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 (Text with EEA relevance)

CHAPTER XII

DEROGATIONS

Article 56

Research and development

1 By way of derogation from Article 17, an experiment or a test for the purposes of research or 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 laid down 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.

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.

- 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.