WENDY S. PARK, State Bar No. 237331
PAUL R. CORT, State Bar No. 184336
Earthjustice
50 California Street, Suite 500
San Francisco, CA 94111
wpark@earthjustice.org
pcort@earthjustice.org

Tel: 415-217-2000 / Fax: 415-217-2040

Attorneys for Plaintiffs Center for Environmental Health, Beyond Pesticides, and Physicians for Social Responsibility

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO/OAKLAND DIVISION

CENTER FOR ENVIRONMENTAL HEALTH, BEYOND PESTICIDES, AND PHYSICIANS FOR SOCIAL RESPONSIBILITY Plaintiffs, v. GINA McCARTHY, in her official capacity as Administrator of the United States Environmental Protection Agency, Defendant.	Case No: **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

INTRODUCTION

1. Plaintiffs Center for Environmental Health, Beyond Pesticides, and Physicians for Social Responsibility ("Plaintiffs") challenge the United States Environmental Protection Agency's ("EPA") unreasonable delay in completing rulemaking to require manufacturers to disclose the hazardous inert ingredients in their pesticide products.

2. Under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136 *et seq.*, pesticide manufacturers must list on pesticide labels the "active" ingredients that prevent, destroy, repel or mitigate a pest. Ingredients that are not "active" are considered "inert"

under the statute, but this does not necessarily mean biologically or chemically inert. These so-called "inert" ingredients can be just as hazardous and may comprise 50 to 99 percent of a pesticide product's formulation. While these other ingredients are not subject to the same statutory labeling mandates under FIFRA, EPA has the authority under the statute to require their identification and listing.

3. On August 1, 2006, a coalition of 22 public health and environmental organizations, including Plaintiffs, and a coalition of 15 state and territory Attorneys General, submitted to EPA petitions requesting that EPA require pesticide labels to disclose the presence of over 370 chemicals that are commonly used as inert ingredients and also appear on lists of chemicals determined by EPA or Occupational Safety and Health Administration ("OSHA") to present hazards to humans or the environment.

4. In response, EPA granted the petition on September 30, 2009, stating it "intends to effect a sea change in how inert ingredient information is made available to the public." EPA Response to Petition at 3 (attached as Ex. A).

5. On December 23, 2009, EPA initiated rulemaking with an advanced notice of proposed rulemaking to require the disclosure of potentially hazardous inert ingredients. It has been over four years since that advanced notice of proposed rulemaking, and EPA has taken no further action to follow through on its commitment to adopt a rule.

6. EPA's unreasonable delay continues to leave the public uninformed and unable to protect themselves from the hazardous chemicals they are being exposed to through the use of pesticide products. EPA's failure to complete the rulemaking, or otherwise conclude the matter presented in Plaintiffs' 2006 Petition, violates the Administrative Procedure Act's requirement that an agency conclude matters presented to it in a reasonable time. This lawsuit seeks to compel EPA to complete the rulemaking, to ensure the public, consumers, and workers have the information they need to protect themselves from the full range of health and safety risks posed by pesticide products.

JURISDICTION AND VENUE

7. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question). This action arises under the APA, 5 U.S.C. §§ 551 *et seq.*

8. Venue is properly vested in this Court under 28 U.S.C. § 1391(e) because Plaintiff Center for Environmental Health resides and maintains its headquarters in Oakland, California in the Northern District of California.

9. Similarly, because Plaintiff Center for Environmental Health resides in Oakland, assignment to the San Francisco/Oakland Division of this Court is proper under Civil Local Rule 3-2(c) and (d).

