National Organic Standards Board
Livestock Committee
National List Proposal
Vaccines from Excluded Methods

April 3, 2012

Summary of Proposed Action:
See attached document Recommendation of Livestock Committee, on Vaccines derived from Excluded Methods, dated March 24, 2012
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.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)	**Criteria Satisfied? (see "B" below)**
1. Impact on Humans and Environment	Yes X No ☐ N/A
2. Essential & Availability Criteria	Yes X No ☐ N/A
3. Compatibility & Consistency	☐ Yes X No ☐ N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for § 205.606)	☐ Yes ☐ No X N/A

Substance Fails Criteria Category: [1, 2, 3] **Comments:** 1. and 2. fail because of the necessity to evaluate individual vaccines on a case by case basis. 3 fails because vaccines derived from excluded methods are not consistent with organic agriculture

Proposed Annotation (if any): 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*.

Basis for annotation: ☐ To meet criteria above ☐x Other regulatory criteria ☐ Citation
Notes:

Recommended Committee Action & Vote, including classification recommendation (state actual motion):
1. Modify language in 205.238(a) (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*.

Classification Motion: Vaccines are already classified as synthetic on the National List at section 205.603, Synthetic substances allowed for use in organic livestock production. The Committee did not propose to reclassify the substance.
Motion by: N/A Seconded by: N/A
Yes: # No: # Absent: # Abstain: # Recuse: #

Listing Motion: To accept the recommendations of the committee for listing, as above:
Motion by: Colehour Bondera Seconded by: Jean Richardson
Yes: # 5 No: # 0 Absent: # 3 Abstain: # 0 Recuse: # 0

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.*

Refine definition of Emergency pest, disease, and treatment program Motion:
Motion by: Nick Maravell Seconded by: Jean Richardson
Yes: # 8 No: # 0 Absent: # 0 Abstain: # 0 Recuse: # 0

Crops	☐	**Agricultural**	☐	**Allowed[1]**	**X**
Livestock	**X**	**Non-synthetic**	☐	**Prohibited[2]**	☐
Handling	☐	**Synthetic**	**X**	**Rejected[3]**	☐
No restriction	☐	**Commercial unavailable as organic**	☐	**Deferred[4]**	☐

[1]Substance voted to be added as "allowed" on National List to § 205.603 with Annotation (if any): Biologics—Vaccines*, provided, with regard to vaccines produced with excluded methods, the requirements of 205.105(e) are satisfied*.

[2]Substance to be added as "prohibited" on National List to § 205. with Annotation (if any):

Describe why a prohibited substance:

[3]Substance was rejected by vote for amending National List to § 205. . Describe why material was rejected:

[4]Substance was recommended to be deferred because
If follow-up needed, who will follow up:

Approved by Committee Chair to Transmit to NOSB

Wendy Fulwider, Committee Chair **April 3, 2012**

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment? Substance: Class of vaccines derived from excluded methods

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]			X	
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		The TR (lines 248-255) finds that any effects would be similar to conventional, non-GMO vaccines. The impact of any environmental contamination will be specific to each individual vaccine and difficult to address for a whole class.
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		This is difficult to address since this review addresses a broad class of materials, but the TR at line 217 finds that GMO vaccines are not expected to persist in the environment any longer than traditional vaccines.
4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]			X	
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		Generally any vaccines causing adverse reactions would not be allowed on the market unless risks were mitigated (TR at lines 263-264)
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		GMO and conventional vaccines are evaluated for side effects by manufacturers and results are similar (TR at lines 287-290). It is difficult to answer such question for a class as a whole.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		As cited above, and it is difficult to answer this except on a case by case basis rather than as a whole class.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		As cited above, and it is difficult to answer this except on a case by case basis rather than as a whole class
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		Vaccines, both conventional and GMO, are short lived in the environment (TR)

10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]		X		The TR (lines 307-323) finds that all vaccines are evaluated for potential risk to human health risk before being licensed; such risk is minimal. It is difficult to conclusively answer this with reference to an entire class of vaccines.
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]			X	
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]			X	
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]			X	

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 2. Is the Substance Essential for Organic Production? Substance: class of vaccines derived from excluded methods

