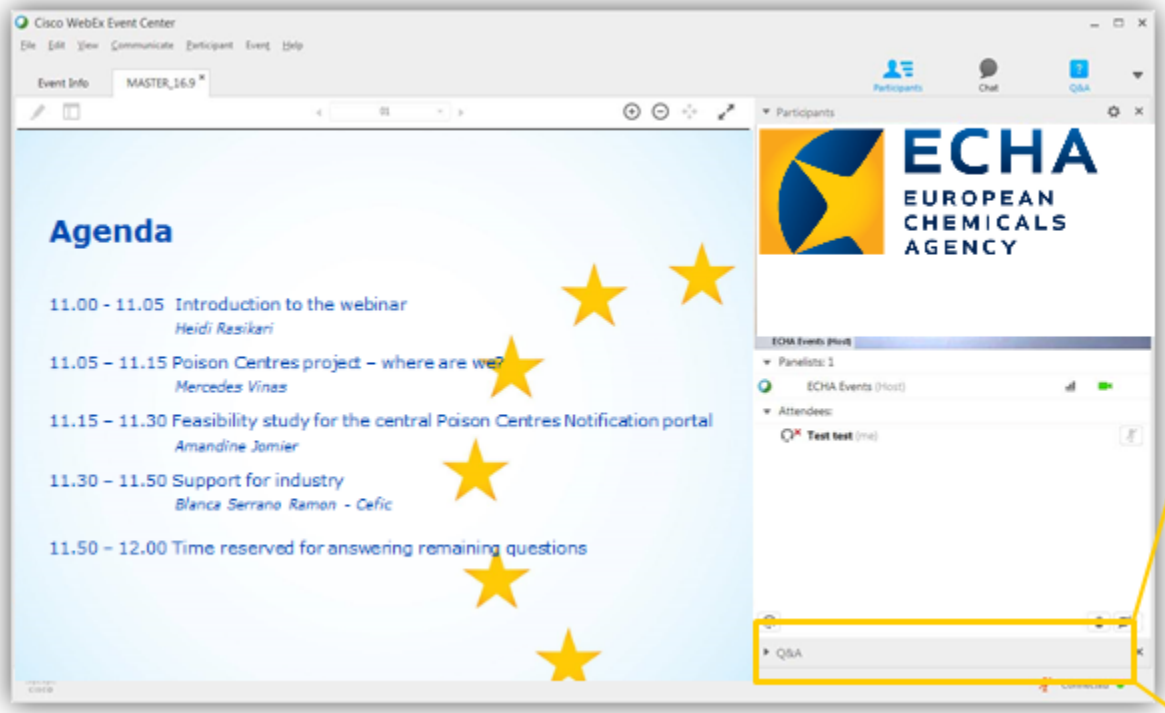
Introduction

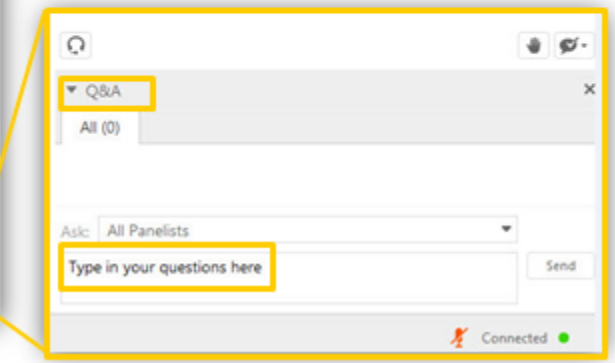
Webinar: Revised completeness check: what changes and how you can prepare

29 January 2020

Robert Lucas, ECHA

Q&A panel

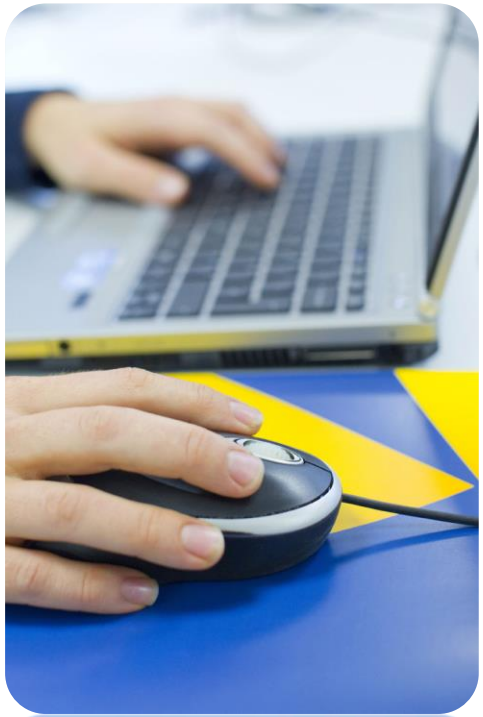




- Send questions about the presentations
- Send messages if you have any technical difficulties

Q&A panel

- Send questions at any time
- We can only answer questions related to the scope of the webinar
- If your question is not answered by the end of the webinar, send it via our contact form: echa.europa.eu/contact



Agenda

11:00 **Introduction**
Robert LUCAS, ECHA

11:10 **Revised completeness check of Annex VII-XI information requirements**
Ella LAKKONEN, ECHA

11:20 **Completeness check of the chemical safety report: what is covered**
Valérie LASSEIGNE-PHRAKONKHAM, ECHA

11:30 **Practical advice: ensuring a complete chemical safety report**
Soile NIEMI, ECHA
Andreas AHRENS, ECHA

11:55 **Conclusions**
Robert LUCAS, ECHA

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

Completeness check process

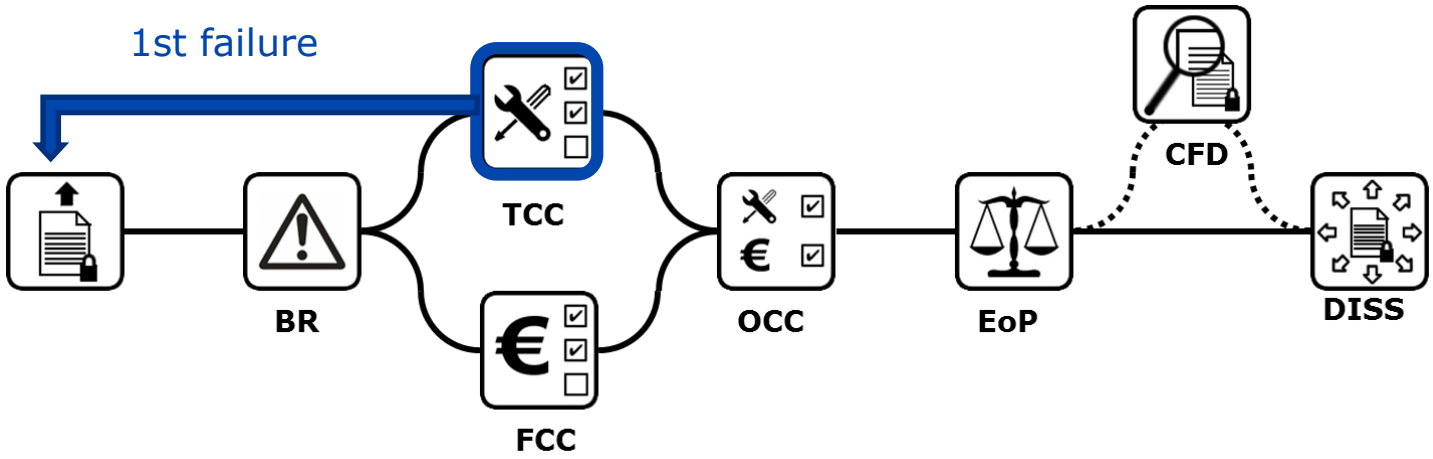
Background

Completeness check process

- Completeness check implements REACH Article 20(2) to ensure all required elements are in a registration dossier
- All registration dossiers undergo a completeness check when submitted to us:
  - Both new registrations and updates
  - Two attempts to pass the completeness check
  - Only complete dossiers are accepted into our database

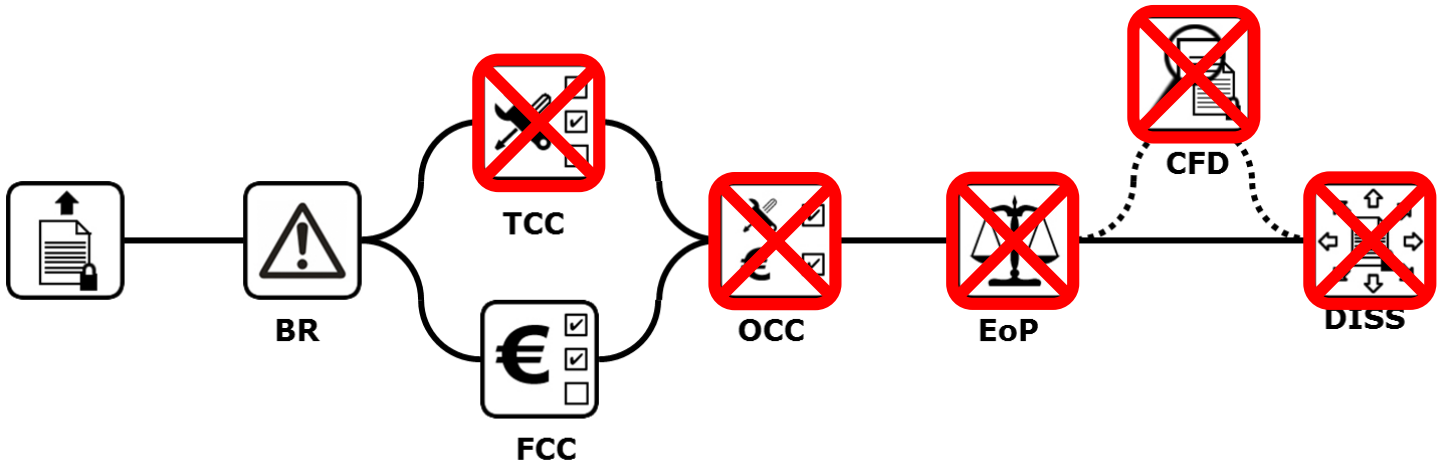
Completeness check failure

- First failure of completeness check
  - Letter in REACH-IT
  - One more possibility to submit a complete dossier
  - Deadline specified in the letter



