Briefing Paper

The Use of Genetically Engineered Vaccines in Organic Livestock Production

While various cultures began using methods to immunize people from infectious diseases more than 500 years ago, late in the 18th century, Edward Jenner first used the term vaccine. [1] In the 1880s, Louis Pasteur developed vaccines for chicken cholera, anthrax, and rabies.[2] Thus began the modern era of vaccination.

In the late 20th century, the introduction of recombinant DNA and whole-genome sequencing techniques were major milestones in vaccine development. This gave researchers the tools to develop new vaccines against pathogens, which was not possible before.[3]

Genetic Engineering Prohibited in Organics – History

In response to these developments, the law establishing the USDA National Organic Program (regulations adopted in 2002 enabling the legislation in the Organic Foods Production Act of 1990—OFPA) specifically defines excluded methods as: "A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and **are not considered compatible with organic production** (emphasis added). Such methods include cell fusion, microencapsulation and macro-encapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the position of genes when achieved by recombinant DNA technology)."[4]

The recent successful deployment of mRNA vaccines against Covid 19, using a technology that targets any pathogen for which a protein can be identified as an antigen that elicits protective immunity, has created a potentially disruptive technology for the vaccine industry in domesticated animals as well as in humans.[5] And a number of academic institutions and private corporations have developed or are developing a large number of solutions targeted at the livestock industry.

The Problem: USDA/FDA/APHIS are not doing their jobs—they are protecting economic interest rather than the public's interest

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[1] https://www.who.int/news-room/spotlight/history-of-vaccination/a-brief-history-of-vaccination
[2] https://www.britannica.com/biography/Louis-Pasteur/Vaccine-development
[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8386248/
[4] https://www.ams.usda.gov/sites/default/files/media/NOP%20Preamble%20Full%20Version.pdf
[5] https://www.jci.org/articles/view/153721

There have been inconsistencies between certifiers about allowable vaccines. Two areas in the organic regulations address use of vaccines: one on the National List (NL) of allowed and prohibited substances at §205.603(a)(4), and one in the section detailing excluded methods at §206.105 (e).

The National List of Allowed and Prohibited Substances (mandated by Congress) addresses the use of non-organic agricultural materials and synthetics in organic farming and food production. Section § 205.603, refers to synthetic substances allowed for use in organic livestock production and "**In accordance with restrictions specified in this section the following synthetic substances may be used in organic livestock production (emphasis added):**

(a) As disinfectants, sanitizer, and **medical treatments (emphasis added)** as applicable.
(4) Biologics—Vaccines

Subsection 4 contains no text or descriptor for "biologics," however the NOP definition of Biologics (§205.2 Terms defined), is:

> *Biologics*. All viruses, serums, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms, and the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment, or prevention of diseases of animals.

In the past, some certifiers did not allow the use of vaccines based on prohibited methodology (genetically engineered), relying on the NOP regulation at §206.105 (e) which only allows use of this type of vaccine if it has gone through NOSB review and NOP placement on the National List. Other certifiers have allowed any type of vaccine to be used and may or may not have inquired if the vaccine has been produced through excluded methods. These certifiers relied on the presence of vaccines on the National List at § 205.603(a)(4) without any restriction or clarification.

This inconsistency, along with other major controversial issues in the organic movement being interpreted in diametrically different ways by various certifiers (as seen with hydroponic/soilless production of produce and giant livestock factories producing meat, milk, and eggs), is in stark contrast to the stated intent of Congress in the passage of OFPA — which was to consolidate various organic certification schemes under a single standard overseen by the USDA. The long legacy of the regulatory agency deferring to the judgment of individual certifiers is considered by many to be patently illegal.

To allow certifiers to choose the sections with which they will conform not only causes confusion and potentially gives users of forbidden vaccines a competitive edge, it encourages certifiers to act outside the law for expediency and in deference to the interests of their agribusiness clients. In all cases, vaccines produced using methods of genetic engineering/modification are clearly forbidden by the national organic standards and are currently excluded from use.

