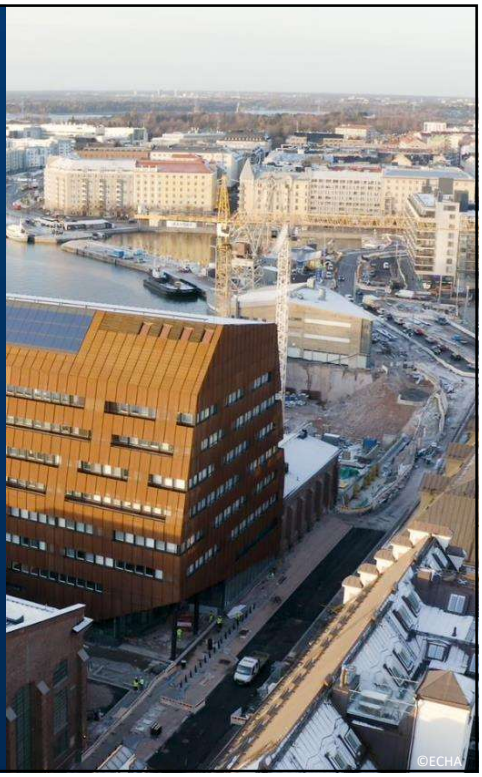
Poison centre notifications - status and support

13th BfR User Conference
21 September 2022

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



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Annex VIII and implementation of the harmonised system – providing the tools

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Harmonisation is key

- Same (relevant and complete) information requirements available to all Poison Centres and Appointed Bodies (AB)
- Preparation of data in a harmonised format
- Facilitate identification of the mixture

Going further than that…

- (Optional) Preparation and submission of dossiers possible via central system (ECHA portal)
- (On demand) Tools to include format in industry's own system and automatic submission
- (Optional) Central searchable database for Poison Centres (PCs) and Appointed Bodies (ABs)
- (On demand) Automatic delivery of information to AB's own database

Tools development

Before 2017	**Art.45**:Differences in formats, information available to PCs and submission systems
2017	**Annex VIII publication**
2018	*Consultations and development*
2019	**Submission Portal live** *(April)* Submissions available to PCs/ABs via **central database**
2020	Group Submission and Standard Formulas features available *(October)*
	1st compliance date
2021	Additional features available, e.g. disabling *(October)*
2022 …..	Validation assistant refinement and system maintenance…

Two+ years into the system – where we are

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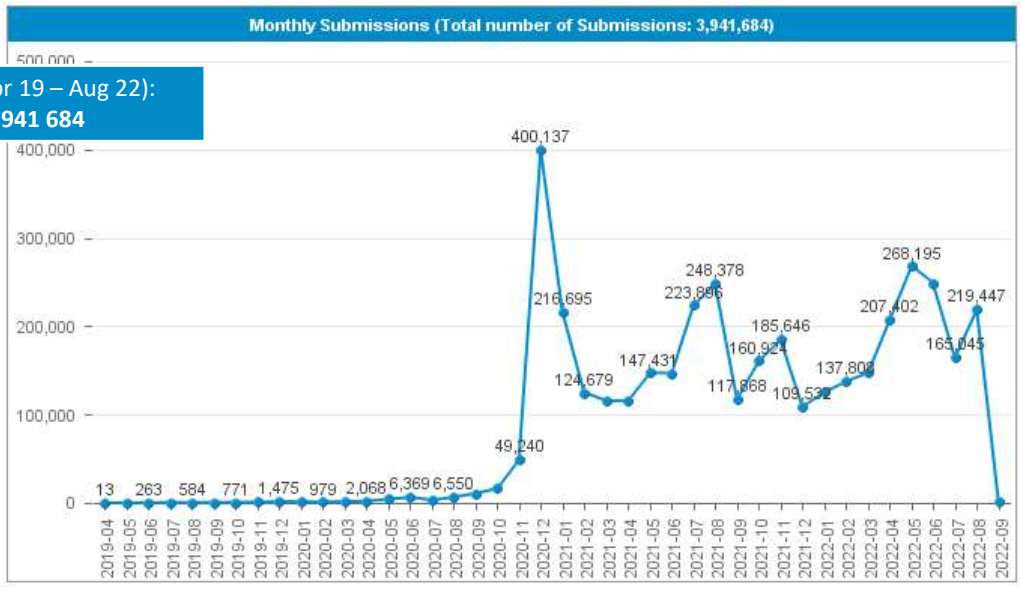
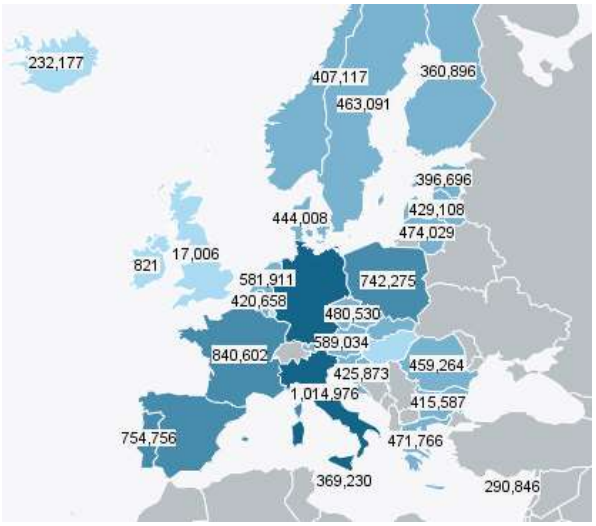
Submission figures

