

# “Completeness check, ECHA’s approach”

**ECHA’s Second Stakeholders Day**

27 May 2009

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*Registration*  
*European Chemicals Agency*



## Technical Completeness Check

Carried out according to Article 20:

*„The Agency shall undertake a completeness check of each registration in order to ascertain that **all the elements required** [...], as well as the **registration fee** [...] have been provided.*



## 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)

## Technical completeness check:

### **PPORD dossiers:**

- 95 % of dossiers passed at first time, almost all passed at second submission (total 88 submissions\*)

### **Isolated Intermediate dossiers:**

- 61 % of dossiers passed at first time, almost all passed at second submission (total of 123 submissions\*)

### **Registration dossiers:**

- 48 % of dossiers passed at first time, almost all passed at second submission (total of 100 submissions\*)

\* Numbers are given for the dossiers submitted between 5 Jan 09 – 15 May 09 and which have been accepted for processing (i.e. passed Business rules)

## Technical completeness check:

### Registration dossiers:

- Section 2.1 GHS (classification and labelling CLP): all hazards have to be addressed, don't forget Carcinogenicity, Specific target organ toxicity, etc (create a new block in IUCLID 5!)
- Section 2.2 DSD (classification and labelling 67/548/EEC): "Classification" or "Reason for no classification" has to be provided for all dangerous properties
- Reasons why spontaneous updates (tonnage level increase) often fail the TCC: not all required endpoint study records are provided or are not complete

# Technical Completeness Check

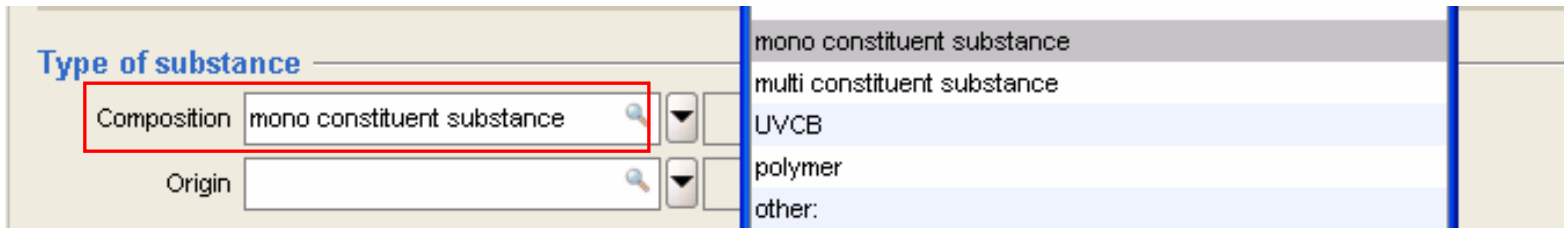
Updated manual available since beginning of May:

## Data Submission Manual 5: How to Complete a Technical Dossier for Registrations and PPORD Notifications (RELEASE 2.0) !

[http://echa.europa.eu/doc/reachit/compl\\_tech\\_dossier\\_manual.pdf](http://echa.europa.eu/doc/reachit/compl_tech_dossier_manual.pdf)

Main changes:

1) Composition must be selected:



**Type of substance**

Composition	mono constituent substance	<input type="checkbox"/>
Origin		<input type="checkbox"/>


- mono constituent substance
- multi constituent substance
- UVCB
- polymer
- other:

# Technical Completeness Check

Main changes:

2) Reference Substance: Structural formula must be provided if possible (i.e. for a mono-constituent substances in section 1.1, and for constituents of mono- and multi-constituent substances in section 1.2).

