Welcome

Webinar: Completeness check of REACH registration dossiers: what changes in 2023 and how you can prepare

8 February 2023

Henri Honkalammi
European Chemicals Agency

What you can expect today

- → Overview of the completeness check process
- → Learn about amendments to completeness check in 2023
- → Get advice on how changes impact you and how you can prepare
- → Get answers to your questions

Live Q&A

- → Join Q&A at: slido.com
  Event code: # cc2023
- → Send questions from
  11:00 to 13:00 (EET, GMT +2)
- → Only questions within scope
- → Question not answered by the end of the webinar? Send it via our contact form:
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Material available

→ Video recording, presentations and Q&A:
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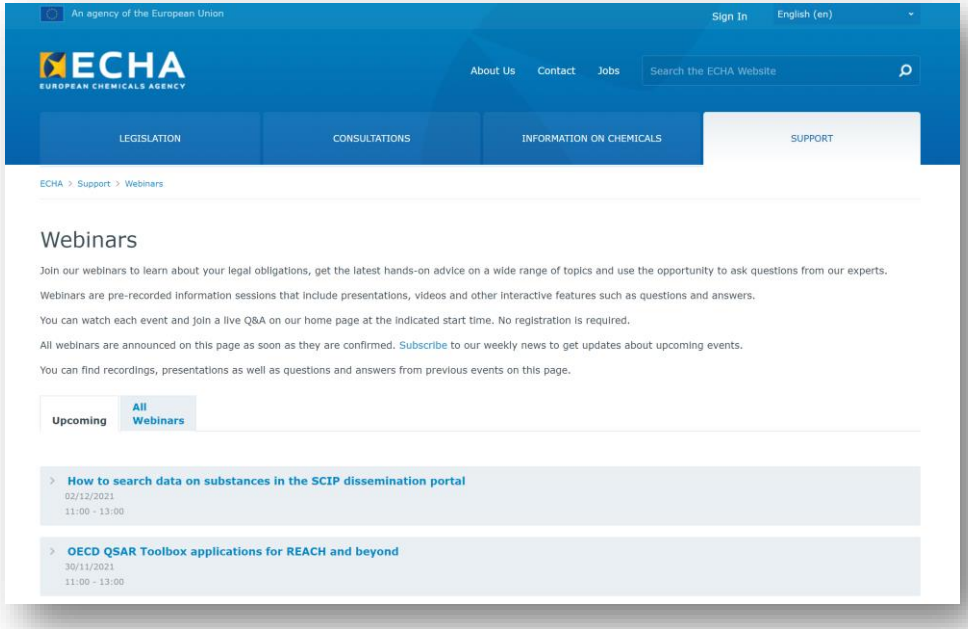

Programme

Time	Topic	Speaker
11:00	Introduction	Henri Honkalammi, ECHA
11.05	Completeness check process	Veneta Nieminen, ECHA
11.15	Substance identification	Jordan Esson, ECHA
11.25	Annex VII-XI information requirements	Cristian Caramida, ECHA
11.40	Use description	Mila Marinovic, ECHA
11.50	Conclusions	Henri Honkalammi, ECHA
11:00-13:00	Webinar open for questions	

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Completeness check process

Webinar: Completeness check of REACH registration dossiers: what changes in 2023 and how you can prepare

8 February 2023

Veneta Nieminen
European Chemicals Agency

Overview

→ Completeness check process:

- Automated completeness check
- Manual completeness check
- Completeness check outcomes

→ Amendments to completeness check in 2023

Completeness check process

Registration process

Completeness check

- → Implements REACH Article 20(2) to ensure that required information has been provided in the dossier
- → Applies to all registration dossiers submitted to ECHA (both initial submissions and updates)
- → Contains automated and manual checks
- → Must be carried out by ECHA in 21 days

Automated completeness check

- → Automated completeness check rules are displayed by IUCLID validation assistant
- → Validate your dossier and correct all failures before submitting to ECHA
- → Only latest version of validation assistant can be fully relied on (updating IUCLID is important)
- → Check tutorial: "How to run the validation assistant"
- → List of automated completeness check rules available in Annex 2 of the manual 'How to prepare registration and PPORD dossiers'

Manual completeness check

→ Checks performed by ECHA include additional manual verifications
  - E.g., justifications to deviate from standard information requirements are checked manually

→ Manual verifications cannot be replicated with validation assistant

→ More information on manual verifications here

Completeness check outcomes

1st completeness check

2nd completeness check

Rejection

Completeness check outcomes

1st completeness check

- Pass: Submission accepted
- Fail: List of missing/incomplete information sent via REACH-IT. Updated dossier required within 4 months

2nd completeness check

Rejection

Completeness check outcomes

1st completeness check

- Pass: Submission accepted
- Fail: List of missing/incomplete information sent via REACH-IT. Updated dossier required within 4 months

2nd completeness check

- Pass: Submission accepted
- Fail: Rejection process starts

Rejection

Completeness check outcomes

1st completeness check

- Pass: Submission accepted
- Fail: List of missing/incomplete information sent via REACH-IT. Updated dossier required within 4 months

2nd completeness check

- Pass: Submission accepted
- Fail: Rejection process starts

Rejection

- Initial submissions: registration number **not** granted
- Updates of existing registrations: Updated information not accepted into ECHA's database

Amendments to completeness check in 2023

Background

- → REACH Annexes revised
  - Action 1 in January 2022
  - Action 2 in October 2022
- → ECHA Board of Appeal decisions A-011-2018 and A-005-2021 on information requirements concerning aquatic toxicity and degradation
- → Shortcomings in use description identified by ECHA

Implementation

- → Amended and new completeness check rules implemented in **May 2023**
- → Most rules will be automated and visible in IUCLID validation assistant
- → Start preparing now

Thank you

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Substance identification

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8 February 2023

Jordan Esson
European Chemicals Agency

Overview

New rules for **boundary composition(s)** in section 1.2 to improve reported information:

→ State/form field

→ Consistency of compositional information

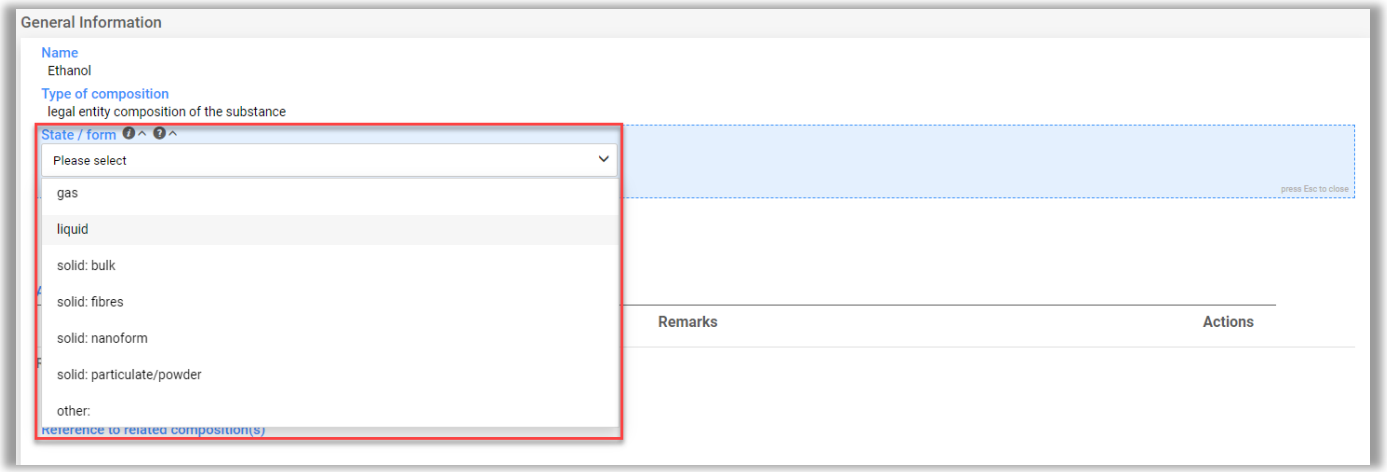
→ Molecular and structural information

→ Additives

Boundary composition

- → Mandatory in lead registration dossiers since 2016
- → Specifies boundaries of the substance agreed to be covered by jointly submitted data
- → Establishes inherent link between substance identity and Annex VII-XI data, classification and labelling and PBT assessment
- → Displayed on joint submission page in REACH-IT

