Support for applicants

Biocides Stakeholders' Day

24 September 2014

Valerio Spinosi
Biocides Assessment Unit
European Chemicals Agency

Today I will be covering…

- Website – where to find information
- Guidance and Practical Guide – A practical help to understand the regulation! NEW
- Submissions and Manuals – planning a better service
- ECHA Helpdesk – One year (and six months) after entry into operation
- Communicating – Stay tuned

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Regulations

The new EU chemicals legislation applies to all industry sectors dealing with chemicals and along the entire supply chain. It makes companies responsible for the safety of chemicals they place on the market.

REACH

REACH is a regulation of the European Union, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. It also promotes alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals.

› Read more

CLP

The CLP Regulation ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the European Union through classification and labelling of chemicals.

› Read more

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.

Prior Informed Consent Regulation

The Prior Informed Consent Regulation (PIC, Regulation (EU) 649/2012) administers the import and export of certain hazardous chemicals and places obligations on companies who wish to export these chemicals to non-EU countries. It implements, within the European Union, the Rotterdam Convention on prior informed consent procedure for certain hazardous chemicals and pesticides in international trade.


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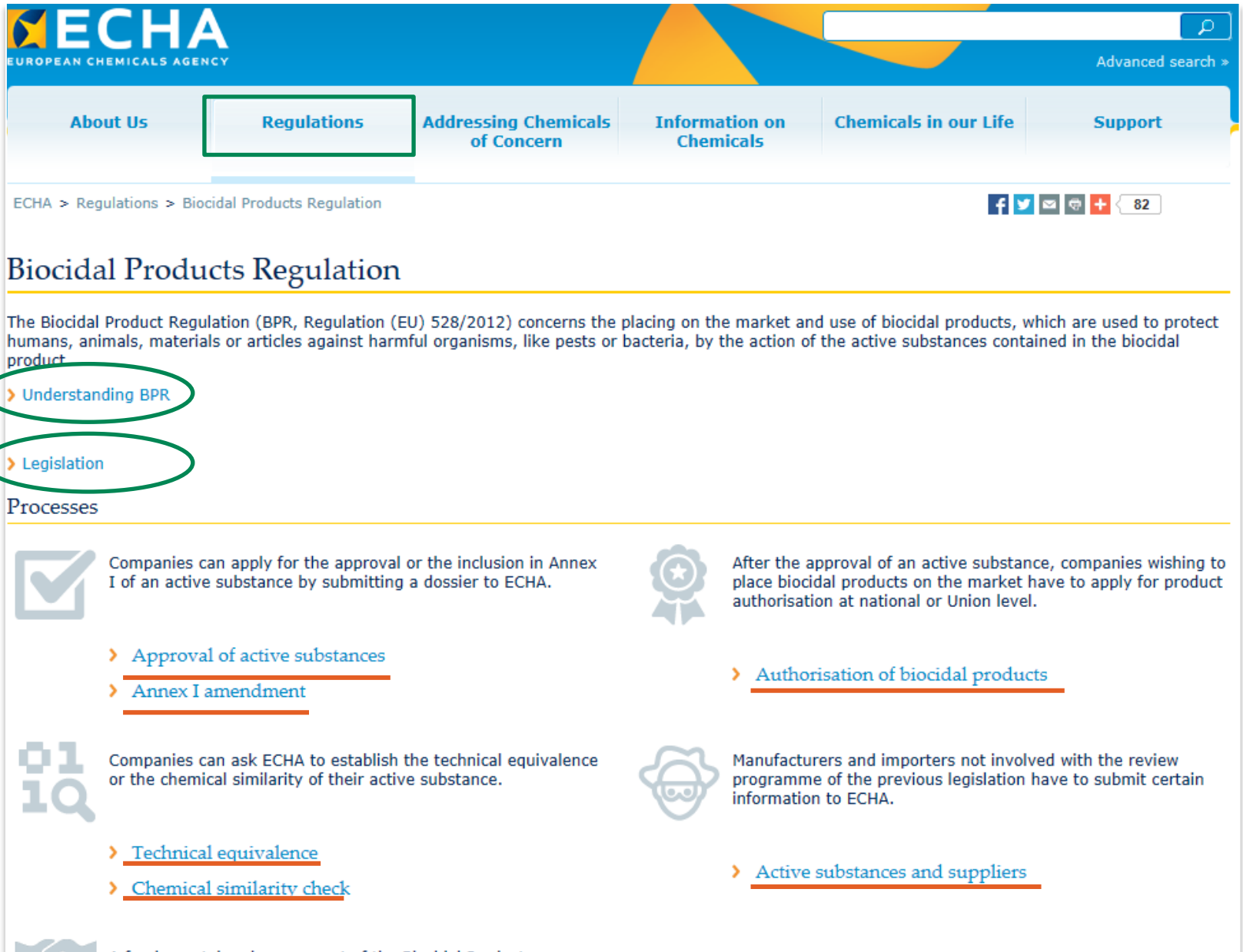
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Biocidal Products Regulation
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Understanding BPR
Legislation
Processes
Companies can apply for the approval or the inclusion in Annex I of an active substance by submitting a dossier to ECHA.
Approval of active substances
Annex I amendment
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 or the chemical similarity of their active substance.
Technical equivalence
Chemical similarity check
Manufacturers and importers not involved with the review programme of the previous legislation have to submit certain information to ECHA.
Active substances and suppliers

Support

This section of the website provides tools and practical guidance to companies which have responsibilities under the EU chemicals legislation.

