UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 2 2 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

The Honorable Kamala Harris
Attorney General of the State of California
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Dear Madam Attorney General, Ms. Leval and Mr. Schlenker-Goodrich:

This is an amended response to two petitions you submitted in 2006 identifying 371 pesticide inert ingredients as hazardous and requesting that the U.S. Environmental Protection Agency require that the identities of those inert ingredients appear on the labels of products that include any of the ingredients in their formulations.

On September 30, 2009, the EPA partially granted the petitions (Reference 1). The agency stated that the EPA agreed with the petitioners that the public should have a means to learn the identities of hazardous inert ingredients in pesticide formulations. The agency indicated that it believed that increased transparency could lead to better informed decision-making and to better informed pesticide use.

The agency's 2009 response committed to pursuing both voluntary and regulatory actions to address the petitions as follows:

> EPA is initiating rulemaking to increase the public availability of hazardous inert ingredient identities for specific pesticide formulations. In connection with this rulemaking EPA will also be discussing ideas to increase the disclosure of inert ingredient identities to an even greater degree than requested by the petitions, for example, by requiring disclosure of all inert ingredients, including ingredients not deemed hazardous.

* * *

Therefore the Agency is initiating this rulemaking via an Advance Notice of Proposed Rulemaking.

We continue to support what we believe is our common goal: to ensure that all substances in pesticides – both inert ingredients and active ingredients – are safe for humans and the environment. While the EPA's regulation of pesticides focuses primarily on pesticide active ingredients because of their well-recognized biological activity, we have been moving ahead with respect to inert ingredients. I would like to describe the steps the EPA has taken since the 2009 response to your petitions, what we have learned, and why we now think we should pursue a somewhat different approach to address the safety of inert ingredients in pesticide products, notwithstanding the value of public knowledge of the identities of the ingredients in pesticide formulations. As explained more fully below, the EPA has now decided not to pursue finalization of the rulemaking it initiated seeking to mandate the disclosure on the label of a pesticide of the presence of a hazardous inert ingredient.

On December 23, 2009, the EPA published an Advance Notice of Proposed Rule Making in the *Federal Register* (74 FR 68215; FRL-8803-3) (Reference 2). The ANPRM initiated rulemaking to increase public availability of the identities of both potentially hazardous inert ingredients and of inert ingredients in general. Our intention was to look at various ways to assist consumers and users of pesticides in making informed decisions and to reduce the presence of potentially hazardous ingredients in pesticides. The EPA sought feedback on whether the rule should mandate disclosure only of potentially hazardous ingredients or require disclosure of most or all inert ingredient identities, regardless of hazard. We noted that the EPA's ability to mandate disclosure of all inert ingredients regardless of hazard may be limited by laws requiring the EPA to protect the confidentiality of trade secrets and confidential business information. The ANPRM also posed a number of specific questions for response.

In response to the ANPRM, the agency received 405 distinct comments. These comments were very general in nature, either advocating for or against mandatory disclosure of inert ingredients of pesticides, or offering only broad, general reasons articulating their positions. The EPA did not receive many responses to the specific questions asked by the agency in the ANPRM that were intended to assist in developing a thorough and comprehensive disclosure rule. For example, there were few suggestions on how information should be disclosed, how the information would be used, or what the impact of inert disclosure on consumer behavior would be. Some companies did comment, however, that disclosure of inert ingredients would be extremely harmful to their businesses because it would reveal valuable trade secret information, enabling competitors to copy their products. The comments received also revealed considerable disagreement among various sectors of the public regarding the appropriateness and even legality of the possible requirements discussed in the ANPRM. For example, some registrants urged the EPA to develop risk-based criteria that included both hazard and exposure considerations because they did not believe the EPA has authority under the Federal Insecticide, Fungicide and Rodenticide Act to require inert ingredients disclosure based on hazard alone. Other registrants said they believed the EPA has "no plausible legal argument to support an assertion, that as a class, inert ingredients are not entitled to confidential treatment."

