Article 95: Obligations on suppliers

Biocides Stakeholders' day

25 June 2013

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Overview

- Concept and purpose of Article 95
- Consequences of the Article 95 list
- Practical steps: what, who, when and how
- Pending issues: Commission's proposed amendments

Concept and purpose

- New concept: list of approved active substance suppliers published and maintained by ECHA
- Object: recital 8

  *"To ensure the **equal treatment** of persons placing active substances on the market, they should be required to hold a dossier, or have a letter of access to a dossier, or to relevant data in a dossier, for each of the active substances they manufacture or import for use in biocidal products."*

Consequences

- **1 September 2015**: a biocidal product shall not be made available on the market if the manufacturer or importer of the A.S. it contains is not included in the list published by ECHA
- **Result**:

  - sharing of costs *pre approval* of A.S. by entities not part of the Review Programme

  - sharing of costs *post approval* of A.S. by preventing switching to a supplier not on the list

(i) what to submit?

- Submission of a dossier complying with Annex II to BPR or a LoA, or a combination (a reference to a dossier where data protection has expired will also be possible)

=>note: technical equivalence is not a condition

=>ECHA compliance check

- Prohibition on repeating tests on vertebrate animals – mandatory data sharing
- Fair chance to prepare submission within deadline - extension of mandatory data sharing to "all toxicological and ecotoxicological studies"

(ii) Who must submit?

- Article 95(1): "**any person** wishing to place active substance(s) on the Union market on its own or in biocidal products (the 'relevant person')

=>aimed mainly at "alternative suppliers" of A.S. under assessment in the Review Programme

=>will also impact new entrants

=> ECHA will publish Guidance

(iii) Who will be on the list?

- Alternative suppliers who make the submission
- Participants in the Review Programme
- Supporters of new A.S.

=>note: if non EU entity, submit through an importer

=>note: formulators may not make the submission: Article 95 (1) refers to “every A.S. that they manufacture or import…”

(iv) when to make the submission?

- As from **1 September 2013** for alternative suppliers wishing to remain on market post 1/9/15
- For new entrants, any time as from 1/9/13
- ECHA encourages early submission
- ECHA will publish first version of list on its internet site on 1/9/13 and will add to it gradually

(v) how to fulfil obligations?

- Practicalities: submit electronically through R4BP
- Prepare submission in good time
- Legal obligations to share data: Article 62 inquiry process and Article 63 data sharing dispute process apply.
- Data owners and prospective applicants "shall make every effort to reach an agreement…"

Pending issues: draft amendments

- Formulators cannot place products on the market post 1/9/15 unless the importer or manufacturer of the A.S. is on the list
- The Commission has proposed amendments to the BPR, including Article 95: maintains the concepts yet allows scope for formulators to make a submission
- ECHA will review and amend the list as and when the BPR is amended

Thank you

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