

**FORMAL RECOMMENDATION BY THE  
NATIONAL ORGANIC STANDARDS BOARD (NOSB)  
TO THE NATIONAL ORGANIC PROGRAM (NOP)**

**Date:** 11-05-09

**Subject:** Excipients

**Chair:** Jeff Moyer

**Recommendation**

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: \_\_\_\_\_

Guidance Statement: \_\_\_\_\_

Other: Material Annotation Technical Corrections & Clarifications

**Summary Statement of the Recommendation (including Recount of Vote):**

This recommendation proposes to correct some key oversights when the original recommendation for (f) was written. The topic of excipients is simultaneously vague and hair-splitting while incredibly important to certified organic livestock producers since few formulated livestock products are without excipients. This recommendation proposes to clear up misconceptions and the wide divergence of certifier interpretations that currently exist regarding excipients.

**NOSB Vote: Motion: Hubert Karreman Second: Tina Ellor**

*Board vote: Yes - 13 No- 0 Abstain- 0 Absent - 2*

**Summary Rationale Supporting Recommendation (including consistency with OFPA and NOP):**

7CFR238(a)(6)

7CFR238(c)(2)

7CFR238(c)(7)

7CFR603(a)(4)

Also, in an e-mail from OGC (via NOP) on March 24, 2009, it was stated: "In terms of the board recommending a substance to be added to the national list without a petition, (An OGC person sees) nothing in the OFPA or NOP regulations that would prohibit such action. (Another OGC person) agrees as well, and indicated that he believes the original NL was created by the board without any petitions. In either event, it would seem like the board's primary function is to make recommendations concerning the NL (to add, remove, renew, etc.) and that petitions are just one mechanism through which the board can make such recommendations."

**Response by the NOP:**

# National Organic Standards Board (NOSB)

## Livestock Committee

### RECOMMENDATION TO CHANGE 205.603 (f):

#### Current 205.603(f):

(f) Excipients, only for use in the manufacture of drugs used to treat organic livestock when the excipient is: Identified by the FDA as Generally Recognized As Safe; Approved by the FDA as a food additive; or Included in the FDA review and approval of a New Animal Drug Application or New Drug Application.

#### I. Introduction:

This recommendation proposes to correct some key oversights when the original recommendation for (f) was written. The topic of excipients is simultaneously vague and hair-splitting while incredibly important to certified organic livestock producers since few formulated livestock products are without excipients. This recommendation proposes to clear up misconceptions and the wide divergence of certifier interpretations that currently exist regarding excipients.

#### II. Background:

Prior to the 12/17/07 Federal Register notice which added section (f) to the National List at 205.603, no excipients were officially allowed. Certifiers decided to allow formulated products on a case by case basis, often basing decisions on the acceptability of the product's excipients (preservatives, stabilizers, etc). Upon addition of section (f) to 205.603, clearly prescriptive language helped certifiers review excipients. However, two points quickly came to the attention of anyone who is interested in the review process of livestock products: (1) the excipients clause (f) only applies to drugs and (2) there was no mention of APHIS approved excipients which are commonly used with vaccines and biologics. These two points are very problematic. Certified organic producers are not allowed to use drugs in the absence of illness – however, almost all farmers will give animal health care products of various types even though the animal is obviously not ill i.e. injectable vitamins or trace mineral formulations may be used in times of stress, and these all have excipients. Additionally, it was an honest oversight in the original writing of (f) to not state that APHIS approved excipients were to be allowed. The most likely reason is that the petitioned materials at the time were all under FDA oversight and not APHIS oversight. That excipients in formulated biologics under APHIS oversight were also intended to be covered by section (f) but unfortunately forgotten during that long process is regrettable.

#### III. Relevant areas in the Rule:

§ 205.238 Livestock health care practice standard.

