



Lohmann Animal Health International (LAHI) is a major supplier of autogenous vaccines to US chicken and turkey producers. It is our intention to supply you with only the very highest quality product produced in modern, licensed facilities guided by USDA regulations in the production of these important disease prevention tools.

Just what is an autogenous vaccine?

Sometimes, diseases in flocks occur even though the flocks have been vaccinated properly with a USDA licensed commercial vaccine designed to prevent just such an outbreak. The causative agent, usually a bacterium, a virus or a mycoplasma can sometimes be isolated and identified through efforts of your company

veterinarian, the state and/or university diagnostic laboratory or your vaccine supplier.

Once in hand, the suspected disease-causing microorganism can be used to construct a vaccine that, in turn, can be used on a subsequent flock, exposed to the same challenge, in hopes of preventing a recurrence of the outbreak in that and future flocks. This is called an autogenous vaccine (or bacterin).

Makers of these vaccines must have a USDA Autogenous Vaccine License and must abide by the rules of the USDA which are designed to protect you, the consumer, and to limit this approach to disease control to times when it is required and no effective commercial alternative exists.

The WHEN, WHERE, HOW, and HOW LONG of Autogenous Vaccine/Bacterin Usage:

WHEN can an autogenous vaccine or bacterin be used?

- Autogenous biologics are defined as vaccines or bacterins prepared from viruses or bacteria isolated from infected birds in a particular flock to be vaccinated.
- There should also be just cause to believe the microorganism(s) isolated are causing the disease.
- The causative microorganism used in the vaccine must be inactivated (killed) and the vaccine must be ordered and used under the direction of the attending veterinarian.

WHERE can an autogenous vaccine or bacterin be used?

- Generally, the autogenous biologic can only be used in the diseased flock from which the microorganism(s) were isolated.
- If a disease link can be established between adjacent flocks, the vaccine can be used in these flocks also.
- Specific information is required by USDA from the attending veterinarian to use the biologic in adjacent flocks.

HOW do you obtain permission to use an autogenous vaccine or bacterin in non-adjacent flocks?

- The attending veterinarian must apply to the State Veterinarian or other appropriate state official in writing for permission to use.
- The attending veterinarian must also submit information to the Director, Center for Veterinary Biologics, Inspection and Compliance who will validate the risk of transmission between the infected flock and the non-adjacent flocks.

HOW LONG can an autogenous vaccine or bacterin be made from a microorganism?

- Generally, the microorganisms used to produce autogenous biologics may only be used 15 months from the date of isolation, or 12 months from the date of production of the first serial of product, whichever comes first.
- Date of isolation is defined as the date the microorganism is taken from the bird and is required when the isolate is submitted for production of a biologic.
- Resubmission of an isolate is prohibited – It is not acceptable for a licensee or permittee to return autogenous isolates. It is also not acceptable for a licensee or permittee to facilitate resubmission of an isolate as a “new” isolate. APHIS will consider these practices an infraction of the product license under 9CFR (105.1 (a)(5), and 9 CFR 105.1 (b).
- USDA will allow for an extension of the use of an isolate beyond the 15 months from the date of isolation to 24 months provided certain information is provided:
 - Assessment of Continued Involvement – A current assessment, by the attending veterinarian, of the continued involvement of a flock with the originally isolated microorganism(s), including diagnostic work that has been done to support this assessment.
 - Documentation of Satisfactory Performance – Documentation to support a reason to believe that satisfactory protection occurred due to previous use of the autogenous biologic. This may consist of showing that there is no commercially licensed product or

products available, or showing that commercially licensed products did not provide equivalent protection.

