Note for agreement by the Coordination Group Members

This document is drafted in the interest of consistency of the implementation of Regulation (EU) No 528/2012 and with the aim of finding an agreement between Member States' Competent Authorities for biocidal products on a harmonised approach. Please note, however, it does not represent the official position of the Commission and 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: Mutual Recognition of authorisations granted by mutual recognition.

1. BACKGROUND AND PURPOSE OF THE DOCUMENT

(1) The question of whether a biocidal product authorised in accordance with Article 32 of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (the 'BPR') can be subjected to mutual recognition in accordance with Article 32 of the BPR, was raised by a Member State during the 50th meeting of the Coordination Group.

(2) Similar discussions on whether is it possible that a same biocidal product authorisation can be recognised in other Member States by mutual recognition in sequence, have taken place in the past, and specifically in the meeting of the coordination group of September 2015 (CG-13 agenda point 14(6)), in the 61st meeting of the Competent Authorities for biocidal products (agenda point 4.1), the 62nd meeting of the Competent Authorities for biocidal products (agenda point 4.2) and the 93rd meeting of the Competent Authorities for biocidal products (agenda point 4.6) .

(3) The conclusion that was reached in those discussions is that Regulation 528/2012 ('the BPR') does not contain any provision restricting mutual recognition of same biocidal products authorisations (CA-September21-Doc.4.6).

(4) The purpose of this document is to clarify whether authorisations granted in accordance with Article 32 of the BPR can be recognised in other Member States.

2. RELEVANT PROVISIONS OF REGULATION (EU) NO 528/2012 AND COMMISSION IMPLEMENTING REGULATION (EU) NO 414/2013.

The relevant provisions are listed in the Annex to this document.

3. ANALYSIS AND AGREED WAY FORWARD

(5) Article 3(1)(m) of the BPR provides the definition of national authorisations. There is no distinction in the concept of 'national authorisation' under Article 3(1)(m) as to the procedure under which the national authorisation was granted

(whether it was granted through full application of Chapter VI of the BPR or with some derogations from that Chapter). Therefore, there is no legal reason to distinguish national authorisations of biocidal products granted by mutual recognition from other national authorisations, as both fulfil the definition of 'national authorisation' under Article 3(1)(m).

(6) Article 32(1) of the BPR establishes that applications for mutual recognition of a national authorisation can be made. Since there is no distinction in the concept of 'national authorisation' under Article 3(1)(m) as to the procedure under which the national authorisation was granted, any national authorisation as defined in Article 3(1)(m) of the BPR can be recognised in other Member States.

(7) The fact that Article 33(1) of the BPR refers to "*national authorisation granted in another Member State in accordance with Article 17*" does not exclude national authorisations granted under mutual recognition. Article 17 of the BPR is a general provision on granting authorisations, which is relevant for both Chapters VI (national authorisations) and VII (mutual recognition procedures) of the BPR.

(8) Therefore, during the CG-52 meeting it was agreed by two-thirds majority of the CG members that biocidal product authorisations granted in accordance with Article 32 of Regulation (EU) No 528/2012, can be recognised in other Member States subjected to a mutual recognition procedure, as established in Article 33 of the BPR.

Annex. Relevant provisions in the BPR

BPR:

Article 3. Definitions

(1)(m)'national authorisation' means an administrative act by which the competent authority of a Member State authorises the making available on the market and the use of a biocidal product or a biocidal product family in its territory or in a part thereof;

Article 32. Authorisation through mutual recognition

(1) Applications for mutual recognition of a national authorisation shall be made in accordance with the procedures set out in Article 33 (mutual recognition in sequence) or Article 34 (mutual recognition in parallel).

Article 33. Mutual recognition in sequence

(1) Applicants wishing to seek the mutual recognition in sequence, in one or more Member States ('the Member States concerned'), of the national authorisation of a biocidal product already granted in another Member State in accordance with Article 17 ('the reference Member State') shall submit an application to each of the competent authorities of the Member States concerned containing, in each case, a translation of the national authorisation granted by the reference Member State into such official languages of the Member State concerned as it may require.