

Welcome

Webinar: REACH-IT new functionalities

4 March 2021

11:00 – 13:00 Helsinki time

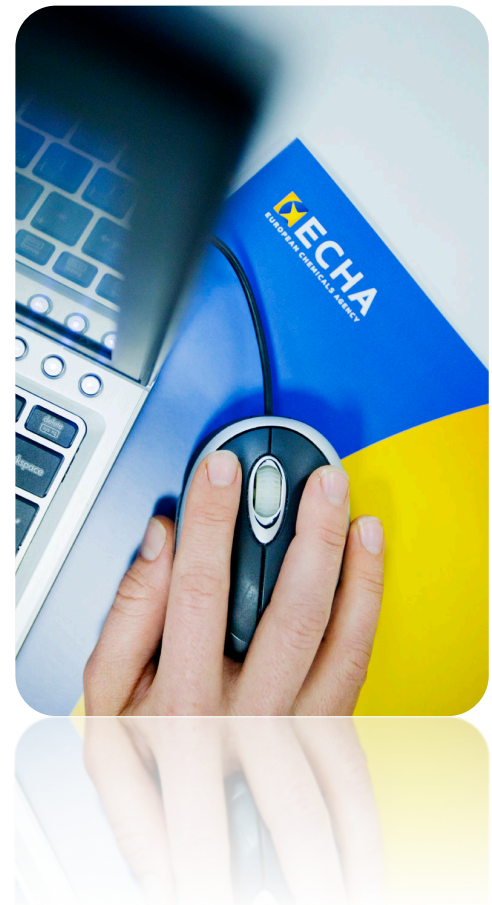
Eduardo Lopez, ECHA

Tuomas Aitasalo, ECHA

Reka Vataja, ECHA

What you can expect from today

- **Overview of** REACH-IT features implemented in 2020
- **Learn about** the new features: New information in the co-registrant page and dossier evaluation status
- Get **answers** to questions

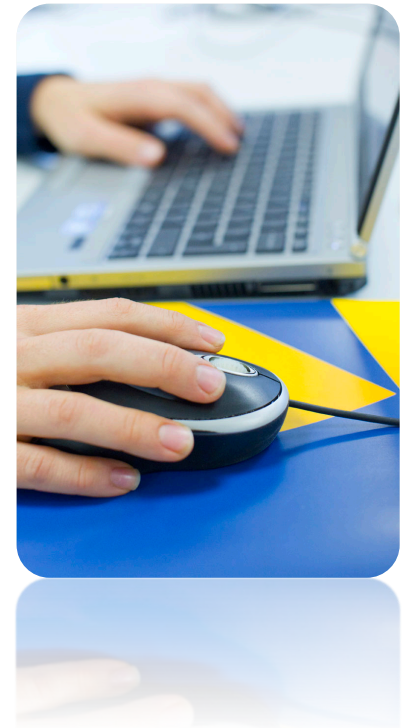


Programme

Time	Title	Speaker
11:00	Introduction	Eduardo Lopez, ECHA
11:05	REACH-IT 2020/2021	Eduardo Lopez, ECHA
11:15	Co-registrants page: submitters and submission dates of (robust) study summaries	Tuomas Aitasalo, ECHA
11:40	Dossier evaluation status in the joint submission	Reka Vataja, ECHA
12:05- 13:00	Webinar remains open for questions	

