

Making Your Registration Successful

Top 10 Business Rules Failures

08. 09. 2010

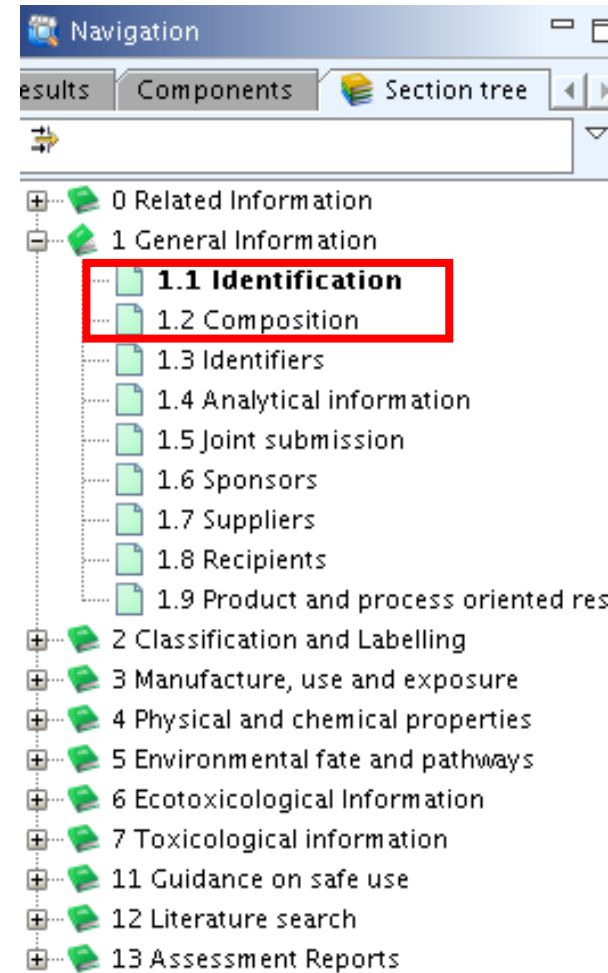
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ECHA – Registration and Dossier Submission Unit

Agenda

- Substance Identification – **BR020, BR019, BR090**
- Change of Tonnage Band – **BR082**
- Joint Submission – *BR027, BR063, BR091*
- Initial and Update Submission – *BR033, BR038*
- Legal Entity Inconsistency – *BR131*

