Review Programme - What you need to know

Biocides Stakeholders' Day

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- Notifications to take over the role of participation
- Re-definitions, *in situ*
- Declarations of new active substances for inclusion in the Review Programme
- Article 95 list implications

Review Programme

Review Programme

- Original Regulation (EC) 1451/2007 Biocidal Products Directive
- New Regulation (EU) No 1062/2014 Biocidal Products Regulation
- **750** active substance/product-type combinations are in the Review Programme

  About 120 are approved. There are still 630 AS/PT combinations to evaluate until 2024

Review Programme

Annex II lists all AS/PT combinations

- Part 1 supported
- Part 2 not supported

Notifications to take over role of participation

What is a notification?

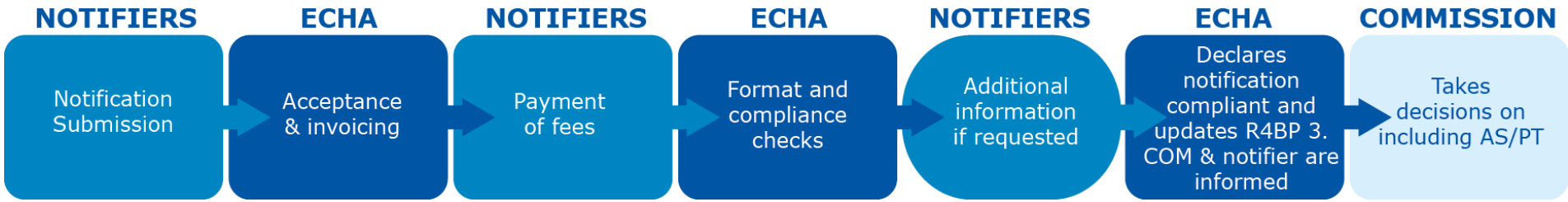
Notification

- To take over AS/PTs currently not supported
- IUCLID file, R4BP 3

⇒ Notifications must be submitted by 30 October 2015

http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/existing-active-substance/notification-procedure

