AAC Recommendation on autogenous vaccines

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I. Background

Vaccines: Prevention is Better than Cure: Vaccination—including the use of **autogenous vaccines**—combined with robust biosecurity measures, has been key to this success. However, under the new Veterinary Medicinal Products (VMP) Regulation, we now face significant challenges in prescribing autogenous vaccines. This regulatory hurdle risks resulting in increased disease outbreaks and, in the worst-case scenario, a forced reliance on antibiotics—directly contradicting the EU's core ambition that "prevention is better than cure."

The Challenge of Vaccine Availability in Aquaculture

The limited availability of aquaculture vaccines within the EU remains a critical challenge. This shortage is particularly acute for:

- Minor species
- Emerging diseases (a threat expected to intensify due to climate change)
- Geographically specific disease outbreaks

While vaccination is one of the most effective tools for reducing antimicrobial use and combating antimicrobial resistance (AMR) in aquaculture, the current lack of authorized vaccines leaves many farmers without adequate preventive options.

The Role of Autogenous Vaccines and Regulatory Fragmentation

In practice, autogenous vaccines could bridge these gaps by providing **tailor-made solutions for** specific epidemiological situations. However, because autogenous vaccines fall outside the harmonized scope of the VMP Regulation (Reg UE 6/2019), their availability and usage rules vary significantly among Member States. This fragmented approach creates an uneven regulatory landscape, undermining the level playing field within the EU aquaculture sector.
The current wording of Article 2(3) of Reg **(EU)** 2019/6creates regulatory hurdles for fish health professionals and farmers, restricting the prescription and use of autogenous vaccines even when they represent the most effective preventive measure.

> *In addition to the products referred to in paragraph 1 of this Article, Articles 94, 105, 108, 117, 120, 123 and 134 shall also apply to inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals in an epidemiological unit and used for the treatment of that animal or those animals in the **same epidemiological unit** or for the treatment of an animal or animals in a unit having a **confirmed epidemiological link**.*

II. Justification

Examples of EU-wide challenges in prescribing and using autogenous vaccines

The following points outline the main difficulties encountered across EU Member States regarding the prescription and use of autogenous vaccines in aquaculture:

1. **Cross-Border Restrictions & Production Issues**

   - There is a near-total ban on the movement of autogenous vaccines between Member States, even in cases of clear epidemiological interconnection.
   - Variations in production methods result in highly restricted volumes and prolonged timelines; this is frequently exacerbated by a general shortage of authorized vaccines tailored to the specific diseases affecting farmed fish.
   - Autogenous vaccine regulations are excessively modelled after terrestrial livestock standards, failing to account for the unique health dynamics of aquaculture.

2. **Rigid Interpretations of "Epidemiological Link"**

   - Authorities strictly reject use if no epidemiological link is proven between the facility where the pathogen was isolated and the facility where the vaccine will be deployed.
   - Regulators often use a rigid, kilometre-based distance to determine epidemiological links, ignoring hydrological connections (water currents/basins) that span much wider areas.
   - New aquaculture sites, or isolated facilities with no nearby farms, cannot establish an epidemiological link to obtain a starting isolate.

3. **Obstacles Related to Pathogen Isolation**

   - Autogenous vaccines are often rejected if the isolate is deemed "too old" or if the facility has not experienced a recent outbreak.
   - If an autogenous vaccine successfully prevents disease over multiple production cycles, authorities may reject renewal prescriptions due to the lack of active outbreaks—ignoring the fact that the absence of disease is a direct result of the vaccine's efficacy.
   - In areas where a pathogen is known to be present, but no local isolate exists, fish health professionals are prevented from proactive vaccination. Instead of allowing expert discretion—knowing that an autogenous vaccine provides better immunity than none—farmers are forced to wait for multiple disease outbreaks to occur before being allowed to vaccinate.

4. **Logistical and Allocation Dilemmas**

   - Fish must be healthy at the time of vaccination, but logistical constraints mean large batches are often split across multiple production sites later on. For instance, if a batch of 400,000 fish is split between two sites, but only one site has the required isolate and authorization, it is impossible to separate the fish during

vaccination. Due to rigid VMP Regulation requirements, the entire batch ends up unvaccinated, compromising overall herd immunity.

- Significant uncertainty remains regarding how to handle and allocate specific sub-groups of fish within a facility where autogenous vaccine use is permitted.
- Combining different vaccines may lead to adverse effects, whether due to incompatibility between products or to the volume of product administered in fish that are, at times, smaller than 10 g.

5. **Interaction with Commercial Vaccines**

- It remains unclear when an autogenous vaccine can be used if existing commercial vaccines have not been updated by manufacturers to cover shifting pathogen strains.
- When commercial vaccines fail to provide protection, autogenous vaccines offer a superior, immediate alternative. However, current rules do not easily accommodate this transition while waiting for commercial updates.
- If multiple commercial vaccines exist for the same pathogen (even if they all share the exact same antigen), regulations require farmers to test *every single one* before qualifying for an autogenous vaccine.

III. Recommendations

In light of disease outbreaks—which are frequently localized, species-specific, and driven by climate change— developing a commercial vaccine is often economically unviable for the industry **or involves** a regulatory process **that is** too lengthy.

Consequently, the challenges outlined above prompt us to formulate the following **Recommendations to the European Commission**:

- Define a specific regulatory framework for autogenous vaccines that considers the unique characteristics and requirements of the aquaculture sector.
- 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.
- 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.
- Allow the formulation of multivalent or adjuvanted autogenous vaccines whenever a diagnosis or the need for effective prevention warrants their use.

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