



Staying on top of your obligations

Safer Chemicals Conference

2 June 2020

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#SAFERCHEMICALS



Overview

- Annex VIII to CLP: changes in information to be provided
- Key points to consider
- Support and guidance

First amendment to legal text

- Entered into force **20 January 2020**
- Outcome of two-year discussions with stakeholders about specific areas which needed further clarification
- Amendments to
 - Annex VIII
 - Supplemental labelling information (Article 25)
 - Exemption from labelling and packaging requirements (Article 29)
- Scope
 - Postponing first compliance date
 - Modifying some requirements
 - Editorial corrections

* Commission Delegated Regulation (EU) 2020/11



Compliance date

Compliance date for consumer use mixtures postponed from 1 January 2020 to **1 January 2021**

UFI and labelling

More flexibility, for example:

- Not necessarily “within” the label but close to the label elements
- Not necessarily on all packaging layers





Components identification

Mixture in mixture composition not fully known:

- a) if UFI was previously notified to the relevant appointed body → **UFI** and **product identifier**
- b) if UFI not previously notified to the relevant appointed body → **SDS composition**, **product identifier** and **supplier's details**

pH information

Justification required when pH not available
PCN format to provide a predefined list of options

More in our [webinar](#)



Second amendment to legal text

- Currently undergoing final steps of legislative process → changes to Annex VIII and Article 25
- **Main objective** is to address workability issues raised by specific sectors
- **Purpose** is to balance need for information and administrative burden





High composition variation: cross-sectors solution

Issue: High variability of very similar components; mixture composition at each given time not known

Solution: Possibility to group components in one interchangeable components group when:

- components have the same toxicological profile and classification
- components have the same technical function
- final mixture's classification and additional information do not change





High composition variation: sector-specific solution

Issue: High variability or unknown composition of raw materials combined in continuous production processes; need to fulfil specific standards defined by properties rather than composition

Solution: Mixtures with composition corresponding to specific standard formulas can be notified according to that formula and deviate from default Annex VIII

- Cement
- Gypsum
- Concrete
- Fuels





Point of sale paints

Issue: Formulations on demand at the point of sale (“*bespoke paints*”); high number of notifications and generation of UFI by retailers

Solution: No need to notify bespoke paints themselves. Requirement to include in the label UFIs of hazardous components (and concentration when exceeding a threshold)



Timelines

- Commission inter-service consultation ended in April
- Final consultation with competent authorities 15 May
- WTO notification (60 days)
- Commission adoption (foreseen in summer)
- Entry into force after scrutiny period

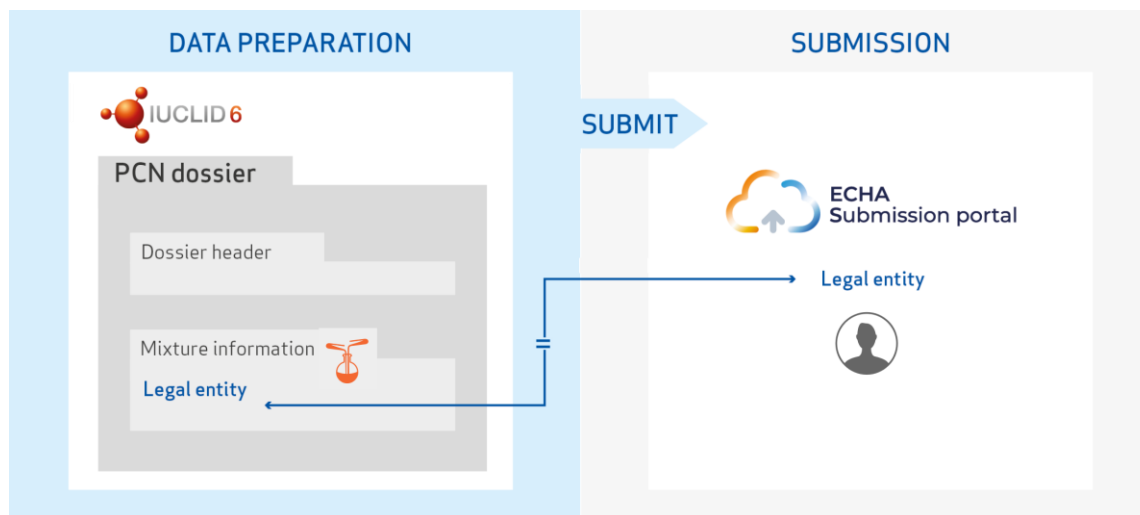


Important to consider



Legal entity management

- Legal entity details mandatory at mixture level
- **Consistency** with the legal entity in the submission portal is essential to avoid validation rule failure
- Legal entity in your final mixture and the portal should both represent the duty holder



Legal entity management

- Before you submit, check the legal entity in the dossier (mixture level) against the legal entity of the logged-in user in the Portal – **must be the same**
- Potential issue mostly for third parties preparing on behalf of duty holder and user of IUCLID stand-alone
- Foreign user explained in additional support
- Checking the legal entity and establishing a 'Foreign user' to work on your behalf – instructions available in the [PCN practical guide](#)

Know your obligations

Duty holders under Article 45: Downstream users and importers



Formulator, toll formulator, re-filler, re-packager

→ Direct notification and labelling obligations according to Annex VIII

Potential duty holders under Article 4: Distributors



Retailer, re-labeller, re-branding

→ Mixtures placed on the market have to be CLP compliant (shared responsibility)

Suppliers and distributors

- Working together to avoid information gaps
- Communication is a two-way street



- Upstream supplier can include any changed distribution information in their submission, e.g. trade name

If the relevant information is not included in the original submission made by the upstream supplier, the distributor may need to make their own submission







Multilingual notifications






- Information must be in language accepted by the Member State
- All relevant market areas and languages need to be indicated
- Free text fields, e.g. toxicological information and some C&L, required in all languages
- Multilingual notifications not supported in older versions of IUCLID 6 (offline) – **update your IUCLID** to the latest version

Toxicological information (section 11 of SDS)

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





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


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Support and guidance



Useful guidance

- Annex VIII
(update published in May)
- Labelling and packaging
(update published in May)
- Substances in articles
- Safety data sheets

echa.europa.eu/guidance-documents/guidance



Guidance



Support

- Targeted tool [support](#)
 - Guides, manuals and key documents
 - Examples and more
- General [support](#) page for translated publications, Q&As, eLearning
- [Steps](#) for industry



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ECHA's poison centre notification group



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