

CLP developments in 2020:

12. ATP, UFI and PCN

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13 May 2019

12. ATP

- Commission Regulation (EU) No 2019/521 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on the classification, labelling and packaging of substances and mixtures
- Harmonisation with revisions 6 and 7 of GHS
- Changes in labelling and classification of hazardous substances and mixtures
- No new harmonised classifications
- Mandatory after 17 October 2020, can be applied earlier

Changes

- New hazard classes – desensitised explosives and pyrophoric gases
- Modified method of classifying flammable gases
- Added cut-off limit values for some health hazards
- Four new H-sentences
 - H206 – Fire, blast or projection hazard; increased risk of explosion if desensitising agent is reduced.
 - H206 – Fire or projection hazard; increased risk of explosion if desensitising agent is reduced.
 - H208 – Fire hazard; increased risk of explosion if desensitising agent is reduced.
 - H232 – May ignite spontaneously if exposed to air.
- Modified P-sentences

Modified P-sentences

- Completely modified P103
 - Read label before use -> **Read carefully and follow all instructions.**
- Supplemented P280
 - Wear protective gloves/protective clothing/eye protection/face protection/ ... -> Wear protective gloves/protective clothing/eye protection/face protection/**hearing protection/**
- “... the precautionary statements that appear on labels or in safety data sheets may incorporate minor textual variations from those set out in this Annex where these variations assist in communicating safety information and the safety advice is not diluted or compromised. These may include spelling variations, synonyms or other equivalent terms appropriate to the region where the product is supplied and used.”

Further activities

- Manufacturers: verify the criteria for the classification and labelling and make sure that products are properly classified and labelled.
- General: make sure that the modified P-sentences on labels will use the appropriate text after October 2020.
- Allowed deviations from the text in the CLP Regulation – only minor deviations are possible in the declination, spelling or choice of words that do not alter the meaning of the sentence or cause obscurities.

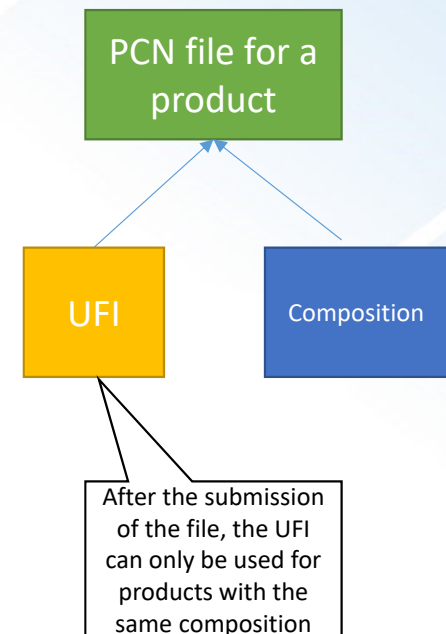
UFI and PCN

The purpose of UFI and PCN

- Annex VIII of Regulation CLP 1272/2008
- Harmonising the method of providing information and the information itself that is available to poison centres in EEA member countries
- Greater transparency and more accurate data about hazardous mixtures that are available to poison centres
- Faster and more accurate courses of action in cases of poisonings with hazardous mixtures

Glossary

- **UFI – Unique Formula Identifier**
 - A 16-character alphanumeric code that must be put on the label of every hazardous mixture (or on SDS, if it is used for industrial purposes), placed on the market in the EEA.
- **PCN – Poison Centre Notification**
 - Notification procedure performed in a specific EEA member country to notify a hazardous mixture. With a notification, a specific mixture composition is fixed to a specific UFI. When a chemical is notified, its UFI(s) can only be used to notify the mixture with the same composition.
- **PCN file**
 - File, prepared with software tools issued by the ECHA. The file is, during the PCN notification procedure, sent via ECHA's portal to the poison centre database.



What, for whom and until when must UFI and PCN be performed?