REACH

- Guidance documents
- Identify your obligations
- Practical examples of exposure scenarios
- Testing methods and alternatives
- Downstream user report
- How to improve your dossier
- Restriction
- Authorisation
- Socio-economic analysis in REACH
- Small and Medium Enterprises

CLP

- Guidance documents
- Submission of CLH dossiers
- Small and Medium Enterprises
- Mixture classification

Biocidal Products Regulation

- Guidance documents
- Emission scenario documents
- R4BP 3
- Small and Medium Enterprises

- Publications
- Document library
- Helpdesks
- Q&As Support
- Webinars
- Croatian accession

Dossier Submission Tools

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Information on Chemicals

This is unique source of information on the chemicals manufactured and imported in Europe. It covers their hazardous properties, classification and information on how to use them safely. It is generated by industry in line with their responsibilities under the EU chemicals legislation. This information is a valuable resource for advancing the safe use of chemicals and for the replacement of the most hazardous ones by safer alternatives.

Search for Chemicals

I have read and I accept the legal notice

Name, EC or CAS No

REACH

- Registered substances
- EC Inventory
- Pre-registered substances
- Substances identified by industry to be registered by 31 May 2013
- Identified substances for registration in 2010
- Registration statistics
- REACH 2013
- Testing Proposals
- Transitional Measures
- Community Rolling Action Plan (CoRAP)
- Candidate List substances in articles
- Information from the Existing Substances Regulation
- Overview of downstream user reports

