Dissemination filter rules

Dissemination & confidentiality claims

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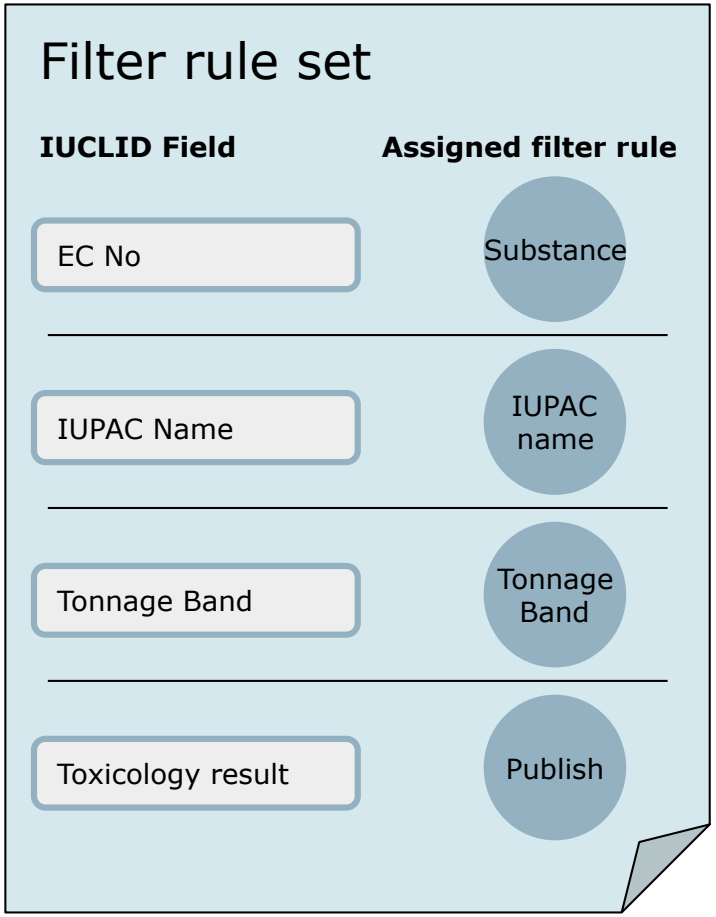
ECHA

Introduction

- What are dissemination filter rules?
- Basic filter rules
- Conditional filter rules
- Feedback from ECHA

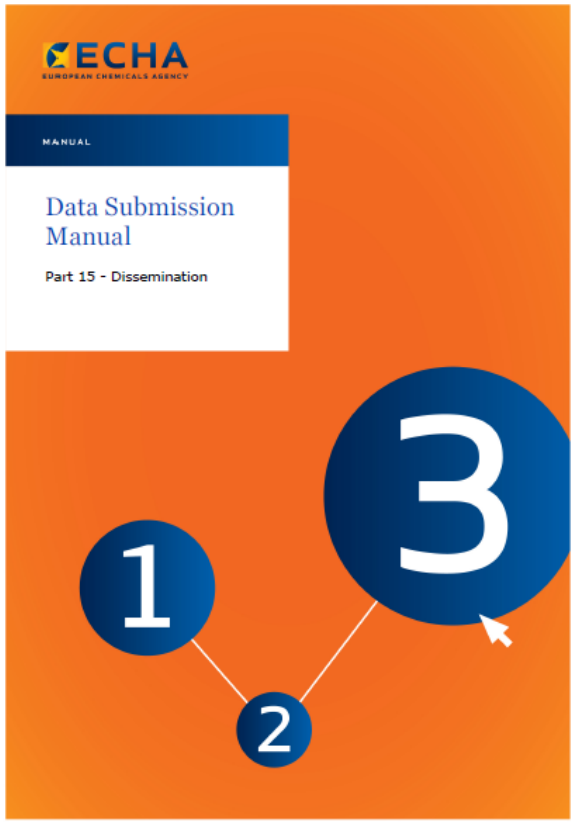
Dissemination filter rules

- A filter rule is assigned for each IUCLID field, enabling the filter tool to automatically determine if the content of the field is disseminated or not



Dissemination filter rules

- The technical annexes to the "Data Submission Manual 15 – Dissemination" explain the rules for the standard dissemination of REACH registration dossiers.
- NONS will initially be disseminated with a reduced set of information.



