

ECHA Communications and Helpdesk support

Biocides Stakeholders' Day

25 June 2013

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Link yourself to ECHA

- Keep yourself updated
- Tell us about your views
- If you have an issue – ask for help



Keep yourself up-to-date

- Sign up to ECHA's
 - weekly e-News
 - bi-monthly Newsletter
- Participate in our events
 - webinars
 - Stakeholders' Days



The screenshot shows the ECHA website interface. At the top, there is a navigation bar with links for 'About Us', 'Regulations', 'Addressing Chemicals of Concern', 'Information on Chemicals', 'Chemicals in our Life', and 'Support'. Below this, a news article titled '23 June 2013 - Press release' is visible, discussing REACH 2013 registration statistics. A 'Subscribe' button is highlighted with an orange box, and an orange arrow points from it to the 'Events' section on the right side of the page. The 'Events' section lists upcoming activities for April-May 2013, including a seminar on applications for authorization, a Helsinki Chemicals Forum, and a Biocides Stakeholders' Day. Below the main content, there is a 'Webinars' section and a 'Newsletter' section with a 'Subscribe' button. The newsletter section features an article titled 'Fair sharing of costs for active substance approval' with a sub-image of red rubber boots.

Consult ECHA's website



Biocidal Products Regulation

The Biocidal Product Regulation (BPR, Regulation (EU) 528/2012) concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms, like pests or bacteria, by the action of the active substances contained in the biocidal product.

[Understanding BPR](#)

[Legislation](#)

Processes



Companies can apply for the approval of an active substance by submitting a dossier to ECHA.

[Approval of active substances](#)



After the approval of an active substance, companies wishing to place biocidal products on the market have to apply for product authorisation at national or Union level.

[Authorisation of biocidal products](#)



Companies can ask ECHA to establish the technical equivalence of their active substance.

[Technical equivalence](#)



Manufacturers and importers not involved with the review programme of the previous legislation have to submit certain information to ECHA.

[Approved suppliers](#)



A fundamental and new aspect of the Biocidal Products Regulation is the common obligation to share information about active substances and products approved and authorised in the EU.

[Data sharing](#)

Nanomaterials and the Biocidal Products Regulation

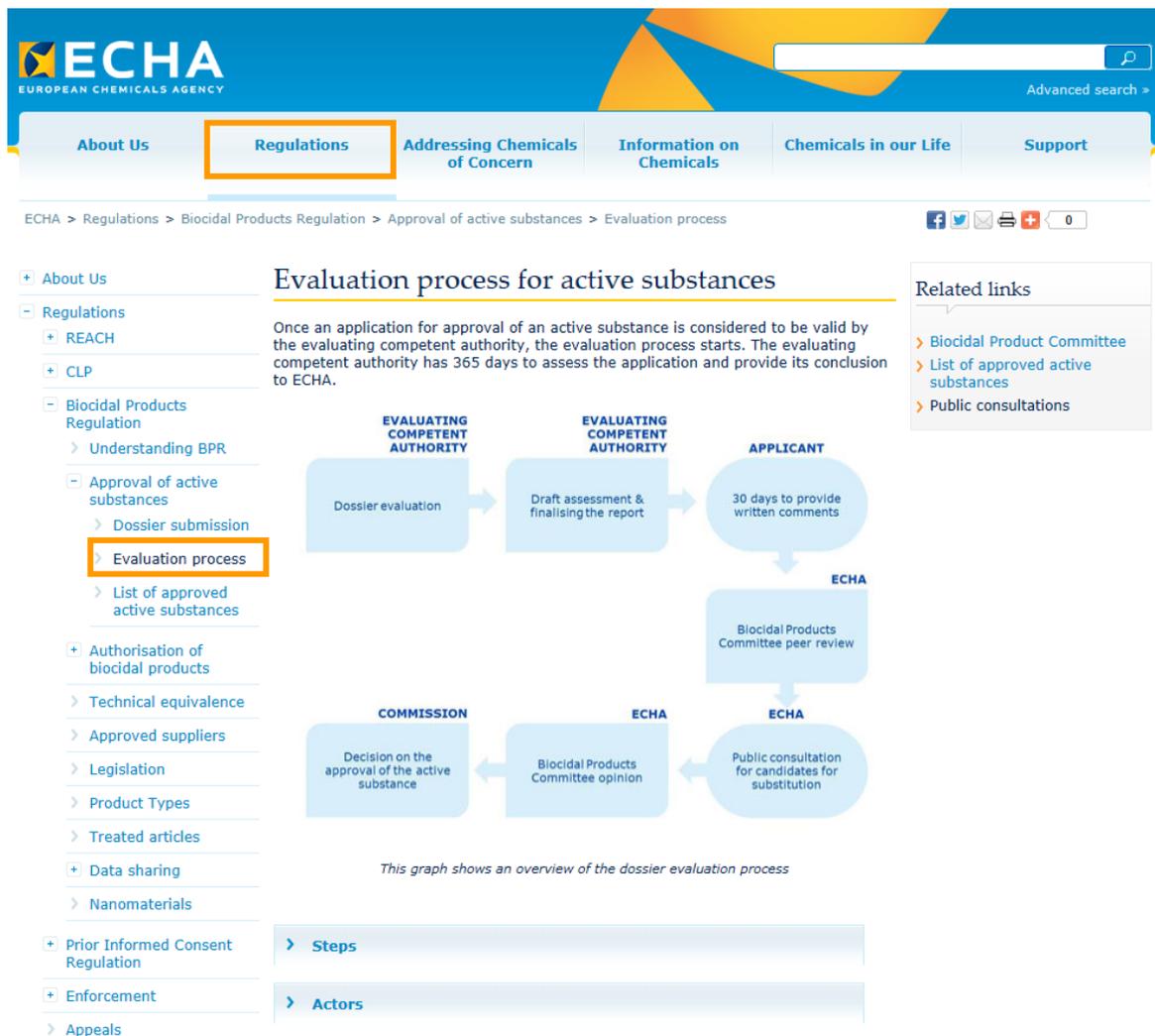
The provisions for nanomaterials apply to products and substances which meet the criteria defined in the Biocidal Products Regulation. These definitions are based on the Commission recommendation on the definition of nanomaterials.

