

**National Organic Standards Board
Livestock Subcommittee
Findings and Recommendation in Response to September 2010 NOP Memorandum
Livestock Vaccines Made With Excluded Methods - Proposal**

August 19, 2014

I. Introduction:

Vaccines are critical for the prevention of disease and to prevent needless suffering of livestock. For the vast majority of diseases for which a vaccine may be used there is a vaccine available which is not made with excluded methods. However, most certifiers do not require producers to document that the livestock vaccine used is not made with excluded methods. The National Organic Standards Board (NOSB), working with the National Organic Program (NOP), has spent considerable time over the last several years reviewing how best to address the issue of vaccines made with excluded methods in order to be in compliance with the Organic Food Production Act (OFPA) and the Regulations. The NOSB unanimously passed a resolution requesting that the NOP help obtain a comprehensive list, similar to the coded list of registered vaccines maintained by the Animal Plant Health Inspection Service (APHIS) that could be provided to the NOSB and certifiers, to help guide policy and practice. However, attempts to create such a list have not been successful. One key finding of our work to date is that the definition of “excluded methods” requires revision, and that the use of the term “GMO” (genetically modified organism), while commonly used, nationally and internationally, reflects an oversimplification. This document outlines the central issues related to vaccine use in organic livestock production, and notes that 7 CFR Section 205 allows for petitions for specific vaccines made with excluded methods. We also present the history of NOSB work to clarify apparent inconsistencies in practice, review in brief the complexity of the definition of “excluded methods”, reiterate some of the Working Group Interim Report, provide a synthesis of public comment received, comments on international vaccine use, and recommend that the NOP provides Guidance on this subject.

II. Background:

In 2009 the NOSB commented on the use of livestock vaccines. They noted that with no antibiotics used in organic livestock production, the basic measure of prevention through use of vaccines is critical to the health of the animals. They pointed out that all vaccines are produced in federally regulated and licensed facilities and in November 2009 the NOSB recommended that all vaccines be allowed, as practiced at that time, in order to prevent disease and needless suffering of livestock, with the caveat *“that vaccines made by non-excluded methods be used before those made by excluded methods”* (Board Vote: Yes-11; No-2; Abstain - 0; Absent- 2)

In September 2010 the NOP asked the NOSB to formally review GMO vaccines in accordance with the criteria in Section 205.600. The NOSB requested a Technical Report which would address the evaluation criteria as specified in the Act (7 U.S.C 6517 and 6518).

In November 2011 the Technical Report, “Vaccines made from Genetically Modified Organisms”, was received by the NOP. This document provided some critical information to the NOSB

The NOSB conducted a review of Vaccines made with excluded methods using the Checklist and criteria as specified at 205.600. The NOSB prepared a Proposal dated April 3, 2012, for public comment and possible vote at the Public Meeting in May 2012. This proposal included the following recommendations:

“This recommendation concerns the class of livestock vaccines derived from excluded methods, commonly called GMO vaccines. There are approximately 73 registered animal vaccines, of which 13 are GMO. Only 2 vaccines, Bovine and Avian Salmonellosis, appear to be presently available only as GMO. At present livestock producers use all vaccines and are not required to determine if they are using non-GMO (conventional) or GMO derived vaccines. GMO vaccines are not legally allowed in organic production. This recommendation proposes a change which will allow GMO vaccines only in a declared emergency and, further, that at such time producers could use GMO vaccines without losing organic status of livestock. The recommendation also proposes changes to the definition of “emergency treatment program”. The entire recommendation applies to the class of vaccines derived from excluded methods, but does not foreclose petitions for individual vaccines or a class of vaccines to treat specific diseases.”

Recommended Committee Action & Vote,

1. Modify language in 205.238 (6) as follows, change shown in italics.

Administration of vaccines and other veterinary biologics, *provided, vaccines produced with excluded methods, can only be administered in accordance with §205.105(e).*

2. Modify 205.105 (e) as follows: Excluded methods, except for vaccines: Provided,

(1) such vaccines are administered only due to a Federal or State emergency pest or disease treatment program, and

(2) such vaccines are approved in accordance with §205.600(a);

3. Modify language in 205.603(a)(4) as follows: Biologics—Vaccines, *provided, with regard to vaccines produced with excluded methods, the requirements of 205.105(e) are satisfied.*

4. Change the Definition of “Emergency pest or disease treatment program” in section 205.2 with the additions shown in italics.