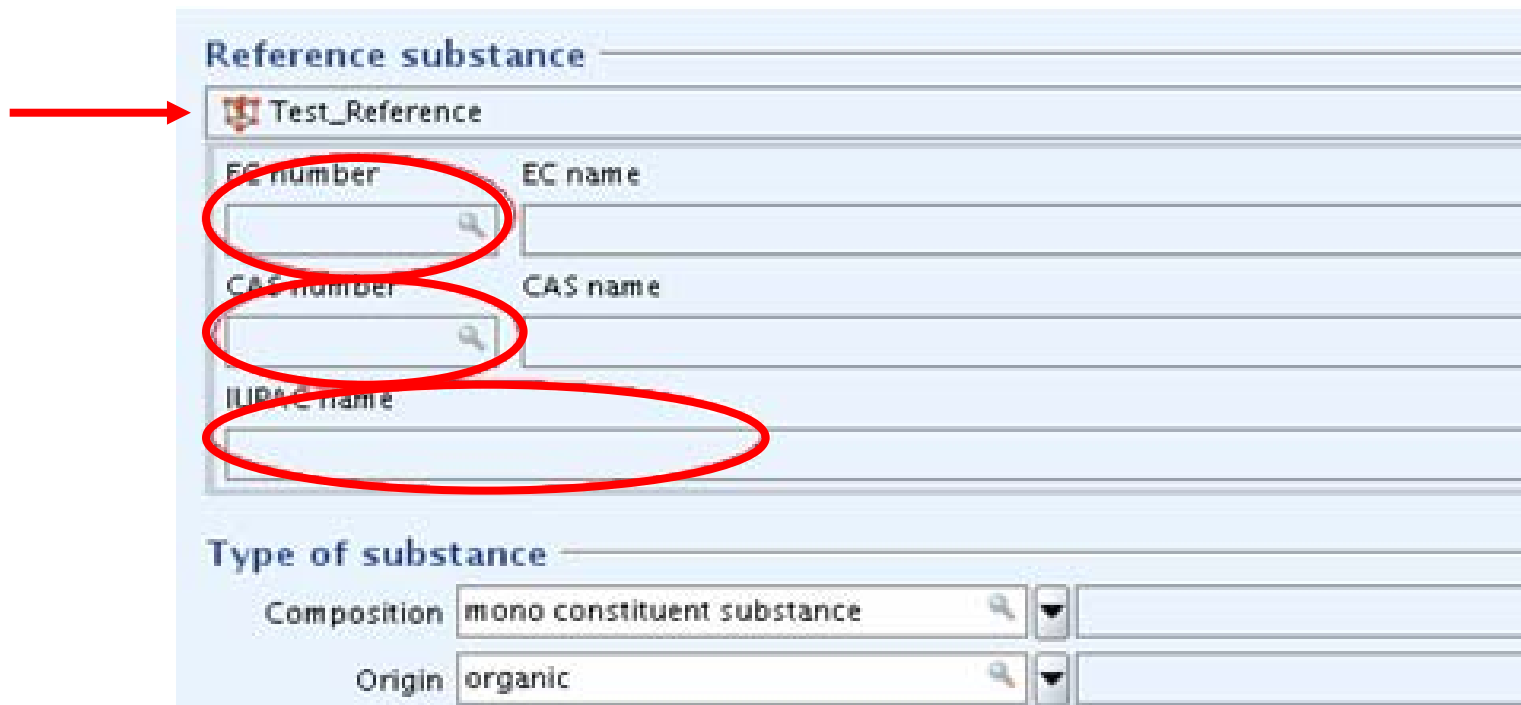
Substance Identification (BR020, BR019, BR090)



- What REACH-IT checks?
 - Section 1.1 (Substance Identification) & section 1.2 (Substance Composition) of the IUCLID 5 dossier
- Why?
 - Clear understanding of the substance submitted in order to be processed accordingly

- **BR020** checks that either an EC number or a CAS number or a IUPAC name is provided in the corresponding IUCLID 5 fields (Sections 1.1 and 1.2), for each reference substance.