[More](#)

Treated articles

The Biocidal Products Regulation (BPR) sets rules for the use of articles treated with, or intentionally incorporating, one or more biocidal products.

Understand the processes



ECHA
EUROPEAN CHEMICALS AGENCY

Advanced search >

About Us **Regulations** Addressing Chemicals of Concern Information on Chemicals Chemicals in our Life Support

ECHA > Regulations > Biocidal Products Regulation > Approval of active substances > Evaluation process

[+ About Us](#)
[- Regulations](#)
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 > Approved suppliers
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 > Product Types
 > Treated articles
[+ Data sharing](#)
 > Nanomaterials
[+ Prior Informed Consent Regulation](#)
[+ Enforcement](#)
 > Appeals

Evaluation process for active substances

Once an application for approval of an active substance is considered to be valid by the evaluating competent authority, the evaluation process starts. The evaluating competent authority has 365 days to assess the application and provide its conclusion to ECHA.

```

    graph TD
      subgraph "EVALUATING COMPETENT AUTHORITY"
        A[Dossier evaluation] --> B[Draft assessment & finalising the report]
      end
      B --> C((APPLICANT  
30 days to provide written comments))
      C --> D[ECHA  
Biocidal Products Committee peer review]
      D --> E[ECHA  
Public consultation for candidates for substitution]
      E --> F[ECHA  
Biocidal Products Committee opinion]
      F --> G[COMMISSION  
Decision on the approval of the active substance]
  
```

This graph shows an overview of the dossier evaluation process

[> Steps](#)
[> Actors](#)

Related links
[> Biocidal Product Committee](#)
[> List of approved active substances](#)
[> Public consultations](#)

Participate in public consultations



ECHA > Addressing Chemicals of Concern



Addressing Chemicals of Concern

ECHA works together with the European Commission and the EU Member States for the safety of human health and the environment by identifying the needs for regulatory risk management at EU-wide level. When necessary the Member States or ECHA (on a request from the Commission) initiate the authorisation requirements, restrictions, or the need for harmonised classification and labelling of chemicals of concern.

ECHA welcomes all stakeholders to give their contributions during the different consultation phases of the authorisation, restriction and harmonised classification and labelling processes. Under Biocidal Products Regulation the stakeholders can provide information on potential candidates for substitution.

Search for Chemicals

I have read and I accept [the legal notice](#)

Name, EC or CAS No

Registry of Intentions



The notifications of intention to submit a dossier to ECHA related to these risk management processes are included in the Registry of Intentions.

[> More](#)

