Guidance on Annex VIII to CLP – V.3.0

Guidance on Labelling and Packaging – V.4.1

PEG Meeting

13 February 2020

ECHA (Extended) Poison Centres Team

Welcome

PEG meeting 13 February 2020

- Welcome and adoption of agenda
  - List of participants and 'tour de table'
  - Adoption of the agenda & AOB
- Housekeeping
  - House rules
- Presentation of the Guidance update
  - Guidance update process in a nutshell
  - Objectives of the meeting
- Discussion of the comments received
  - Overview
  - Discussions on selected issues

List of participants and ‘tour de table’

Participants

PEG members (MSs)	PEG members (Stakeholders)	
Ronald Keipert (DE)*	Dominic Byrne (AISE)	Christian Schrangen (EuFIAs)
Toke Thomsen (DK)*	Peter Slijkhuis (ATIEL)	Marco Perfetti (EuPC)*
Iciar Lazaro Trueba (ES)*	Blanca Serrano Ramon (Cefic)*	Sebastian Kruells (FECC)*
Caroline Walsh (IE)	Miette Dechelle (CEMBUREAU)	Dimitrios Soutzoukis (FEICA)
Ronald deGroot (NL)	Janice Robinson (CEPE)	Inneke Claes (Fuels Europe)
Monika Avizieme (LT)	Rene DeGraf (ECETOC)*	Cristina Arregui (IFRA)*
Johanna Lofbom (SE)*	Antonio Caballero Gonzales (EMO)	
	Claudio Medana (ETRA)*	
An Jamers (DG GROW)*		

***Connected remotely**

Participants

ECHA participants
Daniele Ape (Chair)
Delphine Gerbaud
Sari Jaanu
Kirsi Myohanen
Heidi Rasikari
Claudia Rimondo
Outi Tunnela
Daniel Sompolski

Participants

Apologies from:

Eric Brasseur (EUROFER)

Beatrice Marchal (CONCAWE)

Adoption of the agenda

Agenda – Day 1

Time (approx)	Topic/agenda item	by
9.00-9:30	Arrival of participants and registration	
9.30-9.45	Welcome and adoption of agenda Introduction and Housekeeping	ECHA
9.45-10.00	Guidance update in a nutshell Objectives of the meeting What happens next	ECHA
10.00-10:10	Overview of the comments received Proposed structure of the discussion	ECHA
10:10-11.00	Comment discussion 1. Labelling requirements 2. UFI and SDS	ECHA/Comm (intro) All (discussion)
11.00	**Coffee break**	
11:15-12.30	Discussion on comments received: 3. Reference to Annex II.5 4. Relabellers Vs Rebranders 5. Submission "on behalf"	 3. EMO 4.5. ECHA (introduction) All (discussion)
12.30	**Lunch break**	

Time (approx)	Topic/agenda item	by
13.30-15.00	Discussion on comments received: 6. pH requirements 7. MiMs notification & MiM identification 8. Transitional period 9. Toll formulators	ECHA (introduction) All (discussion)
15.00	Coffee break	
15.15-16.45	Discussion on comments received: 10. MiMs notification 11. Workability issues and 2nd amendment – ICG solution and Guidance needs 12. IT tools development and plan (info session)	ECHA (introduction) All (discussion)
16.45-17.15	Summary and conclusions	ECHA
17.15	**Close**	

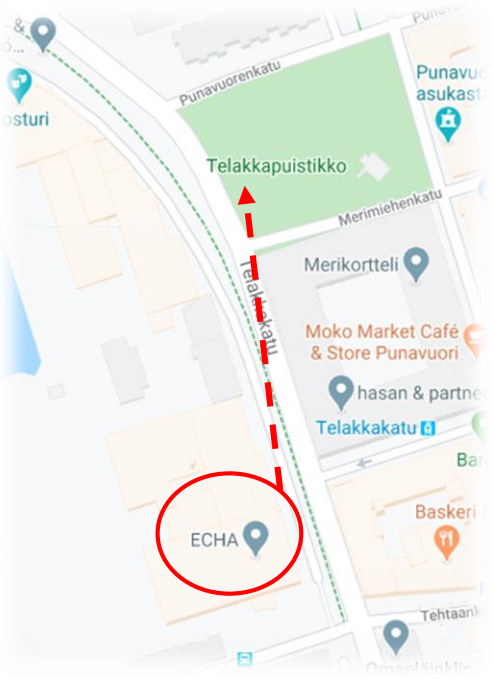
House Rules

Administrative and security issues

- Badge
  - The badge must be carried visibly in the ECHA premises.
  - Visitor badge must be returned to the ECHA reception desk at the end of the day.
- Administrative documents
  - Sign the attendance list **twice** a day (morning and afternoon)
  - Reimbursement documents to be handed to the Event Assistant by 4pm
- Lunch – coffee breaks
  - Lunch will be served in ECHA restaurant located on the first floor.
  - During the breaks, coffee will be served in the same restaurant area
- Technical equipment
  - For your laptop there is a possibility to connect to a wireless network (**WIFI**: ECHA_Guests; **password:** GuestW1F1).

Emergency

- The emergency exits are indicated with green signs;
- In case of emergency follow the instructions of the security personnel or ECHA conference team;
- Do not use the lifts, please take the stairs and go outside;
- Assembly point in the Telakkapuisto park close to the ECHA building.



Smoking

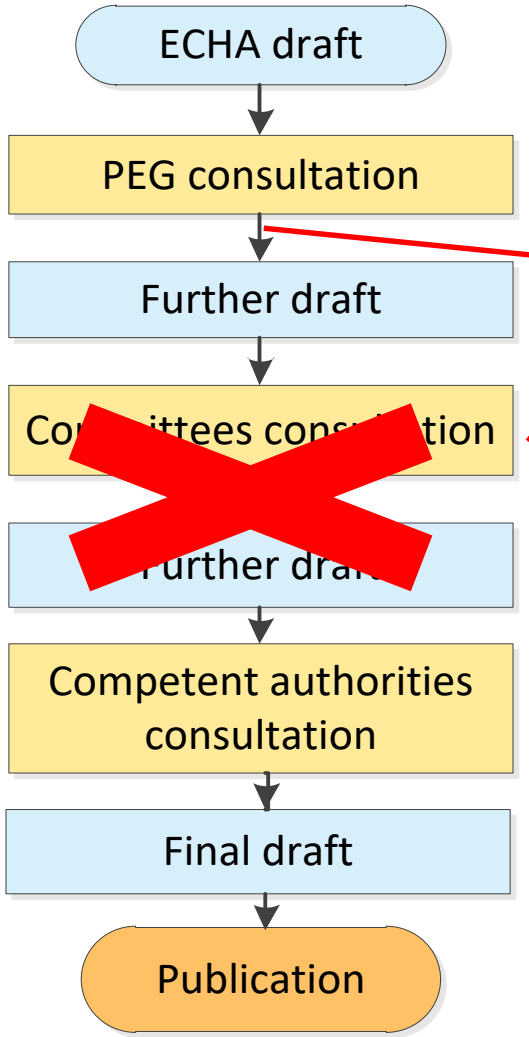
- Allowed only outside, away from main entrances.

Remote participation

- Request for the floor
  - Raise the hand function in WebEx
- The chairperson will assign the turns

Guidance update process in a nutshell

Guidance update process in a nutshell (1)



"Interim" draft and responses to comments sent again to PEG to cross-check **ONLY** that the comments have not been misunderstood or overlooked.

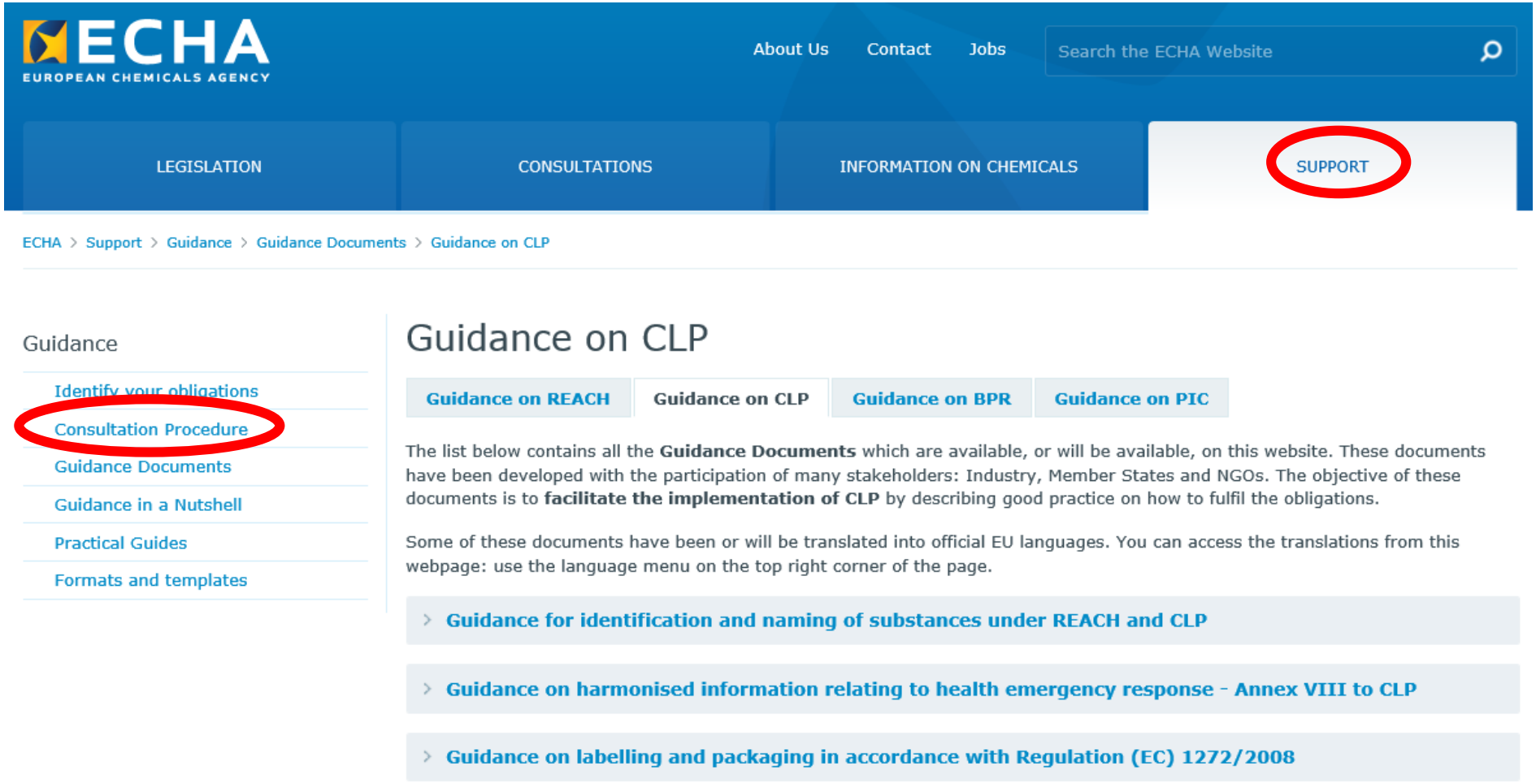
(No new comments accepted)