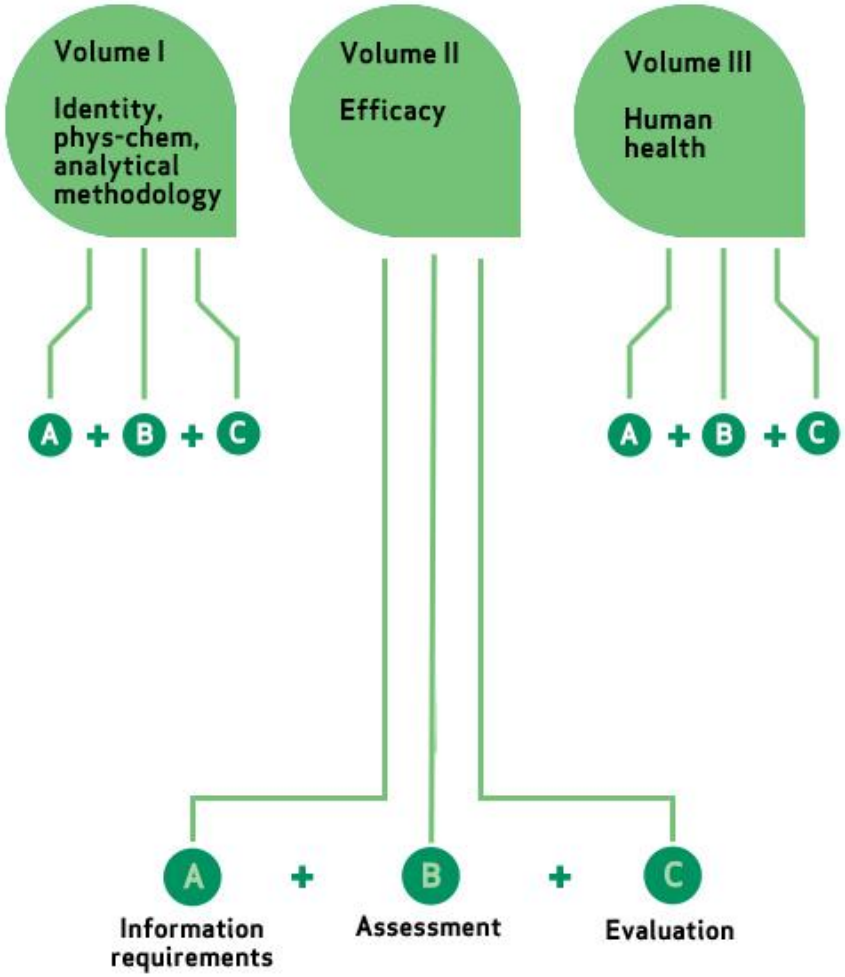
CLP

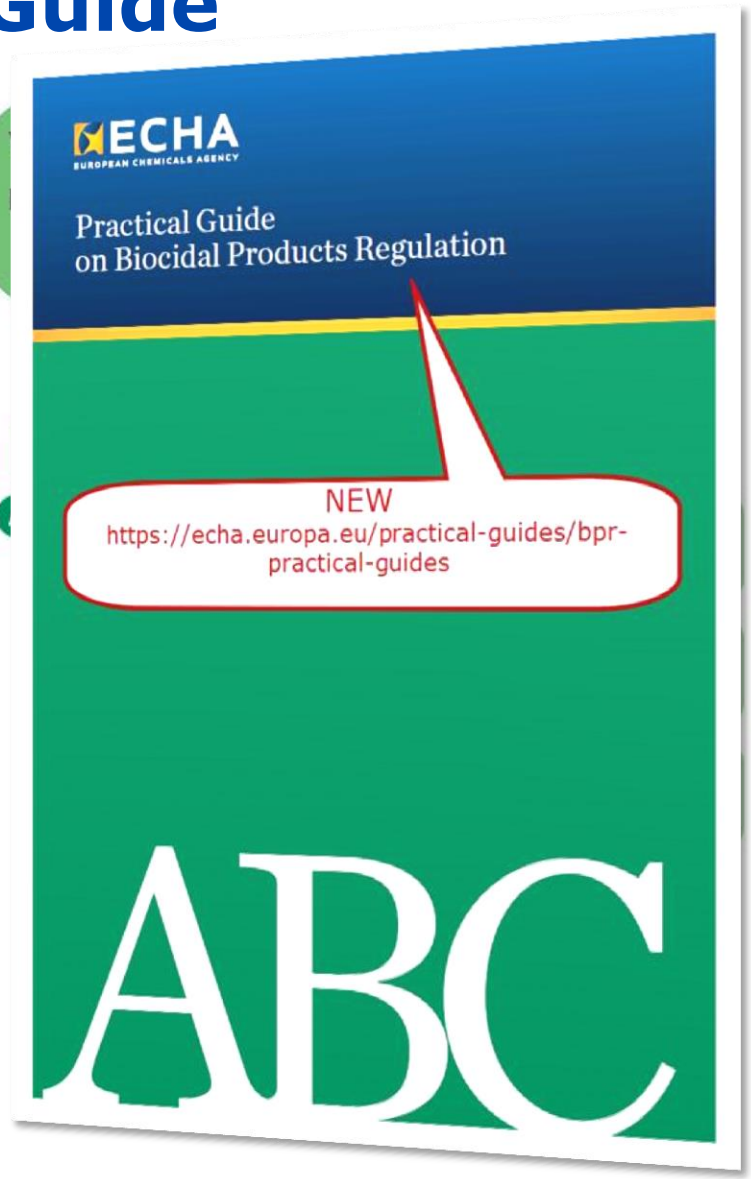
- C&L Inventory
- C&L Platform

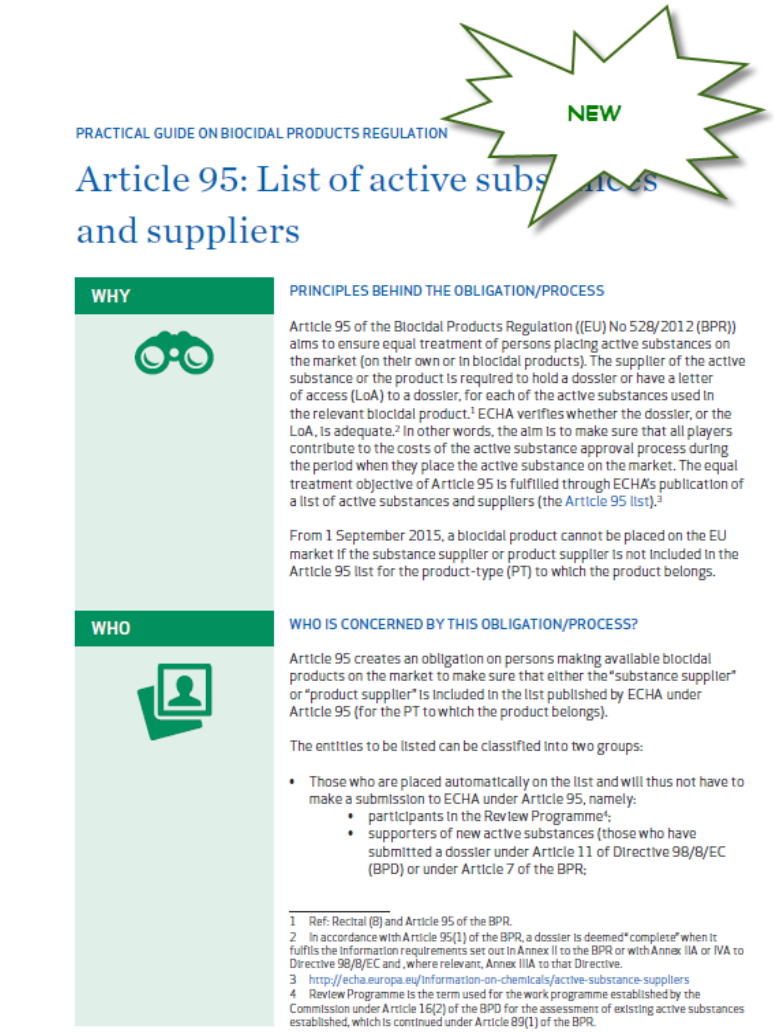
Biocidal Products Regulation

- Biocidal Active Substances
- Biocidal Products
- List of active substance and suppliers

Guidance and Practical Guide







PRACTICAL GUIDE ON BIOCIDAL PRODUCTS REGULATION

NEW

Article 95: List of active subs[illegible] and suppliers

WHY

PRINCIPLES BEHIND THE OBLIGATION/PROCESS

Article 95 of the Biocidal Products Regulation ((EU) No 528/2012 (BPR)) aims to ensure equal treatment of persons placing active substances on the market (on their own or in biocidal products). The supplier of the active substance or the product is required to hold a dossier or have a letter of access (LoA) to a dossier, for each of the active substances used in the relevant biocidal product.[1] ECHA verifies whether the dossier, or the LoA, is adequate.[2] In other words, the aim is to make sure that all players contribute to the costs of the active substance approval process during the period when they place the active substance on the market. The equal treatment objective of Article 95 is fulfilled through ECHA's publication of a list of active substances and suppliers (the Article 95 list).[3]

From 1 September 2015, a biocidal product cannot be placed on the EU market if the substance supplier or product supplier is not included in the Article 95 list for the product-type (PT) to which the product belongs.

WHO

WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?

Article 95 creates an obligation on persons making available biocidal products on the market to make sure that either the "substance supplier" or "product supplier" is included in the list published by ECHA under Article 95 (for the PT to which the product belongs).

