Article 95

Biocides Stakeholders' Day

24 September 2014

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Overview

Article 95 list

- Obligations and consequences
- Article 95 list
  - Persons placed automatically on the list
  - Who should apply?
- How to comply
- First speak with your supply chain

Overview

Applications

- How to prepare Article 95 applications
  - Letters of access
  - Data requirements for complete substance dossiers
- Interaction with applicants during the evaluation

Objectives of Article 95

- Recital 8 of Biocidal Products Regulation:
  - To ensure the equal treatment of persons placing active substances on the market

- Aim: ensure that all players (including alternative suppliers) contribute to the costs of the active substance approval process

Article 95 list

Obligations & consequences

How to comply

Obligations and consequences

As of 1 September 2015, biocidal products consisting of, containing or generating a relevant substance should not be made available on the market if either the "substance supplier" or the "product supplier" is not included on the list of active substances and suppliers for the relevant product-type(s)

Article 95 list as it will be published

Article 95 List 1 (1)

Entity Name	Country	Reason for Inclusion	Supplier Type
Polyvinylpyrrolidone iodine		-	**25655-41-8**
Product Type: 1			
[redacted]	Spain	RP Participant	Substance Supplier
[redacted]	Germany	RP Participant	Substance Supplier
[redacted]	Germany	RP Participant	Substance Supplier
Product Type: 3			
[redacted]	Spain	RP Participant	Product Supplier
[redacted]	Belgium	RP Participant	Product Supplier
[redacted]	Belgium	RP Participant	Product Supplier
[redacted]	Netherlands	RP Participant	Product Supplier
[redacted]	Netherlands	RP Participant	Product Supplier
[redacted]	Germany	RP Participant	Product Supplier
[redacted]	United Kingdom	RP Participant	Product Supplier
[redacted]	Germany	RP Participant	Product Supplier
[redacted]	United Kingdom	RP Participant	Product Supplier
[redacted]	France	RP Participant	Product Supplier
[redacted]	United Kingdom	RP Participant	Product Supplier

Persons placed automatically on the list

- Participants in the Review Programme
- Supporters of new active substances
- Submitters of “third party dossiers” recognised as complete by a competent authority (alternative active substance dossier submitted within a product authorisation application)

Persons who should make applications

- Alternative suppliers of active substances in the Review Programme
- Alternative suppliers of new active substances after their approval
- Manufacturers of biocidal products consisting of, containing or generating a relevant substance, if the supplier of the active substance used in their biocidal product is not on the list

ⓘ established in the EU or their EU representative if they are not

ⓘ Non-EU entities can be listed next to their EU representative

How to comply with Article 95

- In practice, for each biocidal product available on the market, the company should be able to demonstrate that:

- the product originates (directly or indirectly) from a product supplier included in the list for the relevant product-type(s)

or

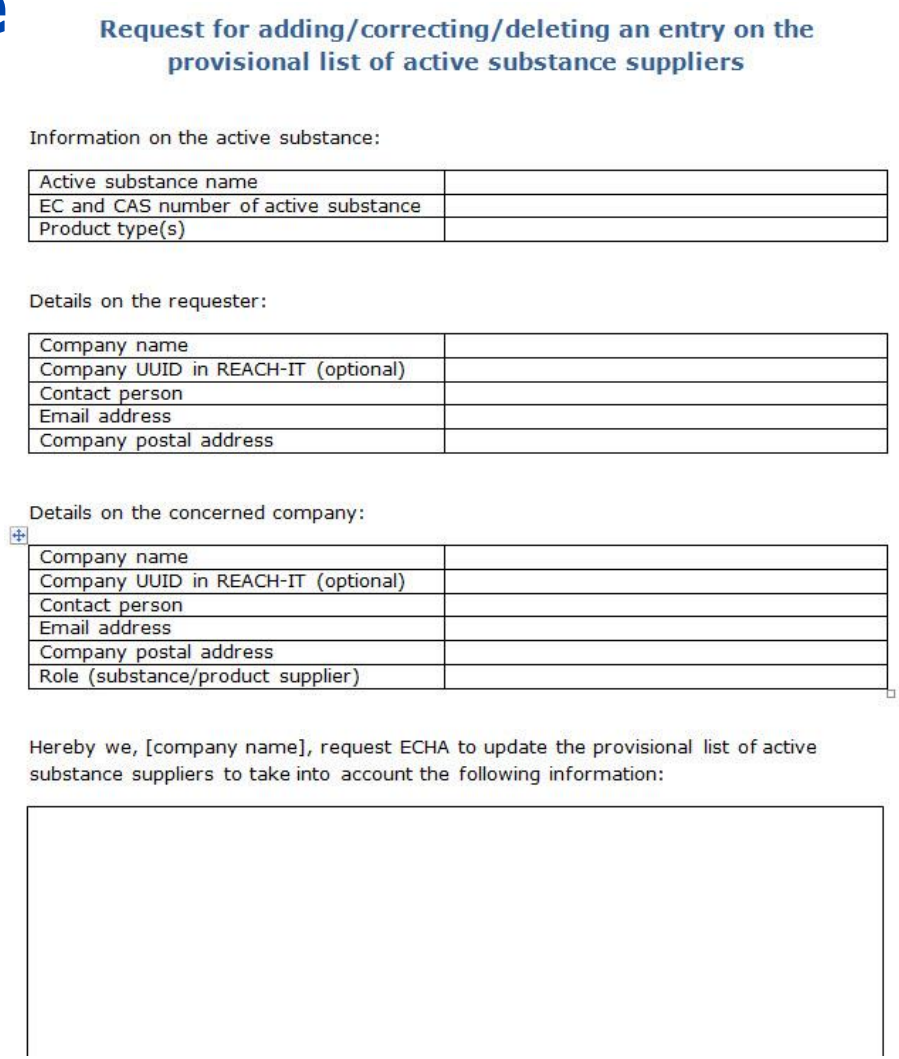
- the active substance(s) originate from a substance supplier included in the list for the relevant product-type(s)

