The importance of substance identity in ensuring a successful registration

Ninth Stakeholders' Day

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Key messages

- You need to know the identity of your substance
- You need to be able to express your substance identity in REACH language
  - For authorities
  - For your potential co-registrants
- ECHA provides support
  - Webinars to get basic understanding
  - Documents of varying detail to guide you through your substance identification
  - Validation Assistant to check substance identity information in your dossier
- ECHA takes large-scale actions to improve substance identification in the registrations

Why correct and unambiguous substance identification is important

- What do I manufacture /import?
- What are my obligations under REACH?
- Can two (or more) of my substances be regarded as the same?
- Is there a (pre)SIEF for my substance? Can I register jointly?
- Can I share existing data with other registrants?
- Is my substance concerned by other regulatory processes (e.g. harmonised classification & labelling, Candidate List for substances of very high concern, etc.)?

The information on substance identity must:

- Be submitted individually by each registrant
- Be specific to the substance actually manufactured/imported by the registrant
- Allow unambiguous identification of the substance
- Be supported by qualitative and quantitative analytical data
- Be consistent throughout the registration

How to identify your substance?

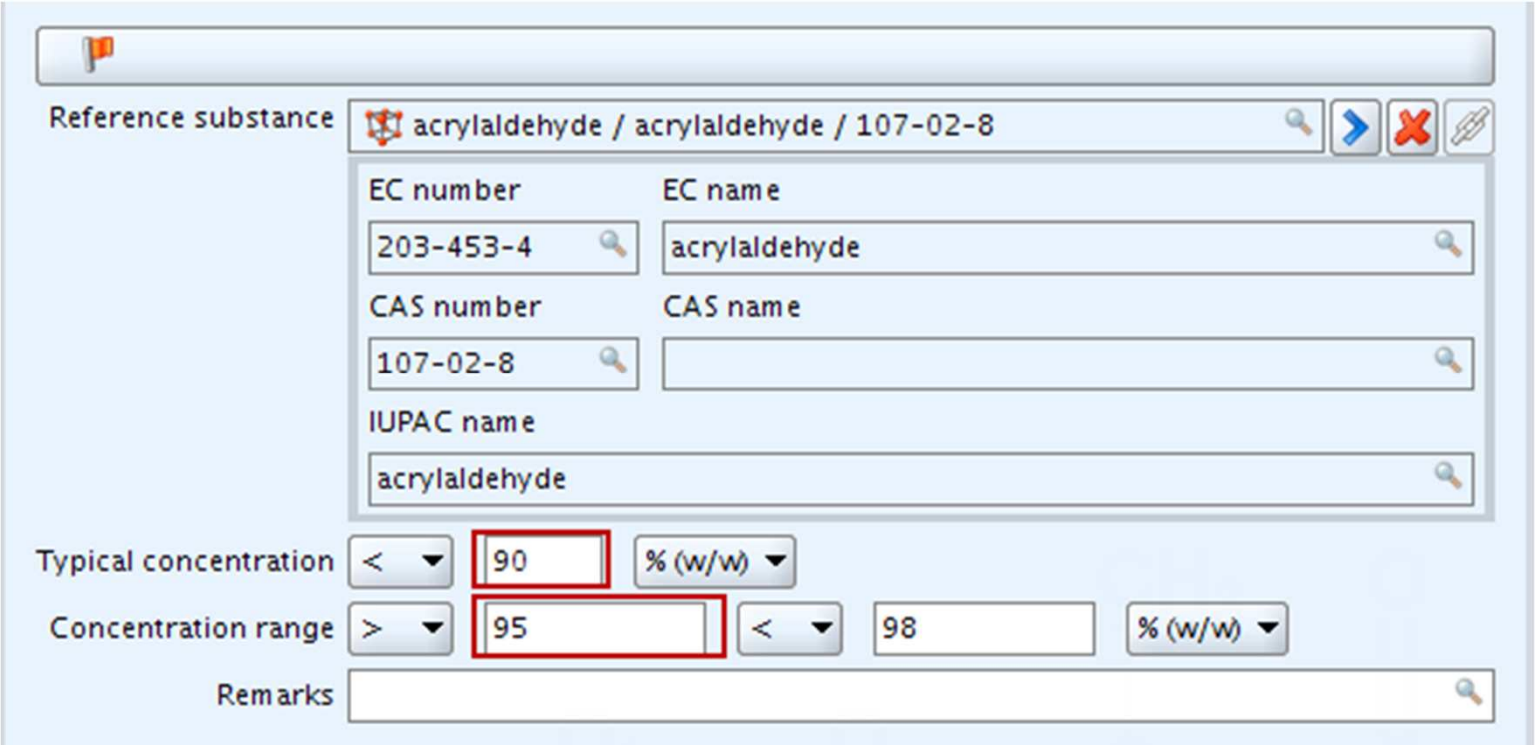
Steps to be considered

- Identify the type of your substance based on its composition:
  - Well-defined (mono/multiconstituent);
  - Substance of unknown or variable composition, (UVCB);
- Provide all necessary information as defined in Annex VI of REACH:
  - Identifiers: Chemical/IUPAC name, CAS, EC numbers (if available and appropriate) etc.
  - Information on molecular and structural formula
  - Composition
  - Spectral and analytical data, description of methods.