Emergency pest or disease treatment program: *A mandatory program authorized by a Federal, State or local agency for the purpose of controlling or eradicating a pest or disease, except for a program requiring substances described in section 205.105(e) regarding only vaccines produced with excluded methods, in which case such program is defined as a mandatory treatment program authorized by a declared Federal or State emergency for the purpose of controlling a pest or disease.”*

Based upon public comment and the need for additional technical information before voting, the NOSB decided to table the proposal until a future meeting, but passed a resolution.¹ The resolution requested: 1) That NOP identify all vaccines registered with USDA as GMO or non GMO; 2) That Vaccine manufacturers voluntarily and truthfully label vaccines about their absence of GMO content; and 3) That the NOP or other USDA agency publish a real time tracking system to identify GMO and non GMO vaccines.

In response to the NOSB’s May 2012 resolution, the NOP convened the Vaccines Made With Excluded Methods (MWEM) Working Group. The working group included two members of the NOSB, NOP staff, and staff from the Center for Veterinary Biologics (CVB), the division in the Animal Plant and Health Inspection Service (APHIS) that approves and regulates vaccines for use in livestock and pets.²

¹ <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5098924>

² **Working Group Participants:**

In February 5 2013 the Working Group prepared an Interim Report summarizing its work, and this report was sent to the Livestock Subcommittee and subsequently was posted to gather public comment.

In April 2013 an update was provided at the Public Meeting.
(Note that there was no public meeting in fall 2013 owing to government shutdown).

In April 2014 the results of a pilot project analysis conducted by one certifier was presented as part of the Livestock Subcommittee report indicating that none of the vaccines used by livestock producers certified by that certifier were made with excluded methods according to verification received by the certifier from manufacturers. The NOSB requested further comment from certifiers.

In summer 2014 the Accredited Certifiers Association (ACA) conducted a simple survey amongst its certifiers which indicated that because of the considerable complexity of verification there is a lack of consistency nationwide in how certifiers are verifying that vaccines used in organic livestock production are not made with excluded methods.

III Relevant Areas of the Rule:

The USDA organic regulations at 7 CFR part 205 contain several references that are relevant to the discussion on the use of vaccines in organic livestock production.

The first reference, under the “Livestock healthcare practice standard”, requires that “the producer must establish and maintain preventive healthcare practices, including... administration of vaccines and other biologics” (205.238(a)(6)).

The second reference on the National List of Allowed and Prohibited Substances allows the use of livestock vaccines, which are synthetics as follows: 205.603(a)(4) as follows: “Biologics – vaccines” (205.603(a)(4)) (without annotation).

The third reference at 205.672 deals with emergency pest or disease treatment which is defined in 205.2 as a “mandatory program authorized by a Federal, State or local agency for the purpose of controlling or eradicating a pest or disease.” The OFPA Statute (7 USC 6506(b)(2)) refers to exemptions for organic “farms subject to a Federal or State emergency pest or disease treatment program.” This suggests that Congress did not intend to include locally declared programs. In the past, vaccines MWEM have been required as part of disease eradication programs. It is unclear as to the effects of these eradication programs on organic livestock producers.

The fourth reference is:

Section 205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.

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“To be sold or labeled as “100 percent organic”, “organic,” or “made with organic (specified ingredients or food groups)”, the product must be produced or handled without the use of:...

(e) Excluded methods, except for vaccines: *Provided*, That, the vaccines are approved in accordance with 205.600 (a).”

Section 205.600 (a) “Evaluation criteria for allowed and prohibited substances, methods and ingredients” specifies:

“The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List:

205.600(a) Synthetic and nonsynthetic substances considered for inclusion on, or deletion from, the National List of allowed and prohibited substances will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518)”.

Thus, under this section (205.105(e)), the use of excluded methods is prohibited in organic production.

To date the NOSB has not recommended any vaccines made with excluded methods be added to the National List.

