Article 95: List of active substances and suppliers

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 (BPs)). 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 BP.¹ The European Chemicals Agency (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 BP 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 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).

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 Programme⁴;
  - 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 BPs) 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 BPs) 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.

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.

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

The concerned companies (alternative 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 BP 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.

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.
INFORMATION REQUIREMENTS AND SOURCES

Information requirements:
Companies can submit a full dossier, a LoA, a combination of a dossier and an LoA or a reference to an existing dossier for which all data protection periods have expired.

*Biocides Submission Manual 3a: Active substances Part A, Initial submissions* 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.

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

For more information see: Practical Guide chapter on data sharing.

PROCEDURE TO FOLLOW

Creation of a IUCLID 5 dossier:
The entity seeking inclusion on the Article 95 list is required to submit the required information using a IUCLID 5 format.

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

- *BPR dossier creation/IUCLID Quick Guide*, available on the IUCLID website;
- Video tutorial *Creation of a biocidal product dossier with IUCLID*, available in ECHA’s YouTube channel;
- *Biocides Submission Manual 1: Using IUCLID for biocide applications*, available on ECHA’s website;

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5 Under revision (September 2014).
For a submission based on an 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 should be submitted through R4BP 3. Following confirmation that the submission has passed the initial checks by ECHA, the application will be evaluated 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.

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:
- *Biocides Submission Manual 2: Using R4BP 3 for biocide applications*;

More information related to invoicing and R4PB 3 can be found in the *Biocides Submission Manual 5: Invoicing in R4BP 3.*

**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.

From 1 September 2015, a BP 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.
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. As a consequence, BPs containing such active substances can be made available on the market after 1 September 2015, provided they are authorised.

For substances listed in category 6 of Annex I, companies responsible for placing BPs containing such 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.

RELATED FEES
Fees related to this process are described in the fifth entry of Annex III to Commission Implementing Regulation (EU) No 564/2013.
TO CONTACT FOR FURTHER INFORMATION

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

National authorities providing support

INFORMATION

Legislation relevant to biocides

Regulatory aspects
Active substances and suppliers

Guidance on biocides legislation

Submission
• Submission instructions
  Inclusion on the list of active substances and suppliers (Article 95)

• Biocides Submission Manuals
  » http://echa.europa.eu/support/dossier-submission-tools/r4bp/biocides-submission-manuals

Biocides Submission Manual 2: Using R4BP 3 for biocide applications

Biocides Submission Manual 3a: Active substances Part A, Initial submissions

Biocides Submission Manual 5: Invoicing in R4BP 3
• BPR specific IUCLID 5 Manuals

  BPR dossier creation / IUCLID Quick Guide
  » http://iuclid.eu/download/documents/usermanual/IUCLID_5.5_BPR_dossier_creation_quick_guide_v1.0.pdf

  Video tutorial Creation of a biocidal product dossier with IUCLID
  » http://www.youtube.com/watch?v=QQ9z4LacDnE

Q&As
  » http://echa.europa.eu/support/qas-support

Questions and Answers on Active substances and suppliers