PARTIES

10. Plaintiff CENTER FOR ENVIRONMENTAL HEALTH is a non-profit public interest organization with over 20,000 supporters, whose mission is to protect people from toxic chemicals by working with communities, consumers, workers, government, and the private sector to demand and support business practices that are safe for public health and the environment. Based in Oakland, California, the Center teams up with other effective organizations, public health experts, community groups, academics, and public officials to help the government develop and enforce sensible measures to protect people from dangerous chemicals, litigates under California's Safe Drinking Water and Toxic Enforcement Act (Proposition 65) to eliminate toxics from industrial emissions and consumer products, supports communities that suffer the worst effects of chemical pollution in their struggles for cleaner environments, and works with ethical businesses to clean up the electronics and food industries, including the production, distribution, consumption, and disposal of these products. In addition, the Center informs and educates supporters and the general public regarding: legislation, regulations, and policy issues that affect health and the environment, including federal and state pesticide regulations; effective corporate campaigns to protect public health; and how the public can protect themselves and their families from toxic chemicals in consumer products, food, and the environment.

11. Plaintiff BEYOND PESTICIDES is a non-profit public organization based in Washington, D.C., with over 930 members and supporters, whose mission is to work with allies in protecting public health and the environment to lead the transition to a world free of toxic pesticides. The organization's primary goal is to effect this change through local action, by providing the public and community organizations information about the risks of conventional pest management

practices, and by promoting non-chemical and least-toxic management alternatives so that individuals and local communities can make informed choices about pesticide use. This information assists the public in protecting themselves and their families from unnecessary exposure to pesticides and enables communities to effect changes on community-wide pest management decisions and policies, such as pesticide uses in parks, schools, and other public areas. Beyond Pesticides provides various resources regarding pesticides to the public and its members, including a pesticides hazards database on its website, a quarterly magazine, daily news blog, and factsheets about conventional and alternative pest management practices.

12. Plaintiff PHYSICIANS FOR SOCIAL RESPONSIBILITY ("PSR") is a non-profit organization based in Washington, D.C., with 23 chapters in the U.S., including the San Francisco Bay Area. PSR works to prevent the use or spread of nuclear weapons and to slow, stop and reverse global warming and the toxic degradation of the environment, by giving voice to the values and expertise of medicine and public health. PSR has over 35,000 members and activists, many of whom are medical, health care, and public health professionals. With respect to its program for Environment and Health, PSR engages in chemical policy reform, climate policy advocacy, and practitioner education. These efforts include advocating for policies to hold industry accountable for the safety of their chemicals and products and developing practitioner education to prevent the public's exposure to toxic chemicals. For example, PSR has developed a Pediatric Environmental Health Toolkit that trains doctors, medical residents, and staff and community health workers of the Head Start Seasonal and Migrant Farmworker program and provides health education materials on preventing exposures to toxic chemicals and other substances that affect infant and child health.

13. Plaintiffs' members use, purchase, and/or work with pesticides or products to which pesticides have been applied, as well as live in communities, have children that attend schools, and work in buildings and environments where pesticides are applied. Plaintiffs' members also treat patients suffering adverse health effects from pesticides. Their members wish to know the identities and hazards of inert ingredients contained in these pesticides, so that they can make informed choices as to how to best protect themselves, their families, their crops, the environment, and their communities from harmful inert ingredients, choose less hazardous alternatives, ensure that less

hazardous alternatives are used in their communities to minimize risks to health and the environment, and/or provide appropriate and timely treatment to patients who have been exposed to pesticides. They are adversely affected by the non-disclosure of inert ingredient information and EPA's failure to timely complete the rulemaking requested in Plaintiffs' Petition. The adverse effects of EPA's failure and the lack of access to this information include actual or threatened harm to their health, their families' health, their patients' health, and their professional, educational, and economic interests.

14. EPA's failure to timely complete the rulemaking requested in Plaintiffs' Petition also frustrates and harms Plaintiffs' efforts to assist their members and the public in protecting their children, families, and communities from toxic chemicals. Without disclosure of inert ingredient information on pesticide labels, the public is in the dark about the risk of many pesticides, health-care providers are thwarted in providing appropriate and timely treatment to patients exposed to pesticides, and manufacturers have little incentive to use less toxic alternatives. As a result, the public, workers, and the environment are subject to *unknown* or higher risks of adverse health effects and unreasonable environmental impacts from pesticide exposure, and Plaintiffs must expend significant resources to conduct outreach and educate their members, the public, and/or constituents on how to reduce, avoid, and prevent pesticide exposure, to counteract these risks. These activities drain and divert time and resources away from Plaintiffs' other programs and activities to carry out their mission.