Basic filter rules

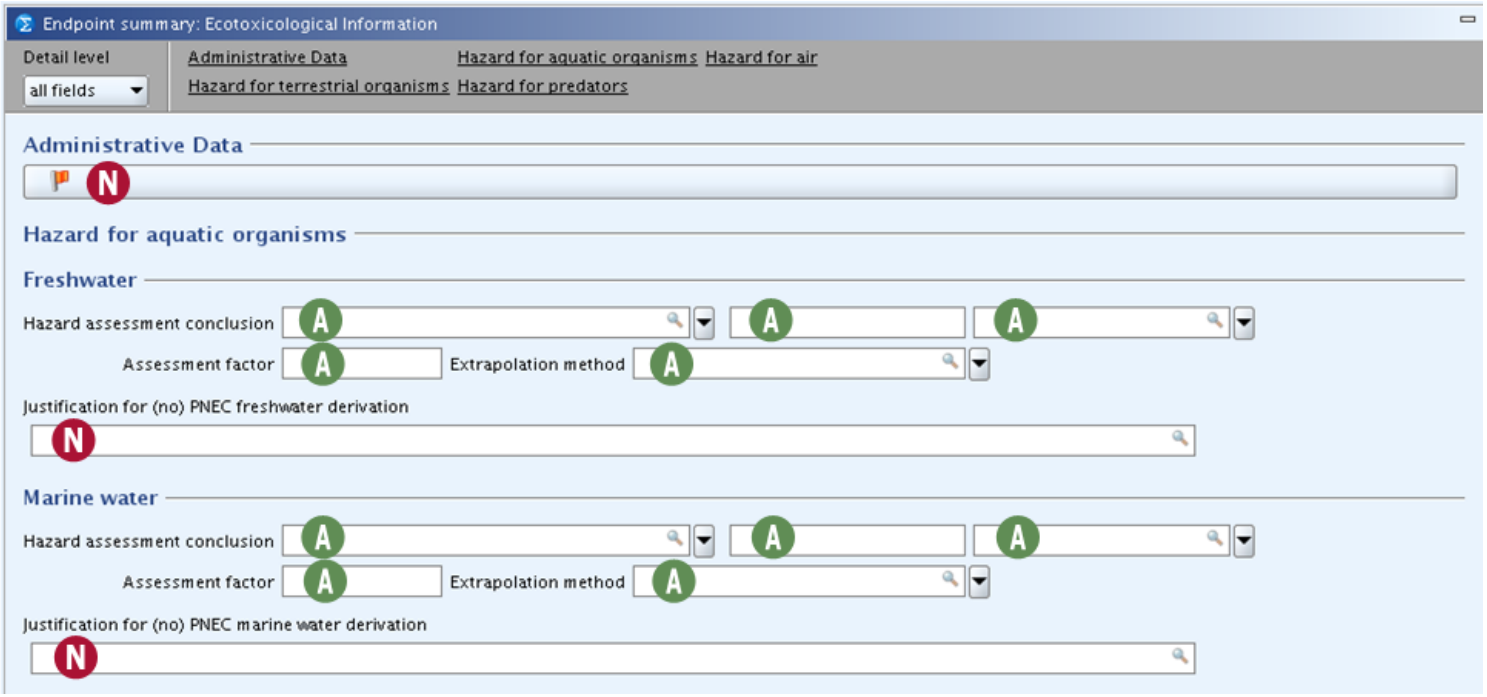
is **not** automatically disseminated

is automatically disseminated unless **confidentiality** has been claimed for this section