Completeness check failure

- Second failure of completeness check
  - Negative decision in REACH-IT informing submission is rejected
  - Initial submission: Registration number not granted
  - Update of existing registration: Updated information not accepted into our database and subsequent processes



Improving the process

- **2010**: REACH information requirements converted into automated completeness check rules
- **2016**: Enhanced completeness check entered into force: revised automated rules and additional manual checks performed by us
- **2020**: Next revision of completeness check includes:
  1. More explicit completeness check rules on hazard information in key endpoints
  2. Extension of completeness check to chemical safety report

Implementation principles

- Quality or adequacy of information is not assessed (Article 20(2))
- REACH requirements don’t change, only implementation of completeness check
- Incompleteness during update of an existing registration does not lead to revocation of registration number
- We will support you to minimise any negative impact on your registration process

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Revised completeness check of Annex VII-XI information requirements

Webinar: Revised completeness check: what changes and how you can prepare

29 January 2020

Ella Laakkonen

Background

- Article 10(a) requires that the registration dossier contains:
  - (vi) study summaries of information derived from application of Annexes VII to XI;
  - (vii) robust study summaries of information derived from application of Annexes VII to XI
- Current completeness check implementation does not ensure that specific requirements have been addressed for some key endpoints
- New: Computer-based checks will ensure specific requirements are addressed

Completeness check of Annex VII-XI

IUCLID endpoints impacted by revision

- Biodegradation
  - Section 5.2.2 Biodegradation in water and sediment: simulation tests
- Mutagenicity
  - Section 7.6.1 Genetic toxicity *in vitro*
  - Section 7.6.2 Genetic toxicity *in vivo*
- Reproductive toxicity
  - Section 7.8.1 Toxicity to reproduction
  - Section 7.8.2 Developmental toxicity/teratogenicity

Degradation (1/3)

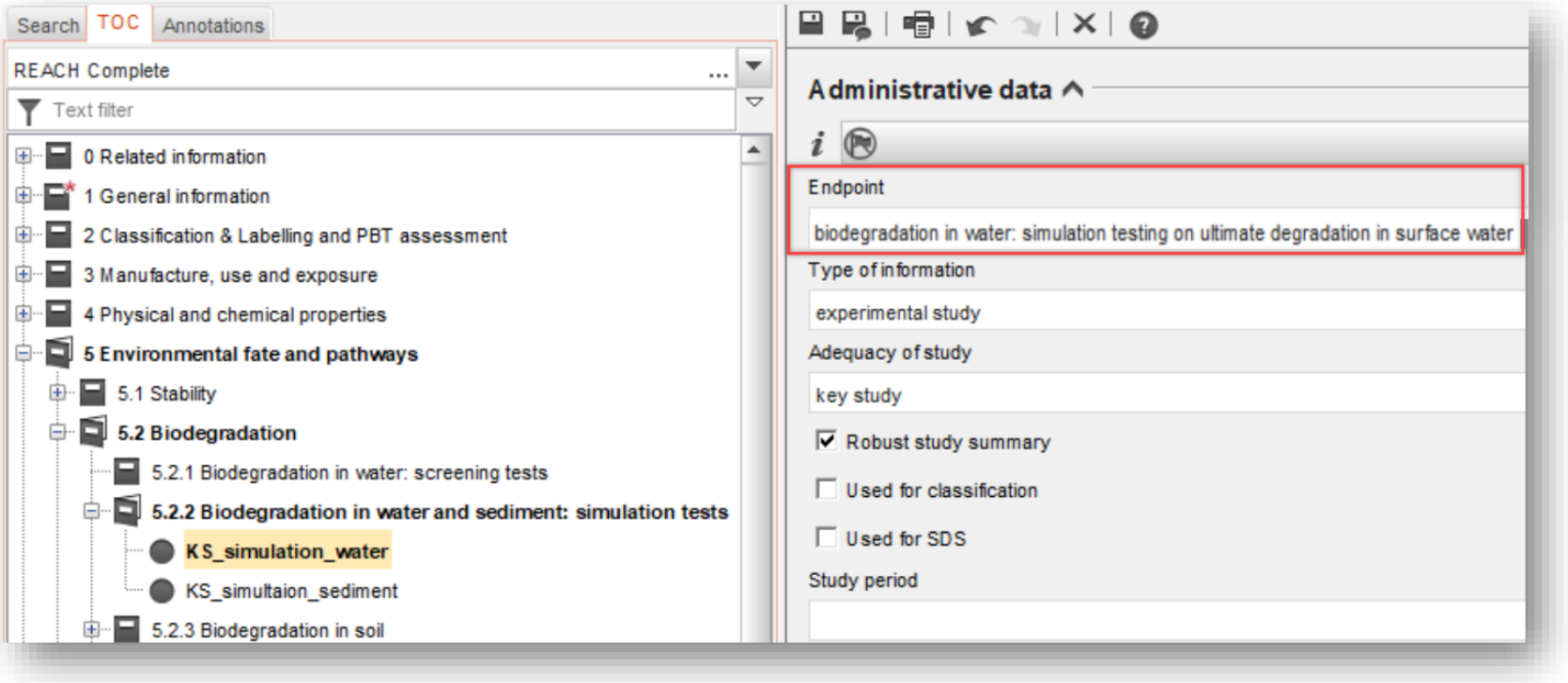
- REACH 9.2.1.2/9.2.1.4: Endpoints *simulation testing on ultimate degradation in surface water* and *sediment simulation testing* must be addressed by separate records in the dossier (Annex IX and above)

- Must be reported in IUCLID section 5.2.2:
  - 1 record with endpoint *simulation testing on ultimate degradation in surface water*
  - 1 record with endpoint *sediment simulation testing*

- Endpoint study records must be indicated either as key study, weight of evidence, data waiving or experimental study planned

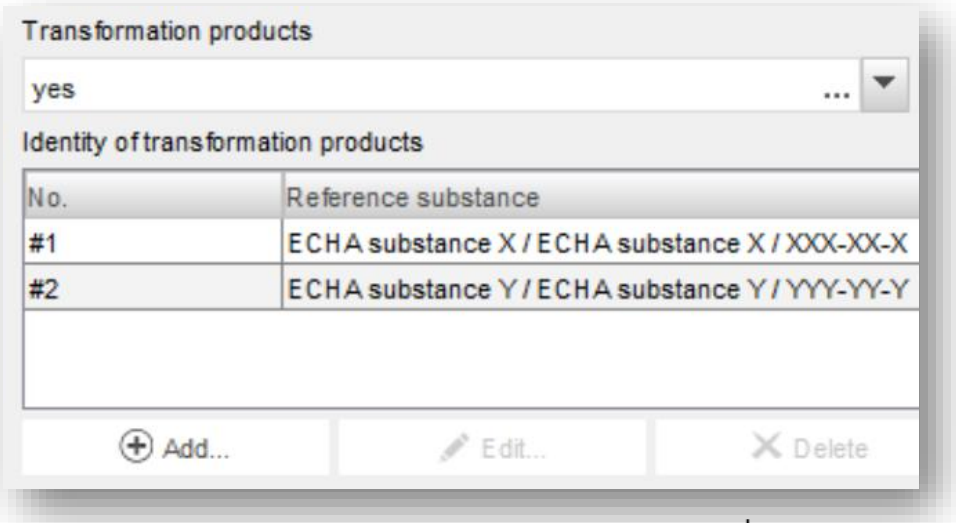
- Principle applies for all endpoints that follow

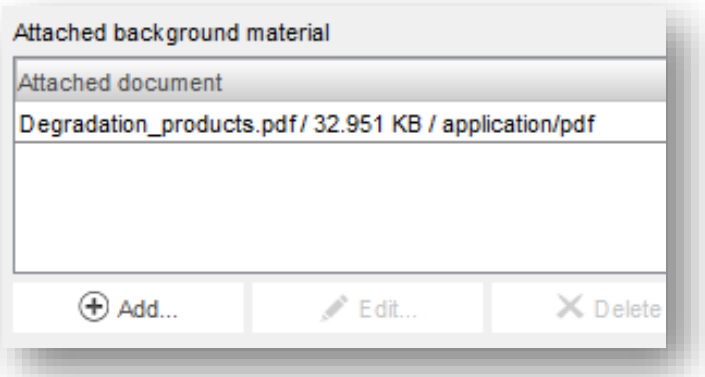
Degradation (2/3)



Degradation (3/3)

- REACH 9.2.3: Endpoint *identification of degradation products* must be explicitly addressed (Annex IX and above)
  - Make a selection in the field 'Transformation products'
  - Select 'yes' and link reference substances identified with EC number, CAS number and/or IUPAC name. If not available, a spectrum or analytical information can be attached under 'Attached background material' heading

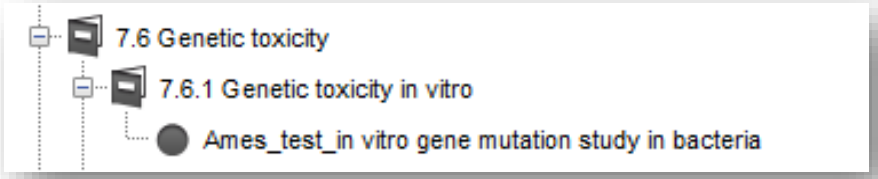


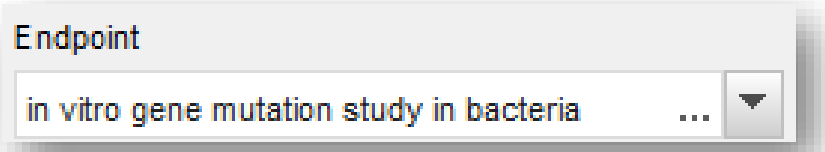


Mutagenicity (1/3)

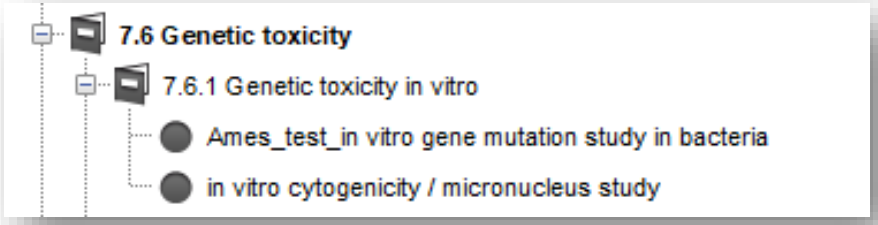
- REACH 8.4.1: Endpoint *in vitro gene mutation study in bacteria* is addressed (Annex VII and above)
- REACH 8.4.2: At least one of the endpoints *in vitro cytogenicity/chromosome aberration study in mammalian cells* or *in vitro cytogenicity/micronucleus study* is addressed (Annex VIII and above)