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	X			All vaccines, both conventional and GMO, are formulated by a chemical process (discussion with manufacturers)
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]	X			All vaccines, both conventional and GMO, are manufactured or extracted from naturally occurring sources (discussion with manufacturers, and TR)
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		GMO vaccines are derived from excluded methods, not created by naturally occurring biological processes (TR and discussions with manufacturers.)
4. Is there a natural source of the substance? [§205.600 b.1]			X	
5. Is there an organic substitute? [§205.600 b.1]			X	
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X	X		At present conventional vaccines are available for all but 2 diseases, avian and bovine salmonellosis (TR line 416 Table 1.)
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			X	
9. Is there any alternative substances? [§6518 m.6]	X	X		At present conventional vaccines are available for all but 2 diseases, avian and bovine salmonellosis (TR line 416 Table 1.) In addition there are homeopathic substances available (TR)
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X	X		Depending upon each vaccination on a case by case basis. Management practices might have an influence on whether the substance is necessary.

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 3. Is the substance compatible with organic production practices? Substance: class of vaccines derived from excluded methods

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]			X	
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]		X		Based on extensive comments received during the formulation of the NOP regulations in 2000 and in response to USDA's questions posed to the public, excluded methods, also known as GMOs, were not considered consistent with an organic production and handling system.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X	X		This would have to be determined on a case by case basis.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			X	
5. Is the primary use as a preservative? [§205.600 b.4]			X	
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]			X	
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;		X		
b. toxins derived from bacteria;	X	X		Generally No (discussion with manufacturer), but this would need to be determined on a case by case basis
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		X		
d. livestock parasiticides and medicines?	X			
e. production aids including netting, tree wraps and		X		

seals, insect traps, sticky barriers, row covers, and equipment cleaners?				

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)] **Substance: vaccines derived from excluded methods**

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?			X	
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?			X	
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?			X	
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?			X	
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following: a. Regions of production (including factors such as climate and number of regions);			X	
b. Number of suppliers and amount produced;			X	
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;			X	

d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
e. Are there other issues which may present a challenge to a consistent supply?			X	

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Livestock Committee Proposal
Expanded narrative on Vaccines derived from Excluded Methods
March 24, 2012

SUMMARY
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 or GMO 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 vaccines as a class but does not foreclose petitions for individual vaccines or a class of vaccines to treat specific diseases.

I Introduction
At the present time organic livestock producers are allowed to use all vaccines as provided in 205.105 (e) and 205.603 (a)(4). Genetically Modified Organism (GMO) vaccines, also referred to as vaccines derived from "excluded methods" in regulation, are not currently allowed in organic production. The National Organic Progam (NOP) received advice from the USDA General Counsel that GMO vaccines could only be allowed if specifically added to the National List. Currently, GMO vaccines are not on the National List.

II Background
Vaccines are used by a majority of organic livestock producers throughout the various geographic regions of the U.S. The use of vaccines is considered critical to disease prevention. A significant number of organic livestock producers do not routinely use vaccines, especially for smaller poultry flocks and for closed herds.

"All vaccines" includes, de facto, both GMO and non-GMO derived vaccines.

The use of genetic engineering is prohibited in organic production and handling under the NOP regulations. However, on most organic farms the producer does not ask if the vaccine to be administered is GMO or Non-GMO.

Producers are presently not required to ask to document use of GMO vaccines.

Since implementation of the NOP regulations in 2002, certifiers were routinely allowing all vaccines. Thus, in November 2009 the NOSB recommended that if non-GMO vaccines were not commercially available, then a GMO vaccine would be allowed, as practiced at that time.

Nonetheless, consumers continue to assume that all organic products reaching market are Non-GMO in production and handling.

III Relevant Areas of the Rule
Section 6509 (d)(1)(C) of the Organic Food Production Act (OFPA) of 1990, authorizes the use of vaccinations as an allowed healthcare practice in the production of organic livestock.

This authorization was implemented in Section 205.238(a)(6) “Livestock health care practice standard” which requires that “producers must establish and maintain preventive livestock healthcare practices including: …(6) the administration of vaccines and other veterinary biologics”.

In 2002 the NOP implemented Section 205.603(a)(4) “Synthetic substances allowed for use in livestock production.” This section lists without annotation, “Biologics-Vaccines.”

