

# “Preparation and submission of registration dossiers and ECHA’s first experiences”

**ECHA’s Second Stakeholders Day**

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# Topics

- Dossier preparation (IUCLID 5)
- Dossier submission (REACH-IT)
- Dossier processing at ECHA
- ECHA experiences so far

## Main steps to preparing and submitting a registration:

(pre-requisite: IUCLID installation and REACH-IT accounts)

1. Prepare the 'substance dataset' in IUCLID 5
2. Export the dossier from IUCLID 5
3. Upload the dossier via REACH-IT



4. ECHA checks 'business rules', sends invoice (if needed) and performs Technical Completeness Check (TCC)
5. (Re-submission may be required due to business rules and/or TCC)
6. Following fee payment, ECHA issues registration number

## Structure of registration dossier

1-10 tonnes: **Technical  
Dossier**

>10 tonnes: **Technical  
Dossier**

**+ Chemical  
Safety  
Report**

**(CSR Tool)**



## Technical dossier

**Annex VI of REACH:** Identity of registrant, Identity of substance, Information about uses, C&L, Guidance on safe use ...

**Annexes VII to X:** Physicochemical, toxicological and ecotoxicological studies requested depends on tonnage :

- 1-10 tons: Annex VII
- 10-100 tons: Annex VII + VIII
- 100-1000 tons: Annex VII + VIII + IX
- >1000 tons: Annex VII + VIII + IX + X

PS: Annex XI: general rules for adaptation of Annexes VII to X

# Dossier Preparation (IUCLID 5)

(pre-requisite: IUCLID installation and Legal Entity)

- Create and complete 'substance dataset' for the substance being registered
- Export dossier (select dossier type and fill 'dossier header')

Full details on IUCLID installation and use manual:

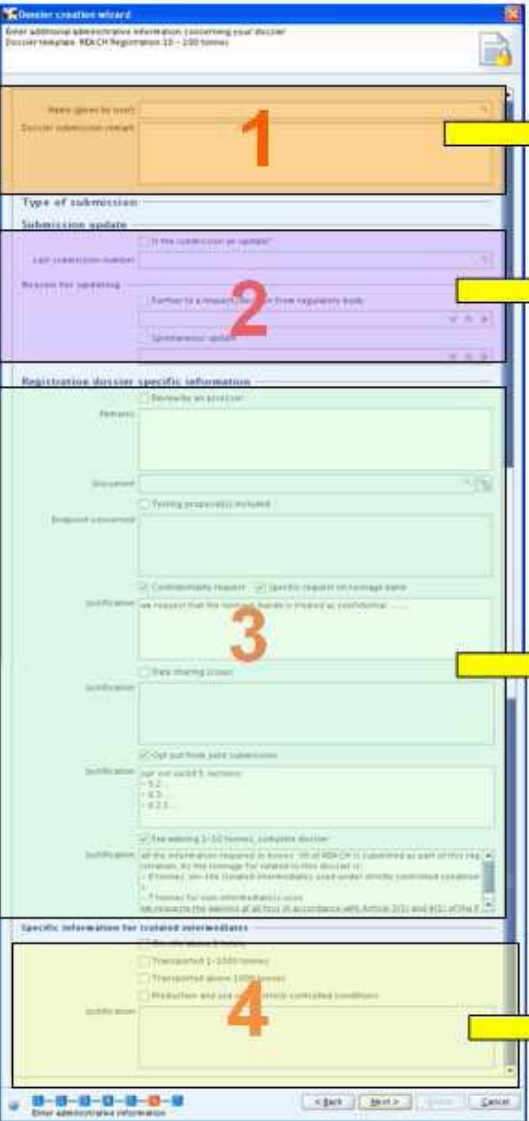
<http://iuclid.echa.europa.eu/>



# Dossier Preparation (IUCLID 5)



## The 'Dossier Header'



1) Dossier submission name and remarks

2) Submission update information (only in case of update)

