EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B. Quality, Research & Innovation, Outreach

Brussels
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I would like to thank you for your email of 19 August 2021 (Ares (2021)5187265) following up on our reply with reference Ares (2021)1730391 regarding the authorized practices to fight *Varroa destructor* in organic beekeeping.

In your email, you refer to Article 25 (6) of Commission Regulation (EC) No 889/2008[1] stating that "*formic acid, lactic acid, acetic acid and oxalic acid as well as menthol, thymol, eucalyptol or camphor may be used in cases of infestation with Varroa destructor*" and you ask "*whether is it authorised to use the products based on the pharmacologically active substances mentioned above, which are not registered as a veterinary medicinal products according to Article 1 of Directive 2001/82/EC, and described on the label by a manufacturer (to circumvent the regulations) as a hygenizing, disinfecting, balancing the smell, etc. product (e.g. glycerine strips with oxalic acid) in bee colonies? Once it has been determined in the opinion that these substances have a therapeutic effect in bee colonies, can they be used in these colonies for a different purpose then therapeutic?*"

I would like to start by recalling that the rules related to organic production laid down in Regulation (EC) No 834/2007[2] on organic production and the labelling of organic products and Regulation (EC) No 889/2008 apply without prejudice to other Union provisions or national provisions in conformity with Union law concerning in particular live animals and food like bees and honey, such as provisions governing the production, preparation marketing, labelling and control, including legislation on foodstuffs and animal nutrition.

These include the rules laid down, respectively, in Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products[3] and in Regulation (EU) No 528/2012 of the European Parliament and of the

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R0889-20210101&qid=1629809662271&from=EN

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02007R0834-20130701&qid=1629809592018&from=EN

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02001L0082-20090807&qid=1629809292296&from=EN

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Council concerning the making available on the market and use of biocidal product[4], as well as the national provisions adopted in conformity with these acts apply in organic production.

Article 2 (2) of the Regulation (EU) No 528/2012 on biocidal products states the following: "*Subject to any explicit provision to the contrary in this Regulation or other Union legislation, this Regulation shall not apply to biocidal products or treated articles that are within the scope of the following instruments:*

(c) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency".

Notwithstanding the first subparagraph, when a biocidal product falls within the scope of one of the abovementioned instruments and is intended to be used for purposes not covered by those instruments, this Regulation shall also apply to that biocidal product insofar as those purposes are not addressed by those instruments."

In practice, there may be cases where the substances listed in Article 25 (6) may be used for another purpose than a veterinary treatment such as a biocidal product. The purpose of the use of the substances has to be assessed on a case-by-case basis depending in particular on the purpose for which the product containing the substances was marketed and authorized , if required, under the relevant national rules.

Please note, as mentioned in our previous correspondence, that, from 1 January 2022, Regulation (EU) 2018/848 on organic production[5] will apply and that, from 28 January 2022, Regulation (EU) 2019/6 on veterinary medicinal products[6] will apply.

Please note also that, under Article 14 of Regulation (EU) 2018/848 on organic production, the Commission has the empowerment to adopt delegated acts amending points 1.9.6.3 (b) and (e) of Part II of Annex II as regards the acceptable treatments for the disinfection of apiaries and the methods and treatments to fight against *Varroa destructor*. Consequently, the Commission has the possibility to clarify the abovementioned rules if deemed necessary by the Member States or the sector. At the same time in line with Article 3(2) of Regulation 2019/6 in case of borderline products, the Commission would decide by means of implementing acts whether a specific product or group of products is to be considered as a veterinary medicinal product.

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[4] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02012R0528-20210610&qid=1629809727220&from=EN

[5] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02018R0848-20201114&qid=1629809471582&from=EN

[6] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0006&qid=1629809390443&from=EN

The present opinion is provided on the basis of the facts as set out in your email of 19 August 2021 and expresses the view of the Commission services and does not commit the European Commission. In the event of a dispute involving Union law it is, under the Treaty on the Functioning of the European Union, ultimately for the European Court of Justice to provide a definitive interpretation of the applicable Union law.

Yours faithfully,