



The Danish Beekeepers Association

FUTURE OPTIONS FOR VARROA CONTROL

Danish beekeepers have a long tradition of varroa control using organic acids in pure form following the regulation for organic beekeeping. This practice has been developed over 30 years and introduced to all beekeepers. The experience shows that this practice works well for beekeepers and bees. Beekeepers in several European countries seem to prefer a practice where organic acids can be used in pure form.

With reference to dialog with DG Sante and Regulation 2019/6 new veterinary regulation (NVR), the Danish Food Authorities has announced that all treatment of varroa in the future must only be carried out with registered veterinary medicines (appendix 1)

The challenges of the new regulation are:

- There may be a shift towards more use of synthetic pesticides in beekeeping.
- Varroa control is complicated as multiple treatments are needed over the season and each treatment must be adapted to the specific beekeeper management and the environmental conditions at the time of treatment. Experience says that we need a varroa strategy, not just individual treatments.
- Only very few products based on organic acids are registered and cannot stand alone.
- Several products have not been tested in Denmark. Furthermore, the instructions are not adapted to Danish conditions and beehives.

Even with the ideal varroa strategy, beekeepers lose colonies every year due to Varroa problems. If treatment options are reduced, increased colony losses must be expected. On this background we strongly recommend that the possibilities for continued use of organic acids in pure form in beekeeping should be investigated.

The following conditions must be noted:

- Not all transmissible animal diseases can or should be prevented and controlled through regulatory measures, for example if the disease is too widespread, if diagnostic tools are not available, or if the private sector can take measures to control the disease by itself (appendix 2)
- The ecology regulation states that varroa control with organic acids is only healthcare. If treated with chemically produced allopathic products, the conversion period of 12 months applies (appendix 3)

We kindly request to WP-honey to:

- a) sharing information about the practice (implementation of the EU regulation) of availability and use of organic varrocidicides in other member states
- b) support for changing the interpretation or scope of the legislation in place.

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Appendix 1:

Fra: SANTE-VETERINARY-MEDICINES@ec.europa.eu <SANTE-VETERINARY-MEDICINES@ec.europa.eu>

Sendt: 5. oktober 2023 16:27

Til: Anne Rath Petersen <ARP@fvst.dk>

Cc: Christian Strøyer <CHSTKO@fvst.dk>; AGRI-B4@ec.europa.eu; SANTE-VETERINARY-MEDICINES@ec.europa.eu

Emne: RE: VMP - treatment of Varroa destructor in honey bees

Dear Dr Rath Petersen,

We are sorry for the delay in replying to your question.

A substance presented as having properties for treating a disease, like varroosis, would meet the definition of '*veterinary medicinal product*' laid down in Article 4 of Regulation (EU) 2019/6.

Regulation (EU) 2019/6 aims at ensuring a high level of public and animal health and environmental protection. That Regulation stipulates that veterinary medicinal products within its scope can be placed on the market only after a marketing authorisation has been granted. Once a marketing authorisation has been granted, the veterinary medicinal products are also subject to pharmacovigilance.

In the case of food-producing species such as honeybees, the pharmacologically active substances included in the medicinal products used need to be allowed in accordance with Regulation (EC) No 470/2009 and any acts adopted on its basis. A withdrawal period is attached to the use of medicinal products in food-producing animals as relevant.

There are veterinary medicinal products authorised within the EU with the indication of treatment of *Varroa destructor* infestations in honeybees and containing, either alone or in combination, active substances referred to in Annex II, Part II, point 1.9.6.3 of Regulation (EU) 2018/848 on organic production and labelling of organic products. Those veterinary medicinal products are to be dispensed in accordance with their classification in accordance with Article 34 and used in accordance with Article 106(1) of Regulation (EU) 2019/6.

Only where there are no veterinary medicinal products authorised for the treatment of varroosis or those authorised are not available in a Member State, consideration can be given to use outside the terms of the marketing authorisation in accordance with Article 113.

We would like to draw your attention to the established principle that derogations from the Union law governing medicinal products should be interpreted strictly.