Section 205.105 – “Allowed and prohibited substances, methods and ingredients in organic production and handling,” states, in part, as follows:
“To be sold or labeled as “100% organic”, “organic”, or “made with organic”... the product must be produced and handled without the use of :....(e) Excluded methods, except for vaccines: Provided, that the vaccines are approved in accordance with 205.600(a).”

The phrase “excluded methods” is defined in section 205.2 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 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 relevant Section 205.600(a)“Evaluation criteria for allowed and prohibited substances, methods and ingredients” states: “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)”.

A Technical Report (TR), dated November 29, 2011, entitled “ Vaccines Made from Genetically Modified Organisms - Livestock” utilizing the criteria as specified in the Act (7 USC 6517 and 6518) has been submitted to the NOSB.

Thus the NOSB is now in a position to clarify whether the use of GMO vaccines as a class of substances is allowed or prohibited under the requirements stipulated in 205.105(e), and 205.600 (a).

IV Discussion

1. Should the present practice allowing use of all livestock vaccines, whether GMO or Non-GMO, continue?
The current regulation has a provision for a Federal or Sate emergency pest or disease treatment program (section 205.672). Plants and animals treated with a prohibited substance are taken off the market--plants and meat animals may not be sold as organic. Milk animals must wait one year before the milk can be labeled organic. For mammalian brood stock, newborns must be from livestock under continuous organic management from the last third of gestation to be labeled organic. The organic operation does not loose it certification, but the loss of certified organic plants and animals for sale could lead to immediate economic ruin.

Previous NOSB Action in 2009

The text of the Livestock Committee recommendation adopted by the NOSB on November 5 2009 is in italics:

> §205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.
>
> To be sold or labeled as “100 percent organic”, “organic”, or “made with organic” the product must be produced and handled without the use of:
>
> (e) Excluded methods, except for vaccines***, Provided, that, vaccines made from non-excluded methods are used if commercially available.***

The livestock committee summary rationale in 2009 was:

> Previously, vaccines made by excluded methods were to be individually petitioned to the Board for allowance or prohibition for use. In reality since implementation of the Rule, certifiers have routinely allowed all vaccines, since they are used to prevent disease and needless suffering of animals. This recommendation will more closely align what has been occurring in the field since 2002. However, it will actually make it encumbent[sic] upon the producers and certifiers that vaccines made by non-excluded methods are located and used before those made by excluded methods can be used.

NOP 2010 Response to the NOSB 2009 Action

The NOP responded to this NOSB recommendation on September 30, 2010, in part, as follows:

> The preamble to the National Organic Program final rule (FR Vol. 65, No. 246, page 80554) states:
>
> > The Act allows use of animal vaccines in organic livestock production. Given the general prohibition on the use of excluded methods, however, we believe that animal vaccines produced using excluded methods should not be allowed without an explicit consideration of such materials by the NOSB and without an affirmative determination from the NOSB that they meet the criteria for inclusion on the National List. It is for that reason that we have not granted this request of commenters but, rather, provided an opportunity for review of this narrow range of materials produced using excluded methods through the National List process.
>
> The NOP’s understanding is that excluded methods are prohibited under Section 205.105(e) *except for* vaccines. Further, this exception applies to vaccines that are produced through excluded methods only if those GMO vaccines are approved according to 205.600(a). Vaccines are listed under 205.603(a)(4) under ―Biologics-Vaccines‖. The NOSB has not reviewed vaccines in accordance with 205.600(a). The listing under 205.603(a)(4) of Biologics-Vaccines does not include the allowance of GMO vaccines. The NOP requested a legal review from USDA’s Office of General Counsel (OGC) to determine whether vaccines produced through excluded methods are currently allowed under 205.603(a)(4). The OGC opinion supports the position that GMO vaccines are allowed only if they are approved according to 205.600(a).
>
> The NOP recommends that the NOSB review GMO vaccines under the provisions of 205.600(a).

2.If GMO vaccines are allowed ONLY if non-GMO vaccines are unavailable, or commercially unavailable, how can vaccines be identified by GMO content or origin.?

APHIS List
The Animal and Plant Health Inspection Service (APHIS) maintains a periodically updated list of all registered vaccines with coded alpha-numeric annotations that could allow a certifier or a producer to identify which individual vaccines are produced with GMO methods. Most producers are not aware of this list and the coding on the list requires some skill to use properly. In addition, most vaccines are given as combinations of vaccines which makes cross checking with the APHIS list a complex process.