Supply chain communication

Case	Need to apply	The role you will be given
Person X manufacturing and placing on the European market an active substance for which a dossier has been submitted under the Review Programme or BPR by person X.	No, X automatically listed	RPP, listed as substance supplier
Person X placing on the European market an active substance (on its own or in biocidal products) for which a dossier has been submitted under the Review Programme or BPR by Company Y.	Yes	Substance supplier
Person X placing on the European market a precursor of an active substance (on its own or in biocidal products) for which a dossier has been submitted under the Review Programme or BPR by Company Y.	Yes	Substance supplier
Person X importing to the European market an active substance (on its own or in biocidal products) for which a dossier has been submitted under the Review Programme or BPR by Company Y.	Yes	Substance supplier
Person X placing in a non-European market an active substance for which a dossier has been submitted under the Review Programme or BPR by Company Y.	No	Not included in the list
Person X formulating a biocidal product including an active substance for which a dossier has been submitted under the Review Programme or BPR by Company Y.	Yes	Product supplier

Article 95 list update

- **Non-EU companies can appoint an EU representative** for the purposes of Article 95, and appear on the list next to their EU representative
- **Further correction requests for updating the list are possible** using the form that has been available so far



Request for adding/correcting/deleting an entry on the provisional list of active substance suppliers

Information on the active substance:

Active substance name	
EC and CAS number of active substance	
Product type(s)	

Details on the requester:

Company name	
Company UUID in REACH-IT (optional)	
Contact person	
Email address	
Company postal address	

Details on the concerned company:

Company name	
Company UUID in REACH-IT (optional)	
Contact person	
Email address	
Company postal address	
Role (substance/product supplier)	

Hereby we, [company name], request ECHA to update the provisional list of active substance suppliers to take into account the following information:

How to prepare an application

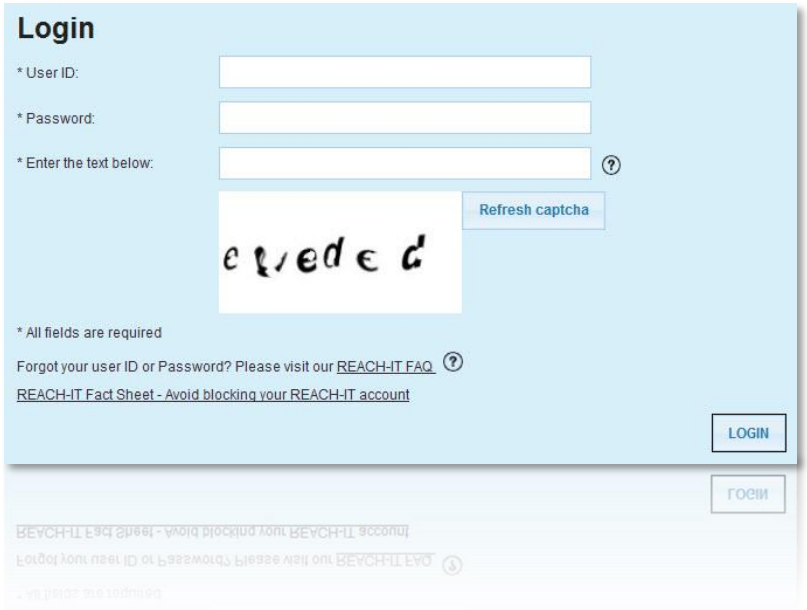
Types of applications

- A letter of access (LoA) to a 'complete substance dossier'
- A 'complete substance dossier' complying with the requirements of Annex II to the BPR

- [A reference to a 'complete substance dossier' for which all data protection periods have expired]
- ['Mixed application' - both an LoA and data for the endpoints not covered by the LoA]

Submission of an application

- Article 95 does not require prior establishment of technical equivalence
- Submit through the Register for Biocidal Products (R4BP)