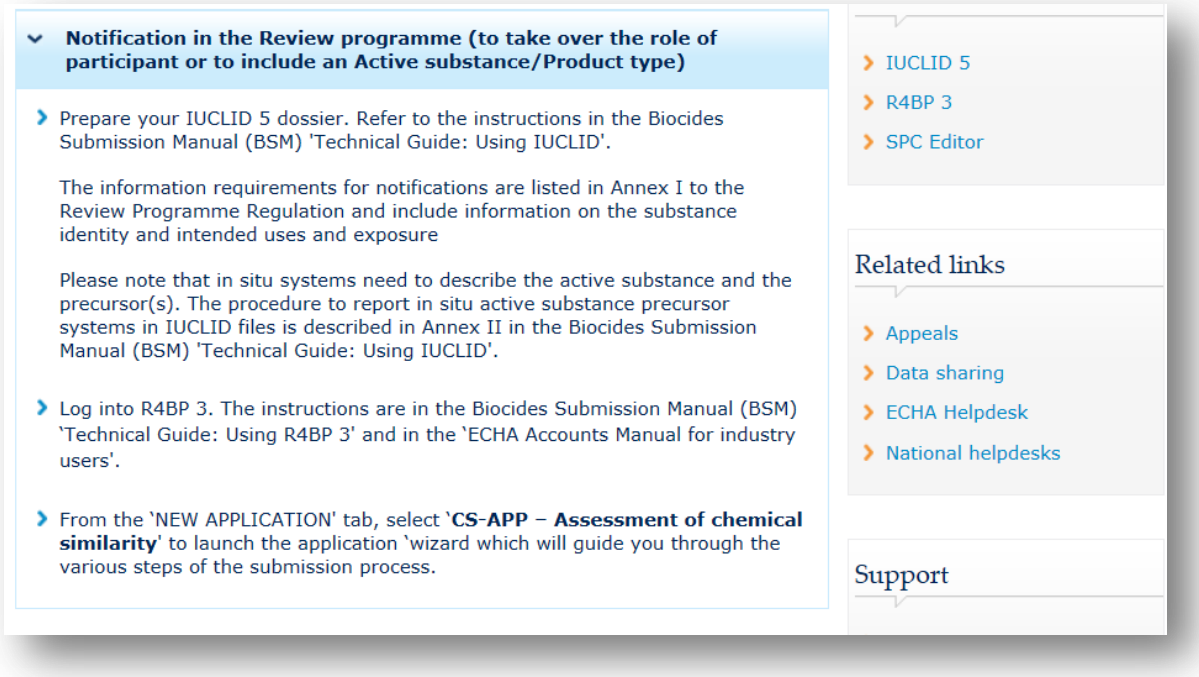
Notification procedure



echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/existing-active-substance/notification-procedure

How to submit a notification

R4BP 3



echa.europa.eu/support/dossier-submission-tools/r4bp/active-substances

Information requirements for notifications

- Active substances
- Product-type(s)
- Studies that have been commissioned
- IUCLID file
  - Administrative (section 1), and
  - Substance identity (section 2), and
  - exposure related data (7.1 to 7.5)

You need to act

- If you want to take over the role of participant of an AS/PT combination currently not supported

  → submit a notification to take over the role of participant

Re-definitions, *in situ*

What is a re-definition of an active substance

Re-definition of an active substance

The active substance is renamed, and

For the old ‘original’ name:
ECHA publishes an open call for notification

→ Notify within 12 months of the publication

Example of re-definition *in situ*

Old: 'Ammonium sulphate'

New: 'Monochloramine generated from ammonium sulphate and a chlorine source'

***In situ* active substance/precursor-combination open for notification**

Former identity in the Review Programme	PTs (supported in RP)	Redefined identity (*in situ* active substance generated from precursor)	In situ active substance/precursor-combination open for notification	PTs (open for notification)	eCA	Deadline for notifying
[939] Active Chlorine: manufactured by the reaction of hypochlorous acid and sodium hypochlorite produced *in situ*	2, 3, 4, 5,	Active chlorine generated from sodium chloride by electrolysis	Active chlorine generated from precursor system(s) other than those already included in the Review Programme as per the redefinition (see column 3)	2, 3, 4, 5, 11[1], 12[1]	SK	27 April 2016
[424] Sodium bromide	2, 11, 12,	Active bromine generated from sodium bromide and sodium hypochlorite	Active bromine generated from precursor system(s) other than those already included in the Review Programme as per the redefinition (see column 3)	2, 3, 4[1], 5, 11[1], 12,	NL	27 April 2016
		Active bromine generated from sodium bromide and calcium hypochlorite				
		Active bromine generated from sodium bromide and chlorine				
		Active bromine generated from sodium bromide by electrolysis				
[529] Bromine chloride	11	Active bromine generated from bromine chloride	Active bromine generated from precursor system(s)	11	NL	27 April 2016

Notifications for *in situ* by **27 April 2016**

You need to act

- To support an *in situ* generated active substance precursor system currently not supported

  → submit a notification to take over the role of participant

Declarations of active substances/product types for inclusion in the Review Programme

What is a declaration of interest to notify an active substance/product-type combination?