Boundary composition: state/form



Boundary composition: Constituents

- → **Mono-constituent** substance expected to contain only one constituent
- → Reported constituent must match reference substance reported in section 1.1
- → Reporting of multi-constituent composition in a mono-constituent dossier must be justified under 'Justification for deviations'

Boundary composition: Constituents

→ **Multi-constituent** substance expected to contain more than one constituent

→ Reported constituents must not match reference substance reported in section 1.1

→ Reporting of mono-constituent composition in a multi-constituent dossier must be justified under 'Justification for deviations'

Guidance for identification and naming of substances under REACH and CLP

Boundary composition: Constituents

→ **UVCB** substance expected to contain more than one constituent

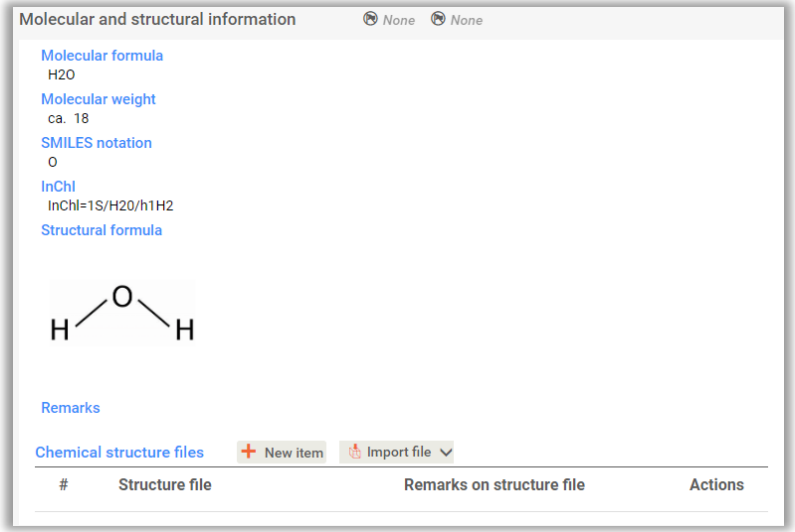
→ Reporting only one constituent (or group(s) of constituents) must be justified under 'Justification for deviations'

Guidance for identification and naming of substances under REACH and CLP

Constituents: Molecular and structural formula

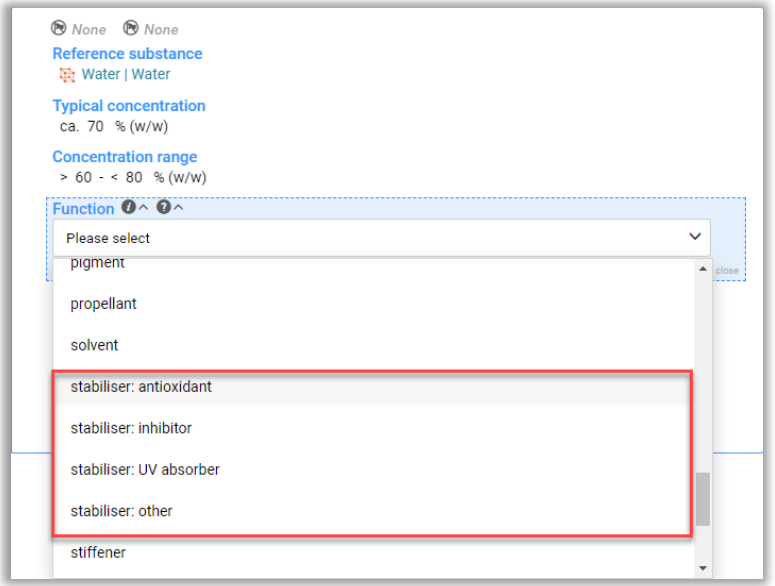
→ At least *molecular* and *structural formulas* and *molecular weight* required for constituents of mono- and multi-constituent substances

→ If *molecular formula* or *molecular weight* cannot be provided for a UVCB substance, explanation must be included in 'remarks' field



Boundary composition: Additives

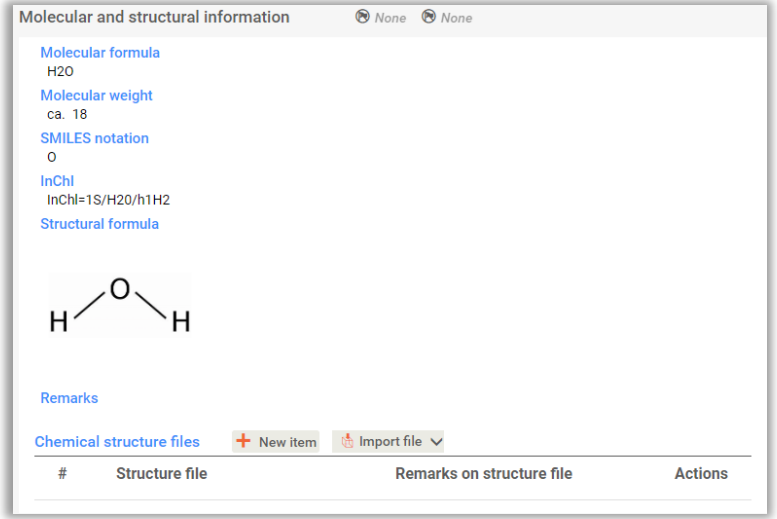
→ For each **additive**, **stabilising function** must be confirmed by selecting relevant value starting with 'stabiliser' in ‘function’ picklist



Additives: Molecular and structural formula

→ *Molecular* and *structural formulas* and *molecular weight* required for additives

→ If molecular or structural formulas or molecular weight cannot be provided, explanation must be included in 'remarks' field



Take home messages

→ Rules for boundary composition apply to lead registration dossiers

→ All required information can already be provided as IUCLID formats exist

→ Consult Guidance for identification and naming of substances for how to report compositional information

Thank you

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Annexes VII-XI information requirements

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Cristian Cărămidă
European Chemicals Agency

Overview

→ Updated IUCLID formats:

- Standard phrases to omit standard information requirements (justification for data waiving)
- Updated endpoint names

→ Mutagenicity

→ Annex XI 1.2 weight of evidence approach

→ Long-term aquatic toxicity and degradation

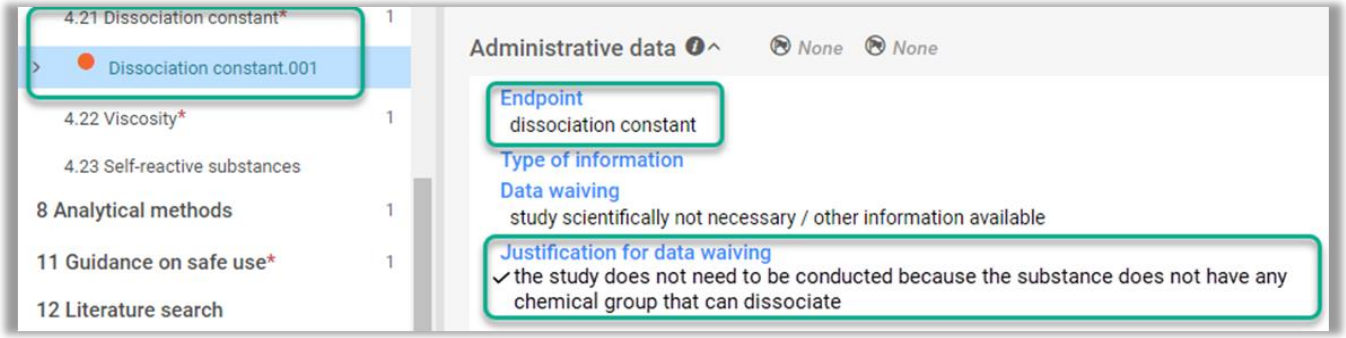
Standard phrases to justify data waiving

