

Reach 2013 – Status Update and Next Steps

Eighth Stakeholders' Day

26 March 2013

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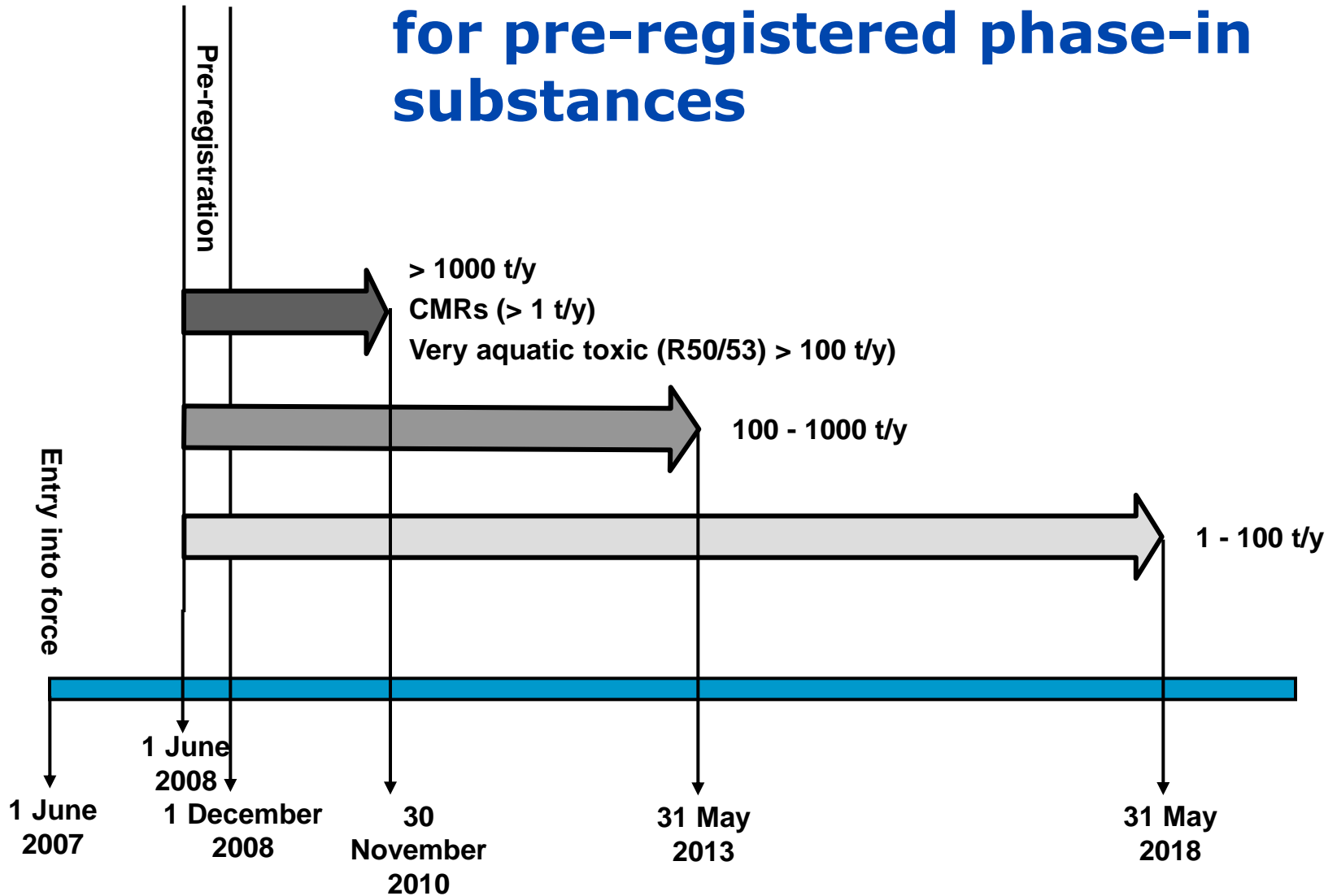


REACH Registration 2013

- **Current status and expectations**
- Revised REACH fees and charges
- Member registrants:
Steps to successful registration



Timelines for Registration for pre-registered phase-in substances



Substances: Industry intentions - 2013 Support page updated

ECHA > REACH 2013 > REACH 2013 - registration progress



REACH 2013

31 May 2013 is the deadline for industry to register all phase-in substances manufactured or imported in the EU at or above 100 tonnes a year.

Data as of: xx/xx/2013

Overview	Registration Intentions	Lead Registrants Nominations	Registration Progress	Support
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Registration Progress

Details on the number of substances registered and of registration dossiers received to date for the 2013 deadline.

