April 16, 2012

Dear NOSB members:

We request the NOSB board to further define GMO in terms of use in poultry vaccines by creating a list of the nationally approved vaccines for use in poultry production.

The Technical Evaluation Report dated November 29, 2011 states that 'Genetic engineering of vaccines includes the process of deleting, adding, or otherwise genetically modifying the viral or bacterial organism used for vaccination' (page 1). It goes on to say that 'GMO vaccines are composed of inactivated or weakened viral or bacterial organisms that have had genetic material added, deleted, or otherwise modified' (page 1). Then on page 2, it states, 'genetic modification is considered an "excluded method," which is generally prohibited from organic production and handling under 7 CFR 205.105(e). However, the prohibition of excluded methods includes an exception for vaccines with the condition that the vaccines are approved in accordance with §205.600(a). That is that vaccines must be included on the List of Allowed and Prohibited Substances (hereafter referred to as the National List) (page2). At present, the National List identifies all vaccines, as a group, as synthetic substances allowed for use in organic livestock production (7CFR §205.603(a)(4)). Vaccines are not individually listed on the National List, but rather are included on as a group of synthetic substances termed "Biologics – Vaccines," that may be used in organic livestock production (7 CFR §205.603(a)(4)).'

7CFR §205.105(e) – Excluded methods, except for vaccines: Provided, That, the vaccines are approved in accordance with §205.600(a).

7CFR §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).

7CFR §205.603(a)(4) – Biologics – Vaccines

The '*Salmonella typhimurium* Deletion Mutants Lacking Adenylate Cyclase and Cyclic AMP Receptor Protein Are Avirulent and Immunogenic' article written by Roy Curtiss III and Sandra M. Kelly published in the American Society for Microbiology ©1987, Volume 55, No. 12, pages 3035 – 3043; states, '*Salmonella typhimurium* and, presumably, other Salmonella species with invasive properties enter deep tissues after oral ingestion by attaching to, invading, and proliferating in cells of the gut-associated lymphoid tissue (GALT) (11). Delivery of an antigen to the GALT elicits generalized secretory (8, 12, 37, 43) humoral (2, 19a, 21), and cellular (10) immune responses. Therefore, avirulent Salmonella mutants that have lost the ability to cause disease without impairment of their ability to attach to and invade the GALT are likely to serve as effective means to deliver foreign antigens to the GALT and to induce protective immunity against the pathogen supplying such colonization or virulence antigens (13, 17, 19a, 22, 41, 42, 60). Now if we return to the 7CFR §205.538 titled Livestock health care practice standard, it notes in (a) that 'The producer must establish and maintain preventive livestock health care practices, including:' (6) 'Administration of vaccines and other veterinary biologics.' Thus, Lohmann Animal Health vaccines AviPro® Megan® Egg and AviPro® Megan® Vac 1 are 'attenuated S. Typhimurium belonging to O-antigen serogroup B and contains a naturally-occurring 91 kb cryptic plasmid. This plasmid is stable and its large size makes mobility highly unlikely. The *cya* and *crp* gene products are necessary for positive and negative regulation of a number of operons that are subject to catabolite suppression. Mutations in the *cya* and *crp* genes result in defects in global gene expression via the catabolite repression system. The mutations were transferred by transduction by bacteriophage P22Ht*int* using a series of transposon Tn10 insertions linked to nearby mutations in the *cya* and *crp* genes (Curtiss and Kelly, 1987). Thus, no recombinant DNA methodology was used, only naturally-occurring methods of gene transfer' (Ms. Sandra Kelly-Aehle).

'In general, the use of genetic engineering is prohibited in organic production and handling. Substances, methods, and ingredients that may and may not be used in organic production and handling are defined in 7CFR §205.105. Among the provisions of this section is a requirement that organic products must be produced and handled without the use of "excluded methods", which are defined as follows: "A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture."(7CFR §205.2) However, vaccines are specifically excluded (7CFR §205.105(e)) from the prohibition of excluded methods, provided that the vaccines are approved for use by inclusion on the National List. At present, the National List identifies all vaccines, as a group, as synthetic substances allowed for use in organic livestock production (7CFR §205.603(a)(4)). Vaccines are not individually listed and no distinction is made between vaccines made with and without the use of genetic engineering'.

Therefore, Lohmann Animal Health's AviPro® Megan® Egg (APHIS 19C1.02) and AviPro® Megan® Vac 1 (APHIS 19C1.01), although attenuated, are vaccines that are able to reduce risk to the livestock, protect transfer to progeny and protect the transfer to the human food supply and therefore the people and are permitted for use in Organic production. These vaccines were modified in a laboratory but could have been done in nature under 'natural conditions and processes' such as conjugation, fermentation and hybridization. No foreign genetic material was introduced into these organisms. These vaccines are not now and will never be considered genetically modified. In order to enable an easier distinction for the organic livestock producer's community, please institute an approved vaccine list to which the Lohmann vaccines in question can be added. The question regarding the organic nature of our vaccine is more related to the confusion regarding the regulation and not the nature of the vaccine itself.

Sincerely,

Katrina Bragg
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Lohmann Animal Health International