Biocidal Products Regulation

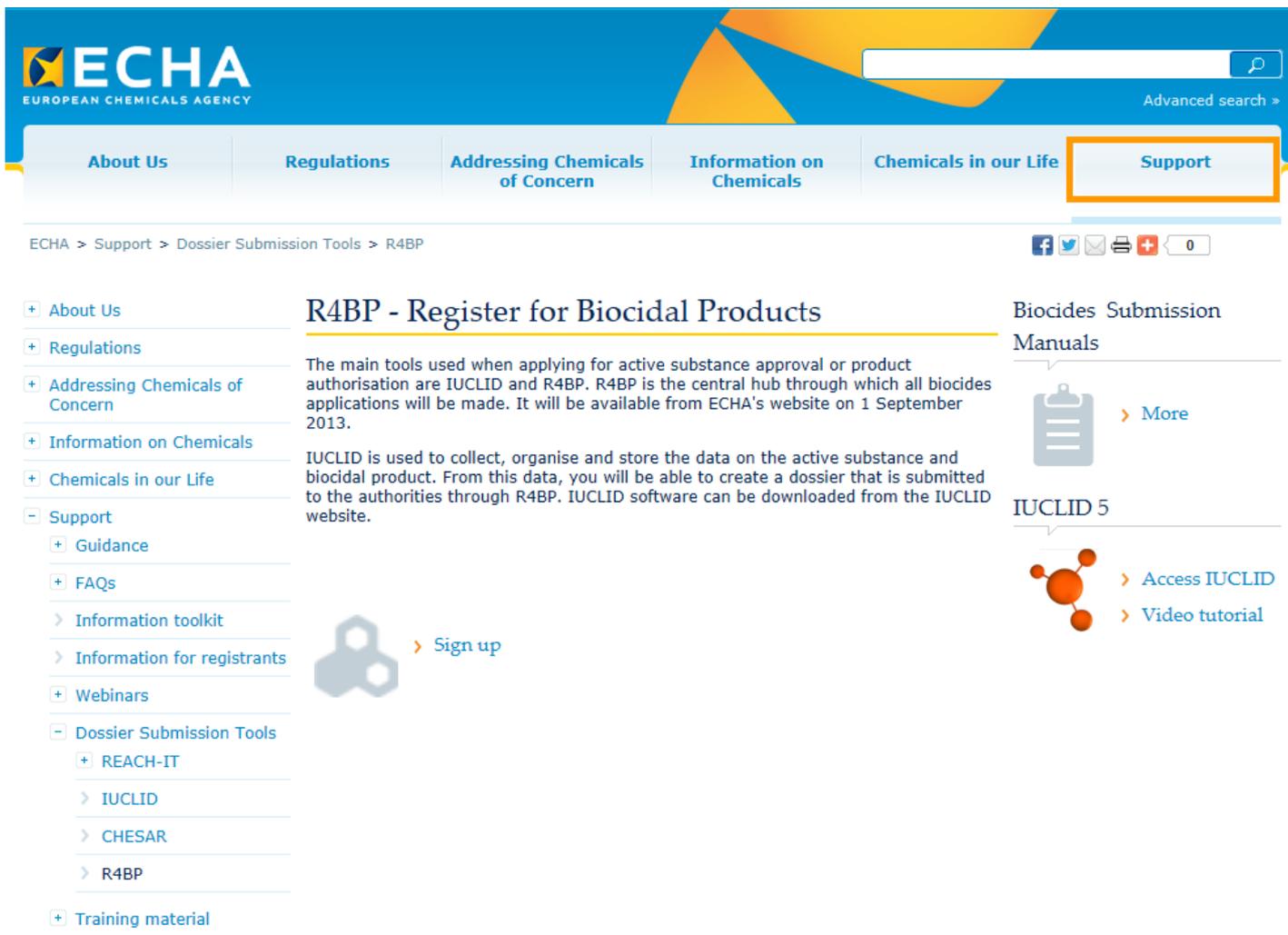


Under the Biocidal Products Regulation, the evaluating Member State Competent Authority may identify an active substance as a potential candidate for substitution. Following the identification, a public consultation is launched. Products containing substances on the list will need to undergo a comparative assessment which will be taken into account for their authorisation.

[> More](#)

[> Consultation on potential candidates for substitution](#)

Access the submission tools



The screenshot shows the ECHA website interface. At the top, there is a navigation bar with the ECHA logo and a search bar. Below the navigation bar, there is a menu with several options: 'About Us', 'Regulations', 'Addressing Chemicals of Concern', 'Information on Chemicals', 'Chemicals in our Life', and 'Support'. The 'Support' option is highlighted with an orange border. Below the menu, there is a breadcrumb trail: 'ECHA > Support > Dossier Submission Tools > R4BP'. To the right of the breadcrumb trail, there are social media icons for Facebook, Twitter, Email, Print, and a counter showing '0'. On the left side of the page, there is a sidebar menu with a tree view structure. The main content area features a section titled 'R4BP - Register for Biocidal Products' with a yellow underline. Below the title, there is a paragraph of text explaining the purpose of R4BP. To the right of the text, there is a 'Sign up' button with a gear icon. On the right side of the page, there is a section titled 'Biocides Submission Manuals' with a 'More' link and a 'Biocides Submission Manuals' icon. Below this, there is a section titled 'IUCLID 5' with a 'Video tutorial' link and an 'IUCLID 5' icon.

ECHA > Support > Dossier Submission Tools > R4BP

[+ About Us](#)
[+ Regulations](#)
[+ Addressing Chemicals of Concern](#)
[+ Information on Chemicals](#)
[+ Chemicals in our Life](#)
[- Support](#)
 [+ Guidance](#)
 [+ FAQs](#)
 [> Information toolkit](#)
 [> Information for registrants](#)
[+ Webinars](#)
[- Dossier Submission Tools](#)
 [+ REACH-IT](#)
 [> IUCLID](#)
 [> CHESAR](#)
 [> R4BP](#)
[+ Training material](#)

R4BP - Register for Biocidal Products

The main tools used when applying for active substance approval or product authorisation are IUCLID and R4BP. R4BP is the central hub through which all biocides applications will be made. It will be available from ECHA's website on 1 September 2013.

IUCLID is used to collect, organise and store the data on the active substance and biocidal product. From this data, you will be able to create a dossier that is submitted to the authorities through R4BP. IUCLID software can be downloaded from the IUCLID website.

 [> Sign up](#)

Biocides Submission Manuals

 [> More](#)

IUCLID 5

 [> Access IUCLID](#)
[> Video tutorial](#)

Find support material



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Advanced search >

About Us | Regulations | Addressing Chemicals of Concern | Information on Chemicals | Chemicals in our Life | **Support**

ECHA > Support > Guidance > Guidance Documents > Guidance on biocides legislation

[+ About Us](#)
[+ Regulations](#)
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 Support
 Guidance

[Identify your obligations](#)
[Consultation Procedure](#)
[Guidance Documents](#)
[Guidance in a Nutshell](#)
[Guidance Fact Sheets](#)
[Practical Guides](#)
[Formats](#)
[Q&As Support](#)
[Information toolkit](#)
[Information for registrants](#)
[Webinars](#)

Guidance on biocides legislation

The list below contains all the **guidance documents** which are available, or will be available, on this website. These documents have been developed with the participation of Member States, industry and accredited stakeholders. The objective of these documents is to **facilitate the implementation of the Biocidal Products Regulation (BPR)** by describing good practice on how to fulfil the obligations.

In addition to BPR guidance, Biocidal Products Directive (BPD) guidance and other related documents are considered applicable for new submissions under the BPR in the areas where the BPR guidance is still under preparation. Furthermore these documents are still valid in relation to the applications for active substances for Annex I inclusion or applications for product authorisation under the BPD that may still be under evaluation.