Lack of clarity: NOP position on the use of excluded method vaccines in organic livestock production

The **National Organic Standards Board** (NOSB) was established to provide recommendations to the Secretary of Agriculture that help shape organic standards. The members have a statutory responsibility to review substances and make recommendations about their use in organic production and processing. If the NOSB recommends adding a substance to the National List of Allowed and Prohibited Substances, USDA reviews the recommendation and determines whether to move forward with the rulemaking process.[6]

Unique in terms of federal advisory boards, the NOSB has real power. The USDA Secretary cannot add any synthetic substance to the National List without the explicit approval and recommendation of the board.

By 2019, confusion—and likely pressure from biotech and livestock industries–resulted in the NOP's Response to National Organic Standards Board Recommendations from the fall annual meeting recommending the recommended changes to the Use of Excluded Method Vaccines in Organic Livestock Production.

The NOSB passed a questionably legal formal recommendation on the issue of excluded method vaccines. It requested the NOP change the USDA organic regulations at § 205.105(e), from:

> *(e) Excluded methods, except for vaccines: Provided, That, the vaccines are approved in accordance with §205.600(a), to:*
>
> *(e) Excluded methods, except for vaccines: Provided, That, vaccines produced through excluded methods may be used when an equivalent vaccine not produced through excluded methods <u>is not commercially available</u>.* [7]

The NOP announced that the NOSB recommendations were under consideration.

At the same time, the NOSB Fall 2019: National Organic Program Update,[8] a presentation by Jennifer Tucker, Deputy Administrator, National Organic Program, displayed a slide clearly stating that the "**Excluded Methods definition in the USDA organic regulations does not allow for gene editing: it is prohibited**." And another slide showing a statement indicating that, "**changing the definition of Excluded Methods is not on the USDA regulatory agenda.**"

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[6] https://www.usda.gov/media/blog/2012/06/28/organic-101-role-national-organic-standards-board
[7] https://www.ams.usda.gov/sites/default/files/media/NOPResponsetoNOSB_Fall2019.PDF
[8] https://www.ams.usda.gov/sites/default/files/media/NOP-NOSB-Fall2019_Update.pdf

It can—and should—be argued that none of these interpretations can legally overrule the clear regulatory language on prohibited methods (genetic engineering) for use in organic production.

At the April 2023 NOSB meeting, the entire class of synthetic livestock vaccines, including those made with excluded methods, came up for sunset review, a process that revisits the addition of a material to the National List every five years. The final decision was that the NOSB "encouraged" the NOP to adopt the 2019 recommendation that vaccines produced through excluded methods may be used when an equivalent vaccine not produced through excluded methods is not commercially available.

Thus, neither the current status quo nor the proposed solution is currently legally compliant.

Are mRNA vaccines for livestock really the issue? Or is it broader than that?

While the term "mRNA" has become a triggering term, drawing recent attention and concern in the field of veterinary biologicals and in livestock husbandry in particular, there are a number of genetically engineered vaccines for livestock already on the market, including (but not limited to) those described as:

> Recombinant viruses, RNA particle vaccines, mRNA vaccines, DNA vaccines, Subunit vaccines, Antigens generated by gene cloning, DNA Plasmid Vaccines, Alphavirus Replicons (RNA vaccines), Gene-deleted Vaccines, Recombinant vector vaccines, or Platform or RNA Platform vaccines[9]

Confusion abounds in the US livestock industry about whether there actually are mRNA vaccines (developed using technology similar to that used to create the Covid 19 vaccine) currently available for veterinary use. The real issue here is the phrase "developed using technology similar to that used to create the Covid 19 vaccine." The method used to create Pfizer and Moderna vaccines is based on mRNA[10], but each is a unique method that would have been patentable had the World Trade Organization not adopted the Ministerial Decision on the TRIPS Agreement ("WTO Decision"), which provided for a partial waiver of intellectual property rights.[11]

In other words, creating new veterinary vaccines using the exact methods to produce Covid 19 mRNA vaccines would have had to be licensed by Pfizer and/or Moderna.

