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 XVII

FINAL PROVISIONS

Article 95

Transitional measures concerning access to the active substance dossier

1 As of 1 September 2013, any person wishing to place active substance(s) on the Union market on its own or in biocidal products (the 'relevant person') shall, for every active substance that they manufacture or import for use in biocidal products, submit to the Agency:

a a dossier complying with the requirements of Annex II or, where appropriate, with Annex IIA to Directive 98/8/EC; or

b a letter of access to a dossier as referred to under point (a); or

c a reference to a dossier as referred to under point (a) and for which all data protection periods have expired.

If the relevant person is not a natural or legal person established within the Union, the importer of the biocidal product containing such active substance(s) shall submit the information required under the first subparagraph.

For the purposes of this paragraph and for existing active substances listed in Annex II to Regulation (EC) No 1451/2007, Article 63(3) of this Regulation shall apply to all toxicological and ecotoxicological studies including any toxicological and ecotoxicological studies not involving tests on vertebrates.

The relevant person to whom a letter of access to a dossier on the active substance has been issued shall be entitled to allow applicants for the authorisation of a biocidal product containing that active substance to make reference to that letter of access for the purposes of Article 20(1).

By way of derogation from Article 60 of this Regulation, all data protection periods for substance/product-type combinations listed in Annex II to Regulation (EC) No 1451/2007, but not yet approved under this Regulation shall end on 31 December 2025.

2 The Agency shall make publicly available the list of persons that have made a submission in accordance with paragraph 1 or for whom it has taken a decision in accordance with Article 63(3). The list shall also contain the names of persons who are participants in the work programme established under the first subparagraph of Article 89(1) or have taken over the role of the participant.

3 Without prejudice to Article 93, as of 1 September 2015, a biocidal product shall not be made available on the market if the manufacturer or importer of the active substance(s) contained in the product, or where relevant, the importer of the biocidal product, is not included in the list referred to in paragraph 2.

Without prejudice to Articles 52 and 89, disposal and use of existing stocks of biocidal products containing an active substance, for which no relevant person is included in the list referred to in paragraph 2, may continue until 1 September 2016.

4 This Article shall not apply to active substances listed in Annex I in categories 1 to 5 and 7 or to biocidal products containing only such active substances.