No well-established scientific evidence exists to demonstrate that contamination can be prevented when farmers use GMO technology and that 100 percent containment in open air agriculture can be achieved. Yet, scientific evidence does exist that explains how GMOs cannot be recalled once released into the environment.[1] This is troubling news for organic farmers. Without USDA imposed restrictions and limitations on GMOs, organic growers remain largely unprotected from contamination by GMO crops that have been deregulated and commercially grown. This lack of protection ensues even despite the good faith efforts of farmers, and the associated expenses they incur to protect the organic integrity of their crops. Moreover, because USDA has never mandated restrictions on any GMO crop, there is little empirical evidence to demonstrate how best to prevent contamination. Although we also strongly agree with the Committee's assessment that "the responsibility to prevent GMO contamination of organics is shared by those who develop, use, and regulate this technology," we believe that USDA's policy of allowing unrestricted GMO deregulation makes it nearly impossible to prevent GMO contamination of non-GMO crops and seed.

The organic food industry already shoulders a large and unfair burden to prevent contamination from a technology that provides them with no benefits and only costs. It is time for the USDA to step up to the plate and require those who profit from GMOs to demonstrate how contamination prevention is possible, and to require it. This includes instituting a moratorium on the approval and planting of new GMO crops, unless and until GMO contamination is prevented through mandatory regulatory measures. It would help ensure that those who choose to *not* use GMO technology can freely do so without the threat of contamination or suffering market and livelihood losses. For crops already in unrestricted commercial production, it is incumbent upon USDA to assess where contamination occurs, require restrictions, and assign liability to the GMO patent holder. In the interim, USDA should also determine the best management practices to mitigate GMO contamination and the associated economic harms to organic growers. Such efforts would go a long way in assuring organic consumers that the government is receptive to their desire to eat organic food, free from GMO contaminants.

As the Ad Hoc Committee's letter aptly points out, "USDA actions are critical to the integrity of the organic seal and consumer confidence." We urge the NOSB to approve the Committee's letter and send it to the Secretary at the earliest opportunity.

Livestock Committee—GMO Vaccines

CFS does not support the Livestock Committee's draft recommendation as written.

We oppose the use of GMO technology in organic production systems because we believe that the novel and unproven technology is incompatible with organic principles and practices. In the NOP Final Organic Rule, GMO technology is explicitly identified as an

[1] Marvier, Michelle & Rene C. Van Acker. (2005). "Can Transgenes be kept on a Leash?," *Frontiers in Ecology and the Environment,* 3(2): 96-106.; Altieri, Miguel. A. (2005). "The Myth of Coexistence: Why Transgenic Crops are not Compatible with Agroecologically Based Systems of Production," *Bulletin of Science, Technology & Society*, 25(4): 361-371.

excluded method — a position we strongly support without any caveats. As such, we do not favor the use of GMO vaccines as the exception, even though the Rule allows them to be petitioned for possible inclusion on the National List. Moreover, since the Technical Review (TR) for GMO vaccines (November 2011) demonstrates that non-GMO vaccines are currently available for virtually every known disease for which livestock vaccines are used (see Table 1 in the TR), we believe that GMO vaccines are not essential or compatible with organic livestock production systems.

The apparent trend towards producing GMO vaccines is of great concern to CFS, particularly in the near total absence of any publicly accessible studies to demonstrate that the production, use, and disposal of GMO vaccines and their waste products is safe for humans, animals, and the environment. The TR equates conventional vaccines with GMO vaccines without questioning whether GMOs pose any unique risks or compatibility concerns when considered within the context of organic systems. This represent a major flaw in the methodology used to draw to draw conclusions in the TR. It is also disturbing to see that in the absence of any convincing supporting data, the Livestock Committee still responded "no" to NL criteria questions regarding environmental contamination during manufacture, harmful effects on the environment, biodiversity, human health and animal health, adverse biological and chemical interactions in agriculture ecosystems, etc.

In addition, CFS's own focused literature search of veterinary medicine, animal science, and welfare journals uncovered scant information about the potential risks associated with using GMO vaccines. This is not because such risks do not exist but because of the lack of research performed and published to date. None of the studies reported results of direct animal field or laboratory experiments or slaughter examinations of animals injected with a GMO vaccine to assess the unique threats GMO vaccines may pose. As this dearth of data suggests, more research is sorely needed on GMO vaccines and drugs before any conclusive health, safety, and efficacy claims can be made. Much of the existing data comes from mice experiments and great care and more research must be undertaken before extrapolating these data to other species such as cows and pigs used for food.

