Article 95

Biocides Stakeholders’ Day

24 September 2014

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Biocides Assessment Unit
European Chemicals Agency
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

<table>
<thead>
<tr>
<th>Entity Name</th>
<th>Country</th>
<th>Reason for Inclusion</th>
<th>Supplier Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyvinylpyrrolidone iodine</td>
<td>Spain</td>
<td>RP Participant</td>
<td>Substance Supplier</td>
</tr>
<tr>
<td></td>
<td>Germany</td>
<td>RP Participant</td>
<td>Substance Supplier</td>
</tr>
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**Product Type: 1**

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<tr>
<td></td>
<td>Belgium</td>
<td>RP Participant</td>
<td>Product Supplier</td>
</tr>
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<td>Product Supplier</td>
</tr>
<tr>
<td></td>
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<td>RP Participant</td>
<td>Product Supplier</td>
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<td></td>
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<td>RP Participant</td>
<td>Product Supplier</td>
</tr>
</tbody>
</table>
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

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

<table>
<thead>
<tr>
<th>Case</th>
<th>Need to apply</th>
<th>The role you will be given</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>No, X automatically listed</td>
<td>RPP, listed as substance supplier</td>
</tr>
<tr>
<td>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.</td>
<td>Yes</td>
<td>Substance supplier</td>
</tr>
<tr>
<td>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.</td>
<td>Yes</td>
<td>Substance supplier</td>
</tr>
<tr>
<td>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.</td>
<td>Yes</td>
<td>Substance supplier</td>
</tr>
<tr>
<td>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.</td>
<td>No</td>
<td>Not included in the list</td>
</tr>
<tr>
<td>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.</td>
<td>Yes</td>
<td>Product supplier</td>
</tr>
</tbody>
</table>
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
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:
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...

Applications received by 10 September

<table>
<thead>
<tr>
<th>Applications received</th>
<th>11</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete substance dossier</td>
<td>7</td>
</tr>
<tr>
<td>Letter of Access (only)</td>
<td>3</td>
</tr>
<tr>
<td>Letter of Access + additional data</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Evaluation stage</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Processing ongoing</td>
<td>10</td>
</tr>
<tr>
<td>Additional data requested</td>
<td>6</td>
</tr>
<tr>
<td>Completed – positive decision (LoA case)</td>
<td>1</td>
</tr>
</tbody>
</table>
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


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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