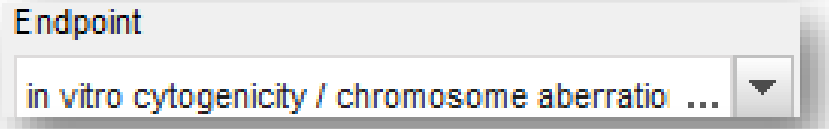
Annex VII

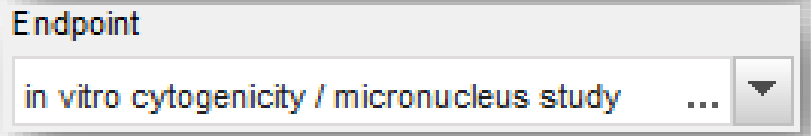




Annex VIII



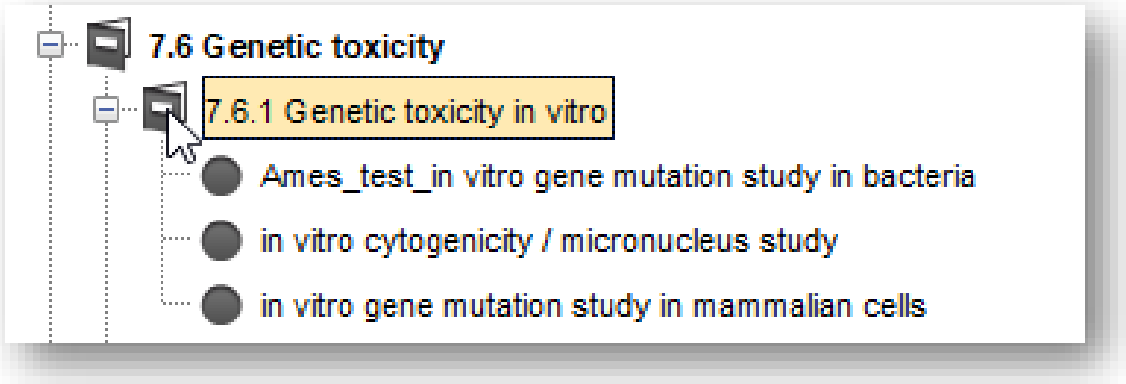




Mutagenicity (2/3)

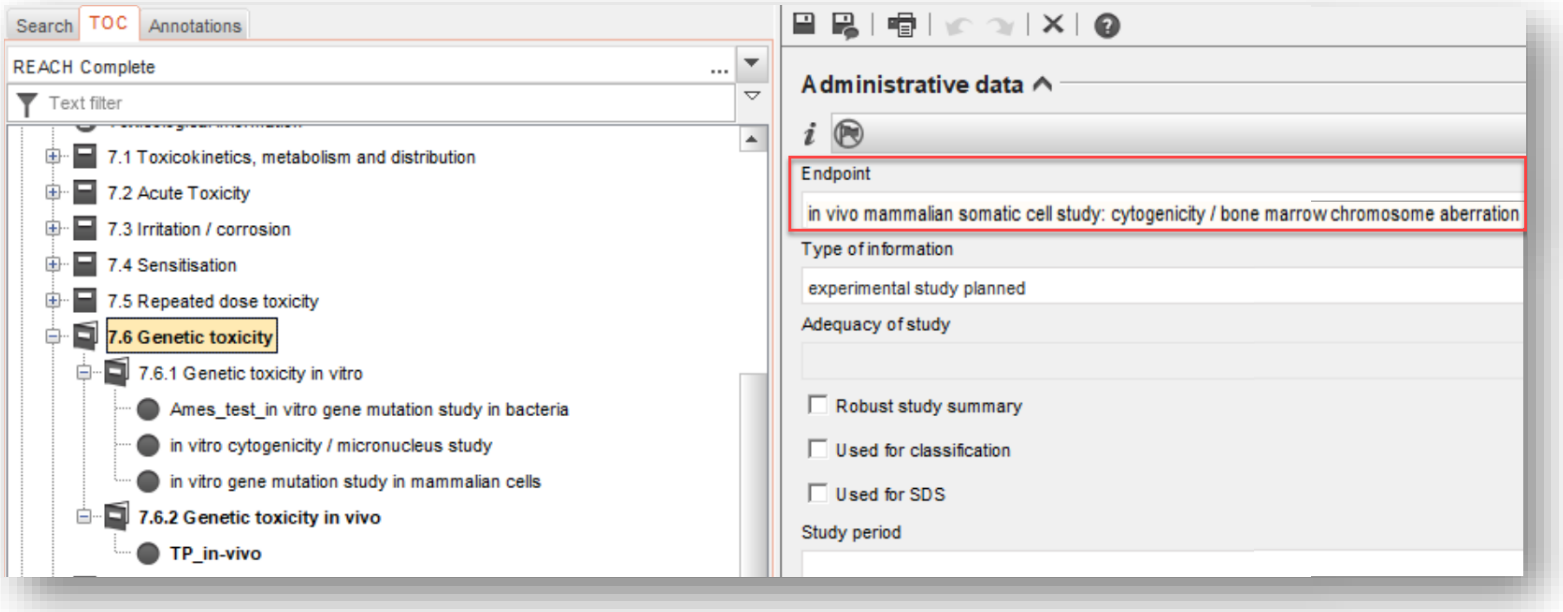
- REACH 8.4.3: Endpoint *in vitro gene mutation study in mammalian cells* is addressed (Annex VIII and above). Requirement can be addressed with a standard waiving if there are positive results in studies required by 8.4.1 and 8.4.2

Annex VIII



Mutagenicity (3/3)

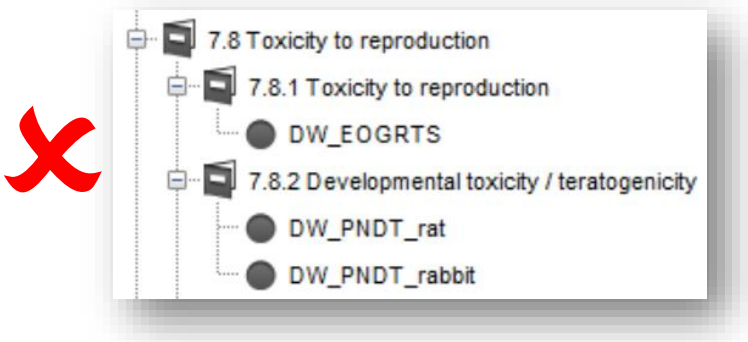
- REACH 8.4: At least one endpoint for *in vivo* genotoxicity is addressed in case of a positive result in any of the genotoxicity studies required by 8.4.1, 8.4.2 and 8.4.3 (Annex VIII and above)

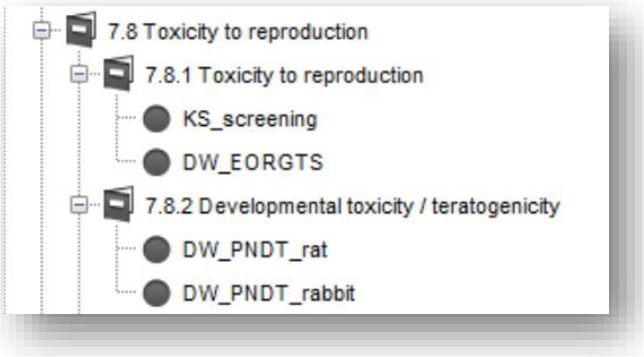


Reproductive toxicity (1/3)

- REACH 8.7: Data waiving of reproductive toxicity endpoints must follow appropriate Annex provisions

- If all higher tier studies are waived, screening study must be addressed (Annex IX and above)





Reproductive toxicity (2/3)

- REACH 8.7.3 Annex IX Column 1 adaptation for waiving extended one-generation reproductive toxicity study:

  Extended one-generation reproductive toxicity study does not need to be conducted because there are no results from available repeated dose toxicity studies that indicate adverse effects on reproductive organs or tissues, or reveal other concerns in relation with reproductive toxicity

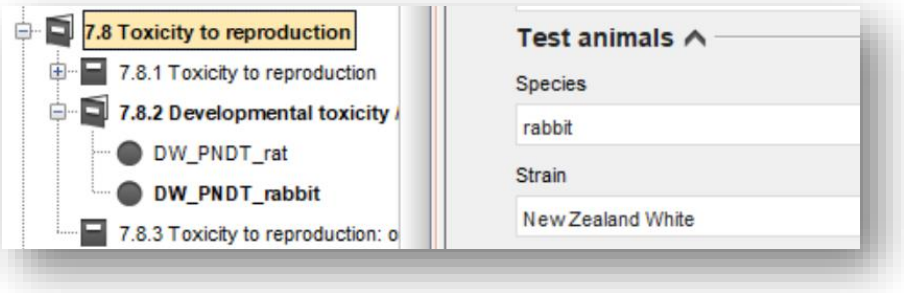
  Conditions

  ✓ Annex IX only, **not Annex X**

  ✓ Repeated dose toxicity studies must be reported in IUCLID dossier

Reproductive toxicity (3/3)

- REACH 8.7.2: Endpoint *developmental toxicity* must be addressed with a different species than at Annex IX (Annex X)
- Applies to endpoint study record indicated either as key study, weight of evidence, data waiving or experimental study planned



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Completeness check of the chemical safety report: what is covered

Webinar: Revised completeness check: what changes and how you can prepare

29 January 2020

Valérie Lasseigne-Phrakonkham

Background

- REACH Article 10(b) requires that a chemical safety report is provided when required under Article 14, in the format specified in Annex I
- So far, content of chemical safety report has remained outside scope of completeness check
- With experience gained in performing manual completeness checks, we are now ready to extend checks to content of the chemical safety report
- With this improvement, we can better fulfil our obligation to ensure that all required elements are included in the registration dossier