(c) The producer of an organic livestock operation must not:

(2) Administer any animal drug, other than vaccinations, in the absence of illness;

In the section 238(c) (2) above, it states clearly that drugs cannot be administered in the absence of illness. One could argue the definition of “illness” – is it only when diagnosed by a licensed medical professional (who has legal rights to prescribe drugs)? Or are there other conditions which also hinder the health of animals that producers can identify simply by being the primary care attendant. The answer is Yes. However, it is only drugs which are referred to in the current excipient language. Therefore, when a farmer would like to use an oral digestive enhancement or rub on a simple peppermint liniment for the udder – which have excipients – it is currently not allowed. An animal thus treated could be directed by a certifier at this time to be permanently removed from certified organic production.

(7) Withhold medical treatment from a sick animal in an effort to preserve its organic status. All appropriate medications must be used to restore an animal to health when methods acceptable to organic production fail. Livestock treated with a prohibited substance must be clearly identified and shall not be sold, labeled, or represented as organically produced.

In the section 238 (c) (7) above, the term “medical treatment” does not necessarily dictate “drug” as used in the excipients section. Indeed, it goes on to say “all appropriate medications” must be used to restore an animal to health. While people steeped in conventional thought would quickly think of standard drugs (as referred to in section (f) as it is currently written, most organic livestock producers and organic health care providers may view medical treatments and medications in a wider context to include complementary and alternative veterinary medicines such as botanical derivatives, homeopathic remedies, injectable nutritives, etc. All these, like “standard” medications, are stabilized or emulsified, etc with the use of excipients.

§ 205.238 Livestock health care practice standard.

(a) The producer must establish and maintain preventive livestock health care practices, including:

(6) Administration of vaccines and other veterinary biologics.

Clearly, vaccines and biologics are encouraged for preventive livestock health care. However, as the current section (f) is written, there is no allowance for the excipients which are universally used with vaccines and biologics. In order to properly enable 238(a)(6), excipients associated with vaccines and biologics need to be explicitly addressed in the positive.

§205.603 Synthetic substances allowed for use in organic livestock production.

In accordance with restrictions specified in this section the following synthetic substances may be used in organic livestock production:

(a) As disinfectants, sanitizer, and medical treatments as applicable.

(4) Biologics--Vaccines.

Again, biologics and vaccines are specifically mentioned as being allowed by 205.603. However, this section is the list of synthetics allowed and pertains only to synthetic vaccines and biologics. There are many, many more vaccines and biologics which are not synthetic, such as colostrum whey products, which are widely used by organic livestock producers. Such natural biologics and vaccines, while addressed in a generic sense in 205.238(a)(6), are allowed in organic livestock production unless prohibited in §205.604, and also need to be covered for their potential excipients as well. This proposal would accomplish that.

#### IV. Discussion:

The intent of this recommendation is to help farmers take the best care of their livestock without reverting to prohibited materials. Many widely embraced and time honored animal health care products that enable farmers to help keep animals healthy contain excipients. Unfortunately it is the excipients, especially as stated under the current section (f), that place many popular animal health care products in peril of being prohibited even though they have been allowed previously. This recommendation will help reviewers be aware that it is the active ingredients of products under review that need the most attention and that the excipients, if allowed by the categories as stated by the proposed recommendation, should not be the deciding factor in whether or not an animal health care product can be utilized by farmers who provide the daily care to their animals. This recommendation also helps clarify and codify what the NOP had intended regarding excipients that APHIS allows for vaccines and biologics. It is acknowledged that there are many excipients that will be allowed for animal health care products; however, as currently written (limiting excipients to drugs with only FDA recognized substances), there already are many allowed. It is worth mentioning that excipients are inert ingredients added to a formulation to help the active ingredient perform more effectively. This recommendation will make it clear that all animal health care products (not just drugs) shall be protected from undue focus regarding their associated excipients.

#### V. Recommendation:

The Livestock Committee recommends the following change to the regulation:

§205.603(f) Excipients, only for use in the manufacture of *animal health care products* used to treat organic livestock when the excipient is: Identified by the FDA as Generally Recognized As Safe; Approved by the FDA as a food additive; Included in the FDA review and approval of a New Animal Drug Application or New Drug Application; *or approved by APHIS.*

#### VI. Committee Vote:

**Motion:** Dan Giacomini

**Second:** Hubert Karreman

**Committee Vote:** Yes: 7      No: 0      Abstain      Absent: