

# How to submit an application & Initial processing by ECHA

Seminar on Applications for Authorisation

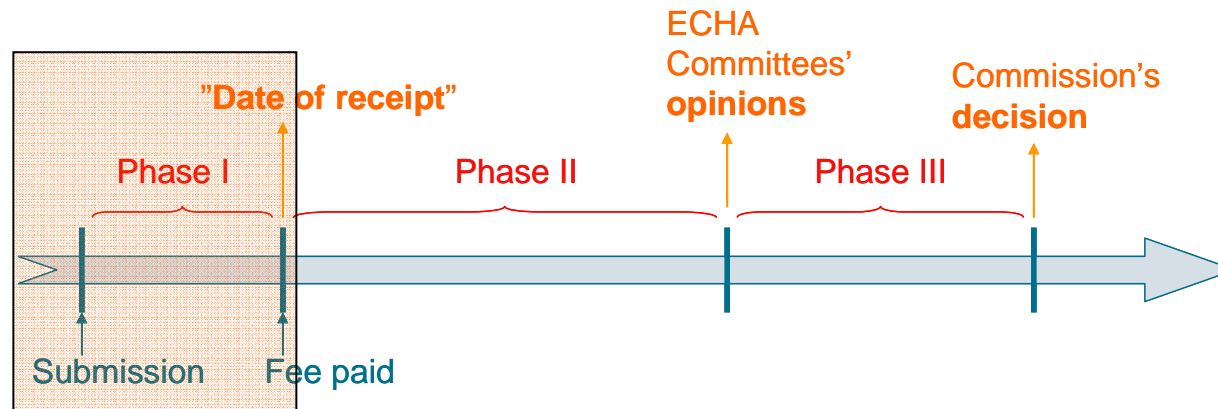
02 October 2012

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*ECHA - Risk Management Identification Unit*

## Objectives of the presentation

# To provide practical details on “Phase I”



- submission of the application (single, joint)
- processing by ECHA before acknowledging the receipt
- timing considerations