→ Standard phrases in ‘justification for data waiving’ field will be improved in line with revised column 2 of REACH Annexes VII–X

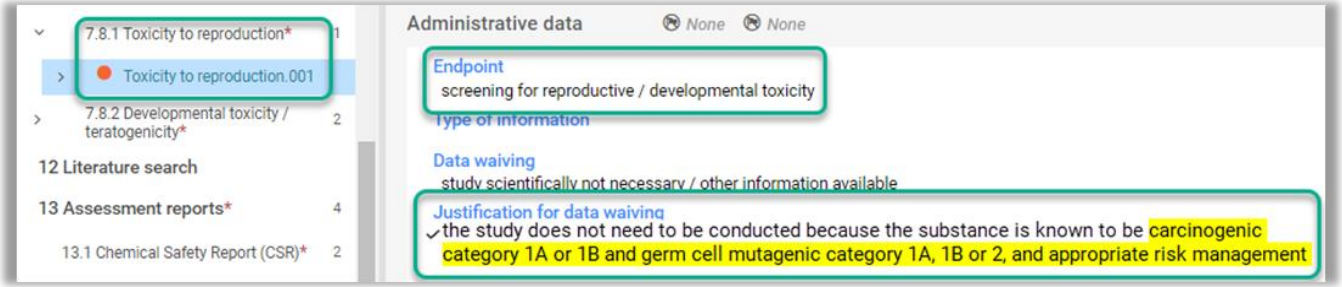
→ Use an applicable standard phrase if available

→ If ‘other’ is selected, provide arguments in related free text field (subject to manual verification at completeness check)

