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(Information)

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EUROPEAN COMMISSION

Commission Notice

on withdrawal periods in case of veterinary treatments of organic terrestrial livestock with veterinary medicinal products

(2022/C 126/01)

RIPAC ([1]) **NOTE N° 2022-XX**

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SECTOR:	ORGANIC FARMING
MEASURE:	VETERINARY TREATMENTS for LIVESTOCK
SUBJECT:	WITHDRAWAL PERIODS - VETERINARY MEDICINAL PRODUCTS
PROVISIONS CONCERNED:	Regulation (EU) 2018/848 ([2]) - Annex II Part II points 1.5.1.2, 1.5.1.3, 1.5.2.5 and Regulation (EU) 2019/6 ([3]) – Articles 4, point (34), 106, 113 and 115

Question 1: Should 'vaccines' be considered 'chemically synthetised veterinary medicinal products' as referred to in point 1.5.2.5 of Part II of Annex II to Regulation (EU) 2018/848?

Regulation (EU) 2018/848 applies from 1 January 2022, as established in Article 61 thereof.

([1]) RIPAC (named after its French acronym Registre d' Interprétation de la Politique Agricole Commune) is a register and database of interpretative notes on agricultural law.

([2]) 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 (OJ L 150, 14.6.2018, p. 1).

([3]) Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

Part II of Annex II to Regulation (EU) 2018/848 sets livestock production rules.

Point 1.5.2.5 of Part II of Annex II to Regulation (EU) 2018/848 states that 'the withdrawal period between the last administration to an animal of a chemically synthetised allopathic veterinary medicinal product, including of an antibiotic, under normal conditions of use, and the production of organically produced foodstuffs from that animal shall be twice the withdrawal period referred to in Article 11 of Directive 2001/82/EC ([4]), and shall be at least 48 hours.'

Points 1.5.1.2 and 1.5.1.3 of Part II of Annex II to Regulation (EU) 2018/848 state respectively the following in relation to disease prevention for livestock: 'immunological veterinary medicinal products may be used', and 'chemically synthetised allopathic veterinary medicinal products , including antibiotics and boluses of synthetised allopathic molecules, shall not be used for preventive treatments'. This establishes an implicit distinction between immunological veterinary medicinal products and chemically synthetised allopathic veterinary medicinal products.

Vaccines are immunological veterinary medicinal products and point 1.5.2.5 of Part II of Annex II to Regulation (EU) 2018/848 is not relevant for their use.

Question 2: **When an organic terrestrial food-producing species of animal is treated with a veterinary medicinal product used in accordance with the terms of the marketing authorisation for that species, which withdrawal period should be applied between the last administration of a chemically synthetised allopathic veterinary medicinal product, including of an antibiotic, under normal conditions of use, and the production of organically produced foodstuffs from that animal?**

Answer:

Regulation (EU) 2018/848 applies from 1 January 2022, as established in Article 61 thereof. Recital (43) of Regulation (EU) 2018/848, describes the intention of the legislator regarding the withdrawal period for animals and states that 'animal health management should mainly be based on the prevention of disease. […] The preventive use of chemically synthetised allopathic medicinal products, including antibiotics, should not be permitted in organic production. In the event of sickness or injury of an animal requiring immediate treatment, the use of such products should be limited to the minimum necessary to re-establish the well-being of the animal. In such cases, in order to guarantee the integrity of organic production for consumers, the official withdrawal period after use of such medicinal products as specified in the relevant Union legislation should be double the normal withdrawal period and have a minimum duration of 48 hours.'

Part II of Annex II to Regulation (EU) 2018/848 sets livestock production rules; livestock production is defined in Article 3, point (27), as meaning the production of domestic or domesticated terrestrial animals, including insects.

Point 1.5.2.5 of Part II of Annex II to Regulation (EU) 2018/848 applies. This provision states that 'the withdrawal period between the last administration to an animal of a chemically synthetised allopathic veterinary medicinal product, including of an antibiotic, under normal conditions of use, and the production of organically produced foodstuffs from that animal shall be twice the withdrawal period referred to in Article 11 of Directive 2001/82/EC ([5]), and shall be at least 48 hours.'

The cross-reference to Article 11 of Directive 2001/82/EC in Regulation (EU) 2018/848 refers in particular to the second indent of paragraph 2 of that article, which states that '[...] **unless the medicinal product used indicates a withdrawal period for the species concerned**, the specified withdrawal period shall not be less than: — 7 days for eggs, — 7 days for milk, — 28 days for meat from poultry and mammals including fat and offal' and should be interpreted as a reference to withdrawal periods of veterinary medicinal products used within or outside the terms of the marketing authorisation.

([4]) 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 (OJ L 311, 28.11.2001, p. 1 which will be repealed by Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 4).