15. The legal violation alleged in this Complaint has injured and continues to injure the interests of Plaintiffs and their members. Granting the relief requested in this lawsuit would redress these injuries by compelling EPA to complete the rulemaking requested in Plaintiffs' Petition, or otherwise conclude the matter presented in the Petition.

16. Defendant GINA McCARTHY is sued in her official capacity as the Administrator of the EPA. She is responsible for taking various actions to implement and administer EPA's legal duties, including implementing FIFRA and performing the actions sought in this Complaint.

STATUTORY BACKGROUND

17. EPA regulates the sale, distribution, and use of pesticides in the United States

pursuant to authority provided under the Federal Insecticide, Fungicide, and Rodenticide Act. 7 U.S.C. §§ 136 *et seq*.

18. FIFRA was enacted to "'protect man and his environment' from the deleterious effects of [pesticides]." *New York State Pesticide Coal., Inc. v. Jorling*, 874 F.2d 115, 117, 119 (2d Cir. 1989) (quoting S. Rep. No. 92-838, p. 1 (1972)).

19. Before a pesticide may be sold or used in the United States, EPA must "register" the pesticide. *See generally* 7 U.S.C. § 136a.

20. Registration requires, among other things, EPA's determination that the pesticide "will not generally cause unreasonable adverse effects on the environment." *Id*. § 136a(c)(5)(C) and (D).

21. FIFRA defines "unreasonable adverse effects on the environment" to mean "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide…." *Id*. § 136(bb).

22. Accordingly, EPA has a "basic obligation under… FIFRA of determining the risks which may be posed by a pesticide and imposing the necessary regulatory requirement to adequately control an unreasonable risk. Depending on the risk involved, the [EPA] Administrator is authorized by the amended FIFRA to … require specific label statements" for pesticide products. 40 Fed. Reg. 28242, 28252 (July 3, 1975).

FACTUAL BACKGROUND

23. Over five billion pounds of pesticides are dispersed throughout the United States each year, entering the nation's food supply, homes, schools, public lands, and waterways.

24. The public knows very little about the chemicals contained in most pesticides.

25. Under FIFRA, manufacturers are required to list on pesticide labels the "active" ingredients, *i.e.*, those that "will prevent, destroy, repel or mitigate any pest." 7 U.S.C. § 136(a)(1), (n).

26. "Inert" ingredients, those chemicals added to improve the delivery, durability, or other properties of the pesticide product, are not subject to the same mandatory listing requirements as "active" ingredients. *See id*. § 136(n).

27. Under FIFRA, "inert" means only that these ingredients are "not active," *id.* § 136(m); it does not mean they are actually biologically or chemically inert.

28. Indeed, an ingredient may be active in one pesticide and inert in another. According to EPA's Substance Registry System, 516 inert ingredients are currently, or were at one time, registered as active ingredients.

29. EPA has identified a list of inert ingredients commonly found in pesticides. *See* "Inert Ingredients in Pesticide Products," 52 Fed. Reg. 13305 (April 22, 1987).

30. Of those identified common inert ingredients, over 370 are either hazardous or suspected toxins. These chemicals included:

- two chemicals that are classified as carcinogenic to humans by the International Agency for Research on Cancer (IARC);
- 17 chemicals that are classified as possibly carcinogenic to humans by the IARC;
- 13 chemicals that EPA has listed as "extremely hazardous substances" under the Emergency Planning and Community Right-to-Know Act, 42 U.S.C. § 1102(a);
- 93 chemicals that EPA has listed in the Toxics Release Inventory, which includes chemicals "known to cause or [that] can reasonably be anticipated to cause in humans" "significant adverse acute human health effects," "cancer or teratogenic effects," "serious or irreversible reproductive dysfunctions, neurological disorders, heritable genetic mutations, or other chronic health effects," 42 U.S.C. § 11023(d)(2); and
- 96 inert ingredients that EPA "believes are potentially toxic" and has identified as "high priority for testing" under FIFRA, in part, because they "are structurally similar to chemicals known to be toxic," 52 Fed. Reg. at 13306.

