



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update from EMA on latest developments on substances for use in aquaculture under the cascade

Scientific advice requested by EC mandate in relation to Article 114(3) of Regulation (EU) 2019/6 regarding the list of substances which may be used in food-producing aquatic species in accordance with Article 114(1)

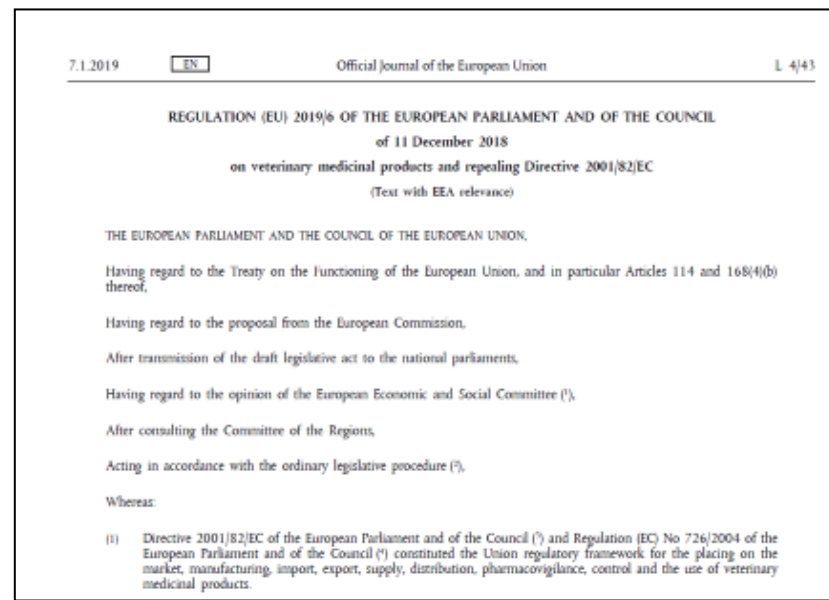
Aquaculture focus group meeting





Legal basis: 'new' veterinary Regulation (EU) 2019/6

- Repeals Directive 2001/82/EC
 - Applies from 28 January 2022
 - Covers various aspects of VMPs
 - Refers to legal acts to come
 - One of them: Implementing act to establish a list of substances which may be used in food producing aquatic species under the cascade Art 114(1)(b)(c)
- [cascade = off-label use]





Article 114(1) of Regulation (EU) 2019/6 – cascade for food producing aquatic species

"[...] where there is no authorised VMP in a MS for an indication concerning a food producing aquatic species, the veterinarian responsible may [...] treat the animals [...] with [...]:

- ***a) a VMP authorised [...] in the relevant MS or in another MS for use **in the same or in another food producing aquatic species** [...] and for the same indication or for another indication***
- ***b) if there is no VMP as referred to in a), a VMP authorised [...] in the relevant MS or another MS for use with a food producing terrestrial species containing a substance present in the **list** established in accordance with paragraph 3 [...]***



Article 114(1) of Regulation (EU) 2019/6 – cascade for food producing aquatic species (Ct'd)

- ***c) if there is no VMP as referred to in a) or b), a medicinal product for human use authorised in accordance with Directive 2001/83/EC [...] and containing a substance present in the list established in accordance with paragraph 3 [...]***
- ***d) if there is no medicinal product as referred to in a) b) or c), a VMP prepared extemporaneously [...]"***



Article 114(3) of Regulation (EU) 2019/6

*"**The Commission shall**, by means of implementing acts, at the latest within five years from 28 January 2022, **establish a list of substances used in VMPs 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 or Regulation (EC) No 726/2004, **which may be used in food-producing aquatic species** in accordance with paragraph 1 of this Article. [...]"*



EC mandate to EMA

- EC requests the EMA to provide [scientific advice on the substances](#) that may be considered for inclusion in 'the list' by 30 November 2024





Substances to be assessed against 3 main criteria (Art. 114(3) and EC mandate)

