Introduction

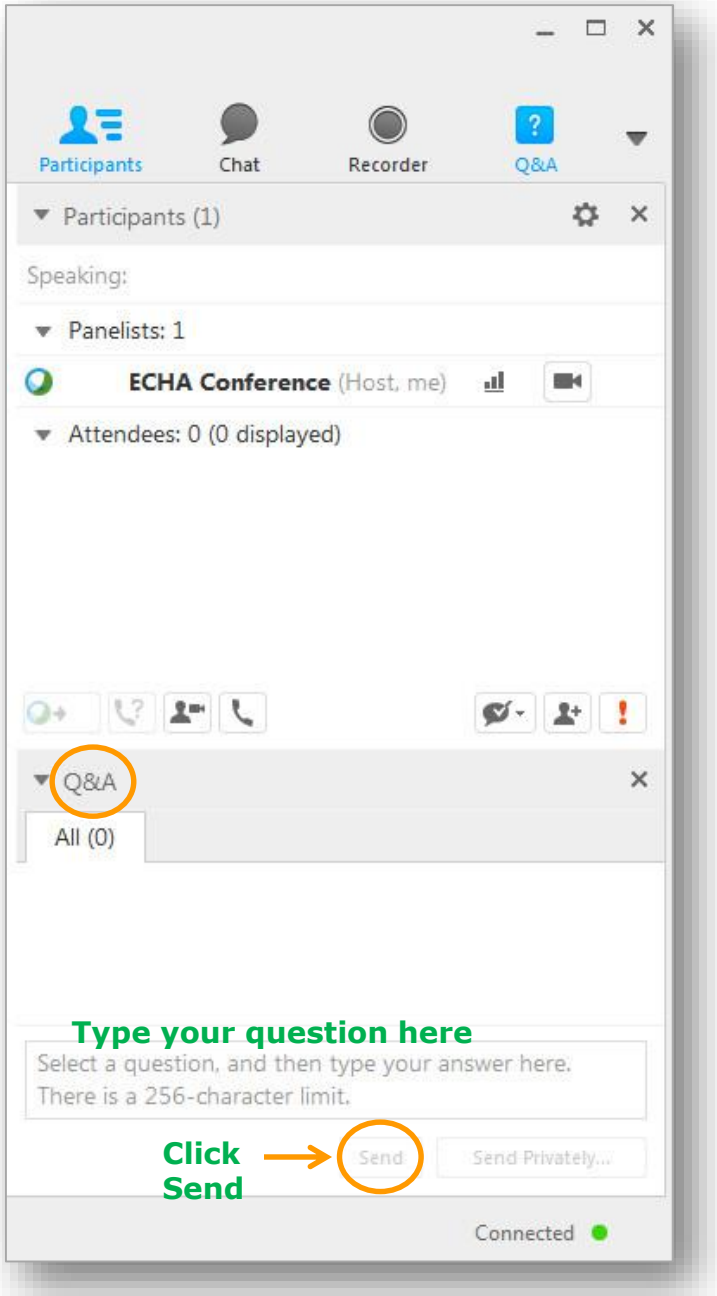
Webinar: Poison centre notifications 2020 – where are we now?

12 February 2020

Heidi Rasikari, ECHA

To ask a question

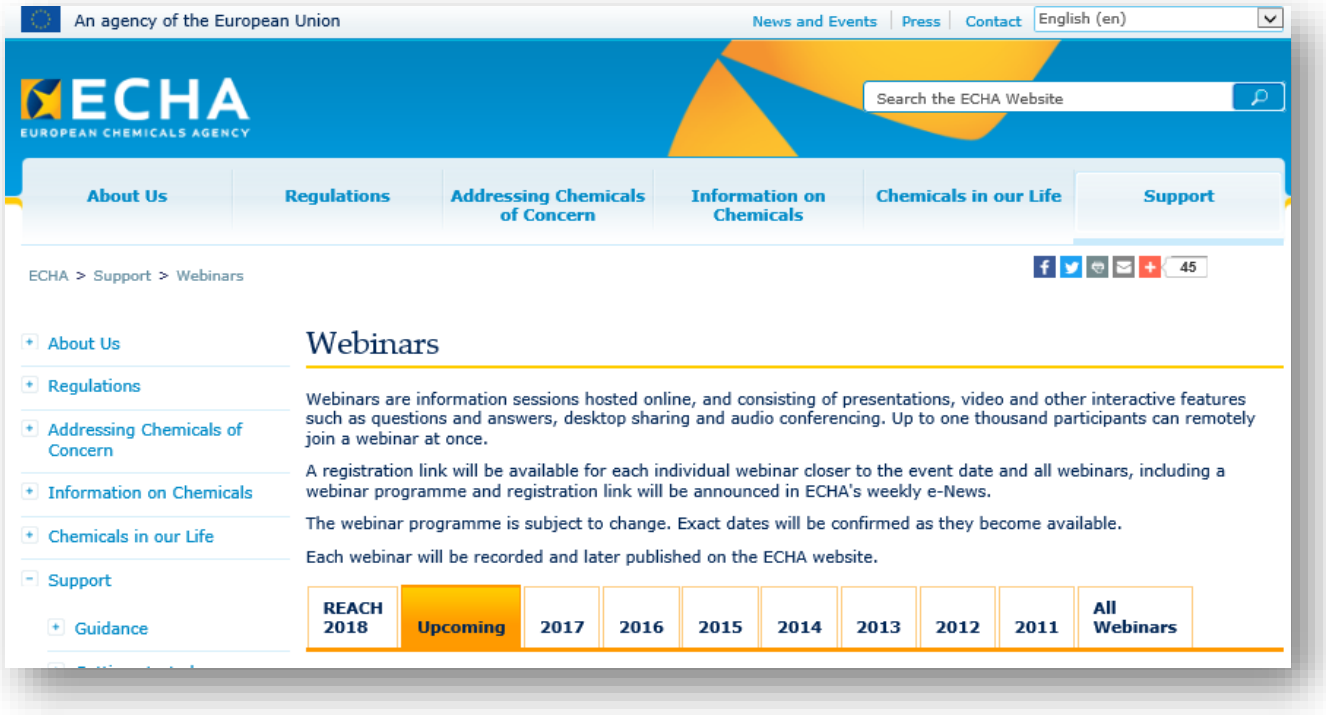
- Use the Q&A panel at any time to ask about the presented material or if you have any technical problems
- We will answer as many questions as we can today until 13.00 Helsinki time
- Any questions after the event to echa.europa.eu/contact
- A transcript of the Q&A will be made available after the event, but you can also download them by selecting 'File' then 'Save'



Material published

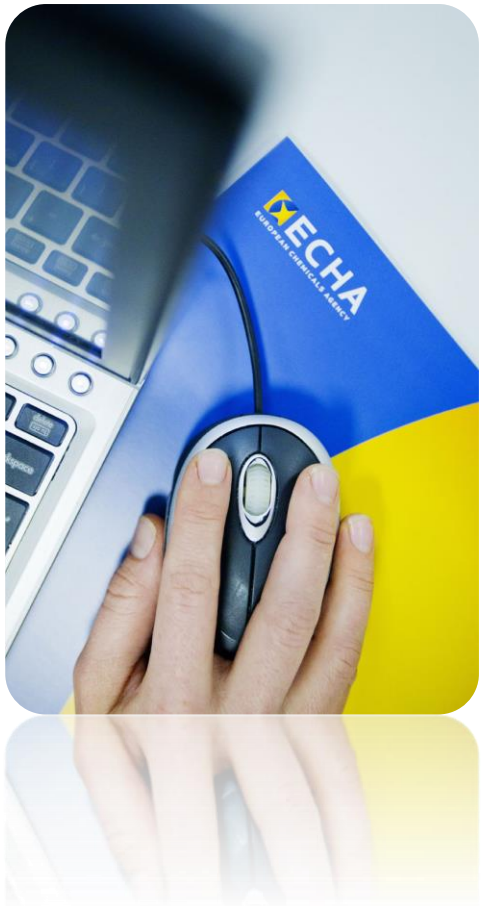
The video recording, presentations and Q&A will be published on the webinar page:

echa.europa.eu/support/training-material/webinars



What you can expect from today

- Get informed about the first Annex VIII amendments, and the proposed second amendments
- Learn about IT improvements to assist you in preparing and submitting notifications
- Get the latest on guidance and support news
- Use the opportunity to ask questions from our panellists



Agenda

11:05 **Introduction**
Heidi Rasikari, ECHA

11:10 **Regulatory update**
Daniele Ape, ECHA

11:30 **PCN IT solution**
Claudia Rimondo, ECHA

11:50 **Meeting your support needs**
Heidi Rasikari, ECHA

11:55 **Conclusions**
Heidi Rasikari, ECHA

12:00 – 13:00 **Webinar open for questions**

Harmonised reporting

- The concept of harmonised reporting of hazardous mixtures for poison centre use stems from Article 45 in the CLP Regulation and is detailed in Annex VIII

- Annex VIII, first adopted in March 2017 proposed stepwise compliance dates for industry – the Annex has recently been amended

- To facilitate industry submissions to the nationally appointed bodies, we have released and updated a number of tools, guidance and support material

Article 45 scope

- Certain mixtures classified for human health or physical effects e.g. biocides, cleaning products, adhesives, paints etc.
- No obligation for mixtures classified only for environmental effects/gases under pressure and/or explosives

! Making a submission under Article 45 for a particular mixture does not exempt you from other legislative obligations e.g. for biocidal product authorisations under the Biocidal Products Regulation

What is out of scope?

- Mixtures out of scope of CLP Regulation - unless the same mixture, can be used differently e.g. flavourings used in e-liquids
- Substances - unless diluted in a solvent as a mixture
- Articles - unless considered as an article combined with a mixture such as candles, cleaning wipes

! Assess your mixture on a case by case basis

Who has to submit information?

- EU importers and downstream users including formulators, toll formulators, repackagers and refillers have direct obligations under Article 45 CLP

- Distributors such as relabellers, if they are placing a mixture on the EU market that is non-compliant with the CLP Regulation (Article 4(10) CLP)

! Distributors' information can also be included in the suppliers' notification in case they distribute to another Member State or make changes to the product

Who can submit information?

- Designated EU-based legal entities on behalf of a duty holder, such as consultant, mother company, i.e. 'Foreign user'

  ECHA accounts manual

echa.europa.eu/documents/10162/21721613/echa_accounts_en.pdf/

- EU importers or downstream users of mixtures out of scope i.e. a voluntary submission

  Guide to dossier preparation and submission

poisoncentres.echa.europa.eu/documents/22284544/22295820/guide_pcn_notifications_en.pdf/

- EU-based legal representatives of non-EU suppliers can also make a voluntary submission

  Guidance on Annex VIII section

echa.europa.eu/guidance-documents/guidance-on-clp

A word on compliance dates

- The two compliance dates are:
  - From 1 Jan 2021 (consumer and professional)
  - From 1 Jan 2024 (industrial)
- The compliance dates are not deadlines!
- A number of considerations to determine when a submitter is obliged to comply with Annex VIII:

If the mixture has not yet been notified then it must comply with the new requirements from the date according to its use type.

If the mixture has already been notified nationally, you can benefit from a transition period until 1 January 2025.

UNLESS you need to update the notification.

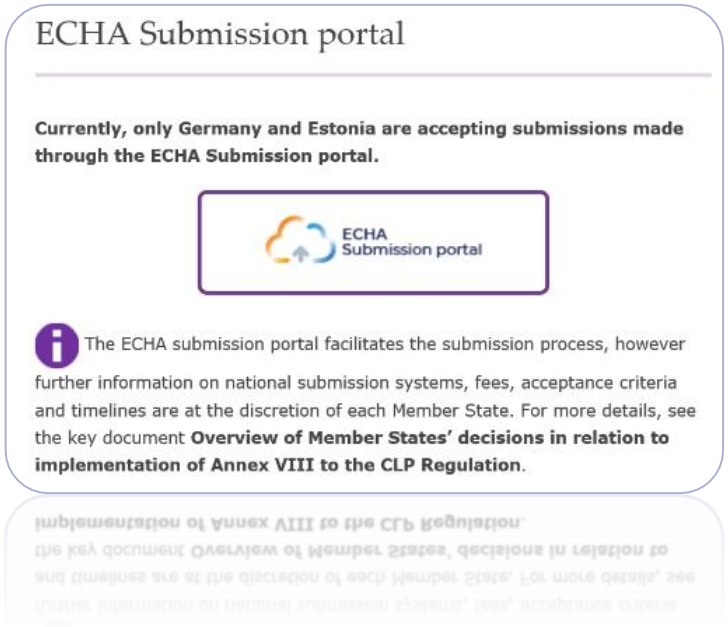
How to submit? (1/2)