The entities to be listed can be classified into two groups:

- Those who are placed automatically on the list and will thus not have to make a submission to ECHA under Article 95, namely:
  - participants in the Review Programme[4];
  - supporters of new active substances (those who have submitted a dossier under Article 11 of Directive 98/8/EC (BPD) or under Article 7 of the BPR;

1 Ref: Recital (8) and Article 95 of the BPR.
2 In accordance with Article 95(1) of the BPR, a dossier is deemed "complete" when it fulfils the information requirements set out in Annex II to the BPR or with Annex IIA or IVA to Directive 98/8/EC and , where relevant, Annex IIIA to that Directive.
3 http://echa.europa.eu/information-on-chemicals/active-substance-suppliers
4 Review Programme is the term used for the work programme established by the Commission under Article 16(2) of the BPD for the assessment of existing active substances established, which is continued under Article 89(1) of the BPR.

  - submitters of third party dossiers (alternative active substance dossiers submitted as part of a product authorisation application).
- Alternative suppliers who must make a submission to ECHA under Article 95 to be included on the list. Such entities would normally include:
  - manufacturers of active substances in the Review Programme who were not participants in the Review Programme;
  - importers of active substances (on their own or in biocidal products) in the Review Programme who were not participants in the Review Programme;
  - manufacturers of new active substances who did not support the approval of the active substance;
  - importers of new active substances (on their own or in biocidal products) who did not support the approval of the active substance;
  - manufacturers of biocidal products, if the supplier of the active substance(s) used in their products is not on the list;
  - entities which make biocidal products available on the market if the supplier of the active substance(s) used in their products is not on the list.

The Article 95 list is structured per active substance. Apart from the names of the entities, the list shows the role of the entities as "substance supplier" and/or "product supplier", the relevant PT, and the date of inclusion of the entity in the list.

WHAT & WHEN

TIMELINES, DEADLINES AND TRANSITIONAL PERIOD RELATED TO THE OBLIGATION/PROCESS

The concerned companies (alterative suppliers) need to make a submission that is compliant with Article 95 to ECHA in time to be included on the list before 1 September 2015. From 1 September 2015, a biocidal product cannot be placed on the EU market if the substance supplier or product supplier is not included in the list for the product-type (PT) to which the product belongs.

For new active substances, a submission can be made as soon as the original new active substance dossier is considered to be complete by the evaluating competent authority. The related entry is published by ECHA in its regular update of the Article 95 list.

Send us your feedbacks on guidance using the form:
https://comments.echa.europa.eu/comments_cms/FeedbackGuidance.aspx

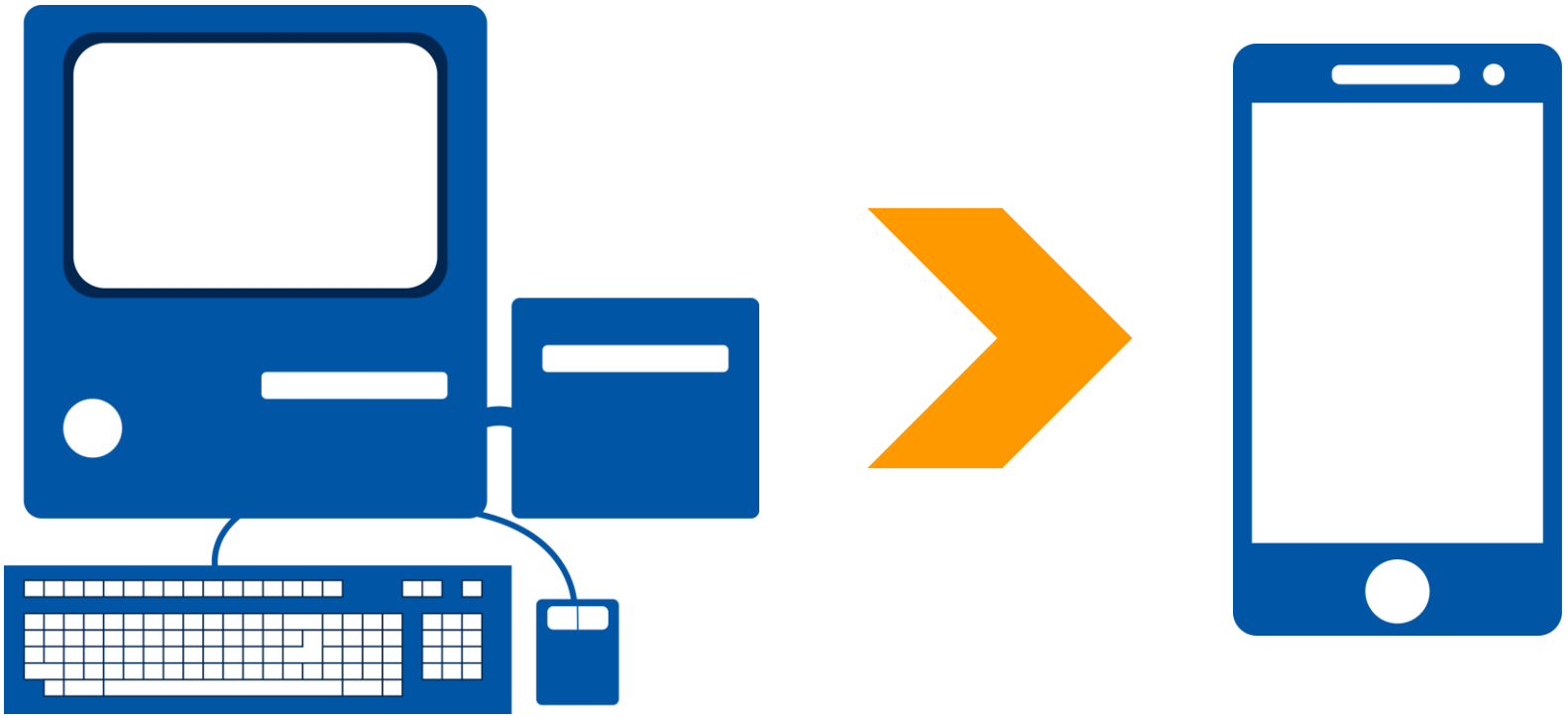
Practical Guide Chapters

- approval of active substance
- Article 95: list of active substances and suppliers
- technical equivalence
- national authorisation
- mutual recognition
- renewal of national authorisation and authorisations subject to mutual recognition
- Union authorisation
- simplified authorisation
- changes of biocidal products
- data sharing
- appeals

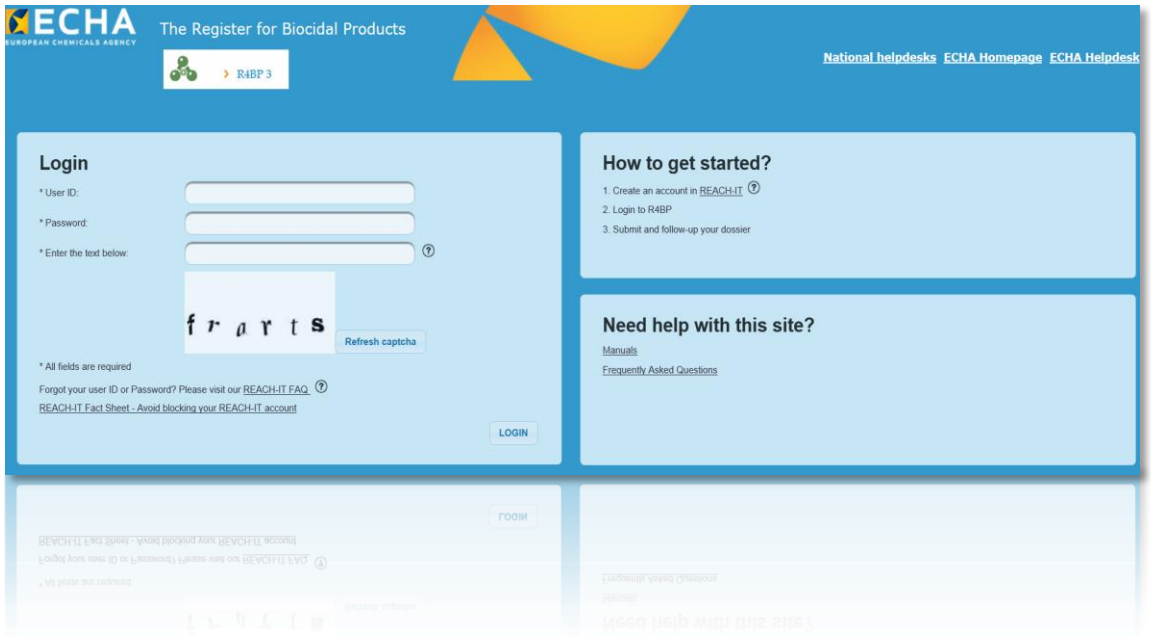
From October 2014:

- renewal of approval of active substance
- review of an approval of active substance
- research and development

IT support



IT support

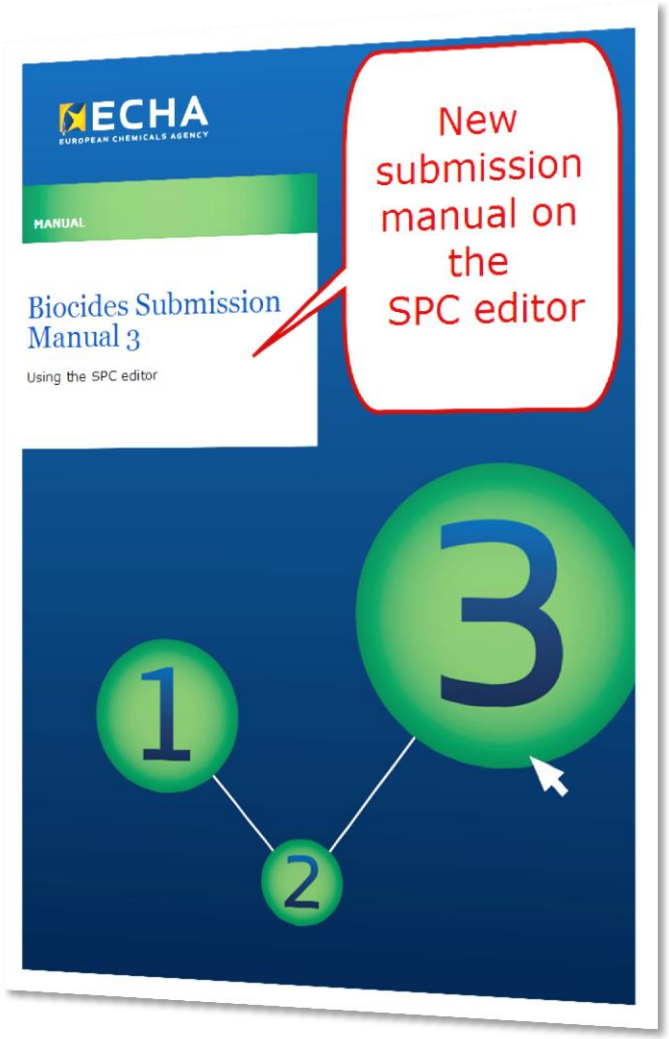


@ ECHA > Support > Dossier Submission Tools > R4BP 3

Submission

- Before submission, check our website:
  - Dedicated web page for each process
  - Biocides Submission Manuals
  - Supporting documents
- During the submission:
  - Biocides Submission Manuals NEW with R4BP 3.2
  - Choose the correct application type and wizard
  - Follow the wizard
  - Use the correct supporting document(s)