RAC / SEAC / Forum

Written consultation only

Guidance update process in a nutshell (2)

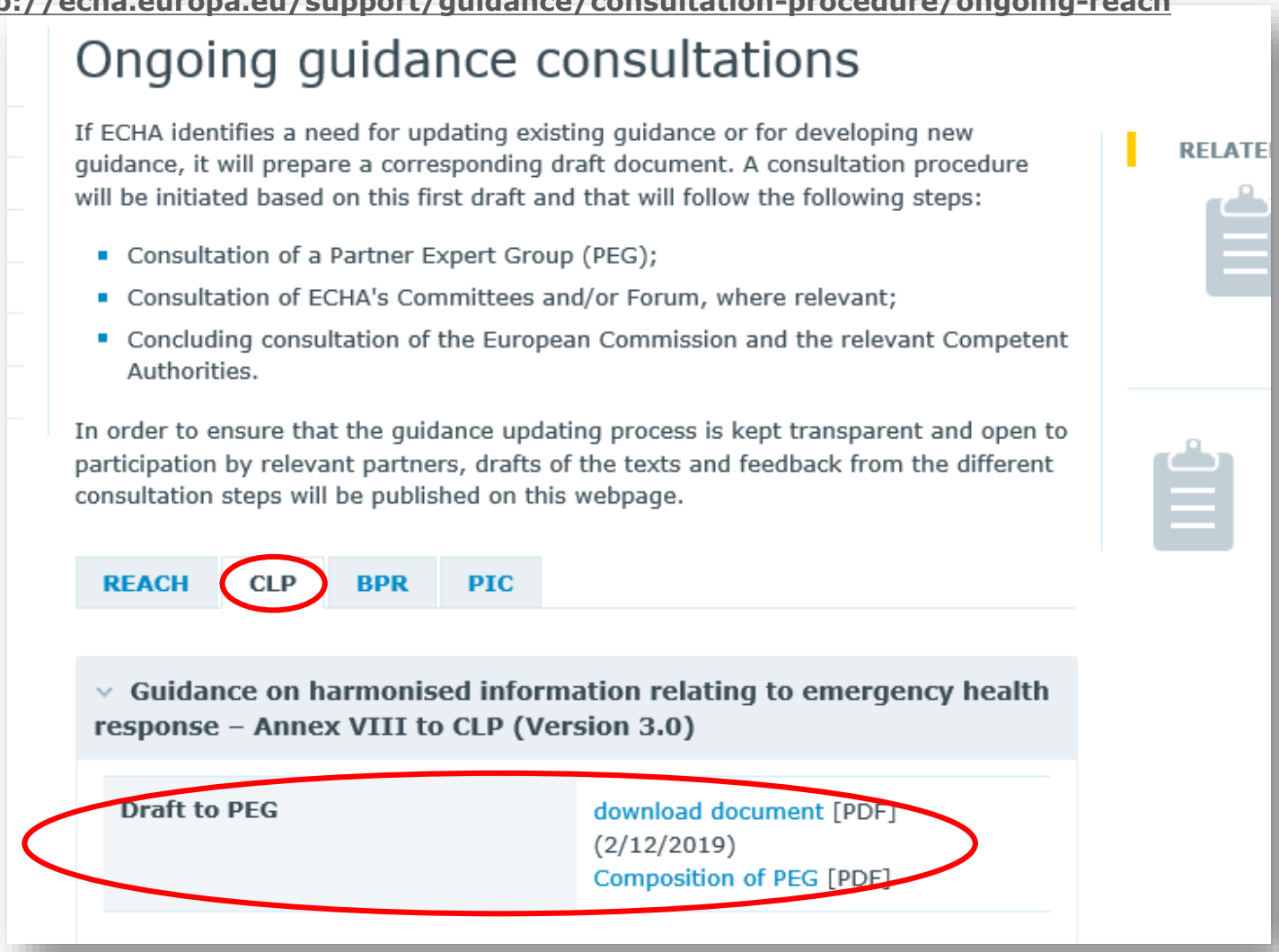
You can track this process: https://echa.europa.eu/guidance-documents/guidance-on-clp



Guidance update process in a nutshell (3)

… and see its output when finalized:

http://echa.europa.eu/support/guidance/consultation-procedure/ongoing-reach



Ongoing guidance consultations

If ECHA identifies a need for updating existing guidance or for developing new guidance, it will prepare a corresponding draft document. A consultation procedure will be initiated based on this first draft and that will follow the following steps:

- Consultation of a Partner Expert Group (PEG);
- Consultation of ECHA's Committees and/or Forum, where relevant;
- Concluding consultation of the European Commission and the relevant Competent Authorities.

In order to ensure that the guidance updating process is kept transparent and open to participation by relevant partners, drafts of the texts and feedback from the different consultation steps will be published on this webpage.

REACH | CLP | BPR | PIC

Guidance on harmonised information relating to emergency health response – Annex VIII to CLP (Version 3.0)

Draft to PEG	download document [PDF] (2/12/2019) Composition of PEG [PDF]

Objectives of the meeting

PEG Consultation

- Ensure that new/updated guidance is **scientifically/technically discussed**, considering the particularities of all concerned stakeholders and ECHA's partners;
- **To be addressed**: not only scientific aspects but also workability, enforceability, efficiency and proportionality;
- Ensure that the guidance is acceptable to all interested parties by providing the basis for ECHA's final draft version;
- If consensus cannot be reached, the majority view position of the concerned PEG should be taken.

Objectives of the meeting

- To discuss and agree on the revised text of the *Guidance on Annex VIII to CLP* (v.3.0) and of part of the *Guidance on Labelling and Packaging* (v.4.1)

- To address selected issues among those raised during the written consultation and explain the main changes triggered by PEG written comments

- To collect feedback, identify key issues and follow-up actions for future Guidance update(s)

What happens next? ....

- ECHA further elaborate the draft guidance document in line with comments and discussion at this meeting (if needed)
- Post-PEG meeting implementation check: **10-day** PEG cross-check
- ECHA finalises the revised draft guidance document for next consultation step
- CARACAL written consultation (March/April 2020)
- Finalisation of update
- Publication of final version 3.0 .... **May 2020**

- ECHA working on draft **version 4.0** (May/June)
- Launch new consultation (late Summer 2020)

Overview of the comments received and proposed structure for the discussion

Proposed structure for the discussion

- 193 + 53 PEG comments received: comments have been categorised and evaluated internally (xls sheet).
- ECHA proposes to accept some changes without further discussion. For each comment not accepted, written justification is provided in the spread sheet.
- ECHA has identified the key comments on which either feedback/further discussion is needed or ECHA already has a position and want to explain it to the PEG.
- ECHA has identified topics where further input is needed for future Guidance development.
- During the meeting the outcome of discussion, proposals and agreements will be minuted and considered for revision of the draft document and implementation of the responses to comments (RCOMs) or possibly considered for the next update.

Overview of the comments received (1)

- **Editorial comments:** (mostly accepted) Reply to comments available in the spread sheet and changes already shown in the latest draft of the guidance.

- **Clarifications (1/2)**:
  - Relabellers Vs Rebranders
  - Obligations with regards of articles+mixtures (wording)
  - Scope (mixture exempted for specific final uses)
  - Voluntary submissions
  - Transitional period and use of ECHA Portal
  - Submission "on behalf"
  - Use of UFI (examples)
  - UFI and SDS requirements
  - Toll formulation
  - Labelling requirements
  - pH requirement

Overview of the comments received (2)

- **Clarifications (2/2)**:
  - Information requirements concerning hazard identification
  - GS examples
  - Technical details (format and submission tool)
  - Validations rules
  - Labelling requirements (standard and exceptional cases)
  - UFI placement

- **Need for further guidance**:
  - Prior notification of MiMs
  - Communication supplier-customer
  - Workability issues
  - Non EU suppliers
  - Multi-component products

Topics selected for the meeting

AP nr	Topic	Agenda point
1	Labelling requirements	For information / discussion
2	UFI and SDS requirements	For discussion
3	Reference to Annex II.5	For information
4	Relabeller Vs rebranders	For discussion
5	Submission "on behalf"	For information
6	pH requirements	For discussion
7	MiM notification & MiM identification	For information
8	Transitional period	For discussion
9	Toll formulator	For discussion
10	Multi-component products	For information
11	2nd amendment – ICGs solution	For discussion
12	Info on IT development plan	For information

1. UFI and labelling

Summary (1) – normal case placement of UFI

Two options provided in CLP

- Art. 25(7): "put UFI on label"
  - Annex VIII, 5.2. in addition specifies that
    - UFI shall be preceded by "UFI"
    - UFI shall be clearly visible, legible etc.
- Art. 29(4a) is a derogation from Art. 25(7): "you don't have to put UFI on the label, you can also put it on the inner packaging (outside of the label) close the mandatory CLP label elements"
  - Annex VIII, 5.2. still applies here, i.e. UFI shall be preceded by "UFI" and it shall be clearly visible etc.