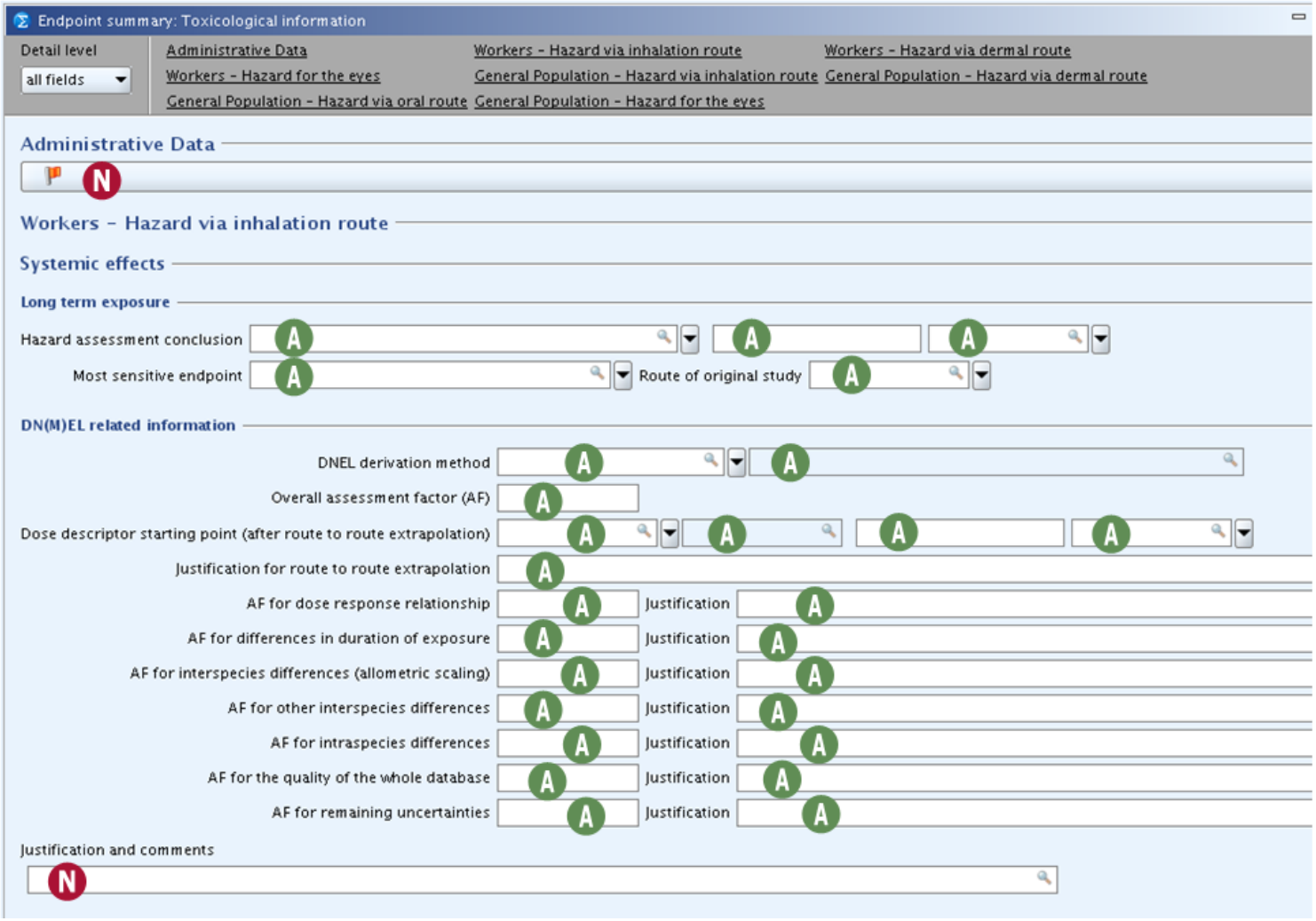
is **always** automatically disseminated

PNEC and DNEL - endpoint summaries

- Justifications for no PNEC derivation, discussion and conclusion on classification are not disseminated.
- All other PNEC information is disseminated, including the assessment factor and the extrapolation method.

