ECHA
EUROPEAN CHEMICALS AGENCY

Practical guide on the list of active substance and product suppliers (Article 95 list)

ABC

Disclaimer

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WHY

PRINCIPLES BEHIND THE OBLIGATION/PROCESS

Article 95 of the Biocidal Products Regulation (EU) No 528/2012 (BPR) aims to ensure the equal treatment of persons placing active substances on the market and to establish a level playing field as quickly as possible on the market for existing active substances. To achieve this, the European Chemicals Agency (ECHA) ECHA publishes a list of relevant active substances and suppliers (substance and product).

Since 1 September 2015, a BP (consisting of, containing, or generating a relevant substance) cannot be made available 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 BPs 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).

A **substance supplier** is defined as a person established in the EU who manufacturers or imports a relevant substance, on its own or in biocidal products.

A **product supplier** is defined as a person established in the EU who manufacturers or makes available on the market a biocidal product consisting of, containing or generating a relevant substance.

The entities listed can be classified into two groups:

- Those who are placed automatically on the list and do not have to make a submission to ECHA under Article 95, namely:
    - Participants in the Review Programme[1].

[1] 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, and implemented under Commission Delegated Regulation (EU) No 1062/2014

  - 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).
  - Submitters of third party dossiers (alternative active substance dossiers submitted as part of a product authorization 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 and importers of active substances in the Review Programme who were not participants in the Review Programme.
  - Manufacturers and importers of new active substances who did not support the approval of the active substance.
  - Manufacturers of BPs, if the supplier of the active substance(s) used in their products is not on the list.
  - Entities which make BPs available on the market if the supplier of the active substance(s) used in their products is not on the list.

Not all companies require being included on the Article 95 list. It is sufficient that one company in the supply chain is listed.

The Article 95 list is structured per active substance. The names of the suppliers (and their country) are listed and their role as "substance supplier" and/or "product supplier" is indicated. The relevant PT and the date of inclusion of the entity in the list are also indicated.

WHEN

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

Since 1 September 2015, a BP (consisting of, containing, or generating a relevant substance) cannot be made available on the EU market if the substance supplier or product supplier is not included in the list for the PT to which the product belongs.

The concerned companies (alternative suppliers) need to submit an application that is compliant with Article 95 to ECHA well ahead of making available BPs on the market to accommodate for the time needed for the processing of the applications.

Not all active substances are at present "relevant substances" for the purpose of Article 95. It is only when the evaluating competent authority has validated (completeness check) the active substance approval application that the substance is added to the Article 95 list.

WHAT

INFORMATION REQUIREMENTS AND SOURCES

Information requirements

Companies can submit to ECHA a complete substance dossier[2], a LoA, a combination of a dossier and a LoA or a reference to an existing dossier for which all data protection periods have expired. ECHA verifies whether the dossier, or the LoA, is adequate.

A template LoA can be found in the Practical Guide Special Series on Data Sharing – Letters of Access.

BSM Application instructions: How to submit an application for Active Substance explains what types of information files should be prepared and included in the application for inclusion on the Article 95 list. For further information on information requirements companies are recommended to consult the *Guidance on active substance suppliers* as well as Annex II to the BPR and the *Guidance for information requirements for Biocides,* available on ECHA's website.

Issues to consider

The duplication of tests on vertebrates for the purposes of the BPR is prohibited. Any person intending to perform such tests should make an inquiry to ECHA to find out if the tests have already been submitted to ECHA or the MSCAs under the BPD or the BPR. If the relevant studies have already been submitted, ECHA will give the inquiring company the contact details of the data submitter.

[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.

Owners of existing data and prospective applicants are obliged to make every effort to share data involving tests on vertebrates. Furthermore, for the submissions under Article 95 relating to substances listed in the Review Programme[3], the respective parties are also obliged to make every effort to share all toxicological, ecotoxicological and environmental fate and behaviour studies (including those not on vertebrates).

For more information see the Practical Guide Special Series on Data Sharing.

HOW

PROCEDURE TO FOLLOW

Creation of a IUCLID dossier

The entity seeking inclusion on the Article 95 list is required to submit the required information using a IUCLID format.