[Search all Guidance documents](#)
[Feedback Form](#)

[Guidance on REACH](#) | [Guidance on CLP](#) | **[Guidance on Biocides legislation](#)**

Biocidal Products Regulation

Guidance on information requirements

Reference name:	<i>Guidance on information requirements</i>
Description:	This guidance describes the information requirements for active substances and biocidal products in accordance with Title 1 of Annexes II and III of the BPR. (To be published in July 2013)

> [Biocidal Products Directive](#)

Consult the legislation



The navigation bar features the ECHA logo on the left, a search bar with a magnifying glass icon on the right, and a menu with six items: 'About Us', 'Regulations' (highlighted with an orange border), 'Addressing Chemicals of Concern', 'Information on Chemicals', 'Chemicals in our Life', and 'Support'. Below the navigation bar is a breadcrumb trail: 'ECHA > Regulations > Biocidal Products Regulation > Legislation'. To the right of the breadcrumb trail are social media icons for Facebook, Twitter, Email, Print, and a plus sign, followed by a counter showing '0'.

ECHA > Regulations > Biocidal Products Regulation > Legislation



- + About Us
- Regulations
 - + REACH
 - + CLP
 - Biocidal Products Regulation
 - > Understanding BPR
 - > Approval of active substances
 - > Authorisation of biocidal products
 - > Technical equivalence
 - > Alternative suppliers
 - > Legislation**
 - > Product Types

Legislation

▼ Biocidal Products Regulation

Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products

The new text was adopted on 22 May 2012 and it will be applicable from 1 September 2013, with a transitional period for certain provisions.

[bg](#) [cs](#) [da](#) [de](#) [el](#) [en](#) [es](#) [et](#) [fi](#) [fr](#) [hu](#) [it](#) [lt](#) [lv](#) [mt](#) [nl](#) [pl](#) [pt](#)
[ro](#) [sk](#) [sl](#) [sv](#)

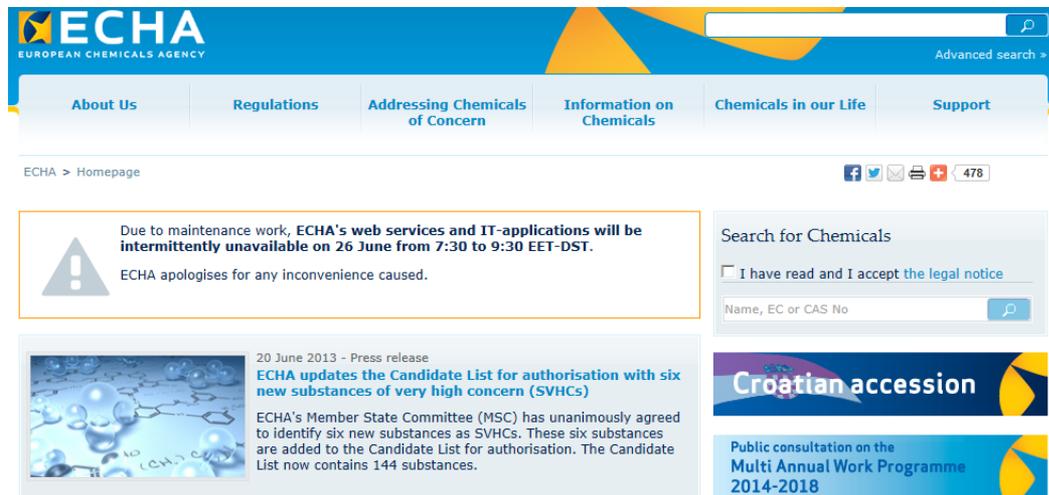
> Implementing Legislation

About us



> Biocidal Products Committee

Understand the terminology



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ECHA > Homepage

Due to maintenance work, ECHA's web services and IT-applications will be intermittently unavailable on 26 June from 7:30 to 9:30 EET-DST. ECHA apologises for any inconvenience caused.

20 June 2013 - Press release
ECHA updates the Candidate List for authorisation with six new substances of very high concern (SVHCs)
ECHA's Member State Committee (MSC) has unanimously agreed to identify six new substances as SVHCs. These six substances are added to the Candidate List for authorisation. The Candidate List now contains 144 substances.

Search for Chemicals
 I have read and I accept the legal notice
Name, EC or CAS No

Croatian accession
Public consultation on the Multi Annual Work Programme 2014-2018
Biocides Stakeholders' Day
25 June 2013 - Helsinki, Finland
REACH 2013

Document Library
REACH IT
IUCLID 5
CHESAR
Guidance
ECHA-term

News

19 June 2013 - Press release
Board of Appeal's press release: The Board of Appeal upholds an ECHA decision

ECHA-term

Multilingual Chemical Terminology by ECHA

Search criteria

BG - Bulgarian Define

Translate to BG - Bulgarian

Show alphabetical list

10/06/2013

Key REACH terminology now available also in Croatian

Nearly 300 REACH terms and their definitions are now available in Croatian on ECHA-term. More Croatian terminology will be added later this year. The terms can be filtered according to the domain and can be downloaded in Microsoft Excel or TermBase eXchange format.

In total, the database contains more than 1 000 REACH, CLP and biocides-related terms and their definitions in all EU languages, including the CLP precautionary and hazard statements, and pictograms.