Direct Inquiry
Some large livestock producers, such as Albert Straus of Straus Family Creamery in California, currently take on the responsibility of asking the manufacturer for a letter of non-GMO origin for vaccines. This approach may be less feasible for small producers: will manufacturers want to answer hundreds of inquiries? Also, could a certifier verify the information, and how "current" or up-to-date does the manufacture's letter have to be? Vaccines change on a constant basis to reflect new strains of disease and other factors. These are issues that might be addressed in guidance by the NOP.

Combinations of Vaccines
Because multiple vaccines are often combined into one dosage, a single GMO vaccine could rule out the administration of 6 other non-GMO vaccines, if the non-GMO vaccines were not available in singular or non-GMO formulations. The TR did not identify vaccines that would be unavailable in non-GMO form due to the combination of vaccines.

3. Should GMO vaccines be allowed ONLY in “extraordinary” circumstances?

Relieving economic hardship in the event of emergency treatment programs
The option of allowing GMOs in emergency treatment programs would change current policy. Under current policy, GMO vaccines are not permitted at all, as the NOP outlined. If they were required as part of an emergency treatment program, then organic producers would be penalized by having the affected products taken out of organic status, creating economic hardship beyond the control of the organic livestock producer, but in the furtherance of a larger public policy goal for all livestock producers. Creating an exception to allow GMO vaccines in organic production in cases of an emergency treatment program, and allow livestock to retain their organic status would relieve the economic hardship or the prospect of destroying entire organic herds or flocks if non-GMO vaccines were not located in time.

Use of GMO vaccines if non-GMO vaccines are not commercially available
In the alternative, the proposal put forward by the NOSB in 2009 would allow GMO vaccines if non-GMO vaccines were simply not commercially available. Under this scenario also, there would be no penalty to the organic product. The use of GMO vaccines would be permitted in the absence of either 1) a declared emergency treatment program, or 2) an indication that a specific vaccine was needed.

Commercial Availability
Commercially available also presents some issues because many “off-the-shelf” and prescribed commercially available vaccines are not effective or not as effective as desired because diseases evolve new strains. It is also difficult to tell whether two vaccines, one GMO and one non-GMO, are functionally equivalent for a specific livestock operation.

Autogenous, or customized, vaccines are prepared from microorganisms which have been freshly isolated from the lesion of the animal which is to be treated with it. These vaccines are

not “commercially available’ in the sense that they are already developed and ready for administration for any given livestock population.

Autogenous vaccines do not appear on the APHIS list. They are subject to different USDA licensing requirements. Autogenous vaccine regulations do not require confirmation of 1) efficacy, 2) potency correlated to efficacy; or 3) host-animal safety data submitted to the USDA prior to product licensure and use.

Variances
A variance cannot be granted for a prohibited substance, ingredient, or method (excluded methods). The current regulations contemplate a possible exemption for GMO vaccines from being an excluded method--hence no variance would be needed. However, GMO vaccines would have to be added to the National List, which they currently are not.

4. Should GMO vaccines be prohibited in livestock production and handling?
The Livestock Committee has concluded that at this point in time there is not enough evidence of essential need to allow GMO vaccines as a class of substances for all diseases in livestock production, except in cases of a declared emergency. A declared emergency may emanate from acts of bio-terrorism or from outbreaks of diseases of major significance or foreign animal diseases. Nothing in the Committee recommendation is intended to preclude the possibility of successful future petitions to the NOSB for specific GMO vaccines or for GMO vaccines as a class for specific animal diseases.

The NOSB should recommend policy based on what is consistent with an organic system of production rather than administrative and enforcement exigencies.

A key factor regarding GMO vaccines is: are we making the decision based on the proper considerations. The NOSB is a policy body, not an administrative or enforcement body. The NOP is responsible for administering and enforcing policy related to GMO vaccine use.

It is the NOSB responsibility to consider, among other things, whether the use of GMO vaccines would be consistent with an organic system of production or considered essential to organic production. In general, GMOs are considered “excluded methods” and not consistent with organic production. In addition information in the TR and information received from other sources in the field did not indicate that GMO vaccines were essential to organic production at this time.