Questions

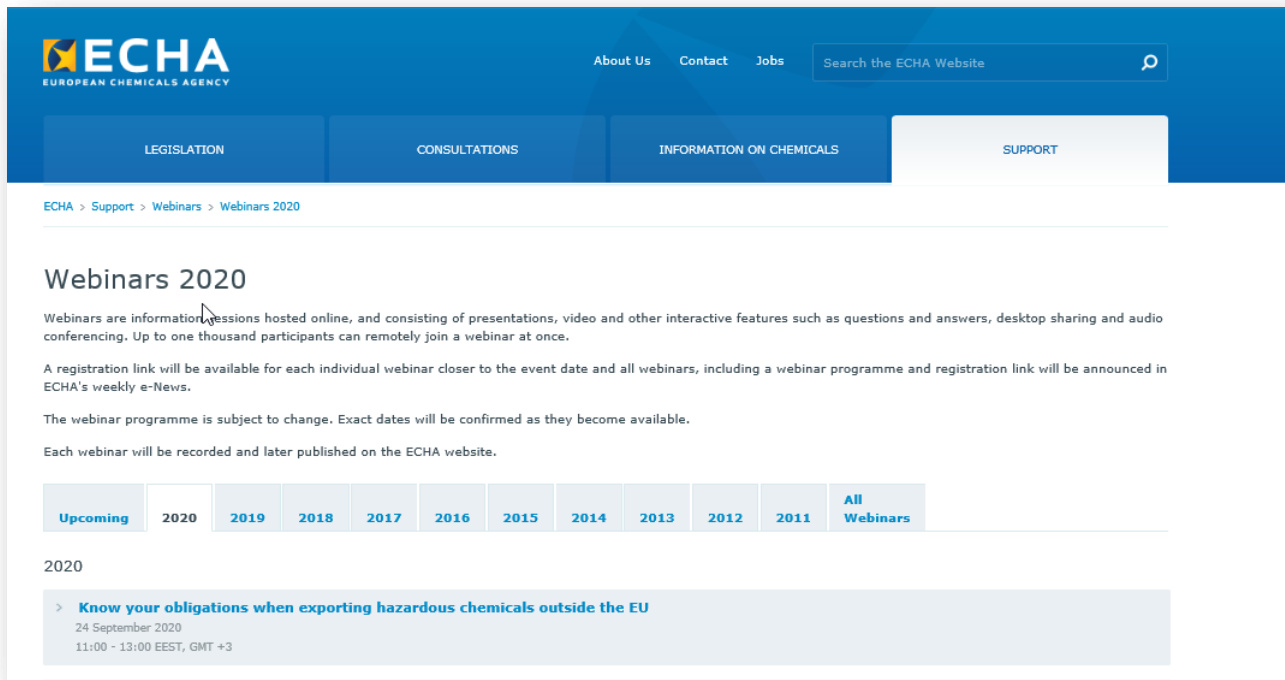
- Join Q&A at: [slido.com](https://www.slido.com)
Event code:
- Send questions from **11:00 to 13:00 EET, GMT+2**
- Only questions within webinar scope
- Question not answered?
Contact us: echa.europa.eu/contact



Material published

Video recording, presentations and Q&A

echa.europa.eu/support/training-material/webinars



The screenshot shows the ECHA website's 'Webinars 2020' page. The header includes the ECHA logo, navigation links for 'About Us', 'Contact', and 'Jobs', and a search bar. A secondary navigation bar contains 'LEGISLATION', 'CONSULTATIONS', 'INFORMATION ON CHEMICALS', and 'SUPPORT'. The main content area features a breadcrumb trail 'ECHA > Support > Webinars > Webinars 2020' and a title 'Webinars 2020'. Below the title, there is a paragraph explaining that webinars are information sessions hosted online, up to one thousand participants can join, and a registration link will be available closer to the event date. A second paragraph states that the webinar programme is subject to change and exact dates will be confirmed. A third paragraph notes that each webinar will be recorded and published on the ECHA website. A horizontal menu allows filtering by year from 'Upcoming' to '2011' and 'All Webinars'. The '2020' filter is selected, showing a list of webinars, with the first one being 'Know your obligations when exporting hazardous chemicals outside the EU' on 24 September 2020 from 11:00 to 13:00 EEST, GMT +3.

REACH-IT 2020/2021

New functionalities

4 March 2021

Eduardo Lopez
European Chemicals Agency



Content

- Improvement areas
- Main features of REACH-IT 2020
- Landscape 2021

Development areas 2020 - 2022

Enhanced information

- Joint application for authorisation
- Study summaries on co-registrants page
- More transparency for joint submission

Improve the submission

- Substance identity change for joint submission
- Joint submission status
- System to System for C&L Notifications

Multi-directional communication

- Join submission dossier evaluation status
- Submission of comments on draft/final decisions via REACH-IT

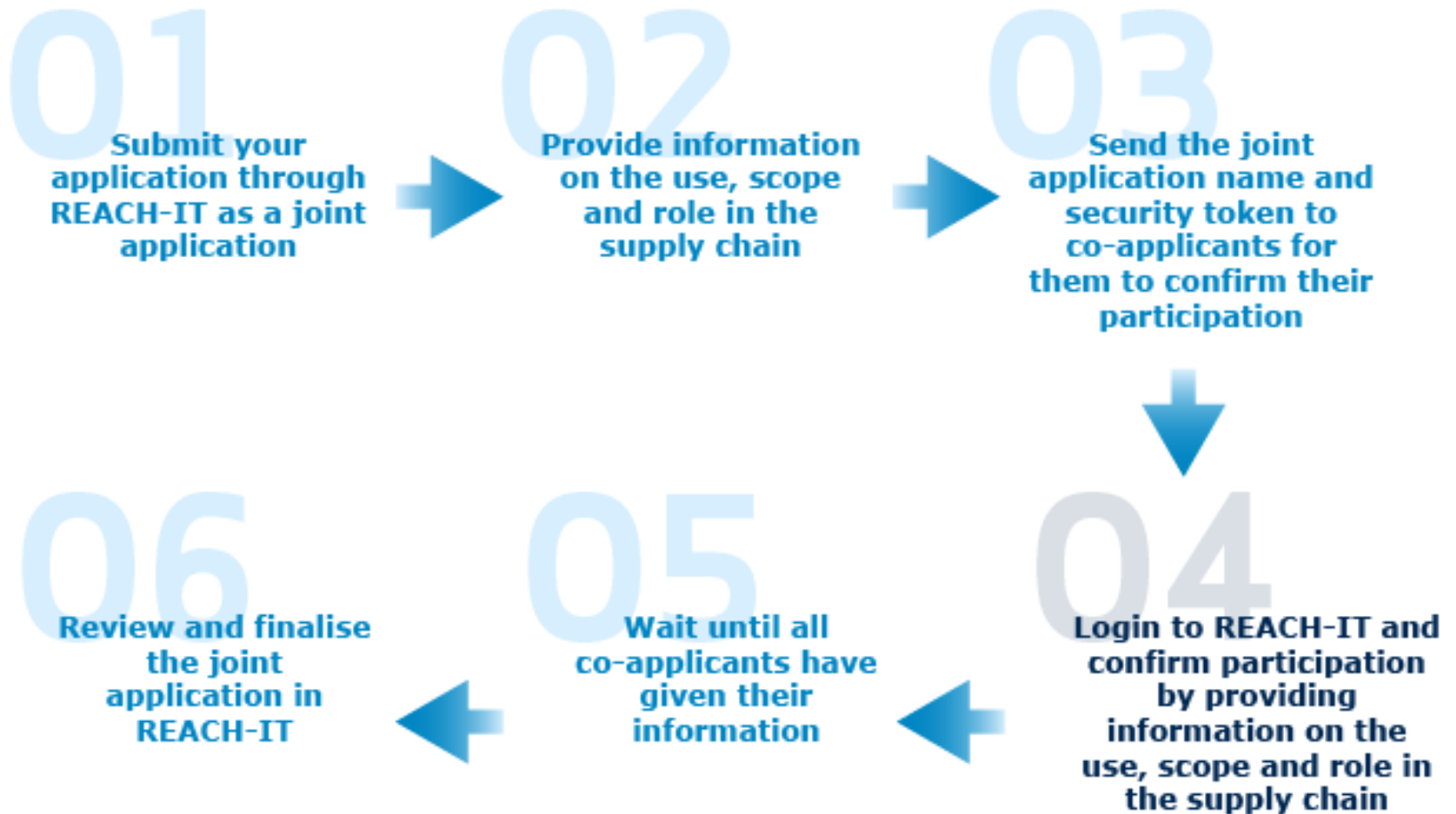
Technical improvements

- IUCLID adaptations
- Technology upgrades

Major enhancements 2020

3.4	Joint application for authorisation
3.5	Adaptations to the communication module
3.6	New DCW for joint submission substance identity change
	Joint submission status
	Enhanced transparency by making more information available for joint submission members
3.7- 3.8	Technical improvements and bug fixing REACH-IUCLID 2020 Adaptations
3.9	Joint submission dossier evaluation status
	Information on submitters and submission dates of (robust) study summaries on co-registrants page