Excluded methods are defined under the USDA organic regulations (205.2):

“A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions and processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing positions of genes when achieved by recombinant DNA technology). Such methods do not include traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture. “

The methods that are excluded and, thus, prohibited, are those 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.

IV Discussion:

The preamble to the final rule (65 FR 80554) in 2000 discussed the NOP’s response to comments about use of vaccines MWEM in organic livestock production. Some commenters wanted all vaccines MWEM to be completely prohibited from organic livestock production while others wanted all vaccines to be temporarily allowed until more information could be assembled in the future to determine if any of the vaccines MWEM were necessary for production. At the time, NOP chose to structure the provision so that vaccines MWEM could only be used by organic production if they are affirmatively included on the National List after review by the NOSB. But, with no information or guidance about how to identify vaccines MWEM, many organic livestock producers, with approval from their certifiers, have chosen vaccines based upon disease prevention and not based on whether they are made with excluded methods.

To rectify this divergence between regulatory language and industry practice, the NOSB, in 2009, recommended a change to section 205.105(e) to allow the use of vaccines made with excluded methods if vaccines made without excluded methods were not commercially available. That recommendation stated

that such a change would not require individual review of vaccines made with excluded methods. The NOP has not implemented this change into the USDA organic regulations. Therefore, the current exception at section 205.105(e) to allow vaccines made with excluded methods only applies to those that are reviewed according to 205.600.

In September 2010, the NOP requested that the NOSB review vaccines made with excluded methods (i.e. GMO vaccines or genetically engineered vaccines) in accordance with section 205.600.

The Livestock Subcommittee requested a Technical Review of GMO Vaccines which used the criteria found at 7 U.S.C. 6517 and 6518. The Livestock subcommittee drafted a proposal and submitted it to the full Board. The NOSB discussed the proposal pertaining to the use of vaccines MWEM at its May 2012 public meeting. The NOSB received considerable public comment on this issue leading up to and at this public meeting. Comment was split with members of the general public advocating for a prohibition on vaccines MWEM and certifiers and producers asking for more detailed information about current vaccine use and clarification about which vaccines were MWEM. Due to the need for additional technical information before voting, the NOSB decided to table the proposal until a future meeting, but passed a resolution that included a request for more information from USDA.

In response to the NOSB's May 2012 resolution, the NOP convened the Vaccines Made with Excluded Methods Working Group.

The Working Group first collected information regarding the use of vaccines, government programs that may require the use of vaccines, technical information about how vaccines are made and how vaccines are regulated. In response to requests from the NOP, CVB and Veterinary Services (VS) from APHIS elaborated on regulations that could require livestock producers to use vaccines. The working group's understanding is that the Secretary of Agriculture has the authority to declare emergencies at various levels depending upon the severity of the outbreak. Emergency declarations allow both state and the federal government to require livestock producers to use specific vaccines, including vaccines MWEM. The only regional emergency in the past decade was an Exotic Newcastle outbreak in unvaccinated backyard poultry and game fowl. No vaccination program was used in this emergency because USDA determined that most commercial poultry operations in the area, whether conventional or organic, had already vaccinated their birds for this disease.

The working group also learned that disease eradication programs authorized by the federal government may include mandated use of vaccines. The two recent eradication programs, Brucellosis in cattle and Pseudorabies in swine both required vaccines. These two eradication programs used vaccines that allow blood tests to differentiate between those animals that have an immune response due to the vaccine and those animals that have an immune response due to the disease. In order to differentiate between vaccinated animals and animals which had the disease, producers must use a modified live vaccine that results in a strong immune response, has mutations that alter at least one epitope and is not virulent. The Brucellosis vaccine was developed using cell culture passages, a presumably allowed technology in organic production. The Pseudorabies vaccines, several vaccines were approved for this eradication program, were developed using excluded methods. Based on discussions with APHIS, the working group believes that vaccines made with excluded methods may be USDA's preferred vaccine choice in future eradication programs.

