

**Formal Recommendation by the
National Organic Standards Board (NOSB)
to the National Organic Program (NOP)**

Date: October 28, 2010

Subject: Clarification of 205.238(c)(2)

Chair: Daniel G. Giacomini

The NOSB hereby recommends to the NOP the following:

Rulemaking Action X
Guidance Statement
Other

Statement of the Recommendation (Including Recount of Vote):

PART 205—NATIONAL ORGANIC PROGRAM
§ 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, preventives,
and pain relief medications, in the absence of illness;

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

The Organic Food Production Act (OFPA) prohibits the administering of medications, other than vaccines, in the absence of illness. The National Rule supports OFPA with 205.238(c) The producer of an organic livestock operation must not: (2) Administer any animal drug, other than vaccinations, in the absence of illness. The Livestock Committee has learned that some certifiers are prohibiting the use of preventatives, which are crucial in organic livestock production, based on a strict interpretation of the OFPA and the National Rule. The recent addition of pain medications to the National List sets a precedent which confirms the Livestock Committee's belief that the use of preventatives and pain medications on 205.603 should be allowed to ensure that organic livestock receive the most humane care possible. Their use also helps to prevent illness from not only progressing, but also from developing in the first place. See the entire Livestock Committee Recommendation below for further detail.

NOSB Vote:

| | | | | |
|-----------------------------|--------------|--------------------------------|------------------|-------------------|
| Moved: Dan Giacomini | | Second: Kevin Engelbert | | |
| Yes: 14 | No: 0 | Abstain: 0 | Absent: 0 | Recusal: 0 |

**National Organic Standards Board
Livestock Committee
Recommendation to Change §205.238(c)(2) in Conjunction with Scientifically
Acceptable Animal Welfare Practices Regarding the Care of Organic Livestock**

August 17, 2010

Introduction

Acceptable animal welfare practices include the treatment of livestock in such a way as to prevent disease and alleviate suffering in the animal. Strict reading and full enforcement of §205.238(c)(2) could make many common and acceptable best-management practices utilized by organic livestock producers to manage their livestock in such a way as to meet those two basic requirements not only discouraged but illegal. This recommendation is to help clarify the current language in the regulation and the Organic Food Production Act (OFPA) in this regard.

Background

The situation where the National List of Allowed and Prohibited Substances (NL) is a listing of specific substances allowed in organic production or processing, and in many cases those substances are rarely used as pure substances in actual production situations, created a conflict between producers and certifiers almost from the day the NOP Organic Rule went into effect.

The National Organic Standards Board (NOSB) attempted to deal with this problem by passing a recommendation to add “excipients” to §205.603 of the NL so that the drug of concern and the legal excipient carriers present in the commercial form of the drug as it was actually administered to the animal were legal in organic livestock production.

Excipients (§205.603(f)) was added to the NL in FR notice TM-07-0123 on December 13, 2007 with a fairly extensive annotation that partly included “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”.

Over time, it was determined that many substances that qualified as animal drugs, and contained excipients, were not reviewed by FDA. In November 2009, the NOSB passed a

recommendation for a technical correction to the annotation for excipients to add “or approved by APHIS” to make the annotation more fully encompassing and complete.

At the same time, public comment was received that appeared to address a problem with another portion of the annotation regarding the use of the term “drugs” in the definition. The problem seemed to be that the excipients were used in many more products than simply “drugs”. The Livestock Committee (LC) recommended, and the full board passed, an amendment to add the term “animal health care products” to the definition to include a wide-range of substances. The LC stated at the time that they would put creating a definition for the term “animal health care products” to the committee’s workplan for the following meeting.

In preparing a recommendation to define the term “animal health care products”, the regulatory language guiding the current definition of “animal drug” was reviewed more completely. The list of substances included in the definition of “animal drug” is so broad that the LC felt it was not possible to parse a definition for the new term that would help alleviate the problem it was trying to correct. In all options considered “animal health care products” remained a subset of the term “animal drug” and bound to its restrictions.

At this point, the LC further reviewed the public comment presented on this topic at the November 2009 meeting. Upon further study including a review of OFPA and the National Organic Program (NOP) Final Rule, it became apparent that the larger problem was not with the use of the term “drug” in the annotation for “Excipients” on the NL but in the problematic nature of §205.238(c)(2) that animal drugs could not be administered in the absence of illness.

The LC was concerned that full and complete enforcement of the regulation, and the intent that it appears to show, would prohibit the use of many substances allowed on the NL. Full enforcement of the section could result in the prohibition of such commonly accepted preventive practices as the use of teat dip at milking time to help prevent the incidence of mastitis, and welfare practices such as the use of pain relief medication during castration, dehorning and surgery not related to illness. These restrictions would completely contradict sound animal welfare practices that many constituents from all sectors of the organic industry believe not only should be allowed in organic livestock production, but at least encouraged if not actually required.

In an effort to more clearly understand the intent of Congress regarding this particular language in OFPA and the NOP regarding the language in the Final Rule, the LC reviewed testimony provided to the NOSB at a public meeting on November 28, 2007, by current Deputy Secretary of Agriculture, Dr. Kathleen A. Merrigan and the Preamble of the Final Rule.

Sec. Merrigan stated that at the time of the passage of OFPA, which was developed in the late 1980s and passed in 1990, it was understood that organic livestock production would eventually include standards for animal health and welfare. Merrigan acknowledged that “rulemaking is a dynamic process and standards may be amended as science emerges to suggest alternative strategies”.