What:

• **Mixtures**, categorised as **health hazards** (H3XX) and / or **physical hazards** (H2XX)

For whom:

• In any case:

- **Manufacturer** of a hazardous mixture
- **Importer** (from third countries) of a hazardous mixture
- Depends on the communication with the supplier:
 - Someone who **pre-packages/renames the hazardous mixture**
 - **Distributor** of a hazardous mixture

When:

- **Consumer use** – from **1 Jan 2020**
- **Professional use** – from **1 Jan 2021**
- **Industrial use** – from **1 Jan 2024**

Exception:

Mixtures, notified according to the national procedures (e.g. ISK in Slovenia) **before the set deadline** can be placed on the market **without an UFI or PCN** until **1 Jan 2025** or **until formulation change!**

Review of the manual PCN notification procedure

- Generation of the UFI code - <https://ufi.echa.europa.eu/> - one code for each formulation
- Company registration on the ECHA portal - <https://ecs.echa.europa.eu/cloud/submissions/list>
- Log-in
- Generation of a PCN file with the IUCLID Cloud tool
- Submission of the PCN file
 - Use of the ECHA tool is normally free of charge, but individual member states can decide to charge administrative fees for the PCN notification

Information, required for the registration

- Trade name(s)
- UFI(s)
- Data about the legal entity (phone number, address, contact person)
- Product category according to EuPCS

• EEA member states where the formulation will be placed on the market

• Types of packaging (volume, type of packaging)

- Physical characteristics (pH and such)
- Attached SDS
- Toxicological data for the mixture and components

• Product classification and labelling

• 100% composition

In the languages of member states where the mixture will be placed on the market

100% composition

- List all substances, even those that are **not hazardous** (if they exceed 1% in quantity).
- Substance name, CAS/EC, index and **classification**
- Concentration range
- Concentration range width depends on the hazard level of a substance
- Formulation with another mixture (mixture in mixture) – list the mixture's UFI
- **If the UFI code is still not mandatory for a mixture in mixture and the manufacturer does not provide 100% composition, a safety data sheet and supplier's contact data must be submitted.**
- Colourants/perfumes can be indicated as generic components (without identifiers)
- Certain other exceptions

Substance concentration [%]	Maximum permitted concentration range width [%]
≥ 25 - < 100	5
≥ 10 - < 25	3
≥ 1 - < 10	1
≥ 0.1 - < 1	0.3
≥ 0 - < 0.1	0.1
H318, H314, H314.1a, H314.1b, H314.1c, H300.1, H300.2 H301, H302, H310.1, H310.2, H311, H312, H330.1, H330.2, H331 and H332	
Substance concentration [%]	Maximum permitted concentration range width [%]
≥ 25 - < 100	20
≥ 10 - < 25	10
≥ 1 - < 10	3
≥ 0 - < 1	1
Other classifications and non-hazardous chemicals	

Obligations of distributors

- Article 4 (10) of the CLP Regulation:
 - Substances and mixtures shall not be placed on the market unless they comply with this Regulation.
- The distributor **must** ensure that only products that conform with the CLP Regulation provisions are placed on the market.

↓

The distributor must verify that a PCN notification has been performed for the mixture they place on the market and for all member states where they place the mixture on the market.

If the formulator / first importer fails to do this, the distributor may perform the notification on their own to be able to place the mixture on the market. However, the distributor is then **responsible for the content and the accuracy of the data.**

Obligations of distributors with own brands

A company that **repackages** or **renames** a mixture is a **distributor** in accordance with the CLP Regulation.

Option 1:

Such a distributor will have to communicate all additional **trade names** and **new packaging** up the supply chain to the formulator, so that they are included in the original PCN notification.

Option 2:

Alternatively, the distributor can **make the PCN notification** (and generate a **new UFI** or use the **previous one**) on their own. However, in this case, **the distributor is responsible for the content and accuracy of the data.**

Obligations of manufacturers and first importers



- Guaranteeing that PCN notifications are submitted for all their formulations in all member states where they are placed on the market **(even through distributors!)**
- Updating PCN notifications if there are additional trade names or packaging changes – also for the buyers who rename the mixture or change their packaging, **because they are not required to submit notifications in accordance with the CLP Regulation!!!**
- Determining UFI codes for products, changing UFI codes when formulations in the product change and updating PCN notifications
- Correspondence with buyers down the supply chain
- The first importer **must** know the entire (100%) product composition.

The following slides include examples of the IUCLID tool developed by ECHA to create PCN files


Submitter information

BENS Consulting d.o.o.