APHIS' CVB regulates vaccines and vaccine manufacturers under the Virus-Serum-Toxin Act. CVB's primary role is to review and license vaccines based upon purity, safety, potency, and efficacy. CVB requires certain label terms depending upon specific configurations of the vaccine seed (form of the agent used to create

the vaccine). CVB also tracks vaccines that are made through the use of biotechnology. However, CVB's evaluation of whether a vaccine is produced through "biotechnology" does not align well with how "excluded methods" is defined under the USDA organic regulations. Because of this lack of alignment, it is difficult to know the extent to which vaccines on CVB's list of biotechnology derived vaccines overlaps with what could be considered produced through an "excluded method". CVB does review the use of biotechnology in manufacturing of the vaccines, e.g. if a vaccine is produced using cells made with excluded methods. However, if only the cell line used to culture the vaccine seed has a genetic insertion, deletion or other mutation, the vaccine itself is not considered to be a recombinant.

Finally, the working group could not identify a comprehensive path of "partial" alignment such that if a vaccine were identified as biotechnology derived by CVB then it is was definitely considered made with "excluded methods" as defined by the NOP.

It must also be noted that European organic standards allow the use of all vaccines if they are needed to prevent a disease in the area. Canadian organic standards forbid genetically engineered vaccines outright. In addition, Canadian organic livestock producers may only use a nongenetically engineered vaccine that was grown in a cell culture system that included genetic modifications if no other vaccine is available.

After considering background research, information from other USDA agencies and public comments, the Working Group came to the conclusion that developing criteria for certifiers and Material Evaluation Programs (MEPs) to use to identify vaccines MWEM would be the only approach to allow the organic industry to determine which, if any, vaccines made with excluded methods are being used and if there are reasonable alternatives to these vaccines.

The working group considered creating a list of all vaccines produced with (or without) use of excluded methods. This would be the easiest resource for organic livestock producers and certifiers to use. However, creation of a negative and/or positive list is difficult for a variety reasons, including the lack of precise criteria to decide whether something should be considered produced through excluded methods. Furthermore, for such lists to be useful, the lists would need to specify the branded vaccine products that livestock producers purchase and use, not just generic names of the disease or pathogen that is being used to create the vaccine. Another reason the working group chose not to create a list is that the CVB does not differentiate vaccines based upon excluded methods. USDA is concerned that creating such a list would imply a deficiency of vaccines MWEM, which would not be scientifically accurate within USDA's responsibility to regulate the purity, safety, potency, and efficacy of vaccines. The working group was also concerned 1) with liabilities due to the possibility of inaccurately placing a specific vaccine on a list, and 2) the possibility of not being able to obtain necessary vaccine manufacturing information, which is often submitted as confidential business information to APHIS CVB.

The working group identified criteria that would allow certifiers and MEPs to identify vaccines MWEM. The three criteria to be used in conjunction are:

- _Label Guidelines
- _Product Codes
- _Methods of Production Analysis

Label Guidelines: CVB regulations require that certain vaccine seed configurations have specific terms on the labels of branded vaccine products. These terms are required for a subset of biotechnology derived vaccines. While these terms are not added to the labels because an excluded method was used, CVB states that all such vaccines were created using methods that the NOP would exclude. The terms on labels that identify vaccines were made with excluded method are "Subunit," "Vector," and "Chimera." Because these

vaccines are labeled with the identified terms, CVB can disclose a trade names list for all of these vaccines.

Vaccines must be labeled with the term “Subunit” when the vaccine is an extracted or purified protein that was expressed in a recombinant system. These vaccines do not contain any genetic information (DNA). These vaccines only contain the protein antigen that induces an immune response. To create “Subunit” vaccines, the gene for the antigenic protein is inserted into an expression vector or expression system. The gene from the pathogenic organism may be expressed in prokaryotic or eukaryotic cell culture systems. The expressed protein is then extracted or purified and used in the vaccine. Currently there are no active licenses for subunit vaccines.