➤ *Example of failure in IUCLID 5 Section 1.1 (Substance Identification):*



Reference substance

Test_Reference

EC number EC name

CAS number CAS name

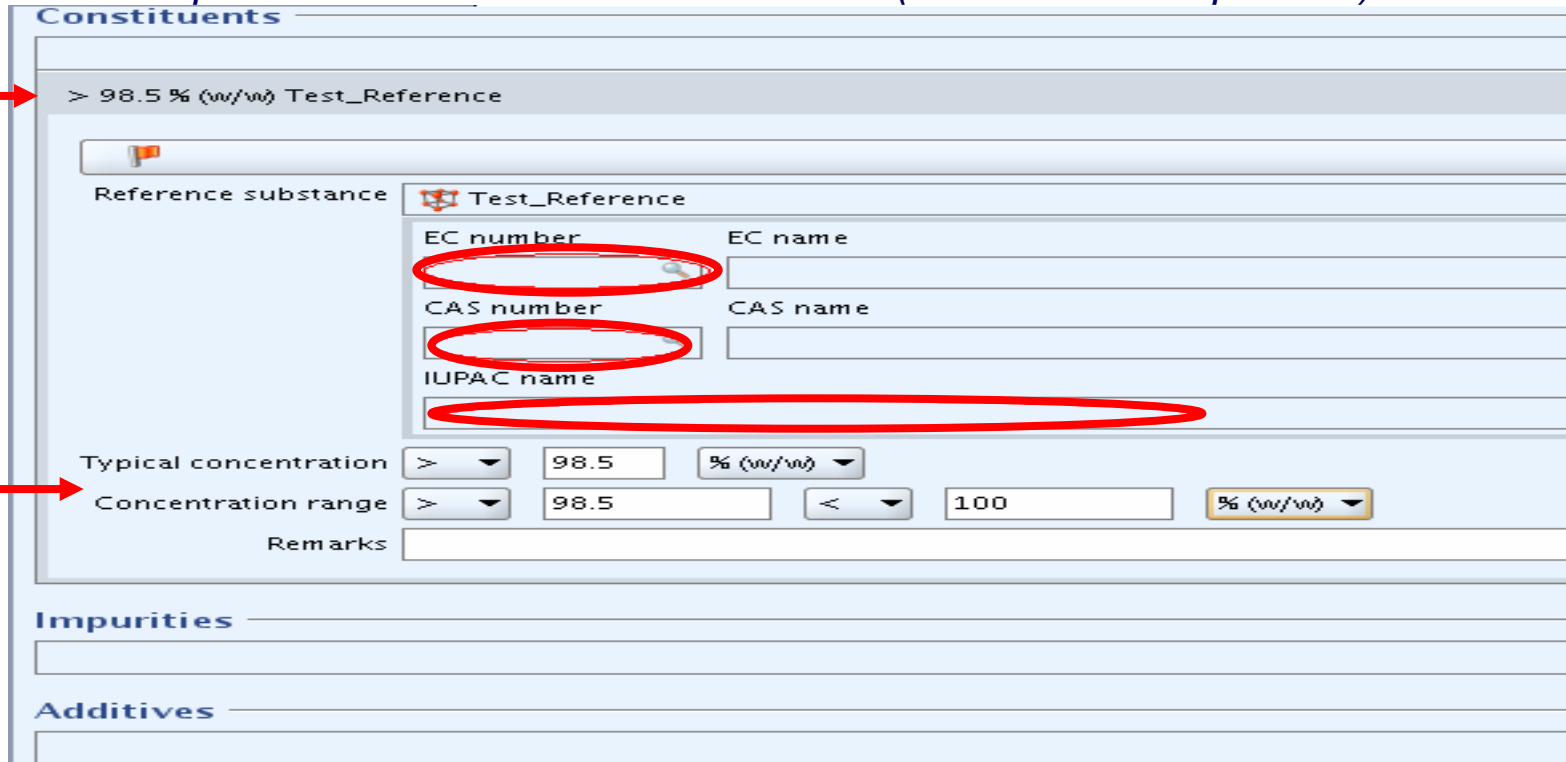
IUPAC name

Type of substance

Composition mono constituent substance


Origin organic

The screenshot shows a web form for substance identification. A red arrow points to the 'Test_Reference' entry. Three red circles highlight the empty input fields for 'EC number', 'CAS number', and 'IUPAC name', indicating a failure in providing identification data.

➤ *Example of failure in IUCLID 5 Section 1.2 (Substance Composition)*

Constituents

> 98.5 % (w/w) Test_Reference

Reference substance  Test_Reference

EC number	EC name
CAS number	CAS name
IUPAC name	

Typical concentration > 98.5 % (w/w)

Concentration range > 98.5 < 100 % (w/w)

Remarks

Impurities

Additives

EC# or CAS# or IUPAC name should be provided in all the related fields of Section 1.2 (including the Impurities and Additives, if any)



Unknown impurity → IUPAC name: “Unknown”

BR019



- **BR019** checks that at least one constituent is given in section 1.2 and all constituents have a valid reference substance.
 - *Example of failure in IUCLID 5 Section 1.2 (Substance Identification):*