Chemical safety report

Completeness check

- Revised completeness check includes a **content check** of the chemical safety report
- Completeness of exposure assessment and risk characterisation checked
- Checks will be done **manually** by us based on standard instructions

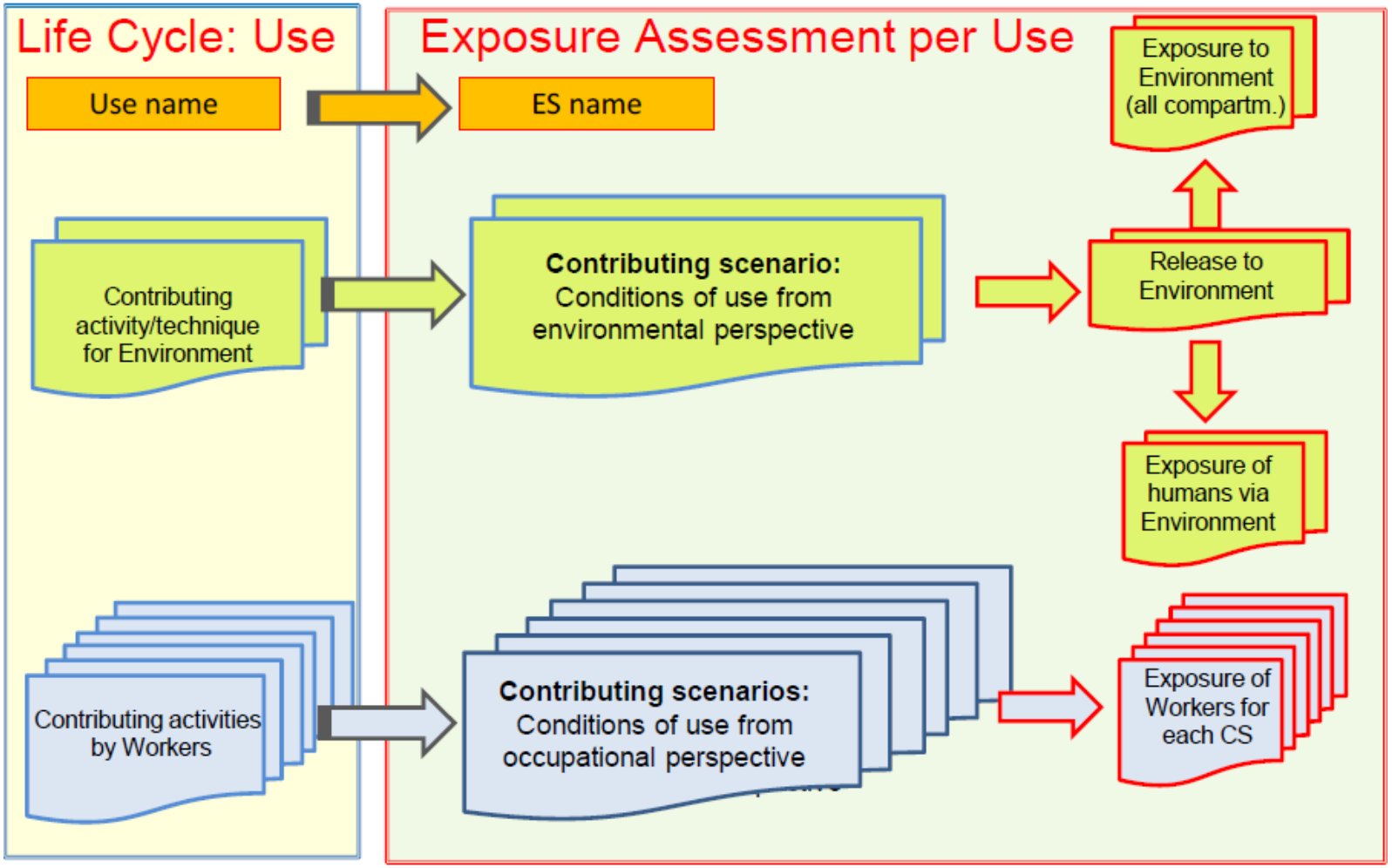
Checked manually during completeness check

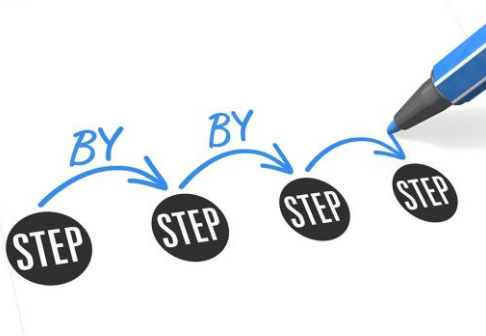
Chemical safety report

When is it checked?

- If registration tonnage is above 10 tonnes per year
- If registrant has classified the substance as hazardous or reported as fulfilling PBT criteria
- If chemical safety report is provided in the dossier (members relying on the joint chemical safety report are not checked)
- If chemical safety report cannot be opened or is not written in EU language, it will be considered incomplete

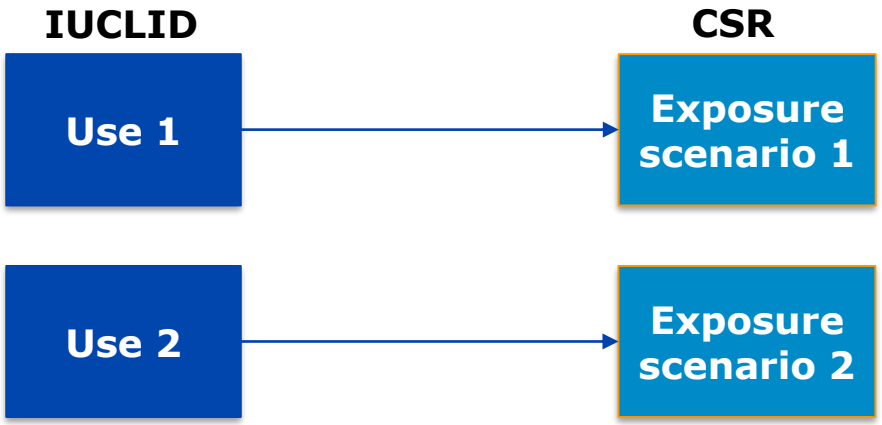
Use – conditions of use - exposure

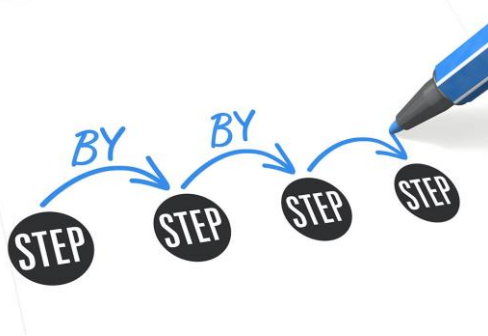




Uses ⇔ exposure scenarios

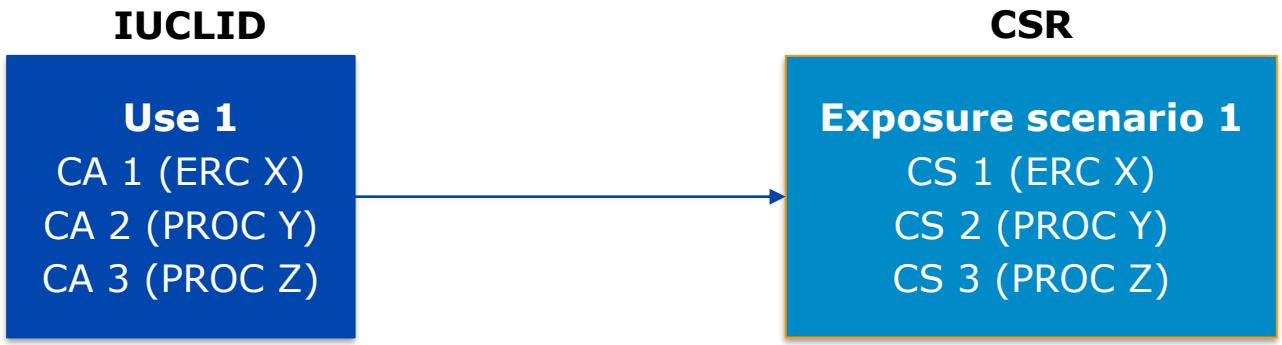
- For all uses reported in the IUCLID dossier, chemical safety report must contain corresponding exposure scenarios (unless explicitly exempted from exposure assessment)
- Exceptionally, several uses can be covered by one exposure scenario if clearly recorded (e.g. in the title of the exposure scenario)





Contributing scenarios

- Exposure scenarios must contain contributing scenarios
- Contributing scenarios must correspond to contributing activities reported in use descriptions:
  - Environment: Environmental release type (ERC)
  - Workers: Process/activity name (PROC)
  - Consumers: Article type (AC) and/or product type (PC)



Contributing scenarios

Required elements

- Conditions of use
  - Operational conditions
  - Risk management measures

- If DNEL/PNEC have been derived
  - Exposure estimates for all relevant routes/compartments
  - Risk characterisation ratio for all individual routes of exposure
  - Risk characterisation ratio for combined routes

- For high hazard substances without DNEL/PNEC derived
  - Exposure estimates for all relevant routes/compartments

Contributing scenarios

Conditions of use

- Contributing scenarios must contain:
  - Operational conditions and risk management measures should typically contain the following information

Core condition of use	Work	Cons	Env
Physical form of substance at use	x	x	
Concentration in chemical applied	x	x	
Frequency and duration of use	x	x	x
Amount per use [per day]		x	x
Dermal contact area (body part in contact)		x	
Room ventilation conditions	x	x	
Emission factors to water and air			x
(Local exhaust ventilation or other engineering controls)	x		
(Goggles, respirator, gloves with specifications)	x		
(Onsite emission controls)			x

Contributing scenarios

Environmental exposure

- Contributing scenarios must refer to reported PNECs, and following information is expected:
  - Exposure estimates for all relevant compartments
  - Risk characterisation ratios for all relevant compartments
  - Local scenarios and combined exposure for region
- If substance has a chronic environmental classification, exposure estimates always expected

Protection target
Freshwater
Sediment (freshwater)
Marine water
Sediment (marine water)
Sewage Treatment Plant
Air
Agricultural soil
Predator's prey (freshwater)
Predator's prey (marine water)
Top predator's prey (marine water)
Predator's prey (terrestrial)