Any recommendation providing an exception to the general policy should not be unduly influenced by administrative and marketplace factors such as 1) currently many certifiers and producers do not know which vaccines are derived from excluded methods 2) current public policy chooses not to identify by label which vaccines contain GMOs or are derived from excluded methods, 3) the larger marketplace may not take GMO status into account in deciding how to produce and market vaccines, and 4) speculatively, some future unknown diseases of non-emergency proportions or new strains of diseases may be addressed by manufacturers with GMO only vaccines.

Further, NOSB recommendations should not be limited by current USDA and FDA discretionary policy that does not require labeling of GMO content because GMOs are considered "functionally equivalent" to non-GMOs. It is clear GMOs are not functionally equivalent in the eyes of the consumer in the organic marketplace and in the legal interpretation of NOP

regulations.

Difficulties in enforcement
The Livestock Committee recognizes several administrative factors making it difficult to manage and enforce a non-GMO vaccine policy, including: 1) a lack of access to an easily identified and up-to-date list of which vaccines are of GMO origin, and 2) a lack of access to an easily identified and up-to-date list of the availability of non-GMO vaccines for all livestock diseases. Given that there are approximately 73 APHIS registered animal vaccines (livestock, feral animals and pets) and only 13 (or 18 %) are thought to be livestock GMO vaccines, the construction of a usable list of GMO and non-GMO livestock vaccines is quite possible. The basic data should be in the APHIS list.

In addition, the TR describes the current state of GMO vaccine use in organic production as follows:

> Because organic certifying agents generally do not consider GMO status, no data are available on how many GMO vaccines are being used in organic production at this time.

Determination of Excluded Method
Because the NOP regulations do not use the words genetically modified organism(GMO) or "genetically engineered"(GE), we are concerned with "excluded methods." A method is usually a process rather than a material or product. As such, how do we evaluate excluded methods when looking at vaccines? Are we looking at the entire method of producing a vaccine? Does the method include all of the materials and steps necessary to produce the vaccine? If any of those methods, steps, or materials resulted from excluded methods (such as a GMO produced substrate that does not remain in the final product or is not the "active" ingredient), then do we conclude the vaccine is a GMO--a result of a process that used excluded methods?

From a purely policy perspective, it would seem that any use of excluded methods could be interpreted to mean that a vaccine is of GMO origin. This interpretation would mean that if a vaccine were only grown in a substrate from a GMO product (e.g. corn), it would be classified as a GMO vaccine even though no GMO substance remained in the finished vaccine. It is highly unlikely that the APHIS list would ever be detailed and precise enough to make these distinctions, since APHIS is not tasked with administering or enforcing organic certification. This conclusion could also lead to an unknown GMO status for a large number of vaccines. The committee recommends that NOP guidance specify that the information from the APHIS list of registered vaccines be used to determine GMO or non-GMO status.

Definition of emergency treatment program.
Background

Organic Foods Production Act of 1990 (OFPA)
OFPA 7 U.S.C. 6506 (b)(2) only confers on the Secretary the power to

"provide for reasonable exemptions from specific requirements of this title … on certified organic farms if such farms are subject to a Federal or Sate emergency pest or disease treatment program." (Complete quotation is included below) No mention is made of "local" or "eradication" programs.

Maryland Department of Agriculture

Committee research indicates that Maryland and most states have very broad powers to enforce eradication programs without ever declaring a state of emergency. If the intent of a recommendation for GMO vaccines in organic production were to limit their use to major outbreaks and to diseases of major significance or foreign animal diseases, such as hoof and mouth disease, then it would be appropriate to require a declared state of emergency. Requiring a declared state of emergency would definitely limit the use of GMO vaccines to major events.

In Maryland and other states, the Secretary of Agriculture would have to go the Governor to declare a state of emergency because only the Governor has such authority. In some states the chief agricultural officer may be able to make a declaration of emergency. A local agency would be unlikely to have the authority to declare an emergency, and in Maryland no local agencies have that authority.

The Secretary of Agriculture in Maryland could not recall a case of a vaccine ever being required within the Maryland. However, they have the authority to investigate outbreaks and to require treatment as necessary without declaring an emergency. It is also possible that they could require animals entering the State to have been vaccinated for a specific disease known to be a problem from the livestock's point of origin, although they were not sure that situation had ever occurred.

