

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



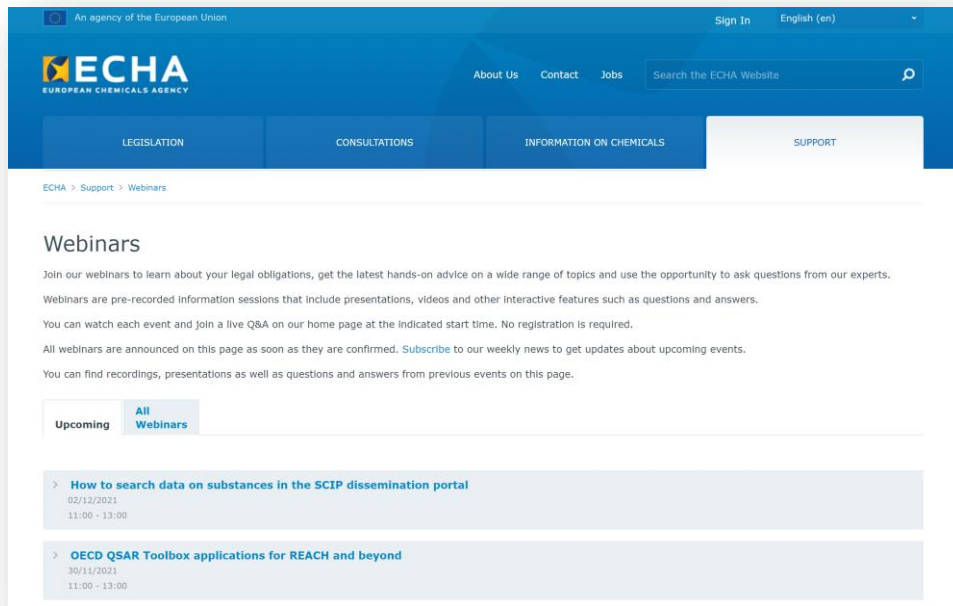
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The screenshot shows the ECHA website's 'Webinars' page. The header is blue with the ECHA logo and navigation links. The main content area is white and contains the following text:

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Navigation tabs: **Upcoming** | **All Webinars**

- > **How to search data on substances in the SCIP dissemination portal**
02/12/2021
11:00 - 13:00
- > **OECD QSAR Toolbox applications for REACH and beyond**
30/11/2021
11:00 - 13:00

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	

Completeness check process

Webinar: Completeness check of REACH
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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

veneta.nieminen@echa.europa.eu

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Substance identification

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

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

General Information

Name
Ethanol

Type of composition
legal entity composition of the substance

State / form   

Please select 

- gas
- liquid
- solid: bulk
- solid: fibres
- solid: nanoform
- solid: particulate/powder
- other:

[reference to related composition\(s\)](#)

Remarks


Actions

press Esc to close

Scope of the joint submission Download scope details

Ethanol-BC State / Form: liquid

Constituents

EC number	EC name	CAS Number	CAS name	IUPAC name	Concentration range
200-578-6	ethanol	64-17-5	Ethanol	Ethanol	> 80.0 < 100.0 % (w/w) 