([5]) 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 (OJ L 311, 28.11.2001, p. 1 which will be repealed by Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 4).

Hence, when an organic terrestrial food-producing species of animal is treated with a veterinary medicinal product used in accordance with the terms of the marketing authorisation for that species, the withdrawal period that applies to the production of organically produced foodstuffs from that animal is twice the withdrawal period set for that species of terrestrial food producing animal in the summary of the characteristics of the marketing authorisation of such a veterinary medicinal product and at least 48 hours.

In the particular case where the withdrawal period for a species of terrestrial food-producing animal laid down in the summary of the characteristics of the marketing authorisation of a veterinary medicinal product is zero days, it should be 48 hours in organic production.

From 28 January 2022, Regulation (EU) 2019/6 on veterinary medicinal products and repealing Directive 2001/82/EC will apply in combination with the specific provisions related to organic production of Regulation (EU) 2018/848 and the situation will remain the same as described above.

Question 3: When an organic terrestrial food-producing animal belonging to a certain species is treated with a veterinary medicinal product used outside the terms of the marketing authorisation for that species, which withdrawal period should be applied between the last administration of a chemically synthetised allopathic veterinary medicinal product, including of an antibiotic, under normal conditions of use, and the production of organically produced foodstuffs from that animal?

In case an organic terrestrial food-producing animal belonging to a certain species is treated with a veterinary medicinal product used outside the terms of the marketing authorisation for that species, between 1 January 2022 and 27 January 2022, the specified withdrawal period **shall not be less than**: — 14 days for eggs, — 14 days for milk, — 56 days for meat from poultry and mammals including fat and offal, which correspond to not less than twice the withdrawal periods set for conventional food producing animal species in Article 11 of Directive 2001/82/EC.

From 28 January 2022, Regulation (EU) 2019/6 on veterinary medicinal products and repealing Directive 2001/82/EC will apply in combination with the specific provisions related to organic production of Regulation (EU) 2018/848.

Articles 113 and 115 of Regulation (EU) 2019/6 set respectively the rules applying for the use of medicinal products outside the terms of the marketing authorisation in food-producing terrestrial animal species, and for the withdrawal period for medicinal products used outside the terms of the marketing authorisation in food producing animal species.

In particular, Article 115 states that:

'**unless a medicinal product used has a withdrawal period provided in its summary of the product characteristics for the animal species in question**, a withdrawal period shall be set by the veterinarian in accordance with the following criteria:

(a) for meat and offal from food-producing mammals and poultry and farmed game birds the withdrawal period shall not be less than:

  (i) the longest withdrawal period provided in its summary of the product characteristics for meat and offal multiplied by factor 1,5;

  (ii) 28 days if the medicinal product is not authorised for food-producing animals;

  (iii) one day, if the medicinal product has a zero withdrawal period and is used in a different taxonomic family than the target species authorised;

(b) for milk from animals producing milk for human consumption the withdrawal period shall not be less than:

  (i) the longest withdrawal period for milk provided in the summary of the product characteristics for any animal species multiplied by factor 1,5;

(ii) seven days, if the medicinal product is not authorised for animals producing milk for human consumption;

(iii) one day, if the medicinal product has a zero withdrawal period;

(c) for eggs from animals producing eggs for human consumption the withdrawal period shall not be less than:

(i) the longest withdrawal period for eggs provided in the summary of the product characteristics for any animal species multiplied by factor 1,5;

(ii) 10 days, if the product is not authorised for animals producing eggs for human consumption;

2. If the calculation of the withdrawal period according to points (a)(i), (b)(i), (c)(i), (d)(i) and (ii) of paragraph 1 results in a fraction of days, the withdrawal period shall be rounded up to the nearest number of days.

4. For bees, the veterinarian shall determine the appropriate withdrawal period by assessing the specific situation of the particular beehive or beehives on a case-by-case basis and in particular the risk of residue in honey or in any other foodstuffs harvested from beehives intended for human consumption.

5. By way of derogation from Article 113(1) and (4), the Commission shall, by means of implementing acts, establish a list of substances which are essential for the treatment of equine species, or which bring added clinical benefit compared to other treatment options available for equine species and for which the withdrawal period for equine species shall be six months. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).'

Hence, from 28 January 2022, if an organic terrestrial food-producing animal belonging to a certain species is treated with a veterinary medicinal product used outside the terms of the marketing authorisation for that species, the withdrawal period that should be applied between the last administration of a chemically synthetised allopathic veterinary medicinal product, including of an antibiotic, under normal conditions of use, and the production of organically produced foodstuffs from that animal should be twice the relevant withdrawal period set out in Article 115(1) of Regulation (EU) 2019/6 and at least 48 hours.