# How to submit an application

From the substance dataset  
to submission to ECHA



# Single applications

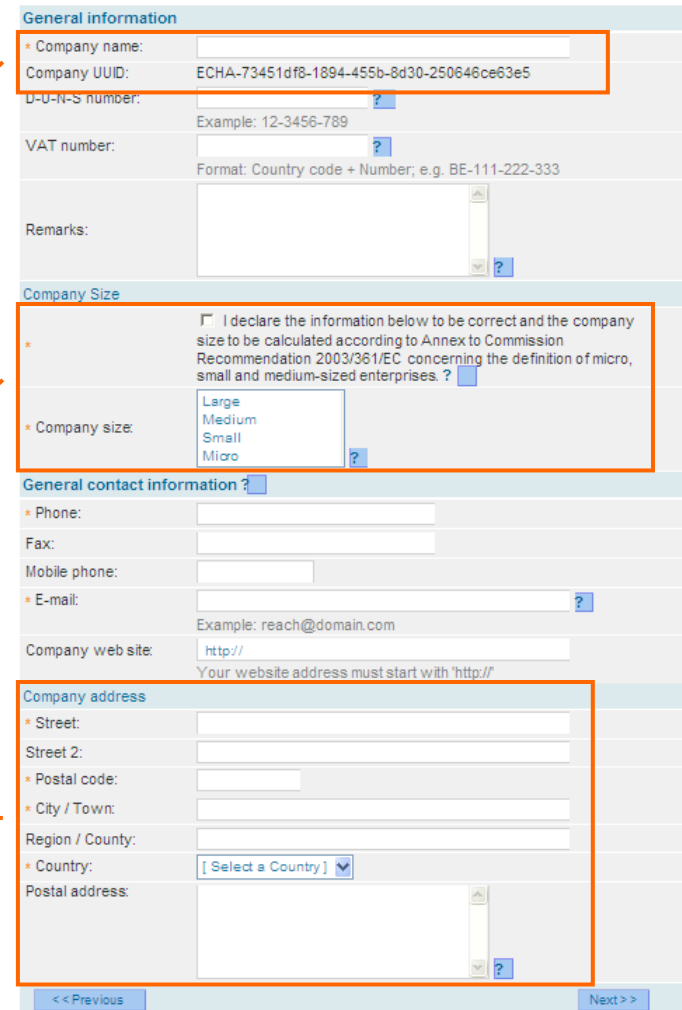


**Company name & UUID**  
(→ *Company identification*)

**SME verification!**

**Company size**  
(→ *Fee*)

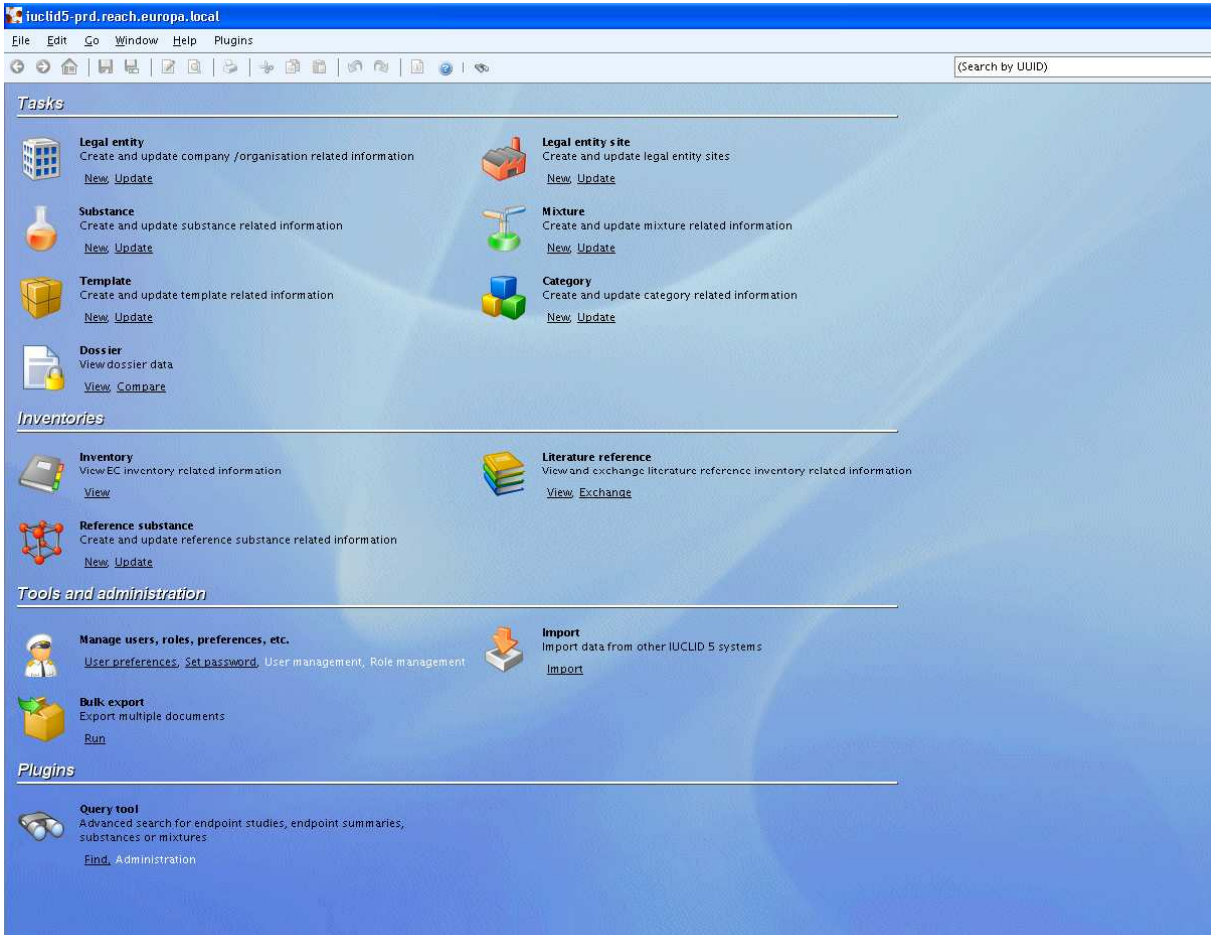
**Company address**  
(→ *Sending of decision*)



The screenshot shows the REACH-IT registration form with several sections highlighted by orange boxes:

- General information:** Includes fields for Company name, Company UUID (ECHA-73451df8-1894-455b-8d30-250646ce63e5), D-U-N-S number, VAT number, and Remarks.
- Company Size:** Includes a declaration checkbox and a dropdown menu for Company size (Large, Medium, Small, Micro).
- General contact information:** Includes fields for Phone, Fax, Mobile phone, E-mail, and Company web site.
- Company address:** Includes fields for Street, Street 2, Postal code, City / Town, Region / County, Country, and Postal address.