Total (Apr 19 – Aug 22):
3 941 684



Submission figures

1. Italy - 1 014 976
2. Germany - 1 006 585
3. France - 840 602
4. Portugal - 754 756
5. Poland - 42 275
6. Spain - 737 841



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Submission figures – Jan ’21 to Aug ’22

IUCLID cloud

5% use the prepare & submit online in the Cloud. Easy alternative for small to medium sized companies

Upload & submit

10% prefer to prepare offline in downloaded IUCLID. PCN format and IUCLID updates to be maintained.

System-to-system

85% of submissions made automatic fashion. Smaller number of companies!

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Member States overview

→ All Member States to use ECHA systems

→ e-Delivery or PCN database

→ 28 out of 30 MS currently accept

→ Fees, language, placing on the market

Overview table available at: https://poisoncentres.echa.europa.eu/appointed-bodies

The ECHA Helpdesk support and current main issues

New page and contact forms for ECHA support

Helpdesk support

I am from a company or a member of the public and I need

Regulatory support
REACH, CLP, BPR, PIC, WFD (SCIP), POPs, DWD, EUON, EUCLEF ...

Technical support
IUCLID, REACH-IT, R4BP3, chemical data on ECHA website...

Additional support
Invoicing, access to documents, speaking requests, visits to ECHA...

I am from an EU/EEA national authority and I need

Authority support
Regulatory support
Technical support

Contact details

Mailing address

P.O.Box 400
00121 Helsinki
Finland

Switchboard:
+358-9-686180

Telefax:
+358-9-6861 8210

Visiting address

Telakkakatu 6
00150 Helsinki
Finland

Opening hours

Press

How to get to ECHA [PDF]

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Regulatory support

ECHA and the national helpdesks work together to provide support to companies on the REACH, CLP and Biocidal Products regulations.

National helpdesks are the first contact points for REACH and CLP questions. Consult the tables below to see who can best help you with your query.

National helpdesks

Contact your national helpdesk on the following questions:

REACH and CLP

- Regulatory and scientific questions from **EU and non-EU** companies on REACH, CLP (including poison center notifications (PCN))

BPR

- Active substance approval – dossier evaluation
- Annex I inclusion
- National authorisation
- Mutual recognition
- Simplified authorisation
- Same biocidal product authorisation
- Parallel trade
- Treated articles
- National laws
- Classification, labelling and packaging of biocidal products
- National fees
- Enforcement
- Scope questions – including Art 3(3) requests

Contact your national helpdesk

ECHA

Contact us on the following questions:

REACH and CLP

- REACH and CLP submission and process
- Evaluation
- Ongoing disputes and pending litigation
- Annex XV SVHC dossiers (or RoI) proposed by ECHA or Commission
- Complex borderline cases of substance in articles
- ECHA's fees and charges
- Questions that require harmonisation and consultation with the European Commission
- Other policy related questions

REACH

CLP

BPR

- Active substance approval – peer review
- Article 95
- Review Programme
- Data sharing and inquiry
- Classification & labelling of active substances
- Union authorisation
- Technical equivalence
- ECHA's fees
- ECHA's guidance

BPR

Other regulation or service

Waste Framework Directive (WFD (SCIP))