Submission manuals



Post submission

- After submission, check R4BP 3
  - For messages regarding Business Rules, Invoicing and Evaluation
  - Payment by the due date – risk of rejection of the applications

- Monitor your application progress (event history, messages, tasks)

- Email notification system NEW with R4BP 3.2

Helpdesk - To keep in mind…

- For companies, especially SMEs, the **complexity of the BPR** is the major challenge

- Furthermore, new legal requirements are also included in the **implementing legislation** that the Commission has been adopting

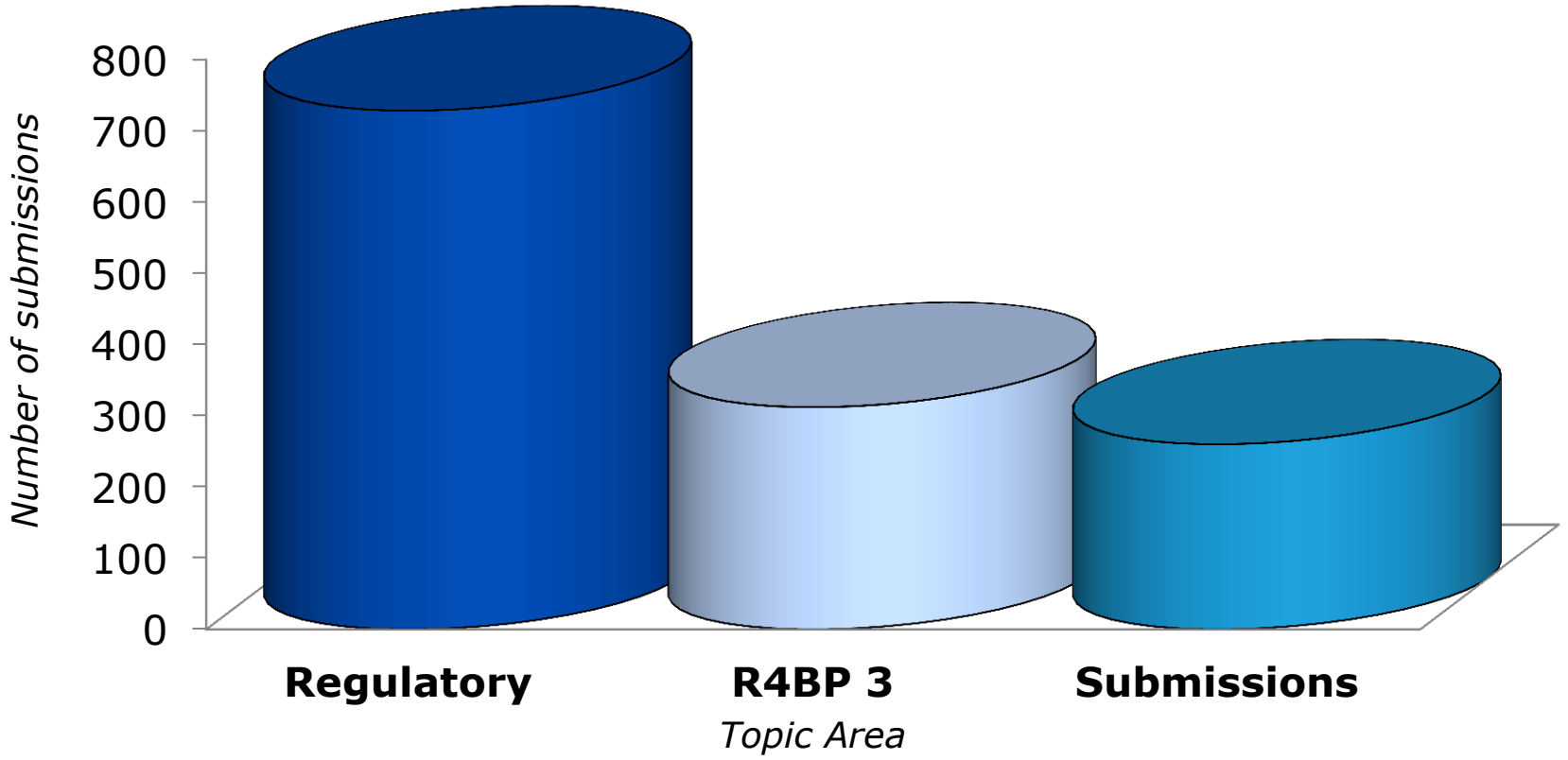
Helpdesk - To keep in mind…

- Adding to this, the **speed of change** of the provisions (**amending regulations, changes of interpretation**) increases uncertainty

- It is therefore difficult for companies to rely on their **existing knowledge**

ECHA Helpdesk after 18 months

Regulatory R4BP 3 Submissions



I’m waiting…!!!

- Nobody likes to wait…
- …therefore all questions are assessed by the helpdesk upon arrival and prioritised where possible
- Multi-expert questions take more time
- In many cases (87% in last quarter), a company will receive a final reply to their questions before 15 days have passed

I’m waiting…!!!

- If providing the final reply takes more than 15 days, you will get an update about the status and reasons for the delay

- Through the HelpNet, ECHA is in touch with the national helpdesks and Commission to solve our common doubts…
  … this, sometimes requires time

Communicating

Non-EU companies to be indicated in the list of biocidal active substances and suppliers

ECHA/NA/14/36

ECHA and the Commission have agreed to publish the company names of non-EU entities together with their EU-representatives in the Article 95 list of the Biocidal Products Regulation.