Examples of new and updated standard phrases

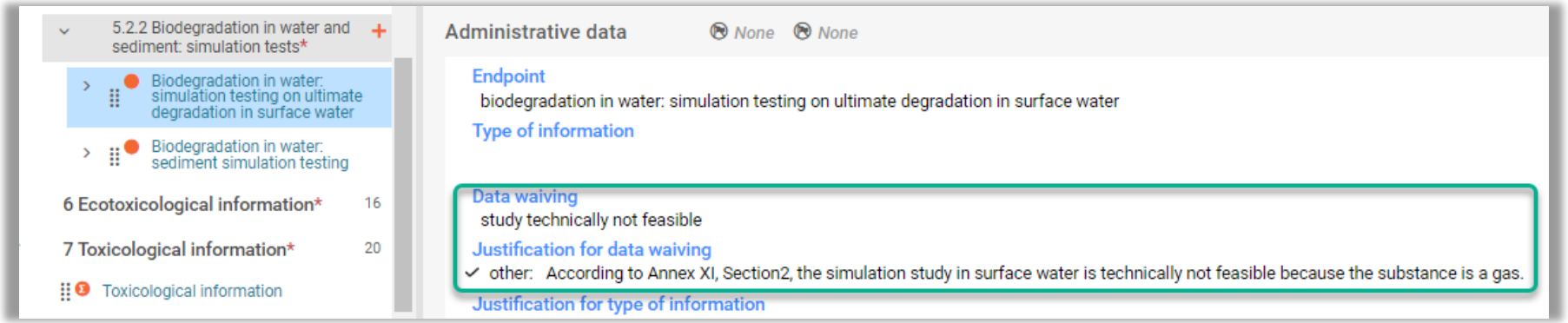


Example 1



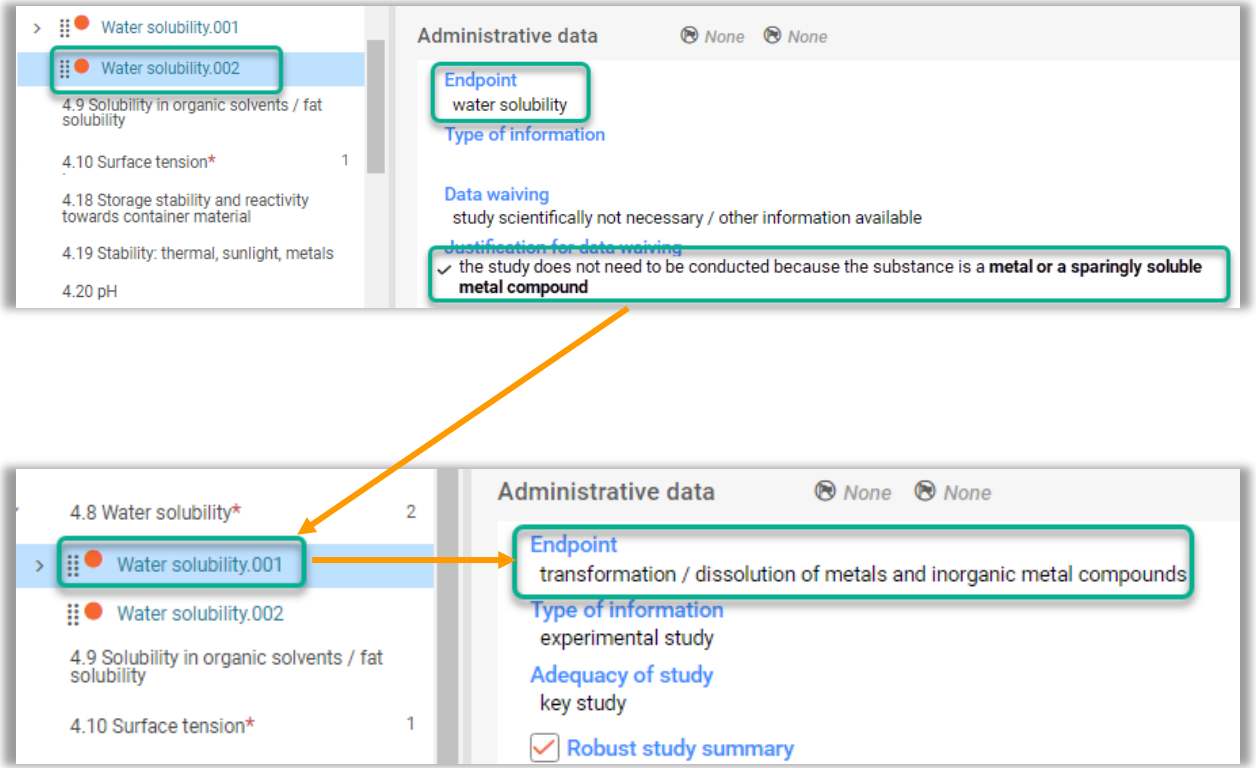
Example 2

Example of data waiving using other argument than a standard phrase



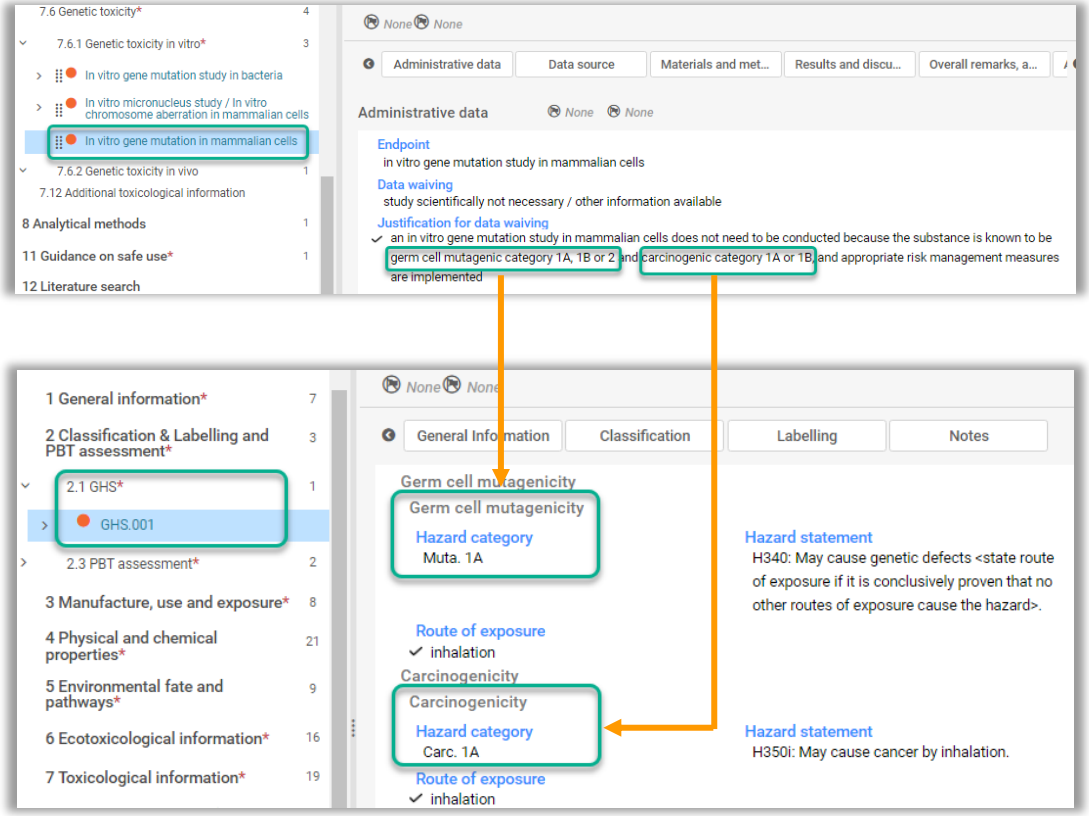
Example 3

Example of a new conditional standard phrase (1)



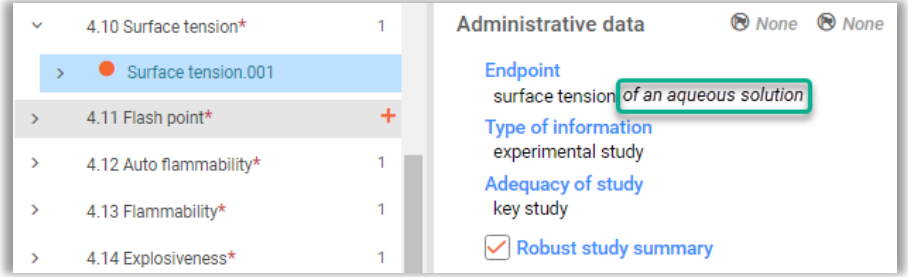
Example 4

Example of a new conditional standard phrase (2)

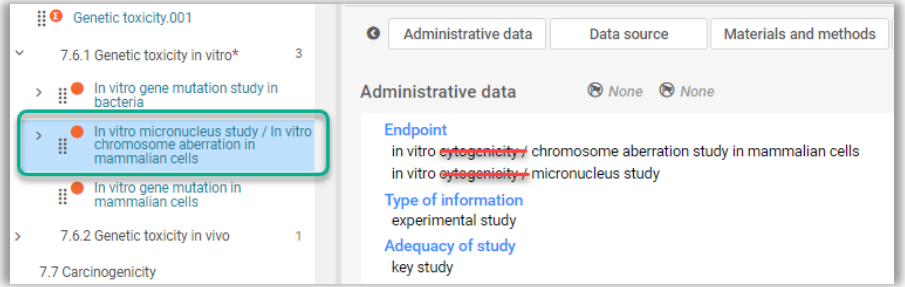


Example 5

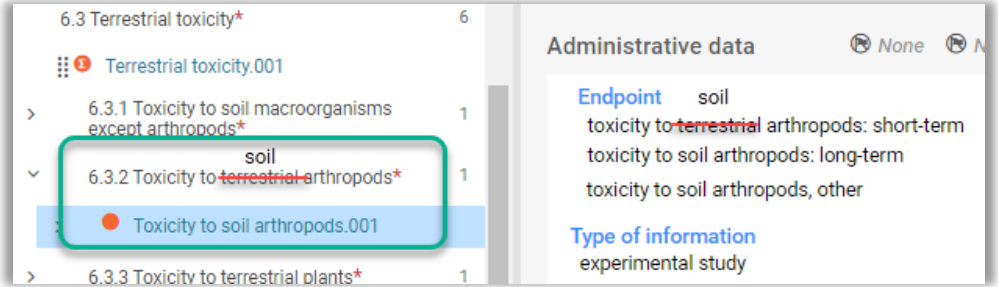
Examples of updated endpoint names



Example 6



Example 7

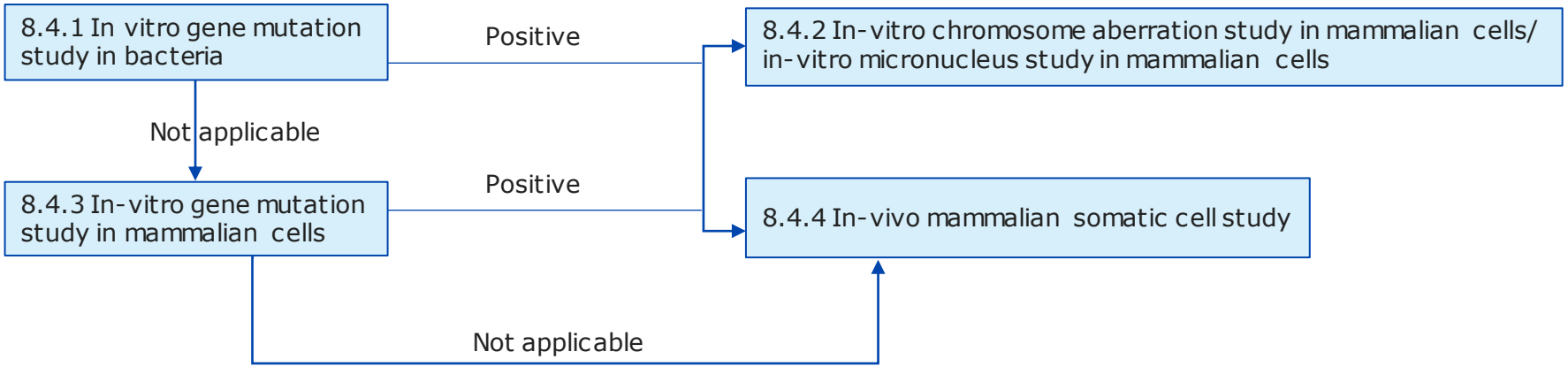


Example 8

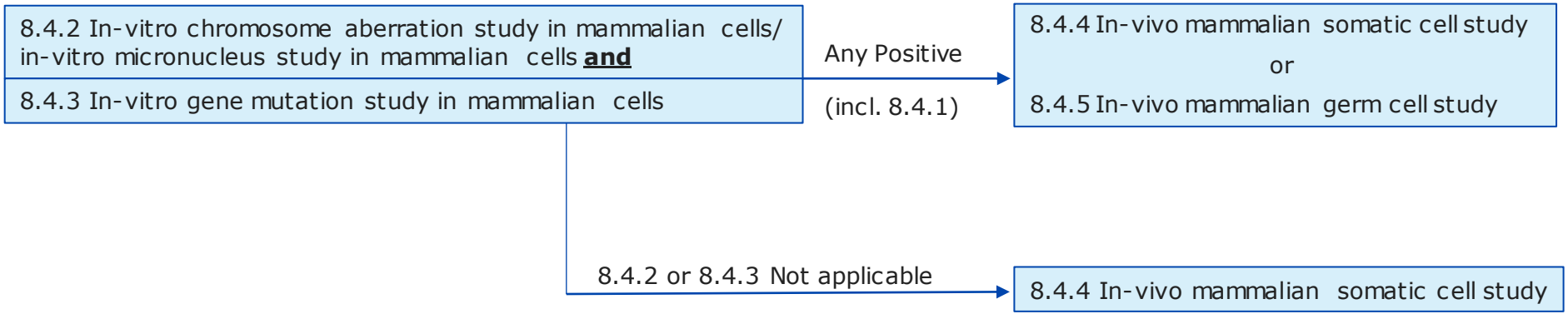
Mutagenicity – sequential information requirements in Annex VII and VIII

