SCVMP 23-6-2026

WORKING DOCUMENT

on the implementing act under Article 107(6) of Regulation 2019/6 as regards Article 114 (food-producing aquatic species)

1. Legal basis

Article 107(6) of Regulation (EU) 2019/6

The Commission may, by means of implementing acts, and taking into consideration scientific advice of the Agency, establish a list of antimicrobials which:

(a) shall not be used in accordance with Articles 112, 113 and 114; or

(b) shall only be used in accordance with Articles 112, 113 and 114 subject to certain conditions.

When adopting those implementing acts, the Commission shall take account of the following criteria:

(a) risks to animal or public health if the antimicrobial is used in accordance with Articles 112, 113 and 114;

(b) risk for animal or public health in case of development of antimicrobial resistance;

(c) availability of other treatments for animals;

(d) availability of other antimicrobial treatments for humans;

(e) impact on aquaculture and farming if the animal affected by the condition receives no treatment.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

2. Title and preamble

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

amending Implementing Regulation (EU) 2024/1973 to include in its scope food-producing aquatic species and set out conditions for the use of cetrain antimicrobials in those animals in accordance with Article 114 of Regulation (EU) 2019/6

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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 ([1]), and in particular Article 106(7) thereof,

Whereas:

(1) On 18 July 2024 the Commission, as required under Article 107(6) of Regulation (EU) 2019/6 and taking into account the criteria listed therein adopted Commission Implementing Regulation (EU) 2024/1973 ([2]) establishing a list of antimicrobials which shall not be used in accordance with Articles 112 and 113 of Regulation (EU) 2019/6 of the European Parliament and of the Council or which shall only be used in accordance with those Articles subject to certain conditions.

(2) Article 114(3) of Regulation (EU) 2019/6 provides for the establishment, by means of implementing acts, of a list of substances used in veterinary medicinal products authorised in the Union for use in food-producing terrestrial animal species or substances contained in a medicinal product for human use authorised in the Union in accordance with Directive 2001/83/EC of the European Parliament and of the Council ([3]) or Regulation (EC) 726/2004 of the European Parliament and of the Council ([4]), which may be used in food-producing aquatic species in accordance with Article 114(1) of Regulation (EU) 2019/6

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1 OJ L 4, 7.1.2019, p. 43, ELI: http://data.europa.eu/eli/reg/2019/6/2022-01-28

2 Commission Implementing Regulation (EU) 2024/1973 of 18 July 2024 establishing a list of antimicrobials which shall not be used in accordance with Articles 112 and 113 of Regulation (EU) 2019/6 of the European Parliament and of the Council or which shall only be used in accordance with those Articles subject to certain conditions (OJ L, 19.7.2024 ELI: http://data.europa.eu/eli/reg_impl/2024/1973/oj)

3 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 (OJ L 311, 28.11.2001, p. 67, ELI: http://data.europa.eu/eli/dir/2001/83/oj).

4 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 (OJ L 136, 30.4.2004, p. 1, ELI: http://data.europa.eu/eli/reg/2004/726/oj).

(3) In order to ensure legal certainty for the competent authorities, veterinarians, animal keepers and economic operators concerned, as well as coherence between the implementing acts under Article 107(6) of Regulation (EU) 2019/6 and the implementing acts under Article 114(3) of the same regulation, food-producing aquatic species were excluded from the scope of Regulation (EU) 2024/1973.

(4) The European Medicines Agency ('the Agency') scientific advice under Article 107(6) ([5]) includes recommendations concerning the use of antimicrobials in all animals species, including food-producing aquatic species. The Agency's scientific advice under Article 114(3) ([6]) contains recommendations for listing several antimicrobials. Those two sets of recommendations are based on different sets of criteria established in Regulation (EU) 2019/6. In respect of nine antimicrobial substances, the Agency recommended certain restrictions under Article 107(6) as antimicrobial resistance risk mitigation measures in the case of use in food-producing aquatic species. In its scientific advice under Article 114(3), the Agency concluded that such restrictions would have a high negative impact on the health of food-producing aquatic animals.