Molecular and structural information



Molecular formula

Molecular weight range

SMILES notation

InChI

Structural formula

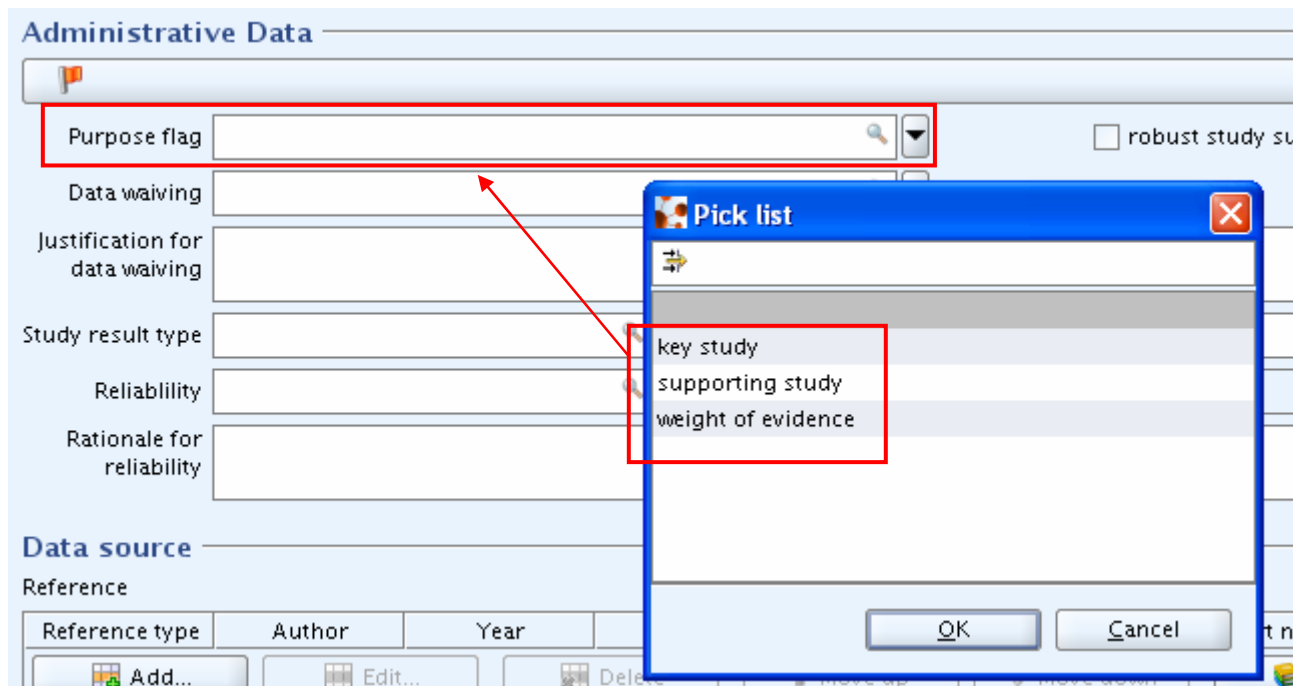
Remarks

# Technical Completeness Check

Main changes:

3) Purpose flag: all key studies, weight of evidence, data waivers and testing proposals per endpoint must be complete.

Tip: Supporting studies are not checked for technical completeness!



The screenshot shows the 'Administrative Data' section of a software interface. A red box highlights the 'Purpose flag' field, which is currently empty. A red arrow points from this field to a 'Pick list' dialog box. The dialog box contains a list of three options: 'key study', 'supporting study', and 'weight of evidence'. The 'key study' option is highlighted with a red box. Below the list are 'OK' and 'Cancel' buttons. The background form includes fields for 'Data waiving', 'Justification for data waiving', 'Study result type', 'Reliability', and 'Rationale for reliability'. At the bottom, there is a 'Data source' section with a 'Reference' table containing columns for 'Reference type', 'Author', and 'Year'. Buttons for 'Add...', 'Edit...', and 'Delete' are visible at the bottom left.

