CROATIAN INSTITUTE OF PUBLIC HEALTH

Experiences with product notifications in Croatia

Toxicology Division
Tajana Lambert

TODAY'S TOPICS

- ABOUT OUR DIVISION
- SDS REVIEW
- WORKER EDUCATION
- WORKSHOPS
- PREPAREDNESS
- PCN REVIEW
- CONCLUSION

INTRODUCTION

- 1997.–2019. – Institute of Toxicology
- 2019 integrated into the Croatian Institute of Public Health → Toxicology Division

TASKS WE PERFORM

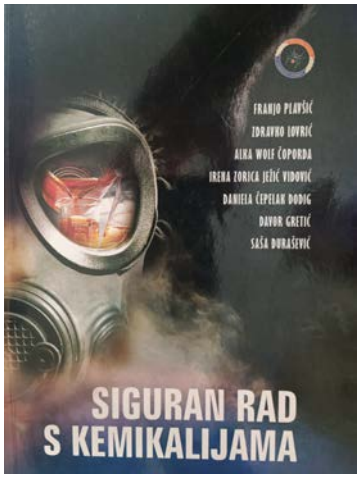
REVIEW OF SDSs

- Article 31 of the REACH Regulation – mandatory SDS → submission to the Toxicology Division
- The chemical register is publicly available
- Before entering into the register, the SDS must be reviewed
  - Documents are reviewed in order of receipt
  - The entire document is reviewed
  - If necessary, the sender is contacted for clarification/questions
- Fees: €31.85 for first entry; €15.93 for revision (+ VAT)

TASKS WE PERFORM

TRAINING ON CHEMICAL SAFETY

Workers



- Duration: 1 day (6 academic hours)
- Exam: 20 questions
- Price: €57.34 (+VAT)

Responsible persons

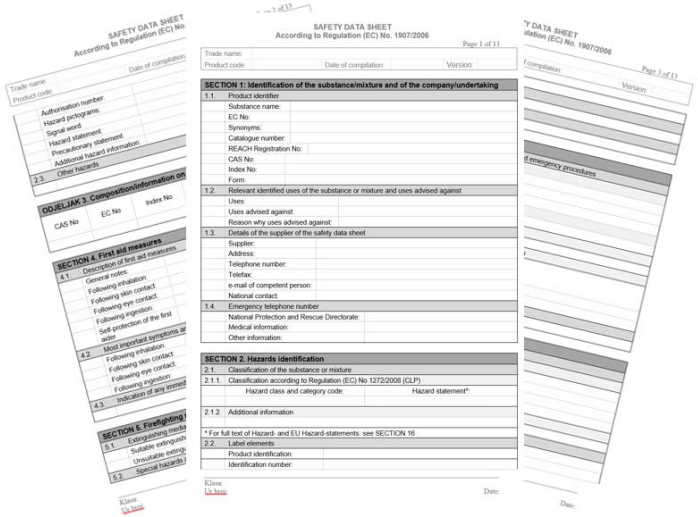
- ensures that workers are trained, have appropriate protective equipment and use it, are familiar with the work process, and prepare an action plan in case of an accident
- Duration: 2 days (10 academic hours)
- Exam: 30 questions
- Price: €161.82 (+VAT)