- Provide any other information as might be required by the Administrator in order to determine the need to use the microorganism to make additional serials.
- In rare circumstances the USDA might allow for an extension of the use of an isolate beyond the 24 months from isolation provided the cultures are tested for antigenicity or immunogenicity according to a protocol approved by The Center for Veterinary Biologics – Licensing and Policy Development. See (CFR 113.113 (c)(2)(iv)).
- Stated simply this means isolates must be destroyed 15 months from the date of isolation or 12 months from the date of harvest of the first serial of product produced, unless CVB-IC approval is obtained.
- This means that you must send a microorganism/culture on an annual basis or provide the information to CVB-IC necessary to extend the use of the original isolate for 24 months.
- In order to provide you with a needed autogenous biologic, you will be notified 3 months prior to the expiration of the isolate. You will then have 90 days to order a supply of product before expiration of your isolate, to obtain a new isolate, or to provide information to CVB-IC for extended use of the original isolate.

HOW LONG does it take to produce and ship an autogenous vaccine or bacterin after it is ordered?

- Shipment of autogenous orders may be directed to:
 - The veterinarian for whom the product was prepared.
 - With appropriate documentation autogenous serials may be shipped directly to an owner if previously approved by the veterinarian.
 - Records and documentation pertaining to shipments of autogenous biologics should be maintained for APHIS inspection.
- The time required from receipt of the microorganism to shipment of the autogenous biologic depends upon whether it is an initial order or a repeat order:
 - First Serial or initial orders – generally takes 6 weeks.
 - Tested primary cells or approved cell lines may be used in production.
 - Sterility and safety tests require only 3 days for completion before shipping.
 - No CVB-IC release or samples to APHIS needed.
 - Recall if tests are not satisfactory.
 - Submit APHIS Summary Form to CVB-IC.
 - Identification of the organism should be sufficient to determine it as the causative agent.
 - Second Serial or repeat orders - generally takes 8 weeks.
 - Product must be tested under the general requirement in 9CFR 113.100 or 113.200 to include purity, safety, and identification (genus and species for bacteria, family for virus).

- Complete all testing and submit APHIS Form 2008 to CVB-IC for release which takes approximately 2 weeks.
- Samples are submitted to APHIS unless the serial is less than 50 containers. Check –testing by APHIS may occur. For less than 50 containers 2 reserve samples are held and may be requested for check testing.
- APHIS must release the serial BEFORE it is shipped.

These regulations are designed to protect users of autogenous vaccines. Lohmann Animal Health International is certain we can provide our customers with safe, high quality products and outstanding service at affordable prices. An understanding by you, our customers, of the guidelines under which we can serve you will enhance our customer/supplier relationship.

Why LAHI?

- We have one the newest facilities for inactivated vaccines in the US. We also have some areas set aside to allow for production of “autogenous sized” batches to allow prompt responses to orders.
- Our Area Managers and Veterinarians are very experienced at coordinating the orders of autogenous vaccines. We produce millions of doses for chicken and turkey customers each year. They can help advise you on the differences between composition, formulation etc.
- We have the most extensive program for adjuvant research in the industry today. We have experimented with a large variety of adjuvant approaches and have a proprietary adjuvant called WOW² (pronounced WOW SQUARED) of which we are particularly proud (patent pending). This particular adjuvant provides less reactivity and post vaccination residue when compared to water in oil but prevents “end of laying cycle failures” common with water/oil/water adjuvants. WOW² gives you the best of both worlds. It also allows for “placement” of antigens in layers within the formula to present them to the bird in the sequence that allows the most appropriate response in the bird from a particular antigen. This is truly a “leading edge” development. Today, this new adjuvant is only available in autogenous vaccines/bacterins and only from LAHI.
- We are committed to following USDA regulations as we create your autogenous product. Although these regulatory requirements are time-consuming, we feel it is important to cooperate with USDA and collect the proper information and handle the isolate and finished product according to regulation. If changes to the regulations are needed, there are channels for this process. We will collaborate with you on efforts to get regulations changed to make them less troublesome.

For initial autogenous orders, submission of isolates, or questions about the current status of your autogenous isolates, contact your Area Sales Manager. We value your business and look forward to working with you in the future.