# Technical Completeness Check

Main changes:

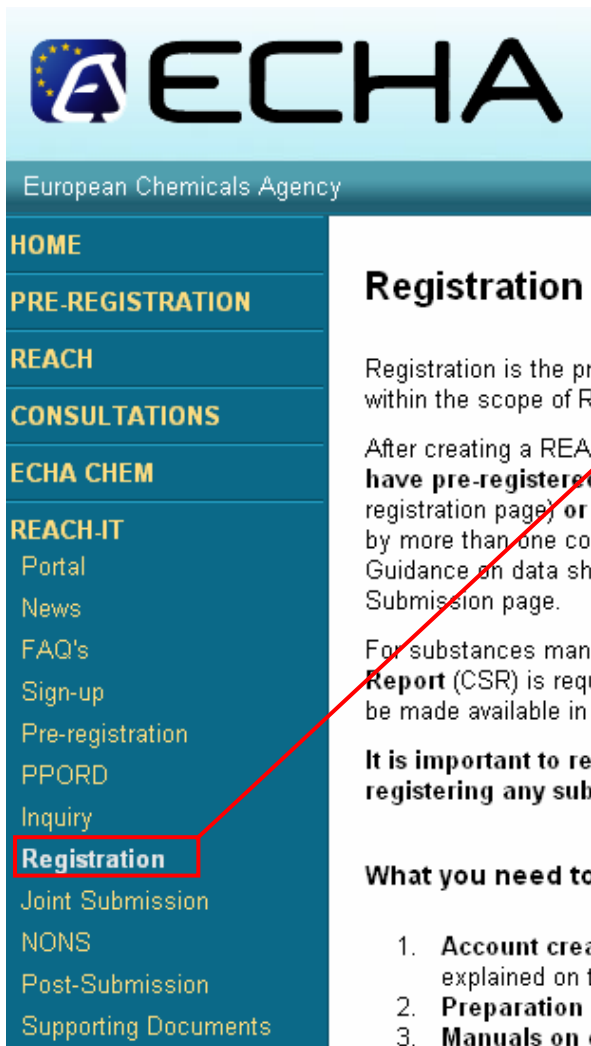
4) New: Information is given on which fields must be filled as a minimum in “Results and Discussion” to pass the technical completeness check

## **ANNEX 2: INFORMATION TO PROVIDE IN THE BLOCK “RESULTS AND DISCUSSION”**

<b>IUCLID 5 tree view</b>	<b>Minimum fields to be filled in the block "Results and discussion"</b>
4.1	The field "Physical state at 20°C and 1013 hPa" must be filled in. In addition the field "Form" should be filled in if relevant.
4.2	The fields "Melt/Freez.pt." or "Decomposition temperature" or "Sublimation temperature" must be filled in.
4.3	The fields "Boiling.pt." and "Atm. Pressure" or "Decomposition" and "Decomposition temperature" must be filled in.
4.4	The fields "Type", "Density" and "Temperature" must be filled in.
4.5	All the fields under "Particle size" or under "Particle size distribution at different passages" must be filled in.
4.6	Both "Vapour pressure" and "Temperature" must be given.
4.7	All the fields under "Partition coefficient" must be filled in.
4.8	The fields "Solubility", "Temp" and "pH" must be filled in.
4.10	The fields "Surface tension", "Temp." and "Concentration" must be filled in.
4.11	Both the flash point and the pressure must be given.
4.12	The self-ignition or autoflammability temperature and pressure must be given.
4.13	At least the fields "Solid/liquid: ignition on contact with air" "Gas: lower explosion limit

# Technical Completeness Check

## Where to find Data Submission Manual 5 and 8:



The screenshot shows the ECHA website navigation menu. The 'Registration' link is highlighted with a red box. A red arrow points from this box to the 'Further information' section of the registration page.

**ECHA**  
European Chemicals Agency

- HOME
- PRE-REGISTRATION
- REACH
- CONSULTATIONS
- ECHA CHEM
- REACH-IT
  - Portal
  - News
  - FAQ's
  - Sign-up
  - Pre-registration
  - PPORD
  - Inquiry
  - Registration**
  - Joint Submission
  - NONS
  - Post-Submission
  - Supporting Documents

### Registration

Registration is the pr within the scope of R

After creating a REA **have pre-registered** (registration page) or by more than one co Guidance on data sh Submission page.