TASKS WE PERFORM

SDS AND PCN WORKSHOPS

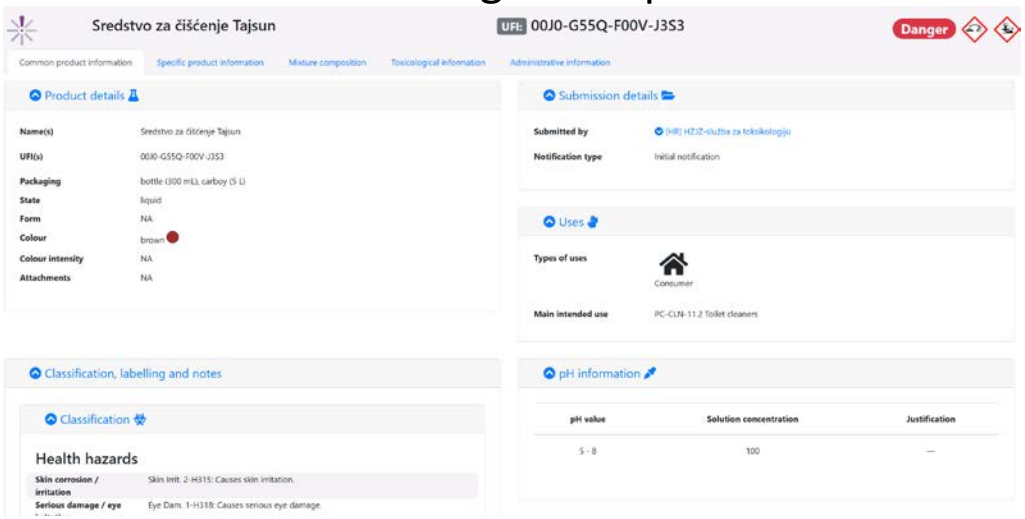
SDS workshop

- Duration: 2 days
- Price: €199,08
- Group size: max 10



PCN workshop

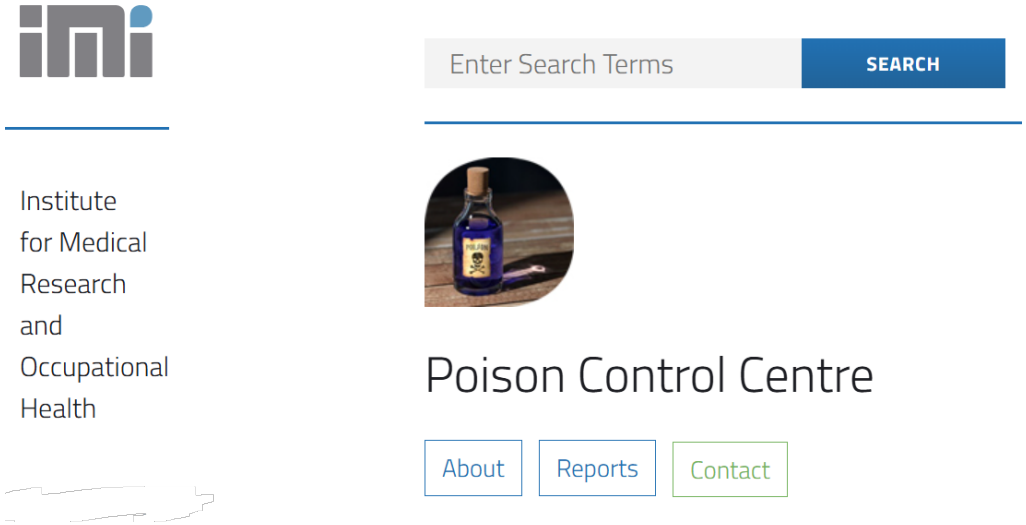
- Duration: 1 day
- Price: €132,72
- Group size: max 6
- Optional: One-on-one training – additional €60; PCN preparation available using client-provided data