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[9] https://www.merckvetmanual.com/pharmacology/vaccines-and-immunotherapy/types-of-vaccines-for-animals

[10] https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/different-types-of-covid-19-vaccines/art-20506465#

[11] https://blog.petrieflom.law.harvard.edu/2022/11/08/what-happened-to-the-covid-19-vaccine-patent-waiver/#

On January 26, 2023, Jessica Gordon, a cattle veterinarian and associate professor at Michigan State University stated, "In livestock, there are no **mRNA vaccines** (emphasis added) that are used in the United States."[12]

At present, however, Merck Animal Health markets what it calls "RNA particle technology" to make swine flu and other virus vaccines customized to specific animal herd needs. That technology has been on the market since 2018, prior to the advent of the mRNA-based COVID-19 vaccine.[13]

And there is currently a research project in place at Iowa State University (project start 2021 through project end 2026) to test a novel mRNA system for inducing immunological protection from bovine RSV infection.[14]

Currently on the list of USDA Veterinary Biological Products (prepared Feb. 2, 2023) are two "DNA" novel vaccines[15]:

Avian Influenza Vaccine 1057.D0 H5 Subtype, DNA 605* - Poultry
Swine Influenza Vaccine 19A5.D3 DNA 605 - Swine

NOTE: The USDA considers the following "livestock:" Beef cattle, dairy cattle, buffalo, alpacas, deer, elk, emus, equine, goats, llamas, poultry, reindeer, sheep, and swine.[16]

USDA looking the other way—Consumer knowledge/education (intentionally) lacking

To date, there is no way for consumers to know or even understand whether genetically engineered "biologicals" (i.e., vaccines) are being used in livestock to produce USDA-certified organic meat, eggs, or milk. The agency should consider the following steps, with guidance from the NOSB, to ensure that meat, eggs, and milk from treated animals complies with federal statutes and the expectation of organic consumers.

1. Create a standardized categorization, with appropriate subgroups, incorporating understandable nomenclature of vaccine types for both vaccine users and for the general public.

2. Test all biologicals before approval for use, including an analysis of the persistence of any "foreign" DNA, RNA, or antibodies in meat, milk, or eggs at the time of consumption. Does there need to be a waiting period before harvest as is the case with certain drugs used in conventional production?

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[12] https://factcheck.afp.com/doc.afp.com.337U7PW
[13] https://www.merck-animal-health-usa.com/species/swine/sequivity
[14] https://portal.nifa.usda.gov/web/crisprojectpages/1027610-novel-mrna-vaccine-technology-for-prevention-of-bovine-respiratory-syncytial-virus.html
[15] https://www.aphis.usda.gov/animal_health/vet_biologics/publications/currentprodcodebook.pdf
[16] 7 CFR § 760.204 - Eligible livestock, honeybees, and farm-raised fish. | Electronic Code of Federal Regulations (e-CFR) | US Law | LII / Legal Information Institute (cornell.edu)

There is research showing the persistence of Covid 19 antibodies in human breast milk after the mother has been vaccinated.[17] In this case, these could be considered "desirable" antibodies, however there is no known research concerning the persistence of antibodies intended to protect animals from disease in the human food chain.

3. Develop a procedure to deal with vaccines that result in persistent animal or plant DNA in the meat, eggs, or milk destined for human consumption, which may include removing the vaccine from approval.

The real solution—protecting the public's interest and the reputation of the organic label

In this era of huge industrial CAFOs (confined animal feeding operations), the close proximity of thousands–if not tens or hundreds of thousands–of animals in a limited space creates an environment where contagious diseases and infections are potentially a high risk. Transporting animals between herds, a common practice on industrial-scale operations but atypical on many family farms and ranches, exponentially adds to the risk of spreading virulent pathogens.

Many veterinarians conclude that the risk of a highly contagious virus spreading throughout a herd is several orders of magnitude higher in a CAFO than at a family-scale farm where animals are allowed outdoors on pasture and able to exhibit their natural instinctive behaviors (all prerequisites for organic certification).

It could be argued that all vaccines are synthetic, whether produced through genetic engineering or not, and should therefore be listed as "restricted" materials only allowed for use when demonstrated risks warrant. True organic management and good animal husbandry mitigate risks to livestock health.

OrganicEye contends that the USDA should invest their time and money promoting the interests of farmers and ranchers complying with the spirit and letter of the law in terms of organic livestock management. This would create healthy animals in low-risk environments and reduce or eliminate the need for most vaccines and antibiotics.

[17] https://jamanetwork.com/journals/jamapediatrics/fullarticle/2786219