Regulatory overview

Webinar on Article 95 of the Biocidal Products Regulation

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Content

- Introduction to the legal framework
- Objective of Article 95
- Legal text: new structure
- Inquiry, data sharing and dispute resolution

Introduction to the legal framework

- **Regulation (EU) No 528/2012** of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (BPR)

Recently amended by:

- **Regulation (EU) No 334/2014** of the European Parliament and Council amending [the BPR] with regard to certain conditions for access to the market => Article 95 re-written

Objective: equal treatment

- **Context**: mainly a consequence of the Review Programme and the existence of alternative suppliers who have not contributed to the costs
- **Objective**: equal treatment of all suppliers placing active substances on the market and equitable compensation for Review Programme participants, avoidance of monopolies (recitals 8 and 57 BPR)

Article 95: structure (1)

- ECHA publishes a list of all "**relevant substances**":

⇒ all active substances, and all substances generating an active substance, for which a complete substance dossier has been submitted and accepted or validated by a Member State in a procedure provided for by the BPR or the BPD

⇒ the "relevant procedures" under the BPR or the BPD are applications for active substance approval and product authorisation

Article 95: structure (2)

- The list also contains the **names of the persons**:
  - having made such a submission (e.g. Review Programme participants) or a submission to the Agency (alternative suppliers)
- their **role**: substance or product supplier (EU only)
- the **product-type(s)** for which they have made a submission, and
- date of inclusion of the substance in the list

Article 95: roles of persons

- Persons established within the Union:
- "**substance supplier**"**:** who manufactures or imports a relevant substance, on its own or in biocidal products
- "**product supplier**"**:** who manufactures or makes available on the market a biocidal product consisting of, containing or generating that relevant substance

Article 95: structure (3)

- Restriction on biocidal products being made available on the market after 1 September 2015: Article 95(2)

=> the substance supplier or the product supplier must be included on the list in the product type to which the product belongs.

Article 95: fees

- Where an alternative supplier applies for inclusion on the Article 95 list, a fee will apply which depends on the information submitted:
  - Letter of access to a complete substance dossier: **2 000 EUR**
  - Letter of access to part of a complete substance dossier, together with complementary data: **20 000 EUR**
  - Submission of a new dossier: **40 000 EUR**

➢ *Letter of access must comply with Article 61 of the BPR*

Article 95 and data sharing

Data sharing: inquiry

- Article 62(1) **prohibition** on repeating tests on vertebrate animals for the purpose of the BPR
- Article 62(2) **inquiry procedure**
- *Obligatory* for any person intending to perform tests or studies on vertebrates
- *Voluntary* for any person intending to perform tests or studies not involving vertebrates

⇒ Inquiry submitted to ECHA through R4BP

⇒ ECHA provides name and contact details of the data submitter to the prospective applicant

Data sharing obligations

- Data owners and prospective applicants "*shall make every effort to reach an agreement*…" (Art 63)
- Communication must be made directly between the parties involved (not via ECHA or including ECHA)
- Compensation: determined in a fair, transparent and non-discriminatory manner
- Mandatory data sharing applies to:
  - Data from vertebrate tests (Art 62), and
  - All tox and eco-tox studies, and environmental fate and behaviour studies <u>including non-vertebrate</u>, for existing active substances in the Review Programme (Art 95)

Data sharing disputes (1)

- Can be launched where:
  - An inquiry has been submitted to ECHA in accordance with Article 62(2)
  - ECHA has replied to the inquiry and at the earliest one month after receiving ECHA's reply
  - agreement with data owner has not been reached during the negotiations in spite of making every effort to reach an agreement
- Last resort after all the possible arguments have been exhausted and the negotiations have eventually failed

Data sharing disputes (2)

- Prospective applicant needs to provide ECHA documentary evidence regarding the negotiations
- Data owner is invited to provide their documentary evidence
- ECHA performs objective assessment of the evidence provided in order to issue a decision
- The ECHA decision can be appealed before the ECHA Board of Appeal within 3 months

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