Cefic tips on how to successfully overcome the REACH-IT business rules (version 10 May 2010)

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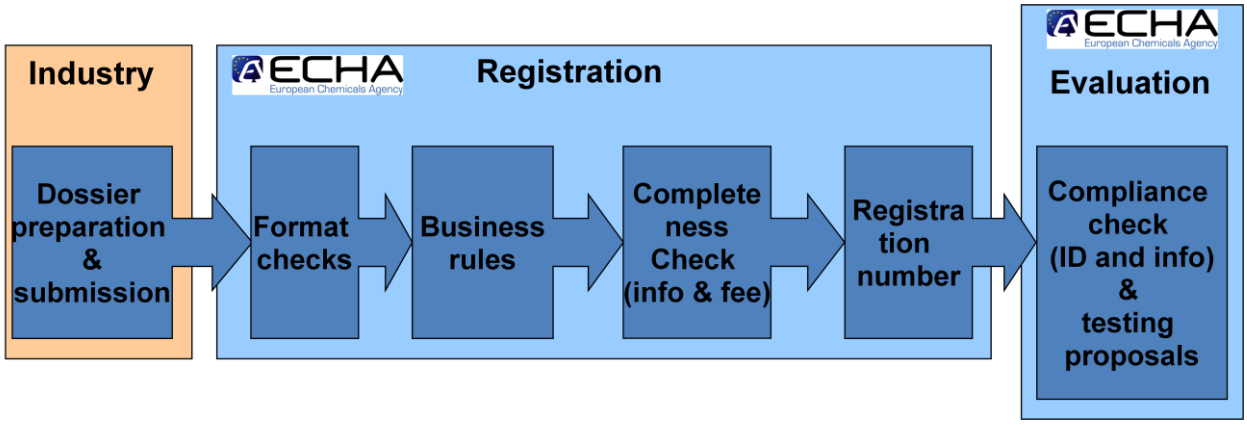
Introduction

Currently, around 40% of the IUCLID dossiers submitted to ECHA fail the Business Rules that are in place in REACH-IT. These rules serve as an initial check to determine if the dossier is both in the correct format and the administrative requirements have been met such that the submission is considered acceptable and the dossier can be further processed. *It is therefore critical that industry has a good understanding of these rules.*

The flowcharts below describe the process that the dossiers undertake when submitted to ECHA via REACH-IT:



Source: ECHA

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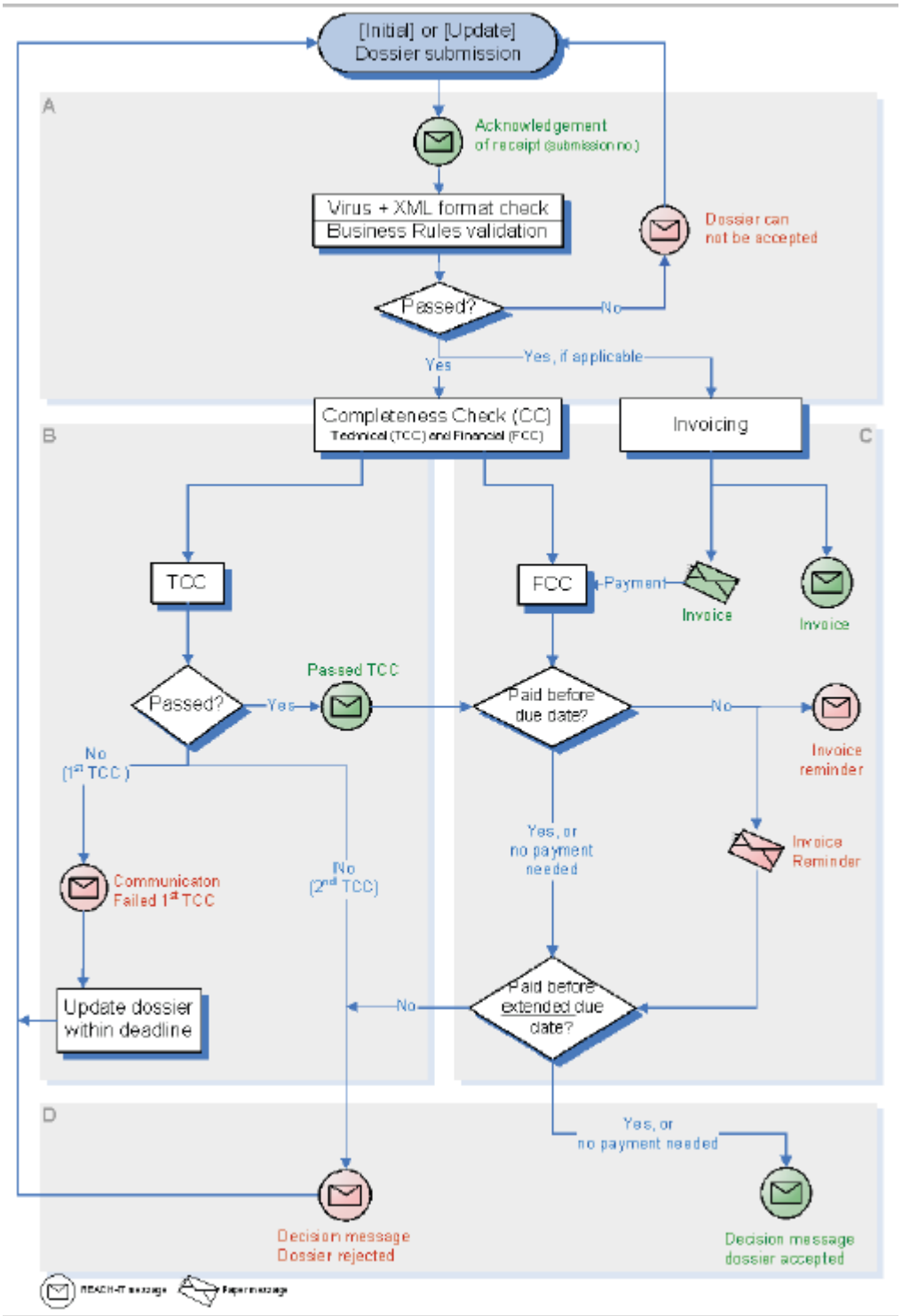