- Before the new requirements start applying to your mixture, notifications must adhere to existing:
  - National information requirements
  - Existing submission systems

- Check with the Member State for details poisoncentres.echa.europa.eu/appointed-bodies

How to submit? (2/2)

- The ECHA Submission portal can be used to submit notifications – provided the Member State is ready to accept them.
- Before making any portal submissions, refer to the latest information available for each Member State regarding:
  - Portal usage
  - Language
  - Fees
  - Timing for placing on the market



poisoncentres.echa.europa.eu/documents/22284544/27487986/msd_en.pdf/982d9115-58cb-75c8-80ae-8eb16f5c0009

Regulatory update

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First amendment of Annex VIII to CLP

- Annex VIII entered into force in 2017.
- Ongoing discussions in 2018 and 2019, with industry, Member States, and the Commission -> areas identified for further clarification.
- Delegated act adopted by Commission November 2019
- Amendment officially published 10 January 2020 – Entry into force 20 days later.
- Amendment currently into force.

What has changed?

- First compliance date
- Editorial clarity
- Modification in requirements

L 6/8 EN Official Journal of the European Union 10.1.2020

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2020/11

of 29 October 2019

amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures as regards information relating to emergency health response

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (1), and in particular Articles 45(4) and 53(1) thereof,

Compliance date

- Compliance date for consumer use mixtures has changed
- From 1 January 2020 to 1 January **2021**
- Allows industry more time to prepare notifications in the new format and Member States more time to develop IT systems
- ECHA continuing to improve and develop industry systems

UFI positioning

- Was: UFI shall be printed on or affixed on the label
- Now: it is possible to print or affix UFI on the label **or on the inner packaging**, but always in proximity to the other label elements → Not necessarily "in" the label
- No need on every layer of packaging
- Due to size/shape reasons can go on an outer layer only

Industrial use mixtures

- Was: UFI may be listed in Safety Data Sheet instead of on product in the case of mixtures for industrial use (i.e. used at industrial sites **only**)
- Now: UFI may be listed in SDS instead of on label in the case of mixtures supplied at **industrial use sites** (possibly used for consumer/professional product downstream)
- Section 1.1 of the SDS

Submitter & contact point

- Was: ‘details of the submitter must be provided’… and consistent with the data on the label
- Now: ‘details of submitter and **contact point**, **where relevant** to be provided’
- Contact point = for Authorities in case more information is needed
- Solve issue e.g. for toll formulators, or mother companies

MiM identification

- If the notifier does not have the full MiM composition then it was possible to provide:

i. known components + UFI (if available), or
ii. Safety data sheet + supplier details

- Now:

i. UFI **if previously notified in that MS**, or
ii. information on known components **from** SDS + supplier details

Other changes

- Justification now required if pH is not provided
- Group submission mixtures not limited to same product category
- ‘Fragrances’ as a generic product identifier is removed

Second amendment coming

- The ‘workability amendment’

- Following discussions from a workability study (June 2018 – June 2019) a number of generic and sector specific issues were identified

- Solutions sought in recent workshops:
  - Balance need for information required and administrative burden
  - Burden of proof remains with industry

Issues

i. Mixture composition variation because of change in component(s), but no changes with regard to classification, hazard or emergency health response

ii. Raw material of natural origin combined with continuous production process. Need to fulfil specific standards defined by properties rather than chemical composition. Exact composition at any given time unknown and variation of components concentrations are out of allowable ranges

iii. Point of sale paints = formulated on demand at point of sale. High number of notifications and UFI to be generated by the retailer before selling the paint

Solutions proposed

i. Mixture composition variation because of change in components due to:
   a. 'same' component, different suppliers
   b. Components chemically different, toxicologically same

- Interchangeable components= components which are different, but sufficiently similar to be considered one and the same component (toxicologically)
  - Same technical function, and
  - Same physical and health hazard, and
  - Same acute toxicological effects

  - AND Same hazard identification and additional information of final mixture

Solutions proposed

ii. Mixtures defined by standard formulas

- Defined standard formulas, specifying mixture composition (components identity and concentrations)
- Mixtures with a composition corresponding to a standard formula can be notified according to that formula and deviate from the default Annex VIII concentration limits
- Standard formulas proposed by 4 sectors:
  - Cement sector
  - Gypsum sector
  - Concrete sector
  - Petroleum sector

Solutions proposed

iii. Point of sale paints

- No need to notify the final point of sale mixture.
- UFI of base paint to be printed on can of final POS paint
- UFI of tinters also to be provided on final POS paint (e.g. via sticker)
- If concentration of hazardous tinters exceed threshold, the % range of tinters has to be displayed besides the UFI

Timelines for 2nd amendments

- Commission currently working on the draft revision following comments from stakeholders
- 31 March 2020: Last consultation on the 2nd amendment
- Mid July: Publication
- 1 January 2021: First compliance date

PCN IT tools for industry preparation and submission

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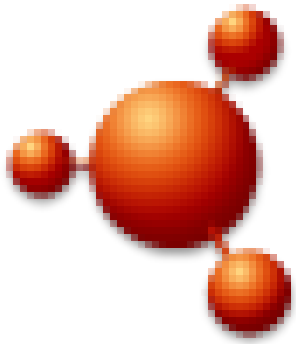
Tools to prepare a notification

ONLINE PREPARATION

IUCLID CLOUD



OFFLINE PREPARATION

IUCLID

SYSTEM PREPARATION

PCN FORMAT

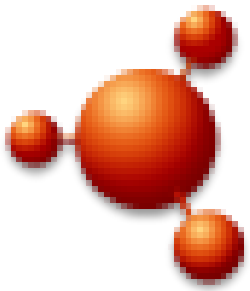
Tools to prepare a notification

ONLINE PREPARATION

IUCLID CLOUD

- Online using IUCLID Cloud available in the ECHA Submission portal.
- Hassle free tool - maintained, backed-up, updated by ECHA.
- Data securely stored in ECHA Cloud.
- Dossier prepare and create functionality
  - Validation assistant
  - Notification preview report