TASKS WE PERFORM

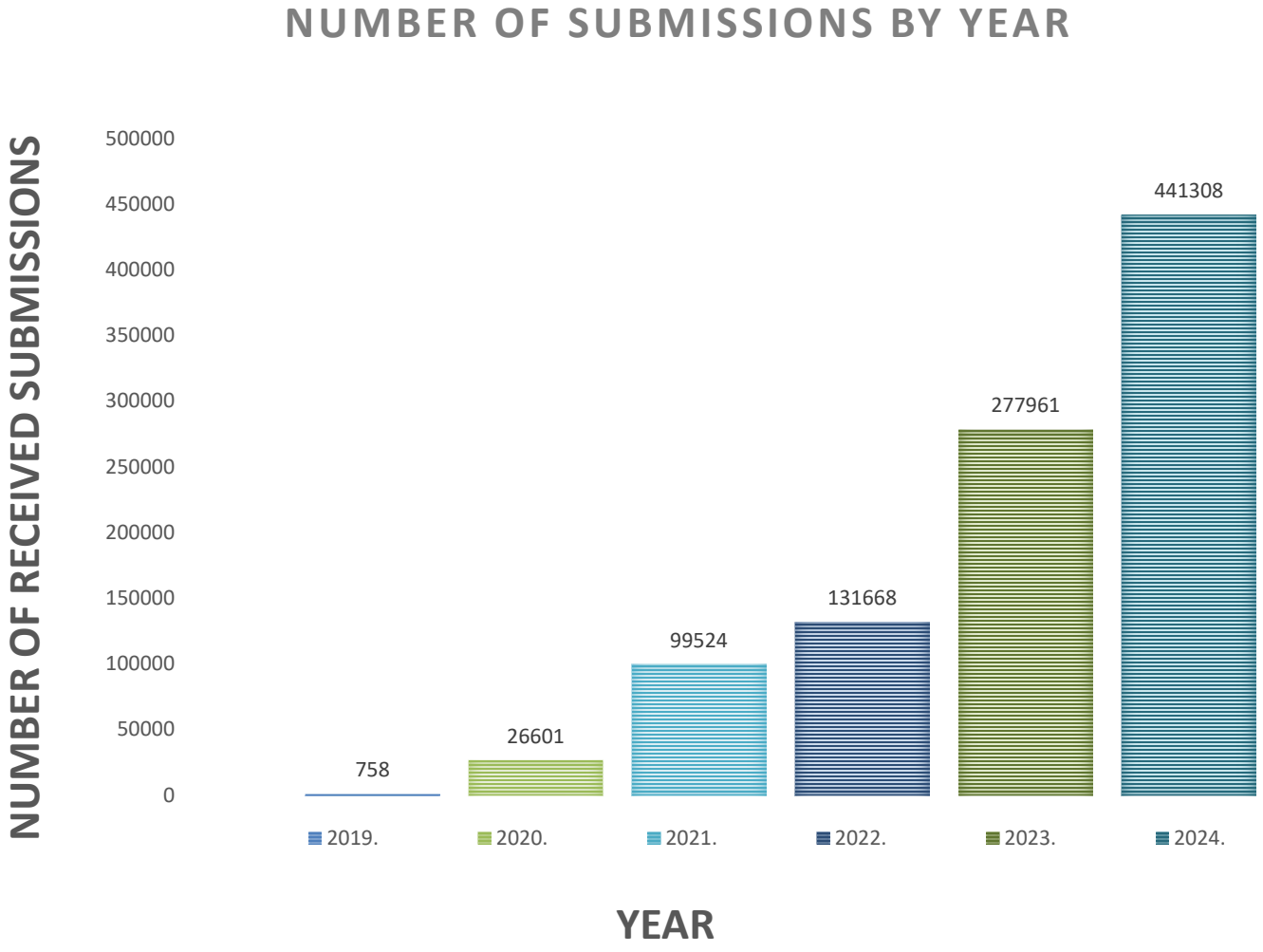
PREPAREDNESS

- Croatia has a Poison Control Center within the Institute for Medical Research and Occupational Health



- The Toxicology Division maintains on-call preparedness

PCN


NUMBER OF SUBMISSIONS BY YEAR
NUMBER OF RECEIVED SUBMISSIONS
500000
450000
400000
350000
300000
250000
200000
150000
100000
50000
0
758
26601
99524
131668
277961
441308
2019.
2020.
2021.
2022.
2023.
2024.
YEAR

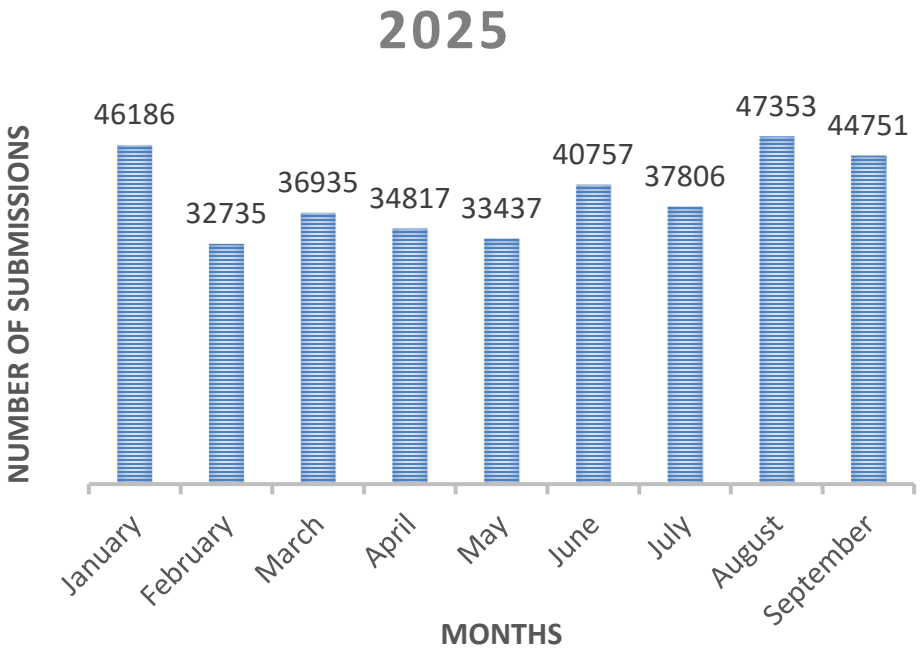
PCN

PCN

- 3 people work on Annex VIII
- monthly number of received PCNs ≈ 40,000

SDS

- 8 people work on reviewing SDSs
- the annual number of received and processed SDSs ≈ 15,000



