



BEYOND PESTICIDES

701 E Street, SE ■ Washington DC 20003
202-543-5450 phone ■ 202-543-4791 fax
info@beyondpesticides.org ■ www.beyondpesticides.org

April 6, 2015

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave. SW.
Room 2648-S, Mail Stop 0268
Washington, DC 20250-0268

Re. LS: Excipients

These comments to the National Organic Standards Board (NOSB) on its Spring 2015 agenda are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and groups around the world.

Current Listing

§205.603 (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.

As defined in:

§205.2 *Excipients*. Any ingredients that are intentionally added to livestock medications but do not exert therapeutic or diagnostic effects at the intended dosage, although they may act to improve product delivery (e.g., enhancing absorption or controlling release of the drug substance). Examples of such ingredients include fillers, extenders, diluents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained-release matrices, and coloring agents.

Like “inert” ingredients in pesticide products, excipients in animal medications are not necessarily biologically or chemically inactive, and are not always listed on the label. If the Board is to do its job in reviewing excipients in accordance with OFPA, it must have adequate information about the identity and function of excipients. Therefore, it must seek information from materials review organizations and animal drug manufacturers to identify the excipients that are present in products used in organic livestock production so that they can be evaluated by the Board.

Just as the Inerts Working Group found that the number of “inert ingredients” present in pesticide products used in organic production is much smaller than the universe of chemicals that could be in those products, the LS will likely discover that the number of excipients actually present in products used in organic production is a fraction of those actually available for use.

The LS should make a commitment to identifying and reviewing the excipients used in organic production. A process for doing so is laid out in two NOSB recommendations on “inert” ingredients from April 2010 and October 2012.

Meanwhile, we recommend that the NOSB place an expiration date on the listing for excipients to ensure that the NOP feels an urgency to assist with the project.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Terry Shistar". The signature is fluid and cursive, with a long horizontal stroke at the end.

Terry Shistar, Ph.D.
Board of Directors