- → Rules on minimum required information in Annex VII aligned with clarified Annex VII section 8.4 provisions
- → In vitro gene mutation study in bacteria (REACH 8.4.1) always required at Annex VII
- → If 8.4.1 result is positive, or study not applicable for the substance, further testing (REACH 8.4.2, 8.4.3, 8.4.4) required
- → New completeness check rules will support you in addressing all required endpoints

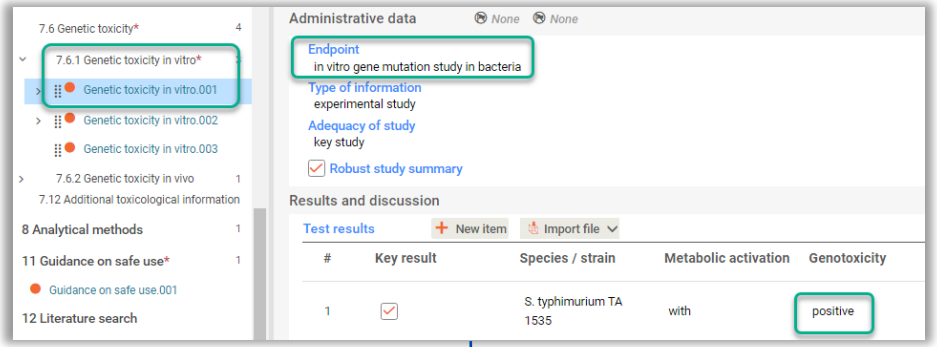
Mutagenicity – sequential information requirements at Annex VII

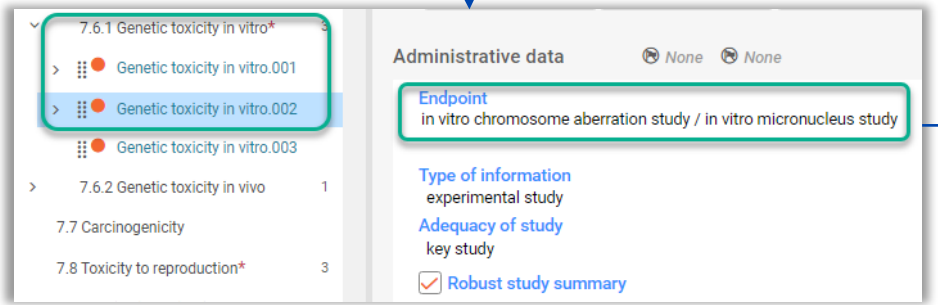


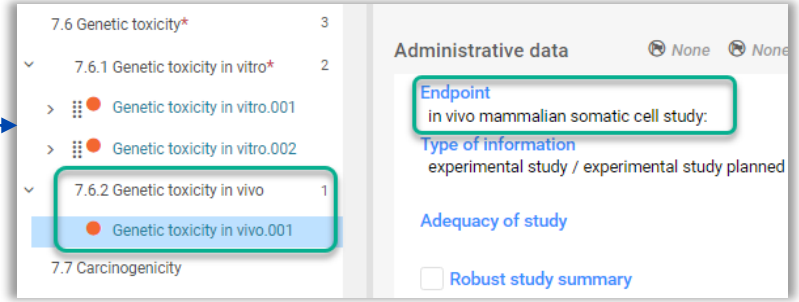
Mutagenicity – sequential information requirements at Annex VIII



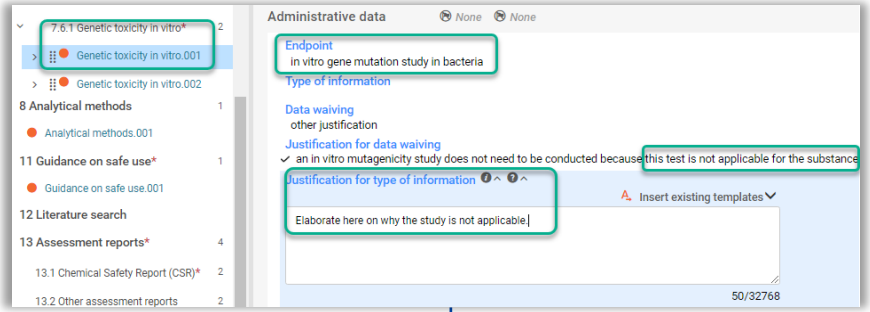
Mutagenicity - 8.4.1 positive (example 1)

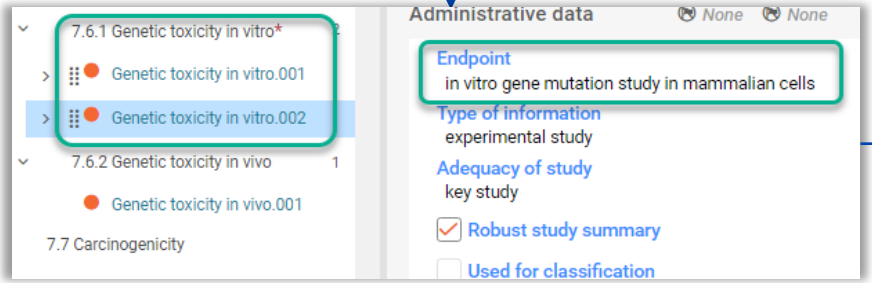




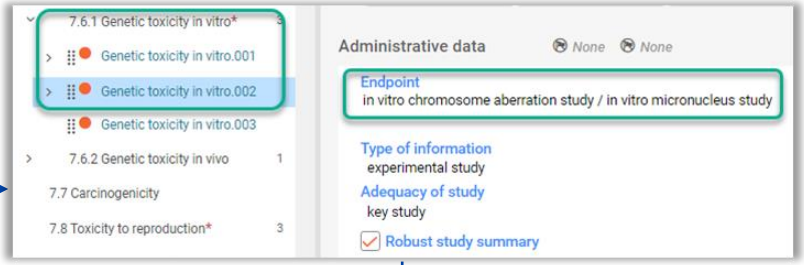


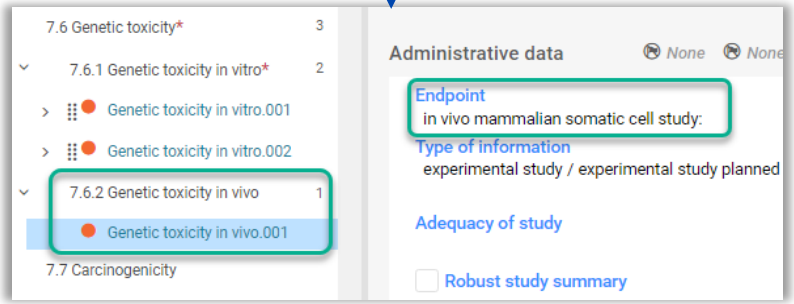
Mutagenicity - 8.4.1 n/a (example 2)