Based in part on the comments, the EPA thinks that further pursuing the rulemaking initiated by the ANPRM would be a very complex, lengthy and resource-intensive activity. Despite the EPA's extensive list of questions, public comments did not provide some of the basic facts necessary to support the rulemaking, such as how effectively disclosure would change consumer behavior and how disclosure

might affect businesses' ability to compete. The comments also indicate that there are many contentious issues – the scope of any disclosure requirement, what types of information to disclose, the most appropriate means of disclosure, the effect of label disclosure on label readability, etc. Moreover, because of the process by which the federal government undertakes rulemaking, continuing this rulemaking would require a long-term effort. Merely drafting the required portions of a complex rule consumes significant staff resources from several parts of the agency. In addition, we must seek and consider the comments of other agencies within the federal government, and this rule would likely undergo review by the Office of Management and Budget. Publishing the proposal, receiving and responding to comments, developing a final rule and undergoing the process of publication can easily last several years. We must also discuss and document market failure as part of the justification for rulemaking, mitigate impact on small businesses, ensure proper legal authority, and adhere strictly to processes outlined in several federal laws. At this time, I am reluctant to further commit a significant level of resources to this rulemaking effort in the absence of data or information clearly indicating that a rule requiring disclosure, but not otherwise affecting the composition or use of a pesticide product, would result in a significant reduction in the human health or environmental risks posed by the presence of inert ingredients in pesticide products.

In the 2009 response, the EPA committed to encourage voluntary disclosure. The EPA has long encouraged registrants to disclose the inert ingredients in their products. In a 1999 policy statement, several examples of disclosure statements were provided for registrants to consider (Reference 3). Because we thought more should be done, we began actively working with pesticide stakeholders and developed the structure for a voluntary program encouraging registrants of antimicrobial products to disclose ingredients. In July 2011, the agency issued guidance for antimicrobial pesticide companies that wish to voluntarily disclose their ingredients on their website (Reference 4). The guidance suggests full disclosure of the product ingredients may be included on the product label or posted on a company's website, with the website address added to the product label. The guidance also recommended including widely recognized chemical names, bilingual language and Safety Data Sheets. Although we have repeatedly reached out through trade associations and other industry contacts to many different pesticide registrants, we are aware of only five companies that make antimicrobial pesticides that are participating by disclosing the identity of the ingredients in their formulations, either on the label or via their company website. While one company has told the EPA it believes there is value in participating in the pilot from a public relations standpoint, the company has not been able to provide any information on whether, much less how, its disclosure initiatives have affected customers' buying patterns or other behavior. While the voluntary disclosure initiative has gained only limited acceptance, we think it is still worth encouraging additional companies to participate. With only a modest investment of resources we hope that we can gain more experience with different methods of disclosure and a better understanding of how disclosure influences customer behavior, and therefore have a stronger basis to evaluate its usefulness as a regulatory tool.

Other information has also shaped our thinking. As part of our efforts to encourage safe pesticide use practices, for more than thirty years, we have sponsored a "Read the Label" program for consumer use pesticides. Over the past ten years we have collected information through survey and focus groups on consumer reading and understanding of labels. Based on this feedback, we believe that most consumers quickly read a minimal amount of information on the pesticide label when making a purchase, without an in-depth reading of the entire pesticide label. These findings suggest most consumers will not pay attention to information on product labels disclosing the identity of inert ingredients.

Based on our review of comments to the ANPRM, our experience with the voluntary disclosure program, and survey and focus group feedback, the EPA has re-evaluated how to best address potentially hazardous inert ingredients in registered pesticide products and now believes that a different approach is more appropriate. Instead of further pursuing the rulemaking the EPA initiated that was aimed at mandatory disclosure of a large number of specific inert ingredients, we will review inert ingredients currently listed for use in pesticides, update that list, establish criteria for prioritization, and select top candidate inert ingredients for further analysis and potential action. I believe that, given our restricted financial and staff resources, this is the best way to address concerns with inert ingredients in pesticides, achieve the human health and environmental benefits that constitute our agency's primary mission, and attain my goal in administering FIFRA to minimize the risk of unreasonable adverse effects from pesticides.

The rationale that led the EPA to initiate, via the ANPRM, a rule requiring disclosure of the identity of inert ingredients was to provide information to pesticide purchasers and users. The theory behind such disclosure is that purchasers would choose those formulations containing less hazardous (but still effective) inert ingredients, thereby moving the market in favor of those less hazardous formulations. I believe that significant shifts in consumer preferences and purchasing decisions can play an important role in the marketplace and could influence manufacturers' decisions about what types of products to offer. In fact, that is the premise underlying the reinvigorated Design for the Environment program in my Office of Pollution Prevention and Toxics. I question, however, the extent to which a sizeable percentage of pesticide users and purchasers would change their behavior based on disclosure of the inert ingredients in pesticides. For inert ingredient disclosure to have a significant effect on the marketplace, a significant number of consumers would need to read the ingredients statement on the label, recognize specific ingredients, understand which ingredients were hazardous, and then act on that information. Neither the voluntary program nor any other information supports a conclusion that a large percentage of pesticide users' decisions would be significantly influenced by that information.