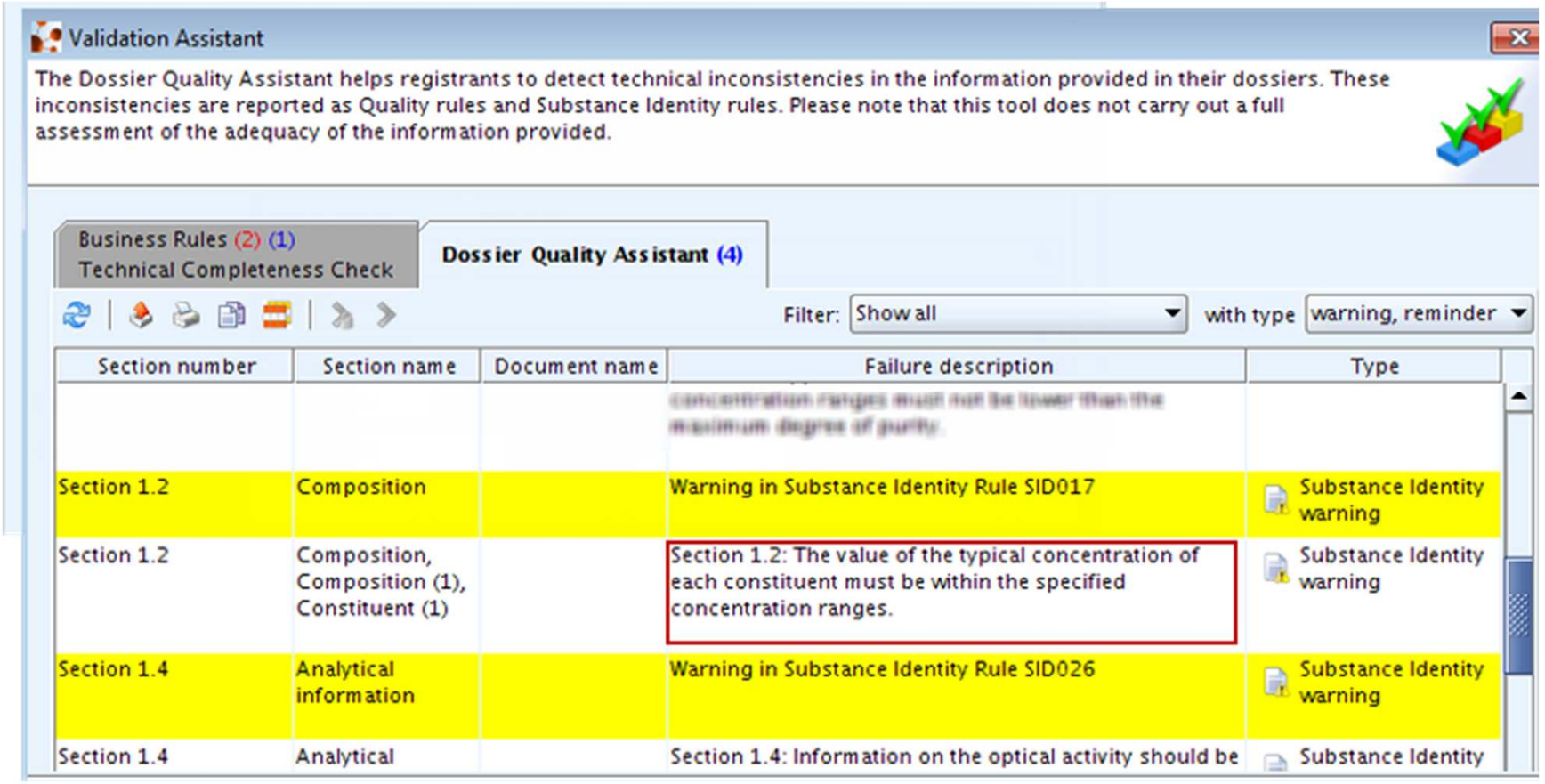
Validation Assistant

- Two tools in one:
  - Technical Completeness Check, including check of Business Rules
  - Dossier Quality Assistant
- Can be used for verifying dossiers before submission
- Dossier Quality Assistant:
  - Contains substance identification rules in line with the Guidance on substance identification
  - Supports registrants to improve the quality of their registrations
  - Identifies substance identity shortcomings

Validation Assistant - example



Validation Assistant - example



Support available on the ECHA website

- Webinars (http://echa.europa.eu/support/training-material/webinars)
- Documents (http://echa.europa.eu/support)
  - Guidance for identification and naming of substances under REACH and CLP
  - Data Submission Manual Part 18 – "How to report the substance identity in IUCLID 5 for registration under REACH"
  - Evaluation under REACH - Progress report 2013
- ECHA pages "How to improve your dossier"

ECHA activities to improve substance identification in the registrations

Substance identification issues need to be tackled in dossier evaluation

- Substance identification is the starting point of the dossier evaluation process
  - Verifies whether only one substance is covered by the registration being evaluated
  - Enables proper assessment of hazard data
  - Allows evaluation of read-across justifications
  - Facilitates effective decision making for further risk management
- Substance identity is a frequent shortcoming observed in registration dossiers
- Decisions on substance identity may affect the joint registration

Letter campaigns

- Systematic screening of all registration dossiers
- Scenarios are based on similar rules as those available in the Dossier Quality Assistant
- Efficient and effective way to address potential substance identification issues
- First step before more severe actions (compliance checks) are taken
- Specific shortcomings are addressed, e.g.
    - Insufficient information
    - Inconsistencies
- Campaign launched in April 2014

Informative letters to the members of joint submissions

- Since 2013, co-registrants are informed whenever a draft decision on substance identification is sent to any member of the joint submission
- To encourage joint submission members to:
  - swiftly contact the lead registrant, and
  - check whether the decision may affect their own registration
- The letter does not specify the aspects covered by the draft decision, but aims to alert the co-registrants

So before you submit…

- Double-check information on the identity of substance(s) you manufacture/import
- Verify whether you are in the right SIEF
- Provide consistent and unambiguous information in your dossier
- Avoid generic identifiers, which do not specifically correspond to your substance
- Make sure that your dossier does not cover multiple substances
- Provide relevant explanations for any information
- Appropriately justify any deviation from standard data requirements
- Run the Validation Assistant before submission

Thank you

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