Define the dossier information


PCN number*  


- In case 'The submission is an initial notification', click on the icon to generate a new PCN number. - In case 'The submission is an update', in the 'PCN number' field you must keep the same PCN number as in the related previous submission (i.e. do not generate a new PCN number). - In case 'The submission is a new notification after a significant change of composition', you must generate a new PCN number. Note that in this case the PCN number of the related previous submission must be indicated under the 'Unique formula identifiers (UFI) and other identifiers' section and specified as 'CLP related PCN number'.


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
36/255


Country (market placement)

slovenia 


Austria 


Belgium 


France 


Slovenia 

Language

german 

French 

German 

Slovenian 

This is the window where market placement countries and the languages are picked. Note that languages are chosen separately and it is possible to accidentally not choose a member states' official language, invalidating the notification.

Every packaging type (both volume and type of packaging) has to be added individually. It is not possible to just choose a packaging type and assign multiple volumes.

Packaging

Type of packaging in contact with the product (container type)

Please select



Size of packaging in contact with the product (container size)

150

mL



Packaging related attachments

[+ New item](#)

No items added

[+ New item](#)

The section where toxicological information has to be entered in the languages chosen at the beginning. Safety data sheets have to be provided in languages chosen at the beginning.

Safety data sheets of mixture / product

[+ New item](#)

No items added
[+ New item](#)

Toxicological information (section 11 of SDS)

fr

Edit	Format	Table								
B	<i>I</i>	<u>U</u>	S	x ²	x ₂	☰	☷	☶	☵	☲
Paragraph	A	A	☰	☷	☶	☵	☲	<i>I</i> _x		

de

Edit	Format	Table								
B	<i>I</i>	<u>U</u>	S	x ²	x ₂	☰	☷	☶	☵	☲
Paragraph	A	A	☰	☷	☶	☵	☲	<i>I</i> _x		

sl

Edit	Format	Table								
B	<i>I</i>	<u>U</u>	S	x ²	x ₂	☰	☷	☶	☵	☲
Paragraph	A	A	☰	☷	☶	☵	☲	<i>I</i> _x		

The section where classification and labelling of the product have to be entered. Note that every category has to be entered separately, and choosing a correct classification does not automatically result in the correct Hazard statement being chosen. The section includes GHS classifications that do not exist in CLP as well.

This section has to be entered for every substance, not just the product itself.