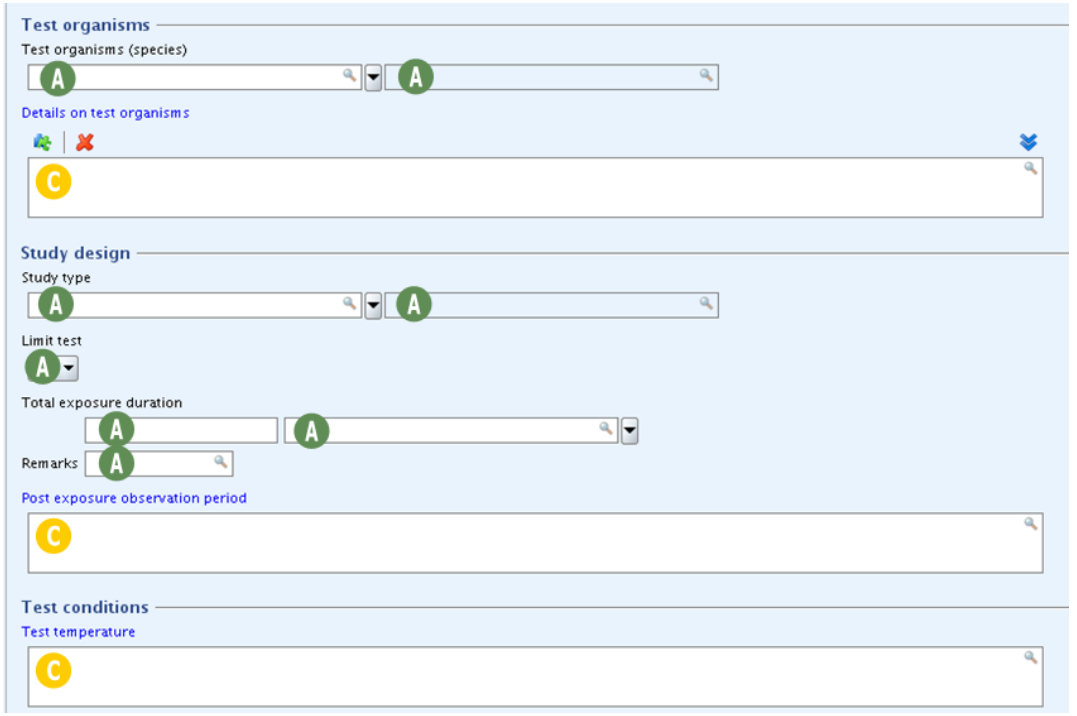


PNEC and DNEL - endpoint summaries



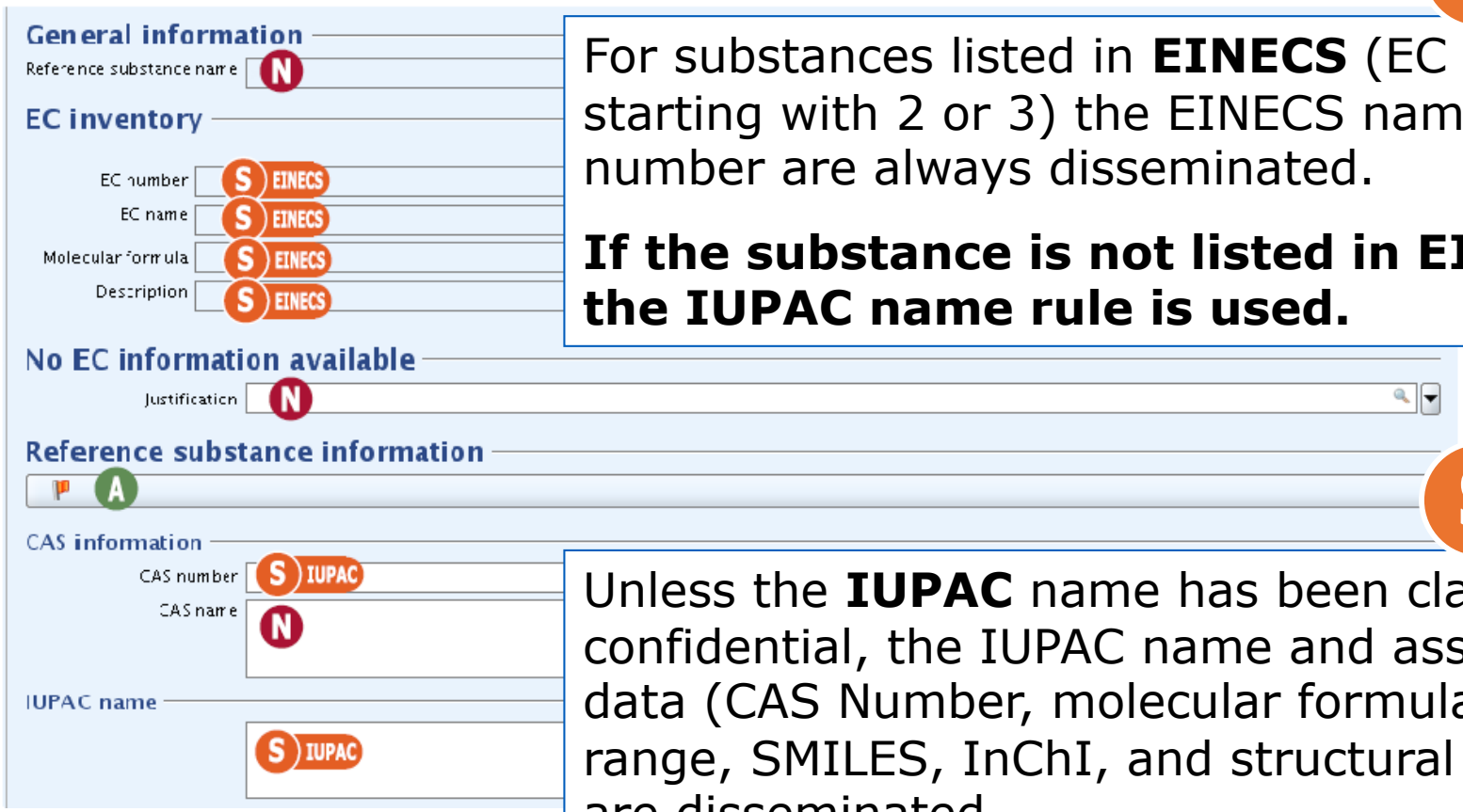
Endpoint study records

- A number of fields in the endpoint study records are always published as part of the study result, even if confidentiality has been claimed on the study.
- These fields are not only under the title ”Results and discussion”