[Applicant has filled in the  
substance dataset in IUCLID]



The screenshot shows the IUCLID5 web application interface. The browser address bar displays "iuclid5-prd.reach.europa.local". The interface is organized into several sections:

- Tasks:**
  - Legal entity:** Create and update company /organisation related information. [New](#) [Update](#)
  - Substance:** Create and update substance related information. [New](#) [Update](#)
  - Template:** Create and update template related information. [New](#) [Update](#)
  - Dossier:** View dossier data. [View](#) [Compare](#)
  - Legal entity site:** Create and update legal entity sites. [New](#) [Update](#)
  - Mixture:** Create and update mixture related information. [New](#) [Update](#)
  - Category:** Create and update category related information. [New](#) [Update](#)
- Inventories:**
  - Inventory:** View EC inventory related information. [View](#)
  - Literature reference:** View and exchange literature reference inventory related information. [View](#) [Exchange](#)
  - Reference substance:** Create and update reference substance related information. [New](#) [Update](#)
- Tools and administration:**
  - Manage users, roles, preferences, etc.:** [User preferences](#), [Set password](#), [User management](#), [Role management](#)
  - Bulk export:** Export multiple documents. [Run](#)
  - Import:** Import data from other IUCLID 5 systems. [Import](#)
- Plugins:**
  - Query tool:** Advanced search for endpoint studies, endpoint summaries, substances or mixtures. [Find](#), [Administration](#)

# 1. Generation of the application form

Webform 1

>1 only for groups according to section 1.5 of Annex XI

\* Total number of substances  
\* Substance 1

1  
1. 5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene) [EC number: 201-329-4]

\* Total number of uses

2

Use 1 # as in section 3.5 in IUCLID

Proposed brief wording for Use 1

[Empty text area for Use 1]

from section 3.10 in IUCLID

for public consultation

\* Use 2

[Empty text area for Use 2]

Proposed brief wording for Use 2

[Empty text area for Use 2]

\* Uses and substances applied for

- Use 1 for Substance 1
- Use 2 for Substance 1

\* Role(s) in the supply chain  
press "Ctrl" for multi-selection

- Manufacturer
- Importer
- Only Representative
- Downstream User

\* Email of submitting applicant

Please ensure that the email address is correct, as ECHA will communicate important information related to your submission, e.g. the application form in .PDF format, and the submission code or the token.

[Empty email input field]



(via email or downloading)

Create application form

## 2. Creation and export of IUCLID Dossier

**Application form**  
for an application for authorisation

**Substance(s) applied for**

Please note that in accordance with Article 62(3) of REACH Regulation, applications may be made for one or several substances that meet the definition of a group of substances in section 1.5 of Annex XI of REACH.

\* Total number of substances 1

\* Substance 1 5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene) [EC number: 201-329-4]

**Use(s) applied for**

\* Total number of uses 2


\* Use 1 Description of Use 1 (as in IUCLID)  
Proposed broad information for Use 1 Broad info for Use 1 for the public consultation

\* Use 2 Description of Use 2 (as in IUCLID)  
Proposed broad information for Use 2 Broad info for Use 1 for the public consultation

**Applicant(s)**

(No)Joint application

\* Uses and substances applied for \*Use 1 for Substance 1  
\*Use 2 for Substance 1



***IUCLID 5  
Dossier***



### 3. Submission of IUCLID Dossier

Webform 3

**Submission code**

\* Submission code provided by ECHA

**Submitting applicant info**

\* Company UUID

\* REACH IT account user name  
*as indicated in the REACH-IT account*

\* Legal entity name  
*as indicated in the REACH-IT account*

\* Email

**Upload application file**

\* Upload IUCLID file

Please ensure that the IUCLID file of your application for authorisation contains also the PDF file of your application form. The maximum file size is 20MB. For the submission of a larger file, please contact the [ECHA Helpdesk](#), providing a justification and your submission code

Purchase order

\* Declaration

I declare that I am an authorised representative of the applicant legal entity for the purpose of submitting this application for authorisation and I am authorised to transmit and to receive documents

*from REACH-IT*



**IUCLID 5  
Dossier**

# Joint applications

*an option*

- \* *one IUCLID dossier*
- \* *one submission, by a "submitting applicant"*
- \* *one (global) invoice for the whole group of applicants*

[All applicants have signed-up in REACH-IT]



**General information**

\* Company name:

Company UUID: ECHA-73451df8-1894-455b-8d30-250646ce63e5

D-U-N-S number:  ?  
Example: 12-3456-789

VAT number:  ?  
Format: Country code + Number; e.g. BE-111-222-333

Remarks:  ?