31. Some of these ingredients identified as "inert" are known to cause developmental abnormalities, damage to vital organs, reduced fertility, and/or genetic mutations.

32. Inert ingredients in pesticide products often comprise 50 to 99 percent of their formulations.

33. These ingredients can also magnify the exposure to active pesticide ingredients by: increasing the absorption or penetration of active ingredients through the skin; reducing the

effectiveness of protective equipment, such as gloves; adversely affecting laundry removal of pesticides from clothing; and affecting the volatilization of active ingredients, resulting in increased inhalation exposures.

34. Under current EPA regulations, these chemicals must only be identified as "inert ingredients" with a total weight percentage listed. 40 C.F.R. § 156.10(g)(1); *see also* 7 U.S.C. § 136(n)(1).

35. The result is that pesticide labels mislead the public into thinking that these "inert" ingredients are innocuous. *See* EPA, Pesticide Registration Notice 97-6: Use of Term "Inert" in the Label Ingredients Statement (Nov. 1, 1997), available at http://www.epa.gov/PR_Notices/pr97-6.html (last visited March 4, 2014) (noting "many consumers have a misleading impression of the term 'inert ingredient,' believing it to indicate water or other harmless ingredients").

36. Consumers therefore have a false sense of the safety of pesticide products.

37. In addition, consumers and workers lack the information they need to protect themselves and their communities from harmful inert ingredients, or to choose less hazardous alternatives.

38. Both conventional farmers and organic farmers cannot accurately assess the environmental impacts of pesticides on necessary environmental support systems, such as pollinators, and choose less harmful alternatives. Organic farmers also cannot meaningfully assess damage from pesticide drift on crops that must meet organic standards.

39. Relatedly, without inert ingredient information on pesticide labels, medical professionals cannot quickly and accurately diagnose patients exposed to pesticides or appropriately treat such patients.

40. Requiring disclosure of hazardous inert ingredients in pesticide products would encourage the use of less toxic ingredients, reducing the presence of hazardous ingredients in pesticide products and thus harmful exposure to these ingredients overall. *See* 74 Fed. Reg. at 68217 (noting that when, in 1987, EPA required disclosure of approximately 50 "inerts of toxicological concern," "most [of these] ingredients disappeared from pesticide formulations").

41. On August 1, 2006, a coalition of 22 public health and environmental organizations,

and a coalition of 15 state and territory Attorneys General, each petitioned EPA to require the disclosure of inert ingredients that EPA and OSHA had already identified as hazardous, citing the above reasons for requiring disclosure, among others.

42. Nearly three years later, EPA had failed to take any action on the Petition.

43. On June 25, 2009, plaintiff Center for Environmental Health filed a complaint in this Court to compel EPA to act upon the petition.

44. Shortly thereafter, EPA granted the petitions on September 30, 2009, stating that "the public should have a means to learn the identities of hazardous inert ingredients in pesticide formulations," and adding that "[t]he Agency believes that increased transparency could lead to better informed decision-making and to better informed pesticide use." EPA Response to Petition at 2.

45. EPA's response to the Petitions noted the Agency's "intention to pursue rulemaking to achieve the type of disclosure described in the petitions." *Id*. at 3.

46. On December 23, 2009, EPA issued an Advanced Notice of Proposed Rulemaking ("ANPR") soliciting comment on two alternative proposals--one that would require listing of "potentially hazardous" inert ingredients and another that would require listing of most or *all* inert ingredients. 74 Fed. Reg. at 68219.

