Commission Implementing Regulation (EU) 2019/637 of 23 April 2019 approving cholecalciferol as an active substance for use in biocidal products of product-type 14 (Text with EEA relevance)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products[(1)], and in particular Article 9(1)(a) thereof,

Whereas:

(1) The evaluating competent authority of Sweden received on 19 April 2013 an application, in accordance with Article 11(1) of Directive 98/8/EC of the European Parliament and of the Council[(2)], for the inclusion of the active substance cholecalciferol in Annex I to that Directive for use in biocidal products of product-type 14, rodenticides, as described in Annex V to Directive 98/8/EC, which corresponds to product-type 14 as described in Annex V to Regulation (EU) No 528/2012.

(2) On 15 April 2016, the evaluating competent authority of Sweden submitted, in accordance with Article 8(1) of Regulation (EU) No 528/2012, the assessment report together with its recommendations to the European Chemicals Agency ('the Agency').

(3) The opinion of the Agency[(3)] was adopted on 13 December 2017 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(4) According to that opinion, cholecalciferol is a pro-hormone and therefore meets the criteria laid down in Commission Delegated Regulation (EU) 2017/2100[(4)] to be considered as having endocrine-disrupting properties that may cause adverse effects in humans. Cholecalciferol therefore meets the exclusion criterion set in Article 5(1)(d) of Regulation (EU) No 528/2012.

(5) In addition, according to that opinion, the use of products containing cholecalciferol raises concerns of primary and secondary poisoning, even when restrictive risk management measures are applied and therefore cholecalciferol also satisfies the criterion to be considered a candidate for substitution in accordance with Article 10(1)(e) of Regulation (EU) No 528/2012.

(6) Pursuant to Article 5(2) of Regulation (EU) No 528/2012, an active substance meeting an exclusion criterion may only be approved if it is shown that at least one of the conditions for derogation set out in that Article is met.

(7) In accordance with Article 10(3) of Regulation (EU) No 528/2012, the Agency organised a public consultation between 17 July 2017 and 15 September 2017 in order to collect relevant information, including information on available substitutes[(5)].

(8) The Commission also carried out a specific public consultation between 7 February 2018 and 7 April 2018 in order to gather information as to whether the conditions for derogation set out in Article 5(2) of Regulation (EU) No 528/2012 were satisfied. The Commission made the contributions received during that consultation publicly available[(6)].

(9) The information obtained as a result of the two above-mentioned public consultations, the experience gained in authorising rodenticide products and the renewal of approval of anticoagulant active substances used in rodenticides, and the information on the availability of alternatives to anticoagulant rodenticides included in Annex 1 to the Commission final report on risk mitigation measures for anticoagulant rodenticides as biocidal products[(7)], were discussed with Member States in the Standing Committee on Biocidal Products.

(10) Rodents can carry pathogens that are responsible for many zoonoses, which can pose serious dangers for human or animal health. Anticoagulant active substances, which are the main active substances used in rodenticides for now, also meet the exclusion criteria laid down in Article 5(1) of Regulation (EU) No 528/2012 as they are classified as toxic for reproduction category 1B and most of them are persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) substances. Other alternative active substances currently approved for product-type 14 and not subject to exclusion, namely carbon dioxide, alphachloralose, aluminium phosphide, hydrogen cyanide and powdered corn cob, have constraints inherent in their nature and restricted conditions of use. Non-chemical control or prevention methods for rodents, such as mechanical, electrical or glue traps, may not be sufficiently efficient and may raise further questions as to whether they are humane and whether they cause unnecessary suffering to rodents.

(11) The approval of cholecalciferol would bring an additional active substance on the market and would be useful to manage the increasing development of resistance of rodents to anticoagulant active substances, as cholecalciferol acts in a completely different way compared to the anticoagulants. The availability of cholecalciferol may also reduce the use of anticoagulant active substances and in particular of the most potent second-generation thereof. Thus, cholecalciferol can play a role in the future to ensure satisfactory control of rodent populations within an integrated pest management approach, in support of the above-mentioned alternatives not subject to the exclusion criteria, and possibly reducing the recourse to anticoagulant active substances in rodenticides.

(12) Furthermore, insufficient rodent control may cause not only significant negative impacts on human or animal health or the environment, but also affect the public's perception of its safety with regard to exposure to rodents or the security of a number of economic activities that could be vulnerable to rodents, entailing economic and social consequences. Despite its endocrine disrupting properties, cholecalciferol may be considered to have overall better toxicological and ecotoxicological profiles compared to anticoagulant active substances as it is neither classified as toxic for reproduction category 1B, nor a PBT or vPvB. Cholecalciferol is Vitamin D3, which — at the right dose — is an essential element for human life, and is expected to present lower risks to humans compared to anticoagulant active substances when used as a rodenticide. The risks to human health, animal health or the environment arising from use of products containing cholecalciferol can be mitigated if certain specifications and conditions are respected. As already explained, cholecalciferol can play a role in the future to contribute to a satisfactory control of rodent populations within an integrated pest management approach, in support of the above-mentioned alternatives not subject to the exclusion criteria, and possibly reducing the recourse to anticoagulant rodenticides which present higher overall concerns. In this context, not approving that active substance would deprive users of a tool for rodent control which could bring added value and which is at least as suitable as many other alternative substances used. Therefore, the non-approval of cholecalciferol as an active substance would have a disproportionate negative impact on society in comparison to the risks arising from the use of the substance. The condition set out in Article 5(2)(c) is thus satisfied.

(13) It is therefore appropriate to approve cholecalciferol for use in biocidal products of product-type 14, subject to compliance with certain specifications and conditions.

(14) As cholecalciferol meets exclusion criterion laid down in Article 5(1)(d) of Regulation (EU) No 528/2012, the approval should be for a period not exceeding five years as set out in the second sentence of Article 4(1) of that Regulation.

(15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

Cholecalciferol is approved as an active substance for use in biocidal products of product-type 14, subject to the specifications and conditions set out in the Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 23 April 2019.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/637. (See end of Document for details)*

ANNEX

Common Name	IUPAC NameIdentification Numbers	Minimum degree of purity of the active substance[a]	Date of approval	Expiry date of approval	Product type	Specific conditions
Cholecalciferol	IUPAC Name: (3β,5Z,7E)-9,10-secocholesta-5,7,10(19)-trien-3-ol EC No: 200-673-2 CAS No: 67-97-0	970 g/kg	1 July 2019	30 June 2024	14	Cholecalciferol is considered a candidate for substitution in accordance with points (a) and (e) of Article 10(1) of Regulation (EU) No 528/2012. The authorisations of biocidal products are subject to the following general conditions: (1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any

a The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.