Summary (2) – derogation for small size packaging

- Art. 29(1): "if packaging is too small, then information on outer packaging, tie-on tag or fold out label".
  - 'in accordance with section 5' i.e. acronym 'UFI' and the clear visibility etc.
- Location of UFI in the fold-out label should be clarified in the guidance. Same applies for the use of multiple UFIs for one product.

1.1. Labelling requirements – location of UFI outside of the label

UFI placement in packaging

Issue: Possibility to place UFI on packaging instead of in the label

Concerns:

- Legal text not clear, where UFI can be placed directly onto the packaging with the other label elements: can it be outside label or only on the label? (as long as it is with the other label elements).
- For emergency situations, it is important to be able to give advice that the UFI code can be found either in the label with hazard information or in proximity of this information

- **Proposed solution**: UFI code can be placed either in the label with hazard information or in the inner package (outside of label) in proximity of obligatory CLP labelling information

1.2 Labelling derogations: Location of UFI in fold-out and tie-on labels

Fold-out labels

***Issue*:**

- Which layers of the fold-out label should include UFI

ECHA's answer:

- When UFI is included in fold-out label UFI should be placed on the **front** page and **back** page.

1.2 Multiple languages –
For information only

Multiple languages – *For information only*

***Issue*:**

- Inclusion on multiple languages of several MSs as a reason to use a fold-out label or tie on tag

ECHA's answer:

- The interpretation in the guidance is considered to be in line with a legal text.
- Article 29(1) specifies that the exemption of point 1.5.1 of Annex I to CLP must be applied in the situation where a 'normal' label cannot be used to accommodate the obligatory label information in the languages of '**the Member State**' where the product is placed on the market.
- The text does not refer to 'Member States'. The past discussions on the topic identified this as a need for amending the legal text (to allow a wider use of fold-out labels), but this amendment has not been advanced. Thus the exemption to putting the label elements on the inner packaging is not triggered if the reason why the packaging is too small is that the supplier wished to include more languages on the label than required in the MS.

1.3 Labelling - multiple UFIs on the label

Multiple UFIs

***Issue*:**

- In case of multiple UFIs, where and how they should be placed on the label
  - Multiple UFIs for 1 MS
  - Multiple UFIs – multiple MSs

ECHA's answer:

- Using multiple UFIs is not recommended!
- In a case 1 product has multiple UFIs in one MS, only one UFI needs to be in the label.
- In cases where a different UFI is used in each Member State (not recommended), the UFI with a country code should be placed with the label elements of the applicable language(s) of that Member State.
- In the fold-out labels, similarly in the case of several UFIs (one for each language/market area), it is advised to include the UFI with a country code with the respective label elements of that MS, even if that would be on the inside pages.

2. UFI and SDS

UFI and SDS

***Issue*:** Clarification needed about inclusion of UFI in SDSs – Cases of multiple UFI

ECHA's answer:

Baseline:

- UFI used should be notified in the relevant MS
- More UFIs can be generated and used for the same mixture
- Different UFIs can be generated and used in different MS for the same mixture
- In each MS only the notified UFI should be used and communicated

UFI and SDS

1) When has to/can go on the SDS?

(Revised) Annex II of REACH, Section 1.1: *"Where a mixture has a unique formula identifier (UFI) in accordance with section 5 of Part A of Annex VIII to Regulation (EC) No 1272/2008 and that UFI is indicated in the safety data sheet, then the UFI shall be provided in this subsection."*

Annex VIII, Part A.5:

- Not by default (i.e. normally it is **not required** but *can* be included)
- In case of hazardous mixtures used at **industrial site** (even if they are used in consumer/professional product downstream) **can** be included on the SDS **as an alternative** to the label (i.e. instead of the label).

- **Mandatorily** for hazardous mixtures placed on the market unpackaged

Guidance: there are few cases when UFI **has to** be included in the SDS, in all other cases the inclusion is **voluntary.**

UFI and SDS

2) What about multiple UFIs for the same mixture?

ECHA's opinion is that all UFIs used in a specific MS should be included in the SDS supplied in that Country.

Agree that confusion should avoided.

No intention to allow mixing of UFIs and Member States.

All UFIs included in the SDS should be notified to the relevant AB.

Recommendation rather than obligation

Pending Commission's feedback – Reference in Guidance temporarily removed.

3. Reference to Annex II.5 to CLP

(for information only)

Annex II.5 to CLP

Issue: Current wording of Annex II.5 to CLP to be revised

Guidance follows current legal text:

In case of *"Ready mixed cement and concrete in a wet state"*

- sold unpackaged
- supplied to the general public
- the UFI has to be included in the copy of the label elements provided for in Article 29(3)

PEG member claims that correct wording should be *"cements and cement-containing mixtures, such as ready-mixed concrete and mortars in the wet state".*

Reason: there are no ready mixed cements in the wet state, except where these are mixed on site (i.e. adding water to a dry cement e.g. prior to injecting it into e.g. ground). But here Annex VIII would not apply, because the wet mixture is made on the construction site.

4. Relabellers Vs Rebrabders

Relabellers Vs Rebranders

Issue: Distinction between relabellers and rebranders questioned

Relabeller: change the label for any reason (adapt corporate colours or identifiers on the label or adapt label in other manners – Translation of label to distribute in different MSs)

Rebrander: Actor who affixes his own brand to a product that somebody else has manufactured.

REACH Guidance on DUs

Nature of the obligations depends on the real activity carried out

Relabeller changing the company's name would **not** be **incompliant** with Article 4(10)

(Required info still available to AB)

ECHA's answer: Even if agrees that *in principles* the two types could be considered as the part of the same "group", prefers to keep both terms.

Possibly more details to be included in a revision of the Guidance on DUs

5. Submission “on-behalf”

Submission "on-behalf"

***Issue*:** Clarification about possibilities in case of non-EU suppliers / EU-based LE / Mother company / 3rd party in general

***Current options*:**

Submissions have to be made via EU-based LE account

- **Option A**: any 3rd party (including non-EU LE) via the "foreign user" functionality assigned by the EU duty holder (i.e. via the EU duty holder's account).
- **Option B**: voluntary submission+UFI by a EU-based LE and submission by EU duty holder referring to that UFI

- **Option C (via S2S)**: Any 3rd party preparing via S2S and including the duty holder's LE UUID (N.B.: currently LE consistency to be assured in Dossier Header-MainMixture-Portal). Use of "foreign user" functionality via the duty holder account still possible.

Non-EU supplier

1. Acting via its EU-based legal entity

- Creates UFI#1 using own VAT number
- Makes voluntary submission
- Communicates UFI#1 to EU importer

<u>EU importer</u>

- Creates UFI#2 using own VAT
- Puts UFI#2 on the label
- Makes mandatory submission
  - of 100% MiM (refers to UFI received from supplier, UFI#2=100% UFI#1)
  - of own final mixture (refer to UFI received from supplier where UFI#1 is only one of the components)

2. Acting as third party (like consultant)

- Creates UFI#1 using VAT number of the EU importer
- Makes mandatory submission 'on behalf' of the EU importer
- Communicates UFI#1 to EU importer

<u>EU importer</u>

- Puts UFI#1 on the label

Note: To protect CBI only option 1 is viable. Option 2 allows the actual duty holder to access submission made on its behalf

Submission “on-behalf”

ECHA recommends using the “foreign user” functionality to have full control.

Guidance

explains the legal requirements and

suggests the preferred ways forward

Further technical details are for Technical manuals.

LEs management currently under analysis and Guidance may be revised at later stage, following adaptation of IT systems.

6. pH requirement

Issue: Requirements with regards to pH value further developed in amended legal text.

Guidance not clear on the relation between pH measurement and percentage and to what the value refers to.

Basis:

Amended Annex VIII: *the pH, if available, of the mixture as supplied, or, where the mixture is solid, the pH of an aqueous liquid or solution at a given concentration. The concentration of the text mixture in water shall be indicated. If the pH is not available, the reasons shall be given.*

Amended Annex II: *Does not apply to gases. The pH of the substance or mixture as supplied, or where the product is a solid, the pH of an aqueous liquid or solution at a given concentration, shall be indicated.*

The concentration of the test substance or mixture in water shall be indicated.

Issue: Requirements with regards to pH value further developed in amended legal text.

Guidance not clear on the relation between pH measurement and percentage and to what the value refers to.

Basis:

Amended Annex VIII: *the pH, if available, of the mixture as supplied, or, where the mixture is solid, the pH of an aqueous liquid or solution at a given concentration. The concentration of the text mixture in water shall be indicated. If the pH is not available, the reasons shall be given.*

Amended Annex II: *Does not apply to gases. The pH of the substance or mixture as supplied, or where the product is a solid, the pH of an aqueous liquid or solution at a given concentration, shall be indicated.*

The concentration of the test substance or mixture in water shall be indicated.

Reasoning

Annex VIII	Guidance
the pH, if available, of the mixture as supplied,…	pH referring to the mixture as placed on the market (i.e. 100 solution concentration)
…or, where the mixture is solid, the pH of an aqueous liquid or solution at a given concentration. …	In case of mixtures supplied in solid form, the pH should refer to a solution of the same solid mixture.
… The concentration of the test mixture in water shall be indicated. …	Where the pH has been measured by diluting the mixture in water, the concentration of the solution must also be provided.

Reasoning

Annex VIII	Guidance
*If the pH is **not available**, the **reason** shall be given;*	If for any reason the pH cannot be provided, a justification must be indicated.
	The provision of a pH value does not apply to mixture in a gaseous state.
	Other cases where not meaningful (**e.g.** insoluble in water)

…explore possibility for further guidance (**not** exhaustive list) on justifications for pH not being available?

Further guidance?