---

**Company Size**

I declare the information below to be correct and the company size to be calculated according to Annex to Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises. ?

\* Company size:  ?  
Large  
Medium  
Small  
Micro

---

**General contact information ?**

\* Phone:

Fax:

Mobile phone:

\* E-mail:  ?  
Example: reach@domain.com

Company web site:  http://  
Your website address must start with 'http://'

---

**Company address**

\* Street:

Street 2:

\* Postal code:

\* City / Town:

Region / County:

\* Country: [ Select a Country ]

Postal address:  ?

<< Previous      Next >>

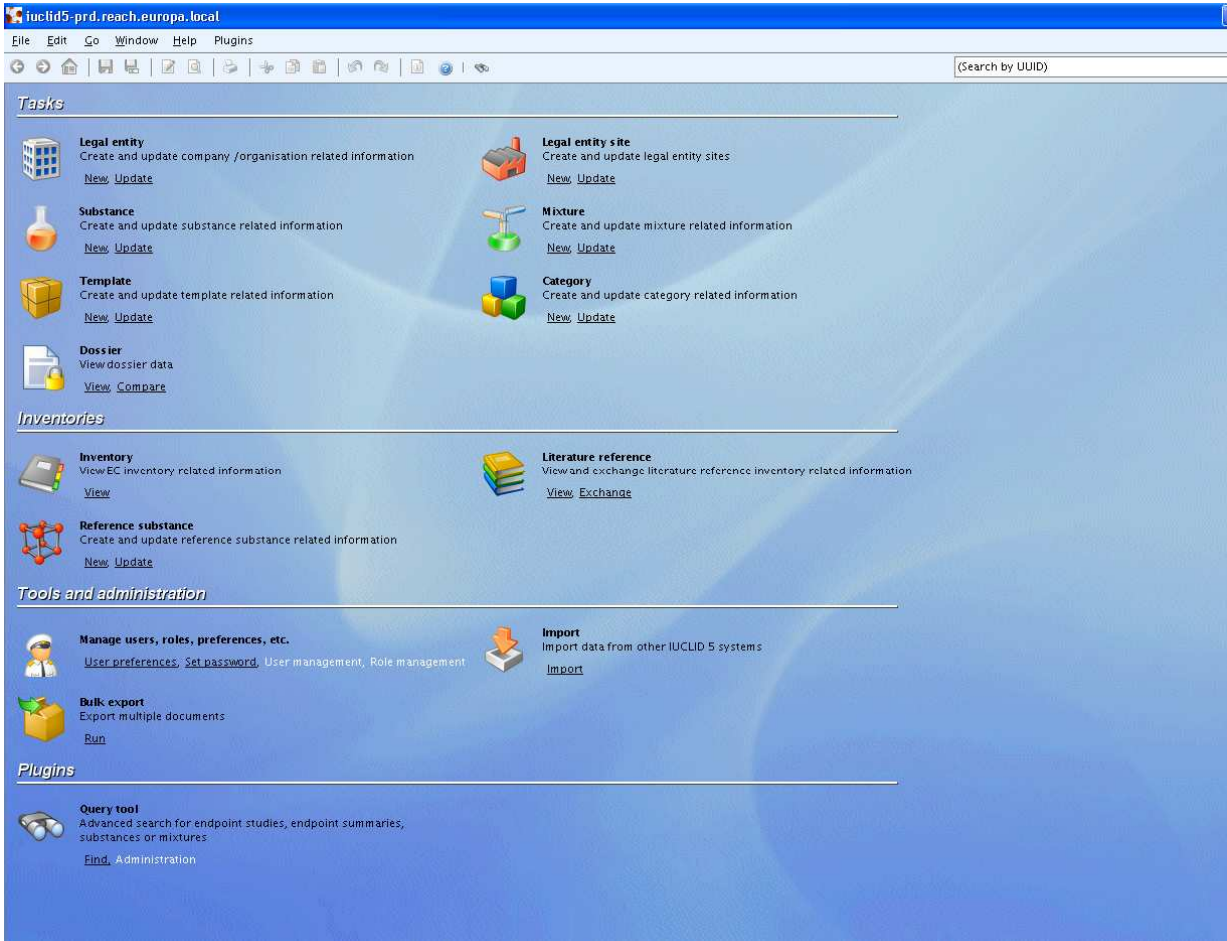
**Company name & UUID**  
( → *Company identification* )