> [Substances Registered for 2013 deadline](#)

> [Registration Statistics for 2013 deadline](#)

> [Registrations detailed by country for 2013 deadline](#)

Related links:

- > [Registration statistics](#)
- > [Registrered substances](#)



Calendar

23 May 2012, Helsinki

ECHA's Seventh Stakeholders' Day

Webinars

28 January 2013

How to bring your registration dossier in compliance with REACH – Tips and Hints (part 2)

25 February 2013

Last minute webinar on submission

> [Webinars calendar](#)

ECHA Newsletter

- Read the [ECHA Newsletter articles about the 2013 deadline](#)

Substances: Industry status

The number of phase-in substances intended to be registered by 31 May 2013 is shown in the table below. It is the result of a survey ECHA conducted with all pre-registrants that indicated 2013 as their registration deadline.

Phase-in substances intended to be registered for 2013 deadline Number of substances for which at least one potential registrant has declared the intention to register the substance	3968
registered by the 2010 deadline	871
substances no longer intended to be registered for 2013	14
'new' substances to be registered for 2013 deadline	3083
Number of 'new' substances to be registered for 2013 deadline	3083
a lead registrant is known to ECHA	2405
subsequently registered by a lead registrant	668
Number of substances for which ECHA has received neither a lead registrant nomination nor a registration	626

2013 Dossiers: Industry status

	Registrations
GRAND TOTAL	3428

Breakdown by registration type

REACH covers different types of registrations: Full registrations (Art.10) and Intermediates (Art. 17&18). A substance can be registered for up to three registration types with one dossier. This is why the numbers below do not add up to the total number of registrations.

	Registrations
Registered as full registration	2377
Registered as intermediate	1078
Transported isolated intermediates	859
On-site isolated intermediates	293

Joint submission

Joint Submission is a fundamental principle of REACH. Its aim is to reduce costs and avoid unnecessary testing on animals. This table provides a breakdown of the number of registrations submitted in a joint submission compared to individual submissions.

	Registrations
Registrations in joint submissions	2987
Lead	702
Member	2285
Individual registrations under REACH	441
TOTAL	3428

REACH Registration 2013

- Current status and expectations
- **Revised REACH fees and charges**
- Member registrants:
Steps to successful registration



Revised Fee Regulation

- **Further reductions in fees for SMEs, to help them remain competitive**
 - 35% - 95% reductions for standard registrations
 - 25% - 90% reductions for authorisation standard fee

	Medium	Small	Micro
Registration	-35%(-30%)	-65% (-60%)	-95% (-90%)
Authorisation	-25%(-20%)	-55% (-50%)	-90% (-85%)
Appeals	-25% (18.2%)	-25% (18.2%)	-25% (18.2%)

(current reductions in brackets)

- **Standard fees (non-SME) increased, also updated in line with inflation**

Revised Fee Regulation

Examples

Joint submission fee	Large (EU)	Medium (EU)	Small (EU)	Micro (EU)
100-1000 tonnes	9237 (8625)	6004 (6038)	3233 (3450)	462 (863)
>1000 tonnes	24901 (23250)	16185 (16275)	8715 (9300)	1245 (2325)

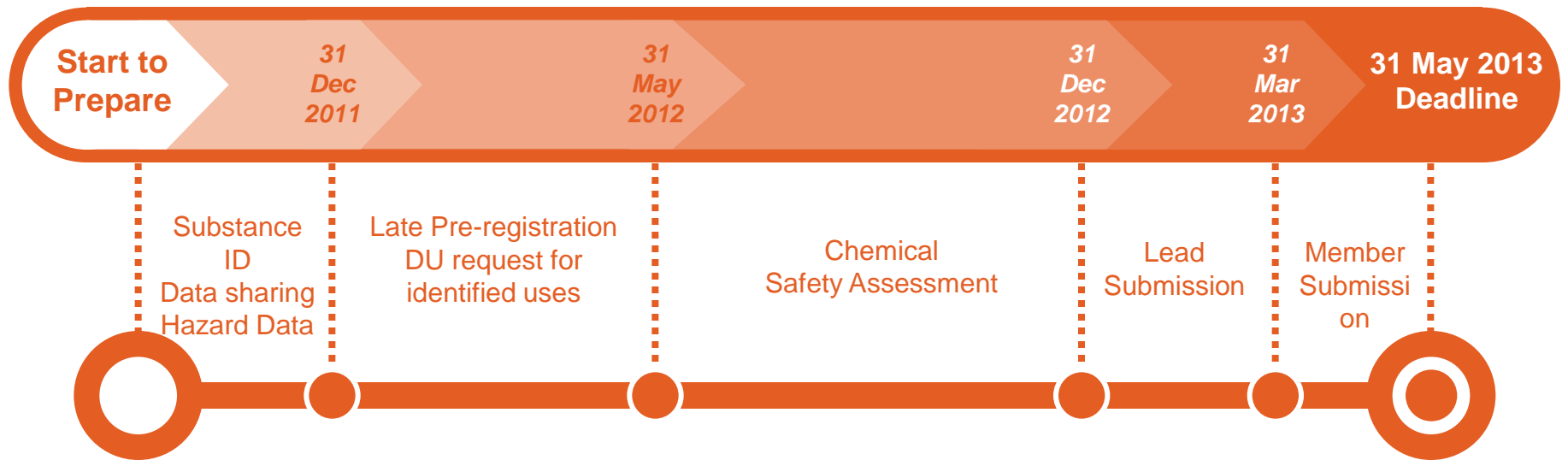
- New fees in effect from 22 March
- Implemented in REACH-IT on 21 March
- Updated IUCLID Fee Calculator available (IUCLID website)
- Full revised Fee Regulation – Official Journal and DG ENTR site

REACH Registration 2013

- Current status and expectations
- Revised REACH fees and charges
- **Member registrants:
Steps to successful
registration**



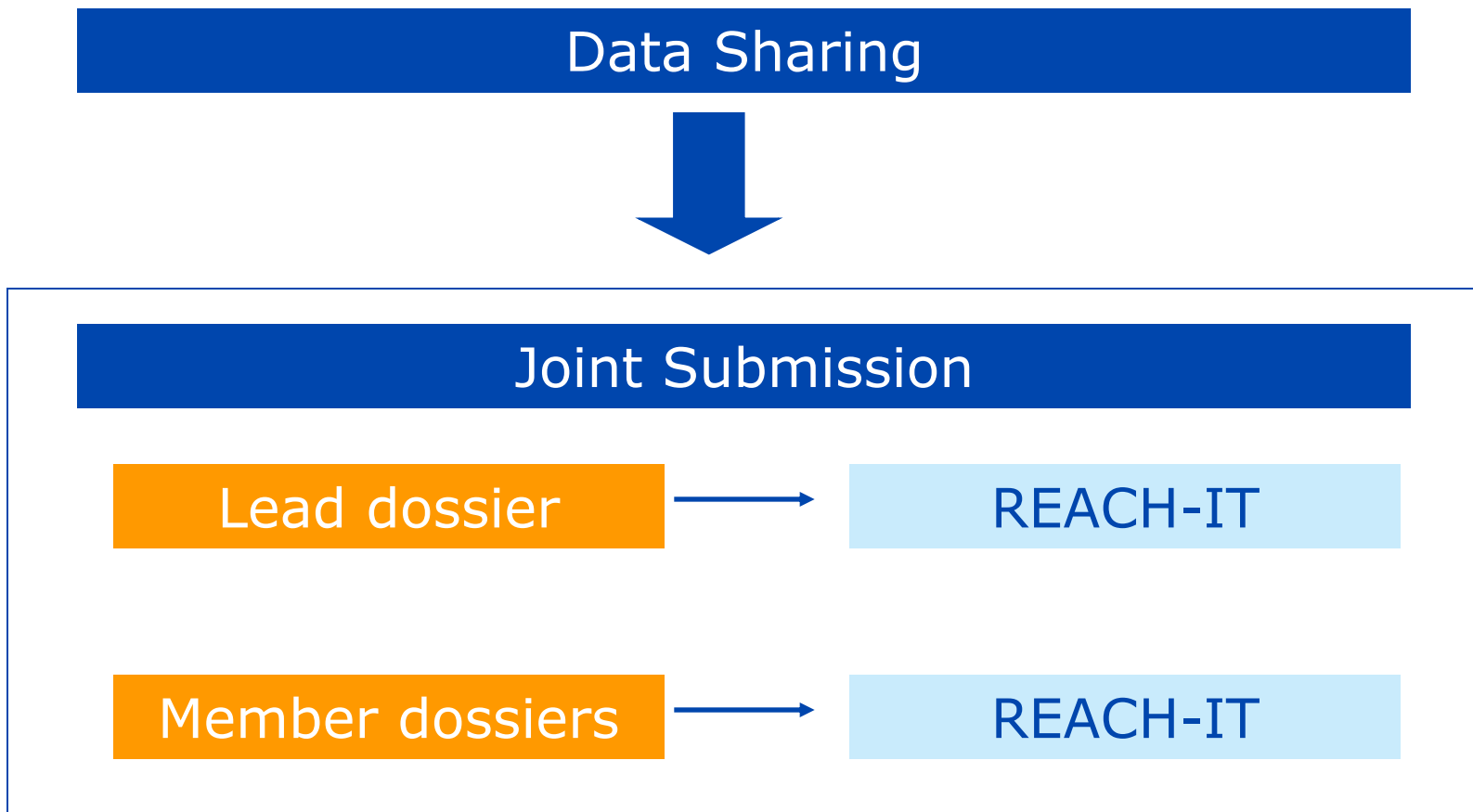
Countdown: optimal situation



Key steps for 'member' registrants

- Make sure that you are in the correct SIEF and substance ID is sufficiently clear in the registration dossier
- Verify what the SIEF agreement will deliver
- If SME, carefully verify your status: ECHA website > Support > SME's
- Main steps:
 - negotiate within the SIEF
 - prepare and submit the member dossier (making use of the TCC, dissemination and fee calculator IT tools)
 - be ready to pay the fee within the deadline
 - maintain and update the dossier when e.g. new information is received

Dossier submission - overview



Building the member dossier in IUCLID



Building the member dossier in IUCLID

- Substance identifiers must be exactly the same
- Lead recommended to provide draft basic dataset in IUCLID for members
- Company/substance specific information which needs to be filled in by each member
 - Composition, analytical data
 - Tonnage, uses

Building the dossier in IUCLID

Lead

Query results | Section tree

REACH Registration above 1000 tonnes

- + 0 Related Information
- + 1 General Information
- + 2 Classification and Labelling
- + 3 Manufacture, use and exposure
- + 4 Physical and chemical properties
- + 5 Environmental fate and pathways
- + 6 Ecotoxicological Information
- + 7 Toxicological information
- + 8 Analytical methods
- + 11 Guidance on safe use
- + 12 Literature search
- + 13 Assessment Reports

Private data submitted by the **LEAD and the MEMBER**

Data submitted only by the **LEAD** (if not opted-out)

Data submitted either by the **LEAD or individually**

Member

Query results | Section tree

REACH Registration member of a joint sub

- + 0 Related Information
- + 1 General Information
- + 2 Classification and Labelling
- + 3 Manufacture, use and exposure
- + 4 Physical and chemical properties
- + 5 Environmental fate and pathways
- + 6 Ecotoxicological Information
- + 7 Toxicological information
- + 8 Analytical methods
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Building the dossier in IUCLID

The screenshot shows the IUCLID software interface. The left navigation pane has a tree structure with '1.1 Identification' circled in red. The main window displays the 'Substance identification' section with fields for Chemical name (Benzene), Public name (Benzene), Legal entity flags, Legal entity (European Chemicals Agency / Helsinki / Finland), Third party flags, and Third party. Below this is the 'Role in the supply chain' section with Role flags and a Role selection (checked: Manufacturer). The 'Reference substance' section is circled in red and contains a table with the following data:

EC number	EC name
200-753-7	benzene
CAS number	CAS name
71-43-2	benzene
IUPAC name	benzene

Below the table is the 'Type of substance' section with dropdown menus for Composition (mono constituent substance) and Origin (organic).

- Lead provides substance identifiers to members



Building the dossier in IUCLID

File Edit Go Window Help Plugins

Navigation

Query results Section tree

REACH Registration 100 - 1000 tonne

0 Related Information

1 General Information

1.1 Identification

1.2 Composition

1.3 Identifiers

1.4 Analytical information

1.5 Joint submission

1.6 Sponsors

1.7 Suppliers

1.8 Recipients

2 Classification and Labelling

3 Manufacture, use and exposu

4 Physical and chemical proper

5 Environmental fate and pathw

6 Ecotoxicological Information

7 Toxicological information

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11 Guidance on safe use

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13 Assessment Reports

Substance: Benzene / Benzene / benzene / benzene / 71-43-2 / European Chemicals Agency / Helsinki / F

Substance composition

Benzene

Name: Benzene

Brief description: Mono constituent

Composition ID: L-c3431c64-95ba-4f9e-b1fc-1cf24d2ee19e

Degree of purity

> 99.8 < 100 % (w/w)

Constituents

> 99.8 % (w/w)

Impurities

ca. 0.1 thioph

- But Composition and Analytical data are member specific!

File Edit Go Window Help Plugins

Navigation

Query results Section tree

REACH Registration 100 - 1000 tonne

0 Related Information

1 General Information

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7 Toxicological information

8 Analytical methods

Substance: Benzene / Benzene / benzene / benzene / 71-43-2 / European Chemicals Agency / Helsinki / F

Analytical information

Analytical methods and spectral data: Description of analytical methods is provided in the attachment.