Tools to prepare a notification



OFFLINE PREPARATION IUCLID

- Offline using IUCLID 6 downloaded from the IUCLID website: iuclid6.echa.europa.eu
- Installed and maintained locally by users – IUCLID instances should be updated ASAP following new releases.
- Server version available for multi-user companies
- New web interface available visually the same as in IUCLID Cloud

Tools to prepare a notification

SYSTEM PREPARATION PCN FORMAT

- System preparation uses the PCN format to prepare IUCLID compatible dossiers in a company's own system
- Subject to annual format updates which need to be maintained by users
- Allows a more automated approach for companies to prepare their notifications
- It will also be reused for other notification types e.g. for SCIP (substances of concern in articles)

ECHA tools to submit

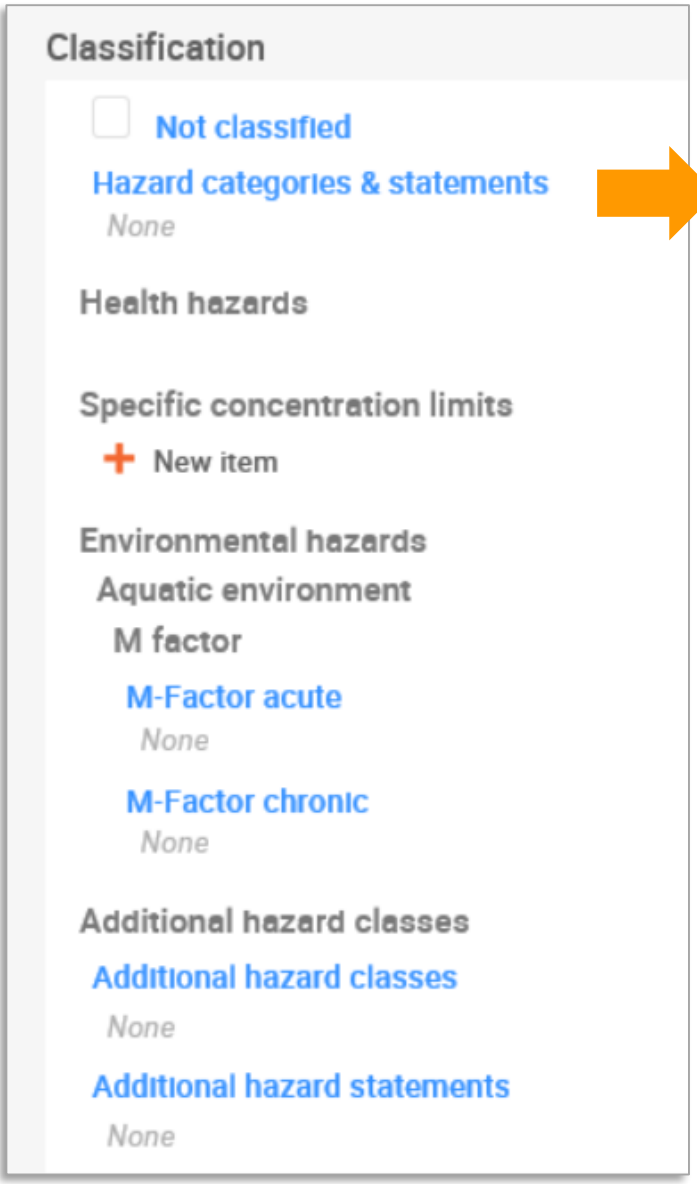
- ECHA submission portal
  - One stop shop for preparing, submitting, managing submissions
  - Multimarket submissions possible

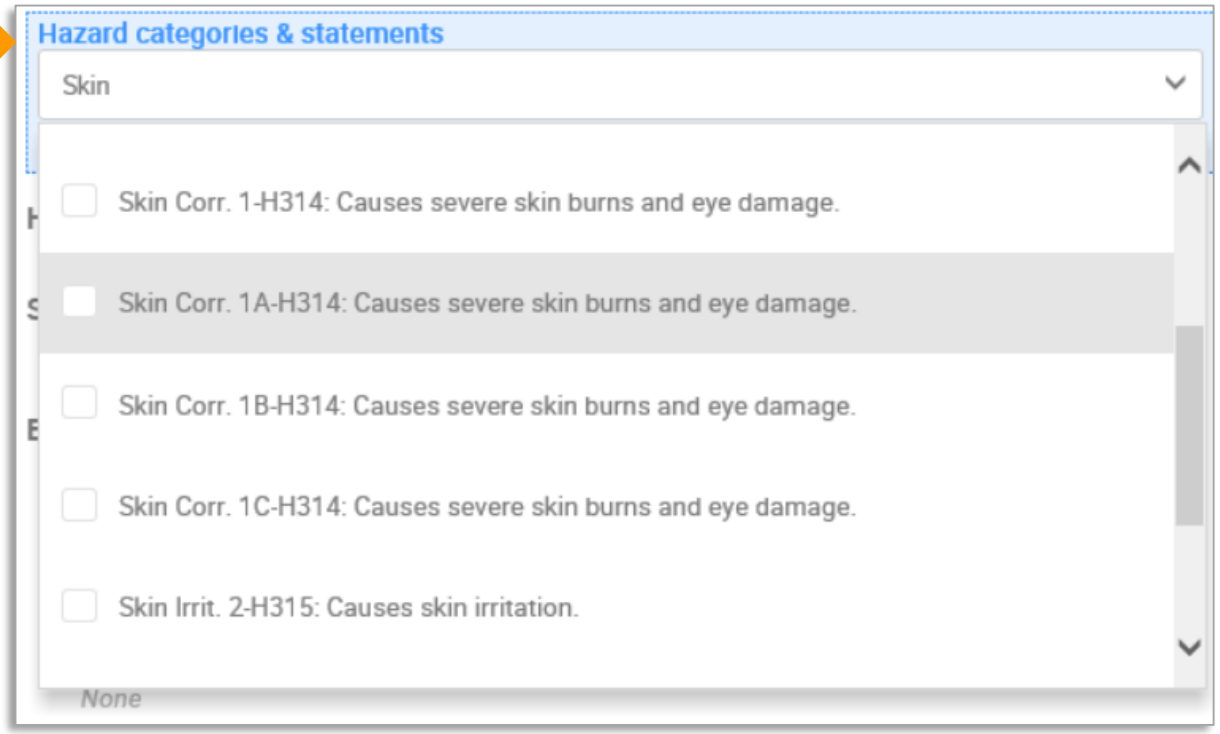
- System-to-system service
  - Automatic transfer of dossiers prepared using the system approach to the ECHA submission portal
  - Bulk submission possibilities
  - To access this service, industry need to submit a request to ECHA via contact form