Helsinki, 18 August 2014 – While preparing the publication of the first EU list of biocidal active substances and suppliers, namely the Article 95 list, the Agency has formally agreed with the European Commission that non-EU companies participating in the EU programme to review all existing biocidal active substances on the EU market (Review Programme) will be listed next to their EU representative. The same will apply for non-EU companies who have supported a new active substance.

To ensure equal treatment, all non-EU manufacturers will from now on have the possibility to appoint an EU representative for the purposes of the Article 95 list.

Non-EU companies participating in the Review Programme will be contacted by ECHA for more information about their EU-representatives. For those companies planning to make a submission representing non-EU entities, ECHA has modified the supporting document to include also this information.

From 1 September 2015, a biocidal product cannot be placed on the EU market if the substance supplier or product supplier is not included in the list for the product type to which the product belongs.

Further information

- Guidance on biocides legislation
- Active substances and suppliers
- Biocidal Products Regulation supporting documents
- List of active substance and suppliers

News alert
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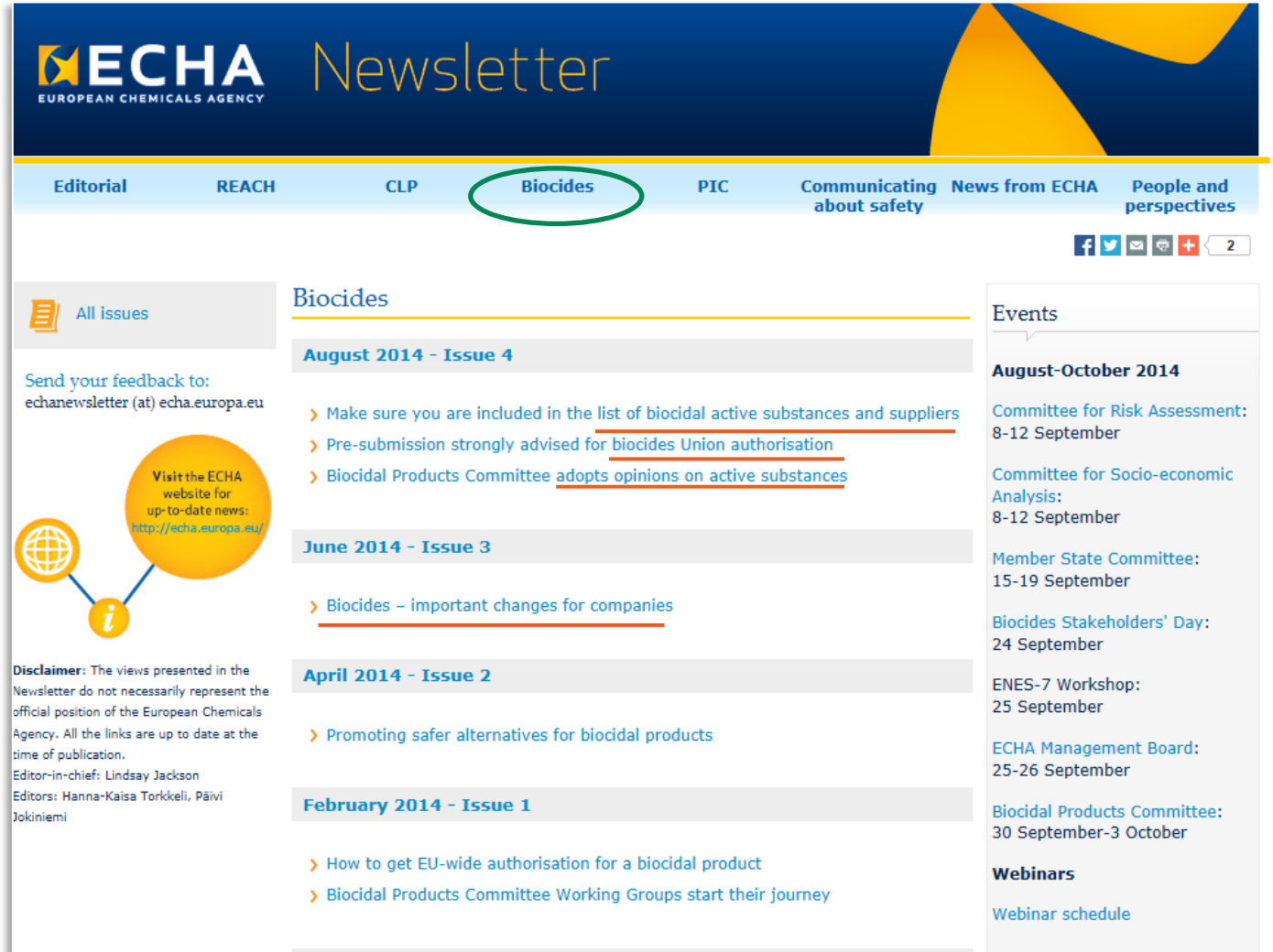