47. In the ANPR, EPA recognized that public disclosure of hazardous inert ingredients in pesticides could:

- "enable consumers and users of pesticides to make more informed decisions when choosing or using pesticide products";
- "provide important information regarding the use of a pesticide, potentially enabling the consumer to avoid choosing a particular product to use in a situation where one or more of the inert ingredients might have an adverse health or ecological impact"; and
- "lead the market to provide more product choices that could reduce overall exposures to potentially hazardous chemicals."

Id. at 68219.

48. In the ANPR, EPA acknowledged its authority to require public availability of

potentially hazardous inert ingredients, which "can be found in the registration requirements of FIFRA section 3, the definition of 'unreasonable adverse effects on the environment' in FIFRA section 2(bb), and EPA's rulemaking authority under FIFRA section 25(a)." *Id*. at 68222.

49. Specifically, it explained that under FIFRA's requirement for EPA to ensure that any pesticide it registers "will perform its intended function without unreasonable adverse effects on the environment," it must take into account "the economic, social, and environmental costs and benefits of the use of any pesticide." *Id*. (citing 7 U.S.C. §§ 136(bb), 136a(c)(5)(C)). Because "formulations that contain hazardous inert ingredients as a general matter may have a less favorable cost/benefit ratio than similar formulations that perform the same function and do not contain potentially hazardous inert ingredients," EPA had the authority to take measures to reduce the use of hazardous inert ingredients in pesticides, including making inert ingredient information public. *See id*.; *see also* EPA Response to Petition at 2.

50. The ANPR also stated: "EPA considers pesticides containing potentially hazardous inert ingredients to be in a separate class from formulations that do not contain such ingredients, and believes it appropriate to use its FIFRA section 25(a) rulemaking authority to take action to reduce the presence of potentially hazardous ingredients." 74 Fed. Reg. at 68222 (citing 7 U.S.C. § 136w(a)(1) (allowing EPA to prescribe regulations that "shall take into account the difference in concept and usage between various classes of pesticides … and differences in environmental risk")).

51. EPA solicited public comment on the proposed rulemaking. On February 22, 2010, EPA extended the public comment period by 60 days, until April 23, 2010.

52. Over seven-and-a half-years have passed since EPA received the petitions for rulemaking and over three-and-a-half years have passed since it closed public comment on the ANPR. To date, EPA has taken no further action to complete the rulemaking, failing to follow-through on its commitment to adopt a rule.

CLAIM FOR RELIEF

EPA Is in Violation of the Administrative Procedure Act Because It Has Failed to Conclude the Matter Presented in the Petition

53. Plaintiffs reallege each and every allegation set forth above, as if fully set forth

herein.

54. Under the Administrative Procedure Act, each agency "shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule." 5 U.S.C. § 553(e).

55. The APA further provides that, "within a reasonable time, each agency shall proceed to conclude a matter presented to it." 5 U.S.C. § 555(b).

56. Where agencies have failed to conclude matters within a reasonable time, the APA empowers courts to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1).

57. After Plaintiffs submitted the Petition on August 1, 2006 and EPA initiated a proposed rulemaking on December 23, 2009, EPA was obligated to complete the rulemaking, or otherwise conclude action on the Petition's request for rulemaking within a reasonable time.

58. EPA has taken no action to complete the rulemaking or conclude action on the Petition's request for rulemaking since the close of the public comment period on April 23, 2010.

59. This failure to complete the rulemaking or otherwise conclude action on the Petition's request for rulemaking constitutes a violation of the APA's requirement to conclude a matter presented to it "within a reasonable time," 5 U.S.C. § 555(b), and constitutes agency action "unreasonably delayed."

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the Court to grant the following relief:

1. DECLARE that EPA has:

   (a) unreasonably delayed concluding action on the Petition's request for rulemaking; and

   (b) unreasonably delayed completion of the rulemaking proposed in the ANPR.

2. ISSUE an injunction directing EPA to:

   (a) publish a notice of proposed rulemaking for a rule requiring the public disclosure of hazardous inert ingredients or all inert ingredients within 60 days of the Court's determination that EPA's delay is unreasonable and publish a final rule within 180 days of the notice of proposed rulemaking; or

(b) otherwise conclude action on the Petition's request for rulemaking within 60 days of the Court's determination that EPA's delay is unreasonable.