(5) To reconcile the two sets of recommendations, the Commission asked the Agency for additional guidance in accordance with Article 141(1)(f) of Regulation (EU) 2019/6. In its resulting guidance ([7]), the Agency focused on the mitigation of antimicrobial resistance risks; the availability of treatment options for food-producing aquatic species and the associated impact on the health of food-producing aquatic animals did not form part of the Agency's considerations. The Agency did not propose further measures that would address both antimicrobial resistance risks and animal health risks.

(6) Regulation (EU) 2019/6 acknowledges that sufficient and effective veterinary medicinal products should be available in the Union, in order to ensure high standards of public and animal health and for the development of the agriculture and aquaculture sectors. It is widely recognised that only few veterinary medicinal products are authorised in the Union for use in food-producing aquatic species and the availability of those products remains limited. This situation constrains the adequate prevention and treatment of diseases common in food-producing aquatic species, which in turn affects animal welfare, hampers the growth of European aquaculture, and may pose risks for food safety and public health as well as for food security.

(7) It is therefore necessary to ensure that antimicrobials remain available for the treatment of food-producing aquatic species and adopt risk management measures aiming to satisfactorily mitigate both antimicrobial resistance risks and animal health risks, taking into account the specificities of the aquaculture sector and the diversity of production systems in the Union.

(8) In order to ensure coherence between this regulation and the implementing acts under Article 114(3) and taking into consideration the Agency's scientific advice under

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5 Scientific advice under Article 107(6) of Regulation (EU) 2019/6 for the establishment of a list of antimicrobials which shall not be used in accordance with Articles 112, 113 and 114 of the same Regulation or which shall only be used in accordance with these articles subject to certain conditions (EMA/CVMP/151584/2021, 15 June 2023)

6 Scientific advice under Article 114(3) of Regulation (EU) 2019/6 on veterinary medicinal products - List of substances used in veterinary medicinal products authorised in the Union for use in food-producing terrestrial animal species or substances contained in medicinal products for human use authorised in the Union, which may be used in food-producing aquatic species in accordance with Article 114(1) (EMA/CVMP/29892/2024,15 May 2025).

7 EMA/CVMP/724/2026, 6 April 2026

Article 107(6) of Regulation (EU) 2019/6 and the Agency's scientific advice under Article 114(3) of the same regulation, the use of certain antimicrobials in accordance with Article 114 of Regulation (EU) 2019/6 should be subject to certain conditions, including, in certain instances, a ban to use them.

(9) Aiming at mitigating environmental risks, the scientific advice of the Agency under Article 114(3) of Regulation (EU) 2019/6 recommends certain conditions to the use of some antimicrobial substances in food-producing aquatic species. In addition to mitigating environmental risks, the recommendation to treat the animals in a setup where the effluent containing the substance can be effectively confined, controlled and treated before being discharged is expected to also reduce the antimicrobial resistance risks by minimising exposure. Therefore, this condition should also be imposed in certain cases in this Regulation.

(10) In order to facilitate the implementation of this Regulation by the veterinarians responsible, it is appropriate to list separately the conditions applicable to the use of each antimicrobial or group of antimicrobials in food-producing aquatic species in accordance with Article 114. Therefore, Regulation (EC) 2024/1973 should have two annexes, one for the uses in accordance with Articles 112 and 113 of Regulation (EU) 2019/6 and another one for the uses in accordance with Article 114 of the same Regulation.

(11) Regulation (EC) 2024/1973 should therefore be amended accordingly.

(12) In order to allow competent authorities, veterinarians, animal keepers and economic operators concerned the necessary time to adapt to the requirements of this Regulation, its application should be deferred.

