

September 18, 2024

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

Docket ID # AMS-NOP-24-0023

Re. LS: Meloxicam

These comments to the National Organic Standards Board (NOSB) on its Fall 2024 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 eliminate a reliance on pesticides. Our membership and network span the 50 states and the world.

Beyond Pesticides opposes the petition of meloxicam as a non-steroidal antiinflammatory drug (NSAID) for livestock. The LS proposes it be listed without the required identification of specific use or application, offering only the general limitation of "[u]se by or on the lawful written order of a licensed veterinarian; and [a] meat withdrawal period of at least two-times that required by the FDA."

We oppose the petition because the LS has not sought independent review through a technical evaluation report (aka technical review or TR), which has become a standard practice in material review by the NOSB. It relies solely on information provided by the petition and hence lacks the complete and independent information that would be provided by a TR. For example, the LS reports being unable to find any information about one of the precursors of meloxicam. Concerning its review of meloxicam manufacture, it says, "We cannot confirm that this information precisely describes the precursor and manufacturing process for any specific manufacturer of this generic drug." Given this lack of information, we do not believe that the

statement, "Environmental impact review of the National Library of Medicine, including the Hazardous Substances Data Bank (HSDB) revealed no generated environmental impact concerns from the manufacturing process, nor have any of the references noted in this petition suggested any such concerns," can be taken as a finding of no environmental impact, as required by OFPA.

Other statements relating to impacts of use on humans and the environment are similarly unconvincing. **On human health**: "Meloxicam is an approved drug for human use. It is available by prescription and not available over the counter. Meloxicam should be taken according to the recommendation of a patient's physician." This does not consider persistence in the treated animal or the sensitivity of consumers. It is making a judgment concerning possible exposure to uninformed consumers based on FDA's approval of the drug by prescription. **On the environment:** "There are no known effects on soil organisms, crops, or livestock." "There are no reported adverse impacts on biodiversity. Meloxicam is an approved drug for humans and dogs. Meloxicam is a drug allowed for use in other livestock species in the US according to FDA regulations established under Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA)." We would expect more specific findings in a TR, and when the TR authors state that something is "not known" or "not reported," we would have access to the references supporting those judgments.

Beyond Pesticides is sensitive to the need for pain relief in organic livestock, but the LS has not complied with expected review procedures to inform a decision on meloxicam. We urge the NOSB to deny this petition at this time and we urge the LS to seek a TR on meloxicam that would give a more complete and independent report of its beneficial use in organic production, as well as health and environmental impacts.

Thank you for your consideration of these comments.

Sincerely,

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Terry Shistar, Ph.D. Board of Directors