EUROPEAN COMMISSION
DIRECTORATE-GENERAL
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Directorate A – Green economy
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NOTE FOR GUIDANCE

This document is an attempt to provide guidance in the interest of consistency, and has been drafted by the Commission services responsible for biocidal products with the aim of finding an agreement with all or a majority of the Member States' Competent Authorities for biocidal products. Please note, however, 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: **Consideration of storage stability, stability and shelf-life data in the context of applications for product authorisation under the simplified procedure**

1.- Background and purpose of the document

(1) At CG-3 a member of the Coordination Group raised the issue of whether storage stability studies should be required within an application submitted in accordance with Article 26 of Regulation 528/2012[1] (BPR), as such a requirement is not no explicitly mentioned in Article 20(1)(b) of that Regulation.

(2) This paper addresses the consideration of stability data in the context of applications for product authorisation under the simplified procedure, as well as how this requirement can be fulfilled while maintaining the simplified spirit of the procedure.

2.- Legal and regulatory analysis

(3) Article 20 of the BPR mentions that the applicant shall submit, for biocidal products that the applicant considers meet the conditions laid down in Article 25 of that Regulation, the following documents:

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

(i) a summary of the biocidal product characteristics (SPC) as referred to in point (a)(ii) of this paragraph;

(ii) efficacy data; and

(iii) any other relevant information in support of the conclusion that the biocidal product meets the conditions laid down in Article 25.

(4) Hence, the application shall contain an SPC including the information referred to in points (a), (b) and (e) to (q) of Article 22(2) of the BPR. As item (p) is included therein, the SPC shall contain the conditions of storage and shelf-life of the biocidal product under normal conditions of storage.

(5) In addition, the application shall contain efficacy data to demonstrate that the product is sufficiently effective according to the criteria laid down in Annex VI to the BPR. It is widely recognised and assumed that degradation of the active content during storage can adversely affect the efficacy and risk assessment of the product[2]. Consequently, this may require an assessment of the degradation on the efficacy assessment.

3.- Conclusion and suggested way forward

(6) The Commission services consider that data on storage stability, stability and shelf-life as requested in point 3.4 of Annex III to BPR shall also be included in applications for product authorisation submitted through the simplified authorisation procedure, as the conditions of storage, the stability and shelf-life of the product directly affect the efficacy of the product.

(7) The above conclusion can be adapted on a case by case basis in order to meet the aim of the simplified procedure, provided that sufficient data is submitted to demonstrate the stability of the biocidal product and to justify the proposed shelf-life. Among others, the following approaches could be considered by the evaluating competent authority:

(a) Where relevant, for some of the substances in Annex I to BPR, such a requirement might be waived (e.g. ready to use carbon dioxide).

(b) Stability data could be waived where the applicant demonstrates that the product is efficacious by the end of the proposed shelf-life (i.e. data from efficacy tests using aged/stored product[3]).

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[2] See Guidance on information requirements. Section 3.4. Storage stability, stability and shelf-life.

[3] This could be the best option for bait-based products, as even if the active substance is still present in the product by the end of the proposed shelf-life, bait palatability is relevant to efficacy and needs to be evaluated through studies on aged product.