Submission of an application

- A supporting document should be completed – specify role of applicant (http://echa.europa.eu/support/dossier-submission-tools/r4bp/supporting-documents)
- Indicate the product-type(s)
- Submission manual: http://echa.europa.eu/documents/10162/14938692/bsm_03a_active_subst_init_subm_en.pdf

A specific type of letter of access

- No need for IUCLID 5 - Attach LoA in the submission wizard
- Specific type of LoA originating from a dossier submitter (not necessarily the data owner)

A specific type of letter of access

- For the purposes of an Article 95 application
  - a list of submitted data is not necessary if the LoA refers to a ‘complete substance dossier’ in its entirety
  - an LoA can also give access rights to ECHA with the applicant as the beneficiary

- In addition: product-type(s), applicant’s role

Complete substance dossier

- In compliance with Annex II to the Biocidal Products Regulation

Content of dossier:

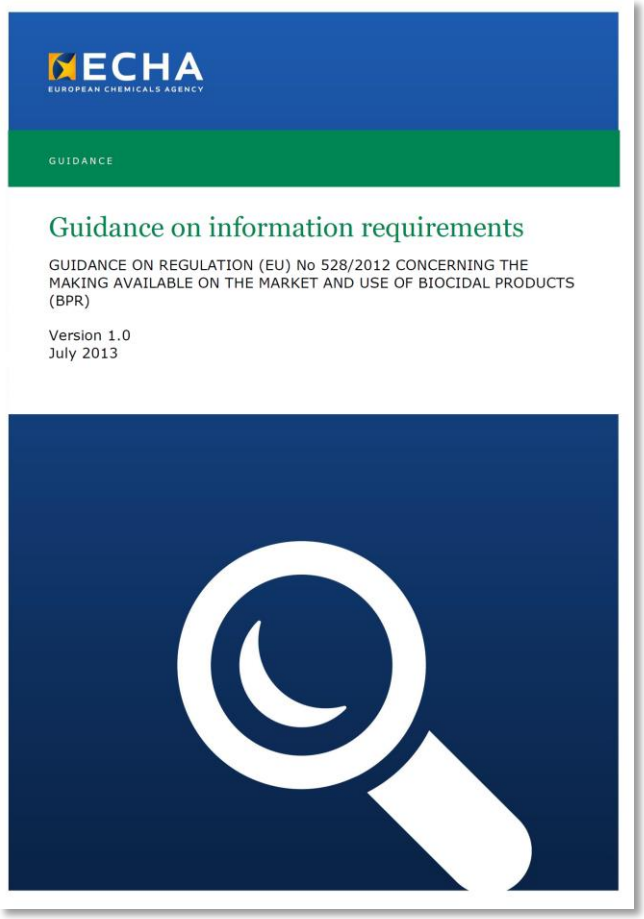
- All core datasets
- A summary, evaluation and draft risk assessment (section 13)
- PT-specific additional datasets will be required (Part V of the Guidance on information requirements)

ⓘ Full study reports need to be provided

Guidance on information requirements

- Information on:
  - Which endpoints to cover;
  - Which tests to provide;
  - Testing protocols;
  - Quality issues;
  - Waivers;
  - etc…

http://echa.europa.eu/documents/10162/15623299/biocides_guidance_information_requirements_en.pdf



Applications received by 10 September

Applications received	11
Complete substance dossier	7
Letter of Access (only)	3
Letter of Access + additional data	1

Evaluation stage	
Processing ongoing	10
Additional data requested	6
Completed – positive decision (LoA case)	1

Evaluation – interaction with applicants

- Provide name and contact details of an ECHA expert to the applicant
- Time for comments on draft decision 1 (+2) months
- One possibility to update application
- No legal deadline
- Total evaluation time depends on application type, level of complexity and ECHA's workload

Guidance on active substances and suppliers (Article 95 list)

- Guidance document is currently under consultation with CAs until 3 October 2014
- Available at: http://www.echa.europa.eu/support/guidance/consultation-procedure/ongoing-bpr
- Foreseen publication is November 2014

Apply as soon as possible

To ensure inclusion in the Article 95 list before 1 September 2015

ⓘ *Provide sufficient time for data sharing negotiations*

More information on

- Active substances and suppliers: http://www.echa.europa.eu/regulations/biocidal-products-regulation/approved-suppliers
- List of active substances and suppliers: http://www.echa.europa.eu/information-on-chemicals/active-substance-suppliers
- Application procedure through R4BP3: http://www.echa.europa.eu/regulations/biocidal-products-regulation/approved-suppliers/application-and-assessment-procedure

Article 95 – Key messages

- Speak with your supply chain to determine which substance supplier or product supplier will apply to be on the Article 95 list
- Don’t underestimate preparation time, especially for data sharing negotiations
- Submit your application as soon as possible – deadline to be on the list is 1 September 2015
- Carefully read ECHA’s new Guidance on Article 95

Thank you

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