→ News archive

article authorisation candidate list clp compliance
check dnel downstream user endpoint exposure
scenario guidance hazard information requirement
inquiry intermediate mixture notification pbt reach
registrant registration registration dossier restriction
risk management measure safety data sheet sief
stakeholder substance svhc testing proposal use

Give us feedback

- Event feedback form
- Stakeholder surveys
- Helpdesk services

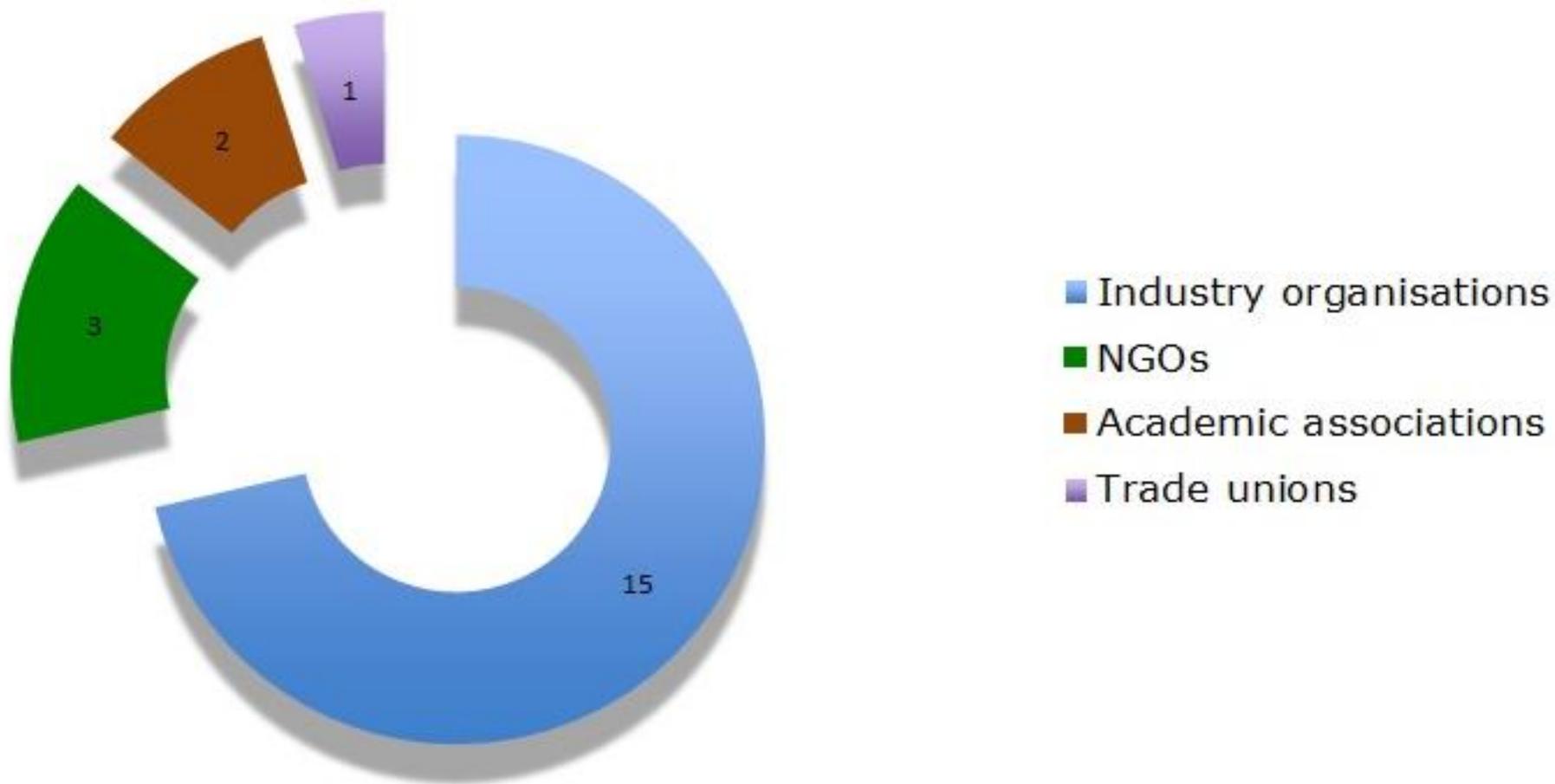


Work with us

- Accredited Stakeholder Organisations are your representatives
 - Participate in Committee meetings
 - Contribute to guidance updates
 - Test IT tools
 - Regular strategic discussions
 - Networks for industry, NGOs and communications



Accredited Stakeholders for biocides



Make use of this channel

- If you represent an EU-wide umbrella organisation for your field
 - apply to become accredited
- If you represent a company or a national/regional organisation
 - be in touch with your umbrella organisation

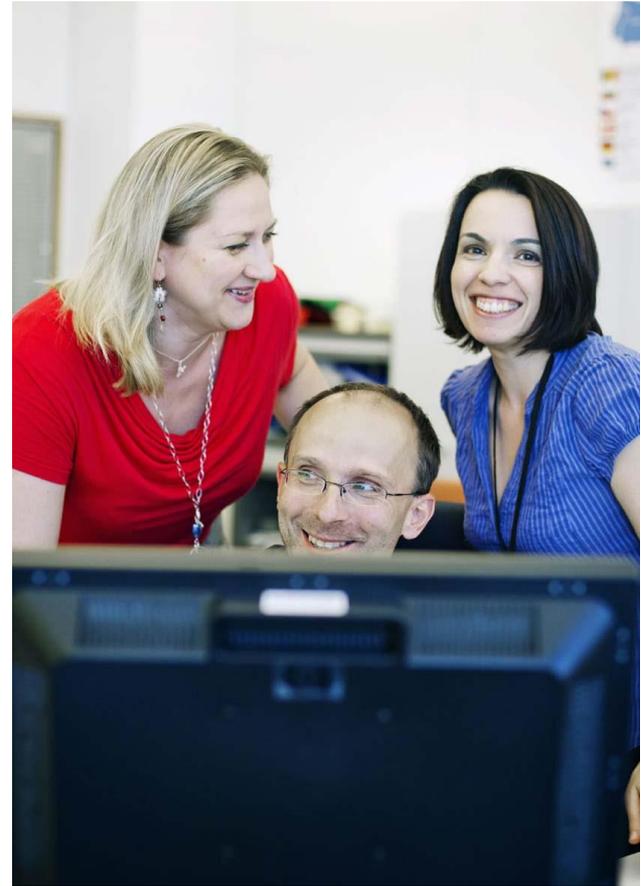


Helpdesk Support



Helpdesk Support

- Support requirements under the Biocidal Products Regulation
- ECHA Helpdesk and HelpNet under REACH and CLP
- ECHA Biocides Helpdesk and Biocides HelpNet