Members of the joint submission Download member details

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

Molecular and structural information

Molecular formula
H₂O

Molecular weight
ca. 18

SMILES notation
O

InChI
InChI=1S/H2O/h1H2

Structural formula

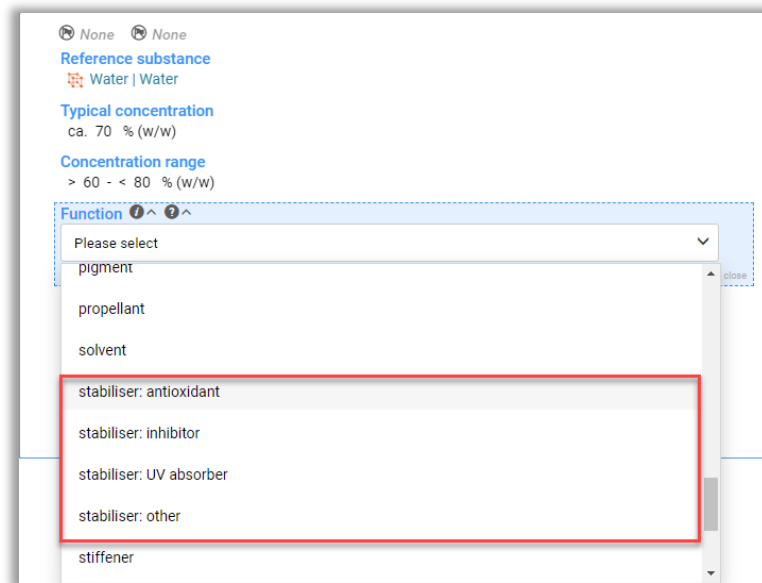
Remarks

Chemical structure files + New item Import file

#	Structure file	Remarks on structure file	Actions
---	----------------	---------------------------	---------

Boundary composition: Additives

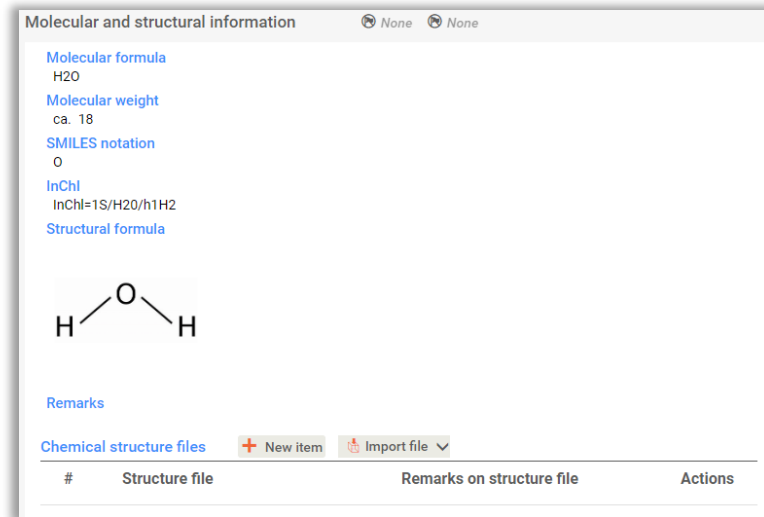
- For each **additive**, **stabilising function** must be confirmed by selecting relevant value starting with 'stabiliser' in 'function' picklist



None None
Reference substance
Water | Water
Typical concentration
ca. 70 % (w/w)
Concentration range
> 60 - < 80 % (w/w)
Function ? ^ ? ^
Please select
pigment
propellant
solvent
stabiliser: antioxidant
stabiliser: inhibitor
stabiliser: UV absorber
stabiliser: other
stiffener

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



The screenshot displays a window titled "Molecular and structural information" with two "None" buttons in the top right. The content is organized into sections:

- Molecular formula:** H2O
- Molecular weight:** ca. 18
- SMILES notation:** O
- InChI:** InChI=1S/H2O/h1H2
- Structural formula:** A diagram showing a central oxygen atom (O) bonded to two hydrogen atoms (H) in a bent arrangement.
- Remarks:** A section for user notes.

At the bottom, there are buttons for "Chemical structure files", "New item", and "Import file". Below these is a table header with columns: "#", "Structure file", "Remarks on structure file", and "Actions".

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

jordan.esson@echa.europa.eu

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Annexes VII-XI information requirements

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Cristian Căramidă
European Chemicals Agency