Conditional filter rules – Substance identifiers

Filter rules – substance identifiers



S EINECS

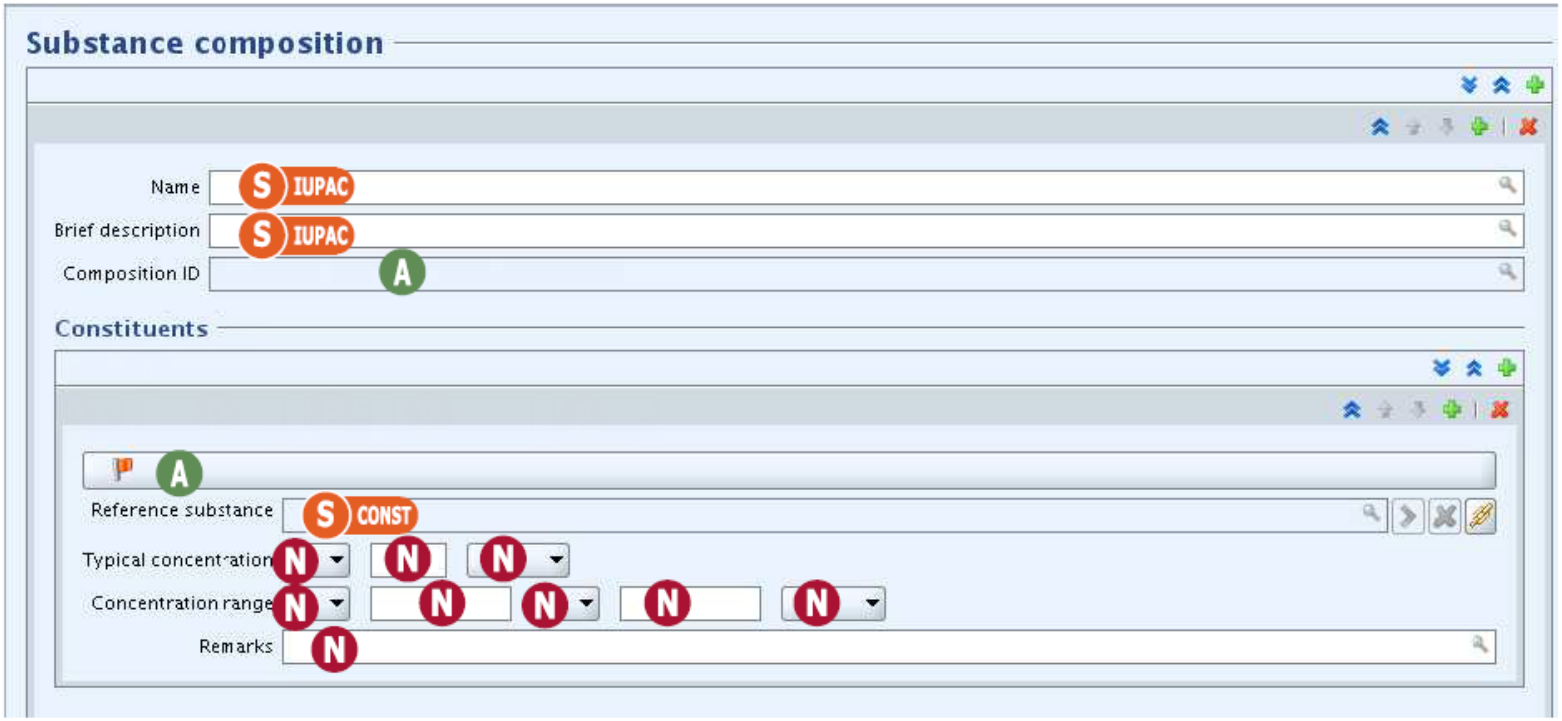
For substances listed in **EINECS** (EC number starting with 2 or 3) the EINECS name and EC number are always disseminated.

If the substance is not listed in EINECS, the IUPAC name rule is used.

S IUPAC

Unless the **IUPAC** name has been claimed confidential, the IUPAC name and associated data (CAS Number, molecular formula, weight range, SMILES, InChI, and structural formula) are disseminated.

Filter rules – substance identifiers



S CONST	Unless the IUPAC name (of the section 1.1 dossier reference substance) has been claimed confidential, and provided the section 1.2 **constituents** have not themselves been claimed confidential, the IUPAC name and associated data for section 1.2 constituents are disseminated.