PCN

REVISION OF ARTICLE 45 OF THE CLP REGULATION

- the amendment to Article 45 of the CLP Regulation did not affect our clients or us
- since the introduction of Annex VIII, we have been advising clients to coordinate with their suppliers
- the SDS must be in Croatian
- the PCN can be in English

PCN

MODIFICATION OF THE ANSWER TO QUESTION ID: 1727

„Can mixtures, subject to Article 45 of CLP, and already placed on the market before 1 January 2025, be further supplied by distributors, without a UFI, after that date?“

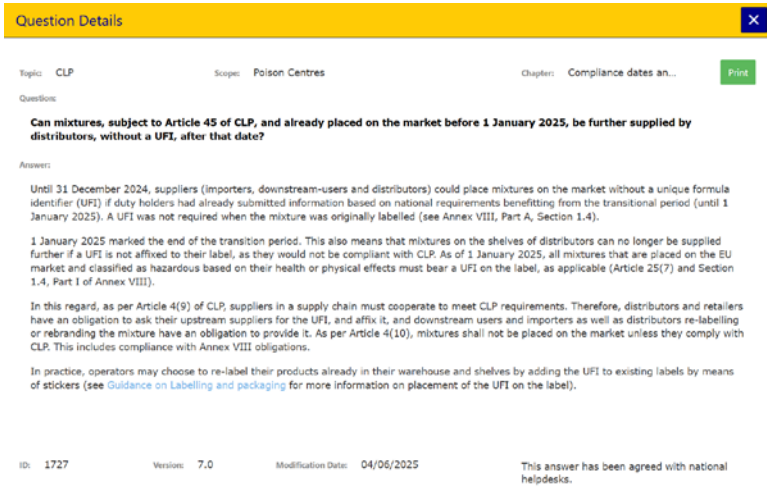
Original answer

Hazardous mixtures may be found on shelves after January 1, 2025, because they were placed on the market before the end of the transition period and in accordance with the rules that were in effect at that time

Our opinion

All hazardous mixtures after the end of the transition period must have a UFI on the label, regardless of when they were placed on the market

New answer



Question Details

Topic: CLP Scope: Poison Centres Chapter: Compliance dates an... Print

Question:

Can mixtures, subject to Article 45 of CLP, and already placed on the market before 1 January 2025, be further supplied by distributors, without a UFI, after that date?

Answer:

Until 31 December 2024, suppliers (importers, downstream-users and distributors) could place mixtures on the market without a unique formula identifier (UFI) if duty holders had already submitted information based on national requirements benefitting from the transitional period (until 1 January 2025). A UFI was not required when the mixture was originally labelled (see Annex VIII, Part A, Section 1.4).

1 January 2025 marked the end of the transition period. This also means that mixtures on the shelves of distributors can no longer be supplied further if a UFI is not affixed to their label, as they would not be compliant with CLP. As of 1 January 2025, all mixtures that are placed on the EU market and classified as hazardous based on their health or physical effects must bear a UFI on the label, as applicable (Article 25(7) and Section 1.4, Part I of Annex VIII).

In this regard, as per Article 4(9) of CLP, suppliers in a supply chain must cooperate to meet CLP requirements. Therefore, distributors and retailers have an obligation to ask their upstream suppliers for the UFI, and affix it, and downstream users and importers as well as distributors re-labelling or rebranding the mixture have an obligation to provide it. As per Article 4(10), mixtures shall not be placed on the market unless they comply with CLP. This includes compliance with Annex VIII obligations.

In practice, operators may choose to re-label their products already in their warehouse and shelves by adding the UFI to existing labels by means of stickers (see Guidance on Labelling and packaging for more information on placement of the UFI on the label).

ID: 1727 Version: 7.0 Modification Date: 04/06/2025

This answer has been agreed with national helpdesks.