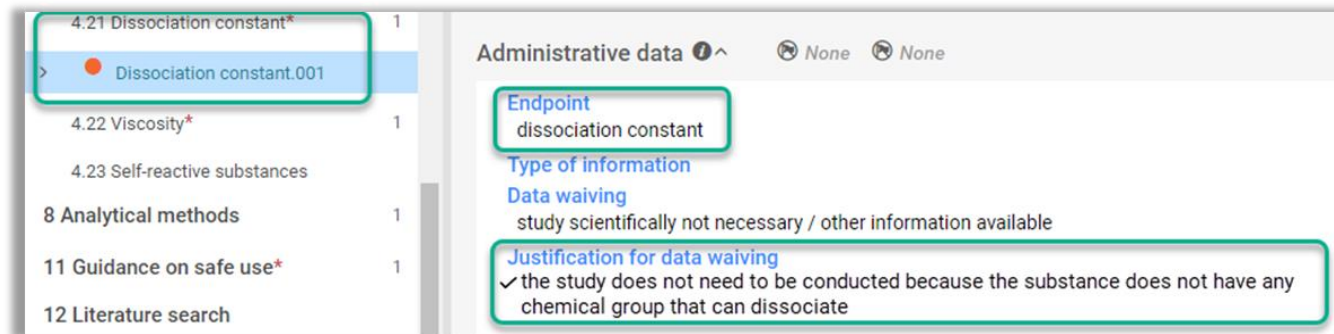
Overview

- 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)

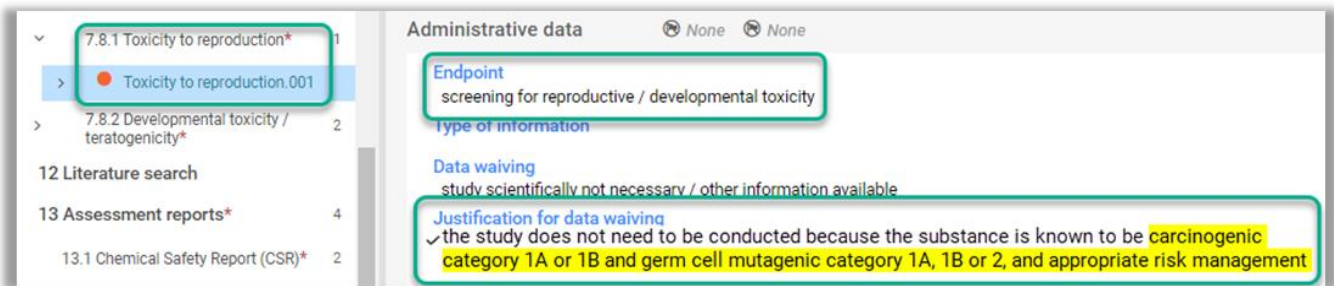
Examples of new and updated standard phrases



The screenshot shows the administrative data for the endpoint "Dissociation constant.001". The left sidebar lists various endpoints, with "4.21 Dissociation constant*" selected. The main content area displays the following information:

- Endpoint:** dissociation constant
- Type of information:** Data waiving
- Data waiving:** study scientifically not necessary / other information available
- Justification for data waiving:** ✓ the study does not need to be conducted because the substance does not have any chemical group that can dissociate

Example 1



The screenshot shows the administrative data for the endpoint "Toxicity to reproduction.001". The left sidebar lists various endpoints, with "7.8.1 Toxicity to reproduction*" selected. The main content area displays the following information:

- Endpoint:** screening for reproductive / developmental toxicity
- Type of information:** Data waiving
- Data waiving:** study scientifically not necessary / other information available
- Justification for data waiving:** ✓ the study does not need to be conducted because the substance is known to be carcinogenic category 1A or 1B and germ cell mutagenic category 1A, 1B or 2, and appropriate risk management

Example 2

Example of data waiving using other argument than a standard phrase

The screenshot displays a web interface for managing chemical data. On the left is a navigation menu with the following items:

- 5.2.2 Biodegradation in water and sediment: simulation tests* (expanded)
- Biodegradation in water: simulation testing on ultimate degradation in surface water (selected)
- Biodegradation in water: sediment simulation testing
- 6 Ecotoxicological information* 16
- 7 Toxicological information* 20
- Toxicological information

The main content area is titled "Administrative data" and shows two "None" status indicators. It contains the following sections:

- Endpoint:** biodegradation in water: simulation testing on ultimate degradation in surface water
- Type of information:** (empty)
- Data waiving:** study technically not feasible
- Justification for data waiving:** ✓ other: According to Annex XI, Section2, the simulation study in surface water is technically not feasible because the substance is a gas.
- Justification for type of information:** (empty)

The "Data waiving" and "Justification for data waiving" sections are highlighted with a green border in the original image.

