EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE GENERAL
Safety of the food chain
Pesticides and Biocides

CA-Dec13-Doc.11.3 – Final.rev1
(updated as per CA-March16-Doc.4.5)

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 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: **Interpretation of the provisions of Article 2(5)(a) of Regulation (EU) No 528/2012**

1.- Background and purpose of the document:

(1) Document CA-May13-Doc.5.3 was endorsed at the 51st CA meeting and included a Q&A on the interpretation of Article 2(5)(a) of Regulation (EU) No 528/2012 (BPR hereinafter). Since then, the Commission services have further discussed with Member States (MSs) and stakeholders the implications of such an interpretation and suggested to MSs a new proposal for that Q&A[1].

(2) At the 53rd CA meeting, a few MSs indicated serious concerns on the Commission's proposal not only in terms of the lack of proof of efficacy for the products that would potentially be covered by the derogation, but also in terms of their safety. Those MSs pointed out that even if the separate ingredients have been evaluated for their safety under the food or feed legislation, this is not the case for the final product. They pointed out that such products could contain concentrations of ingredients much higher than those authorised for the use in the food or feed area (e.g. food or feed additives with maximum incorporation rates). In addition, the exposure scenarios assessed under the food or feed legislation are linked to specific uses, without any information on other patterns of use (e.g. prolonged skin contact, etc…).

[1] Document CA-Sep13-Doc.11.3.rev1

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(3) Those MSs also underlined that the current wording of Article 2(5)(a) of the BPR should only be interpreted as a derogation regarding the use of food or feed, placed on the market as such, as repellents or attractants. Hence, according to those MSs the derogation should not be seen as a provision allowing the making available on the market of ready to use products with a repellent or attractant claim. The Commission services committed to further reflect on these concerns and, where appropriate, present a new proposal to MSs.

(4) This document provides an interpretation of Article 2(5)(a) of the BPR with a view to clarify the regulatory status of food or feed used as repellents or attractants. This document replaces the abovementioned Q&A in Document CA-May13-Doc.5.3, which will be amended accordingly.

2.- Interpreting Article 2(5)(a):

(5) Article 1(2)(d) of the BPR mentions that the BPR lays down rules for the making available on the market and the use of biocidal products.

(6) With regard to the exception set by Article 2(5)(a), the BPR states that "*This Regulation shall not apply to food and feed...*", so it cannot be read as "*This Regulation shall not apply to biocidal products consisting of food or feed...*". In the first case, the point of departure is not a biocidal product but food or feed; in the second it would be a biocidal product. Article 2(5)(a) continues with "*... used as repellents or attractants*", so not covering the option of making available on the market as repellents or attractants.

(7) Consequently, the derogation from the BPR scope unambiguously targets the use of food or feed. This intention of the co-legislator can be justified from a twofold perspective. First, as one the main principles of the BPR is that only authorised biocidal products can be used, the derogation aims to ensure that if a user decides to use food or feed to attract or repel an unwanted organism, this does not constitute an illegal use of a biocidal product. Second, as explicitly mentioned by Recital 21 of the BPR, as the safety of food and feed is subject to Union legislation, in particular Regulation (EC) No 178/2002 (the Food Law), the use of food or feed as repellents or attractants is not expected to pose any significant risk for final users.

(8) However, from the principles set by the Food Law, the use of food or feed as repellents or attractants can only be considered as safe if such use:

a. does not deviate from the normal conditions of use of the food or feed, and

b. is made according to the information provided to the user, including information on the label, or other information generally available to the user concerning the avoidance of specific adverse health effects from a particular category of food or feed.

(9) In the light of the above arguments, the Commission services consider that only food or feed being placed on the market in compliance with EU food or feed legislation (e.g. manufacturing, marketing and labelling requirements) can be used with a repellent or attractant purpose, and that this use falls outside the scope of the BPR.

(10) Conversely, any making available on the market of a product in the form in which it is supplied to the user with a repellent or attractant claim, whether such a product only consists of food or feed or contains other active substance(s) or co-formulant(s), falls within the scope of the BPR[2]. The Commission services consider that repellents or attractants made available on the market with a biocidal claim can have a pattern of use leading to an exposure of the final user which is not compatible with the use in the food or feed area (e.g. bracelets or formulations applied on the human or animal skin; products containing concentrations above the authorised limits in food or feed, etc…). Therefore, those products cannot be considered as safe according to the EU food or feed legislation in order to benefit from the derogation.

(11) Taking however into account the characteristics of such products, they might be eligible for the simplified authorisation procedure according to Article 25 of the BPR, provided that the active substance(s) responsible of the repellent or attractant properties is/are included in Annex I to BPR and the required eligibility conditions are met.

(12) Concerning existing products placed on the market and containing active substances benefiting from the food and feed derogation of Article 6 of Regulation 1451/2007, the draft Commission delegated Regulation on the work programme for examination of all existing active substances foreseen by Regulation (EU) No 528/2012 provides a specific transitional measure. This measure is intended to allow the active substances having benefited from this derogation to be re-instated in the review programme in view of their approval or inclusion in Annex I to BPR. Meanwhile, existing products containing these active substances would benefit of the transitional measures laid down in Article 89 of the BPR.

[2] Provided that the product also meets the definition of "substance" or "mixture" under REACH, as referred to in Article 3(1)(a) of the BPR. Otherwise, the product simply falls out of the scope of the BPR.