The Preamble accompanying the National Organic Program (NOP) Final Rule also anticipated further animal health and welfare standards stating that an organic livestock producer must establish “practices to minimize the occurrence and spread of disease and parasites” and

“conduct all physical alterations to promote the animals’ welfare and in a manner than minimizes stress and pain”.

In a peer-reviewed article published in the Journal of Dairy Science (LeBlanc, et al. 2006. J. Dairy Sci. 89:1267), the authors describe some of the major areas of development in the field of animal health care over the previous 25 years. The greatest scientific advancement noted was the shift from disease treatment to disease prevention. From the mid-1960s to the late 1980s, when OFPA was developed, a major thrust of animal health care was a proactive intervention of both clinical and subclinical disease. The term illness was typically referred to infectious disease and as a stand-alone occurrence. It was during this phase that “pre-treating” in the absence of either clinical or subclinical illness became common. In the late 1980s until today, current developments in animal health care and welfare call for more systematic and holistic management programs to maintain the health and welfare of animals. Modern scientific-based herd management incorporates an integration of many disciplines from nutrition, environment, vaccination protocols, and improved monitoring in an effort to prevent clinical disease from manifesting itself and requiring more invasive treatment.

One peer-reviewed scientific article (Erb, et al. 1985. J. Dairy Sci. 68:3337) showing the value of this recent development in animal health care examined the direct and indirect relationship between diseases on dairy farms. After studying the records of nearly 3000 dairy animals, the authors found that females suffering from dystocia (more commonly called a difficult or assisted calving) were at increased risk to suffer from other disorders such as retained placenta, metritis, mastitis, poor reproductive performance and earlier culling. Prophylactic action to prevent the animal from suffering from a difficult calving decreased the chance of all those other disorders occurring. Many other disease paths were also identified in this study. The path outlined here is only used as an example and is not intended as the breadth that this recommendation is intending to cover.

To further make the point of the change in definition of the term “illness”, only metritis and mastitis would have been described as an illness by many animal health care professionals at the time OFPA was being developed. Today, all of these disorders are considered an illness, disease, or disorder and great effort should be practiced in all livestock operations to prevent this downward cascade from beginning.

Another aspect of critical animal health care which some individuals do not believe is covered in the current language of the Final Rule is the use of pain relief medication. The Preamble clearly states that the intention of animal health care regulations is to minimize stress and pain in the animal. To say that this is the goal but that the use of allowed pain relief medications is prohibited in organic livestock production would be considered cruel by most if not all individuals concerned with the animal health and welfare.

Relevant areas in the Rule

25. ORGANIC FOODS PRODUCTION ACT OF 1990

Title XXI of the Food, Agriculture, Conservation, and Trade Act of 1990
(Public Law 101-624)

SEC. 2110. [7 U.S.C. 6509] ANIMAL PRODUCTION PRACTICES AND MATERIALS.

(d) HEALTH CARE.

(1) PROHIBITED PRACTICES.—For a farm to be certified under this title as an organic farm with respect to the livestock produced by such farm, producers on such farm shall not use subtherapeutic doses of antibiotics; use synthetic internal parasiticides on a routine basis; or

(c) administer medication, other than vaccinations, in the absence of illness.

(2) STANDARDS.—The National Organic Standards Board shall recommend to the Secretary standards in addition to those in paragraph (1) for the care of livestock to ensure that such livestock is organically produced.

PART 205—NATIONAL ORGANIC PROGRAM

Animal drug. Any drug as defined in section 201 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 321), that is intended for use in livestock, including any drug intended for use in livestock feed but not including such livestock feed.

FDCA. SEC. 201. [21 U.S.C. 321] Definitions; generally

For the purposes of this Act—

(g)(1) The term "drug" means

- (A) Articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
- (B) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
- (C) Articles (other than food) intended to affect the structure or any function of the body of man or other animals; and
- (D) Articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement.

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Discussion:

In organic livestock production, scientifically advanced substances and practices help prevent the occurrence of many clinical diseases and disorders. The use of these preventives is not the same as treatment in the absence of an illness. As the definition of illness itself has expanded from infectious disease to all aspect that impair the health and welfare of the animal, the recognition of a new phase in animal health care and welfare is necessary. These substances and practices are encouraged in all areas of animal welfare and they should not only be allowed in organic livestock production, they should be encouraged. Without a proper understanding of the evolution of animal health care and of the definition of the term “illness”, a strict interpretation of the regulation as it is currently written, such practices would not only not be encouraged but they could be prohibited.

The LC is concerned that a strict reading of the current language in the Rule could result in an over-zealous enforcement where accepted animal health care substances and techniques would be prohibited including, but not limited to, the use of injectables for improved immunological, physiological and reproductive response, the use of teat dips during milking to minimize the exposure to mastitis-causing bacteria, supportive therapy during periods of stress, and pain relief medication during practices such as the removal of horns or non-injury related surgery and other veterinary practices.

As the definition of illness has evolved, without clarity of allowed animal health care practices that should not only be not be prohibited but should be encouraged, the LC recommends additional language to §205.238(c)(2) to clarify OFPA to accommodate a more complete understanding of modern health care practices and use of the term “illness”. The LC is not recommending that a definition to the term “illness” be added to the NOP Final Rule. The Committee felt greater clarity would be achieved with a modification of the restrictive language in §205.238(c)(2).

The Livestock Committee intends the practice and enforcement of this recommendation to be consistent with organic regulations 7 CFR 205 et. seq.

Recommendation:

The Livestock Committee recommends the following change be made to §205.238(c)(2), with the additional language shown in italics.

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Committee Vote

Motion: Daniel Giacomini Second: Tina Ellor
Yes: 6 No: 0 Abstain: 0 Absent: 2

Kevin K. Engelbert, Chair