Declaration of interest to notify

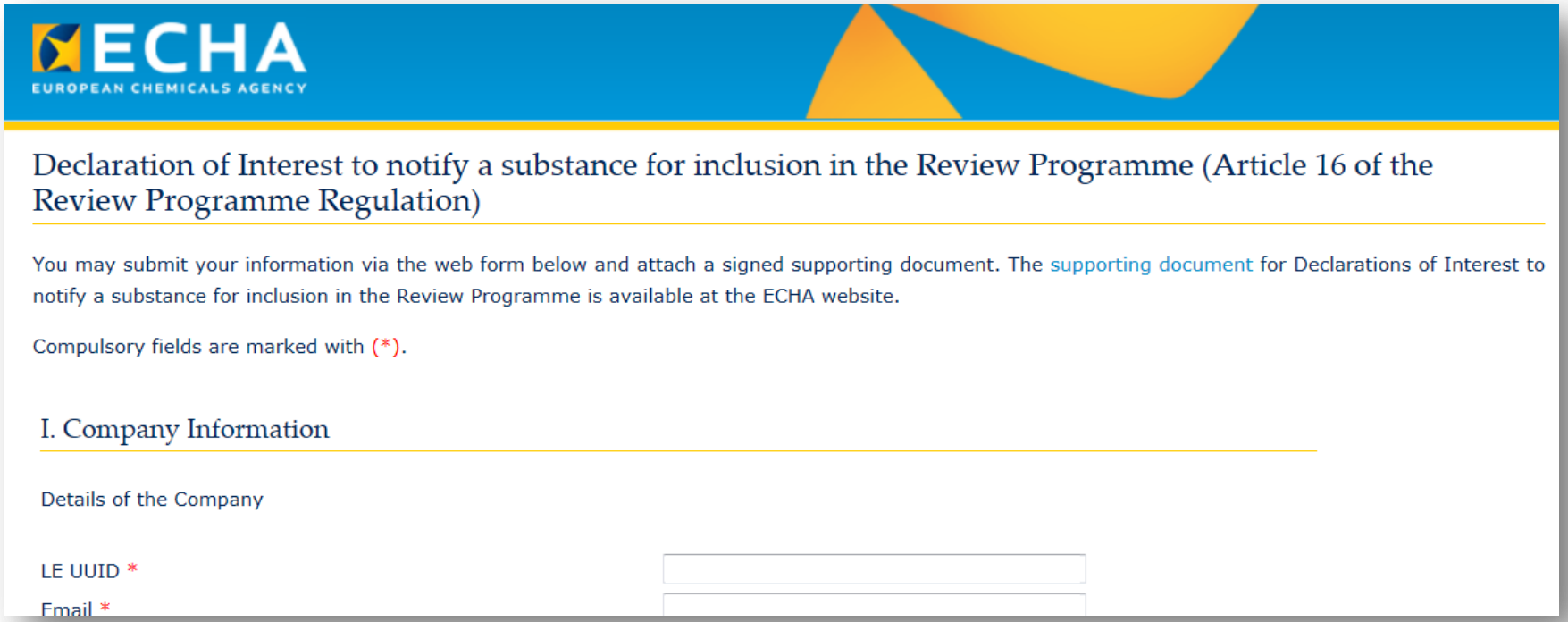
- AS/PTs benefitted from food and feed derogation
- The AS belongs to a different PT

→ Declarations deadline **30 October 2015**

- Person relied on guidance

→ Declarations to be submitted 12 months after

How to submit a declaration



Declaration of Interest to notify a substance for inclusion in the Review Programme (Article 16 of the Review Programme Regulation)

You may submit your information via the web form below and attach a signed supporting document. The supporting document for Declarations of Interest to notify a substance for inclusion in the Review Programme is available at the ECHA website.

Compulsory fields are marked with (*).

I. Company Information

Details of the Company

LE UUID *

Email *

echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/existing-active-substance

Attach the supporting document

Supporting documents

The table below provides a link to the key supporting document needed for each of the application types under the Biocidal Products Regulation. Additional documents are often needed but depend on the specific application type. Further information on this topic is comprehensively outlined in the relevant Biocides Submission Manual.

› Other documents that may be required or relevant in your individual case

Biocides Submission Manuals

› More

Documents that are required for compliance / to enable processing		
Application code	Process	Supporting document

ECHA
EUROPEAN CHEMICALS AGENCY

DI-SUB
Version 1

Supporting document for the Declaration of Interest to notify a substance/ product-type combination for inclusion in the Review Programme (Article 16 of the Review Programme Regulation)

Information on the active substance:

Active substance name	
EC number	

Published on the ECHA website for notification

Successful declarations of interest

Declarations of interest have been submitted to include the substance/product-type combinations in the Review Programme. The proposed combinations that appear in the table below are considered eligible for inclusion in the Review Programme. A notification must be submitted to ECHA by the deadline indicated. If the notification is declared compliant by ECHA, the Commission will include the combination in the Review Programme.