Prior Informed Consent regulation (PIC)

Persistent Organic Pollutants Regulation (POPs)

European Union Observatory for Nanomaterials (EUON)

EU Chemicals Legislation Finder (EUCLEF)

Drinking Water Directive (DWD)

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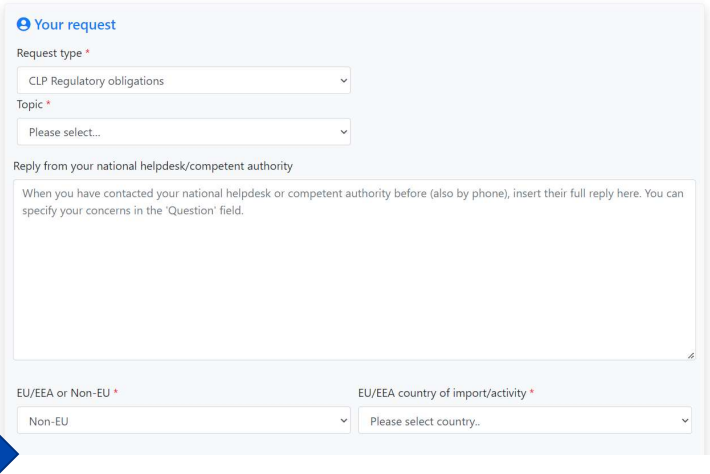
What needs to stay with ECHA

Overview of REACH & CLP enquiries remaining for ECHA	
REACH	▪ Submission-related questions (dossier, joint submission, notification) ▪ Evaluation questions ▪ Questions on on-going data-sharing disputes ▪ Questions on Annex XV dossiers by ECHA/COM ▪ Process-related questions on nanomaterials ▪ Purely scientific questions ▪ Questions on pending litigation ▪ Newly adopted policy questions
CLP	▪ Submission questions on C&L notifications ▪ Questions on CLH submission ▪ Submission questions on requests for alternative name
Other	▪ SCIP and PIC questions ▪ Questions on inventories , IT tools and data dissemination ▪ Questions on ECHA's fees and charges ▪ BPR questions

Criteria for distribution to national helpdesks

Criterion for **EU/EEA based companies**: the national helpdesks of the Member state where you are based.

Criterion: **EU/EEA country of import/activity**, as reflected in the new REACH and CLP contact forms; uniform redistribution to NHDs when possible.



Let's focus on PCN: who should I contact in case of need?

- → Questions about the scope, roles in the supply chain, or duties: your **national helpdesk**
- → When preparing your notification dossier: your **national helpdesk**
- → Once you have submitted your dossier and have a business rule failure: **ECHA**

Questions to be sent to your **national helpdesk**

Ex1: obligations in case of toll formulation. Placing on the market and notification obligations

Ex2: Non EU suppliers and issue with sharing information. Options to fulfill the obligations

Ex3: EU suppliers and issue with sharing information (e.g. only the SDS). Options to fulfill the obligations

Questions to be sent to **ECHA**

Ex1: Business rules failure, issue with the messages and/or unclear how to fix the shortcoming. How can I fix my dossier to get it through?

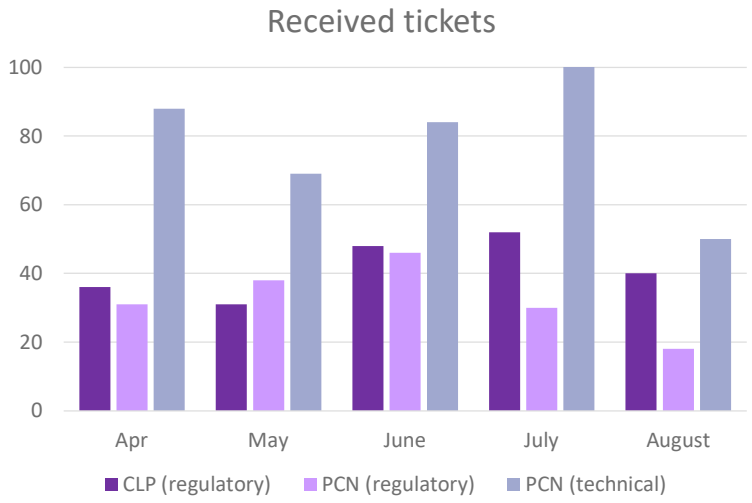
Ex2: Member States implemenation status. Information in the Overview Table and confirmation of reception. What is going on?