3. RETAIN jurisdiction over this matter until such time as EPA has complied with its duties to conclude action on the Petition's request for rulemaking;

4. AWARD to Plaintiffs their costs of litigation, including reasonable attorney and expert witness fees; and/or

5. GRANT such additional relief as the Court may deem just and proper.

DATED: March 5, 2014

Respectfully submitted,

/s/ Wendy S. Park
WENDY S. PARK
PAUL R. CORT

Attorneys for Plaintiffs

EXHIBIT A

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

SEP 30 2009

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Ms. Kim Leval
Northwest Coalition for Alternatives to Pesticides
P.O. Box 1393
1216 Lincoln St.
Eugene, OR 97440

Mr. Edmund.G. Brown Jr.
Attorney General of the State of California
c/o Susan Fiering
Deputy Attorney General
California Department of Justice
P.O. Box 70550
1515 Clay St., 20th fl.
Oakland, CA 94612-0550

Mr. Charles M. Tebbutt
Western Environmental Law Center
1216 Lincoln St.
Eugene, OR 97401

Re: Petition of Northwest Coalition for Alternatives to Pesticides, et al., to Require Disclosure of Hazardous Inert Ingredients on Pesticide Product Labels ("NCAP Petition")
and
Petition of [15 U.S. States and Territories] Requesting That the United States Environmental Protection Agency Amend Its Rules Governing the Disclosure Of "Inert" Ingredients on Pesticide Product Labels to Require the Disclosure of Ingredients for Which Federal Determinations of Hazard Have Already Been Made ("State Petition")

Dear Ms. Leval, Attorney General Brown and Mr. Tebbutt:

I am writing to respond to the above-referenced petitions, received by EPA on August 1, 2006. These similar petitions identified a set of over 350 inert pesticide ingredients as hazardous and requested that EPA act to require that the inert ingredient identities appear on the labels of products that include these ingredients in their formulations. EPA partially grants these petitions as set forth below.

The State Petition requested the following:

> The Petitioners request that EPA issue a determination within 60 days of the filing of this Petition that these substances meet those FIFRA criteria for disclosure on the ingredient statement on pesticide labels. Petitioners further request that, consistent with that determination, the Administrator initiate a rulemaking to amend its regulations governing the labeling of pesticide products to require that those chemical substances identified in the Administrator's determination as posing a hazard to public health or the environment be disclosed on the label of any pesticide product in which they are formulated.

State Petition at 3.

Below is the request of the NCAP Petition:

> Petitioners request that EPA issue a determination within 60 days of the filing of this Petition to amend its labeling regulations, 40 C.F.R. § 156.10, to require that pesticide product labels clearly list any inert ingredients that EPA regulates as a hazardous chemical under other statutory provisions. Should EPA determine that it will not or cannot list all chemicals identified as hazardous under other statutes, petitioners request that EPA assess each enumerated list in this petition and make a section-by-section determination of whether to require labeling for each subset section. Should EPA determine that it will not or cannot make a section-by-section determination, petitioners request that EPA assess each chemical within each enumerated list in this petition and make an individual determination for each chemical of whether to require labeling for that chemical. Separately from the foregoing requests for labeling, petitioners also request that EPA require labeling of the hazardous inerts identified in the Hazardous Substance Data Bank.

NCAP Petition at 1.

EPA agrees with the petitioners that the public should have a means to learn the identities of hazardous inert ingredients in pesticide formulations. The Agency believes that increased transparency could lead to better informed decision-making and to better informed pesticide use.