IUPAC confidentiality – flag above or in 1.1 ref subs

Dossier submitted

Section 1.1

1.1 Substance A+B+C

Linked Ref Substance

Section 1.2

Composition X

1.2 Constituent A

Linked Ref Substance

1.2 Constituent B

Linked Ref Substance

1.2 Constituent C

Linked Ref Substance

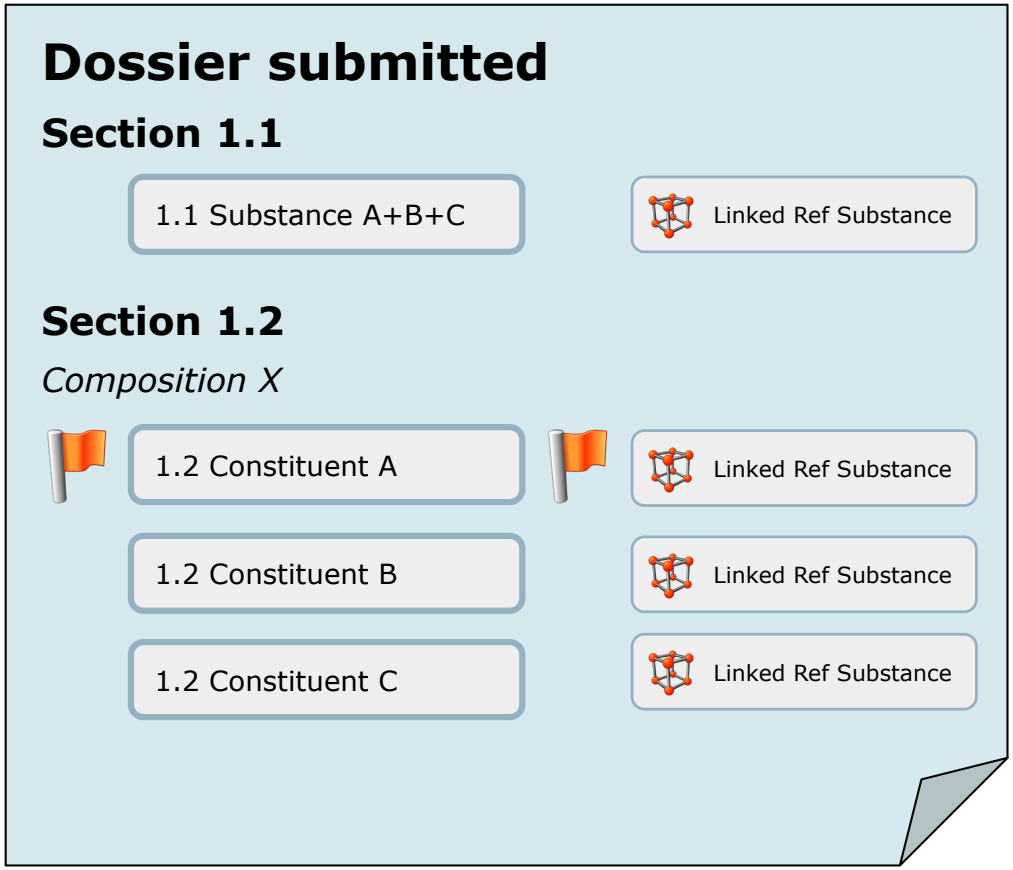
Dossier disseminated

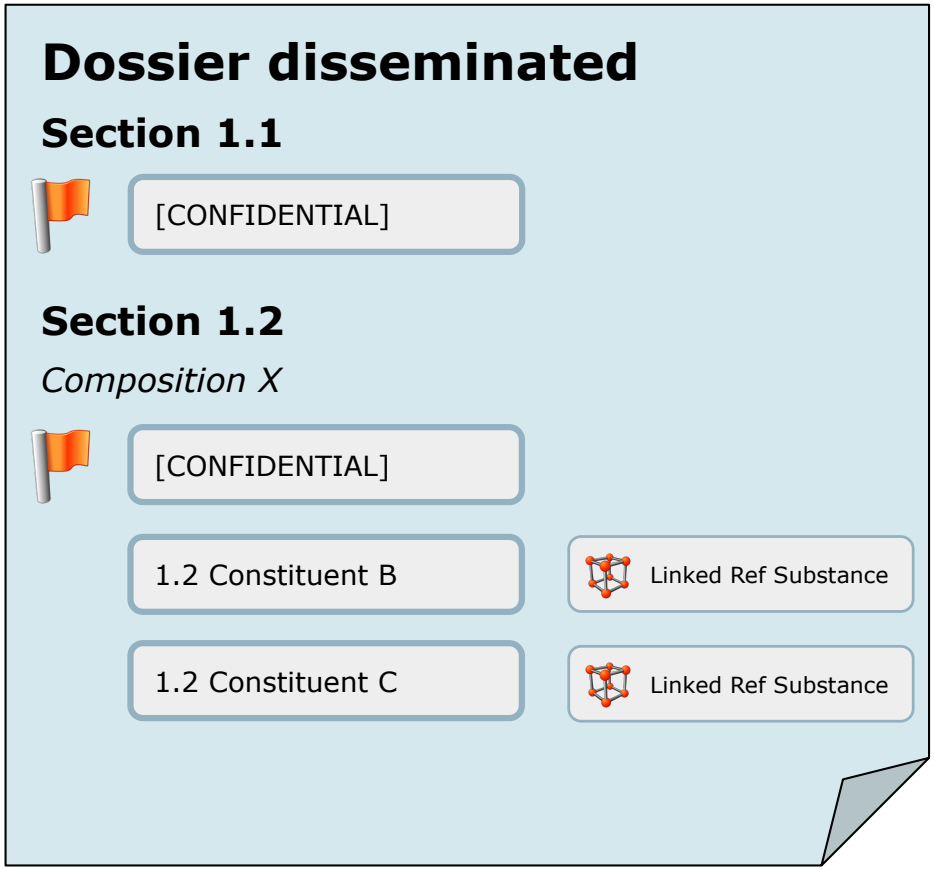
Section 1.1

[CONFIDENTIAL]