Best regards,

SANTE VETERINARY MEDICINES



European Commission

Health and Food Safety Directorate General

Veterinary Medicines

Disclaimer:

*DG SANTE's Unit D4 is not in charge of the legal framework setting rules for organic farming.**The views expressed above are not legally binding, since only the Court of Justice of the European Union can give an authoritative interpretation of EU law.***From:** Anne Rath Petersen <ARP@fvst.dk>**Sent:** Wednesday, June 28, 2023 8:44 AM**To:** SANTE VETERINARY MEDICINES <SANTE-VETERINARY-MEDICINES@ec.europa.eu>**Cc:** ZAMORA ESCRIBANO Eva Maria (SANTE) <Eva-Maria.Zamora-Escribano@ec.europa.eu>;
Christian Strøyer <CHSTKO@fvst.dk>**Subject:** VMP - treatment of Varroa destructor in honey bees

Dear colleagues,

We hope for your assistance to clarify the following:

According to Annex II, Part II, 1.9.6.3, of Regulation 2018/848 on organic production and labelling of organic products 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 in bees.

Would it be in accordance with the VMP Regulation to use the above mentioned substances, which have not been authorised as VMPs, to treat varroa infestation in organic as well as conventional beekeeping?

Kind regards,

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Appendix 2:

REGULATION (EU) 2016/429 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')

(26) Not all transmissible animal diseases can or should be prevented and controlled through regulatory measures, for example if the disease is too widespread, if diagnostic tools are not available, or if the private sector can take measures to control the disease by itself. Regulatory measures to prevent and control transmissible animal diseases may have important economic consequences for the relevant sectors and may disrupt trade. It is therefore essential that such measures are applied only when they are proportionate and necessary, such as when a disease presents, or is suspected to present, a significant risk to animal or public health.

PART III DISEASE AWARENESS, PREPAREDNESS AND CONTROL

CHAPTER 2 The use of veterinary medicinal products for disease prevention and control

Article 46 The use of veterinary medicinal products for disease prevention and control

1. The Member States may take measures concerning the use of veterinary medicinal products for listed diseases, to ensure the most efficient prevention or control of those diseases, provided that such measures are appropriate or necessary. L 84/54 EN Official Journal of the European Union 31.3.2016 Those measures may cover the following:

- (a) prohibitions and restrictions on the use of veterinary medicinal products;
- (b) the compulsory use of veterinary medicinal products.

2. Member States shall take the following criteria into consideration when determining whether or not to use, and how to use, veterinary medicinal products as prevention and control measures for a specific listed disease:

- (a) the disease profile;
- (b) the distribution of the listed disease in:
 - (i) the Member State concerned;
 - (ii) the Union;
 - (iii) where relevant, neighbouring third countries and territories;
 - (iv) third countries and territories from which animals and products are brought into the Union;
- (c) the availability and effectiveness of the veterinary medicinal products in question, and the risks attaching to them;
- (d) the availability of diagnostic tests for detecting infections in animals treated with the veterinary medicinal products concerned;
- (e) the economic, social, animal welfare and environmental impact of the use of the veterinary medicinal products concerned compared to other available disease prevention and control strategies.

3. Member States shall take appropriate preventive measures concerning the use of veterinary medicinal products for scientific studies or for the purposes of developing and testing them under controlled conditions to protect animal and public health.

Appendix 3:

REGULATION (EU) 2018/848 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007

Part II: Livestock production rules

1.9.6. For bees

1.9.6.3. Health care

With regard to health care, the following rules shall apply:

- (a) for the purposes of protecting frames, hives and combs, in particular from pests, only rodenticides used in traps, and appropriate products and substances authorised pursuant to Articles 9 and 24 for use in organic production shall be permitted;
- (b) physical treatments for disinfection of apiaries such as steam or direct flame shall be permitted;
- (c) the practice of destroying the male brood shall only be permitted for the purpose of isolating the infestation of Varroa destructor;
- (d) if, despite all preventive measures, the colonies become sick or infested, they shall be treated immediately and, if necessary, may be placed in isolation apiaries;
- (e) 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;
- (f) if a treatment is applied with chemically synthesised allopathic products, including antibiotics, other than products and substances authorised pursuant to Articles 9 and 24 for use in organic production, for the duration of that treatment, the treated colonies shall be placed in isolation apiaries and all the wax shall be replaced with wax coming from organic beekeeping. Subsequently, the conversion period of 12 months laid down in point 1.2.2 shall apply to those colonies