State of the list, data sharing and information on guidance

Webinar on Article 95 of the Biocidal Products Regulation

16 June 2014 – Presentation
updated October 2014

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Corrigendum (02/10/2014)

- Due to further development of the Article 95 process, slide 9 has been amended in the present version of the presentation.

Overview

- Introduction/Why an application should be made
- Data sharing and related disputes
- List of active substances and suppliers published according to Article 95(1)
  - Who is placed on the list?
  - Maintenance
- Guidance on active substances and suppliers (Article 95 list)

Why an application should be made

As of 1 September 2015

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).

Procedure under Article 95 concerns

- "substance supplier" – manufacturers or importers of a relevant substance, on its own or in biocidal products
- "product supplier" – manufacturers or those who make available on the market a biocidal product consisting of, containing or generating a relevant substance

The relevant substances are all active substances and all substances generating an active substance, for which a dossier has been submitted and accepted or validated by a Member State.

How to comply with Article 95

In practice, for each biocidal product available on the market, you 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)

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 along with 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

If they are established in the EU or their importers if they are not!

Non-EU entities cannot be listed as “substance suppliers” or “product suppliers” but can be included if they have appointed an EU representative

Mandatory data sharing and related disputes

Data sharing

- Data owners and prospective applicants are required to "*make every effort to reach an agreement on the sharing of the results of the tests or studies*"

- "*Compensation for data sharing shall be determined in a fair, transparent and non-discriminatory manner*"

Tips for successful negotiation

- Reaching an agreement is the responsibility of the negotiating parties;
- Continue with the negotiations as far as possible (challenge position, find alternative solutions);
- Fulfil data sharing obligations in a timely manner, i.e. allow reasonable time for the negotiations;
- Prospective applicant to define the scope of negotiations clearly;
- Argumentation against any claim shall be expressed between the parties.

Data sharing dispute claim

- Initiate as a last resort;
- Demonstrate efforts made during the negotiations, i.e. have a record of all communication;
- Obtain the ECHA decision before submitting your application;
- Continue making every effort, even if data sharing dispute claim is submitted.

List of active substances and suppliers published according to Article 95(1)

List of active substances and suppliers

- "existing" active substances; and the respective participant companies;
- "new" active substances, for which applications or a complete dossier were received; and the respective companies supporting their approval;
- Companies who submitted "third party dossiers";
- Applicants for inclusion in the list who made a submission which was found compliant by ECHA with the requirements of Article 95(1).

Maintenance of the list

- Supporters of new active substances, after the evaluating competent authority has accepted or validated the dossier, will be included

- The suppliers who submitted an application under Article 95(1) and passed the compliance check will gradually be added to the list

- Available at http://www.echa.europa.eu/information-on-chemicals/active-substance-suppliers

Guidance on active substances and suppliers (Article 95 list)

Guidance document is being revised

- Guidance document is currently under consultation
- Available at: http://www.echa.europa.eu/support/guidance/consultation-procedure/ongoing-reach
- After PEG consultation to competent authorities
- Foreseen publication date is Q4 of 2014

More information on

- Active substances and suppliers: http://www.echa.europa.eu/regulations/biocidal-products-regulation/approved-suppliers
- Data sharing http://www.echa.europa.eu/web/guest/regulations/biocidal-products-regulation/data-sharing
- Application procedure through R4BP3: http://www.echa.europa.eu/regulations/biocidal-products-regulation/approved-suppliers/application-and-assessment-procedure

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