Annex VIII

*If the pH is **not available**, the **reason** shall be given;*

*Would these reasons be **generally** acceptable?*

pH can possibly be still be determined if the mixture or part of it is somewhat soluble or

according to the solution tested

➔ *measurement meaningful?*

IT Working Group's feedback

- Mixture reacts with water
- Mixture is pure organic solvent/solution
- Mixture is non acidic/basic solution
- Mixture is non polar solvent
- Non ionisable groups present
- No acid/basic groups present
- Does not dissociate
- pH extremely high/low

7. Transitional period

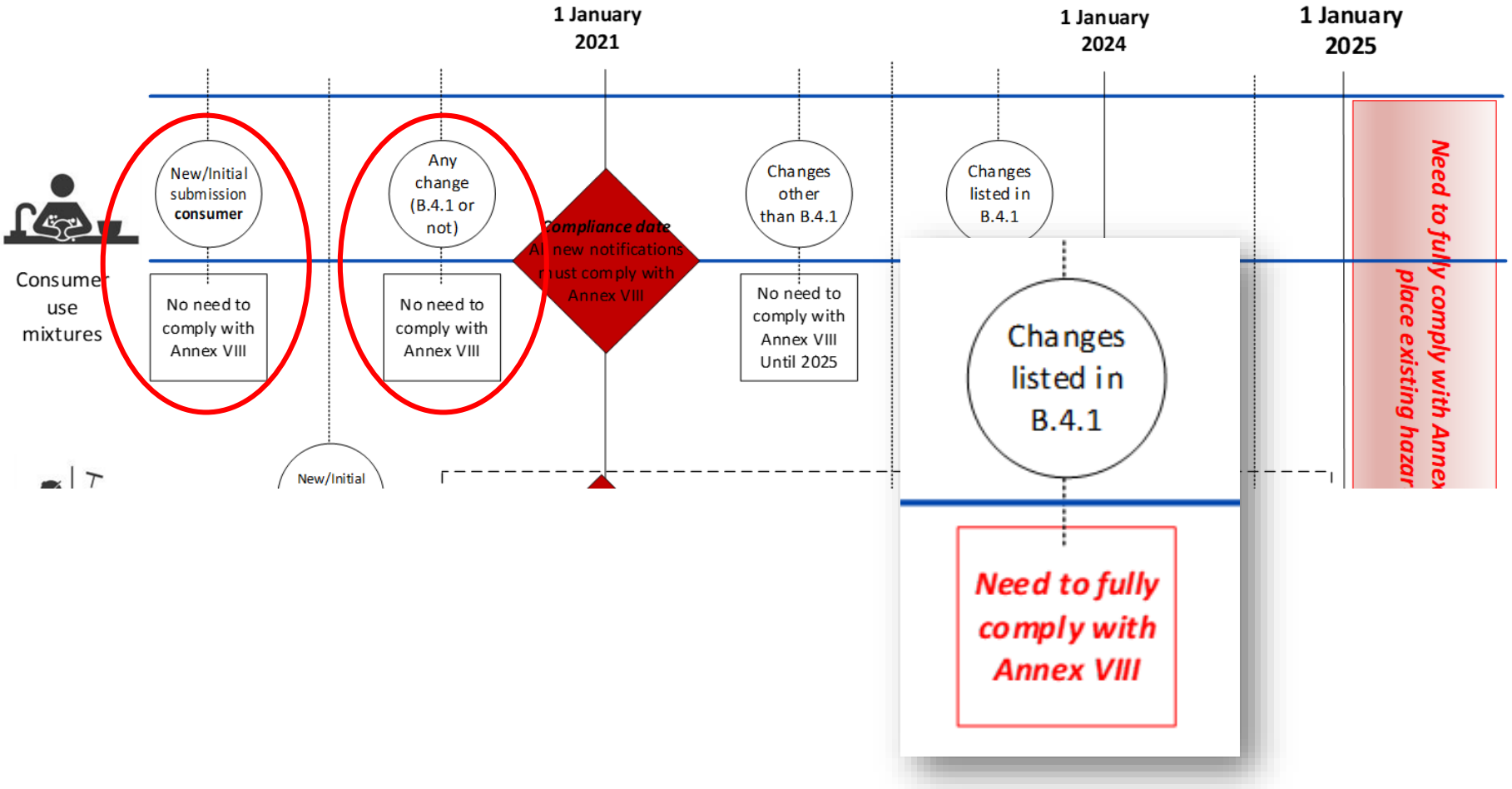
Transitional period

Issue: Clarifications about obligations before and after compliance dates, until end of transitional period.

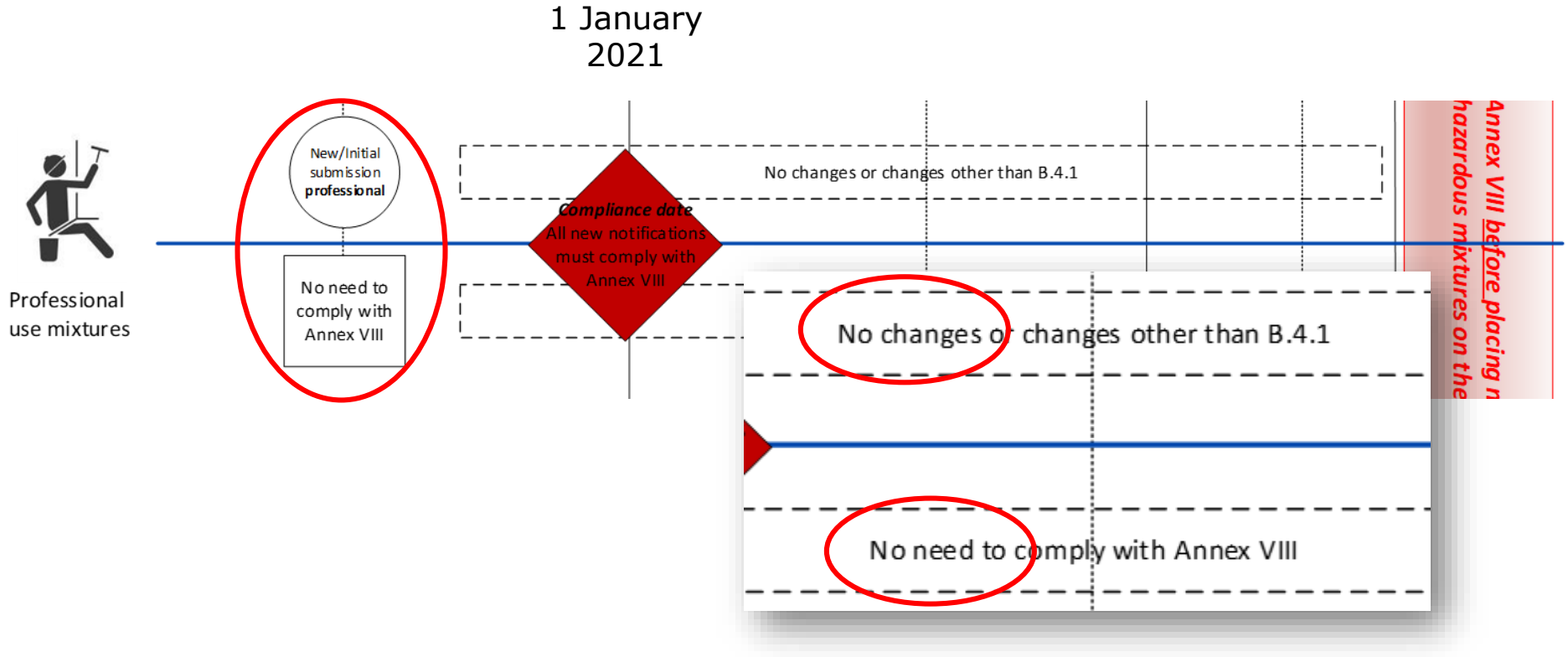
Current Guidance:

- National requirements apply before the relevant compliance date (i.e. according to the end-use);
- **Mixture already notified** according to the national systems do not need to comply with Annex VIII until 1/1/2025 (both submission and labelling requirements);
  - If an update is needed *after the compliance date* because of the reasons listed in B.4.1, Annex VIII applies in full (i.e. submission and labelling obligations.
  - If an update is needed for other reasons, national obligations apply until 2025 (no need to apply Annex VIII);
  - After 1/1/2025 Annex VIII applies (i.e. new submission and UFI on the label)

Transitional period

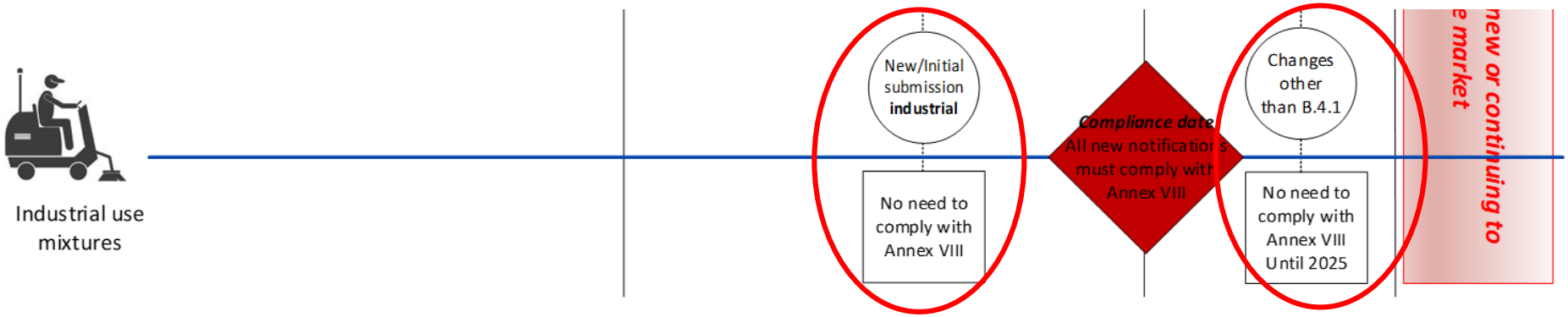


Transitional period



Transitional period

1 January 2021



Transitional period

Current Guidance:

- For **new mixtures** (not previously notified) national obligations apply until the relevant compliance date

  ➔ After the relevant compliance date Annex VIII applies (submission and labelling according to Annex VIII)

The submission tool is always decided by the MS, before, during and after the transition period.