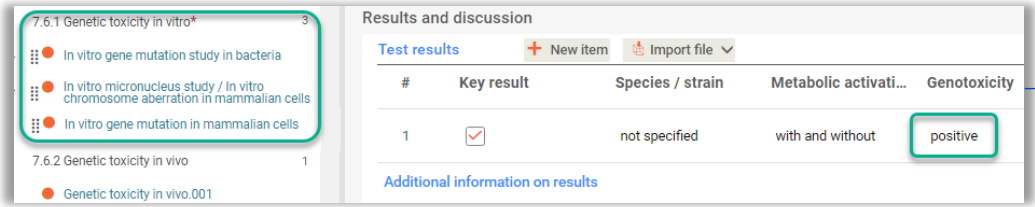


Positive

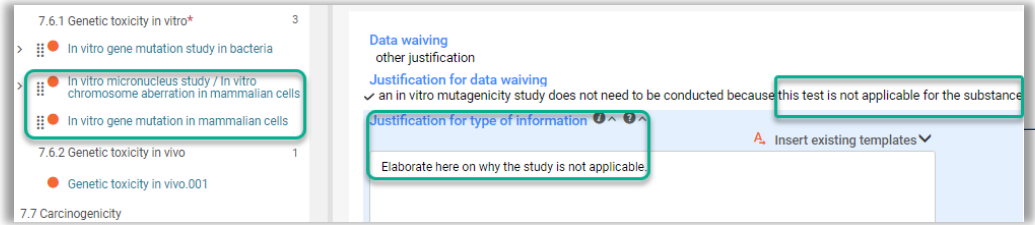


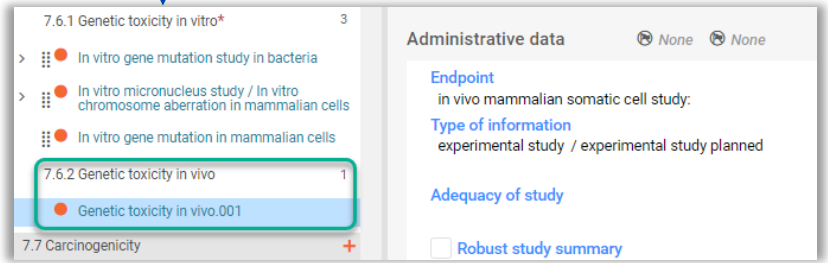


Mutagenicity - Annex VIII (example 3)



or





Mutagenicity - conclusions

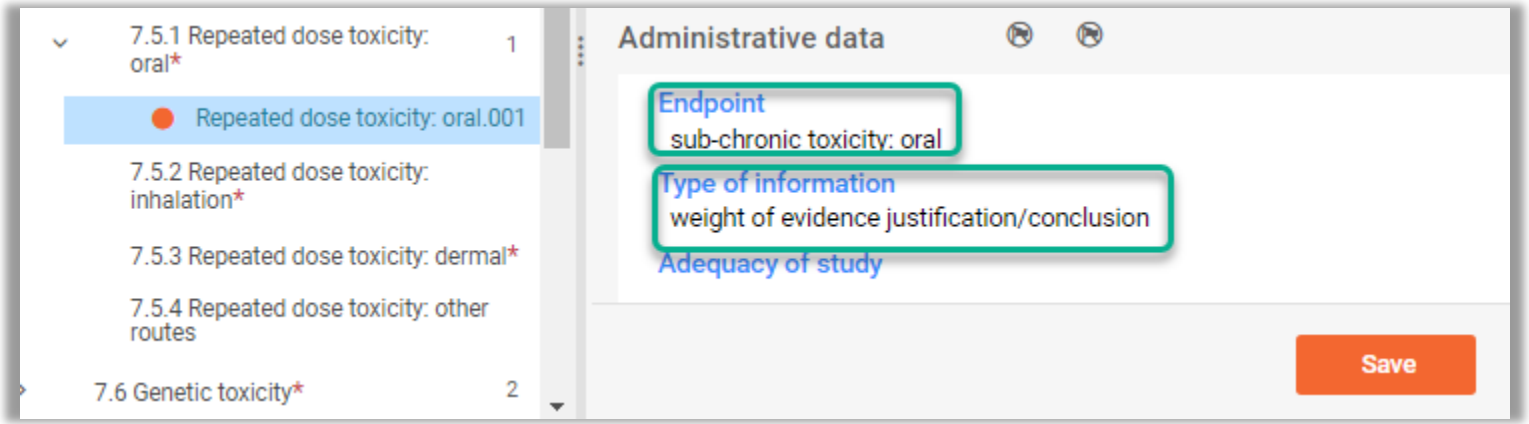
- → New completeness check rules will support you in reporting sequential information requirements
- → Sequential testing strategy available in ECHA guidance documents
- → You may already have all required information available; review how you have reported it in your dossier

Annex XI 1.2 - Weight of evidence

- → Weight of evidence approach must be justified
- → New structured way to provide justification
- → 'Weight of evidence justification/conclusion' document must be created
- → Required when new documents with 'adequacy of study' marked as 'weight of evidence' are added to registration dossier
- → All weight of evidence sources must be linked to justification document

Weight of evidence justification (1)

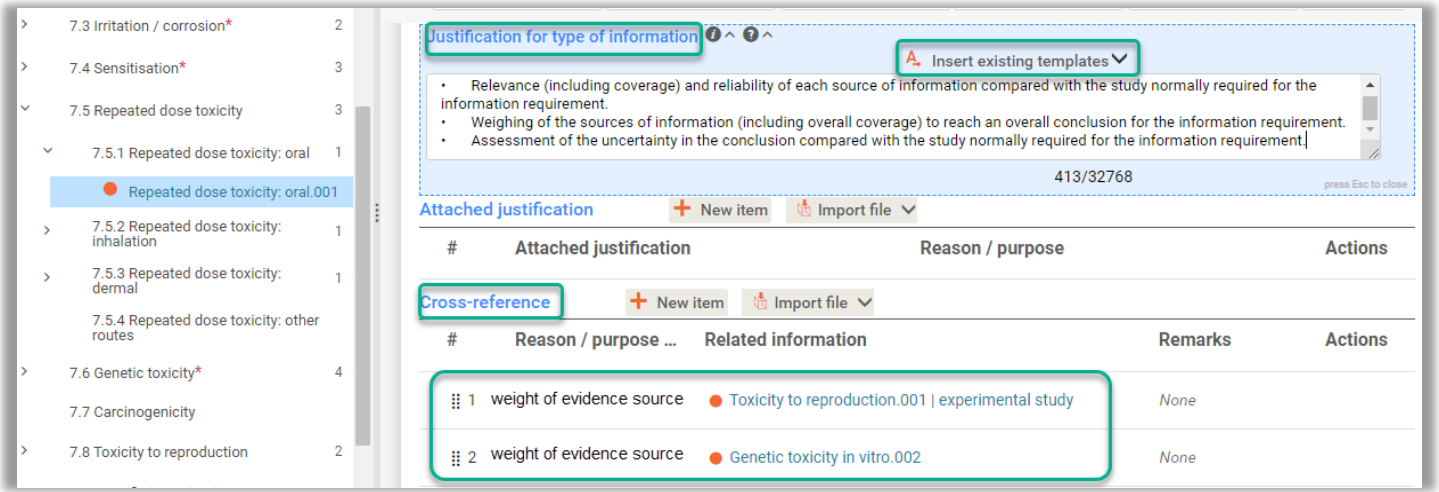
→ Create a new document with type of information ‘weight of evidence justification/conclusion’



Weight of evidence justification (2)