**SME verification!**

**Company size**  
( → *Fee* )

**Company address**  
( → *Sending of decision* )

[Submitting applicant has filled in the substance dataset in IUCLID]



The screenshot shows the IUCLID 5 web application interface. The browser title is "iuclid5-prd.reach.europa.local". The interface is organized into several sections:

- Tasks:**
  - Legal entity:** Create and update company /organisation related information. [New](#) [Update](#)
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- Plugins:**
  - Query tool:** Advanced search for endpoint studies, endpoint summaries, substances or mixtures. [Find](#), [Administration](#)

# 1. Generation of the application form by the submitting applicant

Webform 1

Substance(s) applied for


Use(s) applied for

Applicant(s)

Joint application

\* Total number of applicants

* Applicant legal entity name <i>as indicated in the REACH-IT account</i>	* Applicant UUID <i>as indicated in the REACH-IT account</i>	* Role(s) in the supply chain <i>press "Ctrl" for multi-selection</i>	* Uses and substances applied for
Applicant 1 (submitting)		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input type="checkbox"/> Only Representative <input type="checkbox"/> Downstream User	<input type="checkbox"/> Use 1 for Substance 1 <input type="checkbox"/> Use 2 for Substance 1 <input type="checkbox"/> Use 3 for Substance 1
Applicant 2		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input type="checkbox"/> Only Representative <input type="checkbox"/> Downstream User	<input type="checkbox"/> Use 1 for Substance 1 <input type="checkbox"/> Use 2 for Substance 1 <input type="checkbox"/> Use 3 for Substance 1



## 2. Confirmation of participation by co-applicants

Webform 2

### Token and Application form

\* Token provided by the submitting applicant

\* Application form provided by the submitting applicant  
After verification of its content, please upload the PDF file of the application form which has been provided to you by the submitting applicant.

### Applicant info

\* Company UUID  
as indicated in the REACH-IT account

\* REACH IT account user name

\* Legal entity name  
as indicated in the REACH-IT account

\* Email

*from REACH-IT*

\* Declaration   
I declare that I am an authorised representative of the applicant legal entity for the purpose of submitting the joint application for authorisation and I am authorised to transmit and to



**Application form**

### 3. Creation and export of IUCLID Dossier by submitting applicant

**Application form**  
for an application for authorisation

**Substance(s) applied for**

Please note that in accordance with Article 62(3) of REACH Regulation, applications may be made for one or several substances that meet the definition of a group of substances in section 1.5 of Annex XI of REACH.

\* Total number of substances: 1

\* Substance 1: 5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene) [EC number: 201-329-4]

**Use(s) applied for**

\* Total number of uses: 2


\* Use 1: Description of Use 1 (as in IUCLID)  
Proposed broad information for Use 1: Broad info for Use 1 for the public consultation

\* Use 2: Description of Use 2 (as in IUCLID)  
Proposed broad information for Use 2: Broad info for Use 1 for the public consultation

**Applicant(s)**

(No) Joint application

\* Uses and substances applied for: \*Use 1 for Substance 1  
\*Use 2 for Substance 1




## 4. Submission of IUCLID Dossier by submitting applicant

Webform 3

**Submission code**

\* Submission code provided by ECHA

**Submitting applicant info**

\* Company UUID

\* REACH IT account user name  
as indicated in the REACH-IT account

\* Legal entity name  
as indicated in the REACH-IT account

\* Email

**Upload application file**

\* Upload IUCLID file

Please ensure that the IUCLID file of your application for authorisation contains also the PDF file of your application form. The maximum file size is 20MB. For the submission of a larger file, please contact the [ECHA Helpdesk](#), providing a justification and your submission code

Purchase order

\* Declaration

I declare that I am an authorised representative of the applicant legal entity for the purpose of submitting this application for authorisation and I am authorised to transmit and to receive documents

from REACH-IT



**IUCLID 5  
Dossier**



# Initial processing by ECHA

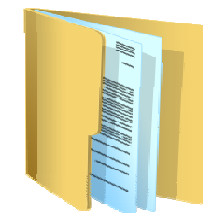
From submission  
to date of receipt





- Purpose:

- to ensure that the application is processible
- *NOT to assess whether application is in conformity*
- *NOT to assess the quality of the content*



**IUCLID 5  
Dossier**

- Examples:

- info in application form consistent (substance, uses)
- fee and broad information on uses can be determined (e.g. Exposure Scenario reference provided for each use, Analysis of Alternatives provided etc.)
- administrative references are valid (e.g. for subsequent applications, requested updates, references to CSR in registration etc.)

