NOTE TO THE COORDINATION GROUP FOR BIOCIDES.

This document is drafted in the interest of consistency of the implementation of Regulation (EU) No 528/2012. 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: Scope issues in mutual recognition procedures.

1. BACKGROUND AND PURPOSE OF THE DOCUMENT

A scope issue recently emerged in the context of a mutual recognition procedure in parallel for the authorisation of a biocidal product.

The purpose of this note is to clarify how to proceed when disagreements occur on whether a product is a biocidal product or not in the context of mutual recognition procedures.

2. RELEVANT PROVISIONS OF THE BPR:

Article 35. Referral of objections to the coordination group:

A coordination group shall be set up to examine any question, other than matters referred to in Article 37, relating to whether a biocidal product for which an application for mutual recognition has been made in accordance with Article 33 or 34 meets the conditions for granting an authorisation laid down in Article 19.

If any of the Member States concerned considers that a biocidal product assessed by the reference Member State does not meet the conditions laid down in Article 19, it shall send a detailed explanation of the points of disagreement and the reasons for its position to the reference Member State, the other Member States concerned, the applicant, and, where applicable, to the authorisation holder. The points of disagreement shall be referred without delay to the coordination group.

PROCEDURE RESOLVING DISAGREEMENTS ON SCOPE ISSUES DURING MUTUAL RECOGINITION.

The question whether a product is a biocidal product or not is a precondition for the application of the conditions of authorisations set out in Article 19 of the BPR. If a product is not a biocidal product, it cannot be authorised as a biocidal product, and it cannot meet the conditions under Article 19.

In the context of a mutual recognition procedure, when the reference Member State (refMS) responsible for the evaluation intends to authorise the biocidal product and the Member States concerned (cMSs) consider that the biocidal product cannot be authorised because it is not a biocidal product, the question of disagreement should be resolved in accordance with Article 35 of the BPR, i.e. through a referral to the coordination group.

If the Member States fail to reach agreement within the 60-day period, the unresolved objection will be referred to the Commission under Article 36 of the BPR. The Commission would be thus bound to decide, by way of implementing act in accordance with the examination procedure, on the referred disagreement, in this case whether the product can be considered a biocidal product or not.