Degree of purity




Constituents

Constituents

Impurities

Additives

Role in the supply chain


Role flags 

Role: Manufacturer Importer Only representative Downstream user

Reference substance


 ethanol / ethanol / ethanol / 64-17-5 

EC number EC name

200-578-6 

ethanol

CAS number CAS name



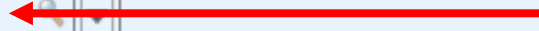
64-17-5 



ethanol

IUPAC name

ethanol

Type of substance

Composition mono constituent substance   


Origin organic  

**Constituents**

≥ 99.9 % (w/w) ethanol / ethanol / ethanol / 64-17-5



Reference substance

 ethanol / ethanol / ethanol / 64-17-5

EC number

200-578-6



EC name

ethanol

CAS number

64-17-5



CAS name

ethanol

IUPAC name

ethanol

Typical concentration

 \geq

99.9

% (w/w)

Concentration range

99.9

100

% (w/w)

Remarks

Impurities

< 0.1 % (w/w) methanol / methanol / 67-56-1



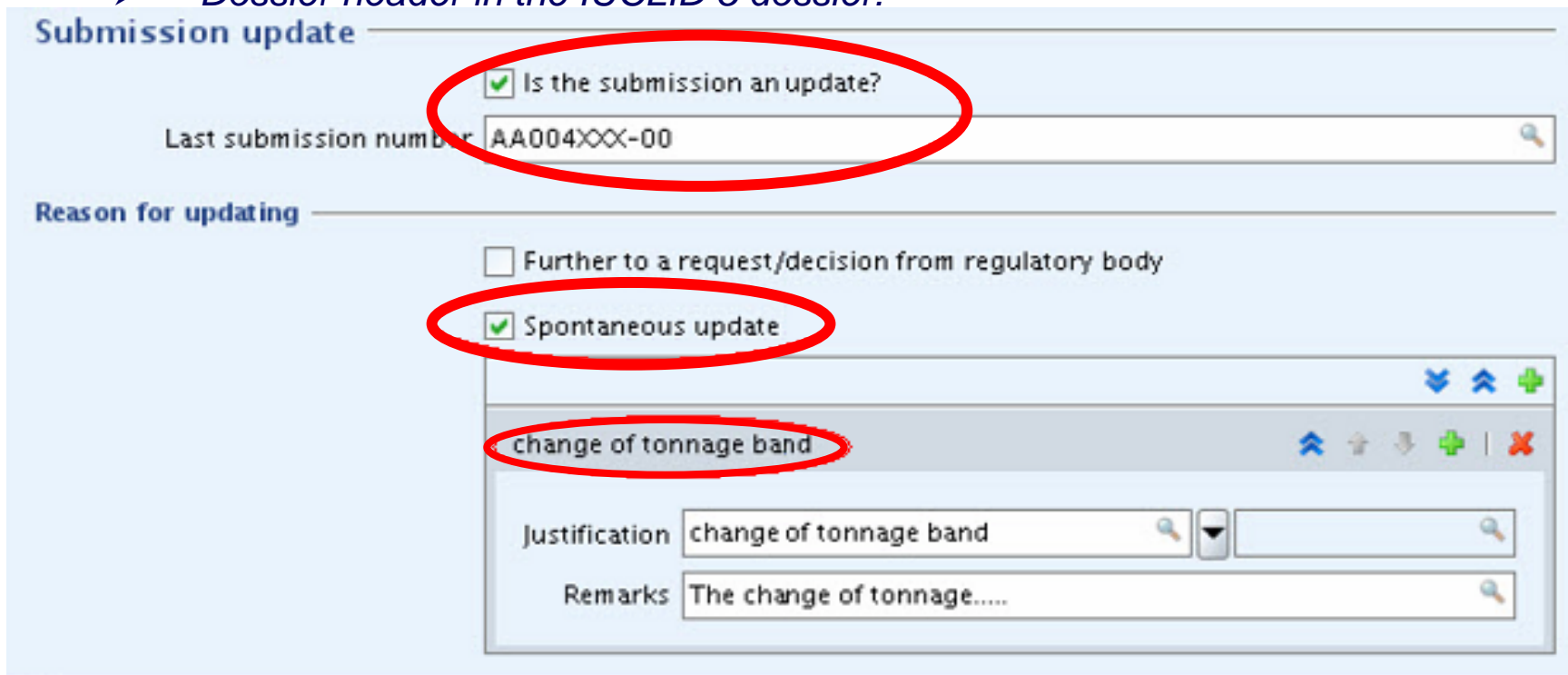
- In case of a mono-constituent substance (mono-constituent is indicated in section 1.1 of the IUCLID 5 dossier), **only one** constituent should be indicated in the IUCLID 5 section 1.2 (Substance Composition)
- The reference substance in IUCLID 5 section 1.1 and the reference substance in the first composition of section 1.2 (i.e. the only constituent in the Constituents section) should be **identical!**