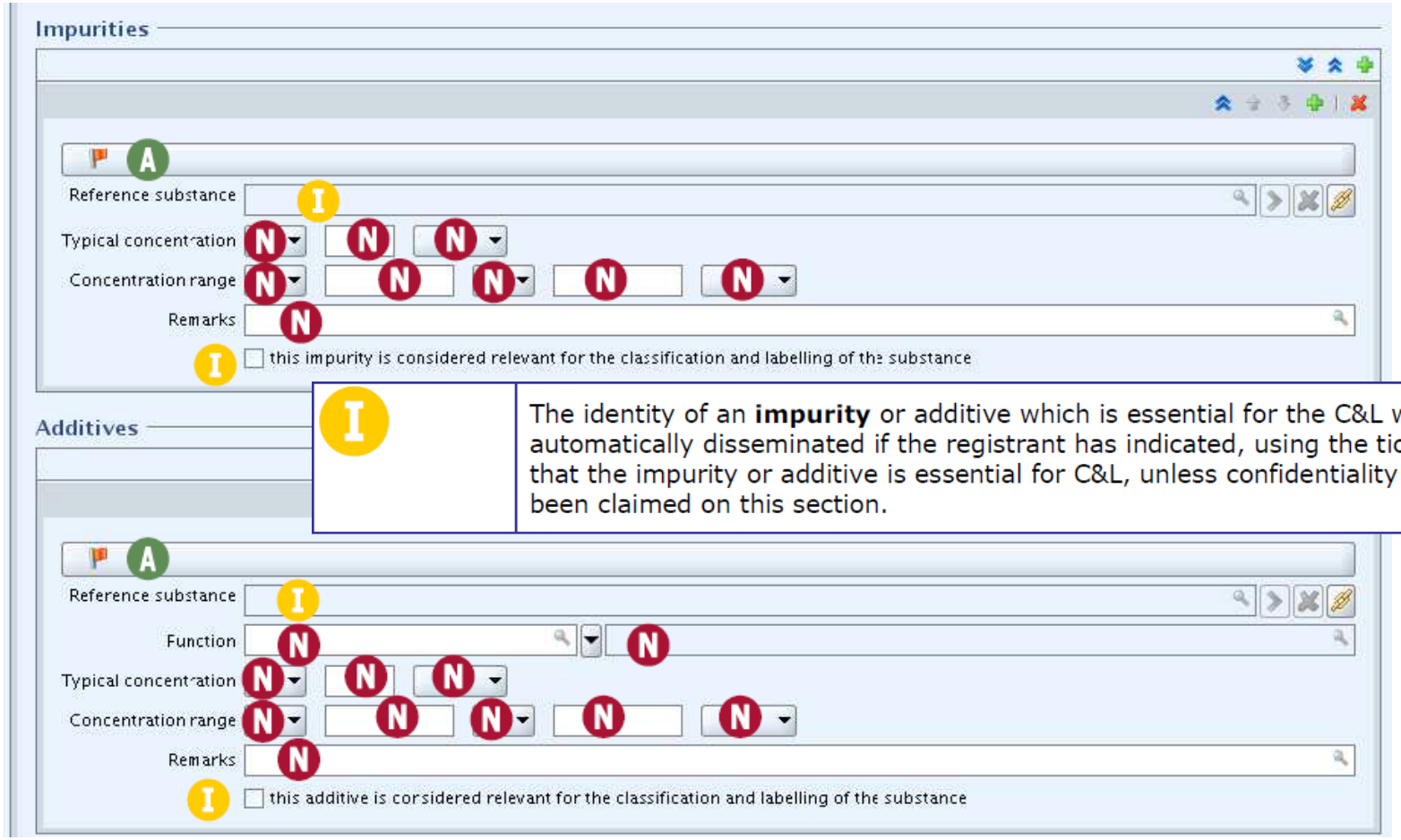
Section 1.2

IUPAC confidentiality – flag(s) above or in 1.2 constituent ref sub(s)