EPA finds support in FIFRA for increased transparency regarding hazardous inert ingredients. The safety of the formulation, including all its ingredients, is a critical factor in whether the pesticide "will perform its intended function without unreasonable adverse effects on the environment" (FIFRA §3(c)(5)(C)). Under FIFRA §2(bb), the term "unreasonable adverse effects on the environment" takes into account "the economic, social, and environmental costs and benefits of the use of any pesticide". EPA believes, as a general matter, that pesticide formulations containing hazardous inert ingredients have a less favorable cost/benefit ratio than otherwise identical formulations that perform the same function and do not contain hazardous inert ingredients. Thus, EPA has the authority under FIFRA to take measures to reduce the use of hazardous inert ingredients in pesticide formulations, including making inert ingredient information public.

In response to these petitions, 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. The Agency is considering regulatory action as well as pursuing voluntary initiatives to achieve this broader disclosure.

As an alternative to rulemaking, the NCAP petition asked that EPA make a chemical-by-chemical determination and then require the labels of specific products containing inert ingredients deemed hazardous to disclose the presence of the ingredient. The Agency thinks that such an approach could potentially involve EPA having to address relative levels of risk of specific inert ingredients on a case-by-case basis via label reviews, approvals of specific formulations for individual products, and even cancellation under section 6. Challenges to individual decisions would have to be addressed individually. In comparison to rulemaking, EPA thinks that a chemical-by-chemical and product-by- product approach to compelling disclosure would be very slow and resource-intensive. It is more efficient to use the authority provided in FIFRA section 25(a)(1) "to prescribe regulations to carry out the provisions of [FIFRA]. Such regulations shall take into account the difference in concept and usage between various classes of pesticides. . . and differences in environmental risk."

There are a number of significant issues regarding the regulatory action that EPA may choose to take, such as the criteria for determining what inert ingredient identities should be made public, the extent to which disclosure independent of hazard can be supported under existing law, whether a concentration threshold should trigger a disclosure requirement, whether public disclosure should made on pesticide labels or other avenues (e.g., web resources), and what form the disclosed ingredient identities should take (e.g., Chemical Abstract Service names, trade names, common chemical names).

By embarking on such rulemaking, EPA intends to effect a sea change in how inert ingredient information is made available to the public. Because of the magnitude of the change and the difficult issues facing the Agency, EPA desires a significant amount of input from the many sectors that would be affected. Therefore the Agency is initiating this rulemaking via an Advance Notice of Proposed Rulemaking (ANPR). EPA is providing a draft of this ANPR to the Office of Management and Budget (OMB) for review in accordance with Executive Order 12866. The status of OMB's review of the ANPR may be viewed at http://www.reginfo.gov/public/do/eoPackageMain. We anticipate that the ANPR will be published by the end of this year.

EPA is not committing, and indeed legally cannot commit, to any particular outcome for rulemaking. Nonetheless, EPA regards its commitment to issue an ANPR as a partial grant of the petitions, in that the ANPR will announce the Agency's intention to pursue rulemaking to achieve the type of disclosure described in the petitions. As noted above, proposals to disclose the presence of inert ingredients in pesticide products raise many complex issues. An ANPR is therefore an appropriate first step because it will enable EPA to gather information and views from potentially affected stakeholders needed to develop a sound, practical and defensible

proposed rule. EPA is not, however, proceeding in the manner requested by the petitioners -- issuing determinations for that the specific substances listed in the petitions must be disclosed on product labels. Doing so would potentially result in numerous challenges regarding individual products Furthermore, the Agency believes there are a variety of criteria that might be used to determine which inert ingredients should be disclosed on the basis of hazard, and desires informed input from diverse members of the public in order to determine the appropriate criteria. These factors, together with the opportunity to put forward a vision for broad disclosure of inert ingredient identities, lead EPA to conclude that a wide-ranging ANPR is the appropriate starting point for achieving inert ingredient disclosure.

The substantial participation of the petitioners in this rulemaking, as well as that of the other affected members of the public, is pivotal to the creation of workable and effective disclosure rules. I am looking forward to a robust and informative dialogue.

Sincerely,

Debra Edwards, Ph.D., Director
Office of Pesticide Programs

cc: Todd Ommen
New York State Attorney General's Office
Environmental Protection Bureau
120 Broadway, 26th Floor
New York, NY 10271