The ECHA Helpdesk



Applicants, particular SMEs

Biocide

Approval of Active Substance, inclusion in Annex I,
Union authorisation



Advice and assistance



Helpdesk contact form, written replies

National Biocides helpdesks



Applicants, in particular SMEs and any other interested party



Respective responsibilities and obligations under the BPR, e.g. possibility of adapting the data requirements of Article 6

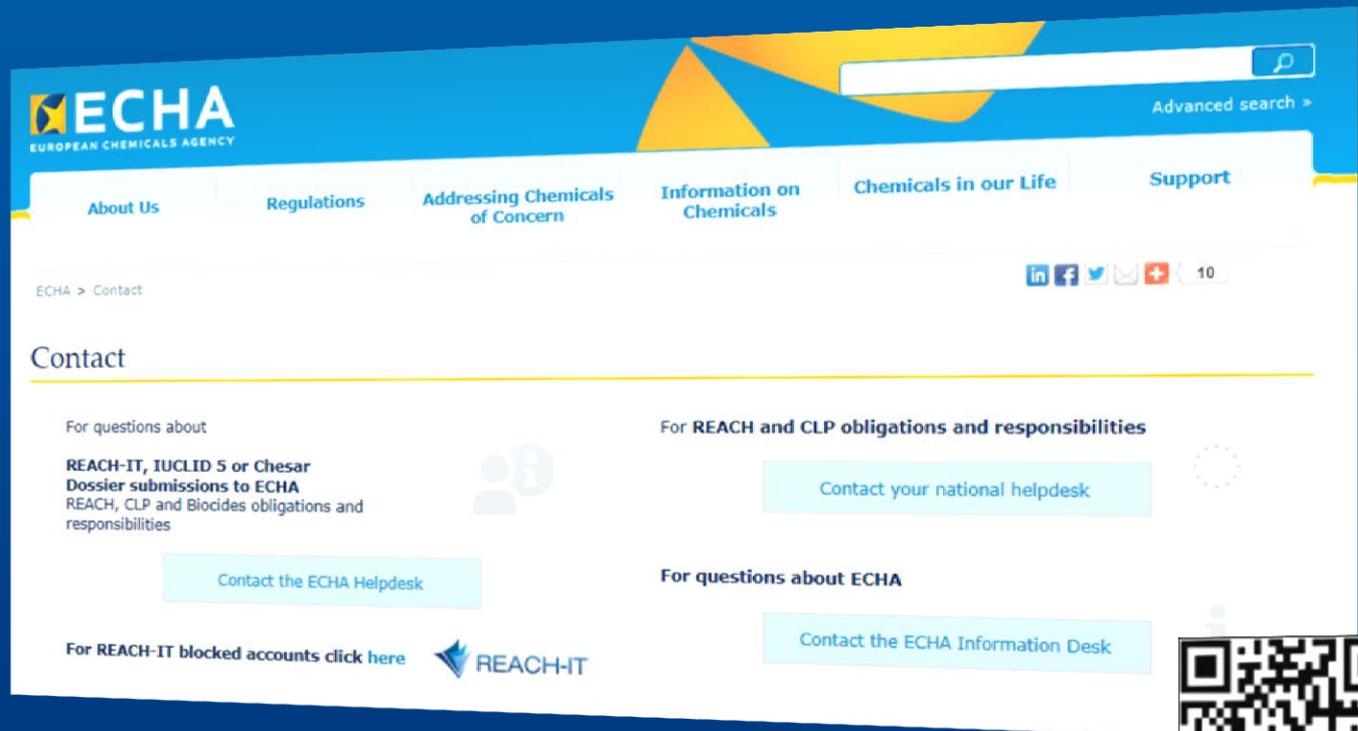


Advice



To be defined by Biocide CA

Contact the ECHA Helpdesk



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ECHA > Contact

in f t v + 10

Contact

For questions about
**REACH-IT, IUCLID 5 or Chesar
Dossier submissions to ECHA**
REACH, CLP and Biocides obligations and responsibilities