- Communication of outcome: *via REACH-IT*



**Failure → rejection (need to fix and resubmit)**

# Determination of fee and Broad Info on Uses (BIU)



} *substances  
uses  
applicants*

**Application  
form**

**IUCLID 5  
Dossier**



} 3.5  
3.10  
13

**IUCLID 5  
Dossier**

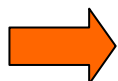


} *proposed  
"brief  
wording"*

**Application  
form**

Company size	
* Company size:	<ul style="list-style-type: none"> <li>Large</li> <li>Medium</li> <li>Small</li> <li style="background-color: #0056b3; color: white;">Micro</li> </ul>

**REACH-IT**



**fee**



**broad info on uses  
(inc. draft "brief wording")**



***ECHA communicates  
draft BIU***



***Applicant can  
comment***

***ECHA communicates  
final BIU***



***ECHA  
assesses  
comments***



***ECHA issues  
invoice***



***payment***



***Date of  
receipt***

# [Public consultation starts, Potential request updates]

- Committees may request updates (via REACH-IT)
- Short deadline to prepare and submit updates!
- Submission as for initial dossier (via webform)



Webform 3

**Submission code**

\* Submission code provided by ECHA

**Submitting applicant info**

\* Company UUID

\* REACH IT account user name  
*as indicated in the REACH-IT account*

\* Legal entity name  
*as indicated in the REACH-IT account*

\* Email

**Upload application file**

\* Upload IUCLID file

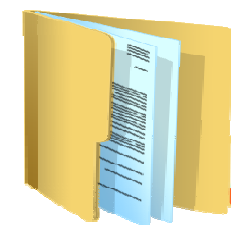
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Purchase order

\* Declaration

I declare that I am an authorised representative of the applicant legal entity for the purpose of submitting this application for authorisation and I am authorised to transmit and to receive documents