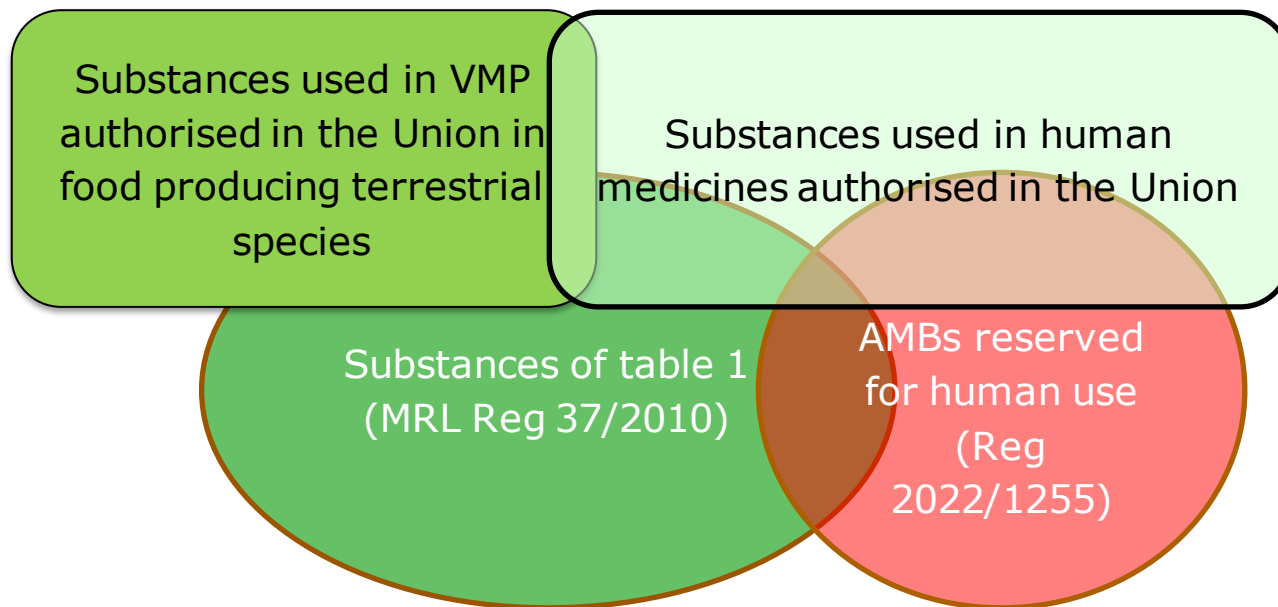
- (a) risks to the environment** *if the food-producing aquatic species are treated with those substances;*
- (b) impact on animal and public health** *if the food-producing aquatic species affected **cannot receive an antimicrobial listed in accordance with Article 107(6);***
- (c) availability or lack of availability** *of other medicinal products, treatments or measures for prevention or treatment of diseases or certain indications in food-producing aquatic species."*



Additional elements to take into account as per EC mandate

- 1. “Overall **objective** of the VMP Regulation is to **increase the availability** of VMPs **while guaranteeing the highest level of public and animal health and environmental protection**.
- 2. Substances included in the Annex to Commission Implementing Regulation (EU) No 2022/1255 designating **antimicrobials** or groups of certain antimicrobials **reserved for treatment of certain infections in humans** are prohibited for use in animals and **outside the scope of this mandate**.
- 3. Pursuant article 114(6) [...] **only the substances included in Table 1** of the Annex to Commission Regulation (EU) No **37/2010** [...] **should be assessed** [...]