Health hazards

Acute toxicity - oral

Hazard category
Please select

Hazard statement
Please select

Acute toxicity - dermal

Hazard category
Please select

Hazard statement
Please select

Acute toxicity - inhalation

Hazard category
Please select

Hazard statement
Please select

Skin corrosion / irritation

Hazard category
Please select

Hazard statement
Please select

Serious eye damage / eye irritation

Hazard category
Please select

Hazard statement
Please select

Respiratory sensitisation

Hazard category
Please select

Hazard statement
Please select

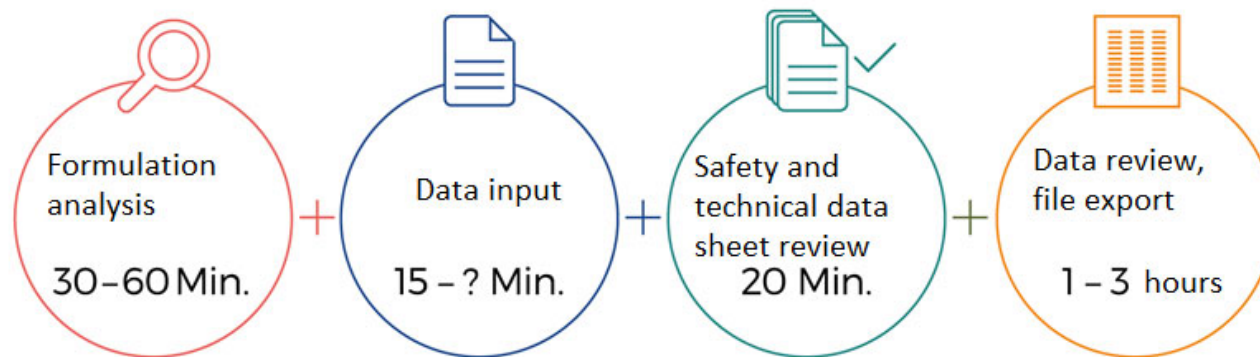
Skin sensitisation

Hazard category
Please select

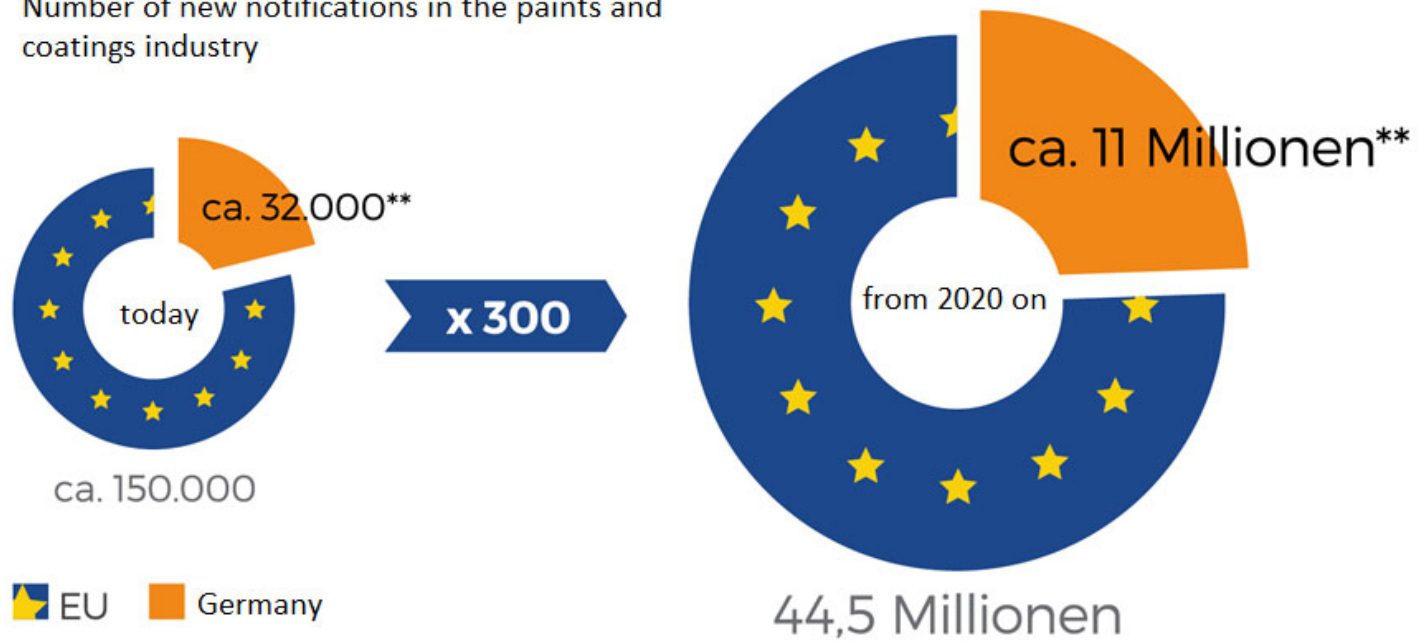
Hazard statement
Please select

Impact on the industry

- According to the assessments made by the *Verband der deutschen Lack- und Druckfarbenindustrie*, the price of an individual manual notification is between EUR 300 and 600.
- Manual notification procedure: 2 to 7 hours
- Updates are conducted using the same procedure as a new notification – extra costs



Number of new notifications in the paints and coatings industry



* Quelle: Wood, Study on workability issues concerning the implementation of Annex VIII, Second Interim Report 2019

