

Poison Centres Validation Rules Working Group Meeting XII

04 March 2021

Poison Centres Team
European Chemicals Agency

**Conclusions and
Post-meeting notes**

Agenda

1. Introduction and current status
2. Follow up from XI Webex:
 - Finalise rules discussed
 - Rules not discussed yet
3. Flagging combinations: ICG/GCI/SF components
4. Conclusions and next steps



Introduction



Objective of the meeting

Follow up on open points and rules not addressed during the 11th Webex

Agree on corrections/deviations as needed.

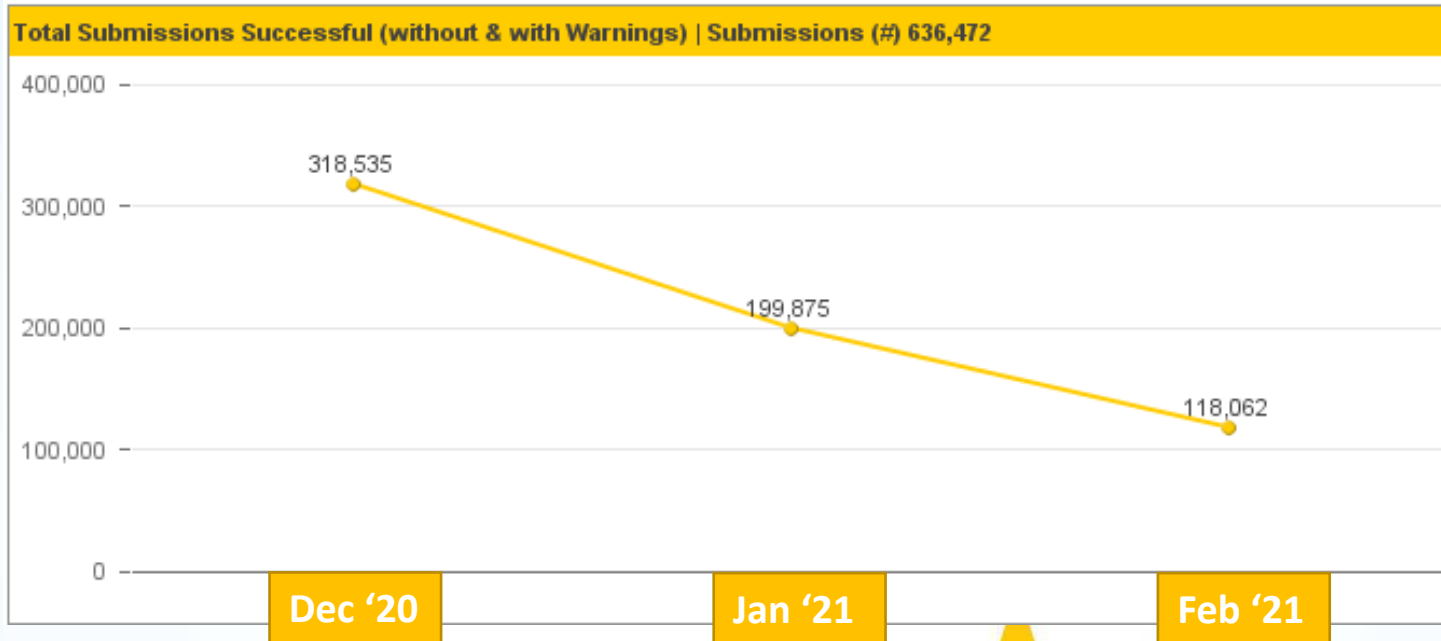
Present components combinations scenarios and suggested rules

Plan the next steps

Validation rules and submissions: current status



Dossier submitted across the 1st compliance date (up to 28 Feb)

