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Aquaculture Advisory Council
Rue Montoyer, 31 - 1000 Brussels

To the attention of
Eva Maria Zamora Escribano
Head of Unit Animal Nutrition, Veterinary Medicines
DG SANTE
Rue Breydel, 4 - 1000 Brussels

Brussels, 22 June 2022

Subject: NEW EU LEGAL FRAMEWORK FOR THE ORAL DISTRIBUTION OF VETERINARY MEDICINES IN THE AQUACULTURE SECTOR

Dear Mrs Zamora Escribano,

The EU legislation covering the delivery to animals of veterinary medicines, i.e. Regulations 2019/4 on medicated feed and 2019/6 on veterinary medicinal products both entered into application on 28 January 2022 and provide among others for restrictions as regards the use of antimicrobials for prophylactic and even metaphylactic treatment.

It is the ambition of the EU aquaculture sector to contribute to the EU One Health and AMR policies and implement good aquaculture practice and biosecurity measures to reduce the exposure of fish to pathogens and thereby reduce the needs for antimicrobial treatments. Preventative measures such as good nutrition, good management and, whenever possible, vaccination enabled to reduce the use of antimicrobials.

However, despite this positive evolution, veterinary treatment of fish may still be needed and therefore a safe and operational measures should be in place to allow farmers to preserve the welfare and health of fish. In practice, for obvious welfare reasons, it is neither possible nor suitable to treat fish individually and therefore oral group treatment remains the standard in the aquaculture sector for the delivery of antimicrobials. Therefore, the entry into application of the new regulations is clearly impacting the aquaculture sector and it is expected that certain implementing rules in the form of delegated acts will further impact on the aquaculture sector.

This is in particular the case for the establishment of maximum limits for carry-over of antimicrobials from medicated feed into non-target feed (article 7 of Regulation (EU) 2019/04): the opinion delivered

recently by EFSA on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed is based on a very conservative approach leading to maximum levels that are not applicable in practice in feed mills. Should these levels become legal standards, this would put a end to the production of medicated feed in feed mills.

The second delegated act of concern for the aquaculture sector is the drafting of rules for the effective and safe use of veterinary medicinal products via routes other than medicated feed, including top dressing (article 106 of Regulation (EU) 2019/6). Although the use of medicated feed in aquaculture is considered by EMA in its Advice on implementing measures under Article 106 (6) of Regulation (EU) 2019/6[1], as the best way to ensure safe and efficient administration of medicines, EMA stresses also that industrial medicated feed is not always adapted (size of the batch not always adapted to the needs of small farms, insufficient availability of veterinary medicinal products authorised for the production of medicated feed).

On both delegated acts, AAC considers of the utmost importance that proper stakeholders' consultations are organized, including with AAC.

Furthermore, in the same Advice, the EMA points to the limited availability of medicines for fish as a source of concern and that pharmaceutical companies should be encouraged to develop medicines (premixes) for use in the preparation of medicated feed for fish. AAC would be interested to learn from you what measures may be considered by the EU Commission to encourage the pharmaceutical industry to operate in that direction.

We thank you for taking our concerns into account and would appreciate the opportunity to exchange with you on the occasion of an upcoming AAC meeting.

Yours sincerely,

Andrea Fabris
Chair
Working Group on Finfish
Aquaculture Advisory Council

[1] Advice on implementing measures under Article 106 (6) of Regulation (EU) 2019/6 on veterinary medicinal products – scientific problem analysis and recommendations to ensure a safe and efficient administration of oral veterinary medicinal products via routes other than medicated feed.
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