Use of Submission Portal before (and after) the first compliance date decided by each MS

➔ Reference to "Overview MSs' decisions" table

8. Toll formulator

Toll formulator

***Issue*:** Realistic scenarios to be better reflected

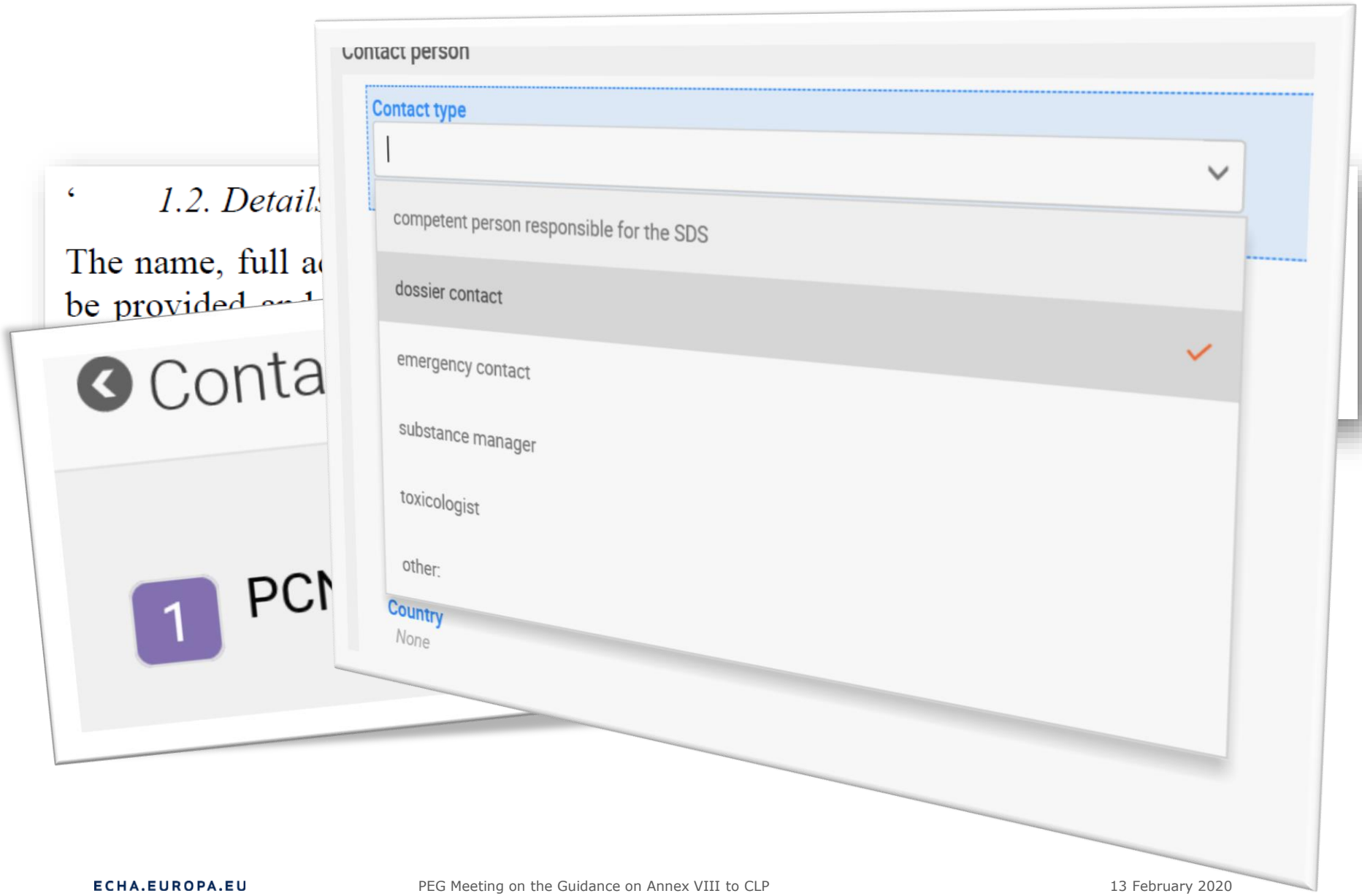
A toll formulator is a service providing company that formulates a mixture on behalf of another company, i.e. a 'third company' (customer)

Current guidance:

- Toll formulator is a duty holder under Article 45
- Customer owing the mixture is a distributor

- Options:
  a) Toll formulator formulates, generates UFI, submits, labels and provides the product to the customer ready to be placed on the market.
  b) Customer creates own UFI to be included in toll formulator's submission.
  c) Customer can make own submission (same as other distributors).

Toll formulator



9. Multi-component products

Multi-component products

***Issue*:**

- Difficulties with labelling: mixtures not separately packaged.
- Multiple UFIs may possibly confuse the consumer.
- Question about practical notification options.

Understanding so far:

1) Definition:

Product containing more mixtures when delivered to the user.
Individual mixtures not suitable for the intended final use.

Mixtures in separated containers (e.g. kit)
Mixtures physically separated but in single container

Multi-component products

2) Types:

- Components mix and react. Composition changes.
- No chemical reaction. Components mixed at will.
- No chemical reaction. Component released separately.
- Component used one after the other (e.g. kits)

3) Final product:

- Mixture with hazard properties different from any of the component;
- Mixture with short life (highly reactive);
- Creation of new components (?)
- No new mixture

Multi-component products

4) Info needed by PCs:

4.1) To identify the product:
- Full trade name;
- Information that it is part of a multi-component product;
- Label of the product;
- Intended use.

4.2) For emergency response:
- Composition of component mixtures;
- Prescribed mixing ratio (if relevant);
- Hazardous properties of final product;
- Physical appearance and pH of final product.

Multi-component products

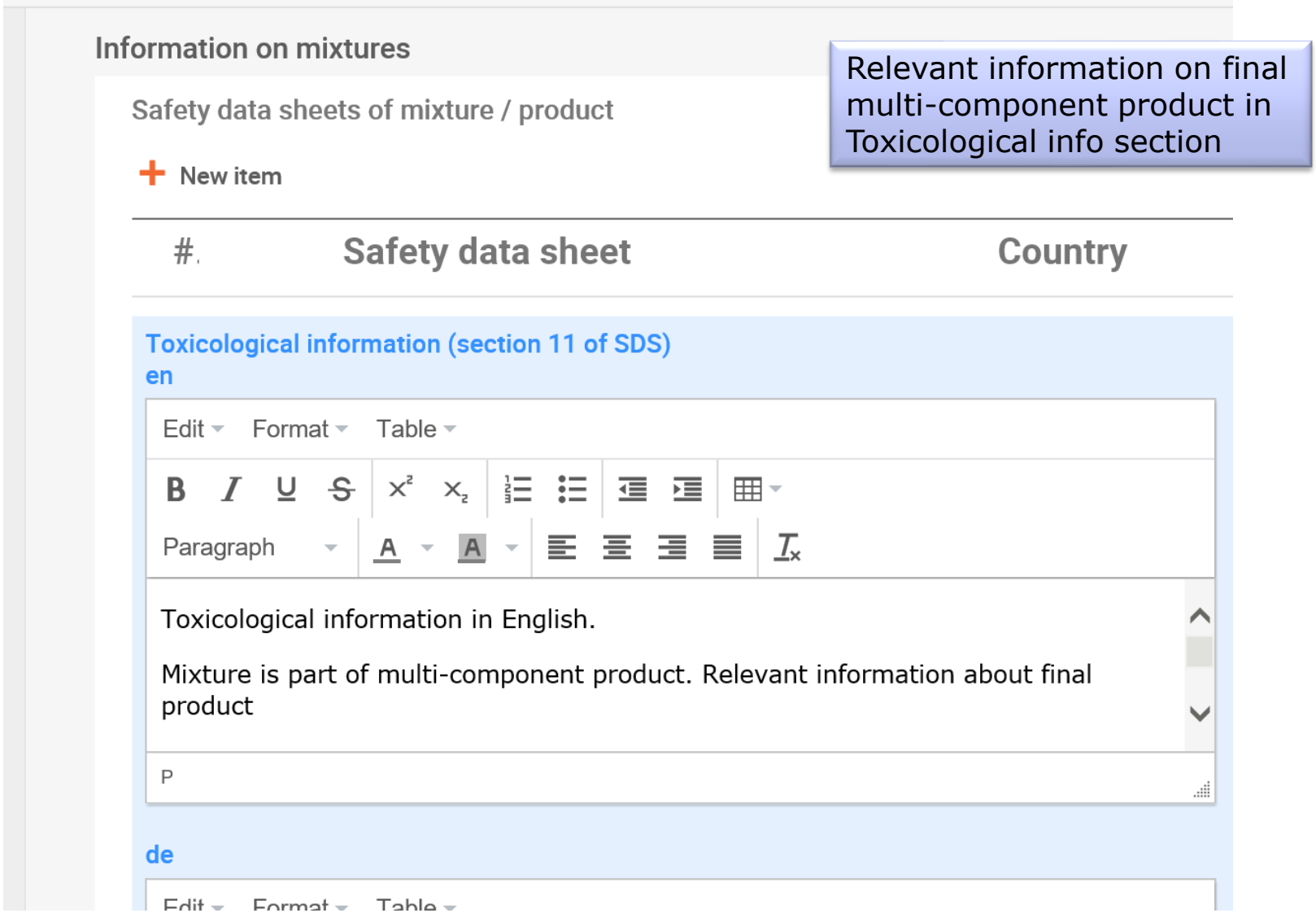
5) Current situation:

- Normally, each component individually notified;
- Seldom, notification of final product's composition (e.g. components considered as MiMs);
- SDSs produced and supplied for each mixture component;
- Hazard/toxicological information on final product often not available.