3) specific information related to the dossier: assessor revision, testing proposal, confidentiality, data sharing, opt out, fee waiver

4) specific information for isolated intermediates

• Identifies the submission type

• Must be correct to pass Business Rules

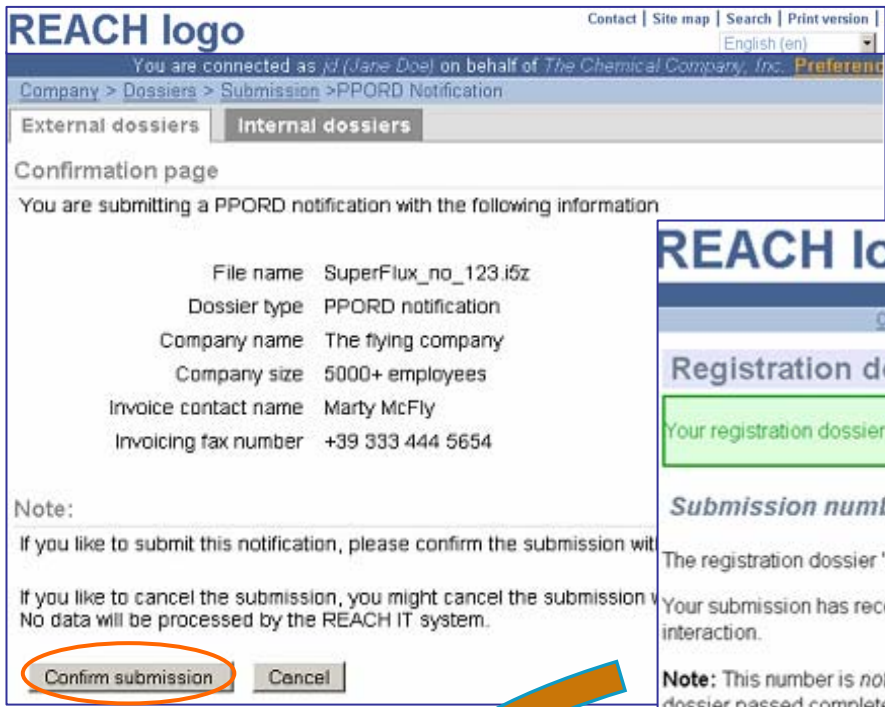
# Dossier submission (REACH-IT)

## Step 1: Dossier Upload – Select dossier

The screenshot shows the REACH-IT web interface. On the left is a navigation menu with 'Dossier' selected. The main content area shows 'Dossier submission' options. A yellow callout box with '1. Select the dossier type to submit' points to the 'Registration (regular)' option. Below this, another yellow callout box with '2. Browse to the file to submit' points to the 'Browse...' button in the 'Registration dossier submission' form. A third yellow callout box with '3' points to the 'Submit dossier' button. A fourth yellow callout box with 'An access code is required to upload large files' points to the 'Access code' input field. A large orange arrow points from the 'Registration (regular)' option to the 'Registration dossier submission' form.

# Dossier submission (REACH-IT)

## Step 2: Dossier Upload – Confirm submission & obtain submission number



REACH logo

Contact | Site map | Search | Print version | English (en)

You are connected as *jd (Jane Doe)* on behalf of *The Chemical Company, Inc.* [Preferences](#)