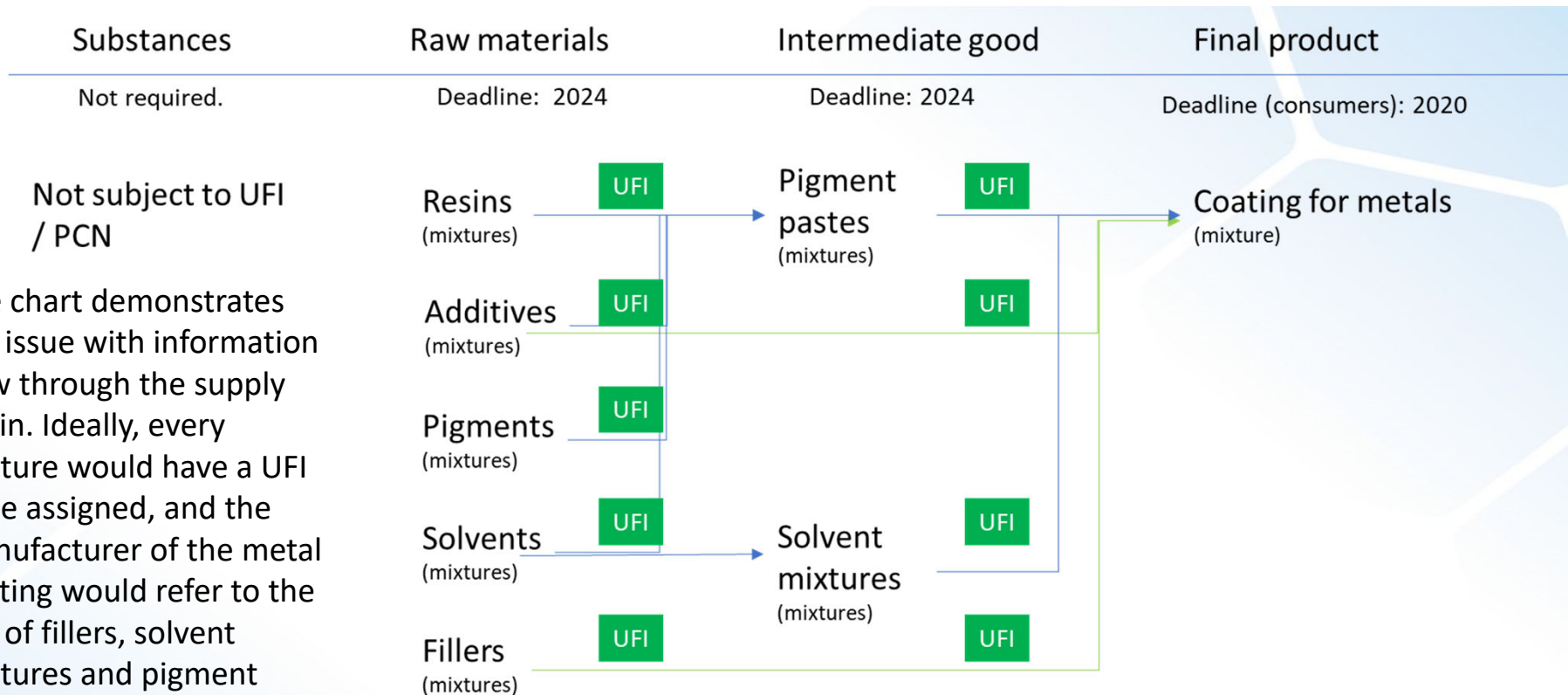
**Estimate

Our role

- For formulators, first importers and distributors who will make their own notifications:
 - Chemius will support automatic composition, submission and delivery of PCN files using information about formulations for all EEA member states.
 - We will also offer a system for managing and keeping track of formulations and their UFI codes
- For distributors
 - General support for fulfilment of legal requirements as per Annex VIII
 - Practical advice in correspondence with suppliers

Expected issues

- Keeping track of formulations and UFI codes
- Manual preparation of PCN notifications
- Correspondence in the supply chain
- 100% composition



However, raw materials and intermediate goods are placed on the market for industrial purposes, so their deadline is in 2024. If the final coating is placed on the market for consumers, the formulator must create a notification – with no raw materials UFI to refer to, as those mixtures do not require UFI numbers. The manufacturer must attach safety data sheets of the materials and list the suppliers' contact numbers.

Further activities

- **Distributors with their own brand**
 - Prepare a strategy regarding UFI and PCN (correspondence with suppliers or own notifications)
- **Distributors**
 - Check with your suppliers if they are aware of their obligations regarding UFI and PCN
- **Manufacturers and importers**
 - Take stock of all formulations that are placed on the market by you or your distributors, in which member states and for what types of use (consumer, professional, industrial use).
 - Think about the system that you will use for managing notifications and UFI codes.
 - Prepare for product labelling with UFI codes.
 - **Importers:** Explain to suppliers what requirements you must fulfil for placing their mixtures on the market and come to terms for reporting compositions.

Everyone: buy yourself extra time by notifying chemicals that are being or will be placed on the market in member state using current national procedures **before 1 January 2020.**

The background features a light blue and white color scheme with abstract, geometric patterns resembling honeycomb or cellular structures. These patterns are primarily located in the corners and along the edges of the slide, fading into a plain white background in the center.

QUESTIONS?