"inert" [the word inert bracketed in quotes] or "formerly known as inert". This would begin to clarify a significant change in fact about these classes of materials. This includes adding quotes around the word "inert" at the definition of the term at §205.2 Terms Defined.

In any case, development of a plan to review "formerly List 4 and 4b inerts" must proceed at a stepped-up pace, but in no way should the lack of such a plan have any interference in the timely and full review of "formerly List 3 inerts" allowed for use in Pheromones.

LIVESTOCK COMMITTEE

GMO VACCINES

NOC opposes the use of GMO technology in organic production. We also do not generally support the use of GMO vaccines. However, we have a high degree of concern for the welfare of all animals, particularly as organic livestock herds may be affected by the rapid spread of disease (i.e., new diseases) from either wildlife or from concentrated animal feeding operations. We are very concerned about the potential lack of availability of non-GMO vaccines in the case of "an emergency," and the possible implications of not taking prophylactic measures to prevent loss (e.g., loss of whole herds/flocks and loss of genetics) should such circumstances arise.

At the same time, it is our opinion that the Livestock Committee did not do an adequate job of defining an emergency and the steps that must be taken to safeguard organic integrity while protecting organic livestock. NOC believes that the Committee's proposal as it stands is inadequate: - there are specific changes that must be made in the current proposal prior moving forward with a recommendation, and there are some significant areas where the lack of knowledge regarding the health and safety of GMOs in general and GMO vaccines in particular may lead to denial of any use.

Specifically, since the use of the emergency designation is the trigger for allowance of a vaccine, much more clarity is needed about who declares the emergency, specifically when a declared emergency triggers GMO vaccine allowance in organic livestock systems, and the duration of a declared emergency period. We refer to a discussion of other emergency programs outlined in the comments of Beyond Pesticides to help clarify this point. In addition, there can be no use of a synthetic material in organic production systems unless the material has been reviewed by the NOSB and included on the National List, so at a minimum, each GMO vaccine must be fully reviewed by the NOSB. Details as to period of time to allow for that review and whether that review can happen <u>after</u> emergency use has been granted must be clearly articulated.

Of significant concern to NOC is also the fact that little is known about GMO vaccines. The TR casually equates conventional vaccines with GMO vaccines – their effect on the environment, biodiversity, chemical and biological interactions, and more. Nonetheless,

we have yet to see any science to document "substantial equivalence". In fact, we are just beginning to understand the significant differences and affects of Genetically Modified Organisms vs. conventional organisms. More research is clearly needed on GMO vaccines and drugs before any health, safety, or efficacy claims can be made.

At a minimum, if the Board is planning to move on this recommendation, there is considerable work that needs to be completed before doing so. Below we illustrate how the highly restrictive use of a GMO vaccine for emergency use only could be allowed as part of the existing NOP regulation on Temporary Variances (§205.290). In addition, we offer an outline of some questions and discussion points that must be clarified before such a proposal could move forward.

§ 205.290 Temporary variances.[proposed added section in bold and underline]

(a) Temporary variances from the requirements in §§ 205.203 through 205.207, 205.236 through 205.240 and 205.270 through 205.272 may be established by the Administrator for the following reasons:

(1) Natural disasters declared by the Secretary;

(2) Damage caused by drought, wind, flood, excessive moisture, hail, tornado, earthquake, fire, or other business interruption; and

(3) Practices used for the purpose of conducting research or trials of techniques, varieties, or ingredients used in organic production or handling.

(4) Vaccines, produced through the use of an excluded method, not currently listed on the National List of Approved Substances, but only under the following conditions:

a. The vaccine is used for the sole purpose of combating an outbreak of disease in organic livestock, that has been declared an emergency by the Secretary of Agriculture or an equivalent State agency; AND

b. There is no non-GMO vaccine available to address the emergency; AND

c. The Secretary of Agriculture has, in consultation with the NOP, specifically approved the allowance of this GMO vaccine on an emergency basis; AND

d. Within 18 months of the approval of a specific GMO vaccine for emergency use, the National Organic Standards Board reviews this vaccine for inclusion on the National List and if approved, the Secretary lists it with a required provision in its annotation indicating that it may be used "for emergency use only".