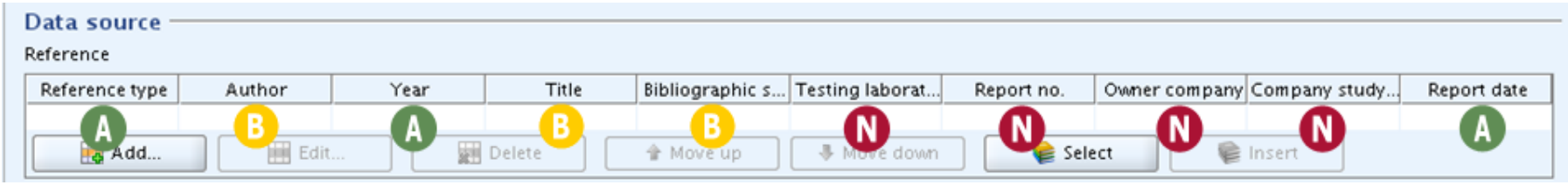


Filter rules – impurities and additives



I — The identity of an **impurity** or additive which is essential for the C&L will be automatically disseminated if the registrant has indicated, using the tick-box, that the impurity or additive is essential for C&L, unless confidentiality has been claimed on this section.

Filter rules – bibliographic references



The **bibliographic references** author, title, and source are disseminated according to the following rule, with the most important criteria listed first:

- not disseminated if the section 1.1 reference substance IUPAC name is claimed confidential;
- not disseminated if the endpoint record is claimed confidential, unless the reference type is publication, review article or handbook;
- not disseminated if the reference type is study report or company data;
- not disseminated if at least one of following is provided: testing lab, report number, owner company or study number.

Filter rules – test material identity

The identity of the **test material** in an endpoint study record will be disseminated if (1) the identifier is CAS number, EC number, EC Name or IUPAC name; and (2) the (robust) study summary data in the endpoint study record is not claimed confidential; and (3) the IUPAC name of the substance being registered is not claimed confidential in the dossier.

Other changes made to the dossier

Additionally, there are a few pieces of information in the IUCLID dossier which are also changed by the filter tool:

- UUIDs in the dossiers are replaced by newly generated random UUIDs
- The registrant's dossier modification history is removed

Other changes made to the dossier

- the registrant's endpoint record titles are removed in the filtering and replaced in the aggregation step by standard endpoint titles
- **NAME** = (Source) + Result Type + Purpose Flag + IUCLID Section + Number

  For example: *(Member) Exp NS Acute toxicity: oral.007*

Table 1: Endpoint study record result types & purpose flags

Result Type	Definition
Exp	Experimental result
Planned	Experimental study planned
Calc	Estimated by calculation
Read-across Cat	Read-across based on grouping of substances (category approach)
Read-across Subs	Read-across from supporting substance (structural analogue or surr
QSAR	QSAR

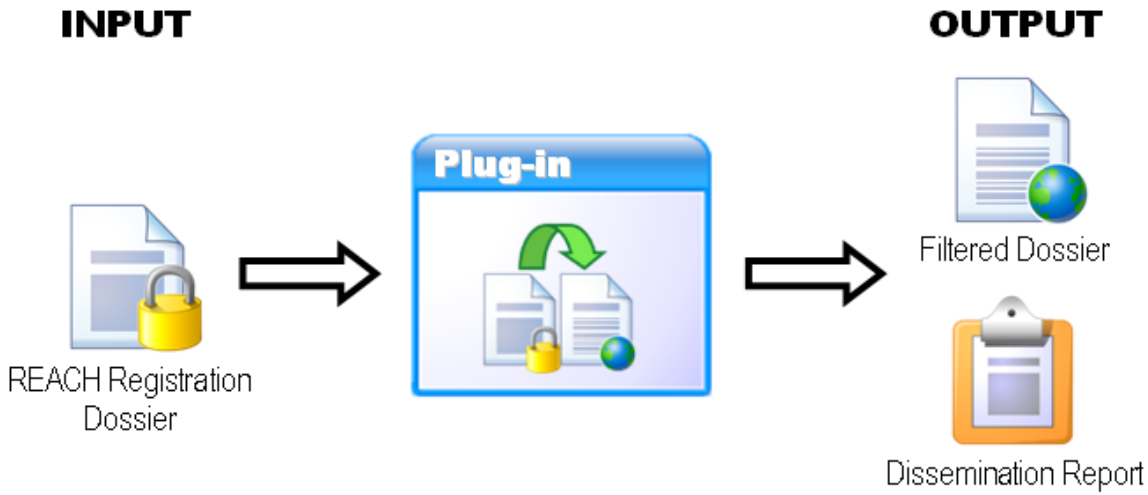
Feedback from ECHA

- IUPAC name claims are triggered if a constituent in IUCLID section 1.2 is flagged confidential. Often, the concern is the typical concentration or the concentration range

  →no flag is needed in these cases
- Remember to fill in the checkbox in section 1.2 if an impurity or additive is relevant for the classification and labelling
- Fill in the information in the correct fields
- Avoid referring to attached documents

Tools available for registrants

- IUCLID 5 dissemination plug-in



- Data Submission Manual 15 – Dissemination + technical annexes

Thank you

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