I believe that the EPA can achieve greater reduction in the risks from use of pesticides containing potentially hazardous inert ingredients through a series of non-rule actions designed to reduce the presence of hazardous inert ingredients in specific pesticide products. Moreover, I expect that the agency would be able to develop and implement these actions in a timelier manner than rulemaking. I therefore intend to pursue a combination of regulatory and focused non-regulatory actions that do not rely on rulemaking.

Steps I am considering include:

Prioritize pesticide inert ingredients for increased scrutiny:

1. Revise the list of inert ingredients approved by the EPA for use in pesticide products: The EPA maintains a list of chemical substances that have been approved for use as inert ingredients in pesticide products. After appropriate evaluation to confirm hazard, the EPA would remove from the approved list those inert ingredients listed in your petitions that are no longer being used in pesticide products. Based on our initial review of the 371 inerts ingredients, 96 of the inert ingredients identified in your petitions could potentially be removed from the approved list. In 1987, the EPA issued its inert ingredients strategy to provide guidance (Reference 5) to applicants seeking approval of a new inert ingredient. Then, in 2010, the EPA published several guidance documents to provide more up-to-date information on the type of data generally needed to approve an inert ingredient (References 6, 7, and 8). The type of data generally needed to evaluate a new inert ingredient include, among others, studies to evaluate

potential carcinogenicity, adverse reproductive effects, developmental toxicity, genotoxicity as well as environmental effects associated with any chemical that is persistent or bioaccumulative. Therefore, before any of those inert ingredients that are removed from the list could be used in the future, this type of data on the ingredient would need to be provided and reviewed by the EPA. Only then would it be possible for the inert ingredient to receive approval as part of a new inert ingredient submission request. This review process will ensure that the presence of such inert ingredients does not cause unreasonable adverse effects on the environment.

2. Give priority focus to non-food use inert ingredients: By law, the EPA is responsible for regulating the pesticides that are used by growers to protect crops and for setting limits on the amount of pesticide chemicals – both active ingredients and inert ingredients in pesticide – that may remain in or on foods marketed in the United States. These limits on pesticides left on foods are called "tolerances" in the U.S. In August 1996, the Federal Food, Drug, and Cosmetic Act was amended to include the Food Quality Protection Act. This Act required the EPA to reassess by August 2006 all of the existing pesticide tolerances to ensure that they meet current safety standards and are adequately supported by scientific data, and to apply the new, stricter standard to all newly established tolerances. The EPA has completed the statutorily-mandated tolerance reassessment for food-use inert ingredients. Consequently, given this review process, we believe that food-use inert ingredients have been evaluated for their safety for humans. Further, we conducted a screening level ecotoxicity risk assessment on the food use inert ingredients in conjunction with tolerance reassessment and the establishment of new tolerance exemptions; these assessments have not identified any significant ecotoxicological risk concerns. However, the inert ingredients that are not used on food crops (non-food use inert ingredients) did not benefit from these tolerance reassessment activities and therefore these ingredients would be the focus of our effort. From your original list of 371, 45 were evaluated as food-use inert ingredients and could therefore be removed from the list. Giving focus to non-food use inert ingredients as well as potentially removing 96 from our approved list, there would remain 230 inert ingredients for further consideration.

3. Set risk-based priorities: For non-food use inert ingredients, the EPA could employ a methodology to identify those inert ingredients that exhibit strong evidence of adverse human health or environmental effects. The EPA could consider the practicality of using lists of hazardous chemicals generated by other parts of the EPA, other federal agencies, or other governmental or international organizations. Understanding the development of these lists could enable the EPA to use these sources of information to take a closer look at inert ingredients in pesticide products to prioritize them for further analysis and possible actions. With respect to adverse effect on human health, because the EPA's review of an application to register a new pesticide product has always considered the acute toxicity and the physical and chemical hazards of the pesticide formulation, this step would focus primarily on chronic adverse effects. In addition, the priority setting approach would take into account indications of potential for significant exposure to humans and non-target organisms. Consideration of both hazard and exposure would help us prioritize which inert ingredients potentially posed the greatest risk and thus might need further action by the EPA.

4. Take appropriate action to address risks from pesticide inert ingredients: After using the priorities determined by the process discussed in Steps 1 through 3 above, the EPA would then evaluate each remaining inert ingredient on a case-by-case basis to determine what combination of voluntary and/or regulatory action(s) would be most appropriate. FIFRA provides the agency with the authority to take a variety of regulatory actions that offer the potential for reducing risk.

