



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 20-10

TO: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Veterinary Services Leadership Team

FROM: Byron Rippke
Director

SUBJECT: Certification of Veterinary Vaccines and Immunotherapeutics as
Containing Genetically Modified Organisms

The purpose of this Notice is to inform interested parties of the Center for Veterinary Biologics' (CVB) policies regarding certification of USDA licensed veterinary vaccines and immunotherapeutics as genetically modified organisms (GMO) or non-genetically modified organisms (non-GMO). CVB classifies products derived using biotechnological techniques as GMOs. CVB will provide confirmation of the presence of Master Seeds or Master Cells used in production that are genetically modified using recombinant and/or synthetic nucleic acid molecules, as defined in the National Institute of Health's (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH GUIDELINES, APRIL 2019):

Definition of Recombinant and Synthetic Nucleic Acid Molecules

In the context of the *NIH Guidelines*, recombinant and synthetic nucleic acids are defined as:

- (i) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell, i.e., recombinant nucleic acids;
- (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or
- (iii) molecules that result from the replication of those described in (i) or (ii) above.

CVB will NOT issue certifications/confirmations of a product as "non-GMO" because there is no universally accepted definition on which to base such an evaluation. No certifications will be issued for *in vitro* diagnostic products.