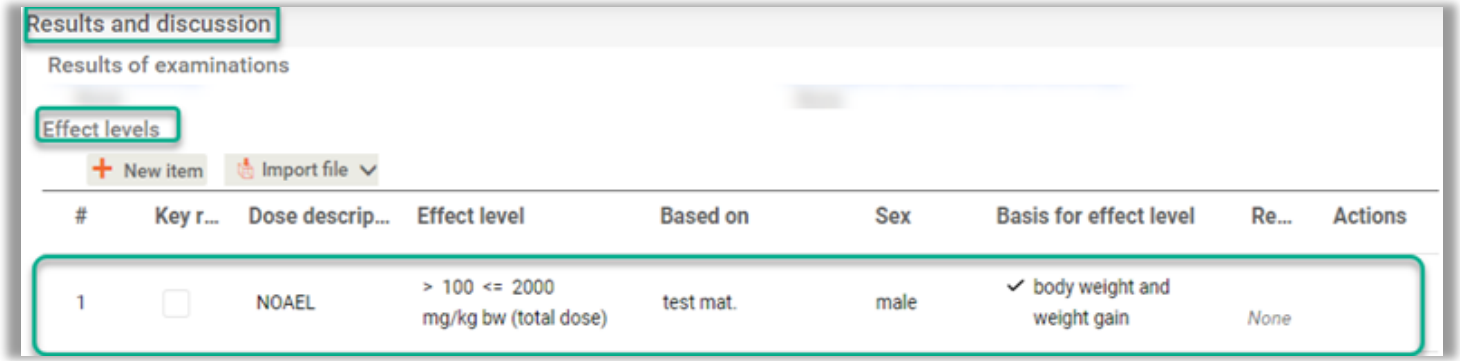
→ Justification for type of information

→ Cross-reference (weight of evidence source)



Weight of evidence justification (3)

→ Results and discussion (reported in tabular form)



Aquatic toxicity: long term (IUCLID 6.1.2 and 6.1.4)

Degradation (IUCLID 5.2.2 and 5.2.3)

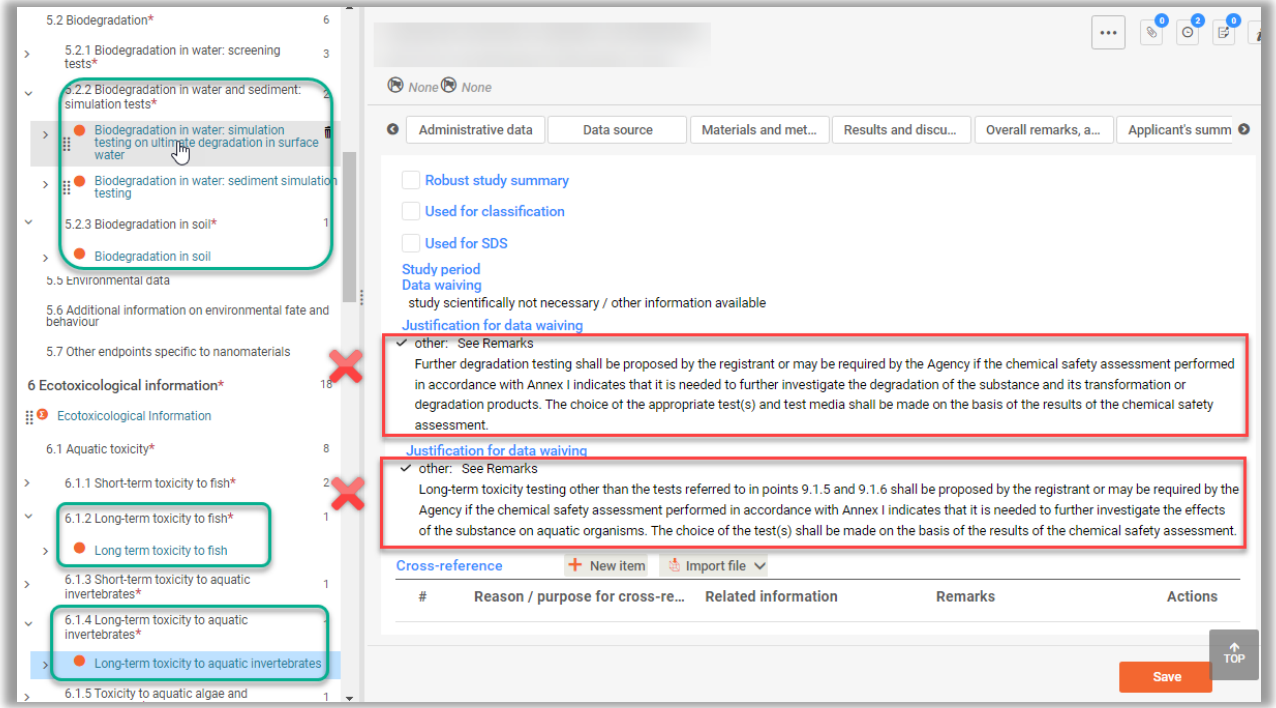
→ Board of Appeal decisions:
- A-011-2018 – Aquatic toxicity (long term)
- A-005-2021 – Degradation

→ REACH Annex IX - Column 2 of Sections 9.1 and 9.2
- Results of chemical safety assessment do not allow to omit information required under column 1
- Trigger for further data beyond standard information requirement if chemical safety assessment indicates such a need

→ As of May 2023, outcome of chemical safety assessment no longer considered as valid data waiving justification in IUCLID sections 5.2.2, 5.2.3, 6.1.2 and 6.1.4

Aquatic toxicity: long term (IUCLID 6.1.2 and 6.1.4)

Degradation (IUCLID 5.2.2 and 5.2.3) – examples



Take home messages

→ Review your existing data on:
- Mutagenicity
- Long-term aquatic toxicity and degradation waivers

→ Use improved IUCLID formats for:
- New weight of evidence documents
- New justifications for data waiving (use new standard phrases)

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Use description

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Mila Marinovic
European Chemicals Agency

Overview

→ Shortcomings in use description identified by ECHA

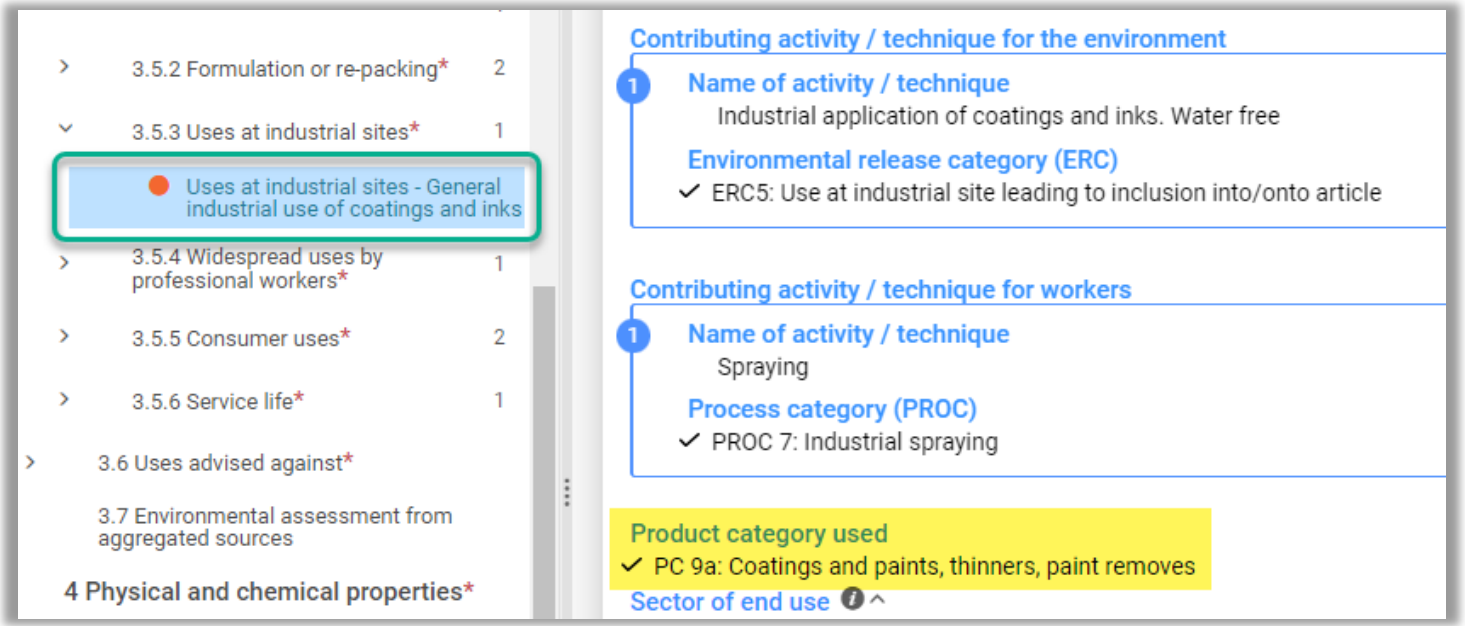
→ New and updated completeness check rules:

- Product category required in sections 3.5.3 and 3.5.4
- Service life required in section 3.5.6 whenever ERC 8c/f used

Product category

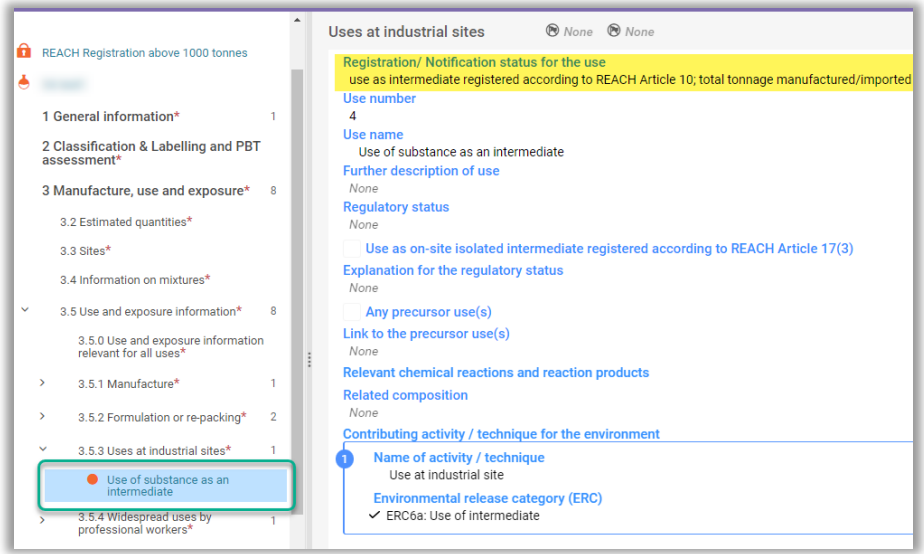
- → Field "product category used" becomes **mandatory** for uses reported in sections:
  - 3.5.3 **Uses at industrial sites**, and
  - 3.5.4 **Widespread uses by professional workers**
- → Product category describes type of chemical products in which the substance is finally contained
- → Examples: paints, fuels, laboratory chemicals etc.
- → Key element in use description but currently missing for ~50% of uses in IUCLID sections 3.5.3 and 3.5.4.
- → Further information: Use description - Appendix R.12.4

Product category example



Exception - intermediates

- → Product category not required for uses as intermediates in IUCLID section 3.5.3
- → Indicate intermediate status in 'registration/notification status for the use' field



Article service life

→ Service life use record required in IUCLID section 3.5.6 whenever preceding uses are described with any of the following environmental release categories:

- **ERC 8c**: Widespread use leading to inclusion into/onto article (indoor)
- **ERC 8f**: Widespread use leading to inclusion into/onto article (outdoor)
- **ERC 5**: Use at industrial site leading to inclusion into/onto article

Article service life (cont.)

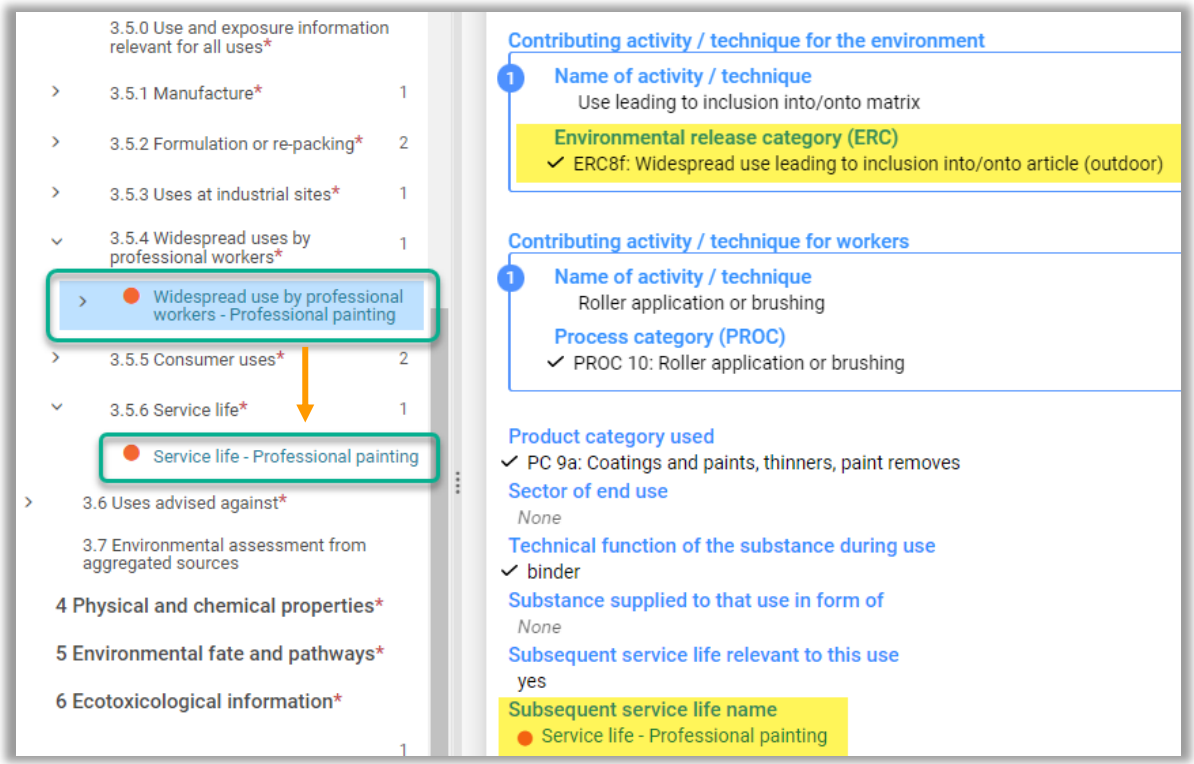
→ Service life describes use of the substance in an article

→ Examples:

- **Dyes in textile articles**
- **Plasticiser in articles made from soft-plastic material**
- **Flame-retardants in plastic articles**
- **Pigment in dried coating after application in/on article**

→ Further information: Q&A 1669, Q&A 1860

Article service life example



Take home messages

→ Change in use description will impact:
- All registrants (lead, member, individual)
- Downstream user sectors with use maps

→ Required information can already be provided as IUCLID formats exist

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Conclusions

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Henri Honkalammi
European Chemicals Agency

Take home messages

→ New and amended completeness check rules enter into force in May 2023

→ Most rules will be visible in IUCLID validation assistant

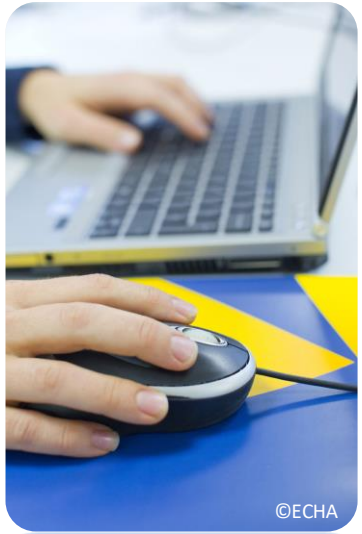
→ Get familiar with the changes already now and revise your dossier if needed

→ Support available:

- Webinars
- Completeness check web page
- Registration manual
- Contact form

Live Q&A

- Join Q&A at: slido.com
  Event code: # cc2023
- Webinar open until 13:00 Helsinki time (EET, GMT+2) to answer questions
- Question not answered by the end of the webinar? Send it via our contact form: echa.europa.eu/contact



Thank you

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