Information on

Autogenous vaccines

Products tailored to an individual site





vaxxinova.no



Targeted disease control

Autogenous vaccines are specially produced vaccines that are based on bacterial strains from individual sites or from a defined geographical area.

This requires that bacterial smears are taken from sick fish from a specific location. The bacteria is grown, identified and used to make a vaccine tailored to that actual aquaculture location.

We adapt the vaccine, vaccination method and vaccination regime to that individual farm site and their production.

An autogenous vaccine will, in many cases be the best and correct solution to disease in a fish farm.

Autogenous vaccines are a good option when:

- Existing vaccines don't give the expected effect
- Disease is caused by variants of bacteria and viruses against which there are no vaccines available.



Definition of autogenous vaccine

«An immunological medicine for animals, made from pathogenic organisms and antigens isolated from an animal or herd and used for the treatment of that animal or herd in the same place»

Medicines regulations (section) § 2-2 first paragraph, letter g

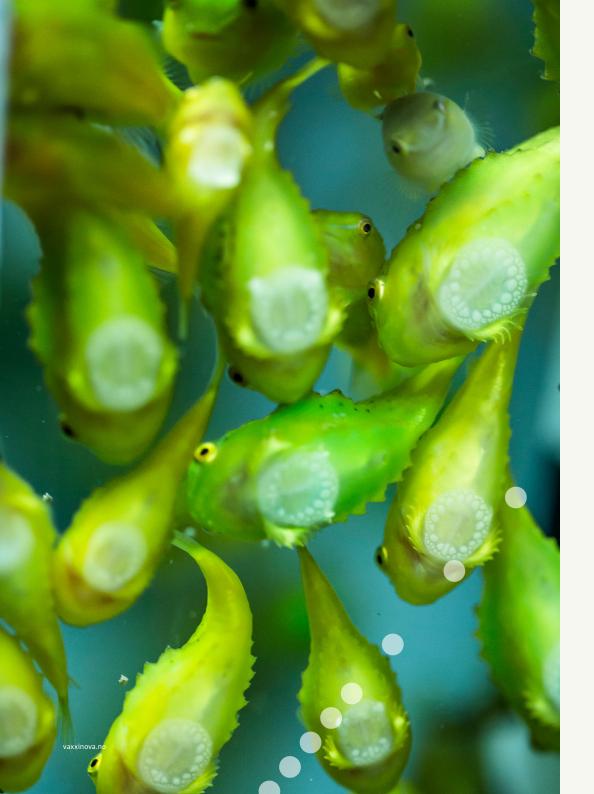
Assumptions for the use of autogenous vaccines

Autogenous vaccines shall only be used when commercial vaccines are not available or don't provide adequate protection.

The Norwegian Medicines Agency has clear guidelines and requirements to approve applications for autogenous vaccines.

If desired, we can assist in the application process, with diagnostics and storage of agents in our own biobank.

vaxxinova.no vaxxinova.n



Procedure for ordering autogenous vaccines (Norwegian)

Fish health biologists and veterinarians may prescribe autogenous vaccines on approval exemption if no other vaccine is available or if those available don't give the expected effect.

- 1. The fish health service for the location gets in contact with Vaxxinova with a disease problem and need for a vaccine
- 2. Vaxxinova can give recommendations on product composition and vaccination regime.
- 3. The fish health service applies to the Norwegian Medicines Agency (SLV) for approval for the use of autogenous vaccine (approval exemption)
- 4. The fish health service applies to the Food Safety Authority (Mattilsynet) for authorisation to use when and approval exemption is received from SLV. The application for an use authorisation is sent to the Food Safety Authority at; post@mattilsynet.no and marked with «Use authorisation, autogenous vaccine».
- 5. SLV and the Food Safety Authority receive and process applications on approval exemption and use authorisation for autogenous vaccine, and send a response to the fish health service, which can now send a prescription to pharmacies (e.g. VESO or Europharma)
- 6. When Vaxxinova has received isolates from the fish health service and orders from the pharmacies, we will start developing and producing the autogenous vaccine

From when we receive the order till the final product is delivered on site, usually takes 8-12 weeks. Submission of isolates can be in parallel with the application process.

vaxxinova.no

Contact us

Vaxxinova Norway AS

Kong Christian Frederiks plass 3, 5006 Bergen, Norway +47 55 900 200 post@vaxxinova.no



Eivind Isdal

Sales and marketing manager
+47 474 82 121
eivind.isdal@vaxxinova.no



Kristian Ulven
Sales and marketing
+47 992 15 779
kristian.ulven@vaxxinova.no



vaxxinova.no

sign: Haltenbanken