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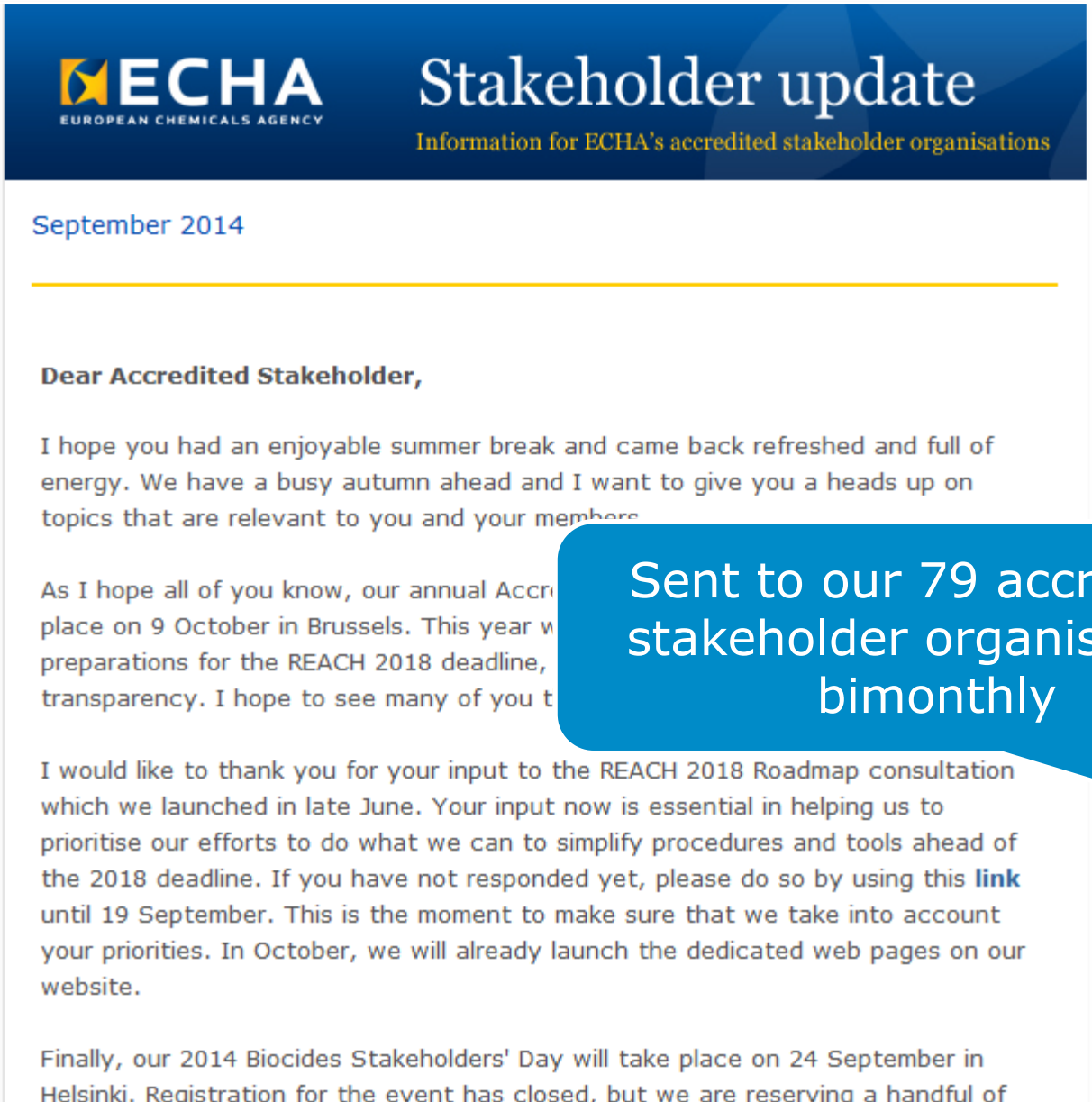

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Stakeholder update

Information for ECHA's accredited stakeholder organisations

September 2014

Dear Accredited Stakeholder,

I hope you had an enjoyable summer break and came back refreshed and full of energy. We have a busy autumn ahead and I want to give you a heads up on topics that are relevant to you and your members.

As I hope all of you know, our annual Accr
place on 9 October in Brussels. This year w
preparations for the REACH 2018 deadline,
transparency. I hope to see many of you t

I would like to thank you for your input to the REACH 2018 Roadmap consultation which we launched in late June. Your input now is essential in helping us to prioritise our efforts to do what we can to simplify procedures and tools ahead of the 2018 deadline. If you have not responded yet, please do so by using this **link** until 19 September. This is the moment to make sure that we take into account your priorities. In October, we will already launch the dedicated web pages on our website.

Finally, our 2014 Biocides Stakeholders' Day will take place on 24 September in Helsinki. Registration for the event has closed, but we are reserving a handful of

Sent to our 79 accredited stakeholder organisations bimonthly

Tips and take home messages

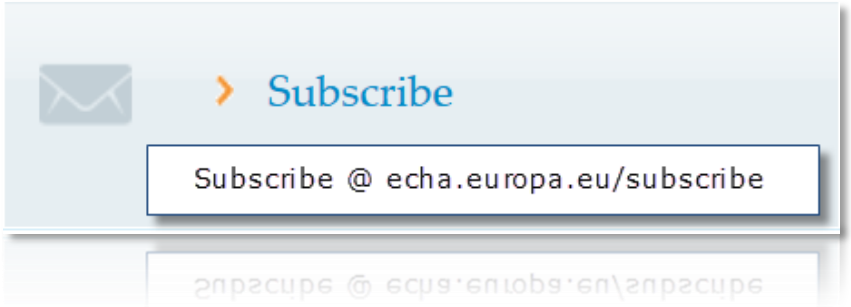
- First consult our website, webinars, Q&A and guidance
- Contact the helpdesks well in advance of a legal deadline
- Contact first the national helpdesk* and afterwards, if needed, the ECHA Helpdesk

*http://echa.europa.eu/support/helpdesks/national-helpdesks/list-of-national-helpdesks

Tips and take home messages

- Try to avoid multiple questions or domino questions

- We try to reach you, make yourself reachable



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valerio.spinosi@echa.europa.eu

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