Analytical_methods.doc / 32.5 KB

Optical activity

Results of analysis

GC


Building the dossier in IUCLID


- Joint CSR? Decide well in advance
- Submission system allows flexibility
 - Fully joint CSR
 - Partially joint CSR
 - Part A
 - Part B




Building the dossier in IUCLID

- Finally, remind them to use these key tools:
 - TCC tool - checks completeness of dossier
 - Fee calculator - estimates fee to be paid
 - Dissemination tool - simulates information to be published

 **TCC tool**
Technical completeness check
[Run](#)

 **Fee Calculation**
Calculate the fees for a REACH dossier
[Calculate](#)

 **Dissemination tool**
Simulate what will be published
[Run](#)

Important steps in REACH-IT

How to best support your members



Important steps in REACH-IT

- Joining the joint submission in REACH-IT
 - Members need name of joint submission and security token
- Submission of member dossiers
 - After lead dossier accepted in the system
 - Must pass 'business rules' before 31 May 2013
 - Payment and (if appropriate) technical completeness according to your dossier specific deadline
- Recommended - Lead dossier submitted by 31 March
(**Extended to 2 April due to REACH-IT closure**)



Important steps in REACH-IT

- Keeping track of key steps in REACH-IT
 - Dossier accepted – pass the 'business rules'
 - Invoice opened
 - Result of completeness check
 - Registration number issued



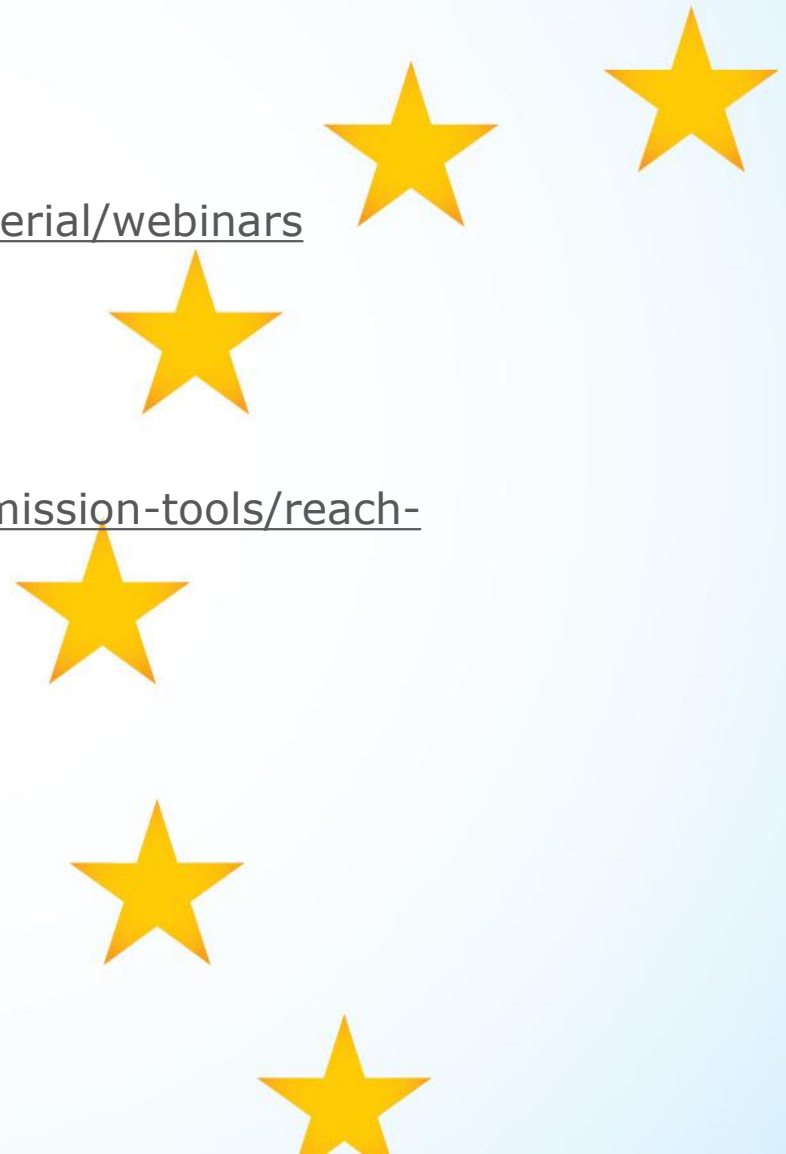
Further Support

Webinars:

<http://echa.europa.eu/support/training-material/webinars>

Manuals:

<http://echa.europa.eu/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals>



Thank you