Name	EC Number	CAS Number	Product type	Date of publication	Deadline to submit a Notification
Dialuminium chloride pentahydroxide	234-933-1	12042-91-0	2	14/4/2015	14/10/2015

See also

› How to submit a notification in the Review Programme

→ Notify by **14 October 2015**

You need to act

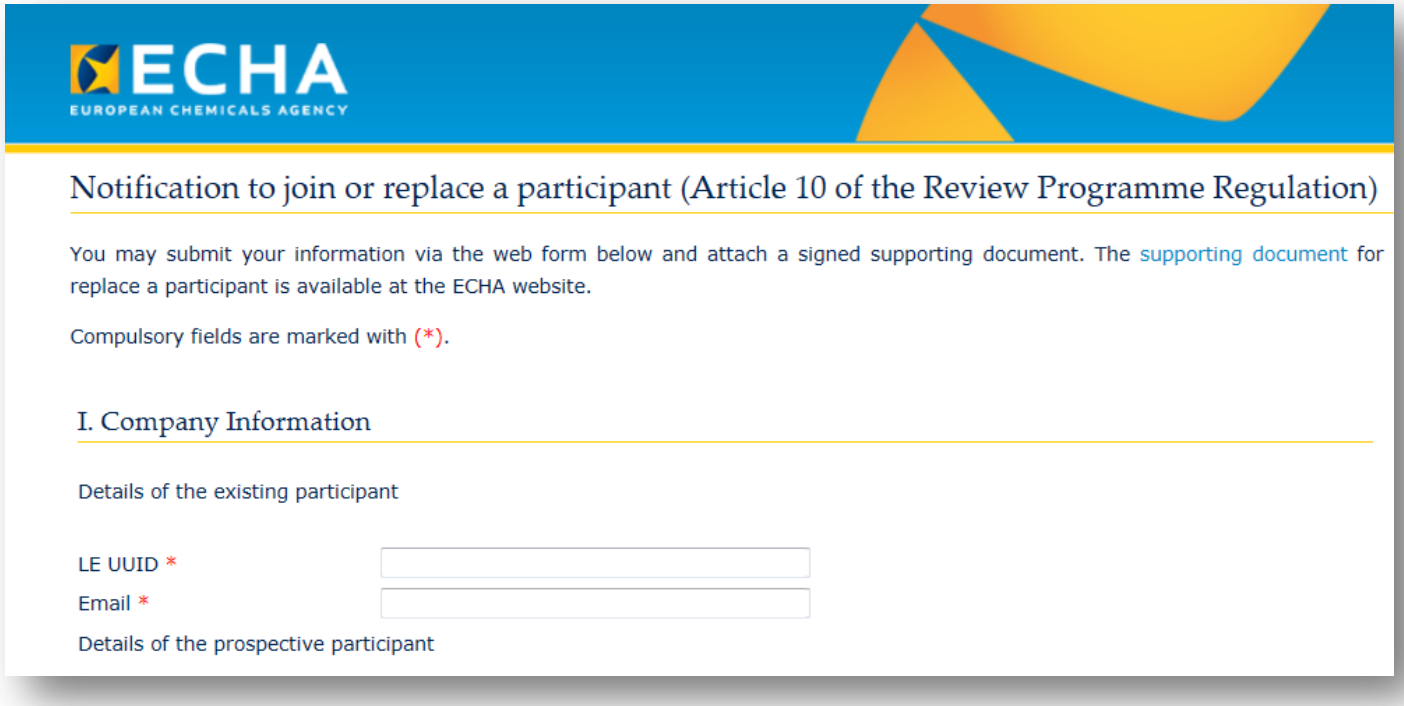
- If you want to add an AS/PT combination currently not in the Review Programme