New process for joint application



 submitting applicant




 co-applicants

Joint application for authorisation

Menu Home Joint application for authorisation 107_JA_VA183523-41


Overview


Dossier in progress
Scope not confirmed

Substance	Joint application information	Submitting applicant contact	Reference number
<p>Name Reaction mass of 2-ethylhex...</p> <p>EC number -</p> <p>CAS number -</p>	<p>Joint application name 107_JA_VA183523-41</p> <p>Supplementary information Hello!</p>	<p>Contact details</p> <p> Test Contact</p> <p> test.contact@jatest.com</p> <p> +3584012345</p>	<p>N/A</p> <p>Company role Co-applicant</p>

Joint application contact

Contact details

 Big Company test1

 reach@domain.com

Edit

Scope of the joint application for authorisation Download applicant details

Uses applied for authorisation ▼

Joint application for authorisation

Improvements

- Improved submission experience
- Simplified creation of joint submission for applicants
- Search functionality for joint application(s)
- Improved visualisation of own application(s)

See also

[Joint application for authorisation user manual](#)

[Application for authorisation submission](#)

Joint submission

Substance identity adaptations

- Upon request, we can modify joint submission substance identity
- “Biggest” group within joint submission able to “stay” => No need to move dossier
- High level benefits:
 - Less admin work for you
 - Less “clutter” in REACH-IT with “abandoned” joint submissions

Joint submission status

Active or closed

- Active or closed joint submission status
 - Active
 - Joint submission as you know it today
 - Remains active if lead submits successful lead dossier (passes at least business rules)
 - Closed
 - Empty joint submission will automatically close after 3 months to avoid blocking market access
 - REACH-IT allows creation of another joint submission for the same substance if the previous is closed
 - No submission is allowed, including updates
 - Registrations (if any) not lost. Can be transferred to another joint submission with a spontaneous update

Joint submission status

Deadline information

- During joint submission creation

Deadline to submit lead dossier: 21/04/2020 23:59 (EEST)

- Inside joint submission prior to successful lead submission

Joint submission status	Active	Lead dossier	Not submitted
Substance	Joint submission infor...	Joint submission cover...	Lead registrant contact
Name Test substance for JS C...	Registration type Full	Tonnage band	Contact details @ ☎
EC number -	Joint submission name Test substance JS		Third party representative -
CAS number -	Latest successful lead dossier completed on -		Publication acceptance Yes
	Deadline to submit lead dossier 21/04/2020 23:59 (EEST)		

Joint submission status

Deadline information

- Lead dossier submitted => deadline no longer displayed, as joint submission set to remain active

Joint submission status	Active	Lead dossier	Submitted
Substance	Joint submission infor...	Joint submission cover...	Lead registrant contact
Name	Registration type Full	Tonnage band > 1000 tpa	Contact details
EC number	Joint submission name	Guidance on safe use Not provided by lead	
CAS number	Latest successful lead dossier completed on 07/06/2012	CSR Not provided by lead	Third party representative
	Supplementary information -		Publication acceptance No
	Edit		Edit
	Security token		
	Expiry date 10/05/2017		
	Create new token		

Joint submission

More transparency

- Shows members using an ECHA token

Company	Joint submission contact	Data requirements	Opt-out	ECHA token	GoSU	CSR	Membership status	Reference status
		Annex IX	No		Not joint	Not joint	Lead	Active
		Annex VIII	Yes		Not joint	Not joint	Member	Active
		Annex VII	No		Not joint	Not joint	Member	In a different JS

- Enhanced status for registrations
 - Also if registration was moved to another joint submission

