



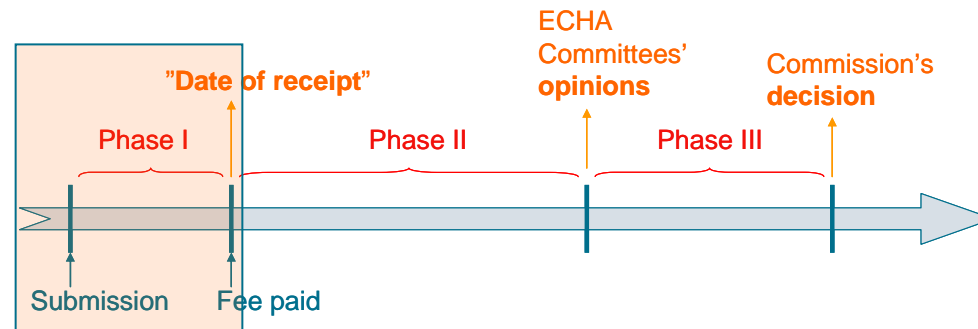
How to submit an application for authorisation & initial checks by ECHA

*Seminar on applications for authorisation
12 April 2011*

*Vasileios Kouloumpos
ECHA –Risk Management Identification Unit*

Objectives of the presentation

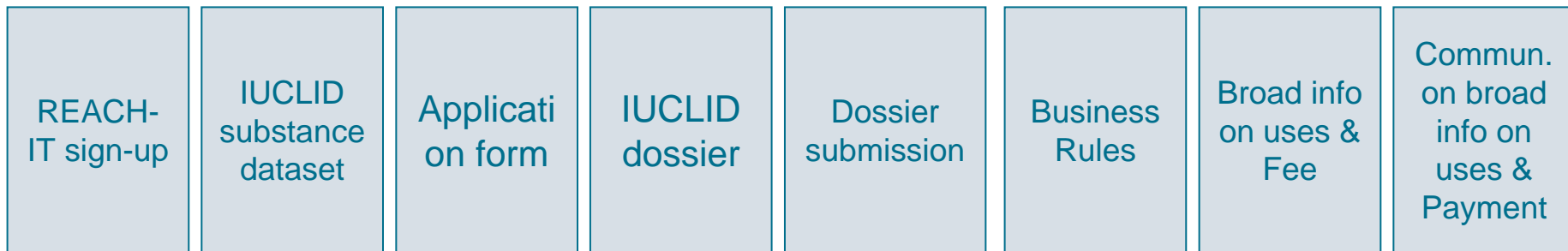
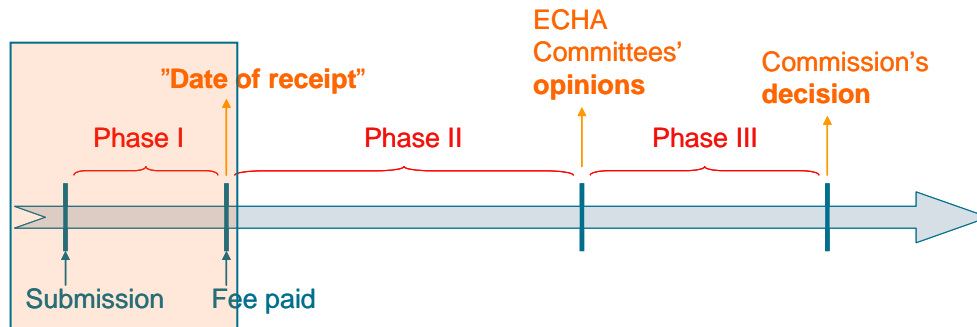
- To provide practical details on “Phase I”:



→ submission of the application (single, joint)