Contact the ECHA Helpdesk

For REACH and CLP obligations and responsibilities

Contact your national helpdesk

For questions about ECHA

Contact the ECHA Information Desk

For REACH-IT blocked accounts click here 



We draft the reply



The ECHA Helpdesk

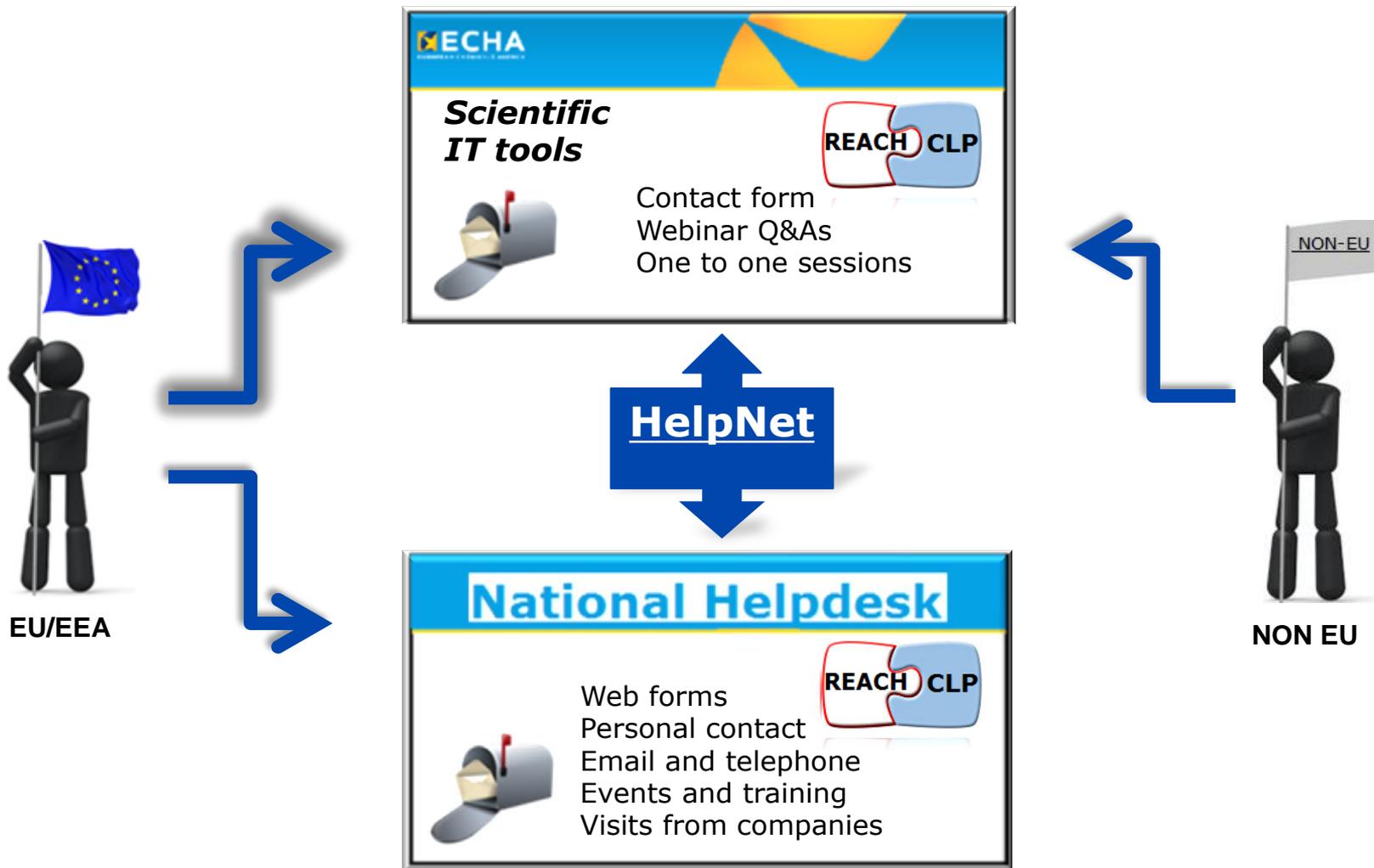


Industry is advised on their roles and responsibilities

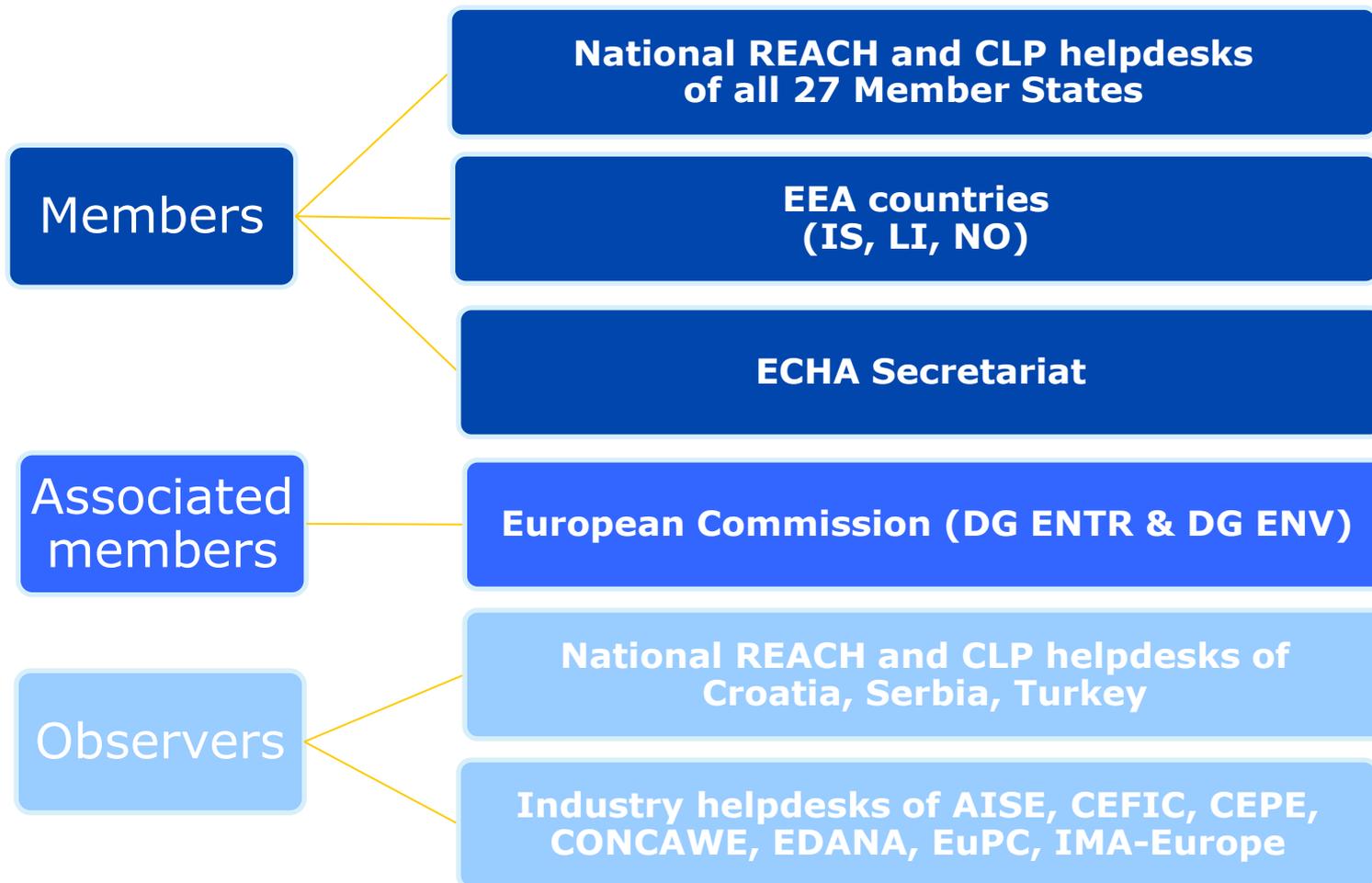
Competence of NHD is strengthened

REACH and CLP is consistently implemented

Quality is in line with ECHA's 'Code of Good Administrative Behaviour'