Certain modified live vaccines must be labeled with the term “Vector” or “Chimera” to denote that the vaccine contains DNA from two pathogens. These vaccines are created by identifying a viral structure that induces a strong immune response. This viral structure is termed the expression vector. In many cases, the expression vector is a virus that in its unaltered form can cause a disease in the target species. The vector will then have at least one gene from another disease causing agent inserted into the viral genome. Vaccines labeled with “Vector” may be efficacious against two diseases, the disease caused by the unaltered vector and the disease caused by the source of the gene that was inserted into the vector or only be efficacious against the disease caused by the source of the gene that was inserted into the vector. Vaccines labeled with “Chimera” are similar to “Vector” labeled vaccines, except that certain genes required for replication competency are supplied by the added genes and not contained in the expression vector.

Product Code: The CVB requires that every biologic, including vaccines, produced must have a product code. The CVB guide on true names and product codes notes that the 5th digit of the product code may contain “D” or “R.” The letter “D” in the fifth digit signifies that the vaccine is a nucleic acid vaccine. Such vaccines, also called DNA vaccines, are made with excluded methods and depend upon foreign genes being expressed in some of the cells of the vaccinated animals. The letter “R” in the fifth digit signifies the vaccine has a recombinant component or is a subunit protein derived from a recombinant organism. The recombinant designation only applies to components in the vaccine and not to methods used to make the vaccine such as genetically engineered cells that are used for cell culturing the vaccine seed.

In public comments, some certifiers stated that they were aware of the R code in the fifth digit of the product code as designating that a component in the vaccine was recombinant or recombinant-derived. However, these certifiers were not able to translate the product code information to actual vaccines on the market. CVB is unable to provide a list of the trade names of the vaccines with a “D” or “R” in the product code because confidential business considerations will not permit discussion of production methods, unless the biologics firm specifically agrees to disclose the information. The working group was unable to develop a method to identify the trade names of vaccines and other biologic products that have a D or R in the product code other than the trade names that are already identified as MWEM, e.g. are labeled as containing a “Vector” or “Chimera.” Vaccines that have a “D” or “R” in the product code may or may not be made with excluded methods since the production methods may not be identified for evaluation. The working group requested input from the NOSB and the organic community to identify methods of linking product codes to trade names in a manner that clearly identifies whether or not an excluded method was used. The pilot project by one certifier in 2013 and by the ACA in 2014 provided some analysis of the use of vaccines in practice.

Method of Production Analysis: Some firms have waived confidentiality by describing how the vaccines were made in public comment to the NOSB. However, some vaccines were and in the future may be made with methods that are not clearly excluded or allowed in organic production. The working group requested

input from the NOSB and the organic community to provide comments on this issue.

Modified live vaccines generally have been found to produce greater immune responses in vaccinated animals and have become more common in new vaccines than killed vaccines. Live vaccines require that the genome of the disease causing organism be modified to create a living, but not virulent, pathogen which can be packaged in the vaccine. The excluded methods definition (205.2) includes methods which genetically modify organisms or influence their growth and development by means not possible under natural conditions or processes which are not considered compatible with organic production. The definition identifies some of the methods that are excluded including recombinant DNA technology (gene deletion, gene doubling, introducing a foreign gene and changing the positions of genes when achieved by recombinant DNA technology). The definition states that some methods to genetically modify organisms are allowed, including traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization or tissue culture.

Many of the older non-biotechnology derived modified live vaccines were made by using bacterial culture, cell culture or tissue culture with multiple passages to induce genetic modifications, including gene deletions, to the disease causing pathogen. The various cultures were then screened to identify a modified version that induced an immune response but that was no longer virulent. This is a process of random genetic modification followed by screening for the desired phenotype. The Brucellosis vaccine that is part of the Brucellosis eradication program was produced by growing the parent strain in various concentrations of an antibiotic cocktail over several passages to induce random mutations in the genome of the bacteria. These random mutations resulted in a non-virulent bacterial strain that did not produce the O-chain component of the lipopolysaccharide that was one of the epitopes for immune response. This change in at least one epitope was required for eradication programs so that vaccinated animals could be differentiated from animals infected by the actual pathogen.