PCN

UFI VERIFICATION

- we verify whether the UFI is registered for Croatia.
- the client can be confident they are correctly informed
  - the supplier claims to have submitted the PCN for Croatia
  - by checking the PCN database, we determine that it has not been submitted
  - this helps the client prevent possible penalties for the absence of a PCN for the UFI indicated on the label
- we also perform checks for inspectors

PCN ERRORS WE ENCOUNTER

- PCN accuracy check
  - harmonized classification of each component
  - toxicological information
  - pH
  - classification of the mixture

PCN ERRORS WE ENCOUNTER

1. INCORRECT IDENTIFIER

- CAS or EC number does not match the data available on the ECHA website
- IUPAC name is incorrect
  - *stärke, verzuckert* – substance name, copied under IUPAC
  - The substance name "peat,,, – IUPAC name "torba" (Italian), means "bag" in Croatian

BR540	'Reference substance' must have at least one of the following identifiers: EC number, CAS number, IUPAC name, INCI or colour index name. (International chemical name should be reported in the IUPAC name field.)
QLT634	If 'IUPAC name/International chemical name' was provided, then it should be meaningful.

PCN ERRORS WE ENCOUNTER

2. HARMONIZED CLASSIFICATION OF SUBSTANCES

3. If a substance is subject to harmonised classification and labelling in accordance with Title V through an entry in Part 3 of Annex VI, that substance shall be classified in accordance with that entry, and a classification of that substance in accordance with Title II shall not be performed for the hazard classes or differentiations covered by that entry.

PCN ERRORS WE ENCOUNTER

3. NUMBER OF DECIMAL PLACES

QLT502	If the concentration is above 1 %, the recommended number of decimals is one.
QLT505	If the concentration value is 0.1-1 %, the recommended number of decimals is two.

4. pH RANGE

QLT504	pH value must be indicated as an integer or specified to one decimal.
QLT501	Maximum pH value range width is 1 unit (when pH =<3 or >=10).
QLT510	Maximum pH value range width is 3 units (when pH 3 < pH <10).

PCN ERRORS WE ENCOUNTER

5. TOXICOLOGICAL INFORMATION

BR538 | Toxicological information must be provided (at least 200 characters) in 'Toxicological information (section 11 of SDS)' field(s) in all relevant languages.

PCN ERRORS WE ENCOUNTER

6. MiM

has UFI;
UFI registered for Croatia;
no composition needed

has UFI;
UFI not registered for Croatia;
composition needed

no UFI;
composition needed

3.2.2. *Mixture in mixture*

When a mixture is used in the composition of a second mixture placed on the market, the first mixture is referred to as a mixture in mixture ('MIM').

Information on the substances contained in a MIM shall be provided in accordance with the criteria of Section 3.2.1, unless the submitter does not have access to information on the full composition of the MIM. In the latter case,

(a) if a UFI has been created for the MIM and the appointed body has received the information on the MIM in a prior submission, the MIM shall be identified by means of its product identifier in accordance with Article 18(3)(a), together with its concentration and UFI;

(b) if a UFI has been created for the MIM, but the appointed body has not received the information on the MIM in a prior submission, the MIM shall be identified by means of its product identifier in accordance with Article 18(3)(a), together with its concentration and UFI and the compositional information contained in the Safety Data Sheet in accordance with Annex II to Regulation (EC) No 1907/2006 of the MIM and any other known components, as well as the name, email address and telephone number of the MIM supplier;

(c) in absence of a UFI, the MIM shall be identified by means of its product identifier in accordance with Article 18(3)(a), together with its concentration and the compositional information contained in the Safety Data Sheet in accordance with Annex II to Regulation (EC) No 1907/2006 of the MIM and any other known components, as well as the name, email address and telephone number of the MIM supplier.

PCN ERRORS WE ENCOUNTER

7. LIMITED SUBMISSION

- Mixtures intended for professional or consumer use contain mixtures submitted with a limited submission

BR587	For limited submissions, 'Use type' can only be 'Industrial'. ''Professional' and 'Consumer' are not allowed.

PCN ERRORS WE ENCOUNTER

8. NEW NOTIFICATION INSTEAD OF REVISION

[QLT574]	Any changes to the notification should be reported as an 'update' and not as a new 'initial' submission. Therefore new 'initial' submissions: (i) for products having the same trade name (ii) made by the same company (iii) targeted at the same market area/country and (iv) and belong to the same product category are not allowed.

9. INCORRECT CONTACT DETAILS

BR519	The contact details of the legal entity must include: • address 1 • town • country • phone • email • postal code.

CONCLUSION

- Over the years, we have given several lectures on Annex VIII.
- On a daily basis, we receive calls and emails requesting assistance with PCN and Annex VIII.
- The Poison Control Center does not have access to the PCN database, so we lack practical experience with the application of PCN.

THE END

AND

THANK YOU