EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Directorate E – Food and feed safety, innovation
E4 - Pesticides and Biocides

67th meeting of representatives of Members States Competent Authorities for the implementation of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

This document is an attempt to provide guidance in the interest of consistency, and has been drafted by the Commission services responsible for biocidal products with the aim of finding an agreement with Member States' Competent Authorities for biocidal products. Please note, however, that Member States are not legally obliged to follow the approach set out in this document, since only the Court of Justice of the European Union can give authoritative interpretations on the contents of Union law.

Subject: **Scope of R&D provisions under Article 56 of the BPR**

The objective of the present document is to clarify the scope of R&D provisions set under Article 56 of the BPR, and clarify which activities can benefit from these provisions[1].

1- Analysis

(1) References to R&D activities are made across the BPR, as illustrated in the Appendix to this document.

(2) R&D activities under the BPR are referred as "*product and process-orientated research and development*" activities and "*scientific research and development'* activities.

[1] A previous document clarified to which type of active substance or biocidal products the R&D provisions can apply (CA-Nov14-Doc.7.5 - Final - Application of R&D provisions.doc).

(3) The same definitions of those activities as those existing in REACH applies in the BPR, and have to be read in the biocides context.

(4) Pursuant to Article 56 of the BPR, "*an experiment or a test for the purposes of scientific or product and process-orientated research and development involving an unauthorised biocidal product or a non-approved active substance intended exclusively for use in a biocidal product*" may take place only under the conditions provided for in this Article.

(5) The notion of experiment or test "*involving*" such biocidal product or active substance has been subject to debate by some stakeholders. In particular, some companies wanted to benefit from the R&D provisions to daily use unauthorised biocidal products, unapproved active substances, or uncompliant treated articles, in a research context.

(6) The recitals of BPR nevertheless clarify the intentions of the Legislators about the R&D activities which can be subject to the provisions of Article 56.

(7) In particular, recital 49 clarifies that specific rules needs to be established to allow the making available of an unauthorised biocidal product or a non-approved active substance "*to encourage research and development **in** active substances and biocidal products* […] *for the purposes of research and development"*. These rules are established by derogation from the basic obligations described in Article 17 to make available on the market and use authorised biocidal products.

(8) These provisions are therefore made to encourage R&D activities to develop new active substances, new biocidal products, and new uses of existing active substances or products. These provisions are not made to allow the daily making available on the market or use of a non-approved active substances, or non-authorised biocidal products, or non-compliant treated articles, in the context of other R&D activities (ex: to disinfect a R&D laboratory, to disinfect materials used in research, test or experiments to develop crops, medicines, cosmetics, any kind of products etc…).

(9) Regulation (EU) No 334/2014 modified Article 56(1) of the BPR to replace the reference of "*research or development*" by "*scientific or product and process-orientated research and development*", to ensure more consistency in the text of the BPR on the concepts and wording used. Indeed, the BPR only defines *scientific research and development* or *product and process-orientated research and development* in Article 3, not "*research or development*" as written in the BPR before its modification (these terms were the old terms used under the BPD).

Appendix

Extracts from the BPR

Recital

(49) To encourage research and development in active substances and biocidal products, it is necessary to establish rules concerning the making available on the market and use of unauthorised biocidal products and non-approved active substances for the purposes of research and development.

Article 3 - Definitions

2. For the purposes of this Regulation, the definitions laid down in Article 3 of Regulation (EC) No 1907/2006 shall apply for the following terms:
[…]
(d) 'product and process-orientated research and development';
(e) 'scientific research and development'.

Article 56 - Research and development

1. By way of derogation from Article 17, an experiment or a test for the purposes of scientific or product and process-orientated research and development involving an unauthorised biocidal product or a non- approved active substance intended exclusively for use in a biocidal product ('experiment' or 'test') may take place only under the conditions provided for in this Article.
Persons carrying out an experiment or test shall draw up and maintain written records detailing the identity of the biocidal product or active substance, labelling data, quantities supplied and the names and addresses of those persons receiving the biocidal product or active substance, and shall compile a dossier containing all available data on possible effects on human or animal health or impact on the environment. They shall make this information available to the competent authority on request.
2. Any person intending to carry out an experiment or test that may involve, or result in, release of the biocidal product into the environment shall first notify the competent authority of the Member State where the experiment or test will occur. The notification shall include the identity of the biocidal product or active substance, labelling data and quantities supplied, and all available data on possible effects on human or animal health or impact on the environment. The person concerned shall make available any other information requested by the competent authorities.
In the absence of an opinion from the competent authority within 45 days of the notification referred to in the first subparagraph, the notified experiment or test may take place.
3. If the experiments or tests could have harmful effects, whether immediate or delayed, on the health of humans, particularly of vulnerable groups, or animals, or any unacceptable adverse effect on humans, animals or the environment, the relevant competent authority of the Member State concerned may prohibit them or allow them subject to such conditions as it considers necessary to prevent those consequences. The competent authority shall, without delay, inform the Commission and other competent authorities of its decision.
4. The Commission shall be empowered to adopt delegated acts in accordance with Article 83 specifying detailed rules supplementing this Article.

Extracts from the REACH

Article 3 – Definitions

22. product and process orientated research and development: means any scientific development related to product development or the further development of a substance, on its own, in mixtures or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance;
23. scientific research and development: means any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than one tonne per year;