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

HAS ADOPTED THIS REGULATION:

3. Enacting terms

Article 1

Regulation (EU) 2024/1973 is amended as follows:

(1) The title is replaced by the following:

'Commission Implementing Regulation (EU) 2024/1973 establishing a list of antimicrobials which shall not be used in accordance with Articles 112, 113 and 114 of Regulation (EU) 2019/6 of the European Parliament and of the Council or which shall only be used in accordance with those Articles subject to certain conditions'

(2) Article 1 is replaced by the following:

'This Regulation applies to the use of antimicrobials in accordance with Articles 112 and 113 of Regulation (EU) 2019/6 in animals other than those of equine species and in accordance with Article 114 of the same Regulation.'

(3) In Article 2 the title is replaced by the following:

'Conditions on the use of antimicrobials in accordance with Articles 112, 113 and 114 of Regulation (EU) 2019/6';

(4) In Article 2, paragraph 1 is replaced by the following:

'1. The antimicrobials or groups of antimicrobials listed in Annex I shall be used in accordance with Article 112 or 113 of Regulation (EU) 2019/6 subject to the conditions applicable to them as specified in that Annex. The antimicrobials or groups of antimicrobials listed in Annex II shall be used in accordance with Article 114 of Regulation (EU) 2019/6 subject to the conditions applicable to them as specified in that Annex.

(5) in Article 2, paragraph 2 is replaced by the following:

'2. The conditions applicable to each antimicrobial or group of antimicrobials listed in the annexes shall be cumulative for the respective animal species.';

(6) in Article 2, paragraph 3 is amended as follows:

(a) the introductory wording is replaced by the following:

'The conditions set out in the annexes shall apply without prejudice to the application of:';

(b) paragraph (a) is replaced by the following:

'Article 113(4) or 114(6) of Regulation (EU) 2019/6 as applicable;';

(c) the following paragraph is inserted:

'(d) any conditions and environmental risk mitigation measures imposed by Regulation [the number of the implementing act under Article 114(3) of Regulation (EU) 2019/6].';

(7) In Article 4 the second paragraph is replaced by the following:

'It shall apply from 8 August 2026 for the uses in accordance with Articles 112 and 113 of Regulation (EU) 2019/6 and from [*OP: please insert date: 12 months after the date of entry into force of this Regulation*] for the uses in accordance with Article 114 of the same Regulation.'

(8) The Annex to Regulation (EU) 2024/1973 is named as Annex I and the Annex to this Regulation is added as Annex II to Regulation (EU) 2024/1973.

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*.

It shall apply from [*OP: please insert date: the date of entry into force of this Regulation*].

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

Done at Brussels,

4. Annex

Annex II

Antimicrobials or groups of antimicrobials	Conditions on the use in food-producing aquatic species in accordance with Article 114 of Regulation (EU) 2019/6
Aminopenicillins in combination with beta-lactamase inhibitors	Aminopenicillins in combination with beta-lactamase inhibitors shall not be used in accordance with Article 114 of Regulation (EU) 2019/6.
Third- and fourth-generation cephalosporins	(1) In the cases of use of third- or fourth-generation cephalosporins for indications not included in the terms of the marketing authorisation of a medicinal product authorised in the Union and containing those antimicrobials, the veterinarian responsible shall prescribe those antimicrobials based, where possible, on prior target pathogen identification and antimicrobial susceptibility testing. The antimicrobial susceptibility testing shall demonstrate that: (a) third- or fourth-generation cephalosporins are likely to be clinically effective; (b) preferable antibiotics in accordance with the Categorisation of antibiotics in the European Union of the European Medicines Agency, or in accordance with stricter rules applicable in the Member State concerned, would not be clinically effective. (2) The use shall be limited to administration to individual animals only [or in a small group of animals]. (3) Treatment shall take place in a setup in which effluent containing the substance can be effectively confined, controlled, and treated before being discharged, including but not limited to 'well-boats' as defined in Article (2)(19) of Regulation (EU) 2020/689, and: a) before discharge in the environment, the substance is removed from or inactivated in the effluent or the solid waste; b) if the removal or inactivation referred to in point i) of this paragraph is not possible, – the effluent is directly discharged into a recognised wastewater treatment system, or where direct discharge is not possible, the effluent shall be securely collected, transported, and subsequently discharged into such a system; and – the solid waste is disposed of in accordance with