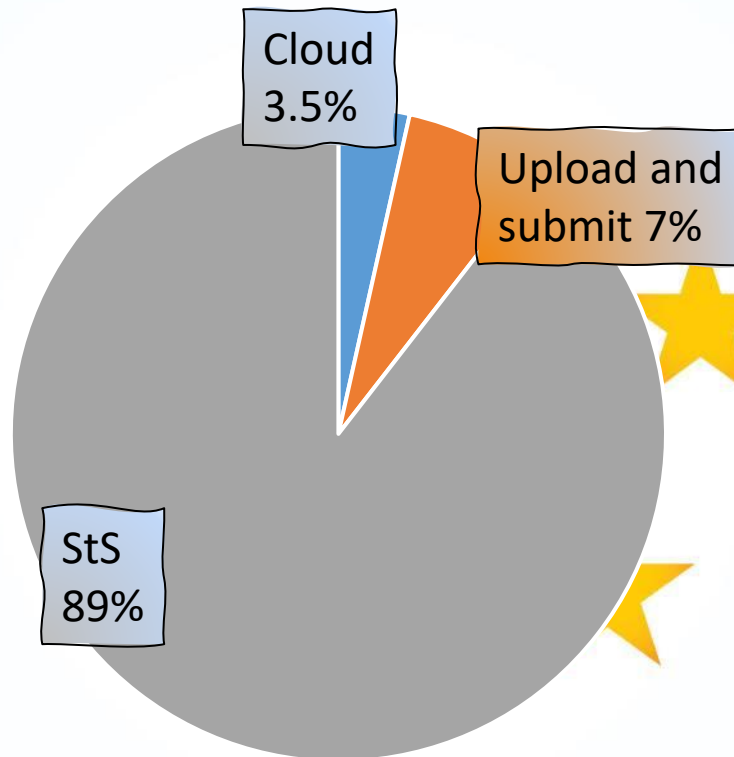


Without warnings	121 385	98 952	61 528
Total	399 072	216 567	124 223
Success rate	80%	92%	95%



Submission per submission channel

(Dec 20 to Feb 21)



