REACH24H CRAC 2022 by REACH24H Consulting Group

14th Chemical Regulatory Annual Conference

Virtual Forum

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Harmonised poison centre notifications system in the EU

CRAC 2022

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Daniele Ape
Poison Centres Team
Submission and Processing Unit
European Chemicals Agency

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Background information

Article 45 of CLP

Notification obligations in place for a long time:

- Importers and downstream users
- Placing mixtures on the EU market
- Classified for health and physical hazards

What:

Provide to Appointed Bodies compositional information

Why:

To allow preventative and curative measures in case of emergency

In practice…

- Differences between national submission systems, formats, information requirements.
- Difficulties for industries in complying with the obligations from one MS to another.
- Information available to medical personnel/Poison centres inconsistent between MSs.
- Problems in the identification of poisoning agent and its chemical composition.

Annex VIII to CLP

Published in March 2017

Objectives:

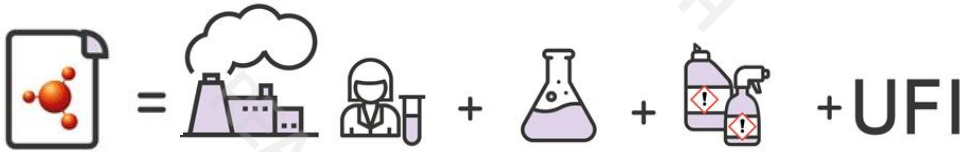
- Same (relevant and complete) information requirements available to all Poison Centres and Appointed Bodies (AB): information to be submitted defined by the legislation
- Preparation of data in a harmonised format: format to be provided by ECHA
- Facilitate identification of the mixture: introduction of Unique Formula Identifier (UFI)

Implementing the system

- Central system (ECHA portal) for preparation and submission of dossiers (optional)
- Tools to include format in industry's own system and automatic submission (on demand)
- Central searchable database for Poison Centres (PCs) and Appointed Bodies (ABs) (on demand)
- Automatic delivery of information to AB's own database (on demand)

Annex VIII and harmonised information requirements

Harmonised requirements in a nutshell



- Submission format – Poison Centre Notification (PCN) format, IUCLID compatible, structured fields for information
- Submitter details – name, address… - consistent with the label
- Mixture information - C&L, tox info, **full composition**, pH, physical state
- Product information - trade name, packaging, uses, colour
- Unique formula identifier – e.g. YV9K-3J9A-G209-C2T7, UFI makes a link between the product and the submitted mixture information

Compositional information

➔ Ideally 100%!

"Component" includes:

- **Substance**

- **Mixture in Mixture** (i.e. mixture from a supplier used in the formulation of a final mixture **and not fully known**); identifiable with
  1. Known components and supplier's details; or
  2. UFI (notified by supplier)

Both to be notified when:

≥ 0,1% if hazardous

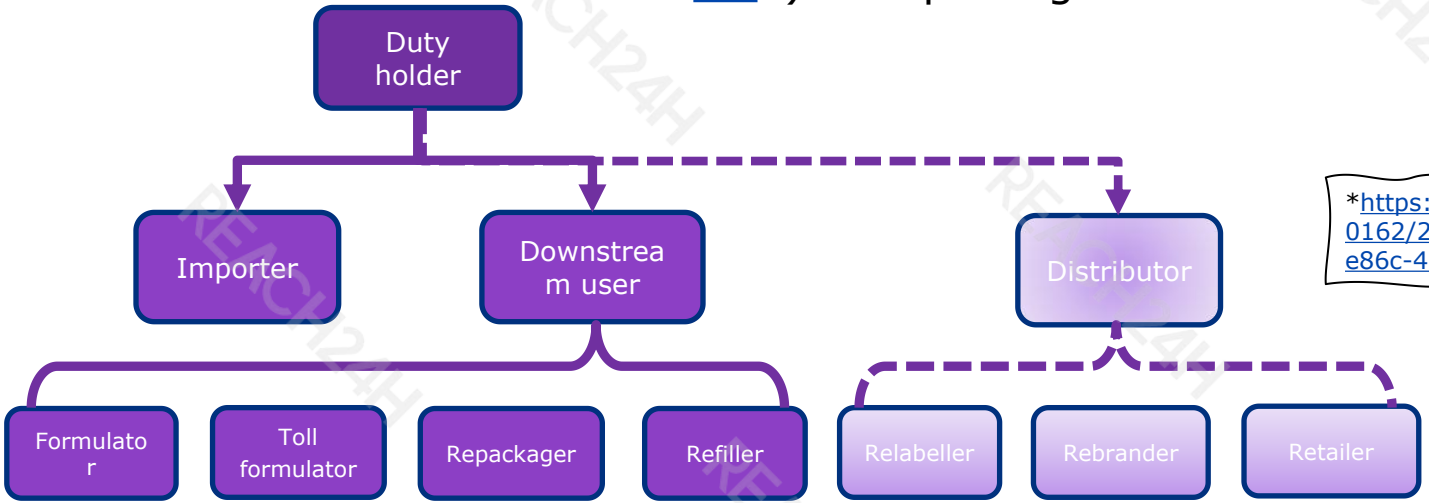
≥ 1% if not classified

N.B.: Information considered relevant and necessary for the purposes of Art.45 provisions

Duty holders

Direct obligations under Article 45

- **Importers**: introducing hazardous mixtures into the European Economic Area (EEA)
- **Downstream users**: *using* substances as defined in REACH and CLP (see ECHA Guidance on DU*) **and** placing on the EEA market



*https://echa.europa.eu/documents/10162/2324906/du_en.pdf/9ac65ab5-e86c-405f-a44a-190ff4c36489

Submitted information

Recipient is the Appointed Body in each Member State

ECHA as facilitator and tools' *supplier*

Each duty holder to fulfil the obligations individually

No data sharing across Member States

Use of data legally limited to:
- Emergency response and curative measures (Poison Centres)
- Statistical analysis and improve risk management measures (Appointed Bodies)

N.B.: Confidentiality ensured by ABs (and ECHA)

Importers and non-EU suppliers

- Non-EU companies do not have any legal obligation
- "Only representative" concept does not exist in CLP
- EU company purchasing directly from non-EU suppliers is a duty holder

ABs have the right (and often the need) to ask for more information or clarifications ➔ Possible to deal with EU companies only

EU duty holder is responsible for the mixtures they place on the market and expected to comply with all relevant obligations (i.e. not only Annex VIII!)

Information required is the same as for any EU-formulated mixture (i.e. full composition!)

Collaboration/support from non-EU supplier expected (and needed!) to:

- make relevant information available to PCs and ABs
- ensure that products are complaint with EU standards
- allow importers to comply with obligations

Technical and legal limitations:

- Non-EU legal entity is not allowed to submit directly via the ECHA Portal (but can open an ECHA account)
- Each duty holder has to submit individually/themselves as they are responsible for the information submitted
- Submissions cannot cover multiple duty holders

Options for non-EU supplier

A) Disclosure of full composition to importer

B) Act as "Foreign user" via the importer's account*

Non-EU supplier can prepare and submit the notification but the information is shared with the importer through their account

C) Appoint a EU-based Legal entity to submit a *voluntary* notification, including a UFI, in all the EU Countries where the mixture is imported

Importer can notify by using this UFI to identify the mixture (either final mixture or MiM)

(* See ECHA Accounts Manual at https://echa.europa.eu/documents/10162/17247/howto_account_manual_industry_en.pdf/9e84c2fb-c876-30a7-7eb9-fde40e968ef5?t=1654174834720)

Option C – Voluntary notification

Objective: ensure compositional information is available to the relevant PCs and ABs
➔ Link from importer's submission to voluntary submission via UFI

Benefit *(for the non-EU supplier):* No need to disclose confidential information to importer

Warnings:
- importer remains responsible for the mixture they import;
- importer needs information to comply with other obligations (e.g. C&L);
- non-EU supplier expected to support the importer in case of further clarifications/additional information requests from authorities (via EU-based Legal entity?).