For substances man **Report** (CSR) is req be made available in

**It is important to re registering any sub**













#### What you need to

1. **Account crea** explained on t
2. **Preparation**
3. **Manuals on**

### Further information

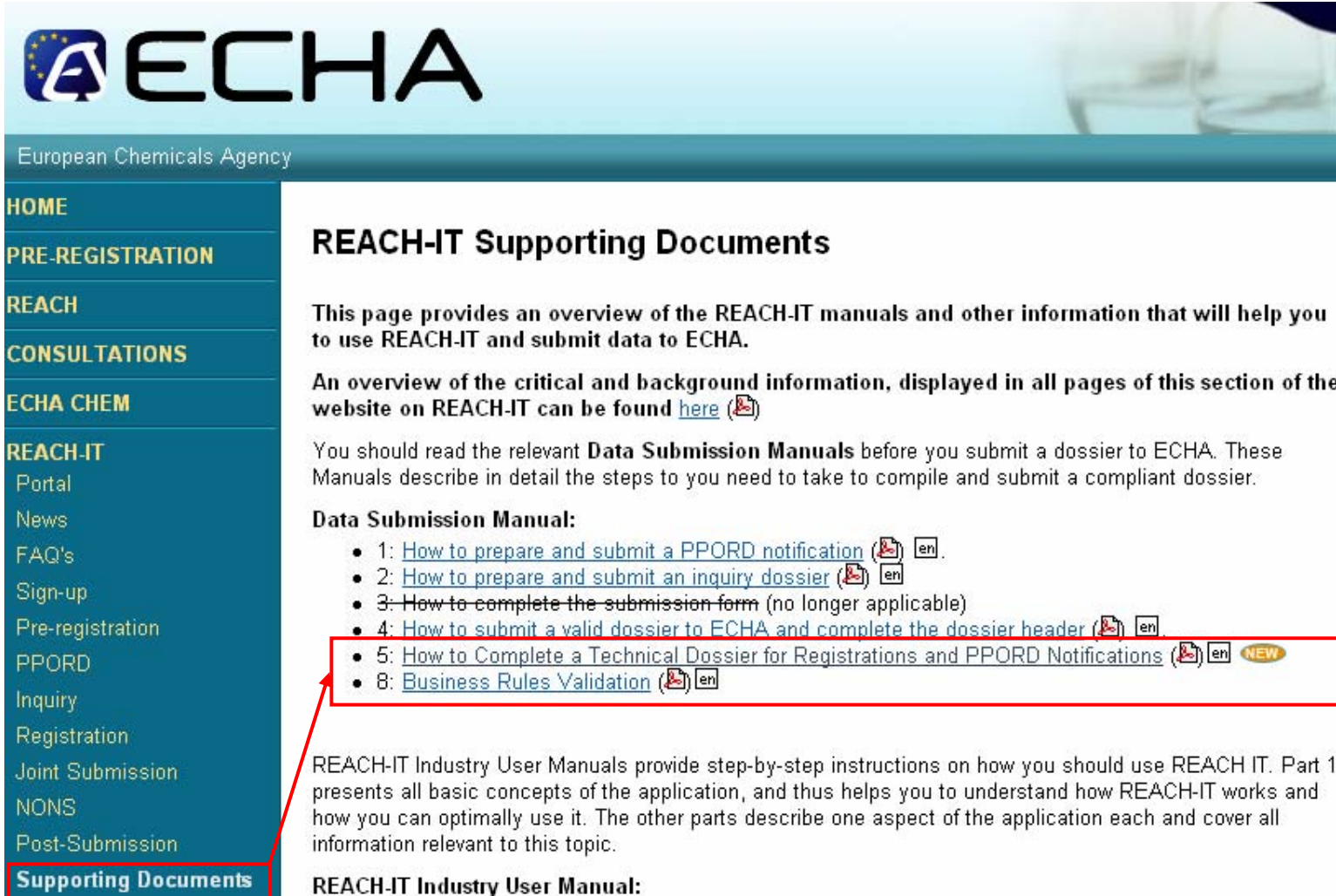
The information below helps you to understand the topics covered and provides access to relevant documents, tools and web pages. The  icon indicates that the linked material is currently available only in English.