Year 2020

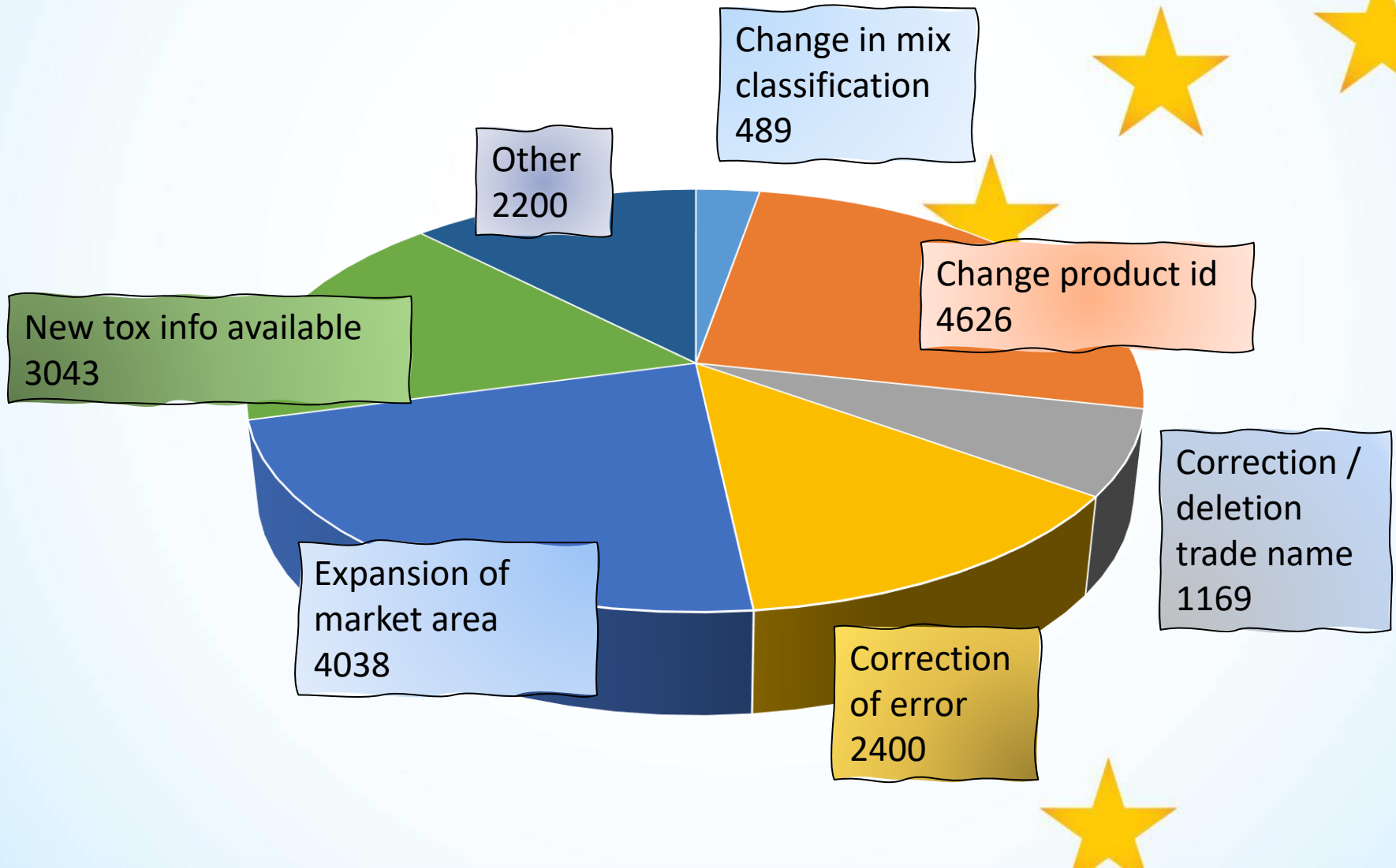
Cloud: 13%

U. and S.: 21%

StS: 66%

Submission update - Reasons

(Dec 20 to Feb 21)



Top 5 Validation rules triggered

(Dec 20 to Feb 21)

Rule	Description	Portal / IUCLID	Hits	
1	BR576	In case of updates, the dossier creation date should be greater than the previously submitted notifications creation date.	Portal	75 336
2	BR567	A new 'PCN number' should be provided for initial notifications and significant change of composition.	Portal	75 252
3	BR564	The exactly same dossier cannot be submitted again.	Portal	75 009
4	BR568	An existing 'PCN number' should be used in updates notified by the same legal entity.	Portal	6 300
5	BR536	Type of packaging must be indicated	IUCLID	2 425



Top 5 Quality rules triggered

(Dec 20 to Feb 21)

Rule	Description	Portal / IUCLID	Hits	
1	QLT502	If the concentration is above 1 %, the recommended number of decimals is one.	IUCLID	137 471
2	QLT574	Changes in notification to be reported as "update" (same UFI, same LE, no conc. changes).	Portal	125 435
3	QLT505	If the concentration value is 0.1-1 %, the recommended number of decimals is two.	IUCLID	123 866
4	QLT592	Repeating same reference substance not allowed unless classification is different	IUCLID	59 478
5	QLT621	Justification required in case pH is not available	IUCLID	54 548



Annex VIII amendment and validation rules



**Follow up from
11th Webex**



GCI

1) WG agreed to deactivate BR604 and BR617 (**discussion closed**).

ECHA suggests that the BR602 and BR603 (checking 25% for “Colouring agents” and 5% for “Perfumes” limits for GCIs) should check the **upper value** in case a range is provided. The rule should **fail** if the sum (in case of more than one same GCI) is >25% or >5%.

Reasoning: if a range is provided, the component could be potentially and realistically present at the maximum % indicated. The existing rules do check the upper values at the moment.

AP WG requested to consider this and propose different check if needed. No comments received → **agreed** as in this slide.

2) WG agreed on an additional QLT to **warn** that different GCIs with same classification should be merged (in case more than one component with same GCI and same classification is included). (**Discussion closed**)

Agreed as in the slide,
ECHA will proceed

pH

Origin	Description	Trigger	Remarks
HU AB QLT680	New rule. Request for a warning message when pH is extreme but not reflected in the classification (e.g. not classified for skin and eye effects)	Warning	Need to define what extreme is and which hazard statements should be considered

ECHA proposal:

1. pH is below 2 or above 11.5, and
2. the classes Skin Corr. Cat.1A/B/C and Serious eye Damage Cat.1 are **not** indicated

→ a WARNING message is triggered

Also: in case the mixture is classified as Acute Tox (inhalation) a warning message is triggered if EUH071 is not included (*based on CLP, Annex I, 3.1.2.3.3 and 3.1.4.1*).

WG (industry) feedback:

- a) Abstain from increasing requirements. No need to move from technical check to content-check
- b) There is no 1:1 correlation ph / classification
- c) Test data overrule this criteria
- d) Many "false negatives" (i.e. misleading warnings)

pH

The WG did not agree on this rule, therefore it was decided to keep it on hold until further data is gathered. To be rediscussed later.

DE and NL supported this new rule and explained the importance for AB/PC. The rule would allow better targeting of notifications to be followed up. Experts would know whether the information is correct, with no need to contact the submitter.

Industry is strongly against this rule, claiming that the false positive would be potentially the majority and an additional warning is not welcome. Submitters may be led to reclassify (incorrectly) the mixture.