Contributing scenarios

Humans exposed via environment

- Contributing scenarios must refer to reported DNELs (general population)
  - Exposure estimates for oral and inhalation route
  - Risk characterisation ratios for combined routes

- Man via environment required:
  - tonnage is above 1000 tpa, or
  - tonnage >100 tpa and substance classified as:
    - STOT RE 1, or
    - carcinogen or mutagen (any category), or
    - toxic to reproduction (categories 1A or 1B)

Protection target
Man via environment - Inhalation
Man via environment - Oral
Man via environment - Combined routes

Contributing scenarios

Direct human exposure

- Contributing scenarios must refer to reported DNELs/DMELs, and following information expected:
  - Exposure estimates for all relevant routes
  - Risk characterisation ratios for individual and combined routes
- If substance has a classification for severe chronic effects on human health, exposure estimates always expected

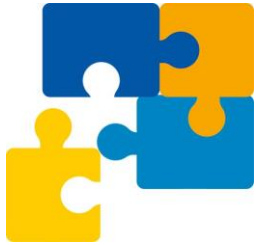
Route	Type of effect
Inhalation	Systemic effects - Long-term
Inhalation	Systemic effects - Acute
Inhalation	Local effects - Long-term
Inhalation	Local effects - Acute
Dermal	Systemic effects - Long-term
Dermal	Systemic effects - Acute
Dermal	Local effects - Long-term
Dermal	Local effects - Acute
Oral	Systemic effects - Long-term
Oral	Systemic effects - Acute
Eyes	Local effects

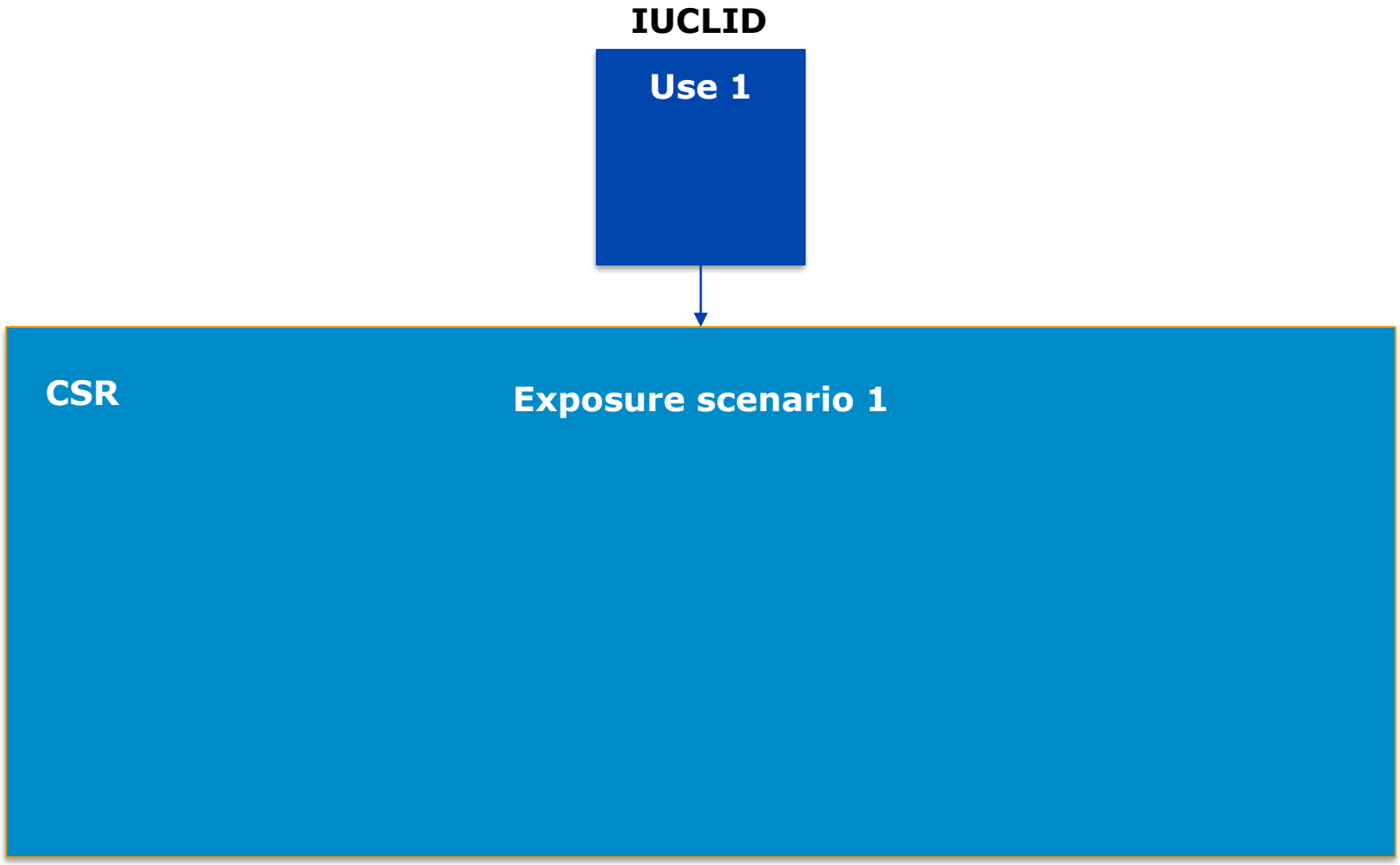
Absence of information

Justifications

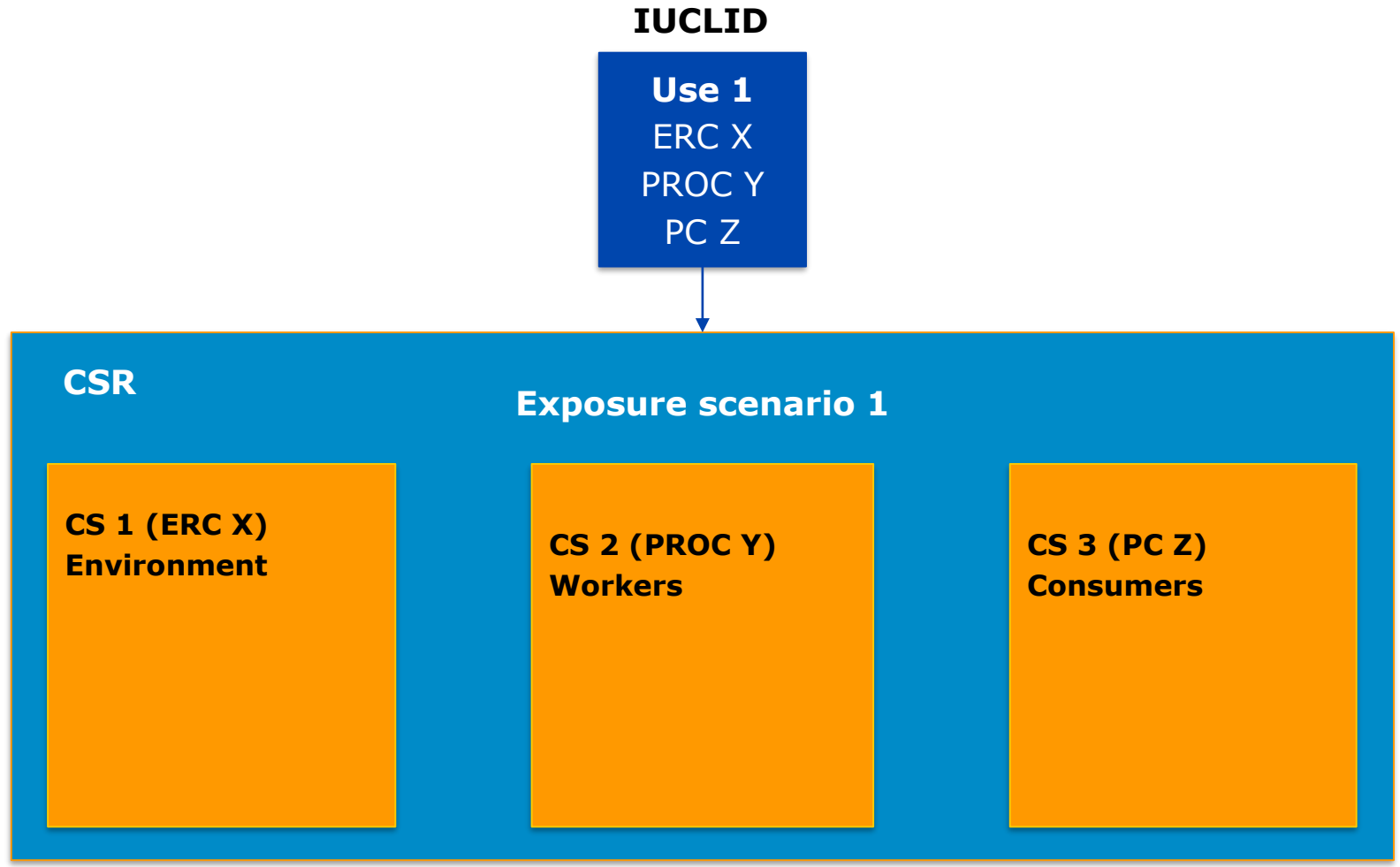
- If one of the expected information is not found, presence of a relevant justification will be checked
- If a relevant justification is not found, it will lead to incompleteness of chemical safety report
- As per Article 20(2), quality or adequacy of justifications will not be checked
- Examples later in the presentation