PCN IT solution releases

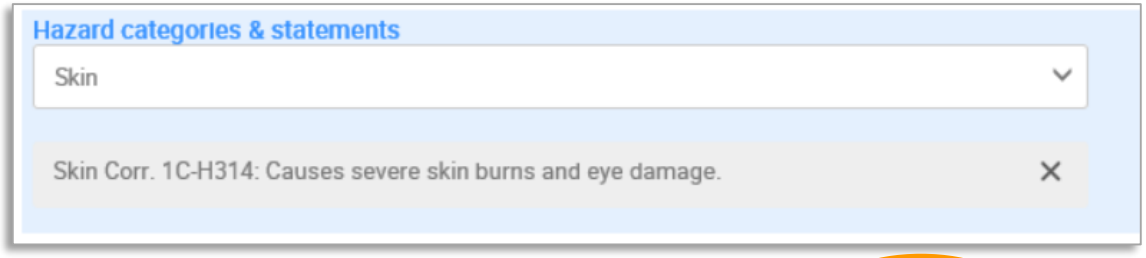
- 2019
  - April - Go-live
  - July - Improvements in IUCLID cloud services
  - October – PCN format changes
- 2020
  - January - Improvements in IUCLID cloud services

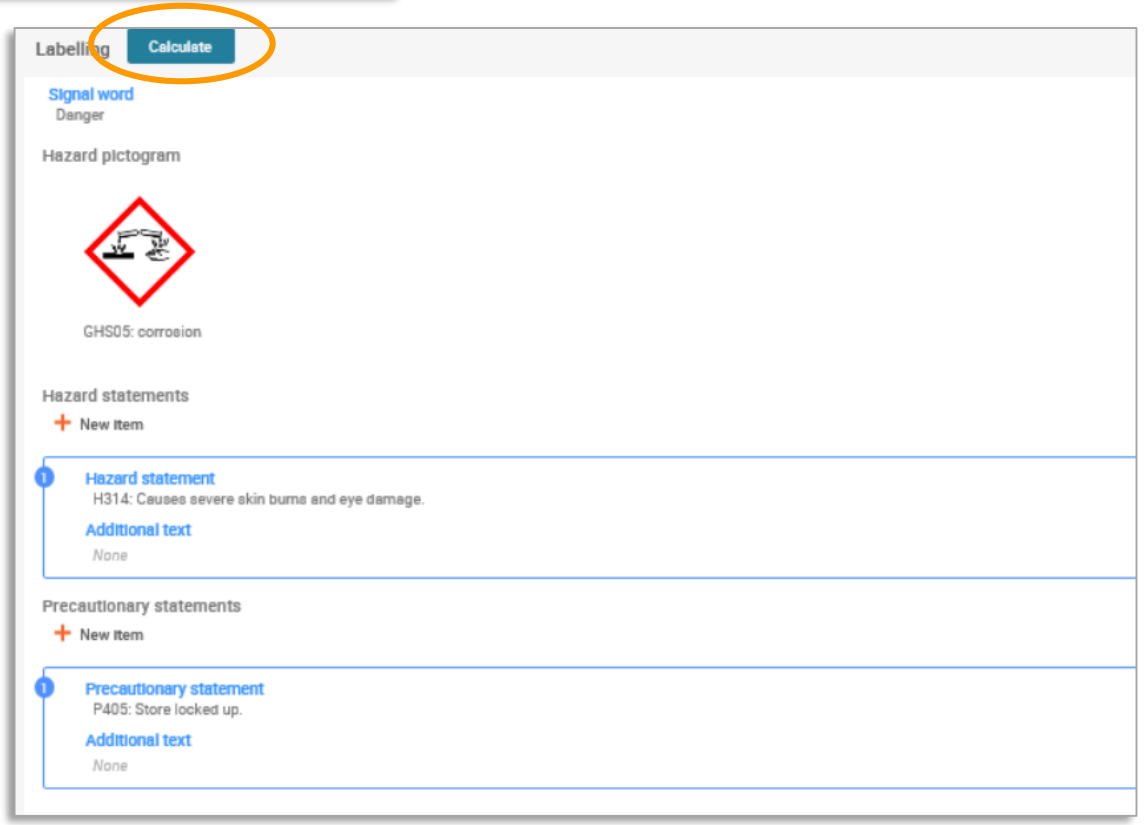
Easier way to provide Classification information