Regulatory Programs:

- Issue Data Call-In Notices requiring registrants to provide data needed by the EPA to conduct risk assessments for inert ingredients of concern.
- For inert ingredients found to pose risks of concern in particular formulations, direct registrants to modify their registration, e.g., by reducing the amount of the inert ingredient in the formulation, replacing the hazardous inert ingredient in their formulation with an alternative, less hazardous chemical, or adding warnings or other labeling requirements.
- In certain cases, if the EPA identifies risks of concern and a company is not willing to take requested actions, consider cancellation of products.
- For inert ingredients of higher toxicity that supply a needed function in the product and there is not a suitable substitute, consider mandatory label disclosure of inert ingredients with a more hazardous profile in specific formulations.

Voluntary Programs:

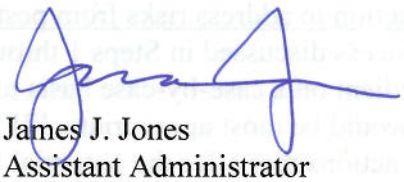
- Seek to expand the existing voluntary disclosure program for antimicrobial pesticide products to include non-antimicrobial consumer-use pesticide products.
- Create incentives for pesticide manufacturers to select less hazardous inert ingredient choices.
- Work with retailers who have demonstrated interest in selling products formulated with less hazardous ingredients to provide information about the EPA's voluntary programs and encourage consistency.

Some of these points were discussed in a meeting with several of the petitioners on February 25, 2014. The agency will look for opportunities to engage the petitioners, registrants, inert ingredient manufacturers, and other interested members of the public on how to implement this strategy. Such opportunities might include meetings, *Federal Register* notices soliciting comment, or other avenues.

In sum, we believe we have identified a more effective and timely way to achieve our common objective; but, because this approach would no longer pursue the rulemaking the EPA initiated via the ANPRM seeking to mandate the disclosure of potentially hazardous inert ingredients on pesticide labels, as requested in the 2006 petitions, this amended response constitutes a denial of the petitions. Other than the decision not to pursue this rulemaking, the remainder of the 2009 petition is not amended.

Thank you for this opportunity to respond to your concerns. I look forward to working with you as our organizations all strive to protect human health and the environment.

Sincerely,



James J. Jones
Assistant Administrator

Copies:

Ms. Wendy Park, Attorney for Center for Environmental Health, Beyond Pesticides, and Physicians for Social Responsibility

Ms. Claudia Polsky, Deputy Director for Pollution Prevention & Green Technology, California Department of Toxic Substances Control

References:

1) Response Letter; Deborah Edwards to Petitioners; (September 30, 2009) (http://www.epa.gov/opprd001/inerts/petitionresponse.pdf) (accessed April 30, 2014)

2) Advance Notice of Proposed Rule Making (ANPRM): Public Availability of Identities of Inert Ingredients in Pesticides; (December 23, 2009; 74 FR 68215; FRL-8803-3) (available at regulations.gov using the docket identifier EPA-HQ-OPP-2009-0635)

3) EPA: Final Report of the Pesticide Program Dialog Committee on the Activities of the Inert Disclosure Workgroup, March 2000 through April 2002; Discussion Paper 12; Inert Disclosure Stakeholder Workgroup; EPA Response to Labeling Questions Raised by Workgroup Members (2001) (http://www.epa.gov/oppfead1/cb/ppdc/inert-finalreport.html) (accessed April 30, 2014)

4) EPA: Guidelines for Voluntary Disclosure of Antimicrobial Ingredient Information on company Websites and/or Labels (http://www.epa.gov/oppad001/voluntary-disclosure.html) (accessed April 30, 2014)

5) EPA: Inert Ingredients in Pesticide Products; Policy Statement (http://www.epa.gov/opprd001/inerts/fr52.htm) (accessed April 30, 2014)

6) General Guidance for Petitioning the Agency for the Establishment of a New/Amended Food Use Inert Ingredient Tolerance or Tolerance Exemption under PRIA 3 (http://www.epa.gov/opprd001/inerts/inertpetition.pdf) (accessed April 30, 2014)

7) General Guidance for Requesting the Establishment of a Tolerance Exemption for a Low Risk Polymer or Nonfood Use Approval of a low Risk Polymer under PRIA 3 (http://www.epa.gov/opprd001/inerts/lowriskpolymer.pdf) (accessed April 30, 2014)

8) General Guidance for Requesting the Approval of a New Nonfood Use Inert Ingredient or Amending a Currently Approved Nonfood Use Inert Ingredient under PRIA 3 (http://www.epa.gov/opprd001/inerts/nonfood_inert.pdf) (accessed April 30, 2014)