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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Director

Brussels,
SANTE/E4

Dear

Subject: Your e-mail of 28/11/2017 concerning the approval process of cholecalciferol under the BPR

Thank you for your e-mail dated 28 November 2017 addressed to Ms Nathalie Chaze, who asked me to respond on her behalf.

In this e-mail, you express your concerns about the approval process of cholecalciferol (vitamin D3) under the Regulation (EU) No 528/2012 (the Biocidal Products Regulation - BPR). You indicate that cholecalciferol is one of the main forms of vitamin D, has been the first innovation in the rodenticides sector in decades, and can represent an alternative to anticoagulant rodenticides which are substances of very high concern meeting the exclusion criteria under the BPR. You are in particular concerned that the consumer market, which would represent an important market of the future total business on this substance, would be lost in case cholecalciferol were to be identified as an endocrine disruptor under the scientific criteria set pursuant to Commission Delegated Regulation (EU) 2017/2100. You consider this at odds with the fact that the same substance may be used freely in the human and animal food chain and may have better toxicological and environmental profiles compared to other rodenticides. Finally, you request that cholecalciferol should not be identified as an endocrine disruptor for regulatory purposes.

Let me recall first that cholecalciferol had been identified as an existing active substance placed on the EU market before 14 May 2000 but, subsequently, has not been supported in the review programme which was set up in 2003 and has consequently been banned from the EU market in 2006. However, an application has been submitted in the past years to seek its approval for rodenticide use, which is in principle to be welcomed, considering that the available anticoagulant rodenticides need to be substituted. As you know, the evaluation process for an active substance includes the evaluation of endocrine disrupting properties now based on the new scientific criteria set under Regulation (EU) 2017/2100.

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I would like to underline that it is the responsibility of the evaluating Competent Authority (in the case of cholecalciferol thus Sweden) and ECHA's Biocidal Product Committee to conclude on the status of cholecalciferol in relation to the scientific ED criteria[1], which they did during the meeting of the Biocidal Product Committee on 13 December 2017. Similarly to any other hazard property, and in particular the other exclusion criteria directly depending on classification (Carcinogenicity, Mutagenicity, and Reprotoxicity) and other environmental criteria (PBT/vPvB), technical experts must assess active substances on their own merits and hazard properties. They are not supposed to take into consideration the regulatory consequences when reaching their technical conclusions whether an active substance can be considered to have ED properties. The Council and the European Parliament decided the regulatory consequences of the identification of an active substance as having ED properties when they adopted the BPR. In any case, Article 3 of Regulation (EU) No 2017/2100 foresees that that an assessment of the experiences gained from the application of the scientific ED criteria is to be conducted at the latest by 7 June 2025. The experience of the implementation of the BPR will also be assessed in the coming years.

If cholecalciferol were to be identified as an endocrine disruptor, it would meet the exclusion criterion set out under Article 5(1)(d) of the BPR, and should normally not be approved. However, possibilities to derogate from the general ban of such substances are also foreseen under certain conditions, as set out in Article 5(2) of the BPR. For instance, approval of such substances is still possible when it can be shown by evidence that the active substance is essential to prevent or control a serious danger to human health, animal health, or the environment, or that a ban would have disproportionate negative impacts for the EU society when compared to the risks linked to the use of the products, in absence of suitable alternatives. In case cholecalciferol is eventually approved, Article 19(4) of the BPR establishes that biocidal products and having endocrine disrupting properties shall not be authorised for use by the general public. Please note that discussions on how to determine precisely whether a biocidal product can be considered to have endocrine disrupting properties are currently ongoing in the meetings of the Competent Authorities on Biocidal Products[2]. The BPR does not provide an exemption for the use of a biocidal product by the general public containing an active substance that is allowed to be used by the general public under other EU rules but generally pursue a safe and sustainable use of biocidal products by limiting exposure of humans, animals and the environment to active substances having properties of very high concern. In this context, please note that the opinion of the Biocidal Products Committee on cholecalciferol has identified unacceptable risks for primary and secondary poisoning for mammals and birds arising from the use of biocidal products containing the substance. Thus, it would in any case be justified to consider whether restricting the use to professional users could ensure that cholecalciferol is handled with great caution and all appropriate and available risk mitigation measures are applied to ensure that exposure is minimised.

Yours sincerely,

Sabine Jülicher

[1] Commission Delegated Regulation (EU) 2017/2100

[2] CA-July17-Doc.7.5c- EDs- biocidal products.docx

Electronically signed on 20/12/2017 15:51 (UTC+01) in accordance with article 4 2 (Validity of electronic documents) of Commission Decision 2004/563