National Organic Program

The NOP currently administers the emergency treatment program provision in the regulations, responding to declared emergencies by an appropriate State official, and all products which are touched by or which received a prohibited substance are no longer eligible to be sold as organic, although the organic operation did not lose its certification.

It was noted that there is a discrepancy between section 205.672 "Emergency pest or disease treatment" and 205.2 "Definitions—Emergency pest or disease treatment program." This is a potential legal ambiguity. Which provision would be controlling, since they say different things?

It is advisable to change the Definition, section 205.2, "Emergency pest or disease treatment program:" (see language in recommendation section at end of document).

1) to comply with the statutory authority in 7 U.S.C. 6506 (b)(2);

2) to clarify any potential legal ambiguity in the reading of 7 CFR 205.672 "Emergency pest or disease treatment" with 7 CFR 205.2 "Definitions-- Emergency pest or disease treatment program;"

3) to reflect what appears to be the current NOP practice and ;

4) to accurately reflect the intent of the NOSB Livestock Committee recommendation on the use of vaccines derived from excluded methods.

Some central questions not completely addressed by the TR

1)WHAT SPECIFIC DISEASE PROBLEM(S) CAN ONLY BE ADDRESSED WITH A GMO VACCINE?

The TR does not point to a single or narrow group of problem diseases in organic livestock that

are creating hardship and urgently need to be addressed with GMO vaccines. Rather than addressing specific vaccines for specific diseases, we are addressing vaccines as a class of substances used in an organic livestock healthcare program. The TR seems to identify two diseases for which a GMO only vaccine is available: 1) Avian Salmonellosis and 2) Bovine Salmonellosis. For salmonella, improved management practices are often the first line of defense, with vaccination as an option if the disease cannot be controlled by management practices alone. Due to the changeable nature of Salmonella, finding an effective vaccination for a specific herd or flock may be challenging and may require customizing the vaccine.

2)WILL CREATING A GMO EXCEPTION LEAD TO LEGAL AMBIGUITY, PERCEPTIONS OF UNFAIRNESS, OR SUCH FREQUENT USE THAT IT LEADS TO POTENTIAL ABUSE?
The exception(s) created are to be narrowly construed and not used as a precedent for allowing excluded methods (GMOs) elsewhere in organic production or handling, unless specifically authorized, vigorously reviewed by the NOSB and NOP, and subject to public comment.

The intention with regard to organic use of GMO vaccines is that they should be legal, fair, and rare. The Committee feels its recommendation meets these tests.

Legality
The use of GMO vaccines, to the extent allowed in organic in emergency treatment programs, has to be clearly and understandably legal--a producer/consumer/certifier/public agency must be able to read and understand the policy easily and not have it subject to questions that could lead to legal challenges.

Fairness
The GMO exception policy must be fair to accommodate both the organic producer's ideals and livelihood and the organic consumer's expectations.

Rareness
GMO vaccine use in organics should be so rare (i.e. emergency use only). The rarity of GMO use should be an accepted outcome with regard to legality--everyone agrees to the ground rules (Federal vs. State authority, for emergency use, etc) and GMO vaccine use does not lead to abuses.

Additionally, the rarity should be recognized as fair and the rationale for the GMO vaccine use should meet the concerns of both producers and consumers, i.e. all livestock producers, both organic and conventional, must take concerted action in the face of a publicly declared emergency to safeguard livestock production for all concerned.

3)HAS THERE EVER BEEN AN EMERGENCY TREATMENT PROGRAM DECLARED BY THE FEDRAL OR STATE LEVEL IN RECENT MEMORY, AND HAS IT LEAD TO TREATMENT WITH GMO VACCINES?
This is a factual question not addressed by the TR because it was never posed.

4) DOES THE CURRENT REQUIREMENT TO USE NON-GMO VACCINES IN ORGANIC LIVESTOCK PRODUCTION LEAD TO UNACCEPTABLE ANIMAL DISEASE AND SUFFERING?
This is not a question that was explicitly posed or addressed in the TR with regard to organic production. The following information that has some bearing on a response to this question was presented to the committee from the TR and other sources.