*from REACH-IT*



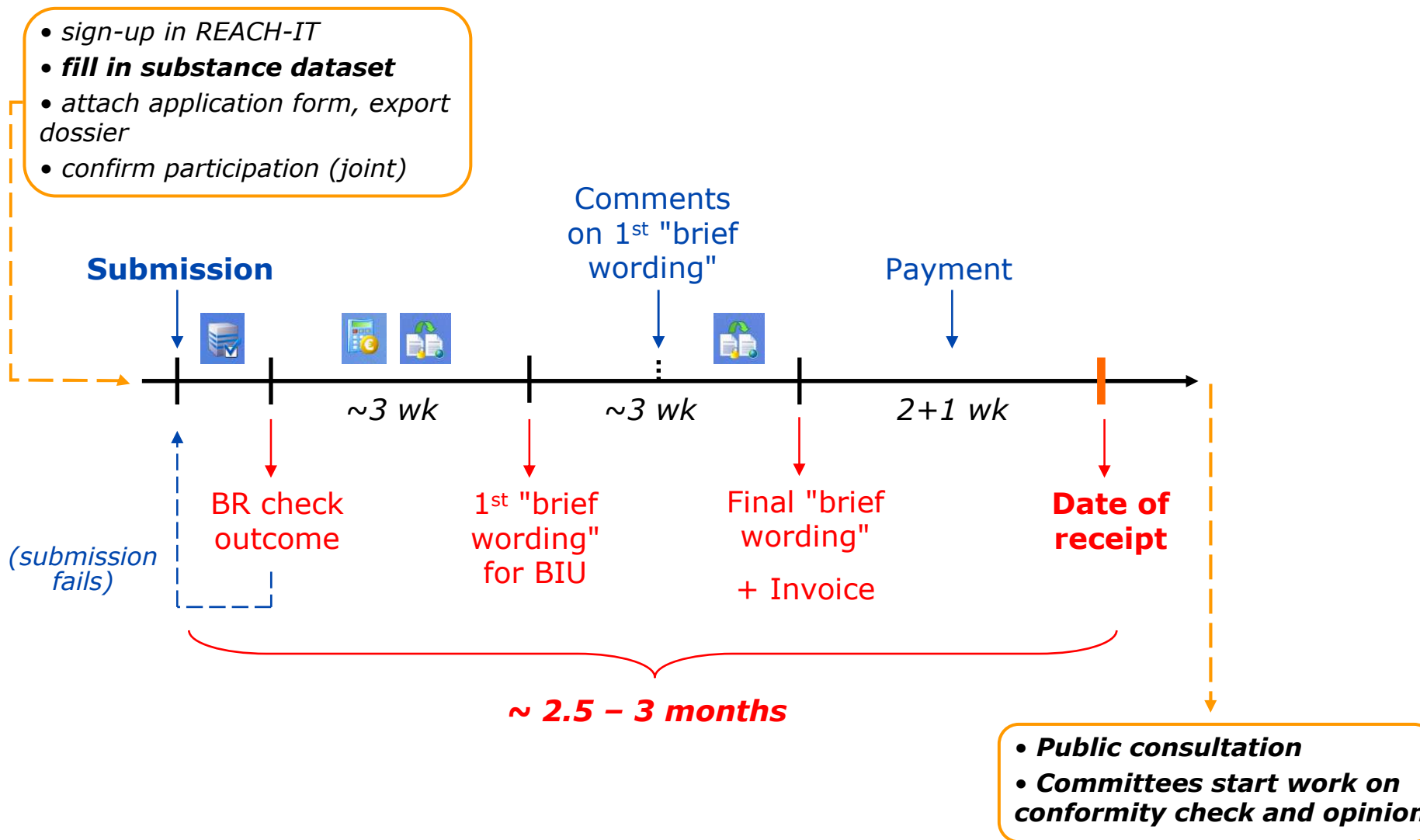
**Updated  
IUCLID 5  
Dossier**

# When to submit an application

Submission  
vs Date of receipt



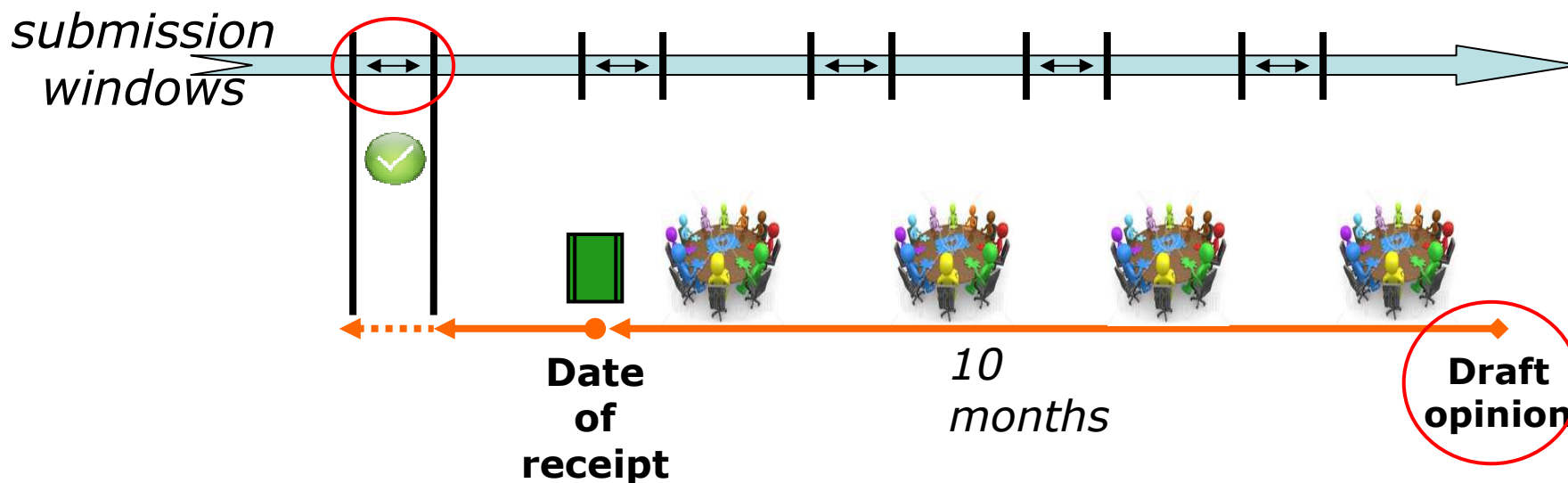
# Initial processing timeline



## Submission windows

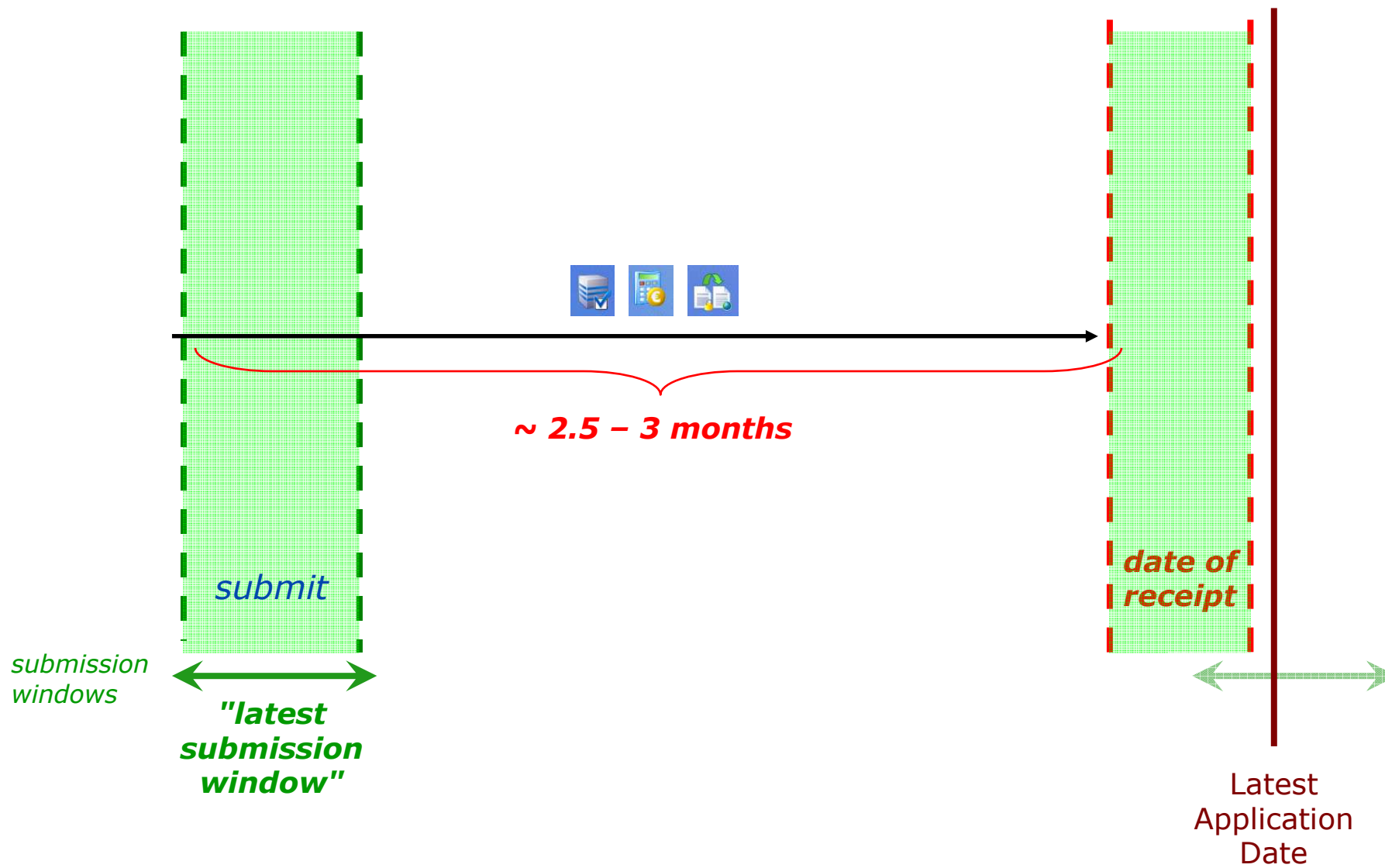
- Applications preferably submitted to ECHA at specific periods (announced on ECHA web pages; every 3 months)

*Reason: synchronise with scheduled Committees meetings, for effective preparation of opinions*





# “Latest submission window”



# Key messages



## Key messages

- **Plan and notify** your submission intention. Plan submission within the preset windows for optimal processing time
- **Keep your company info & size in REACH-IT up-to-date**
- **Submit via the secured web forms at ECHA's website**  
Keep consistency between the information in your IUCLID Dossier & REACH-IT and the data filled in the webforms
- **Monitor communication** sent by ECHA:
  - during the submission steps (email)
  - during processing steps and opinion making (REACH-IT)Joint applications: "submitting applicant" the central contact person; "co-applicants" in copy
  - **Instructions and further information** can be found at the **Data Submission Manual 22** and **ECHA's web pages**

**Thank you**



# Overview