Company > Dossiers > Submission > PPORD Notification

External dossiers Internal dossiers

Confirmation page

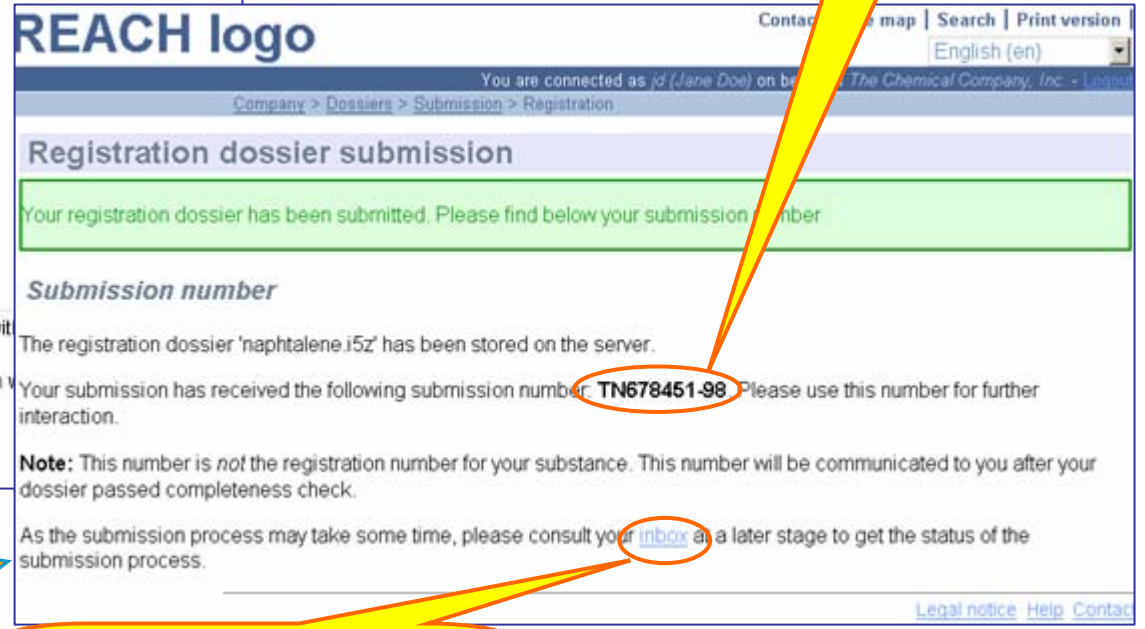
You are submitting a PPORD notification with the following information

File name	SuperFlux_no_123.i5z
Dossier type	PPORD notification
Company name	The flying company
Company size	5000+ employees
Invoice contact name	Marty McFly
Invoicing fax number	+39 333 444 5654

Note:

If you like to submit this notification, please confirm the submission with the **Confirm submission** button.

If you like to cancel the submission, you might cancel the submission with the **Cancel** button. No data will be processed by the REACH IT system.



REACH logo

Contact | Site map | Search | Print version | English (en)

You are connected as *jd (Jane Doe)* on behalf of *The Chemical Company, Inc.* [Logout](#)

Company > Dossiers > Submission > Registration

### Registration dossier submission

Your registration dossier has been submitted. Please find below your submission number

**Submission number**

The registration dossier 'naphtalene.i5z' has been stored on the server.

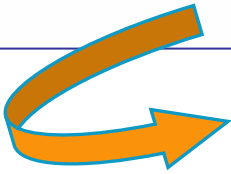
Your submission has received the following submission number: **TN678451-98**. Please use this number for further interaction.

**Note:** This number is *not* the registration number for your substance. This number will be communicated to you after your dossier passed completeness check.

As the submission process may take some time, please consult your [inbox](#) at a later stage to get the status of the submission process.

[Legal notice](#) [Help](#) [Contact](#)

Submission number



Link to the inbox to consult the submission report

## Further information...

### REACH IT User Manual:

- Industry User Manual
  - Part 1: Getting started with REACH-IT
  - Part 2: Sign-up and account management
  - Part 3: Login and Message Box
  - Part 4: Online Pre-Registration
  - Part 5: Pre-SIEF
  - Part 6: Dossier Submission
  - Part 7: Joint Submission
  - Part 8: Invoices
  - Part 10: Claim of a registration number for a notified substance

[http://echa.europa.eu/reachit\\_en.asp](http://echa.europa.eu/reachit_en.asp)

## Workflow



### **Check of Business Rules**

(ensure that dossiers can be processed by the system)



Completeness check:

**Technical Completeness  
Check (TCC)**

+

**Check if payment was  
received in full**



(Request to complete dossier  
+ 2<sup>nd</sup> Completeness Check)

pass



Registration number



fail

Rejection (rare cases)

**Business rules** are a set of pre-requisites that must be fulfilled before ECHA can establish that the dossier can be handled properly and that the required regulatory processes can be successfully carried out.