QUESTIONS AND CONCERNS:

I. "Emergency" What is the definition of an emergency and who 'declares' it?
   a. What is the range of types of emergencies that might allow use of GMO vaccines?
   b. In the case of the Secretary of Agriculture, is the "emergency" a declaration of an animal health emergency, or is it ALSO a specific declaration of an emergency that would allow the use of GMO vaccines for organic farmers, or is it both?
      i. who has the mandate and authority to announce/declare to organic producers that use of a particular GMO vaccine is allowed?
      ii. is it the NOP or NOSB ?
   c. What is the duration of a declared emergency?
      i. An emergency cannot last indefinitely – it must have a beginning and an end.
      ii. Can the NOSB mandate the close of an emergency that is declared by the Secretary after a specific period of time ?
      iii. An emergency can be declared more than once by the Secretary (as in the case of a re-emergence of the disease), but cannot be a regular or ongoing emergency
      iv. USDA must determine the efficacy of the GMO vaccine for organic producers for addressing the emergency in organic systems of production

II. All individual GMO Vaccines must be reviewed for inclusion on the National List for emergency use only. They may not be reviewed as a class
   a. A full TAP review should be required rather than a simple Technical Report.
   b. If a GMO vaccine completes NOSB review, and is approved for emergency use on the NL, it must always contain the annotation: "For Emergency use only, as declared by the Secretary and under a temporary variance "
   c. Why should the general prohibition on excluded methods be waived in the case of vaccines?
   d. Full NOSB review using all OFPA and regulatory criteria would potentially open the door to obtaining answers to significant health and safety questions that are essential to maintaining organic integrity.
      1. What kinds of GMOs will be allowed?
      2. What are the risks associated with these GMOs and their use in vaccines to the treated animals, people who consume the meat, and the ecosystem?
      3. Can the NOSB request proprietary information from patented products?
         a. Can NOSB request that independent health studies, animal and/or laboratory studies, and slaughter examinations be

performed prior to the allowance of the use of any GMO vaccine?

III. Transparent information about vaccines
   a. NOSB and NOP write to Secretary of Agriculture and APHIS Center for Veterinary Biologics requesting that there be mandatory labeling of all vaccines
   b. Require livestock producers (?) to find out if any vaccine is GMO, and certifiers to request that information
   c. NOP compile a list of all non-GMO vaccines and their use. The list should be published on the NOP website, regularly updated, and made easily accessible to organic farmers and certifiers.

IV. If a GMO Vaccine is allowed for emergency use, it triggers an immediate review to be completed no later than 18 months from its initial declaration
   a. If it is not approved, use of the GMO vaccine must stop immediately.
      i. Any organic animal treated with that vaccine during the emergency, prior to the prohibition will still be considered organic
      ii. Any organic animal treated with that vaccine after such prohibition will not be considered organic

ANIMAL WELFARE

In our November, 2011 comments to the NOSB, NOC expressed concern that "heavily prescriptive or quantifiable measures to define the limits of animal welfare standards" are problematic for a wide variety of reasons: they don't allow either the farmer or certifier enough room for considering individualized solutions that are suitable for the wide range of production systems used by organic livestock producers of differing scales and located in different parts of the country and they add an increased burden of documentation with minimal improvement to the organic system, among other issues.

The current "animal welfare standards" being used in the United States were written in response to the problems relating to animal welfare found on some nonorganic, and many times, factory style farms. The farm's effects on and existence within the ecosystem are not typically part of the management strategy implemented by these types of industrially managed farms. To use the same tools and measures designed for such a completely different system does disservice to both these standards and to the organic farmers that would need to implement them. The lack of integration of the livestock with the land which provides them food, exercise and is the recipient of their waste, shines a light on these standards as being incomplete. By trying to stuff the round organic farmer, into the square hole of judging animal welfare by a number scoring system, we take away importance that managing the farm as a whole system is a foundation concept of organic.

While we understand that these animal welfare documents are being offered as "guidance" to certification agencies, we are concerned that some certifiers will judge