  → submit a declaration of interest to notify

Other processes resulting from the Review Programme Regulation

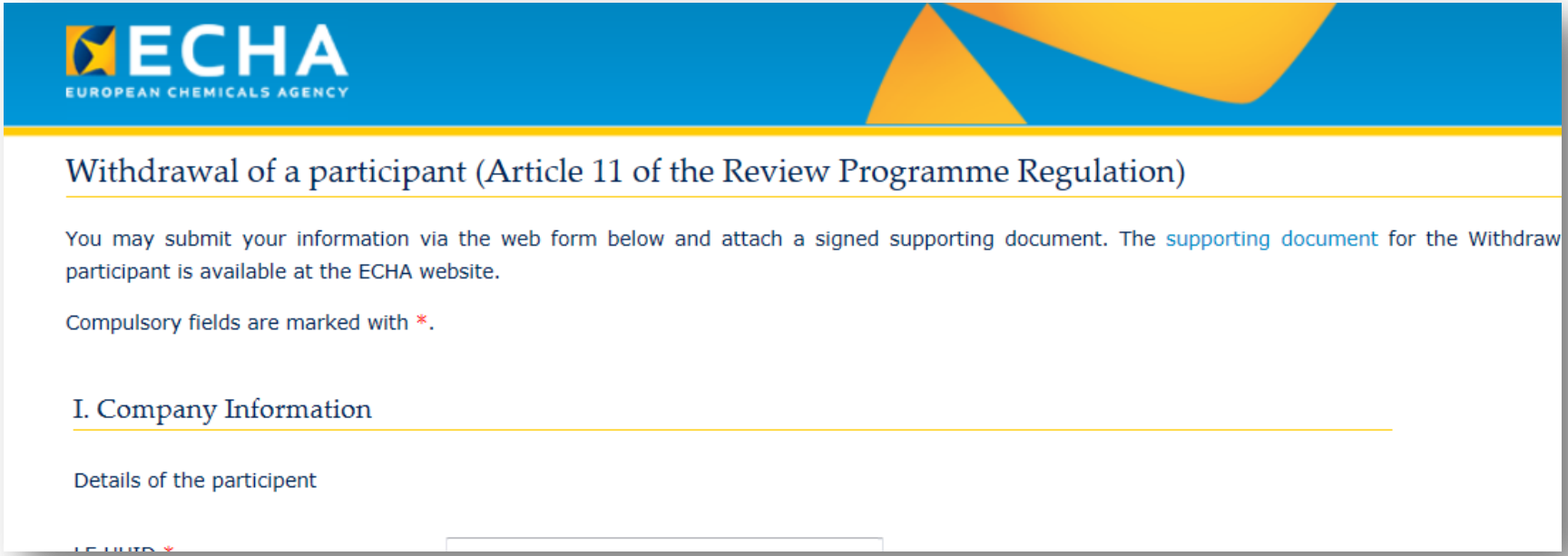
Joining or replacing participants

- Existing participant agrees
- Prospective participants have the right to refer to data



Withdrawing

- Timely (before end of evaluation)



Impact on the Article 95 list

Declaration and notification impact on Article 95 list

- No direct impact

  AS/PT combination added once 'relevant', a submitted dossier is validated/accepted

Re-definition of active substance

- Direct impact - next update

Joining, replacing, withdrawing

- Direct impact – next update
- Except, last participant withdrawing remains on the list because a dossier was validated/accepted

  → The substance remains ‘relevant’

Deadlines

Summary

14 October 2015

- Notify, dialuminium chloride pentahydroxide PT 2

30 October 2015

- Declarations of interest to notify for:
  - exemption from food and feed
  - different PT under the BPR
- Notify not supported AS/PTs

27 April 2016

- Notify AS/PTs from redefinition (*in situ*)

Thank you

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