→ processing by ECHA before acknowledging the receipt

Overview



Single applications

REACH-IT sign-up

IUCLID substance dataset

Application form

IUCLID dossier

Dossier submission

Business Rules

Broad info on uses & Fee

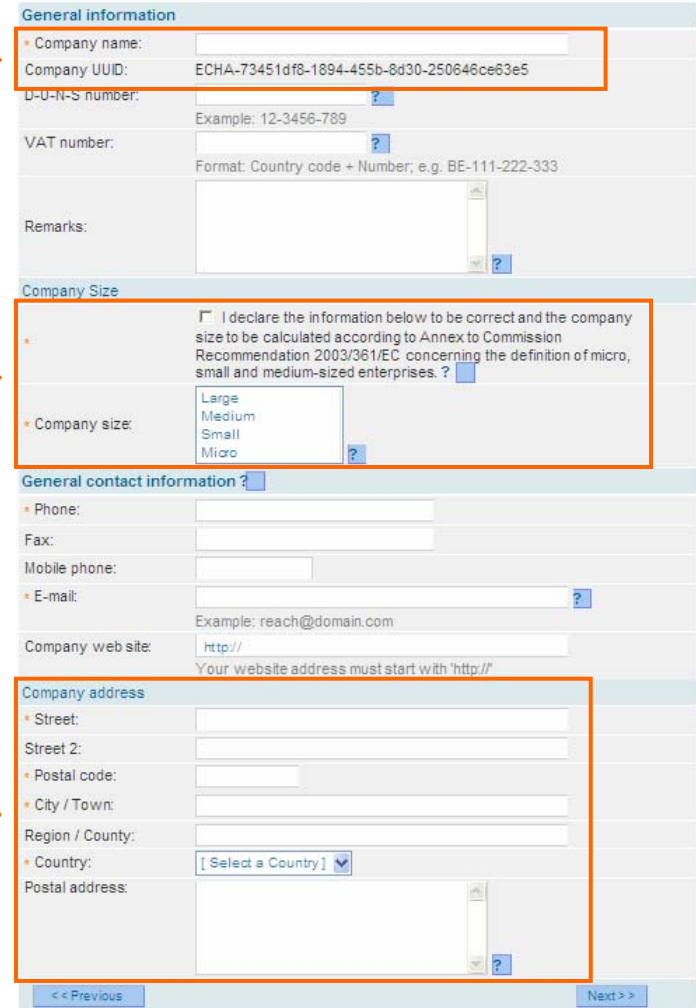
Commun. on broad info on uses & Payment

Single application: > Sign-up in REACH-IT

Company name & UUID
(→ *Company identification*)

Company size
(→ *Fee*)

Company address
(→ *Sending of decision*)



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 >>

REACH-IT sign-up	IUCLID substance dataset	Application form	IUCLID dossier	Dossier submission	Business Rules	Broad info on uses & Fee	Commun. on broad info on uses & Payment
------------------	--------------------------	------------------	----------------	--------------------	----------------	--------------------------	---

Single application: > Creation of application form

Webform 1

* Total number of substances

* Substance 1

* Total number of uses

* Use 1: **# as in section 3.5 in IUCLID**

Proposed broad information for Use 1

* Use 2


Proposed broad information for Use 2

* Uses and substances applied for

Use 1 for Substance 1

Use 2 for Substance 1

* Email of submitting applicant
Please note that a PDF version of this application form and a submission code or token will be sent to this email address.



from section 3.10 in IUCLID

for web consultation

REACH-
IT sign-up

IUCLID
substance
dataset

Applicati
on form

**IUCLID
dossier**

Dossier
submission

Business
Rules

Broad info
on uses &
Fee

Commun.
on broad
info on
uses &
Payment

Single application: > 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

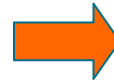
* Use 2: Description of Use 2 (as in IUCLID)
Proposed broad information for Use 2: Broad info for Use 1 for the public consultation

Applicant(s)

(No) Joint application

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





***IUCLID 5
Dossier***

REACH-IT sign-up	IUCLID substance dataset	Applicati on form	IUCLID dossier	Dossier submission	Business Rules	Broad info on uses & Fee	Commun. on broad info on uses & Payment
------------------	--------------------------	-------------------	----------------	--------------------	----------------	--------------------------	---