Ex3: I want to use the System-to-System option to send my notifications. How should I proceed?

How the questions get to the national helpdesks

- Directly from the customer
- ECHA will re-direct the customer to the appropriate national helpdesk for EU and non-EU questions
- ECHA will keep track of the numbers of queries re-distributed
- National helpdesks can ask ECHA for support (Helpnet network)
- Companies can ask ECHA after contacting NHDs, providing the reply from the national helpdesk and explaining their concerns

Overview of PCN enquiries April - Aug 2022



Current issues: MiM identification

Issue: Dossier fails if a **MiM** was notified for **industrial use only** and is included in a mixture intended for consumer/prof uses (BR569)

Reasoning: The relevant use (and information requirements) depends on the *final* use of the mixture, including when used in the formulation of another mixture.

Way forward: request the supplier to update the MiM's notification (i.e. cannot be a *limited* submission).

Otherwise cannot identify the MiM with UFI only (note: the supplier may be incompliant)

Current issues: Assets transfer

Issue: Following **merging or aquisition of legal entities**, submissions cannot be transferred from original Legal Entity (LE) to different/new LE

Reasoning: No asset transfer functionality available.

Dataset including LE information is delivered to AB or stored in Interact portal, submission always needed to udpate the information.

Complex due to need for consistency between LE ECHA account and LE dossier

Way forward: Make a new submission from new LE account and containing new LE information.

Dataset can be shared.

Current issues: Legal entity information change

Issue: Changes in (existing) **LE information** (e.g. company name) lead to misleading/wrong information available to AB/PC

Reasoning: Changes in ECHA account are not automatically reflected in dossier received by AB/PC.

Common case: discrepancy between name of dossier submitter and duty holder information

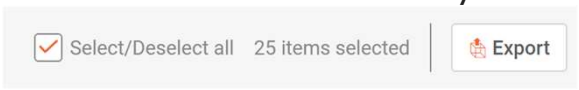
Way forward: Changes need to be pro-actively made in the dossier as well before submitting the update

Current issues: IUCLID data import/export

Issue: **export/import** of IUCLID databases

Reasoning: business need to switch away from existing IUCLID installation (e.g. from local IUCLID to IUCLID Cloud)

Way forward: IUCLID allows for batches of datasets and dossiers to be exported as i6z. Batches are made by selecting all items in list of items.



Resulting file can be imported directly into any IUCLID installation.

Important to export and import related support material (e.g., Legal entities, Templates). Refer to IUCLID manual for more complex cases.

Current issues: System-to-system and multiple failures

Issue: Same submission **failing multiple times**

Reasoning: Automatic submission systems keep submitting and failing for the same reason, possibly with no intervention of the operator (e.g. UFI format incorrect due to hidden characters).

Way forward: Request to put in place an alert system to detect multiple failed submissions for same reason and in short time. Allow manual intervention to avoid jamming the system.

Current issues: Information flow

Issue: Downstream users' **lack of information** about composition and/or MiM's identification

Reasoning: Lack of information exchange from/to supplier, about mixture identification (e.g. non-EU supplier) and/or customer's plans (supplier unaware of market placement).

Way forward: Improve communication; make best use of UFI.

- Protect confidential information about compositon;
- Can be submitted voluntarily by non-EU supplier's "delegate".

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

Support available in German*

Regulatory Guidance document

Practical Guide on dossier preparation

*And all EU languages

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

What's next

The Present and the future

- PCN IT solution moved to maintenance mode
  - Hosts all features that support you to be compliant
  - Continue to improve but no major developments foreseen (e.g. clean validation rules backlog and fine tune existing rules)
  - Monitor ongoing CLP revision (definition of duty holder in Article 45, minor changes in Annex VIII, new hazard classes, online sales)
  - Original working groups merged in one PCN Stakeholders Group; less regular meetings; mainly to share information

October ’22 release

- No major format changes (next format changes release in April ‘23)
- Further work on agreed validation rules (e.g. Group Submission)
- Improved navigation tree
  - Improved information visualisation
  - Expandable records now reduced; access specific information; records on demand, on dedicated window.
  - Possibility to reuse existing records via cross-reference as alternative to create new records

Thank you

daniele.ape@echa.europa.eu

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