The working groups assumed other genetic modification methods that would be allowed are exposure to chemical or physical mutagens. Physical mutagens include ionizing radiation, UV radiation and radioactive decay. These mutagens create genetic modifications in a random manner through a variety of ways. Some chemical mutagens break the double stranded DNA, allowing a recombination event to occur which can cause gene deletion and changing the position of genes. Other mutagens cause DNA bases to switch to other bases, errors in DNA repair or errors in replication. These mutagens all genetically modify organisms in a random manner that is not targeted. Generally, the vaccines working group considered chemical and physical mutagens to be traditional breeding techniques. Biological mutagens are excluded if they are considered to be a recombinant technology. Recombination is the process by which double stranded DNA is broken, rearranged and then rejoined. Recombination naturally occurs between chromosomes during the process of meiosis to form gametes for sexual propagation, in plants, animals and other organisms. Recombination naturally occurs during high frequency recombinant (Hfr) conjugation in which part of the chromosome from one bacterium is transferred to another bacterium, resulting in homologous recombination which genetically modifies the target bacteria. These are just two examples of genetic modifications through recombination events which are allowed by the current definition of excluded methods.

Some biological mutagens are clearly excluded by the current definition. Restriction enzymes are naturally occurring proteins in many bacteria that will cleave DNA at specific sequences. These enzymes are defense against phage (viruses that target bacteria) which insert their genetic material, usually but not always DNA. Restriction enzymes have been used to cleave a gene of interest and then through a targeted recombination event create a specific gene deletion, clone the gene in a vector or cause a changing of positions of genes in a controlled, nonrandom manner.

Other biological mutagens are neither explicitly allowed or excluded and may be allowed when used one way but not when used in a different way. Specifically, the working group discussed the methods used to create a vaccine which the manufacturer has stated, in public comments to the NOSB, was not made with excluded methods. This particular gene-deleted product was created using transposons and phage transduction. Transposons and phage transduction both result in genetic modifications mediated through recombination events. However, the working group was divided as to whether or not these methods were excluded. Are these methods considered traditional breeding techniques?

Transposons, also called transposable elements are naturally occurring, double stranded DNA sequences with a defined structure. Each end of the transposon includes inverted repeats. In prokaryotes, the internal structure includes at least one gene for transposase and may contain many more depending upon the type of transposon. Genes for antibiotic resistance, one example of the types of genes within the transposon occur both naturally and sometimes as a marker in lab modified transposons. When the transposase gene is expressed, the protein binds to the inverted repeats of the transposon, cleaves the genomic DNA and excises the transposon. Transposase can then cleave the genomic DNA at another spot and recombine the transposon into a new position in the genome.

In order to evaluate the use of transposons in vaccine production, the working group considered if transposons would fit into the allowance for traditional breeding techniques. The working group was not clear at which point traditional breeding techniques are divided from modern or non-traditional breeding techniques. Is there a time point at which all techniques before that time are considered traditional and all new techniques developed after that time are not considered traditional? The definition of excluded methods allows all traditional breeding techniques, so the distinction is important for organic producers.

The other method used by the vaccine manufacturer under discussion was transduction, which is the process through which the genomes of bacteria can be modified with the use of bacterial virus, called a phage. Some types of phage attach to the bacterial cell wall and insert the viral genome into the cell. The viral genome may then be inserted into the bacterial genome through a recombination event which is part of the lysogenic cycle. After receiving a trigger, the viral genome will be excised and the lytic cycle will be triggered. The excision of the viral genome is not perfect and in some cases, parts of the bacterial genome will be excised and packaged into the new phage. The phage can then be used to infect additional bacteria. The bacterial genetic material in the phage will be inserted into the newly infected cell. A homologous recombination event may occur so that some of the genes from the originally infected cell's genome will replace the genes in the newly infect cells. This method can stably introduce genetic mutations into the new bacteria.

The working group did not come to a decision about the status of vaccines developed using these methods. Certifiers and MEPs who examine vaccines for compatibility with the organic regulations will need guidance on future determinations of other vaccines as well.

Public Comment on the Interim Report of the Working Group, and the subsequent efforts of Certifiers to clarify how to verify use of vaccines not Made With Excluded Methods, clearly reflects the frustration of certifiers and producers seeking to be fully compliant with the regulations, while needing to ensure the health of organic livestock.

Here are some samples of public comment:

“Any expectation of verifying vaccines made with excluded methods will need a clear and practical framework of how to determine compliance. Even with a stricter rule regarding GM vaccine use, there will likely need to be some exceptions because some critical vaccines are only available from GM sources.”