Three main reasons:

- **Format** - e.g. inquiry dossier in a registration template
- **Administrative** - e.g. registration update does not provide registration number
- **Technical** – REACH-IT cannot ‘understand’ the substance identifiers

### Data Submission Manual 8: Business Rules validation !

Provides list of all business rules and how to avoid failures:

REACH-IT Data Submission Manual 8  
Business Rules validation



<http://echa.europa.eu>

### 3 Annexes

#### 3.1 Annex I – List of automated business rules

	REACH-IT Business rule Code	REACH-IT Rule message	Explanation of the reason of failure	What to do to avoid a failure in your (next) submission
ALL SUBMISSION	SUB_GBL_UC02_F C030 SUB_GBL_UC02_F C010	There was no Reference substance in section 1.1 of your IUCLID 5 dossier and all constituents of the first composition of section 1.2 were not linked to a Reference substance.	You did not provide a Reference substance neither in IUCLID 5 section 1.1 nor in 1.2. A Reference substance should always be present in IUCLID 5 section 1.1 and in section 1.2. If not, the dossier cannot be linked to a substance and it cannot be processed by ECHA. This Business Rule also fails in case an empty repeatable block for "composition" and / or "constituent" is created in a dossier.	Ensure that <u>at least one</u> Reference substance is linked in section 1.1 and in section 1.2 under Constituents in the dossier that you are submitting in REACH-IT. A Reference substance cannot be defined by completing only the field "name". To be valid, a Reference substance should have at least one of the following identifiers: <ul style="list-style-type: none"><li>- EC number, or</li><li>- CAS number and name, or</li><li>- IUPAC name, or</li><li>- Description</li></ul> Note that in case the only available information is related to CAS, both the CAS number and name should be given.  Ensure you indicate at least one 'valid' identifier in every Reference substances that you use in the dossier. In case you have an unknown impurity, you should write "unknown impurity" in the "IUPAC name" field of the corresponding Impurity Reference substance. Finally, in the subsequent Technical Completeness Check step, the presence of the molecular and structural information in each Reference substance (molecular formula, molecular weight range, and structural formula, or justification for not providing the information) will be checked. Please make the necessary modification and submit a new dossier.

[http://echa.europa.eu/doc/reachit/reachit\\_data\\_submission\\_manual\\_8\\_business\\_rules\\_validation\\_20090417.pdf](http://echa.europa.eu/doc/reachit/reachit_data_submission_manual_8_business_rules_validation_20090417.pdf)

## 'Business Rule' failures:

- Since 1 June 2008, 40% of dossier have failed at the business rule stage.
- An increased number of failures was observed after the migration to submission via REACH-IT on 5 January 2009.
- As a result ECHA prepared DSM 8: 'Business rule validation' to supplement DSM 4: How to submit a valid dossier to ECHA and complete the dossier header

## ‘Business Rule’ failures:

- Initial vs. update submissions:

Invalid previous reference numbers (submission no. and previous communication no.) given in dossier header

- Regulatory identifiers:

Invalid pre-registration/inquiry/registration numbers given in Section 1.3

- Confidentiality claim with no justification:

Invoice is based on chargeable services. Without justification is it a genuine claim or a mistake?

- Production site not defined (for a manufacturer):

REACH-IT cannot determine the ‘relevant’ Member State

## Key messages

- Registration dossiers should be prepared **well** in advance
- Carefully consult the relevant guidance and manuals
- Take care to ensure that the dossier header and substance identity sections are completed according to the instructions in the data submission manuals

Thank You  
for your attention