It was concluded that more data would be needed on the extend of the issue and on ratio false/true positive.

AP: Industry and ABs are asked to verify whether information can be gathered and shared.

Type of information

Origin	Description	Trigger	Remarks
BE AB	New rule. "Other name type" to be provided when field is filled in	Warning or failure?	Issue potentially relevant for different information elements (not only substance name)

Version 1 of the issue:

'Other identifiers' table > '**Name type**' > 'other:'

'Other identifiers' table > '**Country**' > 'other:'

'Contact person' > '**Contact type**' > 'other:'

'Contact person' > '**Country**' > 'other:'

'Legal entity owner' > '**Legal entity type**' > 'other:'

'Mixture composition' > 'Components' > '**Function**' > 'other:'

'C&L' > 'Specific target organ toxicity – single and repeated' >

'**System**' > 'other:'

'Packaging' > 'Packaging related attachments' > '**Type of**

attachment' > 'other:'

Type of information

Origin	Description	Trigger	Remarks
BE AB	New rule. "Other name type" to be provided when field is filled in	Warning or failure?	Issue potentially relevant for different information elements (not only substance name)

Version 2 of the issue:

'Other identifiers' table > '**Name type**' & '**Name**'

'Contact person' > '**Contact type**' & 'Last name' & 'Organisation' & '**Phone/e-mail**' & '**Country**'

'Packaging' > 'Packaging related attachments' > '**Type of attachment**' & '**Attached document**'

'C&L' > 'Reproductive toxicity' > '**Specific effect**' & '**Route of exposure**' ??

'C&L' > 'Specific target organ toxicity – single and repeated' > '**System**' & '**Affected organs**' & '**Route of exposure**'

'Safety data sheets of mixture product' > if 'Country' or 'Language' is indicated then '**Safety datasheet**' would be expected

Type of information

Agreed to proceed with development and implementation of a set of rules as illustrated by ECHA in the slides.

To be expected in Summer.

It was clarified that the aim is to support industry by highlighting incomplete information before submission, therefore no additional warning is expected in the final dossier.

It was agreed that information provided voluntarily, should be complete and useful.

Languages

(Rule agreed, info only)

Origin	Description	Trigger	Remarks
BE AB BR650- BR679	New rule. Check correspondence between languages and market area(s) selected.	Failure	Need for a definitive and exhaustive list

Follow up:

ECHA is preparing a list of rules checking each market area against the information on the "Overview Table" published on the ECHA PCs website.

Rules and their id number will be included in the VRs draft document.

The allowed language (if one) or one of the allowed languages (if more than one) have to be selected per each market area.

N.B.: changes to additional allowed languages will be reflected according to the IUCLID update plan.

For info only, ECHA will proceed with designing and implementing rules on the basis of the Overview Table. Possibly in April release.

Clarified that the rules check that as minimum the required language(s) is provided; additional possible.

IC Vs ICG classification

Rule	Description	Purpose	Remarks
BR 685 (suggested by DE)	If ICs' classification is provided in addition to ICG classification, the classification of all ICs and ICG have to be all the same.	If ICs' classification is not the same (i.e. differences at subcat level), classification at ICG level should not be provided (i.e. there is not one common classification)	Same = hazard class, hazard category/subcategory, H statements. Other fields to be checked?

AP WG: confirm which fields the rule should check to verify sameness of classification:

- "Hazard category & statement"
- "Hazard category" and "Hazard statement" (STOT)

(ECHA suggests not to include free text fields in the check)

No feedback received

Agreed as in the slide,
ECHA will proceed

**Remaining rules
from 11th Webex**



EuPCS

Origin	Description	Trigger	Remarks
BE AB	New rule. Check the presence of EuPCS in voluntary submissions .	Warning	Voluntary submissions apply to - not-hazardous mixtures - Hazardous mixtures notified by non-duty holders

Considerations:

- Needed?
- Priority?

Agreed as in the slide (as warning), ECHA will proceed.
Tentatively deployed in April.

DA and BE clarified that, even if it is about voluntary submissions, the information is particularly relevant for statistical activities. Data is requested by industry as well.

In general voluntary submissions are welcome by ABs/PCs and should be as complete as possible in order to be useful.

Update

Origin	Description	Trigger	Remarks
BE AB	Existing rule QLT513. Warning/notice that new MS has been added in update to be extended to "new notif after a sign change of composition"	Warning	For the new MS it is an initial submission

Considerations:

- What do we expect the submitter to do?
- Modify the message to suggest informing the AB?
- Needed? Full information available in "new notif after a sign change of composition".