The following documents describe how to create and complete a IUCLID dossier:

- IUCLID manuals, available on the IUCLID website[4]
- *BSM Technical guide:* How to prepare a biocides dossier , available on ECHA's website;
- *BSM Technical guide:* How to use R4BP 3 , available on ECHA's website.

For a submission based on a LoA to a complete substance dossier, no IUCLID dossier is required.

Submission and processing of an application using R4BP 3

The application for inclusion on the Article 95 list must be submitted through R4BP 3. Following confirmation that the submission has passed the initial checks by ECHA, the application will be verified by the Agency. ECHA will send a draft decision to the applicant for comments, and at this time it is also possible for the applicant to submit missing information. ECHA then takes a decision on the inclusion of the supplier in the Article 95 list.

[3] Ref: Annex II to Regulation (EC) No 1451/2007
[4] http://iuclid6.echa.europa.eu/web/iuclid/documentation

Applicants need to monitor the status of their submission and receive/react to requests from ECHA in R4BP 3. If the applicant fails to meet a deadline, e.g. for payment of fees or to comment or submit additional information further to a draft decision, the application may be rejected. Only one update of the dossier is permitted. Updates of the dossier on the initiative of the applicant are not possible.

Applicants will find the relevant information and instructions for submitting and following-up their application through R4BP 3 in the submission manuals on ECHA's website:

- *BSM Technical guide: How to use R4BP 3;*
- *BSM Application instructions:* How to submit an application for Active Substance

More information related to invoicing and R4PB 3 can be found in the *BSM Process of invoicing in R4BP 3*.

RESULT

OUTCOME OF THE OBLIGATION/PROCESS

If a positive decision is made to include a company in the Article 95 list, it will be included on the Article 95 list as a substance and/or product supplier (as appropriate) for the relevant active substance and PT. The related entry is published by ECHA in its regular update of the Article 95 list.

If a negative decision is made, the company will not be included on the list, and may consider submitting a new application.

Since 1 September 2015, a BP (consisting of, containing, or generating a relevant substance) cannot be placed on the EU market if the substance supplier or product supplier is not included in the list for the PT to which the product belongs.

TO NOTE

EXCEPTIONS AND PARTICULAR CASES

Relation with the technical equivalence process

The assessment of technical equivalence for Article 95 purposes is not mandatory under the BPR and inclusion of a supplier in the Article 95 list does not automatically indicate the technical equivalence of their active substance.

Nevertheless, a company can request a technical equivalence assessment under Article 54 of the BPR (or a chemical similarity check, if a decision to approve the active substance has not yet been adopted) from ECHA before applying to be listed in the Article 95 list to make sure that the data they are about to obtain from an already listed company are relevant for its active substance.

For more information see the Practical Guide chapter on technical equivalence.

Annex I to the BPR

Except for the substances listed in category 6, all other active substances listed in Annex I are not within the scope of Article 95. Therefore, BPs containing such active substances can be made available on the market provided they are authorised.

For substances listed in category 6 of Annex I, companies which make available on the market BPs which consist of, contain, or generate those substances will have to comply with the provisions of Article 95. Therefore, the same rules apply as for other active substances.

Treated articles

Producers or importers of treated articles are not subject to the requirements of Article 95.

COST

RELATED FEES

Fees related to this process are described in the fifth entry of Annex III to *Commission Implementing Regulation (EU) No 564/2013*.

HELP

TO CONTACT FOR FURTHER INFORMATION

ECHA Helpdesk
http://echa.europa.eu/contact/helpdesk-contact-form

National authorities providing support
http://echa.europa.eu/support/helpdesks/national-helpdesks/list-of-national-helpdesks

MORE

INFORMATION

Legislation relevant to biocides

http://echa.europa.eu/regulations/biocidal-products-regulation/legislation

Regulatory aspects

Active substances and suppliers

http://echa.europa.eu/regulations/biocidal-products-regulation/approved-suppliers

Guidance on Biocides legislation

http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation

Submission

Active substances

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

- Inclusion on the list of active substances and suppliers (Art. 95)

Biocides Submission Manuals

http://echa.europa.eu/support/dossier-submission-tools/r4bp/biocides-submission-manuals

IUCLID Manuals

http://iuclid6.echa.europa.eu/support

Q&As

https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/Biocidal+Products+Regulation/active+substance+suppliers