COUNCIL OF THE EUROPEAN UNION

Brussels, 4 July 2013

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ENV	**668**
MI	**608**
AGRI	**452**
CHIMIE	**81**
DELACT	**29**

COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	25 June 2013
to:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union
No Cion doc.:	C(2013) 3844 final
Subject:	Commission Delegated Regulation (EU) No .../.. of 25.6.2013 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

Delegations will find attached Commission document C(2013) 3844 final.

Encl.: C(2013) 3844 final

EUROPEAN
COMMISSION

Brussels, 25.6.2013
C(2013) 3844 final

COMMISSION DELEGATED REGULATION (EU) No …/..

of 25.6.2013

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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Annex III to Regulation (EU) No 528/2012 sets out the information required to be included in the dossier accompanying an application for the authorisation of a biocidal product.

Product authorisation requires prior approval of the active substance in the product. The approval is based on an evaluation of the active substance manufactured in a given location, from given starting materials and by a given manufacturing process (hereinafter the 'reference source'). Products containing the same active substance from 'alternative sources' are also eligible for product authorisation based on the evaluation of the reference source.

Article 54 of Regulation (EU) No 528/2012 sets out the procedure for establishing technical equivalence of substances from different sources. It is necessary to establish technical equivalence in order to guarantee that an alternative source does not have significantly more hazardous properties than the reference source. The delegated act therefore includes proof of technical equivalence as an information requirement for product authorisation.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission has consulted an expert group (the 'Biocides CA meeting') consisting of representatives of Member States' competent authorities for biocidal products, of the European Chemicals Agency, of the biocides industry and of the civil society in meetings of 19-21 September 2012 and of 12-14 December 2012. An updated draft of the delegated act was made public in advance of each of those meetings.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The delegated act amends Annex III to Regulation (EU) No 528/2012 to include proof of technical equivalence as an information requirement for product authorisation.

COMMISSION DELEGATED REGULATION (EU) No …/..

of 25.6.2013

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,

[1] OJ L 167, 27.6.2012, p. 1.

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:

"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, 25.6.2013

For the Commission
The President
José Manuel BARROSO