Source: [ECHA Industry User Manual Part 6 – Dossier submission]
Note on this flowchart: ECHA is not sending paper invoices anymore. For more information see article 'Electronic invoicing' in ECHA Newsletter no. 2 April 2010.

A guidance document "REACH-IT Data submission Manual Part 4 – How to Pass Business Rule Verification ("Enforce Rules")" with useful information is published by ECHA on their website:
http://echa.europa.eu/doc/reachit/how_pass_business_verification.pdf

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It is also worth looking at the recording and /or presentations from the webinar on business rules held on the 22nd of April:
http://echa.europa.eu/news/webinars_en.asp
This document is complementary to the ECHA manual above, it includes a number of 'tips' collected by Cefic member companies and will be regularly updated. Cefic will shortly provide you with more information for a successful registration, including updates on how to pass the most critical Business Rules.

Tips to overcome the most common Business Rules failures

The following points aim to provide clear tips for companies who are preparing IUCLID dossiers, and wish to successfully submit by passing the relevant Business Rules that are in place in REACH-IT.

✓ **The Legal entity (LE) in REACH-IT must be the same as the Legal entity in IUCLID5:**

There are different LEs involved in the dossier creation/submission:

- the one used to create the data set in section 1.1 of the IUCLID dossier
- the one used to create the dossier
- the one you use to log in to REACH-IT when submitting the dossier.

These Legal Entities must be all identical.
Note: once a REACH-IT account is created and Legal Entity information exists within it, the data in that REACH-IT account becomes the master data; therefore it is recommended that only this information is updated and it is exported to IUCLID5 in order to synchronise with REACH-IT.

✓ **The reference substance identifiers in sections 1.1 and 1.2 of the IUCLID5 dossier must be filled in and be valid.**

The 'registerable' substance identified in section 1.1 must be linked to a reference substance (usually an EINECS listed substance in the case of a phase-in substance). The 'registerable' substance must have at least one constituent and it is section 1.2 that should be used to identify the constituent(s) of the substance again by linking to a reference substance. *All constituent(s) in section 1.2, composition, must be entered by links to valid reference substances.*
In order to identify your substance at least an EC number, a CAS number or a IUPAC name should be provided.
Depending on the type of substance, additional checks apply:
• For a mono-constituent, there can only be one constituent in each composition in section 1.2. This constituent has to have the *same identifiers* as the substance specified in section 1.1 of IUCLID.
• For a multi-constituent *at least two constituents* should be present of which *none is the same* as identified in section 1.1 of IUCLID.