Antimicrobials or groups of antimicrobials	Conditions on the use in food-producing aquatic species in accordance with Article 114 of Regulation (EU) 2019/6
	local requirements; c) if the removal or inactivation referred to in point i) or the discharge into a recognised wastewater treatment system referred to in point ii) of this paragraph is not possible, before discharge in the environment, the effluent is diluted to bring the concentration of the substance below 1 μg/L.
Polymyxins	Polymyxins shall not be used in accordance with Article 114 of Regulation (EU) 2019/6.
Amphenicols	In the cases of use of amphenicols for indications not included in the terms of the marketing authorisation of a medicinal product authorised in the Union and containing those antimicrobials, the veterinarian responsible shall prescribe those antimicrobials based, where possible, on prior target pathogen identification and antimicrobial susceptibility testing. The antimicrobial susceptibility testing shall demonstrate that: (a) amphenicols are likely to be clinically effective; (b) preferable antibiotics in accordance with the Categorisation of antibiotics in the European Union of the European Medicines Agency, or in accordance with stricter rules applicable in the Member State concerned, would not be clinically effective.
Quinolones (including fluoroquinolones)	(1) In the cases of use of quinolones (including fluoroquinolones) for indications not included in the terms of the marketing authorisation of a medicinal product authorised in the Union and containing those antimicrobials, the veterinarian responsible shall prescribe those antimicrobials based, where possible, on prior target pathogen identification and antimicrobial susceptibility testing. The antimicrobial susceptibility testing shall demonstrate that: (a) quinolones (including fluoroquinolones) are likely to be clinically effective; (b) preferable antibiotics in accordance with the Categorisation of antibiotics in the European Union of the European Medicines Agency, or in accordance with stricter rules applicable in the Member State concerned, would not be clinically effective. (2) In each of the following cases the administration of the medicinal product containing danofloxacin or marbofloxacin

Antimicrobials or groups of antimicrobials	Conditions on the use in food-producing aquatic species in accordance with Article 114 of Regulation (EU) 2019/6
	shall be limited to individual animals only [or in a small group of animals.]: (a) use of a veterinary medicinal product in accordance with Article 114 of Regulation (EU) 2019/6 via a route of administration not included in the terms of its marketing authorisation; (b) use of a medicinal product for human use authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004; (c) use of a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription. (3) Veterinary medicinal products prepared extemporaneously in accordance with the terms of a veterinary prescription and containing difloxacin, enrofloxacin, flumequine and oxolinic acid shall be used subject to the following condition: When possible, treatment shall take place in a setup in which effluent containing the substance can be effectively confined, controlled, and treated before being discharged, including but not limited to 'well-boats' as defined in Article (2)(19) of Regulation (EU) 2020/689, and: a) before discharge in the environment, the substance is removed from or inactivated in the effluent or the solid waste; b) if the removal or inactivation referred to in point i) of this paragraph is not possible, – the effluent is directly discharged into a recognised wastewater treatment system, or where direct discharge is not possible, the effluent shall be securely collected, transported, and subsequently discharged into such a system; and – the solid waste is disposed of in accordance with local requirements; c) if the removal or inactivation referred to in point a) or the discharge into a recognised wastewater treatment system referred to in point b) of this paragraph is not possible, before discharge in the environment, the effluent is diluted to bring the concentration of the substance below 1 µg/L.
Rifaximin	In the cases of use of medicinal products, other than veterinary medicinal products authorised in the Union, the veterinarian

Antimicrobials or groups of antimicrobials	Conditions on the use in food-producing aquatic species in accordance with Article 114 of Regulation (EU) 2019/6
	responsible shall prescribe rifaximin, based, where possible, on prior target pathogen identification and antimicrobial susceptibility testing. The antimicrobial susceptibility testing shall demonstrate that: (a) rifaximin is likely to be clinically effective; (b) preferable antibiotics in accordance with the Categorisation of antibiotics in the European Union of the European Medicines Agency, or in accordance with stricter rules applicable in the Member State concerned, would not be clinically effective.