Data Submission Manual 18: How to report the substance identity in IUCLID5 for registration under REACH
(http://www.echa.europa.eu/doc/reachit/dsm18/substance_id_report_iuclid_en.pdf)

- **BR082** checks if the information concerning the registration tonnage band(s) is differing from the latest successful submission for the same substance.

➤ *Dossier header in the IUCLID 5 dossier:*



Submission update

Is the submission an update?

Last submission number: AA004XXX-00

Reason for updating

Further to a request/decision from regulatory body

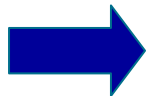
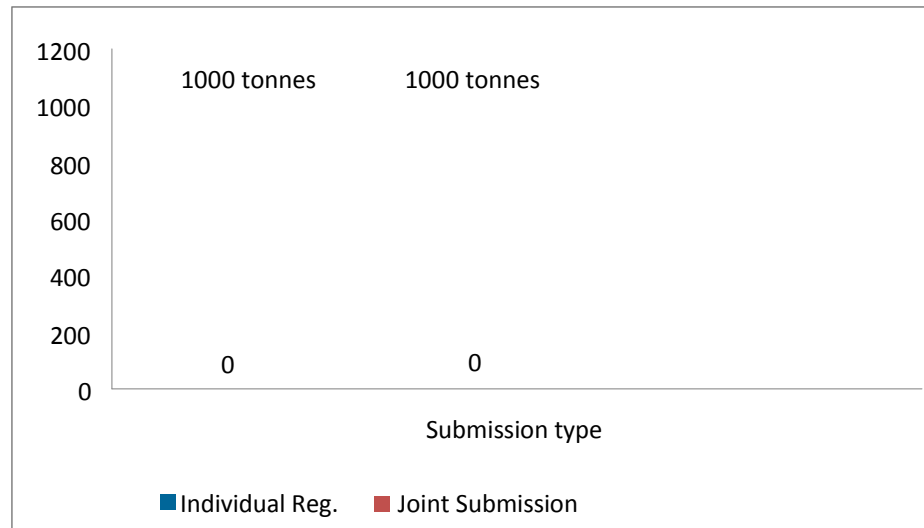
Spontaneous update

change of tonnage band

Justification: change of tonnage band

Remarks: The change of tonnage.....

- Most common mistakes:
 - The registrant changes from a Standard Registration Template to an Intermediate Template, without indicating “change in the tonnage band” in the dossier header (spontaneous update – usually NONS)
 - A previously individual registrant (i.e. has already submitted a dossier without referring to any Joint Submission), becomes the LEAD Registrant of a Joint Submission for the same substance (spontaneous update), without indicating “change in the tonnage band” in the dossier header



Only for LEAD Registrants: A change from an (already submitted) individual submission to a Joint Submission in which you become the LEAD is by default **a change in the tonnage band**

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