

**RESOLUTION #5—2021
Regular Winter Session**

Submitted by
Board of Directors

REVISED POLICY ON GUIDELINES FOR USE OF AUTOGENOUS BIOLOGICS

RESOLVED, that the American Veterinary Medical Association (AVMA) House of Delegates adopt the revised policy on Guidelines for Use of Autogenous Biologics as shown in [Attachment 1](#) (additions are underlined; deletions are ~~struck through~~; clean copy provided as [Attachment 2](#)).

Statement about the Resolution

The suggested revisions are intended to:

- Remove language that provides practical instruction that was closely derived from USDA regulations on autogenous biologics ([9 CFR Sec. 113.113](#)) regarding the use of autogenous biological products. This information is familiar to livestock practitioners that utilize such products.
- Reorganize the remaining parameters of autogenous biologic use that Council on Biologic and Therapeutic Agents (COBTA) recommends AVMA support.
- Add that autogenous biologics should be used only when available vaccines are not sufficiently cross protective, that they should not be confused with exempt biological products, and that adequate records should be maintained by practitioners and manufacturers to demonstrate field efficacy and safety.

Financial Impact: None

	Board of Directors	House Advisory Committee	Reference Committee #5	House of Delegates
Recommend Approval	X	X	X (as amended*)	X (as amended*)
Recommend Disapproval				
Recommend Referral to...				
No Recommendation				
Recommend Postpone Indefinitely				

(use this space for additional narrative, if needed)

*** Guidelines for Use of Autogenous Biologics**

Autogenous biologics are USDA-regulated custom inactivated vaccines that consist of herd-specific (homologous) antigens approved for use by or under the direction of a veterinarian or approved non-veterinarian specialist. USDA can authorize the use of an autogenous biologic in adjacent and non-adjacent herds.

The use of autogenous biological products may provide the licensed veterinarian with a unique opportunity for the control of certain infectious diseases when USDA-licensed commercial vaccines are unavailable or not sufficiently cross protective.

The use of autogenous biologics requires the application of sound scientific principles and good veterinary practice in those situations where USDA-licensed, non-autogenous products are not available or there is evidence that licensed products are not effective. A thorough diagnostic work-up must be completed to provide the microorganism(s) for manufacture of the autogenous product. Autogenous biologics should not be mixed with any other product, ~~and the simultaneous administration of other products should be approached with caution.~~ Veterinary practices utilizing autogenous products are advised to maintain product distribution information as part of the veterinary client/patient record to support restrictions for use. ~~Additionally, it's recommended that veterinary practices and autogenous biologic product manufacturers attempt to maintain adequate records demonstrating field efficacy and safety.~~

Autogenous biologics are regulated in accordance with Title 9 of the Code of Federal Regulations (9 CFR), Section 113.113 and Veterinary Services Memorandum No. 800.69. Autogenous biologics are USDA-licensed products and should not be confused with products exempt under 9 CFR Part 107. For further information please see please see the AVMA policy on [Exempt Biologics](#).