UCDAVIS
VETERINARY MEDICINE
*California Animal Health and Food Safety Laboratory System*

# Autogenous Bacterin Regulations

**LEADING DIAGNOSTICS NATIONALLY, PROTECTING CALIFORNIA LOCALLY • FEBRUARY, 2019**

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The USDA Veterinary Services has issued updated regulations on the productions, importation, distribution, and use of autogenous biologic products including vaccines. Isolates must conform to the requirements summarized below and a NOTICE OF TRANSMITTAL OF ISOLATE TO A BIOLOGIC HOUSE FOR VACCINE PRODUCTION form signed by the veterinarian and owner/agent must also be sent to the lab to qualify for submission to the biologic product manufacturer selected by the submitter.

Links to the appropriate codes which address biologics:

**9 CFR Part 102.5**

**9 CFR Part 113.113**

**Veterinary Services Memorandum 800.69 dated 9-28-16 (General autogenous biologics)**

**Veterinary Services Memorandum 800.103 dated 7-18-18 (Restricted organisms)**

1. Seed isolates must be from the herd of origin (can be from sick or dead animals) and there is reason to believe they are the causative agent(s) of disease in the animals of the herd. Unless there is specific permission from USDA, isolates can't be used for animals from any other herds. The CFR has specific requirements for requesting this permission.

2. Isolates must have been isolated within the previous 15 months from the herd or origin to be used for bacterin production. Submitters can request specific permission from USDA for an extension to use the isolate for 24 months; however, potency information is required before permission will be considered.

3. Isolates must be identified to at least the genus and species level to be sent for bacterin production with specifications for identification to serotype including *Salmonella* sp., *Erysipelothrix* sp., *P. multocida*, *Streptococcus suis*, and *E. coli* among others. Characterization to the strain or serotype level should be done before the isolate is sent unless there is an emergency need and the intent is to use the vaccine on a short-term basis (not for the whole year.)

4. Bacterin production can only be prepared under a valid Veterinarian-Client-Patient relationship, which includes a veterinarian assuming responsibility for making clinical judgements and medical treatments and the client has agreed to follow the veterinarians instructions; the veterinarian has sufficient knowledge of the herd through examinations and farm visits; and the veterinarians is readily available for follow-up-evaluations inn case of adverse vaccine reactions or failure.

5. Bacterins can be prepared for use by a non-veterinarian specialist if approved by USDA. This would include a health specialist with sufficient education and knowledge to make decisions about management and vaccine use of the herd. The bacterin firm is responsible for providing the qualifications of the person to CVB.

6. CDFA requires a permission form signed by the owner, veterinarian, and CAHFS Case Coordinator, Discipline Head, or Branch Chief before the isolate can be sent. Each branch should have a blank form that can be completed for any accession for which the submitter is requesting isolate for bacterin production.