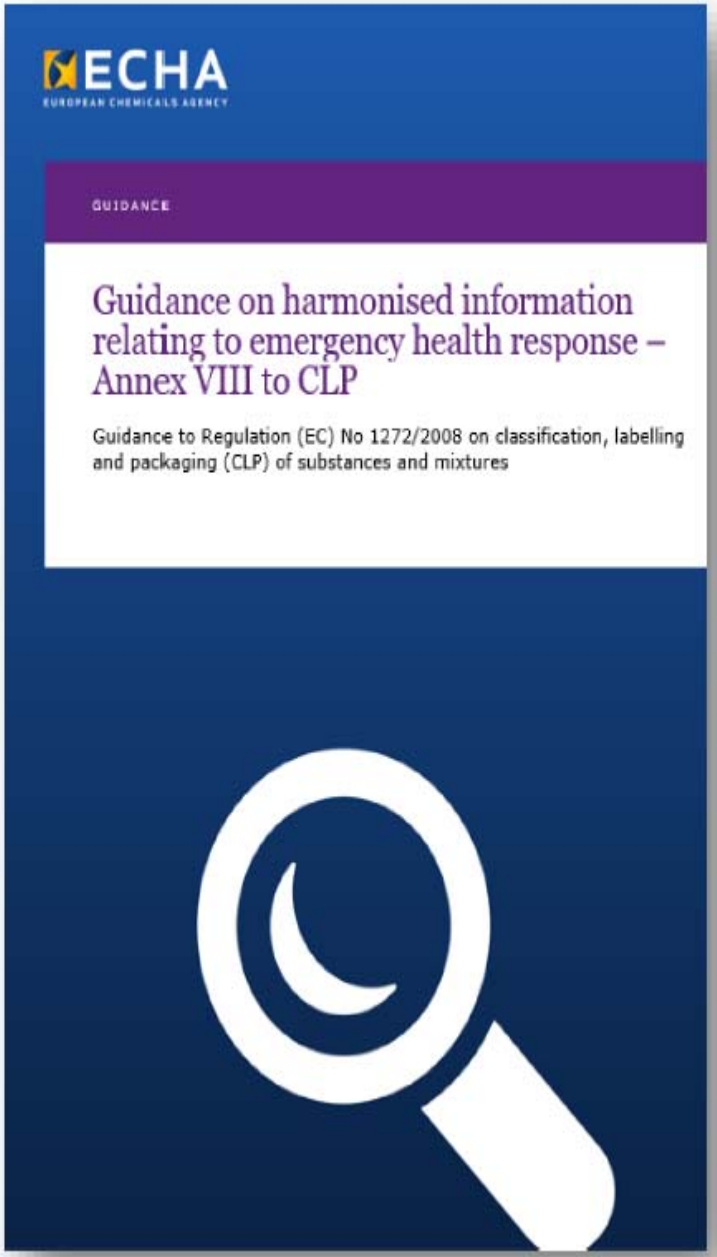
Article 45 of the CLP Regulation ((EC) 2008, w entered into force on 1 June 2017) requires the EU Member States to app eiving information on the composition of hazardous mixtures (e.g. detergents, es) to enable the formulation of preventive and curative measures. The a harmonised information requirements has led to considerable variation in ations ication systems, data formats and information requirements regarding the infor n in each Member State. Thus importers and downstream users placing ure the m et in different Member States have needed to submit similar informatio in different formats. This diversity has led to inconsistencies in the infor evaiabi to medical personnel and the general public in cases of poisoning incidents ent Member States.

The European Co ives a mandate to address these shortcomings and a review was carried ou onsulta with stakeholders and with the support of the European Association of Centr d Clinical Toxicology (EAPCCT). Following the review as foreseen in Artic Commission Regulation (EU) 2017/542 was adopted. The Regulation entered on 12 April 2017, adding to the CLP Regulation an annex (Annex VIII) to harmonise, in s of format and content, the information relating to emergency health response that certain operators placing hazardous mixtures on the EU market are required to notify to the bodies appointed by each Member State (from now on called the "appointed bodies"). This information includes, for example, the cl mixture and of the company responsible for the placing on the mar composition and hazardous ingredients and on the uses. The inform electronic means in a specified format, which enables the appointed the relevant information. Through a new unique formula identifier ("U 4 in detail), the Poison Centres, who are the end user of the submitte able to identify exactly the product of concern and to suggest the app treatment. The appointed bodies and Poison Centres (which are not n entity, although in some Member States this may be the case, see sec need to ensure the confidentiality of the information received.