Joint submission

More transparency

- Last “completion date” of lead dossier

Joint submission status	Active	Lead dossier	Submitted
Substance	Joint submission infor...	Joint submission cover...	Lead registrant contact
Name	Registration type Full	Tonnage band > 1000 tpa	Contact details
EC number	Joint submission name	Guidance on safe use Not provided by lead	Third party representative
CAS number	Latest successful lead dossier completed on 07/06/2012	CSR Not provided by lead	Publication acceptance No
	Supplementary information -		
	Security token		
	Expiry date 10/05/2017		

- Scope of lead dossier update

Joint submission

More transparency

- New or improved set of messages
 - Tonnage band change (upgrade / downgrade)
 - Type change (full / intermediate)
 - Change of lead
 - New member registrant
 - Initial lead dossier completed
 - Lead dossier updated and complete
 - Joint submission created (sent to all with access to co-registrants page)

New export options

- Extended download information
 - Individual reference number, joint submission status (active/closed), registration type (Full/Intermediate), tonnage band, opt-out, guidance on safe use and chemical safety report
- Download all member details
 - One click to export all joint submissions
 - Contact information split in columns
 - New information also available
- Joint submission scope

New export files

Menu Home Advanced search

I am looking for: Joint submissions

Locate

Substance identity (EC, CAS, Name): ? *Please enter a minimum of three characters*

Joint submission name: *Please enter a minimum of three characters*

Reference number: *Please enter a minimum of three characters*

Filters

Company role: *You may select multiple items*

Registration type: Full ✕ ▼

Show other joint submissions? ? Favorite substances only?

Search
Clear

Results 61 results found

Download Joint submission information
Download member details

Joint submission name	Substance name	EC number	CAS number	Company role	Status	
2007144	nitrobenzene	2007144	98053	Member	Active	▼
2007144	nitro	2007144	98053	Member	Active	▼

New export files

Scope of the joint submission Download scope details ^

Boundary composition (SIP) ^

Methods of manufacture of substance (registered information): Sulphurized Dodecylphenol (SDSP), alkylbenzene sulphonic acid, calcium hydroxide and carbon dioxide are reacted in toluene, methanol and water. The residual solids are removed by centrifugation. The solvents are removed by distillation. The final substance is supplied diluted in base oil.

State / Form: liquid

Constituents

EC number	EC name	CAS Number	CAS name	IUPAC name	Concentration range	
215-154-2	Phenol, alkyl-, branched	121-158-98-9		Phenol, paraffinized products with C12-18h branched alkyls derived from propane oligomerisation	= 1.7 - 2.8 % (wt)	^
				na	= 15.0 - 25.0 % (wt)	
				Benzene, alkyl, branched (specifies comprising C12-18 paraffinyl substituents (paraffin))	= 0.8 - 1.2 % (wt)	^
215-127-2	calcium hydroxide	1305-62-0		Benzene sulphonic acid, alkyl, branched, calcium salt (specifies comprising C12-18 paraffinyl substituents (paraffin))	= 15.0 - 25.0 % (wt)	^
				calcium hydroxide	= 4.1 - 6.1 % (wt)	^
207-429-9	calcium carbonate	471-34-1	Carbonic acid calcium salt (1:1)	calcium carbonate	= 42.0 - 52.0 % (wt)	^

Developments in 2021

- Enhanced joint submission
 - e.g. reason for updating lead, dossier evaluation status further improvements...
- Migrate bulk C&L notifications to individual submissions
- System to System for C&L notifications
 - Create C&L dossier in your own systems
 - Submit directly to REACH-IT
 - Using system to system (S2S) key

Update of co-registrants page with studies section

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4 March 2021

Tuomas Aitasalo
European Chemicals Agency



Background

- *Article 25(3)*: (Robust) study summaries submitted at least 12 years previously can be used for the purposes of registration by another manufacturer or importer

Background

- *Article 26(1)*: Potential registrant shall inquire from the Agency whether a registration has already been submitted for the same substance
- *Article 26(3)*: When the substance has been registered less than 12 years earlier, the Agency shall inform the potential registrant:
 - Names and addresses of the previous registrant(s)
 - Relevant (robust) study summaries already submitted