Summary of required elements

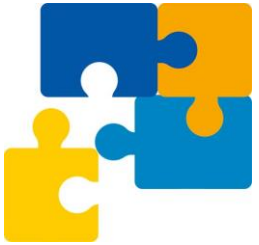


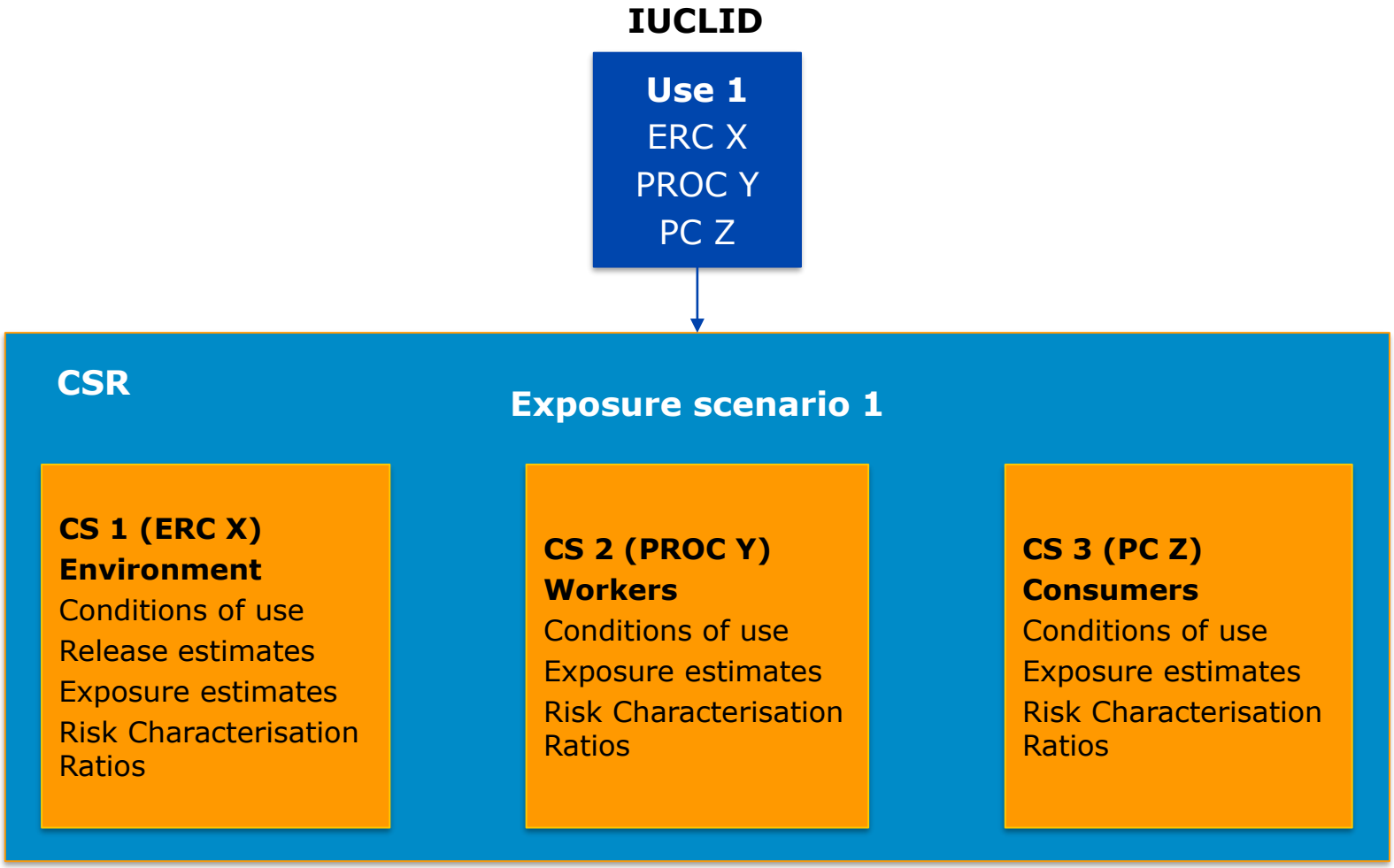


Summary of required elements



Summary of required elements





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Practical advice: ensuring a complete chemical safety report

Webinar: Revised completeness check: what changes and how you can prepare

29 January 2020

Soile NIEMI, ECHA
Andreas AHRENS, ECHA

Own or joint chemical safety report?

Lead registrants

- All uses reported in IUCLID dossier are expected to be assessed in the chemical safety report (CSR)

- Lead with own CSR
  - Include only your own uses in your IUCLID dossier

- Lead with joint CSR
  - Include all your own uses and the uses covered by the joint CSR in your IUCLID dossier
  - Indicate in the dossier header that you provide the CSR on behalf of the joint submission
  - If you cover (some) own uses in a separate own CSR, clarify in IUCLID section 3.5 with the 'Related assessment' field

Member registrants

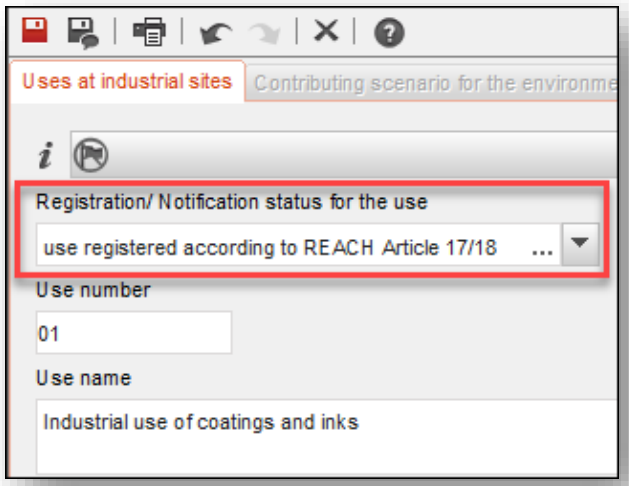
- Member with own CSR
  - Include only your own uses in your IUCLID dossier
  - Make sure that your CSR covers all the uses reported in your dossier

- Member relying on joint CSR
  - Indicate in the dossier header that the lead provides the CSR on behalf of the joint submission
  - In this case the CSR will not be checked as part of your submission but as part of the lead submission

Uses that need assessment

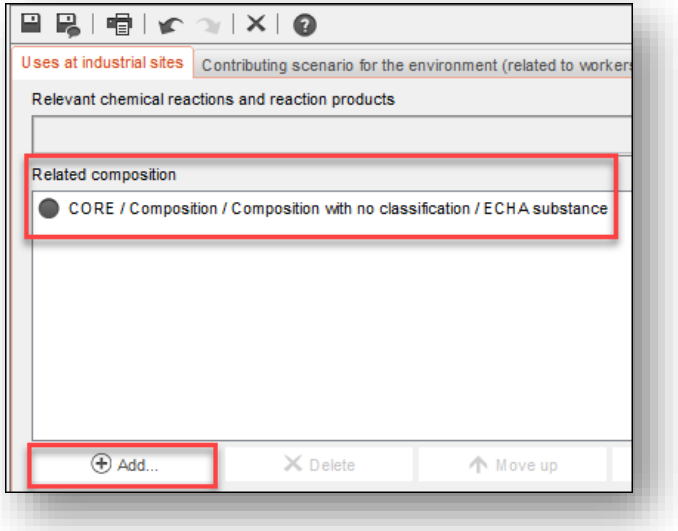
Art 10 or Art 17/18 use?

- Only Art 10 uses require a chemical safety assessment
- Normally Art 17/18 uses are reported in an intermediate registration which is not in the scope of the chemical safety assessment
- If your registration covers uses that fall under both Art 10 and Art 17/18, make sure that you clearly indicate the type for each use
- If there is no indication of the type of use, we consider that the use requires an exposure scenario



Classification

- If the substance is classified or fulfils PBT criteria, an exposure assessment is needed
- If your registration covers different compositions, make sure to link them with relevant classification and use records
- If there is no indication of links between compositions, classifications and uses, we assume all uses correspond to the highest classification of the substance



Examples of chemical safety report structures

Chesar structure

- With Chesar you can generate a CSR that contains all the required elements
- Chesar enables to:
  - Perform chemical safety assessment (CSA) with standard workflow/harmonised format
  - Create and update CSR automatically from the CSA
  - Ensure consistency between the IUCLID dossier and the CSR
  - Ensure consistency between CSRs and exposure scenarios communicated to downstream users

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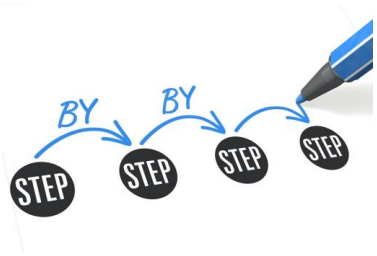
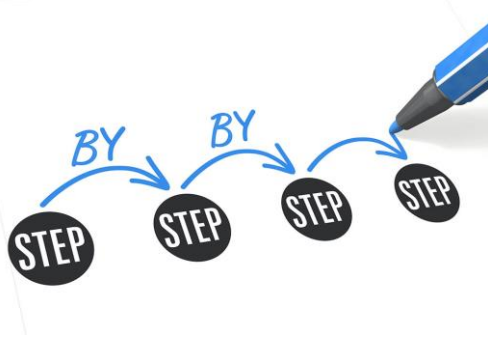


Example of Chesar CSR

9.4. Exposure scenario 4: Widespread use by professional workers - Professional painting

Market sector: Coatings and Inks
Product category used: PC 9a: Coatings and Paints, Thinners, paint removers

Environment contributing scenario(s):		
CS 1	Use leading to inclusion into/onto matrix	ERC 8f
Worker contributing scenario(s):		
CS 2	Transfer of substance or mixture (charging/discharging) at non dedicated-facilities	PROC 8a
CS 3	Roller application or brushing	PROC 10
CS 4	Spraying	PROC 11



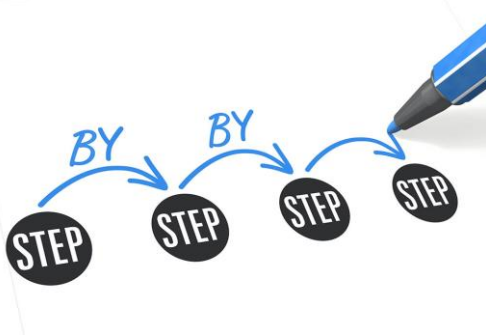
Example of Chesar CSR

9.4. Exposure scenario 4: Widespread … workers - Professional painting

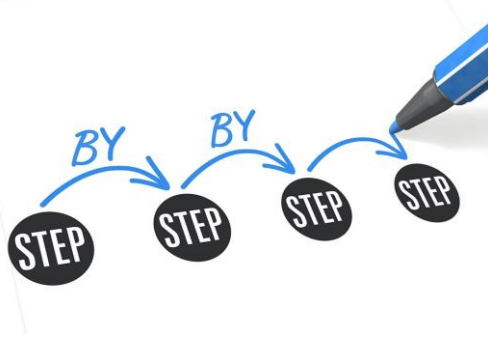
Market sector: Coatings and Inks
Product category used: PC 9a: Coatings and Paints, Thinners, …