Implementation status across EU

Caveat

Harmonised format and same information requirements mandatory in all EEA countries

Submission system and access to data depend on each Appointed body's choice

Challenges

Switching from national systems and formats already established

Differences in resources available

(Pandemic)

Limited usability of data according to Annex VIII.
Information previously requested under national regimes used for additional purposes (e.g. enforcement)
Additional/different information previously requested

*https://poisoncentres.echa.europa.eu/documents/1789887/5674408/msd_en.pdf/982d9115-58cb-75c8-80ae-8eb16f5c0009?t=1642685386895

Current situation

Differences in how authorities access submitted data (Central data base or eDelivery)

But **all** Member States to accept submissions through the **ECHA Submission Portal**

Onboarding and preparedness speed of Member States varies: 2 Member States missing at the moment – Notification according to national ("old") rules required

➔ Summary table* (regularly updated) available on the ECHA PC website

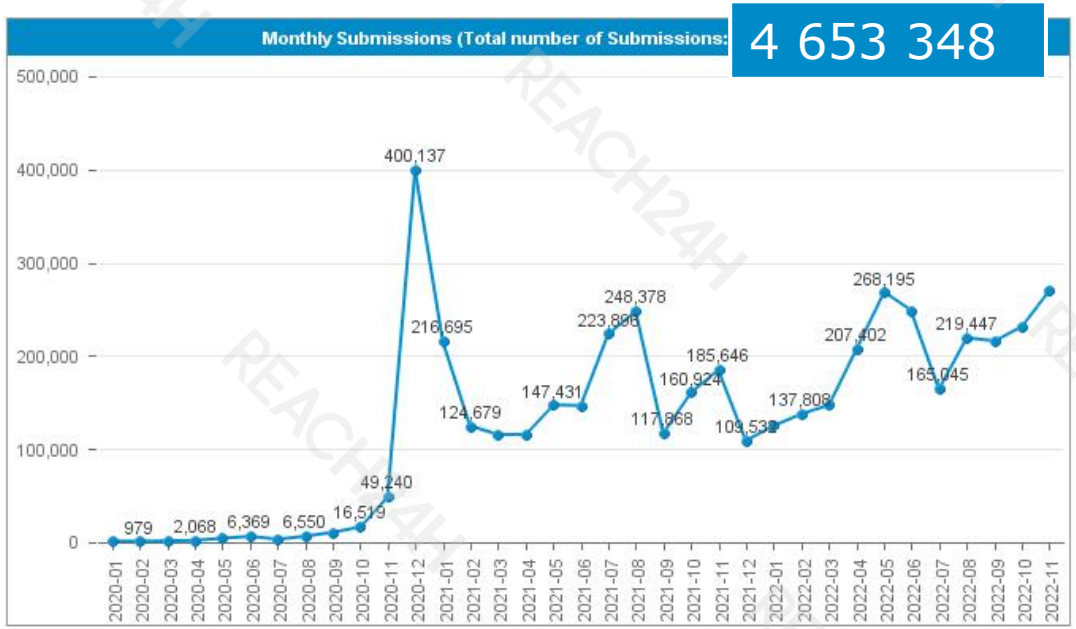
To be noted:

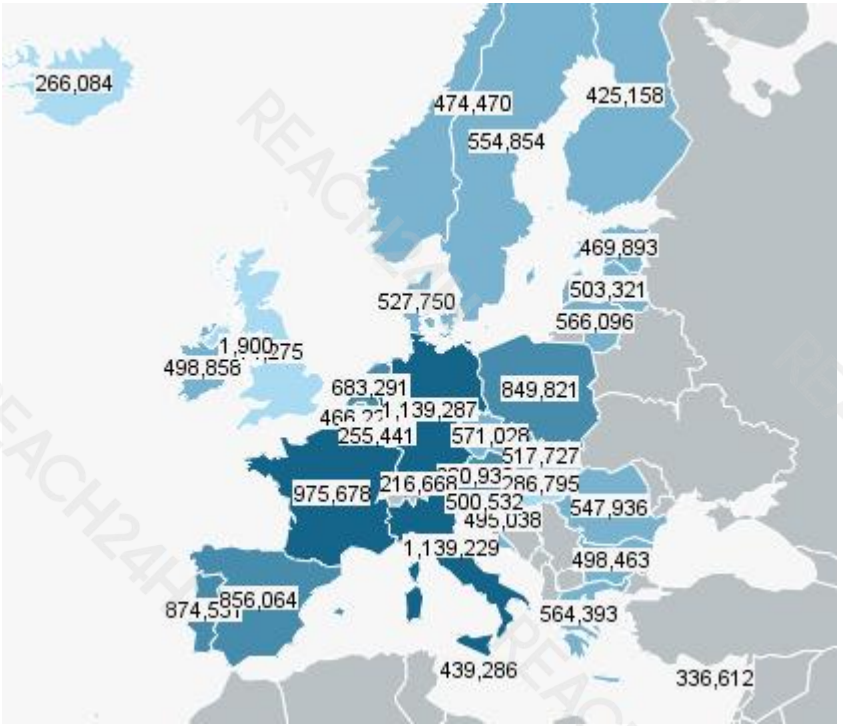
Few Member States maintained a parallel national submission system (e.g. Nordic Countries)
Regulatory frameworks other than Art.45 and Annex VIII

Different scope (possibly different information requirements and use of the data)

Submission figures

1 January 2020 to 30 November 2022



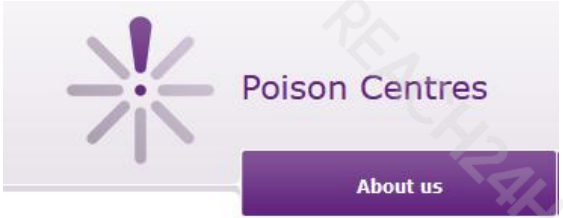


Take home messages

- Full composition needed
- ECHA system is secure:
  - Long and positive experience under different regulatory frameworks
  - More than 4 millions submissions received so far
- Options to limit full disclosure along supply chain exist but collaboration with customers and authorities expected
- Format harmonised and central Portal accepted across EU
- Final objectives to be kept in mind:
  - Ensure human health (and environment) protection
  - Protect consumers and workers
  - Ensure (high) EU products quality standards

Available support channels and tools

The ECHA PC website



Main reference for submitters

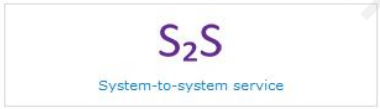
Regulatory Guidance, Q&As, videos and contact forms

Practical guide for dossier preparation, Access to Submission Portal

Format, Guide for developers, Validation rules list

UFI generator and validator

European Product Categorisation system details



How to access the System to System (S2S) service

System to system support

Submission service available for companies that want to use their own IT systems to submit regulatory information

Automated approach:

PCN format included in own IT system

Dossier prepared in own IT system

Automatic transfer of dossier to the ECHA Submission portal

Note:

- Validation possible only upon submission
- IUCLID updates to be maintained by the user

System to system support

S2S support pages available (not only PCN):

- General information on the service
- S2S service manual
- Terms and Conditions
- Developers' Guide to the IUCLID format
- "Application programming interface" (API) specifications
- Specific news subscription

https://echa.europa.eu/system-to-system-submission-service

The LinkedIn Groups

3 relevant Groups managed directly by ECHA and addressed to all stakeholders, in particular submitters and software providers

- *ECHA's poison centre notification group – Annex VIII to CLP*
- *ECHA's system-to-system submission support network*
- *ECHA's IUCLID group*

✓ Updates and news

✓ Ask regulatory and technical questions and find answers to common problems

✓ Share experience and solutions with other members

ECHA
EUROPEAN CHEMICALS AGENCY

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