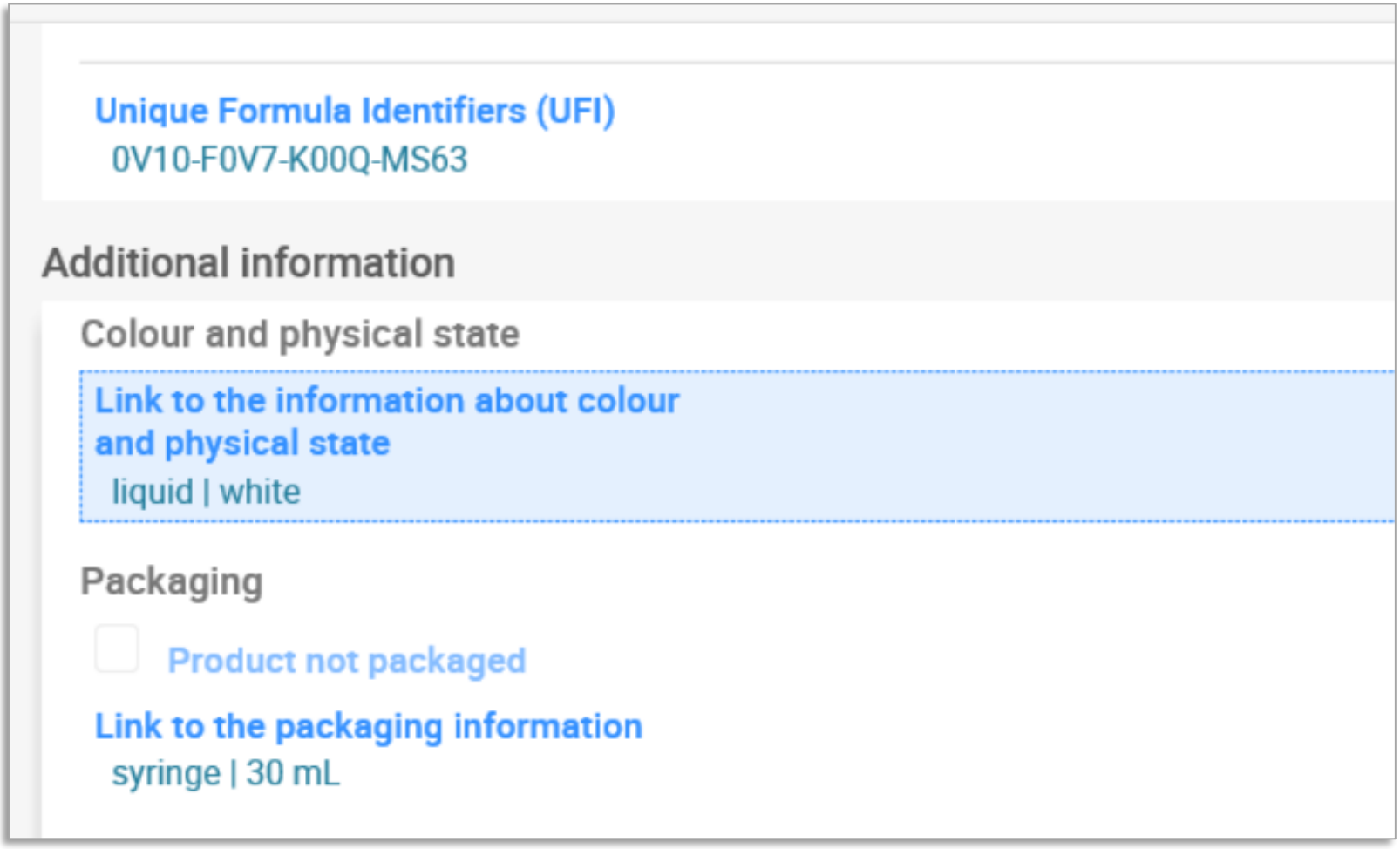


Automatic calculation of Labelling information

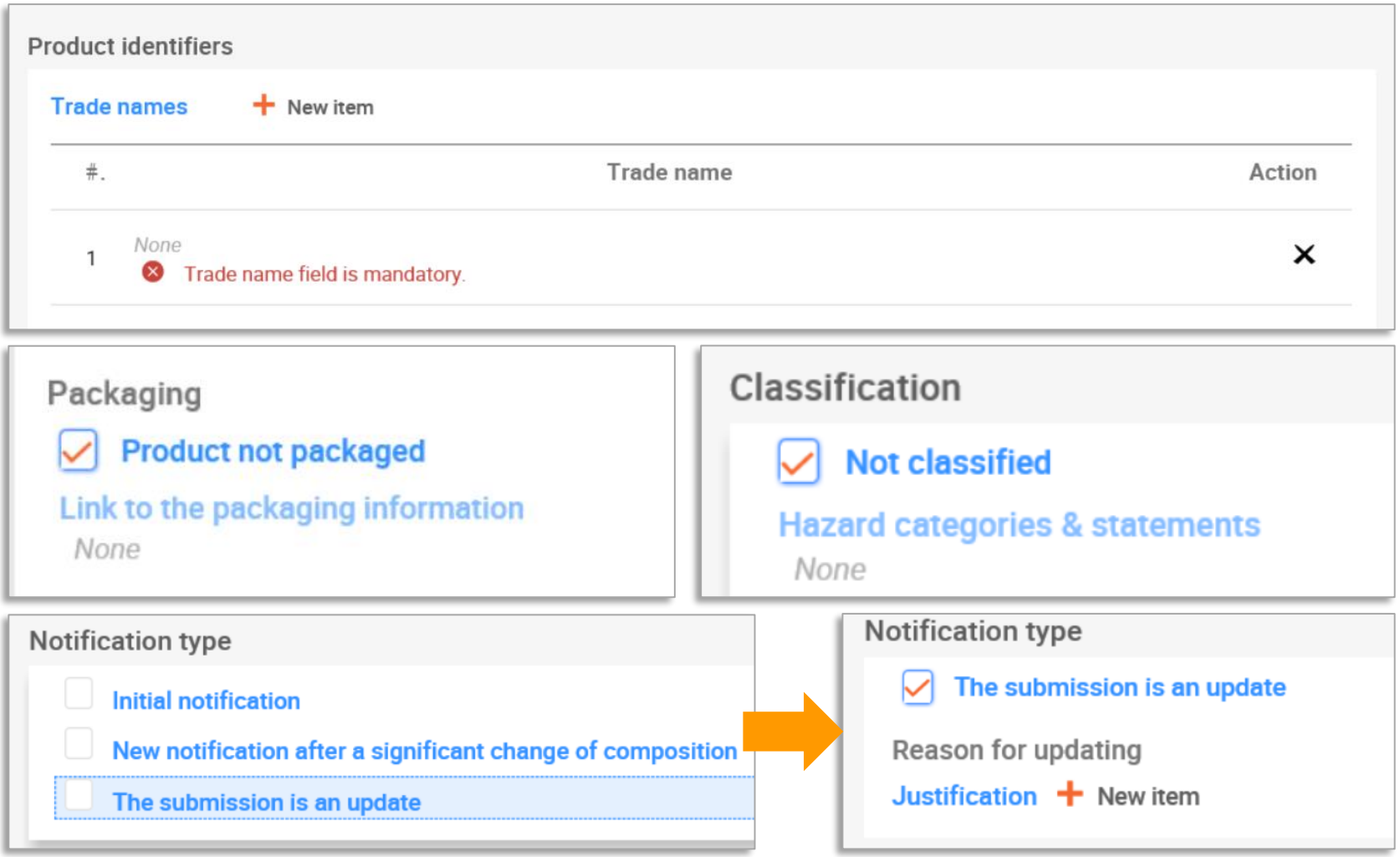




Improved documents naming



Indication of mandatory fields



January release: additional features

- Improvements to the validation report and validation rules
- Cloning a mixture dataset to facilitate significant change of composition and multi-market submission
- Multi-lingual fields available in the dataset view
- Dossier header always displayed
- New widget in the dashboard to manage articles that will be used to prepare SCIP notifications in the future