Environment contributing scenario(s):		
CS 1	Use leading to inclusion into/onto matrix …	
Worker contributing scenario(s):		
CS 2	Transfer of substance or mixture (charging/discharging) at non dedicated-facilities	PROC 8a
CS 3	Roller application or brushing	PROC 10
CS 4	Spraying	PROC 11

Chesar ensures that exposure scenarios and contributing scenarios correspond to use description in IUCLID when the synchronisation is used

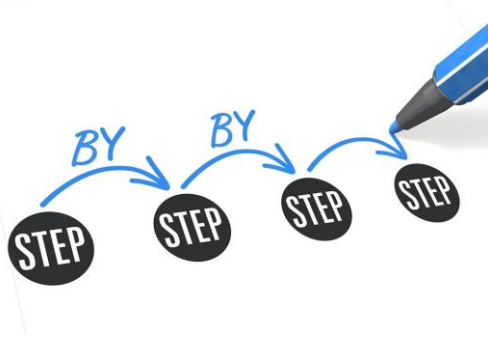


Example of Chesar CSR



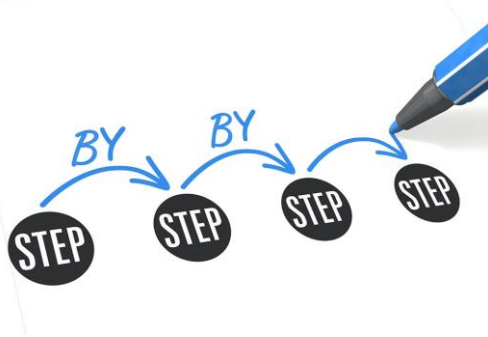
Example of Chesar CSR

Exposure assessment will contain all required elements for a complete CSR



Example of Chesar CSR

	Method
Product (Article) characteristics	
• Percentage (w/w) of substance in mixture/article: <= 2.0 %	TRA Workers 3.0
• Physical form of the used product: Liquid	TRA Workers 3.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8.0 h/day	TRA Workers 3.0
Technical and organisational conditions and measures	
• Local exhaust ventilation: No [Effectiveness Inhalation: 0%, Dermal: 0%]	TRA Workers 3.0
• General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%]	TRA Workers 3.0
• Occupational Health and Safety Management System: Advanced	TRA Workers 3.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal protection: No [Effectiveness Dermal: 0%]	TRA Workers 3.0
• Respiratory Protection: No [Effectiveness Inhalation: 0%]	TRA Workers 3.0
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers 3.0
• Operating temperature: <= 40.0 °C	TRA Workers 3.0



Example of Chesar CSR

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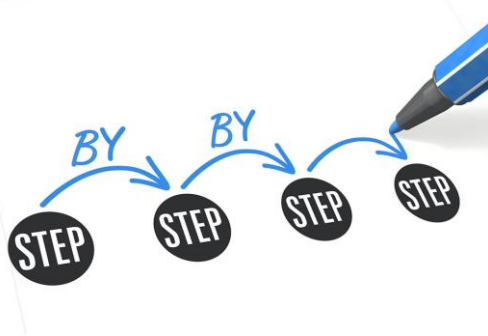
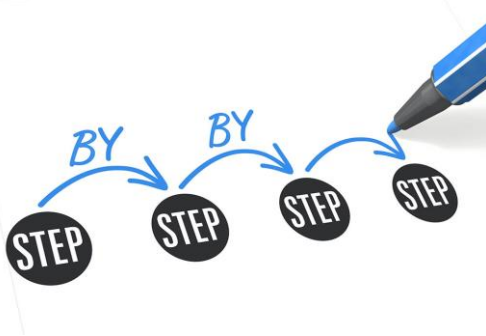
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers 3.0
• Operating temperature: <= 40.0 °C	TRA Workers 3.0

Core conditions of use are pre-defined in Chesar to support completeness and harmonisation



Example of Chesar CSR

Protection target	Exposure concentration	Risk quantification
Fresh water	**Local PEC:** 7.4E-3 mg/L	RCR = 0.718
Sediment (freshwater)	**Local PEC:** 0.601 mg/kg dw	RCR = 0.718
Marine water	**Local PEC:** 7.4E-4 mg/L	RCR = 0.718
Sediment (marine water)	**Local PEC:** 0.06 mg/kg dw	RCR = 0.718
Sewage Treatment Plant	**Local PEC:** 0.074 mg/L	RCR = 0.05
Agricultural soil	**Local PEC:** 0.029 mg/kg dw	RCR = 0.182
Man via environment - Inhalation	**Concentration in air:** 3.43E-4 mg/m³	RCR < 0.01
Man via environment - Oral	**Exposure via food consumption:** 0.043 mg/kg bw/day	RCR = 0.012
Man via environment - combined routes		RCR = 0.012



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Man via environment - combined routes		RCR = 0.012

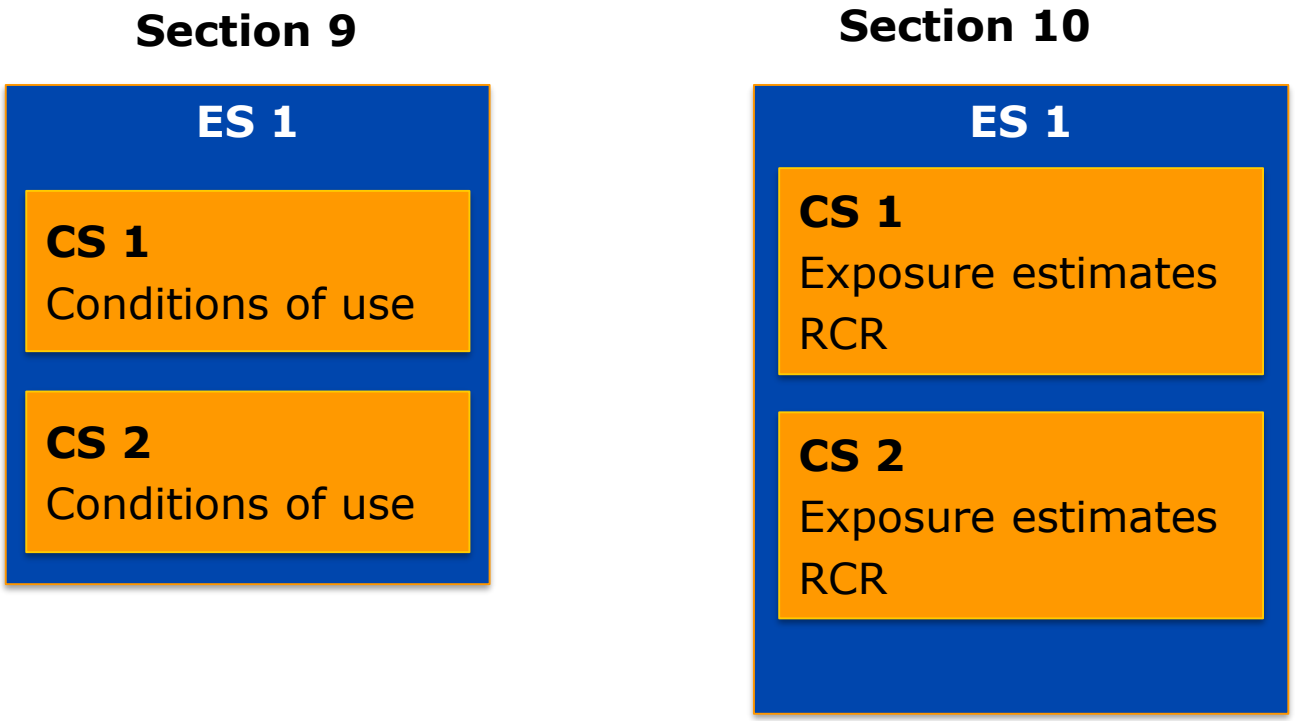
Exposure estimates and RCR will cover all routes where PNEC or DNEL has been reported

Other CSR structures

- Your CSR does not have to be prepared with Chesar – any structure is accepted if:
  - It contains the required elements defined in Annex I
  - We can clearly identify which use and activity is related to which set of use conditions, exposure estimates and risk characterisation
  - Omissions/waivers are justified with a fully substantiated justification

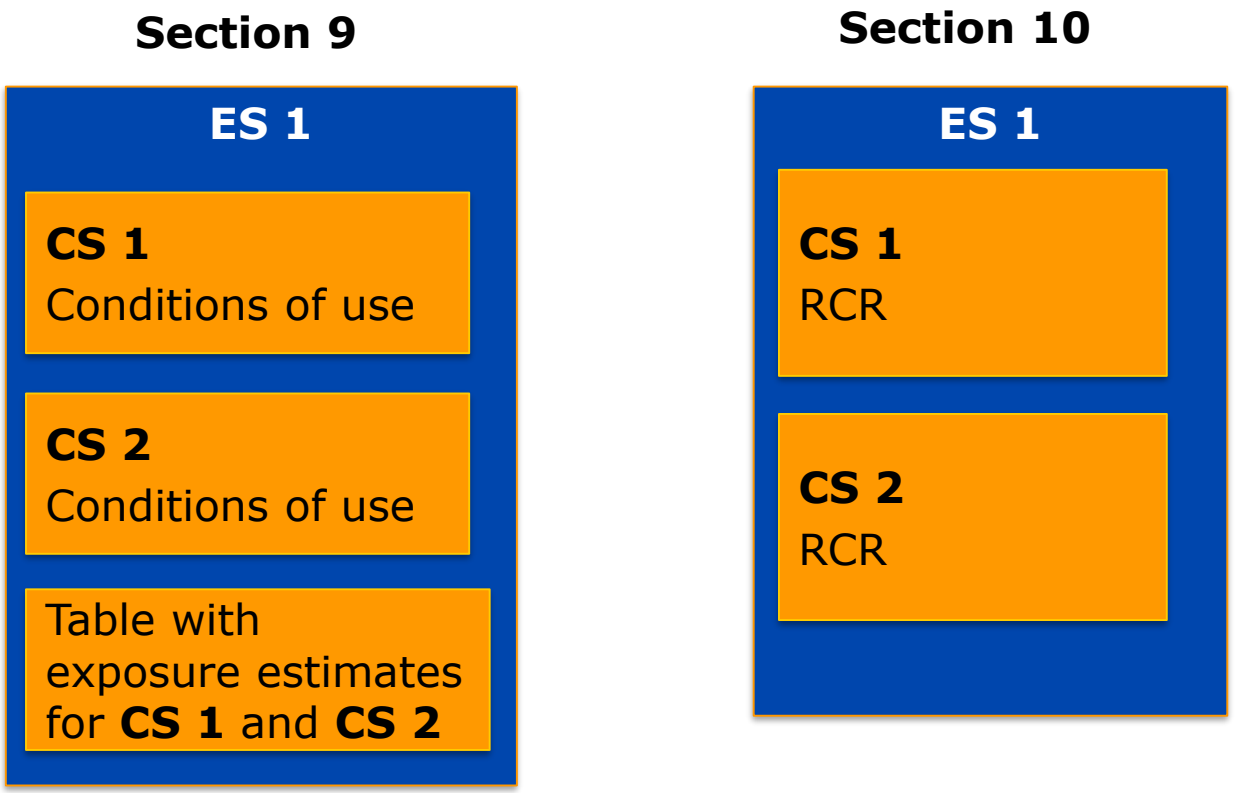
Other CSR structures

Example 1



Other CSR structures

Example 2



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Common shortcomings

No CSR, based on Art 14(2)