Co-registrants page update

Studies section



Demo

See video recording

Summary

- 'Studies' section on co-registrants page in REACH-IT contains:
 - Names and contact details of submitters of (robust) study summaries
 - Information if the (robust) study summaries have been submitted less or more than 12 years earlier
 - UUIDs of the (robust) study summaries submitted more than 12 years earlier

Summary

- Based on the information on the co-registrants page, potential registrant can initiate data sharing negotiations
- Previous registrant should not claim compensation for (robust) study summaries submitted > 12 years earlier
- ECHA is never a party in data sharing negotiations

Dossier evaluation status in the joint submission

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4 March 2021

Reka Vataja
Regulatory Assistant
European Chemicals Agency

Overview

- Demo
 - Dossier evaluation status section
 - Dossier evaluation overview page
- Upcoming features
 - Automatic notification for compliance check
 - List of decision recipients
- Expected advantages
 - Easy access to information
 - Transparency

Joint submission page

Dossier evaluation status



Demo 1

Dossier evaluation

Overview page



Demo 2

Good to know



Icons used

- Dossier evaluation processing:



- Completed



- In progress



- Haven't started



- Not applicable

- Information requests under follow-up:



- In progress



- Data not provided



- Data provided

Additional information

Dossier evaluation processing steps

1	✓	Under assessment	▲
<i>The evaluation of the dossier has formally started</i>			
2	-	Ongoing	
3	-	Information requested	
4	-	Follow-up	
5	✓	Concluded	▲
<i>The evaluation is closed</i>			

Additional information

ECHA has performed an assessment and did not issue a decision.

Dossier evaluation processing steps

1	✓	Under assessment	▼
2	✓	Ongoing	▼
3	⚙️	Information requested	▲
		▶ Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)	▲
		▶ Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.)	▲
4		Follow-up	
5		Concluded	

Additional information

This Decision is currently under Appeal, Case No. A-000-2021. Requests: Sub-chronic toxicity study is suspended, pending Board of Appeal decision. Deadline in the ECHA decision applies to non-appealed request: Pre-natal developmental toxicity study.

Follow-up not started, but information requests displayed

Dossier evaluation processing steps	
1	Under assessment
2	Ongoing
3	Information requested
4	Follow-up
	Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2., Deadline: 08.08.2019)
5	Concluded

Dossier evaluation status section

↕ Dossier evaluation type ?	↕ Start date ?	↕ Status ?
TPE	02/05/2019	<input type="text"/>

-> Assessment has not started

↕ Dossier evaluation type ?	↕ Start date ?	↕ Status ?
		No results found

-> No dossier evaluations concerning the joint submission

↕ Dossier evaluation type ?	↕ Start date ?	↕ Status ?
		Unable to retrieve information. Please try again later.

-> Error message: revisit the page the next day

Warning text

ECHA accepts no responsibility and/or liability for the information provided on this page, including, but not limited to, its timeliness and correctness. Any use and/or reliance of the information falls under the sole of responsibility of the user.

If list of information requests do not match list of studies from the decision:

-> Rely on draft and adopted decision and contact our helpdesk: echa.europa.eu/contact.

Upcoming features



Automatic notification

Compliance check

If you have an active and full registration, you will automatically receive a REACH-IT message, when a compliance check has been initiated, including both members of joint submission(s) and individual registrants

Recipients of current decision

- Recipients of draft/adopted decision listed on overview page
- Table format will be the same as in the decision's appendix that contains the addressees:
 - Includes registrant name, registration number and the highest REACH Annex applicable at the time the draft decision was issued

Expected advantages



Easy access to dossier evaluation information

Easy access to useful information on ongoing and past dossier evaluations:

- List of studies requested in the draft and adopted decision and their recipients
- Status of the requested studies after the assessment
- Additional information on the process: e.g. reason why dossier evaluation was concluded without adopted decision and appeal related information

Transparency

All members get information on:

- Dossier evaluations concerning other joint submission members (e.g. opt-outs, higher tonnage bands)
- Dossier evaluations that have started before a registrant joined the joint submission
- Compliance checks started for a substance you have registered so that you can check that your registration is up-to-date

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