Although vocal critics of GMO vaccines are difficult to find, a doctor from the Singapore Health Sciences Authority's Center for Drug Administration cautioned that the existing knowledge about GMOs is so inadequate that it is impossible to define either the probability of unintended events or consequences of GMO vaccines. In an article in *Toxicology and Environmental Health,* she cautions:

> *Genetically modified (GM) viruses and genetically engineered virus-vector vaccines possess significant unpredictability and a number of inherent harmful potential hazards….Important questions concerning effects on non-targeted individuals within the same species or other species remain unknown. Horizontal transfer of genes, though lacking supportive experimental or epidemiological investigations, is well established. New hybrid virus progenies resulting from genetic recombination between genetically engineered vaccine viruses and their naturally occurring relatives may possess totally unpredictable characteristics with regard to*

> *host preferences and disease-causing potentials. Furthermore, when genetically modified or engineered virus particles break down in the environment, their nuclei acids are released. Appropriate risk management is the key to minimizing any potential risks to humans and environment resulting from the use of these GM vaccines. There is inadequate knowledge to define either the probability of unintended events or the consequences of genetic modifications.*[2]

In terms of the safety and efficacy of new GMO vaccines in food animals, we know from research on non-GMO vaccines shows that different breeds of the same species will react differently to a given vaccine. One of the most concerning issues to researchers is the possibility that injected DNA will actually integrate into the animal's chromosomes inside the cell. The effects can range from no effect at all to a potentially carcinogenic effect through mutation of the normal DNA. Other concerns about GMO vaccines include the possibility of genes controlling cell growth, effects on protein immunogens, the possibility of inducing antibody production against DNA itself, development of tolerance to the antigens produced, and altered processing of bacterial and parasite proteins.[3]

As the Board is acutely aware, organic consumers do not expect GMO technology to be used in organic production systems. Therefore, the very real potential exists for undermining consumer confidence in the organic label if GMO vaccines are allowed, even with emergency restrictions and eventual NOSB review. In fact, the Committee fully acknowledges that "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." That is why it is so important that the NOSB proceed cautiously and transparently by taking steps to safeguard organic integrity and organic livestock.

Please see comments submitted by the National Organic Coalition that detail additional questions and concerns regarding how an emergency is declared, who declares it, how long it lasts, etc.

To avoid the situation where a farmer accidentally uses a prohibited GMO vaccine, we urge the NOSB to recommend to the NOP that it compile a list of all available 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. We further urge the NOSB to recommend to the NOP that it requests USDA's Animal Plant Health Inspection Service's (APHIS) Center for Veterinary Biologics (CVB) to require GMO vaccine labeling to help ensure farmer compliance with the Organic Rule.

CFS shares the real concern with our organic colleagues and the Livestock Committee about the potential lack of available non-GMO vaccines to combat a severe disease

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[2] Chan, Vivian S. (2006). "Use of genetically modified viruses and genetically engineered virus-vector vaccines; Environmental effects," *Journal of Toxicology and Environmental Health Part A*, 69: 1971-1977.
[3] Robinson, Harriet L. and Tamera M. Pertmer. (2000). "DNA vaccines for viral infections: Basic studies and applications," *Advances in Virus Research,* 55: 1-74.

outbreak, in the rare event that some type of "emergency" is declared by either the Federal or State government. We understand that when farmers lose livestock to a disease outbreak, they could lose a lot more than animals. The loss could translate into the complete elimination of decades of breeding by successive generations of livestock farmers, who have worked hard to breed their particular stock so that their herds or flocks are suited for the type of production system and region where their farm is located. Nonetheless, allowing an unreviewed GMO vaccine to be used in organic livestock production will not necessarily protect this important genetic resource that is integral to the livelihood of farmers. Surely, a better solution can be developed, based upon sound science, that upholds the principle of organic integrity.

Handling Committee—Carrageenan

Although CFS agrees with the Handling Committee's recommendation to re-classify carrageenan as a synthetic, we disagree with its recommendation to re-list it on the National List (§205.605(b).

A quick survey of organic products on supermarket shelves that contain carrageenan shows that carrageenan is not essential in the production of organic food and beverages. Producers of many identical products avoid the use of carrageenan altogether or use alternative ingredients that serve the same function during production.

Research has shown that consuming carrageenan may have adverse health effects, ranging from colonic ulcerations to cancer. The foundational review article on carrageenan, written by Joanne Tobacman from the University of Iowa, also referenced in the TR, paints an unfavorable picture of the substance. The author notes that as early as 1982, "sufficient evidence for the carcinogenicity of degraded carrageenan in animals" was proof enough for the International Agency for Research on Cancer to declare that it posed a carcinogenic risk to humans.[4,5] Yet, even in the face of this knowledge, FDA has allowed the use of carrageenan to continue without restriction. Tobacman's article concludes with this strongly worded cautionary note: "The potential role of carrageenan in the development of gastrointestinal malignancy and inflammatory bowel disease requires careful reconsideration of the advisability of its continued use as a food additive."[6] Information contained in Tobacman's study and others[7] provides ample evidence of the many adverse

[4] Tobacman, Joanne K. (2001). "Review of Harmful Gastrointestional Effects of Carrageenan in Animal Experiments", Environmental Health Perspectives, 109(10): 983-994.
[5]WHO International Agency for Research on Cancer. (1998). "Some Food Additives, Feed Additives and Naturally Occurring Substances: Summary of Data Reported and Evaluation," *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*, Vol. 31. Available at: http://monographs.iarc.fr/ENG/Monographs/vol31/volume31.pdf
[6] Tobacman. (2001). p. 993.
[7] Bhattacharyya, Sumit, Pradeep K. Dudeja, Joanne K. Tobacman. (2008). "Carrageenan-induced NFκB activation depends on distinct pathways mediated by reactive oxygen species and Hsp27 or by Bcl10," Biochimica et Biophysica Acta (BBA) - General Subjects, 1780(7–8): 973-982.; Marcus, R. and James Watt. (1980). "Potential Hazards of Carrageenan," The Lancet, 315(8168): 602-603.