Number of GMO vaccines
GMO vaccines became available in the early 1980s. Of the approximately 73 vaccines licensed for use in wild and domesticated animals, 28 are GMO and 13 (about 18%) are given to livestock animals.

Choice of vaccines
In summary, organic producers have choices of non-GMO vaccines in many cases, and only two cases of individual vaccines only available in GMO form were identified in the TR. Combination vaccines were identified as a problem, but often the individual non-GMO components were available, and no specific case was identified when they were not available.

Advantages of GMO vaccines
From the information presented in the TR and other sources, it would appear that GMO vaccines are sometimes, but not always, faster to develop, more quickly targeted to the specific disease, safer and cheaper than their counterparts, and may have advantages for efficacy, lower production costs, better storage and transportation, and ability to track which animals have been vaccinated. In general it was not possible to make broad conclusive generalizations regarding the advantages of GMO vaccines. Non-GMO vaccines generally can more quickly meet Federal registration criteria.

Types and Use of Vaccines
Non-GMO live bacterial vaccines are still used extensively and GMO live bacterial vaccines are still very rare. GM viral vaccines are more prevalent than GM bacterial vaccines, although there are many conventional viral vaccines.

Concerns about GMO vaccines
With bacterial GMO vaccines (which are predominantly administered via the mouth), there are concerns that the engineered bacteria may recombine with natural bacteria in the gastrointestinal tract. Furthermore, it is unclear how long the altered virus/bacteria will remain in the vaccinated animal.

Vaccines manufactured from artificial DNA created by combining several sequences of DNA are not used livestock. DNA from these types of vaccines may integrate into a host's chromosomes and initiate a cancer-initiating event, although results have been negative in experiments thus far. In addition, the modified DNA could theoretically integrate into the sperm or egg cells and be passed on to future generations.

Market for non-GMO vaccines for organic production
While the TR is not explicit about whether organic livestock production is too small to warrant attention from manufacturers to produce non-GMO vaccines, it presents evidence that organic represents a very small percentage of total livestock production. The clear implication is that the organic market does not command enough demand for independent non-GMO vaccine development. Organic poultry production is seen as the largest potential livestock market. Autogenous vaccine development was not specifically addressed.

Findings

1. Section 205.238 (a) (6) requires that producers must establish and maintain preventive healthcare practices, including administration of vaccines and other veterinary biologics, thus to deny use of a vaccine because it is ONLY available as GMO could be construed, incorrectly, by certifying agency as a non-compliance with the Rule.

2. Withholding treatment to an animal to maintain organic status is prohibited. Administering a GMO vaccine would prevent the animal or animal products and some mammalian offspring from being sold as organic.

3. A review of commonly administered livestock vaccines suggests that routine vaccinations are relatively common, and that they tend to be given as combinations of vaccines in single delivery format.

4 A review the USDA's APHIS list of Livestock Vaccines, regulated by the Center for Veterinary Biologics, suggest that there are non-GMO vaccines available for virtually all common potential livestock sicknesses. However there is presently no list which easily allows identification of GMO status.

5. Presently there is no requirement that a producer make inquiries of the veterinarian or pharmaceutical company as to the GMO or recombinant nature of vaccines to be administered.

6. Canada does not allow GMO vaccines (CGSB, 2009)

7. Europe allows GMO vaccines: Council Reg EC No 834/2007, Article 4 , Overall Principles: Organic production shall be based on the following principles: (iii) exclude the use of GMO's and products produced from or by GMO's with the exception of veterinary medicinal products.

8. The WHO, OIE and FAO clarified the difference between GM foods and use of GMO vaccines. With engineered foods the intention is to introduce a new trait into a food; this trait will be present in the food eaten by the consumer. On the other hand, the intention of genetically modified vaccines is to introduce into food animals "a protective immune response by means of an immunogen that is often no longer itself present at the time the animal is slaughtered."

V Recommendations

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.*

VI Committee Vote on Main Motion: Motion : Nick Maravell

Second : Jean Richardson

Yes 5 No 0 Abstain 0 Recuse 0 Absent 3

Committee Vote on Motion to Amend emergency treatment program: Motion: Colehour Bondera

Second: Calvin Walker

Yes 8 No 0 Abstain 0 Recuse 0 Absent 0