#### Critical information for registrations

- Industry User Manual - Part 1: [Getting started with REACH-IT](#)  
- Industry User Manual - Part 2: [Sign-up and account management](#)  
- Data Submission Manual 4: [How to submit a valid dossier to ECHA and complete the dossier header](#)  
- Data Submission Manual 5: [How to Complete a Technical Dossier for Registrations and PPORD Notifications](#)   **NEW**
- Data Submission Manual 8: [Business Rules Validation](#)  
- Industry User Manual - Part 3: [Login and Message Box](#)  
- Industry User Manual - Part 4: [Online Pre-Registration](#)  
- Industry User Manual - Part 5: [Pre-SIEF](#)  
- Industry User Manual - Part 6: [Dossier Submission](#)  
- Industry User Manual - Part 8: [Invoices](#)  

# Technical Completeness Check

## Where to find Data Submission Manual 5 and 8:



**ECHA**  
European Chemicals Agency

**HOME**

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- NONS
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### REACH-IT Supporting Documents

This page provides an overview of the REACH-IT manuals and other information that will help you to use REACH-IT and submit data to ECHA.

An overview of the critical and background information, displayed in all pages of this section of the website on REACH-IT can be found [here](#) (📄) (en)

You should read the relevant **Data Submission Manuals** before you submit a dossier to ECHA. These Manuals describe in detail the steps to you need to take to compile and submit a compliant dossier.

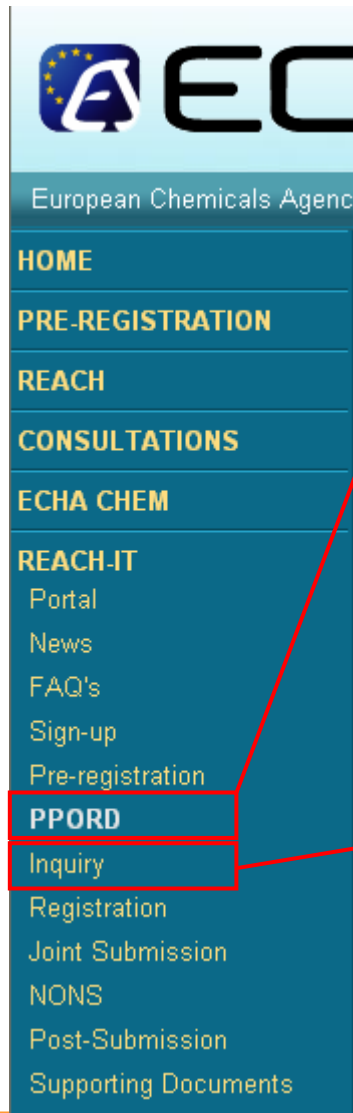
**Data Submission Manual:**

- 1: [How to prepare and submit a PPORD notification](#) (📄) (en)
- 2: [How to prepare and submit an inquiry dossier](#) (📄) (en)
- 3: [How to complete the submission form](#) (no longer applicable)
- 4: [How to submit a valid dossier to ECHA and complete the dossier header](#) (📄) (en)
- 5: [How to Complete a Technical Dossier for Registrations and PPORD Notifications](#) (📄) (en) **NEW**
- 8: [Business Rules Validation](#) (📄) (en)

REACH-IT Industry User Manuals provide step-by-step instructions on how you should use REACH IT. Part 1 presents all basic concepts of the application, and thus helps you to understand how REACH-IT works and how you can optimally use it. The other parts describe one aspect of the application each and cover all information relevant to this topic.

**REACH-IT Industry User Manual:**

# Supporting IT Tools:



## TCC Tool for PPORD dossiers:

<http://iuclid.echa.europa.eu/index.php?fuseaction=home.completenesscheck&type=public>

## Inquiry Dossier Preliminary Check Tool:

<http://iuclid.echa.europa.eu/index.php?fuseaction=home.inquiry&type=public>

# Supporting IT Tools:

## TCC Tool for Registration Dossiers:



- It will offer the possibility to companies to check on their own the completeness before submitting to ECHA
- Tool will be developed as a IUCLID 5 plug-in
- Release to the public at the ECHA website is envisaged **before end 2009**

Please visit ECHA website: REACH IT

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

Thank You  
for your attention