Guidance phase 2

Phase 2: formal consultation with our partners

- Launch in Q1 2018
- Active participation of our accredited stakeholders
- Final Guidance v1.0 by end 2018



POSSIBILITY OF CENTRALISED SUBMISSION SYSTEM

Central portal features

- Collect and dispatch notifications from industry to appointed bodies
  - Secure transfer of information
  - Multilingual support
- Automated submission with agreed validations
  - Technical checks (e.g. virus scan)
  - Business checks and basic verification of key elements (e.g. trade name included in the notification)

POSSIBILITY OF CENTRALISED SUBMISSION SYSTEM

Economies of scale

Ensure high level of security

Increase industry efficiency

Facilitate exchange of information among
Member States

Leverage benefits of harmonised formats

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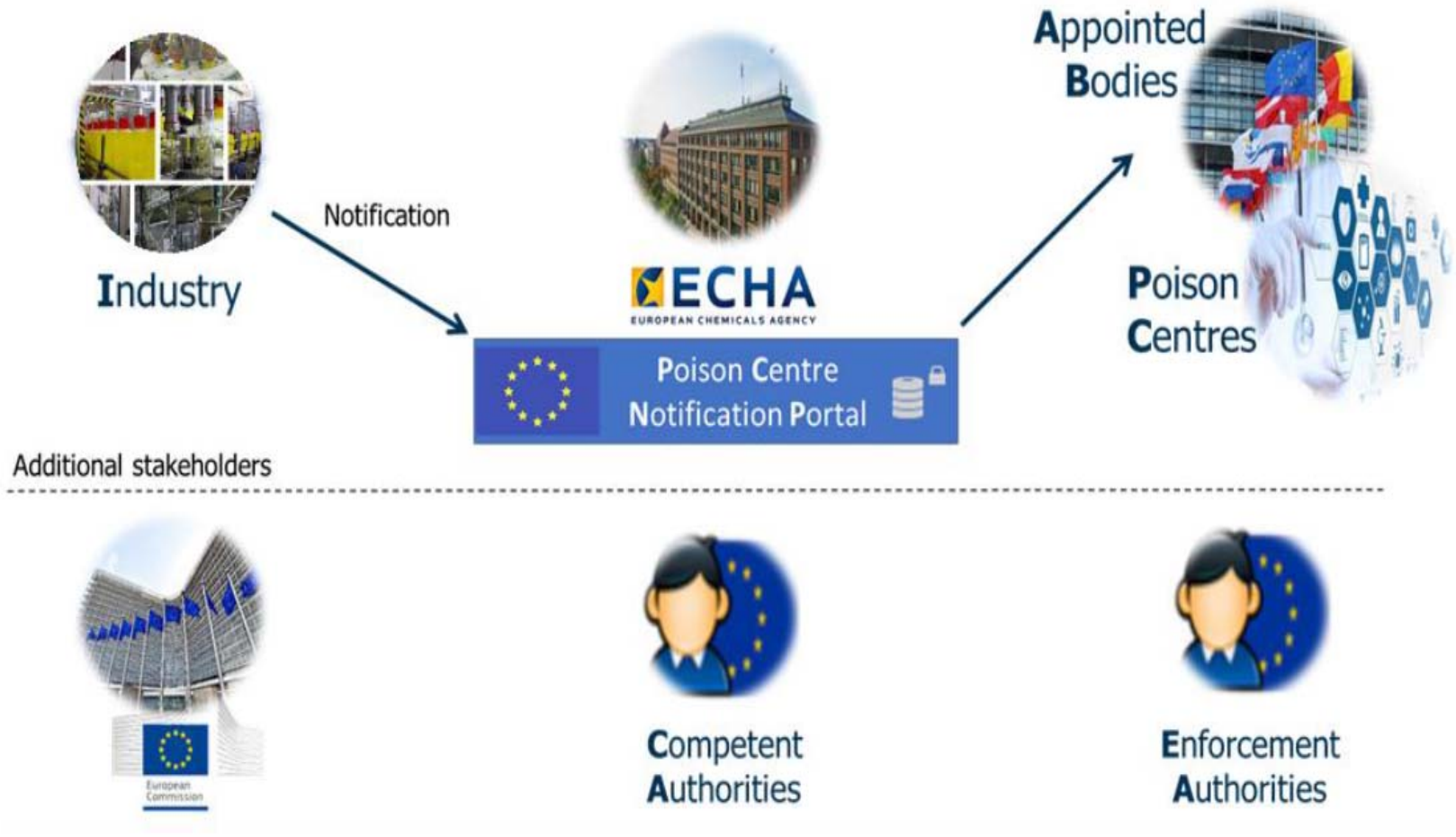
Actors



INDUSTRY WORKLOAD

- New obligations → new resources→ new costs
- Uncertainties due to new requirements not yet clear
- Knowledge of uses along the supply chain not always possible
- New IT tools and guidance ready shortly before the entering into force.
- Still pending issues for some sectors (petroleum products, construction sector etc…)
- Different fees among MSs
- Central portal o mandated bodies?

What is a poison centre?

Poison centres play an important role in the safe use of chemicals and formulate preventive and curative measures in case of poisoning incidents. They provide medical advice to general consumers and physicians on health emergencies arising from exposure to hazardous chemicals or to other toxic agents.

Poison centres in the EU answer on average 600 000 calls for support per year. Roughly half of the cases are related to accidental exposures involving children. Under Article 45 of the CLP Regulation, economic operators placing certain hazardous mixtures on the market have to provide information to national appointed bodies. This information is used by the poison centres.

This website is established by the European Chemicals Agency to facilitate the implementation of new regulations on harmonised information by companies, appointed bodies and poison centres.

News

More news | RSS

24 March 2017

New CLP annex on harmonised information relating to emergency health response has been published

GRAZIE PER L'ATTENZIONE

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