Example 3

Example of a new conditional standard phrase (1)

> Water solubility.001

Water solubility.002

4.9 Solubility in organic solvents / fat solubility

4.10 Surface tension* 1

4.18 Storage stability and reactivity towards container material

4.19 Stability: thermal, sunlight, metals

4.20 pH

Administrative data None None

Endpoint
water solubility

Type of information

Data waiving
study scientifically not necessary / other information available

Justification for data waiving
 the study does not need to be conducted because the substance is a **metal or a sparingly soluble metal compound**

4.8 Water solubility* 2

> Water solubility.001

Water solubility.002

4.9 Solubility in organic solvents / fat solubility

4.10 Surface tension* 1

Administrative data None None

Endpoint
transformation / dissolution of metals and inorganic metal compounds

Type of information
experimental study

Adequacy of study
key study

Robust study summary

Example of a new conditional standard phrase (2)

7.6 Genetic toxicity* 4

- 7.6.1 Genetic toxicity in vitro* 3
 - In vitro gene mutation study in bacteria
 - In vitro micronucleus study / In vitro chromosome aberration in mammalian cells
 - In vitro gene mutation in mammalian cells**
- 7.6.2 Genetic toxicity in vivo 1
- 7.12 Additional toxicological information

8 Analytical methods 1

11 Guidance on safe use* 1

12 Literature search

Administrative data None None

Administrative data None None

Endpoint
in vitro gene mutation study in mammalian cells

Data waiving
study scientifically not necessary / other information available

Justification for data waiving
✓ an in vitro gene mutation study in mammalian cells does not need to be conducted because the substance is known to be germ cell mutagenic category 1A, 1B or 2 and carcinogenic category 1A or 1B and appropriate risk management measures are implemented

1 General information* 7

2 Classification & Labelling and PBT assessment* 3

- 2.1 GHS* 1
 - GHS.001**
 - 2.3 PBT assessment* 2
- 3 Manufacture, use and exposure* 8
- 4 Physical and chemical properties* 21
- 5 Environmental fate and pathways* 9
- 6 Ecotoxicological information* 16
- 7 Toxicological information* 19

General Information Classification Labelling Notes

Germ cell mutagenicity

Germ cell mutagenicity

Hazard category
Muta. 1A

Route of exposure
✓ inhalation

Carcinogenicity

Carcinogenicity

Hazard category
Carc. 1A

Route of exposure
✓ inhalation

Hazard statement
H340: May cause genetic defects <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.

Hazard statement
H350: May cause cancer by inhalation.

Examples of updated endpoint names

4.10 Surface tension* 1

> ● Surface tension.001

> 4.11 Flash point* +

> 4.12 Auto flammability* 1

> 4.13 Flammability* 1

> 4.14 Explosiveness* 1

Administrative data None None

Endpoint
surface tension **of an aqueous solution**

Type of information
experimental study

Adequacy of study
key study

Robust study summary

Example 6

Genetic toxicity.001

7.6.1 Genetic toxicity in vitro* 3

> ● In vitro gene mutation study in bacteria

> ● In vitro micronucleus study / In vitro chromosome aberration in mammalian cells

> ● In vitro gene mutation in mammalian cells

> 7.6.2 Genetic toxicity in vivo 1

7.7 Carcinogenicity

Administrative data Data source Materials and methods

Administrative data None None

Endpoint
in vitro **cytogenicity** chromosome aberration study in mammalian cells
in vitro **cytogenicity** micronucleus study

Type of information
experimental study

Adequacy of study
key study

Example 7

6.3 Terrestrial toxicity* 6

Terrestrial toxicity.001

> 6.3.1 Toxicity to soil macroorganisms except arthropods* 1

> ● 6.3.2 Toxicity to **soil** arthropods* 1

> ● Toxicity to soil arthropods.001

> 6.3.3 Toxicity to terrestrial plants* 1

Administrative data None None

Endpoint soil
toxicity to ~~terrestrial~~ arthropods: short-term
toxicity to soil arthropods: long-term
toxicity to soil arthropods, other