Single application: > 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

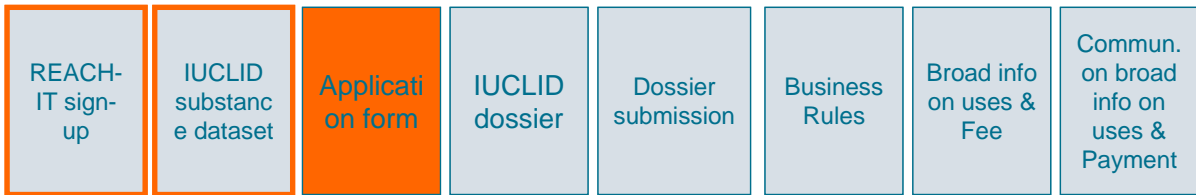
} *from REACH-IT*



**IUCLID 5
Dossier**

Joint applications

- one IUCLID dossier
- one submission, by a “submitting applicant”
- one (global) invoice for the whole group



Joint application: > Creation of application form

Webform 1

by "submitting applicant"

Substance(s) applied for


Use(s) applied for

Applicant(s)

Joint application

* Total number of applicants

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



REACH-IT sign-up	IUCLID substance dataset	Application form	IUCLID dossier	Dossier submission	Business Rules	Broad info on uses & Fee	Commun. on broad info on uses & Payment
------------------	--------------------------	-------------------------	----------------	--------------------	----------------	--------------------------	---

Joint application: > Confirmation of participation

Webform 2

by "co-applicants"

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



Joint application:

> 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


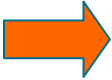
* Use 1: Description of Use 1 (as in IUCLID)
Proposed broad information for Use 1: Broad info for Use 1 for the public consultation

* 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

IUCLID 5 Dossier

REACH-IT sign-up	IUCLID substance dataset	Applicati on form	IUCLID dossier	Dossier submission	Business Rules	Broad info on uses & Fee	Commun. on broad info on uses & Payment
------------------	--------------------------	-------------------	----------------	--------------------	----------------	--------------------------	---

Joint application: > Submission of IUCLID dossier

Webform 3

by “submitting applicant”

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

Processing and further communication (single / joint applications)

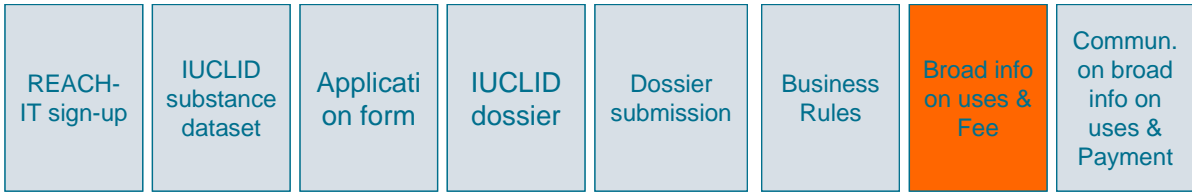
REACH-IT sign-up	IUCLID substance dataset	Applicati on form	IUCLID dossier	Dossier submission	Business Rules	Broad info on uses & Fee	Commun. on broad info on uses & Payment
------------------	--------------------------	-------------------	----------------	--------------------	-----------------------	--------------------------	---

> Business Rules check

- Purpose:
 - to ensure that the application is processible
 - *NOT to assess whether application is in conformity*
 - *NOT to assess the quality of the content*
- Communication of outcome: *via REACH-IT*
- Examples:
 - info in application form consistent (substance, uses)
 - ES reference provided for each use
 - administrative references correct (e.g. subsequent, requested updates, CSR in registration)