Point of departure (Art. 114(3) and EC mandate)





... Additional elements to take into account as per EC mandate

- 4. **Antimicrobials that could be recommended for a prohibition or conditions of use in food-producing aquatic animals in the Agency's scientific advice requested by the Commission in relation to Article 107(6) should be assessed under the criteria [...]**
- 5. Any scientific and technical evidence available that is relevant for the assessment of **risks to the environment** [...]
- 6. **Various production systems** in the EU such as sea cages, ponds, raceways, on-land recirculating aquaculture systems, and their specificities, **as well as various routes of administration or pharmaceutical forms should also be taken into account [...]. In this respect, conditions of use and risk mitigation measures for the protection of the environment could be proposed [...]**



Ad-hoc expert group mandated by CVMP

- Expert group appointed at July 2023 CVMP meeting
- Objective of expert group: draft the scientific advice
- Timetable for expert group
 - 1st meeting in September 2023
 - Monthly meetings (tbc)
 - Draft scientific advice expected by September 2024
- Timetable for CVMP
 - Monthly updates
 - Adoption of scientific advice by November 2024
 - Submission of scientific advice to European Commission by 30 November 2024



9 experts

secretariat by EMA



Thank you for your attention

Further information

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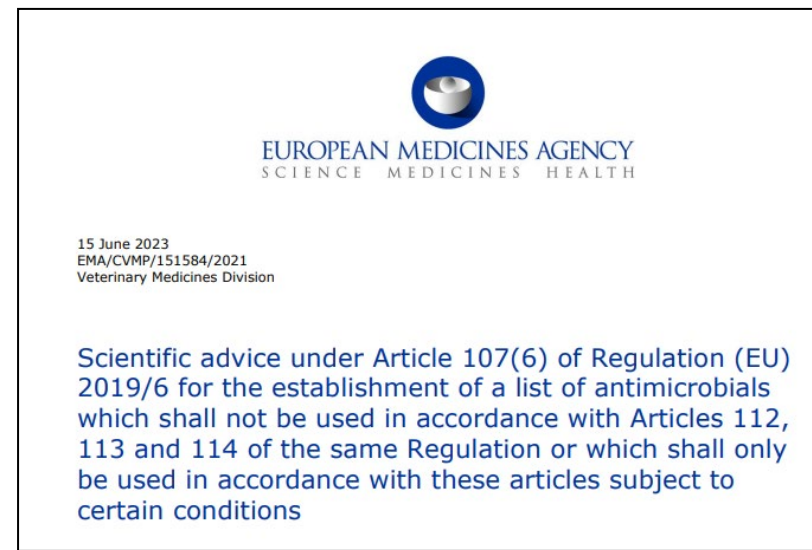
Annexe



EMA Scientific advice under Article 107(6)

- A few antimicrobials recommended as 'not to be used in food producing aquaculture' in this scientific advice :
 - Combination aminopenicillin – beta lactamase inhibitor
 - 3rd and 4th generation cephalosporins
 - Polymyxins

But criteria different from current scientific advice



[Link](#)



Antimicrobials reserved for human use: Regulation 2022/1255

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1255

of 19 July 2022

designating antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council

(1) Antibiotics

- (a) Carboxypenicillins
- (b) Ureidopenicillins
- (c) Ceftobiprole
- (d) Ceftaroline
- (e) Combinations of cephalosporins with beta-lactamase inhibitors
- (f) Siderophore cephalosporins
- (g) Carbapenems
- (h) Penems
- (i) Monobactams
- (j) Phosphonic acid derivatives
- (k) Glycopeptides
- (l) Lipopeptides
- (m) Oxazolidinones
- (n) Fidaxomicin
- (o) Plazomicin
- (p) Glycylcyclines
- (q) Eravacycline
- (r) Omadacycline

(2) Antivirals

- (a) Amantadine
- (b) Baloxavir marboxil
- (c) Celgosivir
- (d) Favipiravir
- (e) Galidesivir
- (f) Lactimidomycin
- (g) Laninamivir
- (h) Methisazone/metisazone
- (i) Molnupiravir
- (j) Nitazoxanide
- (k) Oseltamivir
- (l) Peramivir
- (m) Ribavirin
- (n) Rimantadine
- (o) Tizoxanide
- (p) Triazavirin
- (q) Umifenovir
- (r) Zanamivir

(3) Antiprotozoals

- (a) Nitazoxanide