Commission Delegated Regulation (EU) No 837/2013 of 25 June 2013 amending Annex III to Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the information requirements for authorisation of biocidal products (Text with EEA relevance)

COMMISSION DELEGATED REGULATION (EU) No 837/2013

of 25 June 2013

amending Annex III to Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the information requirements for authorisation of biocidal products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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[(1)], and in particular Article 85 thereof,

Whereas:

(1) Pursuant to Article 19(1) of Regulation (EU) No 528/2012 a biocidal product may be authorised if the active substances in the product have been approved in accordance with Article 9 of that Regulation.

(2) A biocidal product may be authorised even if one or more of the active substances contained therein has been manufactured in a different location or according to a different process, including from different starting materials, than those of the substance evaluated for approval pursuant to Article 9 of Regulation (EU) No 528/2012.

(3) In such cases, for the purpose of ensuring that the active substance contained in a biocidal product does not have significantly more hazardous properties than the substance which has been evaluated for the purpose of approval, it is necessary to establish technical equivalence pursuant to Article 54 of Regulation (EU) No 528/2012.

(4) It is therefore appropriate to include proof of establishment of technical equivalence in the information requirements for authorisation of biocidal products listed in Annex III to Regulation (EU) No 528/2012,

HAS ADOPTED THIS REGULATION:

Article 1

Annex III to Regulation (EU) No 528/2012 is amended as follows:

(1) In the table in title 1, the following entry 2.5 is inserted:

Changes to legislation: *There are currently no known outstanding effects for the Commission Delegated Regulation (EU) No 837/2013. (See end of Document for details)*

"2.5 Where the biocidal product contains an active substance that has been manufactured in locations or according to processes or from starting materials other than those of the active substance evaluated for the purpose of approval pursuant to Article 9 of this Regulation, evidence has to be provided that technical equivalence has been established in accordance with Article 54 of this Regulation or has been established, following an evaluation having started before 1 September 2013, by a competent authority designated in accordance with Article 26 of Directive 98/8/EC."

(2) In the table in title 2, the following entry 2.5 is inserted:

"2.5 Where the biocidal product contains an active substance that has been manufactured in locations or according to processes or from starting materials other than those of the active substance evaluated for the purpose of approval pursuant to Article 9 of this Regulation, evidence has to be provided that technical equivalence has been established in accordance with Article 54 of this Regulation or has been established, following an evaluation having started before 1 September 2013, by a competent authority designated in accordance with Article 26 of Directive 98/8/EC."

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 June 2013.

For the Commission

The President

José Manuel BARROSO