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- As an exceptional case, also multi-constituent substances that have only one constituent are accepted for processing. In these cases the substance identifiers have to match between section 1.1 and 1.2.

These rules have been incorporated into the IUCLID5 TCC tool check plug-in.

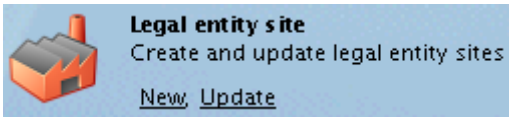
Note: Not all reference substances provided by ECHA in the reference substance inventory are valid references substances, i.e. some mandatory information may be incorrect, or missing, such as molecular formula, structure etc. Registrants must check the adequacy of all reference substance information during preparation of substance identification.

✓ **The country must be indicated for all manufacturing and use sites in the IUCLID dossier for all EU manufacturing and use sites belonging to the legal entity that is registering the substance**

The address of the EU manufacturing and use sites includes the street, postal code, etc. but the country is often missing. This will trigger rejection of the dossier if missing due to ECHA's obligation to inform the relevant EU competent authority of manufacture in that country.

In addition, although sites are not required for importers, if a site is specified in a dossier for an imported substance, then at least the country must be specified. In the case of importers, it is therefore advised to delete the whole field 'site', instead of opening and leaving it blank.

It is recommended to include the country of manufacture when setting up legal entity sites to be linked to legal entity organisations in IUCLID5 for the first time. These data are maintained in IUCLID under "Legal entity site":



✓ **There must not be a submission of an update of a dossier shortly after the initial submission of the dossier**

If the initially submitted dossier is in the 'pipeline' i.e. has not yet been accepted or rejected by the Business Rules, an updated dossier for that same substance will be rejected.

Companies must therefore wait until the initially submitted dossier has undergone either the Business rules or the Technical Completeness check before re-submitting:

- If the dossier was rejected due to a failure in the Business rules check, the re-submission must not be done as an update, and just re-submit the dossier as if it was the first time.

- If dossier was rejected due to a failure in the Technical Completeness Check, the re-submission must be done as an update i.e. dossier header should indicate that the dossier is an update and "further to a request from regulatory body", indicating both the 'last submission number' and

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the ‘decision number’ in their respective submission update fields. The failure letter from ECHA gives instructions on how to do this.

✓ **-IUCLID 5 Section 1.5 Joint Submission**

If the submission is *not* part of a Joint Submission, section 1.5 of the IUCLID 5 dossier must be empty. Also empty blocks that were created will have to be removed before creating the dossier and submitting it.

✓ **-Joint Submission – member dossier tonnage band**

The member dossier can not indicate a higher tonnage band in his dossier header than the tonnage band which the Lead Registrant has selected for the Joint Submission. Only in the case of an opt-out this is allowed.

✓ **The submission context must be correct**[1]

The ‘context’ of the dossier must be correct. This includes factors like whether the dossier is an initial or update submission and whether it is a single or joint submission.
The dossier type or ‘context’ is fixed when creating the dossier by selecting the right template in IUCLID during the first step in the dossier creation wizard window (see below).
Any update information is included within the dossier header when setting up the dossier together with joint submission information:

[1] More information in Annex I

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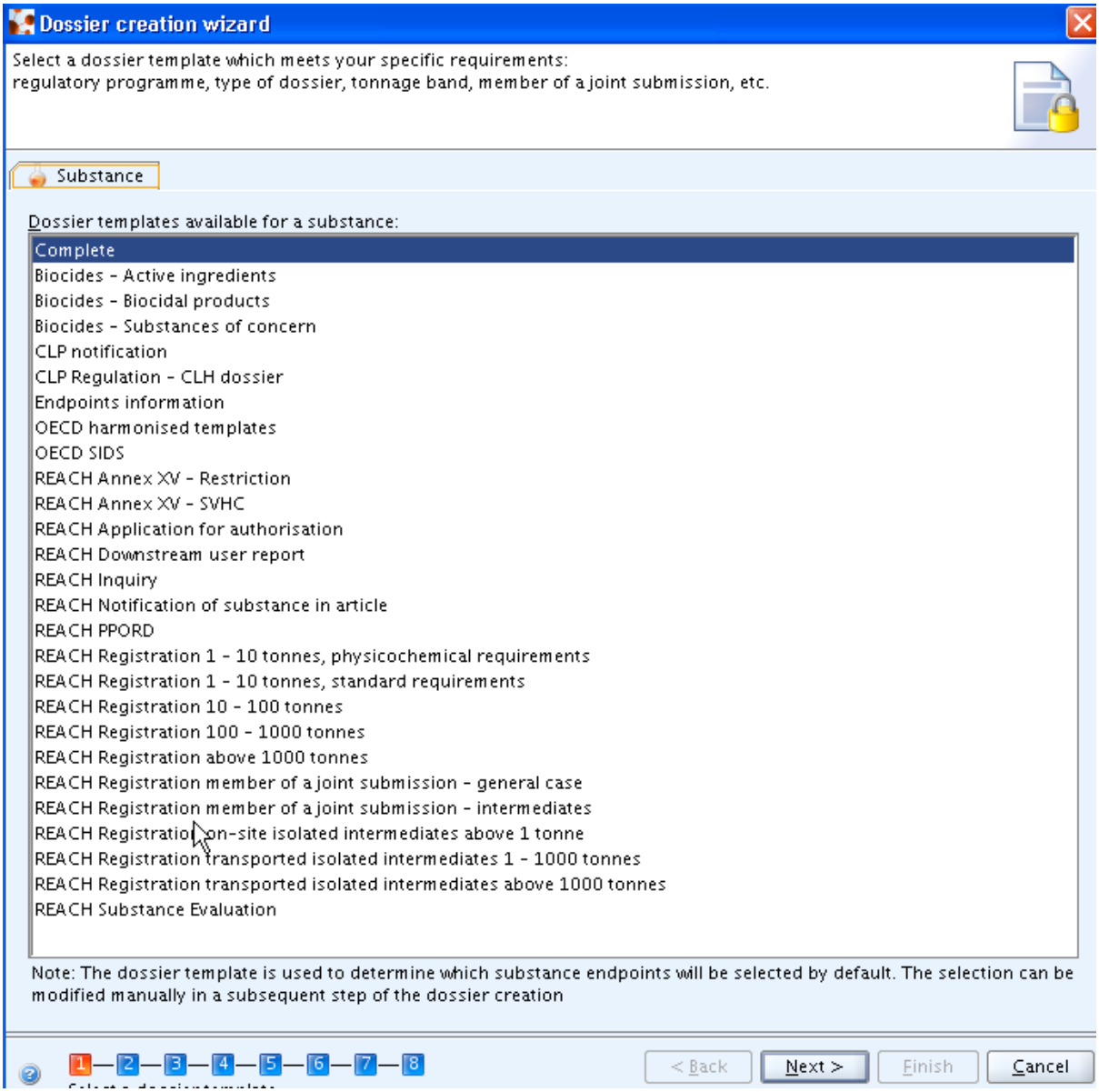

On submission of the dossier, the Business Rules validate that all of the information provided is consistent between REACH-IT, the dossier type and the dossier header.

✓ **Attachments preferable in pdf format**

Depending on document type, BR warnings can be generated; it is therefore advisable to provide attachments as pdf files.

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Annex I: Context vs Dossier type

Context	IUCLID 5 Template	Dossier type in REACH-IT
Individual submission dossier or Lead dossier		
Standard Registration	Registration template with the corresponding tonnage band (e.g. REACH Registration 10-100 tonnes)	Registration
Standard Registration + Intermediate(s)	Registration template with the corresponding tonnage band (e.g. REACH Registration 10-100 tonnes)	Registration
Registration of one type of intermediate (i.e. On-Site OR Transported)	Intermediate template with the corresponding type and tonnage band (e.g. REACH Registration On-Site Isolated Intermediates above 1 tonne)	Registration of transported isolated intermediate or Registration of on-site isolated intermediate
Combination of Intermediates	Transported Isolated Intermediate template with the corresponding tonnage band (e.g. REACH Registration transported isolated intermediates 1-1000 tonnes)	Registration of transported isolated intermediate
Member dossier		
Standard Registration	REACH Registration member of a joint submission – general case	Registration
Standard Registration + Intermediate(s)	REACH Registration member of a joint submission – general case	Registration
Registration of one type of intermediate (i.e. On-Site OR Transported)	REACH Registration member of a joint submission – intermediates	Registration of transported isolated intermediate or Registration of on-site isolated intermediate
Combination of Intermediates	REACH Registration member of a joint submission – Intermediates	Registration of transported isolated intermediate

Source : ECHA manual on how to pass the Business rules verification : http://echa.europa.eu/doc/reachit/how_pass_business_verification.pdf

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