



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR MARITIME AFFAIRS AND FISHERIES

The Director-General

Brussels,
MARE.A.2/BVT

Subject: AAC Recommendation on autogenous vaccines

Dear Mr Brian Thomsen,

I would like to thank you for your mail of 28th July 2026 including the “AAC Recommendation on autogenous vaccines”. Please find below the Commission's replies to the different requests raised by the Aquaculture Advisory Council.

- *Define a specific regulatory framework for autogenous vaccines that considers the unique characteristics and requirements of the aquaculture sector.*

Regulation (EU) 2019/6 ⁽¹⁾ (the “Regulation”) provides a harmonised framework for autogenous vaccines, with a number of provisions applying to their use ⁽²⁾, including for aquaculture. The practical implementation of the existing rules remains within the remit of the national competent authorities.

- *Establish flexible rules that, while respecting specific national situations, ensure production methods capable of meeting the sector's needs in terms of turnaround times, required volumes, and efficacy.*

The Regulation provides for specific measures on good manufacturing practice for autogenous vaccines to be laid down by means of implementing acts. The Commission services are working on that legislation. A public consultation will be launched in the near future, where all stakeholders will have the opportunity to express their views on the draft legislation. You are therefore strongly advised to monitor the launch of the public consultation on the “Have your say” portal ⁽³⁾.

⁽¹⁾ 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, ELI: <http://data.europa.eu/eli/reg/2019/6/oj>).

⁽²⁾ specifically in Articles 94, 105, 106(5), 108, 117, 120, 123, 134 and 159

⁽³⁾ https://ec.europa.eu/info/law/better-regulation/have-your-say_en.

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- *Permit the prescription and use of autogenous vaccines on an area-wide basis, including across Member State borders, rather than restricting them to individual facilities, provided that an epidemiological interconnection is confirmed.*

The Regulation also requires that an autogenous vaccine is used for the treatment of the animal or the animals in the same epidemiological unit from which the pathogens or antigens were obtained, or in a unit having a confirmed epidemiological link. An epidemiological unit is defined as a group of animals with the same likelihood of exposure to a disease agent ⁽⁴⁾. Whether or not there is an epidemiological link requires a case-by-case assessment by the national competent authorities.

- *Allow the formulation of multivalent or adjuvanted autogenous vaccines whenever a diagnosis or the need for effective prevention warrants their use.*

The current framework does not preclude autogenous vaccines from containing multiple pathogens and antigens, provided the relevant conditions are met (5). Their use is however limited to exceptional circumstances, in particular where no authorised immunological veterinary medicinal product is available for the target species and indication ⁽⁶⁾. The basic principle is that veterinary medicinal products must hold a marketing authorisation based on demonstration of their quality, safety and efficacy.

I am looking forward to our continued fruitful cooperation.

Should you have further questions on this reply, please contact Ms Julia Rubeck, coordinator of the Advisory Councils (MARE-AC@ec.europa.eu ; +32.2.296.88.89) and/or Ms Birgit Van Tongelen (birgit.van-tongelen@ec.europa.eu).

Yours sincerely,

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⁽⁴⁾ Article 4, point (44), of Regulation (EU) 2019/6, read together with Article 4, point (39), of Regulation (EU) 2016/429 - 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') (OJ L 84, 31.3.2016, p. 1, ELI: <http://data.europa.eu/eli/reg/2016/429/oj>).

⁽⁵⁾ cf. Article 106(5) of the Regulation

⁽⁶⁾ In accordance with Article 106(5) of Regulation (EU) 2019/6,