Agreed as in the slide (as warning), ECHA will proceed.
Portal rule.

DA and BE clarified the importance of this rule, which makes PCs/ABs aware that there is no initial submission behind. More useful to authorities than industry. Therefore, the message should be constructed in a way that it is clear no actions are expected from the submitter.

Combinations ICG/SF/GCI

Possibility to “flag” components

Components of components



Background (i)

The new workability solutions were addressed by means of technical solutions allowing the creation of new “kinds of component” in addition to the existing ones

Existing: substances, MiMs, GCIs

New: SF components, ICGs, Interchangeable components

These new components require specific sets of rules to reflect the relevant legal provisions.

Temporary short-term solution: *simply* waive existing “standard” rules for components with “*SF component*” and “*ICG*” flags.

Objective: Allow submissions making use of the workability solutions (i.e. waving certain standard provisions)

On hold: (possible) implementation of specific rules based on the new legal provisions on the workability solutions.

Current situation: High flexibility of the system in terms of information to be provided once a component is flagged.

Need to clarify first the limitations of the possible flags and combinations

Background (ii)

Components can be initially included as MiM (mixture record) or substance (substance record)

A **MiM** can be flagged...

...as *SF component* (i.e. this MiM is part of a SF or this MiM is the itself a whole SF);

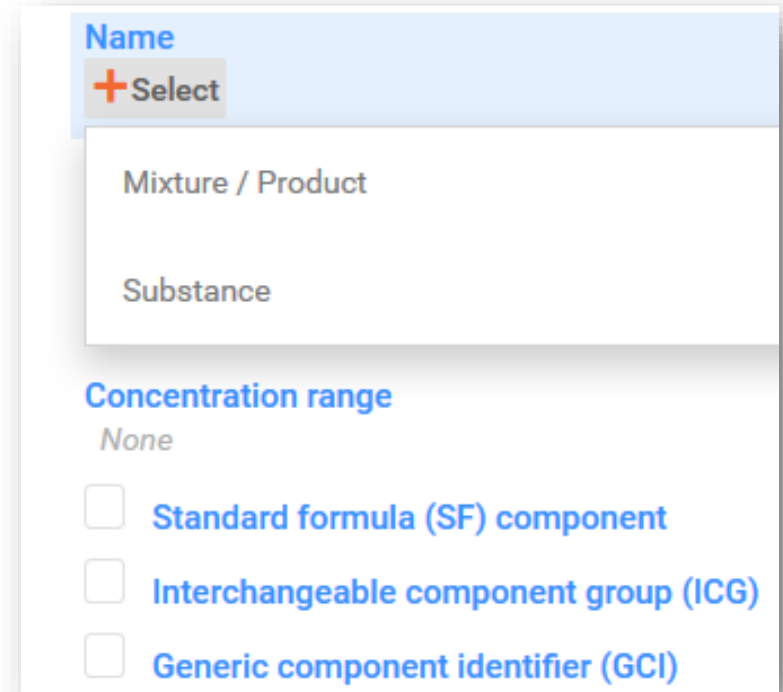
...as *ICG*;

...as *GCI*.

A **substance** can be flagged...

...as a *GCI*;

...as a *SF component* (which means this substance is part of a SF).



The screenshot shows a form with a 'Name' section containing a '+ Select' button and two options: 'Mixture / Product' and 'Substance'. Below this is a 'Concentration range' section with a 'None' label and three checkboxes: 'Standard formula (SF) component', 'Interchangeable component group (ICG)', and 'Generic component identifier (GCI)'. All checkboxes are currently unchecked.

This "first level" component records can be used to encode further information:

- Components of a MiM
- Interchangeable components in a ICG
- Components of a Standard Formula whi



This is a duplicate of the form shown in the previous block, but it is completely obscured by a large, thick red 'X' drawn across the center of the image.

Background (iii)

Currently few rules are in place checking flagged components. Submissions with missing (required) information can go through.

Allowed flags and combinations are to be clarified before being able to define new rules to improve/ensure good quality.