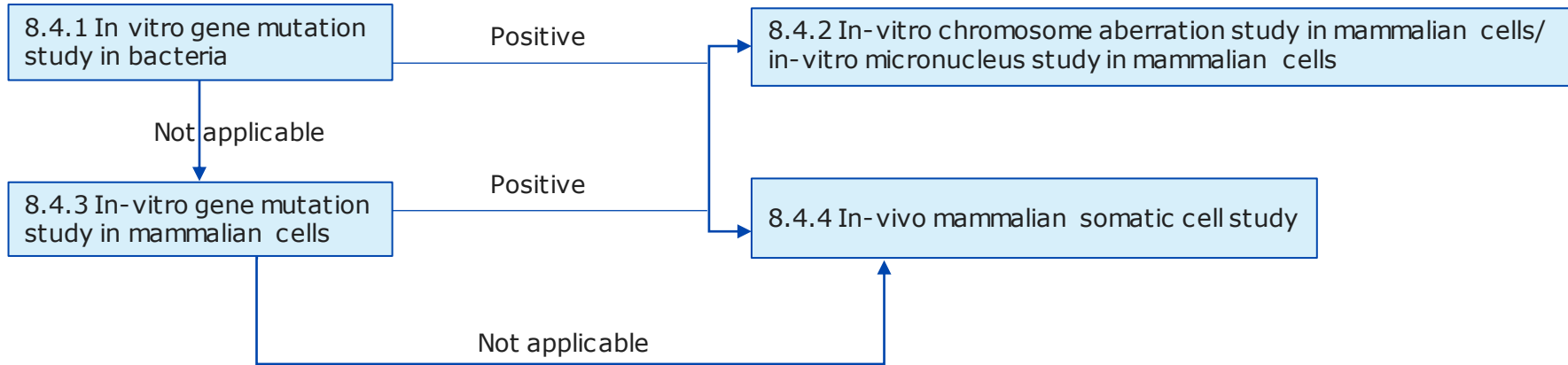
Type of information
experimental study

Example 8

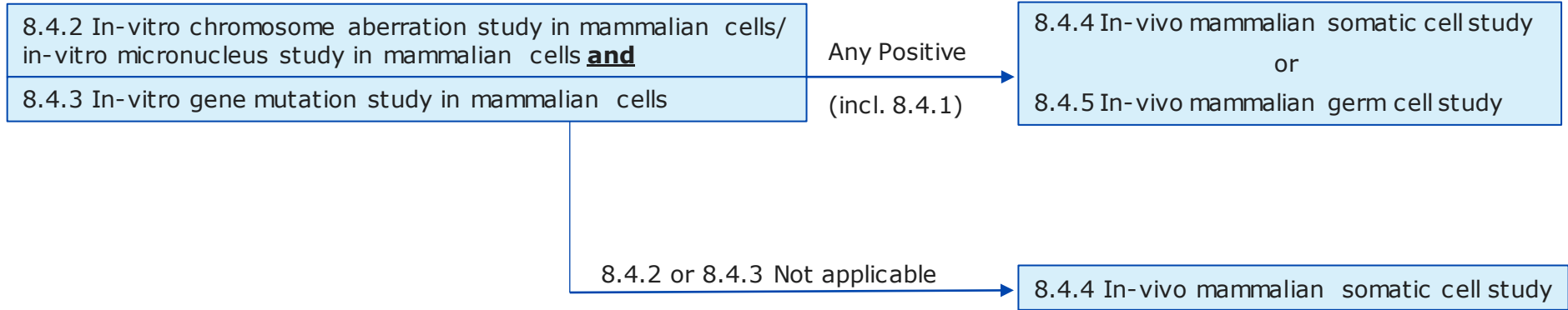
Mutagenicity – sequential information requirements in Annex VII and VIII

- 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)

7.6 Genetic toxicity* 4

- 7.6.1 Genetic toxicity in vitro* 4
 - Genetic toxicity in vitro.001
 - Genetic toxicity in vitro.002
 - Genetic toxicity in vitro.003
- 7.6.2 Genetic toxicity in vivo 1
- 7.12 Additional toxicological information