https://iuclid6.echa.europa.eu/documents/21812392/22308511/IUCLID_6_Release_Notes_v4.8.pdf

Next releases

- Improvements in IUCLID Cloud Services

- IUCLID release with PCN related improvements

- Improvements in IUCLID Cloud Services

- Adaptations to II amendment
- IUCLID format update

Guidance and support

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Relevant ECHA Guidance on CLP

- on Annex VIII
- on labelling and packaging
- on substances in articles
- on Safety Data Sheet

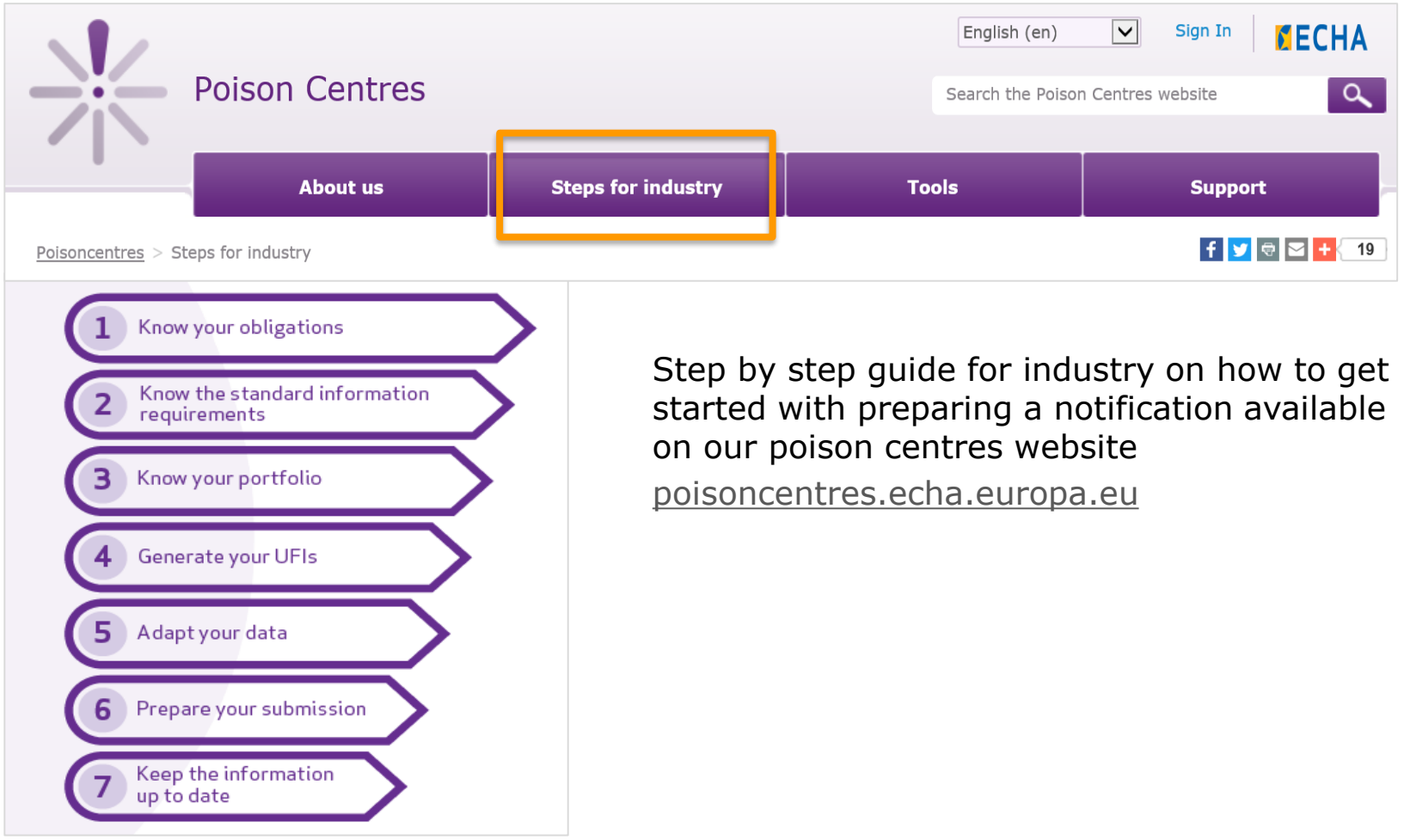
echa.europa.eu/guidance-documents/guidance-on-clp

Guidance on Annex VIII

- Currently available online is **Version 2**
  - Contains a dissenting note from four Member States about the interpretation of certain distributors' obligations according to Article 4(10) of CLP
  - Translations available in all 23 EU languages

- **Version 3** preparations underway due to the forthcoming first amendment to Annex VIII. Expected to be available before summer subject to commenting from ECHA partners