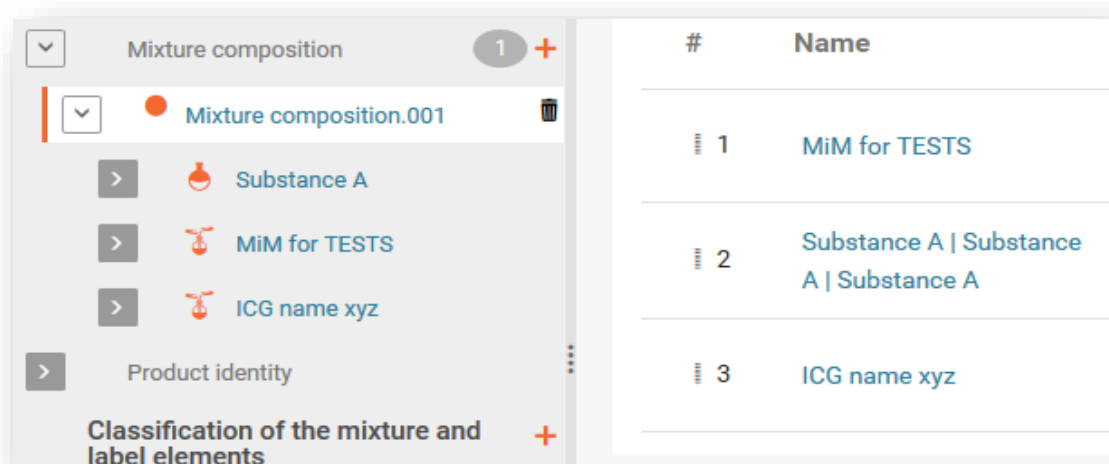
N.B.1: Use of the Standard Formulas and ICGs is potentially highly flexible based on the legal text, e.g.:

- Components conforming with different SFs in the same submission;
 - Components conforming with SF identified according to standard rules.
 - Components conforming with SF and not conforming, in the same submission.
- No specific rules going into the details of each SFs can be designed.

N.B.2: Impact on the format has to be limited due to resources and limited flexibility of the 2021 development plan (e.g. second level flags ruled out)

N.B.2: Certain rules may be needed because of StS users even if may not be needed in the Cloud.

A) Main mixture level



A.1) Substance component

Flag	Allowed	Proposed check	Rule Vs format*	Remarks/reasons
ICG	NO		Format and rule	A substance record cannot be used to encode ICs information.
GCI	YES	Cannot be flagged also as <i>SF component</i>	Format and rule	Concentration to be provided as in Table 2. Substance cannot benefit from GCI provisions and be part of a SF.
SF comp	YES	Cannot be flagged also as <i>GCI</i>	Format and rule	Name and concentration to be provided as in SF (or SDS).

* Rule needed because of StS submitters

A.1) Substance component – New rules

Rule	Description	Purpose	Remarks
BR639	Component record allows one flag (SF/ICG/GCI) only	Avoid multiple flags when dossier is not prepared in the Cloud	Rule to apply to mixture records as well.

Agreed as in the slide, ECHA will proceed.

Possibly in April.

A.2 Mixture component (MiM) - 1

Flag	Allowed	Proposed rules	Rule Vs Format	Remarks/reasons
ICG	YES	Cannot be flagged also as <i>SF component</i>	Format limitation and rule	An ICG cannot be flagged as component of a SF nor as SF itself
		Cannot be flagged also as <i>GCI</i>	Format limitation and rule	An ICG cannot be treated as a GCI and follow the same rules, even if can, in principles, be named the same as a GCI

ECHA proposal is **not** to allow the possibility to flag a component as **both** *ICG* and *SF component*.

In case it is a *SF component*, that one flag should be sufficient.

Do not see the business need for double flag.

Double flag would complicate the validation logic making practically infeasible the introduction of a rule. Furthermore would require a modification of the working context logic.

Cases still supported (if needed):

- Inclusion of different MiMs conforming with different SFs in a ICG (in case ICG criteria apply);
- Same mixture conforming with a SF, included as MiM and purchased from different supplier providing more detailed information can be grouped in a ICG

A.2 Mixture component (MiM) - 2

Flag	Allowed	Proposed rules	Rule Vs Format	Remarks/reasons
GCI	YES	Cannot be flagged also as <i>SF component</i>	Format limitation and rule	A GCI MiM (for which GCI special provisions apply) does not need to be reported as part of a SF and cannot be a SF itself
		Cannot be flagged also as <i>ICG</i>	Format limitation and rule	A GCI MiM (for which GCI special provisions apply) cannot be used to encode interchangeable components. A GCI component already potentially covers multiple components without the need to specify them individually.

