CropLife ★AMERICA★

June 2, 2010

Via E-Mail

Steven P. Bradbury
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N. W.
Mail Code: 7501P
Washington, DC 20460

Dear Mr. Bradbury:

CropLife America has been informed that the U.S. Environmental Protection Agency (EPA) will announce in June, 2010 that it is adopting a policy, requiring any pesticide registrant that is aware that some constituent of a registered pesticide product is nano-sized (*i.e.*, presumably that has particles or structures with a diameter less than 100 nanometers) to submit the information to EPA pursuant to Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA regulations generally limit the obligation of a registrant to report information pursuant to FIFRA Section 6(a)(2) to information that concerns "adverse effects," so this use of EPA reporting requirements appears to be based on a premise that EPA regards the mere presence of any nanoscale materials to be "adverse."

One possible consequence of the new policy will be to stigmatize all use of nanotechnology in pesticides. The message that is likely to be received by the public is that all nanotechnology is "bad" or likely to be hazardous. Even with attempts to state clearly that submission of such information *per se* is no indication of risk, such information will be described by at least some commentators as "adverse effect reports." This would not be consistent with previous EPA policy statements that encourage beneficial uses of nanotechnology and the pursuit of greener chemistry.

We are also concerned with the apparent expansion of the Section 6(a)(2) reporting requirement to include information that is only informational and, by the Agency's own admission, not necessarily related to potential or actual risks. EPA's stated goal in making this policy change is to gather information because a pesticide or a constituent part of its formulation contains a certain particle size. There is no necessary nexus to a risk concern. If EPA now intends to utilize reporting under Section 6(a)(2) to gather a new category of information without regard to its risk implications, and without formally modifying its regulations, this could cause registrants to submit other types of information based on the premise that it falls within a broad category that may be of interest to the Agency. The problem of the Agency overreaching under this provision, which could result in a deluge of information, much of it of little interest to the Agency, was extensively considered during the development of the current reporting rule.

We believe this action may be an expansion of current EPA authority and will not elicit the meaningful information that would assist EPA in its efforts to assess the potential benefits and risks of nanotechnologies as they apply to FIFRA regulated substances. The Office of Pesticide Programs (OPP) has provided us with what has been described as the EPA Office of General Counsel (OGC) explanation behind the new policy, and the justification cited in the OGC explanation is that nanoscale materials have "the potential to affect human health and the environment." Although this rationale might be consistent with EPA's current interpretation of the language of FIFRA Section 6(a)(2), it is not consistent with the more measured approach adopted in EPA regulations, that focus on only those categories of information that would call into question whether a product continues to satisfy the statutory standard for registration. A policy requiring reporting of all information concerning nanoscale materials does not fall within any category deemed reportable under current EPA regulations. Even the provision outlined in 40 C.F.R. § 159.165(a) applies only if "EPA might regard the information alone or in conjunction with other information about the pesticide as raising concerns about the continued registration of the product or about the appropriate terms and conditions of registration of a product."

While we understand and fully support EPA's interest in obtaining information about the possible presence of nanoscale materials in a pesticide formulation, we respectfully suggest there are alternatives, which could fulfill the same goal with far less negative impacts of the proposed approach and would begin to establish a long-term strategy for regulating nanomaterials. EPA could modify the information that it requires to obtain pesticide registration or registration reviews. For instance, EPA could require that applications for pesticide products include information on active ingredient and inert ingredient particle size and distribution. Additionally, EPA can pursue modifying its Part 158 requirements to obtain this information without the "adverse effects" label. By focusing on methods that systematically obtain information for a particular category that is of real interest, EPA can avoid haphazard collection of only the information that registrants happen to obtain (including information that has no risk implications). EPA can also avoid the stigma associated with a policy that implies that all nanotechnology may be associated with adverse effects. Additionally, during the April meeting of the Pesticide Program Dialogue Committee (PPDC), I suggested reviewing the way the Plant Incorporated Protectant (PIP) Rule was developed *and* named as a model process for how to develop a similar rule for pesticide nanomaterials.

Lastly, the announcement of this policy has been indicated as a final decision in this regard, which forgoes the more participatory process involving some element of notice and receiving and considering comments before final implementation. We do acknowledge that OPP

has been available for occasional discussions of the proposal at a staff level, but this does not accommodate a full airing of EPA's specific language for the new requirements and a transparent public process to develop fully any final decisions, which would not necessarily unduly delay any final outcomes or policy determinations.

Thank you for your consideration.

Sincerely,

Jay J. Vroom
President and CEO

cc: The Honorable Robert Perciasepe (via e-mail)
Jim Jones (via e-mail)
Leslye M. Fraser (via e-mail)