8 Analytical methods 1

11 Guidance on safe use* 1

- Guidance on safe use.001

12 Literature search

Administrative data None None

Endpoint
in vitro gene mutation study in bacteria

Type of information
experimental study

Adequacy of study
key study

Robust study summary

Results and discussion

Test results + New item Import file

#	Key result	Species / strain	Metabolic activation	Genotoxicity
1	<input checked="" type="checkbox"/>	S. typhimurium TA 1535	with	positive

7.6.1 Genetic toxicity in vitro* 4

- Genetic toxicity in vitro.001
- Genetic toxicity in vitro.002
- Genetic toxicity in vitro.003

7.6.2 Genetic toxicity in vivo 1

7.7 Carcinogenicity

7.8 Toxicity to reproduction* 3

Administrative data None None

Endpoint
in vitro chromosome aberration study / in vitro micronucleus study

Type of information
experimental study

Adequacy of study
key study

Robust study summary

7.6 Genetic toxicity* 3

- 7.6.1 Genetic toxicity in vitro* 2
 - Genetic toxicity in vitro.001
 - Genetic toxicity in vitro.002
- 7.6.2 Genetic toxicity in vivo 1
 - Genetic toxicity in vivo.001

7.7 Carcinogenicity

Administrative data None None

Endpoint
in vivo mammalian somatic cell study:

Type of information
experimental study / experimental study planned

Adequacy of study

Robust study summary

Mutagenicity - 8.4.1 n/a (example 2)

7.6.1 Genetic toxicity in vitro* 2

- Genetic toxicity in vitro.001
- Genetic toxicity in vitro.002

8 Analytical methods 1

- Analytical methods.001

11 Guidance on safe use* 1

- Guidance on safe use.001

12 Literature search

13 Assessment reports* 4

- 13.1 Chemical Safety Report (CSR)* 2
- 13.2 Other assessment reports 2

Administrative data None None

Endpoint
in vitro gene mutation study in bacteria

Type of information

Data waiving
other justification

Justification for data waiving
✓ an in vitro mutagenicity study does not need to be conducted because this test is not applicable for the substance

Justification for type of information

Elaborate here on why the study is not applicable!

50/32768

7.6.1 Genetic toxicity in vitro* 2

- Genetic toxicity in vitro.001
- Genetic toxicity in vitro.002
- Genetic toxicity in vitro.003

7.6.2 Genetic toxicity in vivo 1

7.7 Carcinogenicity

7.8 Toxicity to reproduction* 3

Administrative data None None

Endpoint
in vitro chromosome aberration study / in vitro micronucleus study

Type of information
experimental study

Adequacy of study
key study

Robust study summary

7.6.1 Genetic toxicity in vitro* 2

- Genetic toxicity in vitro.001
- Genetic toxicity in vitro.002

7.6.2 Genetic toxicity in vivo 1

- Genetic toxicity in vivo.001

7.7 Carcinogenicity

Administrative data None None

Endpoint
in vitro gene mutation study in mammalian cells

Type of information
experimental study

Adequacy of study
key study

Robust study summary

Used for classification

Positive

7.6 Genetic toxicity* 3

- 7.6.1 Genetic toxicity in vitro* 2
 - Genetic toxicity in vitro.001
 - Genetic toxicity in vitro.002
- 7.6.2 Genetic toxicity in vivo 1
 - Genetic toxicity in vivo.001

7.7 Carcinogenicity

Administrative data None None

Endpoint
in vivo mammalian somatic cell study:

Type of information
experimental study / experimental study planned

Adequacy of study

Robust study summary

Mutagenicity - Annex VIII (example 3)

7.6.1 Genetic toxicity in vitro* 3

- In vitro gene mutation study in bacteria
- In vitro micronucleus study / In vitro chromosome aberration in mammalian cells
- In vitro gene mutation in mammalian cells

7.6.2 Genetic toxicity in vivo 1

- Genetic toxicity in vivo.001

Results and discussion

Test results + New item Import file

#	Key result	Species / strain	Metabolic activati...	Genotoxicity
1	<input checked="" type="checkbox"/>	not specified	with and without	positive

Additional information on results

or

7.6.1 Genetic toxicity in vitro* 3

- In vitro gene mutation study in bacteria
- In vitro micronucleus study / In vitro chromosome aberration in mammalian cells
- In vitro gene mutation in mammalian cells

7.6.2 Genetic toxicity in vivo 1

- Genetic toxicity in vivo.001

7.7 Carcinogenicity +

Administrative data None None

Endpoint
in vivo mammalian somatic cell study:

Type of information
experimental study / experimental study planned

Adequacy of study

Robust study summary

7.6.1 Genetic toxicity in vitro* 3

- In vitro gene mutation study in bacteria
- In vitro micronucleus study / In vitro chromosome aberration in mammalian cells
- In vitro gene mutation in mammalian cells

7.6.2 Genetic toxicity in vivo 1

- Genetic toxicity in vivo.001

7.7 Carcinogenicity

Data waiving
other justification

Justification for data waiving
✓ an in vitro mutagenicity study does not need to be conducted because this test is not applicable for the substance

Justification for type of information
Elaborate here on why the study is not applicable

Insert existing templates

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'

The screenshot displays a software interface for managing toxicity data. On the left, a list of endpoints is shown, with '7.5.1 Repeated dose toxicity: oral*' selected. The right panel, titled 'Administrative data', contains the following information:

- Endpoint:** sub-chronic toxicity: oral
- Type of information:** weight of evidence justification/conclusion
- Adequacy of study:** (field is present but empty)

A 'Save' button is located at the bottom right of the 'Administrative data' panel.

Weight of evidence justification (2)

- Justification for type of information
- Cross-reference (weight of evidence source)

The screenshot shows a software interface with a navigation tree on the left and a main content area on the right. The navigation tree lists various toxicity endpoints, with 'Repeated dose toxicity: oral.001' selected. The main content area is divided into two sections:

Justification for type of information (413/32768)

Insert existing templates

- Relevance (including coverage) and reliability of each source of information compared with the study normally required for the information requirement.
- Weighing of the sources of information (including overall coverage) to reach an overall conclusion for the information requirement.
- Assessment of the uncertainty in the conclusion compared with the study normally required for the information requirement!

Attached justification (+ New item, Import file)

#	Attached justification	Reason / purpose	Actions

Cross-reference (+ New item, Import file)

#	Reason / purpose ...	Related information	Remarks	Actions
1	weight of evidence source	Toxicity to reproduction.001 experimental study	None	
2	weight of evidence source	Genetic toxicity in vitro.002	None	

Weight of evidence justification (3)

→ Results and discussion (reported in tabular form)

Results and discussion

Results of examinations

Effect levels

+ New item Import file

#	Key r...	Dose descrip...	Effect level	Based on	Sex	Basis for effect level	Re...	Actions
1	<input type="checkbox"/>	NOAEL	> 100 <= 2000 mg/kg bw (total dose)	test mat.	male	✓ body weight and weight gain	None	

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

The screenshot displays the IUCLID software interface. On the left is a navigation tree with the following structure:

- 5.2 Biodegradation*
 - 5.2.1 Biodegradation in water: screening tests*
 - 5.2.2 Biodegradation in water and sediment: simulation tests*
 - Biodegradation in water: simulation testing on ultimate degradation in surface water
 - Biodegradation in water: sediment simulation testing
 - 5.2.3 Biodegradation in soil*
 - Biodegradation in soil
- 5.5 Environmental data
- 5.6 Additional information on environmental fate and behaviour
- 5.7 Other endpoints specific to nanomaterials
- 6 Ecotoxicological information*
 - 6.1 Aquatic toxicity*
 - 6.1.1 Short-term toxicity to fish*
 - 6.1.2 Long-term toxicity to fish*
 - Long term toxicity to fish
 - 6.1.3 Short-term toxicity to aquatic invertebrates*
 - 6.1.4 Long-term toxicity to aquatic invertebrates*
 - Long-term toxicity to aquatic invertebrates
 - 6.1.5 Toxicity to aquatic algae and

On the right, the data entry form is shown. The 'Administrative data' tab is active. The 'Justification for data waiving' section contains two entries:

- Biodegradation in water: simulation testing on ultimate degradation in surface water**
 - other: See Remarks
 - Further degradation testing shall be proposed by the registrant or may be required by the Agency if the chemical safety assessment performed in accordance with Annex I indicates that it is needed to further investigate the degradation of the substance and its transformation or degradation products. The choice of the appropriate test(s) and test media shall be made on the basis of the results of the chemical safety assessment.
- Long-term toxicity to fish**
 - other: See Remarks
 - Long-term toxicity testing other than the tests referred to in points 9.1.5 and 9.1.6 shall be proposed by the registrant or may be required by the Agency if the chemical safety assessment performed in accordance with Annex I indicates that it is needed to further investigate the effects of the substance on aquatic organisms. The choice of the test(s) shall be made on the basis of the results of the chemical safety assessment.

At the bottom of the form, there is a 'Cross-reference' table with columns: #, Reason / purpose for cross-re..., Related information, Remarks, and Actions. A 'Save' button is located at the bottom right of the form area.

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)

Thank you

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Use description

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

8 February 2023

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

>	3.5.2 Formulation or re-packing*	2
∨	3.5.3 Uses at industrial sites*	1
	● Uses at industrial sites - General industrial use of coatings and inks	
>	3.5.4 Widespread uses by professional workers*	1
>	3.5.5 Consumer uses*	2
>	3.5.6 Service life*	1
>	3.6 Uses advised against*	
	3.7 Environmental assessment from aggregated sources	
	4 Physical and chemical properties*	

Contributing activity / technique for the environment

1 Name of activity / technique
Industrial application of coatings and inks. Water free

Environmental release category (ERC)
✓ ERC5: Use at industrial site leading to inclusion into/onto article

Contributing activity / technique for workers

1 Name of activity / technique
Spraying

Process category (PROC)
✓ PROC 7: Industrial spraying

Product category used
✓ PC 9a: Coatings and paints, thinners, paint removes

Sector of end use ⓘ ^

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

The screenshot displays the IUCLID registration form for 'Uses at industrial sites'. The left sidebar shows a tree view of the registration sections, with '3.5.3 Uses at industrial sites*' selected and highlighted in blue. The main content area shows the details for this section, including a table of uses and a detailed view of the 'Use as intermediate' status.

Uses at industrial sites None None

Registration/ Notification status for the use
use as intermediate registered according to REACH Article 10; total tonnage manufactured/imported

Use number
4

Use name
Use of substance as an intermediate

Further description of use
None

Regulatory status
None

Use as on-site isolated intermediate registered according to REACH Article 17(3)

Explanation for the regulatory status
None

Any precursor use(s)

Link to the precursor use(s)
None

Relevant chemical reactions and reaction products

Related composition
None

Contributing activity / technique for the environment

1 Name of activity / technique
Use at industrial site

Environmental release category (ERC)
 ERC6a: Use of intermediate

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

3.5.0 Use and exposure information relevant for all uses*	
> 3.5.1 Manufacture*	1
> 3.5.2 Formulation or re-packing*	2
> 3.5.3 Uses at industrial sites*	1
∨ 3.5.4 Widespread uses by professional workers*	1
> ● Widespread use by professional workers - Professional painting	
> 3.5.5 Consumer uses*	2
∨ 3.5.6 Service life*	1
● Service life - Professional painting	
> 3.6 Uses advised against*	
3.7 Environmental assessment from aggregated sources	
4 Physical and chemical properties*	
5 Environmental fate and pathways*	
6 Ecotoxicological information*	1

Contributing activity / technique for the environment
1 Name of activity / technique Use leading to inclusion into/onto matrix
Environmental release category (ERC) ✓ ERC8f: Widespread use leading to inclusion into/onto article (outdoor)
Contributing activity / technique for workers
1 Name of activity / technique Roller application or brushing
Process category (PROC) ✓ PROC 10: Roller application or brushing
Product category used ✓ PC 9a: Coatings and paints, thinners, paint removes
Sector of end use None
Technical function of the substance during use ✓ binder
Substance supplied to that use in form of None
Subsequent service life relevant to this use yes
Subsequent service life name ● Service life - Professional painting

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

Thank you

mila.marinovic@echa.europa.eu

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Conclusions

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

8 February 2023

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](https://www.slido.com)
Event code:
- 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



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