Note: the fact that you cannot flag a SF component as *GCI* does not mean it cannot be named with a *GCI*

A.2 Mixture component (MiM) - 2

Flag	Allowed	Proposed rules	Rule Vs Format	Remarks/reasons
SF comp	YES	Cannot be flagged also as <i>GCI</i>	Format limitation and rule	A MiM which is a SF component (or a SF itself) cannot be also a GCI (which has specific provisions)
		Cannot be flagged also as <i>ICG</i>	Format limitation and rule	A MiM which is a SF component (or a SF itself) cannot be also a ICG and follow the special ICG provisions

Note: Technically possible to group *SF components* in an ICG, or include an ICG in a SF (*relevant?*), without the need for further flags.

A.1) Mixture component – New rules

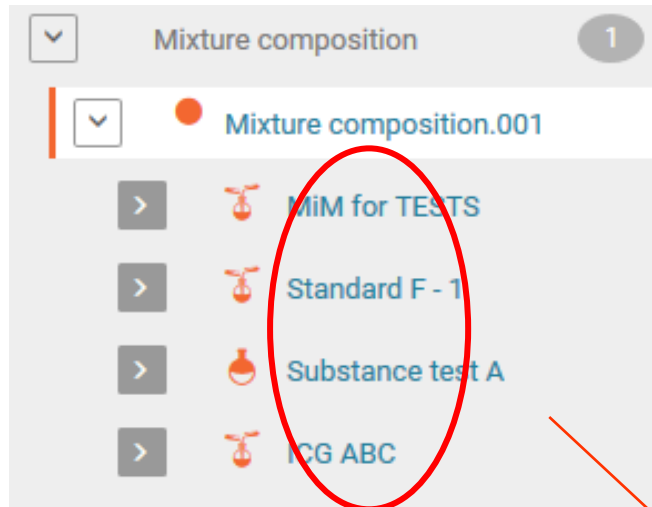
Rule	Description	Purpose	Remarks
BR639	Component record allows one flag only	Avoid multiple flags when dossier is not prepared in the Cloud	Rule to apply to substance record as well.
BR683	MiM flagged as <i>ICG</i> has to contain a composition record with at least one component	Avoid empty ICG records	At the moment standard rules have been waived for ICGs and SF components and no specific rules are in place.
BR681	MiM flagged as <i>SF Component</i> has to contain a composition record with at least one component.	Avoid empty MiM records	
BR682	MiMs cannot be notified as conforming to a fuel from table 3 (based on SF name, if provided, and SF flag).	Fuels from table 3 should not be notified as MiMs but main mixture only.	

Note: Not possible to check correspondence between SF name and composition from Part D due to flexibility of legal provisions.

Not possible to provide SF name to substance record

Agreed as in the slide, ECHA will proceed.

B) Components level – “Second” level



Standard formula (SF)...	Interchangeable com...	Generic component id...	A
<input type="checkbox"/> Standard formula (SF) component	<input type="checkbox"/> Interchangeable component group (ICG)	<input type="checkbox"/> Generic component identifier (GCI)	
<input checked="" type="checkbox"/> Standard formula (SF) component	<input type="checkbox"/> Interchangeable component group (ICG)	<input type="checkbox"/> Generic component identifier (GCI)	
<input type="checkbox"/> Standard formula (SF) component	<input type="checkbox"/> Interchangeable component group (ICG)	<input type="checkbox"/> Generic component identifier (GCI)	
<input type="checkbox"/> Standard formula (SF) component	<input checked="" type="checkbox"/> Interchangeable component group (ICG)	<input type="checkbox"/> Generic component identifier (GCI)	

Main mixture components

- > MiM's components
- > SF components
- >...
- > Interchangeable components

MiM's component – Case 1: MiM not flagged

Type of encoded information	Allowed	Proposed rules	Remarks
ICG	NO	No rule	At the moment MiMs in MiMs is not allowed. Change considered not needed. See below.
GCI	YES	No rule	MiM's components can be named with a GCI (no need for flag). No checks on MiM's components

Business case:

If the supplier of the **same** MiM:

- has himself several alternative suppliers supplying him with interchangeable substances, and
- gives the formulator of the final mixture the full composition of his MiM and indicates that the two substances are interchangeable with each other.

Solution: inclusion of an ICG at main composition level covering the two variants of the same MiM. No need for ICG in MiM.