Steps for industry



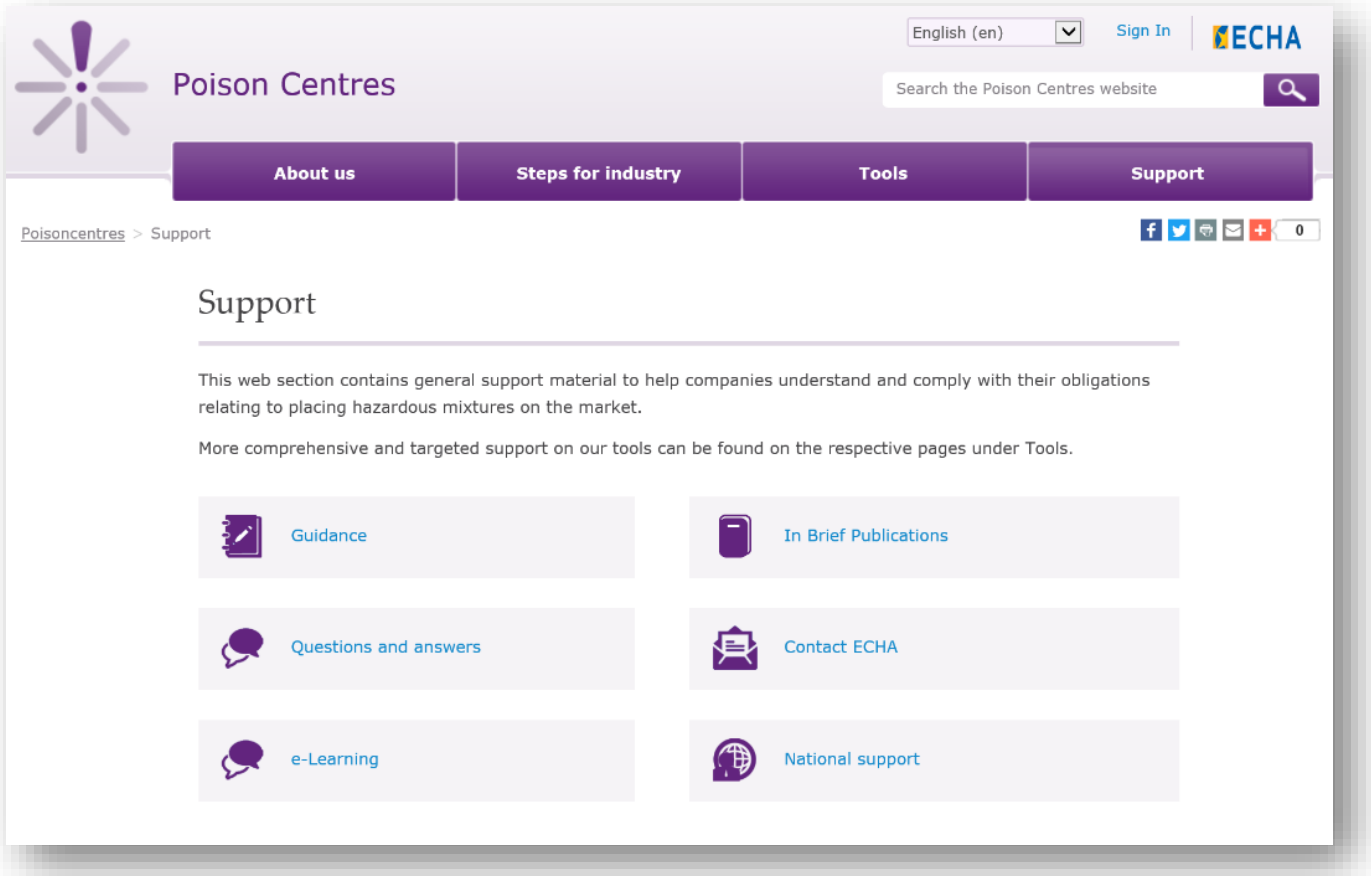
Step by step guide for industry on how to get started with preparing a notification available on our poison centres website

poisoncentres.echa.europa.eu

ABC guides and manuals

- For UFI tools and support
  poisoncentres.echa.europa.eu/ufi-generator
- For EuPCS system and support
  poisoncentres.echa.europa.eu/eu-product-categorisation-system
- For PCN format, support, example dossiers
  poisoncentres.echa.europa.eu/poison-centres-notification-format
- System-to-system
  poisoncentres.echa.europa.eu/system-to-system-service
- Submission portal tool, support
  poisoncentres.echa.europa.eu/echa-submission-portal

Visit our support page



poisoncentres.echa.europa.eu/support

Need more help?

- First check with your national Helpdesk at echa.europa.eu/support/helpdesks

- ECHA contact form echa.europa.eu/contact/clp

- New! Connect with us on LinkedIn linkedin.com/groups/12364138
  - get alerts on our regular news items
  - receive updates from our team members
  - post questions or interact with other members

Conclusions

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Take home messages

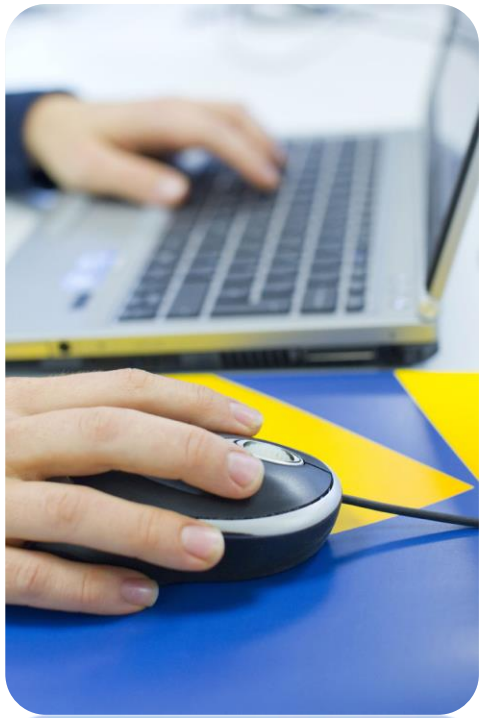
- Get familiar with the new requirements now
- Keep preparing even though the compliance date has been postponed
- Guidance activities ongoing to provide information on the best advice to fulfil information requirements

Take home messages (2)

- ECHA and Member States are here to support you – ask your national Helpdesk
- Check which Member States can receive an Annex VIII notification before you submit one
- Adaptation of tools to meet the changes - stay tuned to our website for news on next releases and training events
- Join our community and connect with us on LinkedIn

Q&A panel

- Webinar open until **13:00 Helsinki time** to answer questions
- You can save the Q&A transcript from the ”file” -> ”save” menu in your Webex window
- If your question is not answered by the end of the webinar, send it via our contact form: echa.europa.eu/contact



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