***IUCLID 5
Dossier***



> Determination of fee and broad info on uses

Application form **IUCLID 5 Dossier**

} *substances
uses
applicants*

Company size	
* Company size:	Large Medium Small Micro

REACH-IT

fee

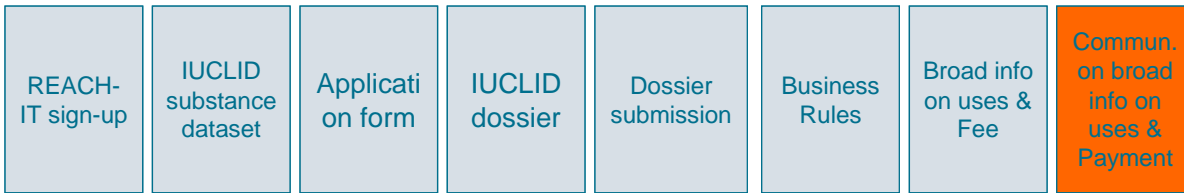
IUCLID 5 Dossier

} 3.5
3.10
CSR

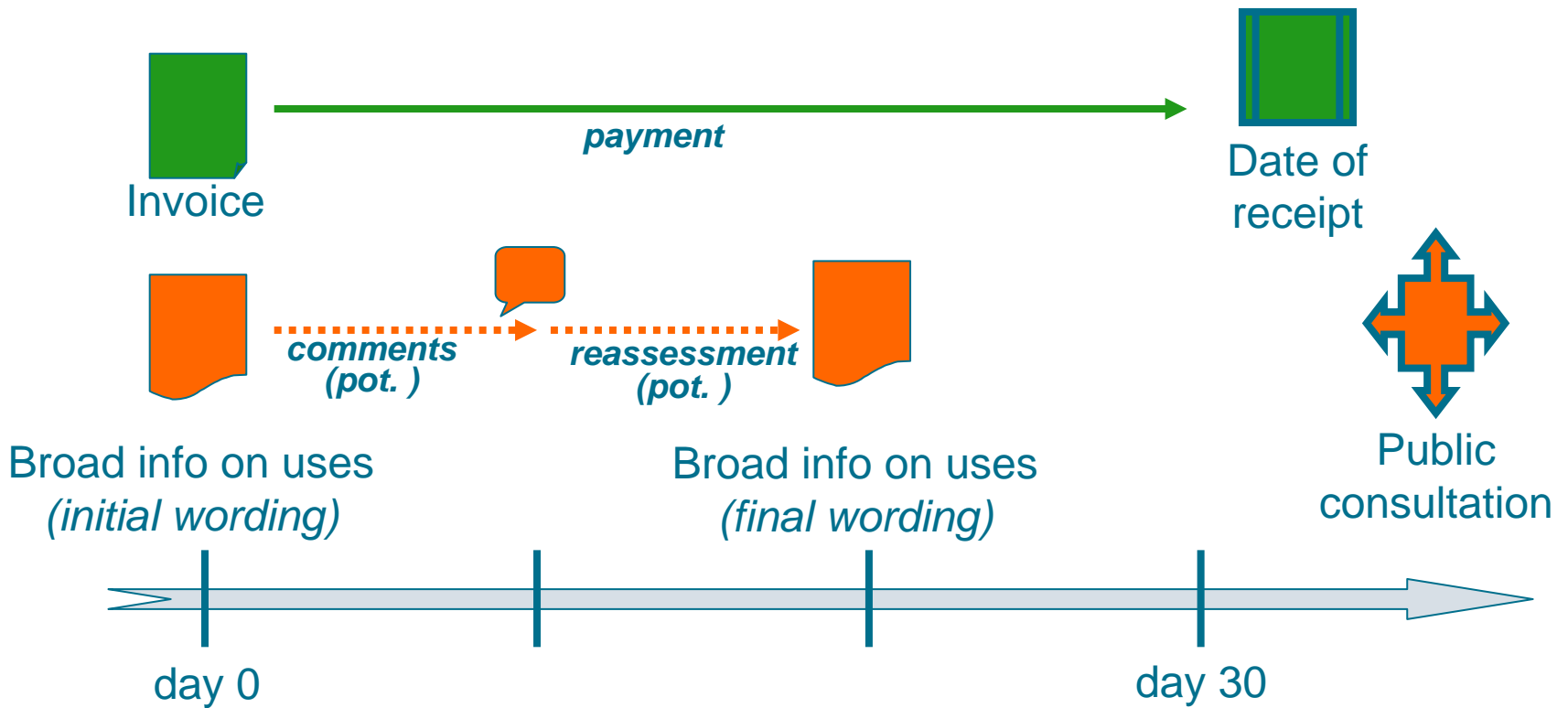
Application form

} *proposed
broad info
on uses*

**broad info on uses
(initial wording)**



> Communication on broad info on uses & Fee payment



Requested updates

- Short deadline to prepare and submit updates!
- Submission as for initial dossier

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

Webform 3

by “submitting
applicant”

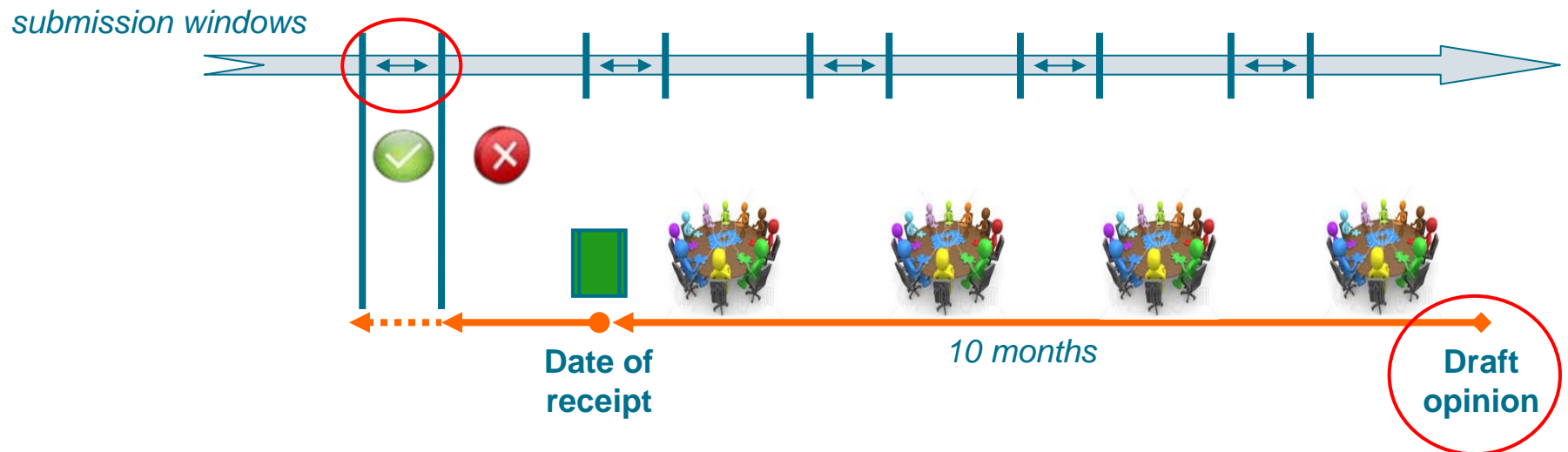


**updated
IUCLID 5
Dossier**

Submission windows

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

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



Conclusions

- Submission tool:
 - until 2012: via a secured web form
 - in the longer run: in REACH-IT
- Communication by ECHA:
 - via email during the submission steps
 - via REACH-IT during processing steps and opinion making
 - for joint applications, “submitting applicant” the central contact person; all “co-applicants” in copy
- Plan and notify your submission intention. Submit within the preset windows for optimal processing time
- Keep consistency between the data filled in the webforms and IUCLID / REACH-IT information
- *Your feedback is welcome!*
echa_application_for_authorisation@echa.europa.eu