MiM's component – Case 2: MiM flagged as ICG

Type of encoded information	Allowed	Proposed rules	Remarks
ICG	NO	No rules - MiM's components cannot be flagged as <i>ICG</i>	An ICG cannot contain others ICGs*
SF	Potentially YES	No rules - MiM's components cannot be flagged as <i>SF components</i>	If MiMs conforming with SFs are to be grouped (because used in the final formulation interchangeably), there is no need for specific SF flag. The concentration is to be provided for the ICG only.
GCI	NO	No rules - MiM's components cannot be flagged as GCI	An ICG cannot contain components identified with a GCI*

* Legal basis Annex VIII, B.3.5.1

MiM's component – Case 3: MiM flagged as SF component

(Applies to both cases: MiM is the full SF and MiM is a SF component)

Type of encoded information	Allowed	Proposed rules	Remarks
ICG	Potentially YES	No rules - MiM's components cannot be flagged as <i>ICG</i>	Not all components [mentioned in the SF] need to be necessarily notified as specified in the SF. <i>Real cases and relevance to be verified</i> , but no flag needed.
SF	NO	No rules - MiM's components cannot be flagged as <i>SF components</i>	
GCI	Potentially YES	No rules - MiM's components cannot be flagged as GCI	Component named with a GCI could be included in a SF with no need for flags.

MiM's component – Case 4: MiM flagged as GCI

(Both substances and MiMs can be identified with a GCI)

Type	Allowed	Proposed rules	Remarks
ICG	NO	No rules - MiM's components cannot be flagged as <i>ICG</i>	Seems irrelevant
SF	NO	No rules - MiM's components cannot be flagged as <i>SF components</i>	Seems irrelevant
GCI	NO	No rules - MiM's components cannot be flagged as GCI	Seems irrelevant

MiM's components ("second level") - Conclusions

- 1) No need for rules - Components and concentrations within a MiM are not checked. But record cannot be empty.
- 2) No need for flags.
- 3) Not possible to design specific rules checking SFs composition due to the flexible application.

Agreed as in the slide. No actions for the moment.

ECHA to analyse the possibility to add the field for the SF name also for substances. This would allow the creation of more specific rules. To be rediscussed later.

**Feedback
Opinions
Experiences**

**from WG
users**



Reminder

- We aim to add the rules regarding **'Language'** requirements based on 'Market placement country' in April

	Rule no	Market placement Country	Languages
1	BR650	Austria	German
2	BR651	Belgium	French OR Dutch OR German OR English
3	BR652	Bulgaria	Bulgarian
4	BR653	Croatia	Croatian OR English
5	BR654	Cyprus	Greek
6	BR655	Czech Republic	Czech
7	BR656	Denmark	Danish OR English
8	BR657	Estonia	Estonian OR English
9	BR658	Finland	Finnish AND Swedish
10	BR659	France	French
11	BR660	Germany	German OR English
12	BR661	Greece	Greek
13	BR662	Hungary	Hungarian
14	BR663	Iceland	Icelandic OR English
15	BR664	Ireland	English
16	BR665	Italy	Italian OR English
17	BR666	Latvia	Latvian OR English
18	BR667	Liechtenstein	German
19	BR668	Lithuania	Lithuanian OR English
20	BR669	Luxembourg	French OR German OR English
21	BR670	Malta	Maltese OR English
22	BR671	Netherlands	Dutch OR English
23	BR672	Norway	Norwegian OR Danish OR Swedish OR English
24	BR673	Poland	Polish
25	BR674	Portugal	Portuguese
26	BR675	Romania	Romanian
27	BR676	Slovakia	Slovak
28	BR677	Slovenia	Slovenian
29	BR678	Spain	Spanish OR English
30	BR679	Sweden	Swedish OR English

Reminder

QLT621 to **BR621**

“If ‘pH not available’ was indicated,
then justification must be provided”

→ rule to be changed back from
warning to **failure** in April

AoB

- WG suggested the inclusion of a specific update reason for update of ICG. **ECHA to consider.**
- DE suggested a rule to check the product name, which should be of a reasonable length. In some cases it is only one character. Markus suggested 255 characters max. **Feedback needed from WG:**
 - What minimum and maximum?**
 - Warning only?**
 - What recommendation should be included in the message?**

Next steps

- ECHA start working on new rules/changes agreed today.
- ECHA to start streamlining WGs (ABs/PCs, IT, VRs, EuPCS) management and involvement – Transition to PCN maintenance mode
- VRs work to be focused on issues in scope: GS and dossier withdrawal + fixing issues on exiting rules
- Next WebEx tbd

Thank you!

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