HelpNet and its members



HelpNet and its objectives

Establish common understanding on legislative requirements

Harmonise answering approaches to industry

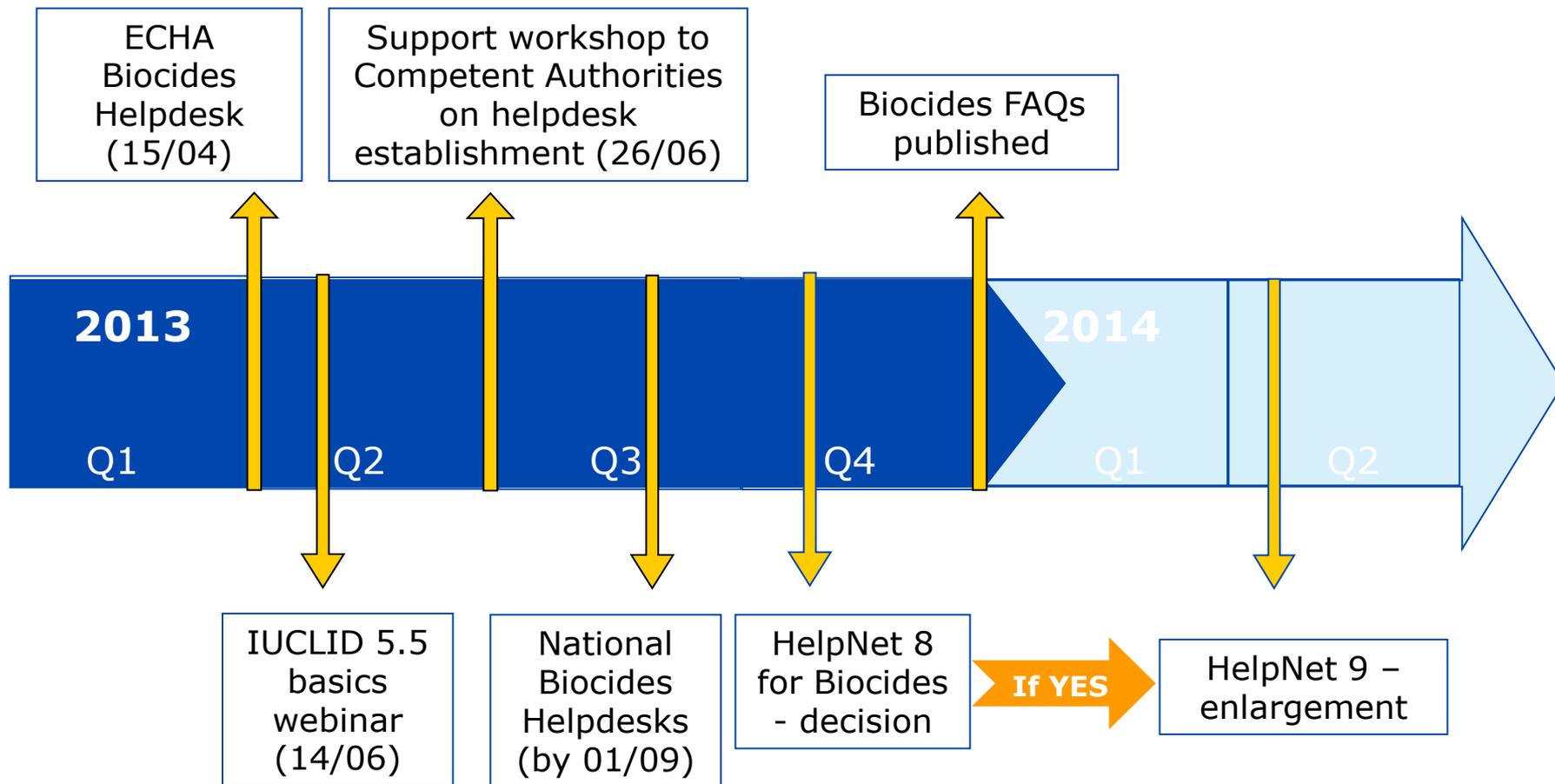
Facilitate the exchange of information

Ensure the efficient handling of difficult questions submitted to the Commission for legal interpretation

ECHA Biocides Helpdesk and Biocides HelpNet



Biocides implementation milestones



We encourage you to
make use of our
support!

