

January 5, 2007

Office of Pesticide Programs Regulatory Public Docket (7502P) U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, NW Washington DC 20460-0001

Re. EPA-HQ-OPP-2006-0175 Pesticides; Food Packaging Treated with a Pesticide

Dear Madam/Sir:

Please treat this comment as an adverse comment in response to EPA's direct final rule, "Pesticides; Food Packaging Treated with a Pesticide," December 6, 2006. We believe that the issues raised by the direct final rule are not non-controversial and should therefore be subject to broader review and comment in a full rulemaking process.

There are several issues that we believe must be addressed in the area of pesticides and food packaging in the context of the proposed rule change. Below are six points.

1. Definition of inert.

The rule, in not defining inert, adopts the definition of the *Federal Insecticide*, *Fungicide and Rodenticide Act* (FIFRA). As interpreted by EPA, the definition of inert casts a broad net that includes materials classified as toxic under the *Comprehensive Environmental Response, Compensation, and Liability Act* (CERLA), pesticides under FIFRA as long as a pesticide claim is not made by the registrant, and toxic materials under other statutes. These toxic chemicals should be reviewed in the context of the tolerance setting process. EPA's regulatory review of inert ingredients has been the subject of considerable controversy and the rule's reliance on this categorization raises serious issues that may enable pesticides to avoid necessary regulatory review.

2. Pesticidal purpose or pesticidal characteristics.

Under the proposed rule, a pesticide may be exempt from regulation under the *Federal Food Drug and Cosmetic Act* (FFDCA) section 408 as a pesticide chemical

residue if the manufacturer of the packaging does not make a pesticidal claim or state a pesticidal purpose. Under this scenario, the proposed rule creates a loophole that must be closed. For food consumers, the question is whether the use of a substance known to have pesticidal characteristics, regardless of a pesticidal claim, is being used and whether its use creates residues.

3. Expansion of 1998 rule exception (40 CFR 180.4)

The expansion of 40 CFR 180.4 requires a more indepth review and analysis of the impact that the 1998 decision has had on food safety, and this rulemaking would be an appropriate time. The 1998 exception may be ill-founded, especially given the proposed expansion. While an ingredient of packaging may be defined by EPA as "inert" (which may be biologically and chemically active, and under other circumstances classified as a pesticide) and it is a component of food packaging material, this classification does not ensure protection from possible food residues.

4. FDA and sole jurisdiction

While FDA may be given sole jurisdiction over food packaging, that should not exempt those toxic pesticides in food packaging from review under section 408 of FFDCA, particularly in the case of food packaging for which there are no pesticidal claims even though it may contain pesticides.

5. Section 201(q)(3) of FFDCA, as amended by the Food Quality Protection Act (FQPA).

Section 201(q)(3) of FFDCA, as amended by the *Food Quality Protection Act* (FQPA), does not support the proposed action. The exception from the definition of pesticide chemical can be triggered under this provision if the manufacturer of the packaging does not make a pesticidal claim. EPA has long held that without a pesticidal claim for a product the agency does not treat the toxic substance as a pesticide. As a result, there are a host of consumer products on the market that contain pesticides for which manufacturers do not make pesticidal claims and skirt regulatory review for adverse impacts on health and the environment. As a result, under the proposed rule, a pesticide could be incorporated into packaging material, result in a residue on food, while avoiding regulatory scrutiny.

6. EPA jurisdiction

While the rule justification states that EPA's jurisdiction under FIFRA is retained under 408, it does not require EPA to act in the case of pesticide components for which there are no pesticidal claims.

7. Conclusion

EPA and FIFRA define pesticides very broadly, including a broad array of materials that can be incorporated into packaging –from fungicides to antimicrobials. As a result, the rulemaking raises serious issues associated with the noted increase in EPA applications for a wider variety of pesticide-treated

food packaging products since 1998. Again, this proposed rule change requires an opportunity for broader and more indepth review under a full rulemaking process.

Beyond Pesticides asks that EPA, in response to these adverse comments, publish a withdrawal in the Federal Register confirming this rule will not take effect and urges the agency to pursue a broader review in the future if it deems the rule change necessary.

We appreciate your consideration of our comments and look forward to your response.

Sincerely,

Jay Feldman Executive Director