Current guidance:

- Text reflects legal text: submission (and a UFI) needed separately for each mixture of the multi-component product placed on the market
- Information on the final mixture is not legally required but the Guidance advises to provide the available information (& relevant for poison centres) in each submission of the multi-components mixtures in the toxicological section as free text.
- Additional technical (temporary) solution is to provide relevant info on the product in packaging record (text and/or attachment)

Multi-component products



Relevant information on final multi-component product in Toxicological info section

Multi-component products

Indication of being part of a multi-component product in packaging info section (attachment possible)

Packaging related attachments + New item

#	Type of attachment	Attached document
1	other: Mixture part of a multi-component laundry tablet	Laundry tablet mix.jpg
2	other:	*None*

10. Mixture in a mixture

12a. Previously notified

12b. Identification – non hazardous

MiM previously notified

Issue: Need for guidance on how to obtain information about MiM being notified by supplier

ECHA's answer:

No specific Guidance available.

Best way remains communication.

Support from Submission portal checks

a. BR566 warns if UFI has not been notified before;

b. New/modified rule (under discussion) to check the MS of submission of MiM's UFI.

Limits:

- check only upon submission;
- check possible only against data present in central database (i.e. submitted via the ECHA Submission portal)

Non-hazardous MiM identification

MiM to be identified:

1) MiM fully known:

➔ all component substances to be indicated at final mixture level (i.e. no MIM in its composition)

2) MiM not fully known and UFI available and previously notified to the relevant AB:

➔ Product identifier and UFI

2) MiM not fully known and UFI not available or not previously notified to the relevant AB:

➔ Product identifier, compositional information contained in the SDS (+other known components) and supplier details

MiMs which do **not need an SDS** (non-hazardous) do not necessarily need components to be indicated.

I.e. product identifier and supplier's details suffice

(to be reflected in the validation rules).

11. Workability issues

MiM – Different suppliers

Issue: Workability issues for certain sectors not addressed (e.g. multiple suppliers)

ECHA's answer:

- Discussions took place with regards certain specific workability issues, originally raised by some industry sectors and analysed with dedicated study in 2018 and 2019.
- Second amendment of Annex VIII under preparation.
- New Guidance update (v.4.0) already planned. Works to start once the amendment is approved (tentatively before the Summer). The same PEG will be consulted.

Issues to be addressed and solutions now identified and under refinement

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. Interchangeable Components (ICs) and Interchangeable Components Groups (ICG) - (general solution)

ii. Standard formulas - (sector specific solution)

iii. Special provisions for point of sales paints - (sector specific solution)

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Interchangeable components groups

Mixture composition variation because of change in components due to:

a. 'same' component, different suppliers
b. Components chemically different, toxicologically same

A) Interchangeable components= components which are different, but sufficiently similar to be considered one and the same component (toxicologically)

- Same technical function, and — Guidance possibly needed
- Same physical and health hazard, and
- Same toxicological profile (no reference to mechanism of action) — Guidance possibly needed
- AND Same hazard identification and additional information of final mixture

Interchangeable components groups

B) Concentration to be provided at ICG level (Tables 1 and 2 apply)

C) Classification to be provided at ICG level

D) More than 1 IC from one ICG can be present at each time

E) Each IC has to be identified

F) More than one ICG can be included in one mixture

G) If a IC change, notification to be updated but not the UFI

Interchangeable components groups

G) Derogation: only classification has to be the same (no tox profile) for ICs classified for skin corrosion, skin irritation, eye damage, eye irritation, aspiration toxicity, respiratory or skin sensitisation (or combination), when:

- pH neutral/alkaline of all ICs classified for skin corrosion, skin irritation, eye damage, eye irritation; and
- maximum 5 ICs

Example – 'same' component, different suppliers

Notification

Name: 'Mixture X'
Classification: Skin Sens.
Composition:

Comp.	Class.	Conc.
'A'	Not classified	50%
'B'	Not classified	30%
ICG 1	Skins Sens.	20%

'C1'	'C2'	'C3'

Each C identified following 3.2.2

Justification, not to be submitted

- Classification of C1, C2, C3 is the same
- Technical function of C1, C2, C3 is the same
- Any acute tox effects caused are the same for C1, C2, C3
- At 'Mixture X' level, hazards identification and additional information is always the same, regardless whether C1, C2 or C3 is actually present

Interchangeable components groups

Same toxicological profile (possibly no reference to mechanism of action as not always known)

Same target organs?

Same effects on same target organ?

Which are hazards classes relevant for acute medical effects?

Same technical function

Guidance needed?

Interchangeable components groups

Risk to reduce usability of information

To be addressed?

Solution generally available whenever criteria are met: recommendations on when/why ICG *should* be avoided?

Interchangeable components groups

Mixture AA

Composition: 100% ICG xy

- MiMa
- MiMb

MiMa contains X1, Eye Dam. Cat1 – 4%

MiMb contains X1, Eye Dam. Cat1 – 9%

Table 1 would apply:
3-4%
9-10%

PCs may need to work based on 4-9% or even 3-10% (possibly, if based on supplier's submissions)

IT tools development and plan (info session)

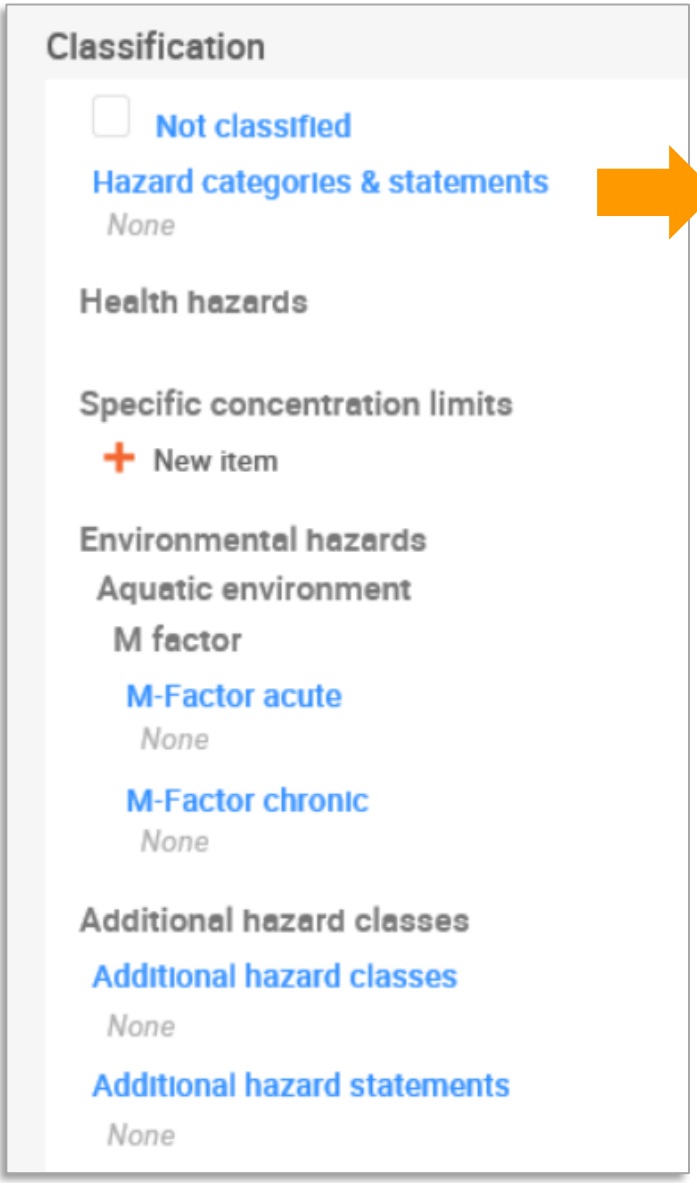
PCN IT solution releases

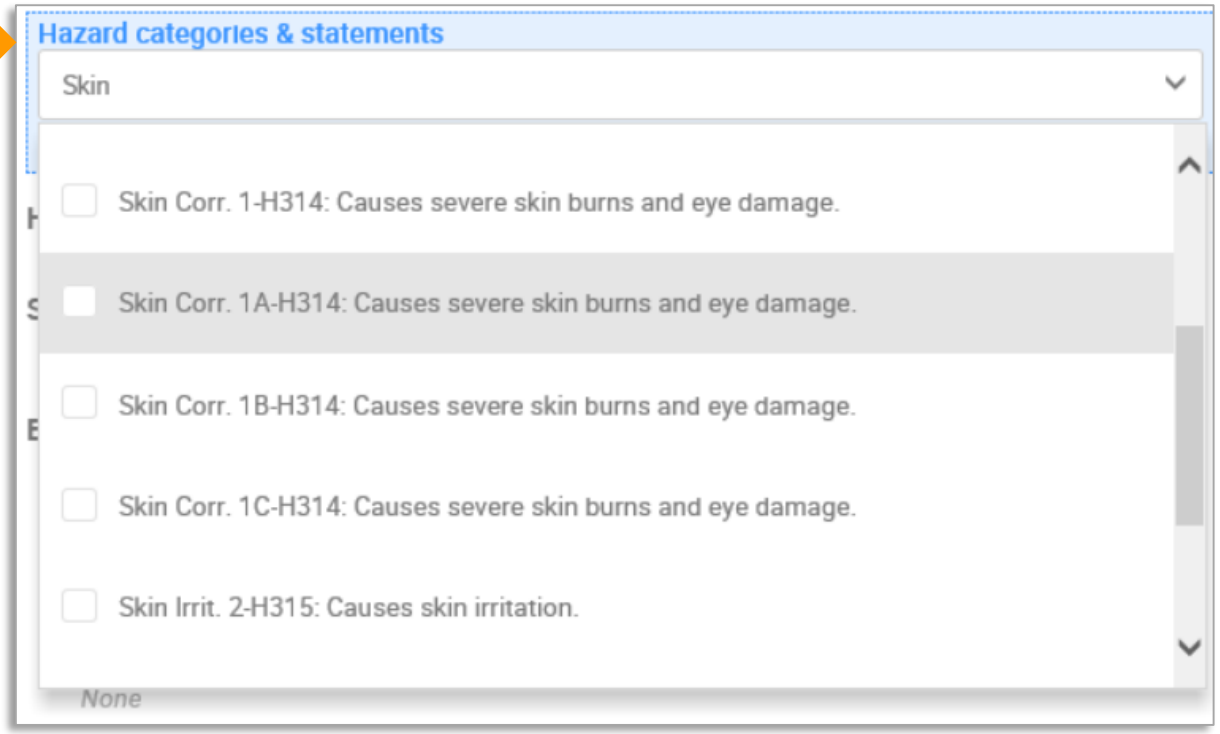
- 2019
  - April - Go-live
  - July - Improvements in IUCLID cloud services
  - October – PCN format changes
- 2020
  - January - Improvements in IUCLID cloud services

January 2020 release scope

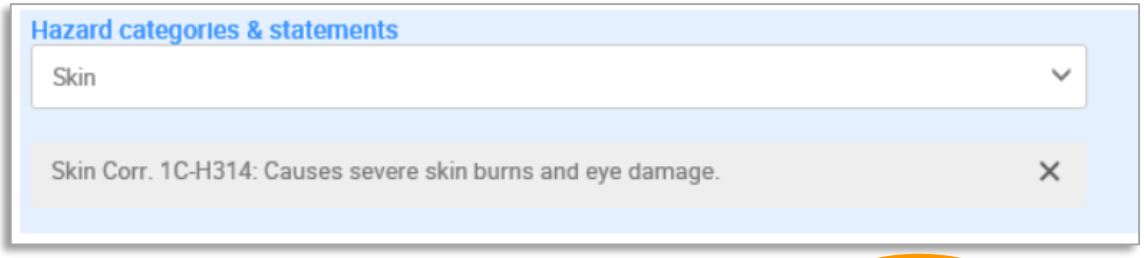
- Easier way to provide Classification information
- Automatic calculation of Labelling information
- Cloning a mixture dataset to facilitate significant change of composition and multi-market submission
- Dossier header always displayed
- Multi-lingual fields available in the dataset view
- Improved documents naming
- Indication of mandatory fields
- Improvements to the validation report and validation rules
- New widget to manage articles that will be used to prepare SCIP notifications

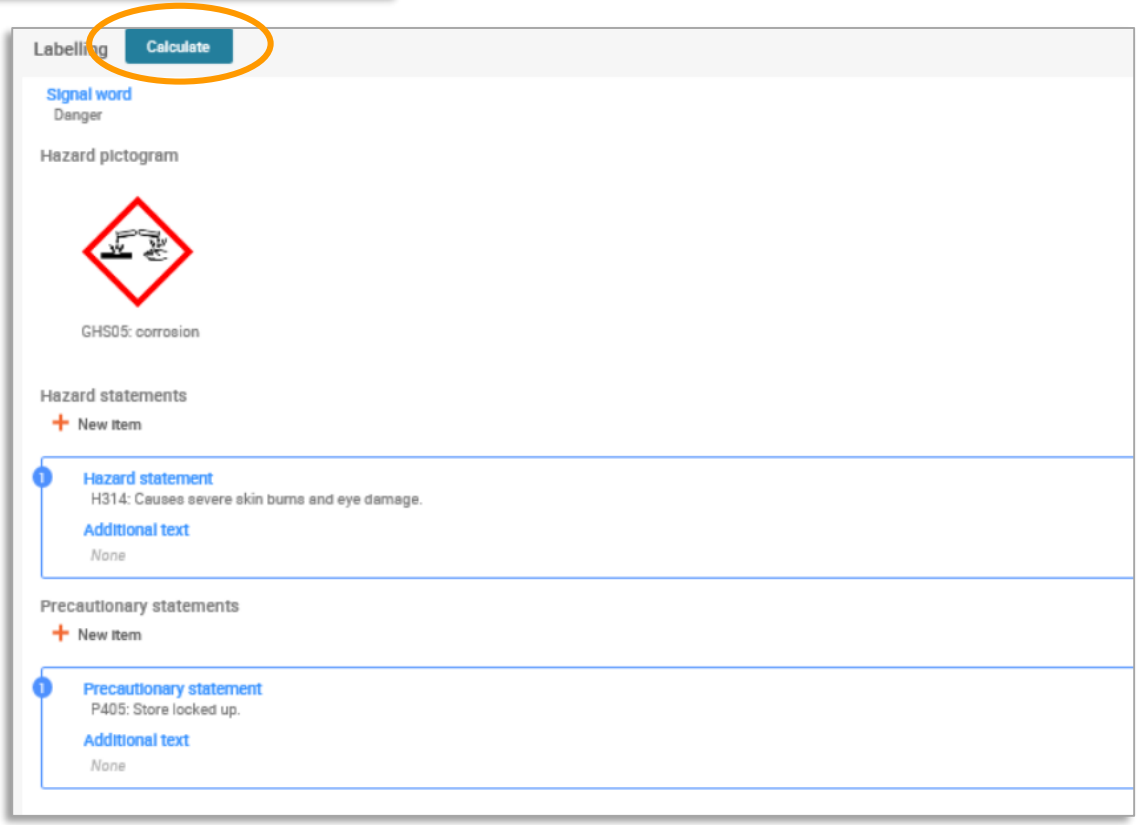
Easier way to provide Classification information



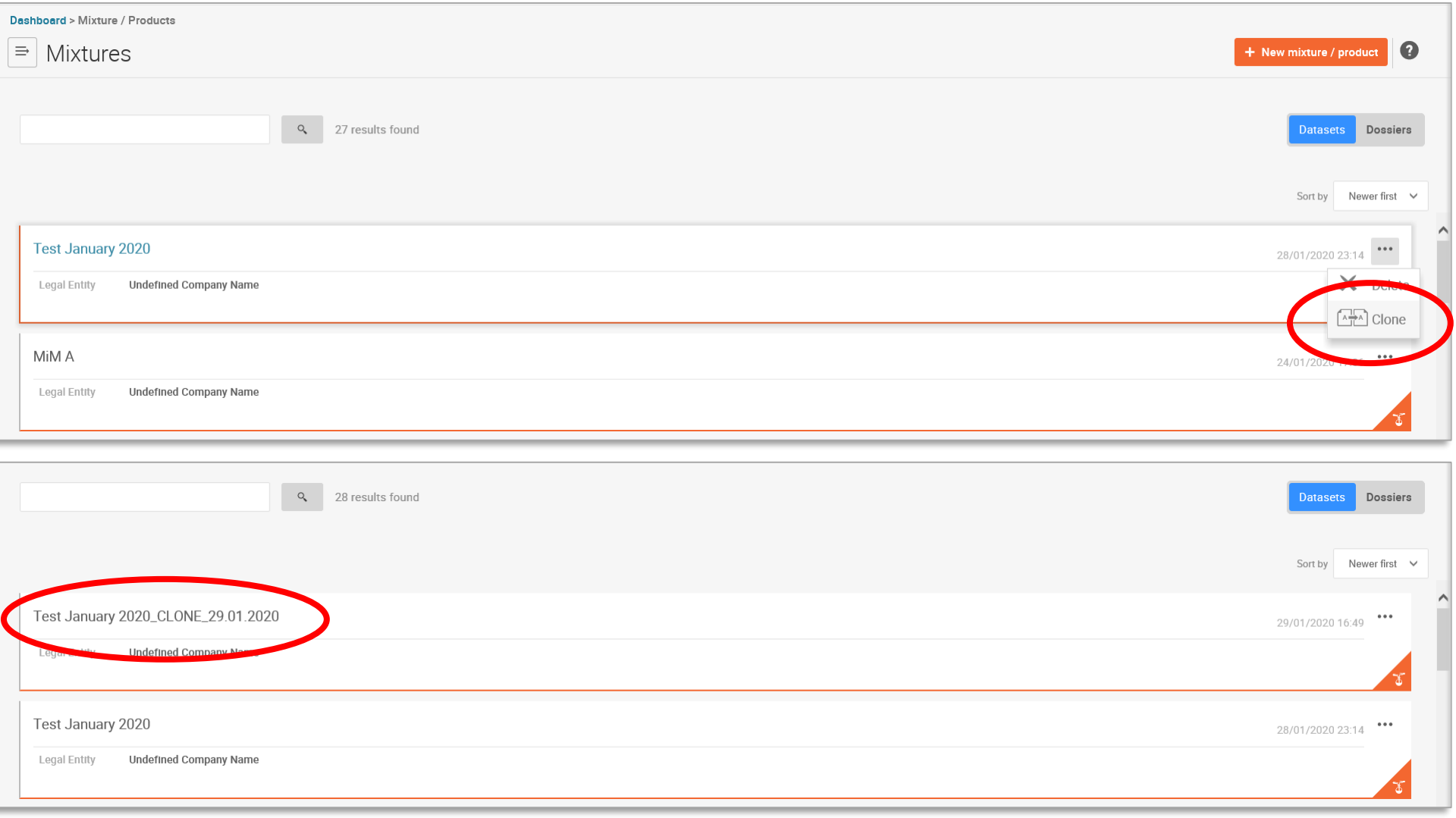


Automatic calculation of Labelling information

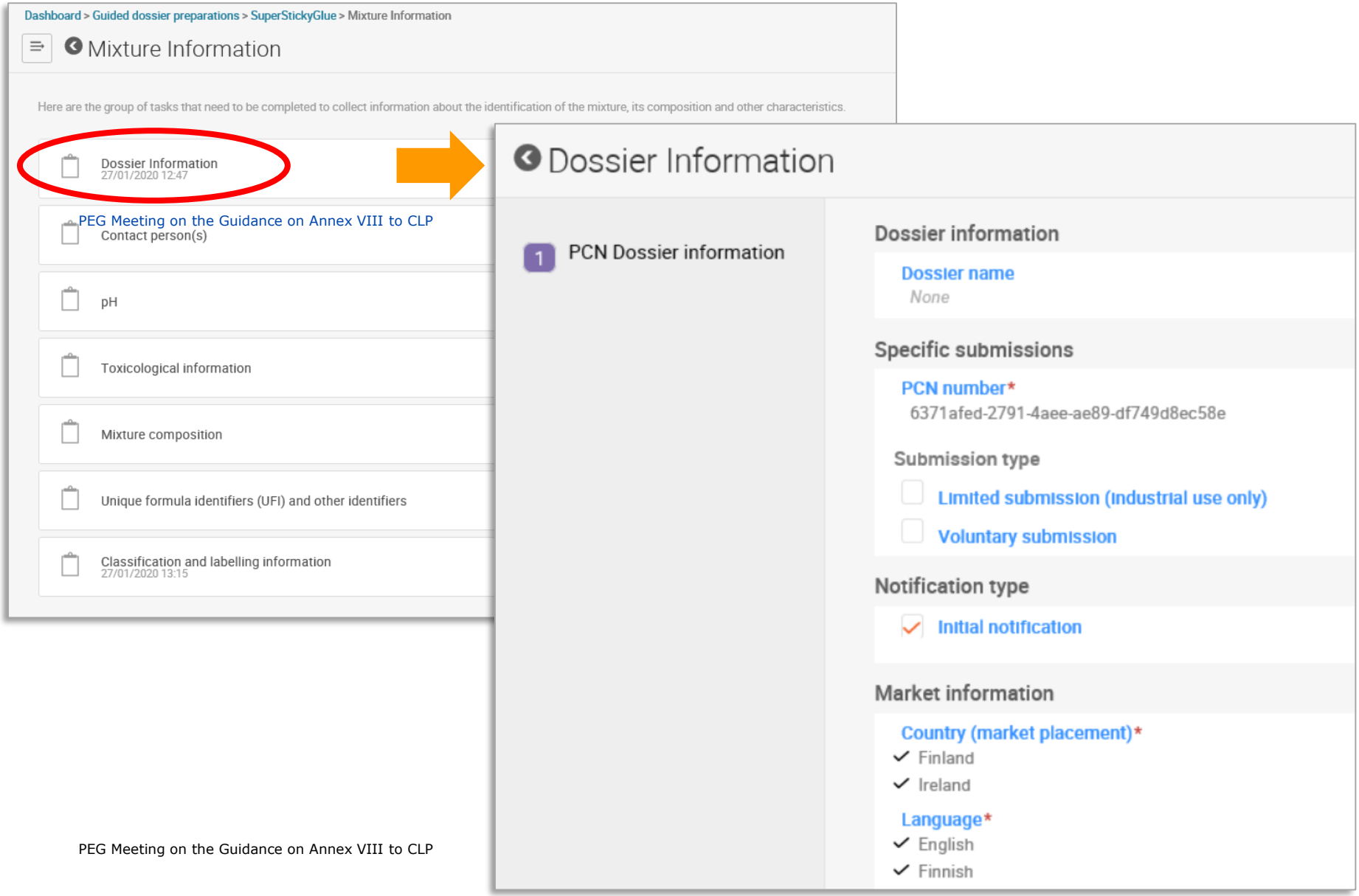




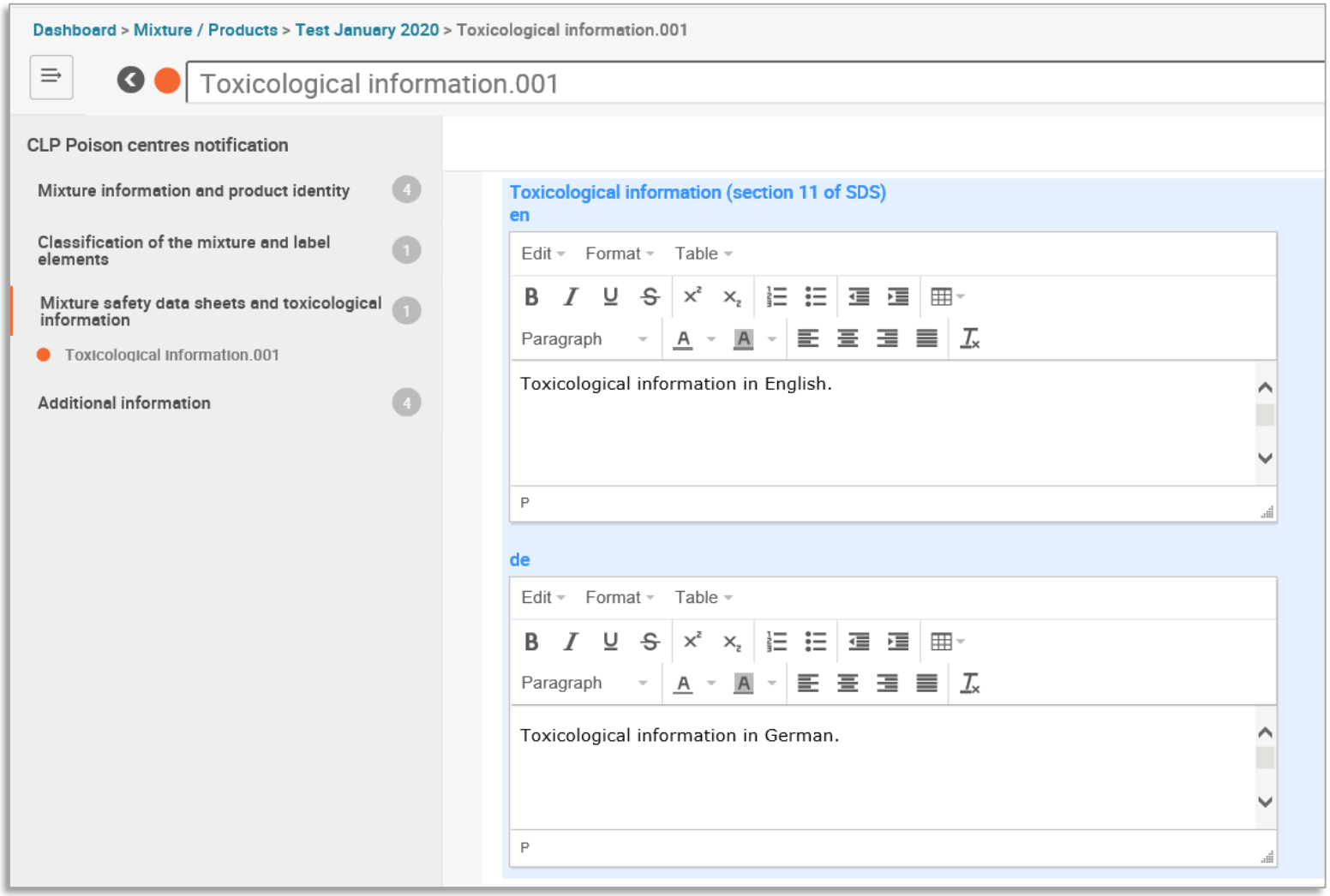
Cloning a mixture dataset



Dossier header always displayed



Multi-lingual fields in the dataset view



Coming soon…

- Submission graph in the Submission report showing:
  - All submissions made for the same mixture
  - Updates and significant changes of composition related to that mixture

- S2S testing supports real processing of the submitted dossiers

2020 High-level scope

- Adaptations to I and II amendment to Annex VIII
- New validation rules coming from the WG and the amended legal text
- Improvements in the IUCLID standard view to facilitate the preparation of PCN dossiers
- Integration of dossier preparation with Substances Master List of ECHA
- User friendly dossier viewer for Appointed Bodies and Poison Centres
- Partial adaptations of PCN database coming from consultation plan
- 3 more releases (April, June*, October)

Next releases

Jan 2020	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct 2020

- Improvements in IUCLID Cloud Services

- IUCLID release with PCN related improvements

- Improvements in IUCLID Cloud Services

- Complete adaptation to I amendment
- (Partial) adaptations to II amendment
- IUCLID format update

Conclusions and agreements

Agreements /Action points

- AP1 (Labelling)

1.Agreed with the interpretation that UFI does not have to be **in** the label. It can be outside, as long as is "with" the other label elements (=very close to) and easily identifiable.

Raised concerns with current legal text which may create interpretation and enforcement issues.

Align wording in Annex VIII Guidance with Labelling Guidance (do not use "in proximity with").

2. Fold-out labels. Modify the text not to give the impression that its removal is the norm (not "when" but "if" it is removed)

Agreements /Action points

- AP1

3. Multiple UFIs for same mixture is possible. UFI(s) on the label used in a certain MS, only if this(these) notified to the relevant AB.

Recommend one UFI only on the label. If multiple UFIs (e.g. multi-language label), it must be clear which UFI is notified in which MS (e.g. country code). Make sure the guidance reflects this.

- AP2 (SDS)

Agree not to recommend/require all UFIs on the SDS. It is still a possibility. Make sure the guidance reflects this.

- AP3 (Annex II.5)

No action for the Guidance.

- AP4 (RelabellerVsRebranders)

No action for the Guidance.

Agreements /Action points

- AP5 (Submission o behalf)

No actions for the Guidance

- AP6 (pH)

No action for the Guidance. Further details should be for Annex II. IT user Group will discuss about list of possible justifications to be provided in the IT tool.

- AP7 (Transitional period)

Agreed to remove figure 2. Make clear in the Guidance that **from** 1/1/2025 everything has to be Annex VIII compliant.

ECHA to work on a new infographic to be published on different channels.

Agreements /Action points

- AP8 (MiMs)

No actions

- AP9 (Multi-components products)

Suggestion (industry) of a notification for final product with its own UFI and containing the individual mixtures to be discussed with Commission/Authorities.

Guidance to reflect legal text. Each mixture has to be notified and UFI assigned. No changes at the moment.

PEG acknowledges lack of practical solutions for certain products which are not individually packaged in terms of labelling (e.g. washing tablets).

Agreements /Action points

- AP10 (Toll formulators)

No actions

- AP11 (ICG)

Discussion about names, which should be meaningful. Possibly referring to technical function and toxicological effects.

ECHA to consider the option to facilitate the creation on a first list. Feedback to be provided by industry and to be checked by PCs. To be verified the possibility to provide non exhaustive pick list in format.

Guidance to be possibly general.

Thank You.

Thank you for your attendance at this PEG meeting and for your participation and contributions to the discussions.

We wish you a safe trip back home