- Often justification is incomplete
- Conditions to be fulfilled:
  - Substance in mixture (2 conditions)
    - imported mixture
    - substance concentration is below cut-off values as set in Annex I to the CLP regulation [< 0.1%; 0.1%; 1%; depending on hazard profile]
  - Monomer in polymer (3 conditions)
    - polymer imported as such
    - residual monomer concentration is below the cut-off values as set in Annex I to the CLP regulation
    - demonstration that monomer cannot be formed back during the life cycle of the polymer

Use description

- All life cycle stages to be addressed, including article service life
- We expect to see a clear relation between:
  - Uses and contributing activities reported in IUCLID

    and
  - Exposure scenarios, contributing scenarios, exposure estimates and RCR reported in CSR
- Clean up use descriptions and make sure they are synchronised with the CSR. This may require some interaction between lead and members
- Note: If your use description was ambiguous or inconsistent in IUCLID 5, the migration to IUCLID 6 may have created issues to be cleaned

Substance “disappears”, no assessment needed

- If your substance reacts on use or in contact with water/air, the need and scope for an exposure assessment will depend on:
  - Speed of the reaction
  - Hazardousness of the reaction product

➡ These factors must be demonstrated in the justification if the assessment is waived

(No) Hazard identified

- Within an assessment, DNEL/PNECs (to extent available) drive the scope of the assessment, not the presence/absence of classification
  - Absence of environmental classification is no relevant reason to waive the environmental assessment part

- When you report a DNEL or PNEC in IUCLID, ECHA interprets this as “hazard identified”, and hence exposure estimates required
  - Thus, do not report a PNECs/DNELs when ‘no effect was observed’ at limit dose. The correct entry in IUCLID would be “No hazard identified”

High hazards without threshold

- For substances with certain high systemic hazard (Carc., Muta., Resp. sens.), often no quantitative hazard conclusions (DNEL , DMEL) can be derived
- This is however no justification for omitting exposure quantification
- Exposure estimates are still expected, as they indicate how “closed” the handling in closed system is in practice

Man via the environment

- Assessment "forgotten" for substances for which
  - no environmental hazard has been identified
  - no consumer uses exists (and hence no DNELs for general population have been derived)
  - the current EUSES does not support reasonable exposure estimates
- Assessment can be waived only when:
  - tonnage < 100 tpa, or
  - the tonnage < 1000 tpa and the substance is not classified as:
    - STOT RE 1, or
    - carcinogen or mutagen (any category), or
    - toxic to reproduction (categories 1A or 1B

Secondary poisoning

- Sometimes a proper reasoning for not addressing secondary poisoning is missing
- Do this in the IUCLID section 6 endpoint summary:
  - "no potential for bioaccumulation" – for instance if log Kow <3 and if there is no other evidence of accumulation potential
  - "no potential to cause toxic effects if accumulated (in higher organisms) via the food chain" – if no indication of reproductive toxicity or toxicity after prolonged exposure on the basis of mammalian toxicity data

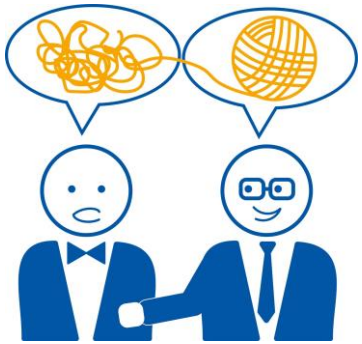
No release

- Exposure assessment fully or partly skipped with the argument that no relevant releases from the use are to be expected (often for article service life)

- Such reasoning is usually incomplete because:
  - It does not demonstrate/explain how the conditions of use lead to “no relevant release” (exposure scenario)
  - It does not quantify what “relevant” means. Is the release zero, or is the release small (compared to a relevant benchmark)

Support

Support



- Updated IUCLID validation assistant allows companies to detect failures in computer-based rules before submitting their dossiers to us
- For completeness of CSR, various types of support foreseen:
  - Chesar supports completeness of CSRs and consistency between IUCLID data and CSR; the tool is increasingly used by registrants
  - Webinars and written support material will be available; proactive company support will be put in place (phone calls, emails)
  - Use our contact form for any further questions

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Conclusions

Webinar: Revised completeness check: what changes and how you can prepare

29 January 2020

Robert LUCAS, ECHA

Conclusions on TCC revision

- Enters into force end of April, on new registrations and updates of existing registrations
- Ensures specific requirements are addressed for key hazard endpoints
- Verifies that a complete CSR is provided when required
- REACH requirements are unchanged
- Support is available via different channels

Take home messages

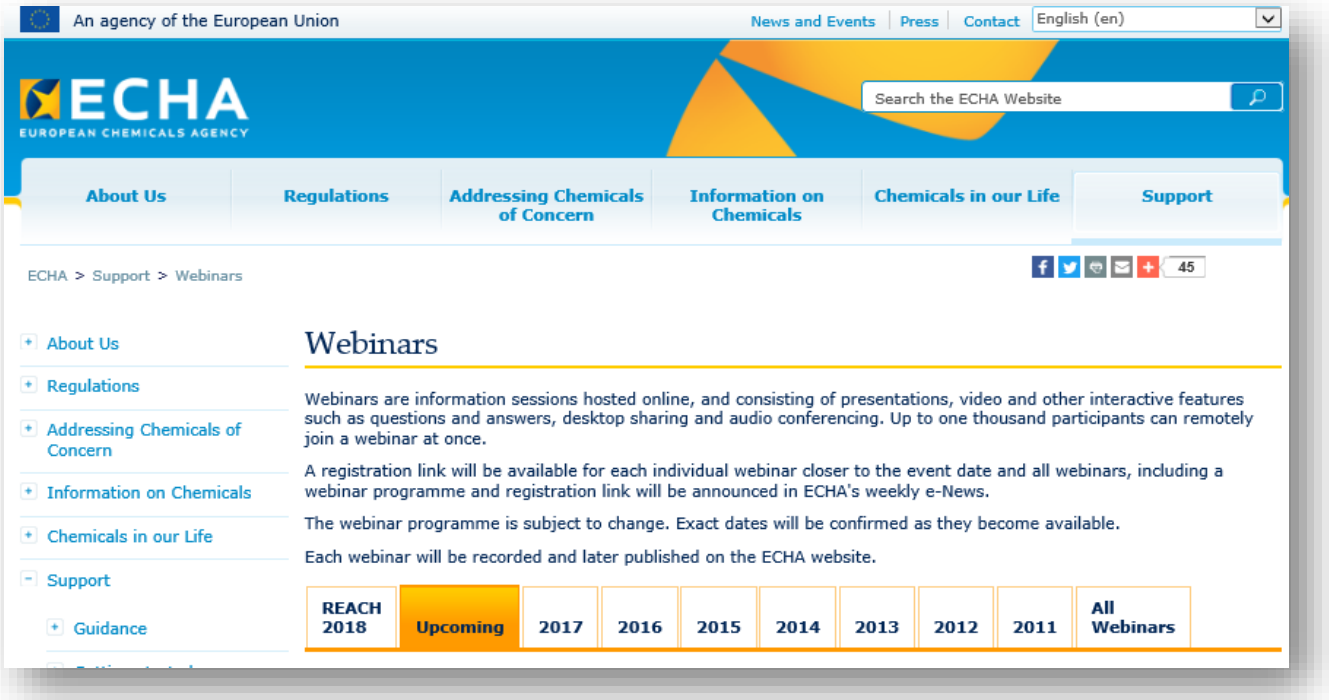
- Get familiar with the changes in the completeness check already now – avoid issues during submission

- Make use of the support material and tools:
  - IT tools
  - webinar
  - written support

- Contact us via the contact form

Material published

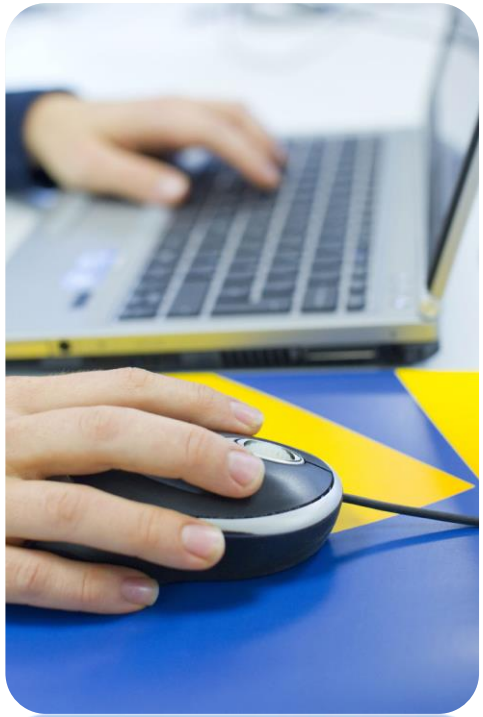
- Video recording, presentations and Q&A: echa.europa.eu/support/training-material/webinars



Q&A panel

- Webinar open until **13:00 Helsinki time** to answer questions

- If your question is not answered by the end of the webinar, send it via our contact form: echa.europa.eu/contact



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