“We find that the technology itself is quite difficult for the layperson to understand, and phrases such as “excluded methods” and “traditional breeding” are surprisingly challenging to define. “

“One of the most difficult aspects of understanding the use of genetic engineering in vaccines is the lack of disclosure to the public or public understanding about these techniques. Without government regulation and increased disclosure, it will be very difficult for organic agriculture to make strides in the goal of refraining from the use of vaccines developed using excluded methods.”

“Developing a clearer definition of “excluded methods,” although outside of the scope of the Vaccines Working Group’s Interim Report, was discussed as an option in that report.”

“It seems clear that the definition needs to be revised. Certifiers experience difficulty interpreting “excluded methods” at present, especially because the language of the NOP’s definition does not always align with the language used by vaccine manufacturers. However, revision of terminology must be done extremely carefully. We ask that, in any revision of the definition, or tightening of restrictions on vaccines, be done with consideration of the following questions:

- 1) GE is an evolving technology. How are producers, veterinarians, certifiers, and the NOP to keep up with the knowledge needed to interpret these evolving techniques?
- 2) When considering implementation of a stricter rule with regard to GM vaccine use, how far back into the development or manufacture of a substance should the excluded methods prohibition apply? How far back is practical and verifiable? As indicated in the recent discussion document, many challenges exist in this area.”

“We are informed that Canadian Organic Standards prohibit all GE vaccines. How are Canadian certifiers able to verify this, especially given the international nature of the pharmaceutical supply chain? In terms of implementing a system of transparency in this area, is there anything we can learn from Canadian certifiers?”

“In the case that a reliable system of disclosure is developed and implemented, it will be essential for the National List to include certain vaccines that, while essential, are not available except through genetic engineering. One of our foremost concerns is a Salmonella vaccine for poultry. We also need to take into account emergency situations and eradication programs that may require the use of vaccines developed by excluded methods. Overall, food safety needs to be our largest concern.”

“In our experience, it is too much to expect certifiers and material review organizations to be able to analyze the effects of each method to determine if the genetic modifications are random or targeted. In order to make this determination on a consistent basis, the organizations would have to have geneticists or equally qualified staff. This is simply too difficult to achieve on a regular basis, given the amounts of vaccines and combinations of brand names that certifiers have to review every year. Thus, it is logical to suggest that a given technique should be declared excluded or allowed.”

“Vaccines are also used in other countries as well. Those vaccines are regulated and labeled differently internationally and we cannot expect that international certifiers should be held to different standards. Please consider the international implications of any final recommendation that the livestock subcommittee proposes.

A veterinarian commented: “The working group is to be commended for their extensive work on this subject. The relevant issues have been identified and described. The group has solicited input from certifiers and the greater organic community. This is not a simple topic with clearly defined boundaries and limits. I encourage the NOSB and NOP to approach this area with a system of regulation that is not rigid but will be open to further review and rule modification as time progresses and technology continues to evolve.”

In summary: Organic livestock producers, certifiers and material evaluation programs can, theoretically, identify certain vaccines as being produced with excluded methods by the presence of the words “chimera,” “vector,” or “subunit” on the label of the vaccine. However, in practice, this is an extremely difficult process, and thus there is lack of consistency in verification that livestock vaccines used in organic livestock production are not Made with Excluded Methods. Given this complexity and the need for revision of the definition of excluded methods, as detailed in this report, NOP Guidance is needed on how to make a determination of whether a vaccine has been produced with Excluded Methods. Actions could eventually include a rule change. It is certainly clear that the definition of excluded methods seems to be a less than ideal fit with vaccine production methods.

Motion: The Livestock Subcommittee requests that the NOP review this document and provide Guidance to the NOSB, certifiers and MRO’s on the use of Vaccines MWEM in organic Livestock production.

Motion by: Jean Richardson

Seconded by: Colehour Bondera

Yes: 6 No: 0 Abstain: 0 Absent: 2 Recusals: 0

Approved by Tracy Favre, Subcommittee Chair, to transmit to NOSB, August 26, 2014