Kerry Leifer
Office of Pesticide Programs
(OPP) Regulatory Public Docket (7502P)
Environmental Protection Agency
1200 Pennsylvania Ave., NW.
Washington, DC 20460–0001

Dear Mr. Leifer:

The Center for Environmental Health and 42 supporting organizations submit the following comments on the U.S. Environmental Protection Agency's proposal to seek disclosure of inert ingredients (Docket ID # EPA-HQ-OPP-2009-0635).

First we congratulate the Agency on taking a monumental step forward by seeking to increase disclosure about inert ingredients in pesticides. We will support the Agency's efforts as it seeks to provide the public with important information. At the same time, we do not believe that EPA has yet provided an adequate response to the rule-making petition submitted to the Agency in 2006 by CEH and some of the other organizations signing this comment letter. So far, the Agency has proposed options but has not provided a specific response.

Next we offer a comment on EPA's overall strategy.

In the advance notice of proposed rulemaking (ANPR), the Agency states that "EPA is considering two general approaches to increasing public availability of inert ingredient identities. One would mandate disclosure only of potentially hazardous ingredients, and the other would promote or mandate public availability of most or all inert ingredient identities, regardless of hazard." The 2006 petition mentioned above asked EPA to mandate disclosure of hazardous ingredients. Our support for that policy has not changed since 2006. We recommend that the Agency move forward as quickly as possible to require identification of all hazardous ingredients on product labels. We believe that the rule-making process must identify a specific timeline to implement the disclosure that was requested in the petition. We incorporate by reference the requests made, and the reasons stated, in the 2006 petition. At the same time, we understand clearly the benefit to mandating disclosure of all inert ingredient identities.

We do not believe that the two strategies are inconsistent with each other. We recommend that EPA move forward as quickly as possible with the first option, the identification of potentially hazardous ingredients as set forth in the 2006 rule-making petitions which prompted this ANPR. We also recommend that EPA move forward with the second option, the public availability of most or all inert ingredient identities, recognizing that this option will take longer to implement than the first option. The first option then becomes an interim step to protect public and environmental health while the Agency implements the broader second option.

Third, we answer two of EPA’s questions from Unit II regarding the feasibility of reverse engineering to identify inert ingredients.

Do registrants and inert ingredient manufacturers know (or can they easily find out) what is in their competitors' products?

In the 1990s the Northwest Coalition for Alternatives to Pesticides contracted with a commercial laboratory to deformulate two herbicide products. The process was neither difficult nor expensive. If a small nonprofit organization could do this two decades ago when analytical techniques were not as well developed as they are now, it is safe to assume that registrants and inert ingredient manufacturers can also easily reverse engineer competitors' products. The existence of commercial laboratories that specialize in "deformulation analysis" also indicates that the process is feasible, practical and commercially available.

To what extent do patents or other public sources of information provide this kind of information?

Material safety data sheets identify inert ingredient information, although the identification is not complete or consistent. For examples, see http://www.cdms.net/LDat/mp6KL003.pdf ; http://www.cdms.net/LDat/mp3QT000.pdf ; and http://www.cdms.net/LDat/mp239003.pdf

The organizations signing these comments are not experts in patent law and procedures. However, we asked a student volunteer to see how much information about inert ingredients was available from patent searches. She reported that "a cursory search in USPTO's patent database revealed that the identity of the chemical compounds used in developing pesticides are available in the patent descriptions."

Finally, we answer some of the specific questions that EPA identified in the advance notice of proposed rulemaking.

1a. How should the list of potentially hazardous ingredients be identified? EPA is interested in comments on three potential approaches.

(1) EPA could by rule require disclosure of the identity of an ingredient if the ingredient appeared on specified lists; this is the approach advocated by the petitioners. The petitions identify a variety of statutory, regulatory, and other listings that relate in some way to hazard. Some of the ingredients have been placed on these listings by Congress, and some have been included based on EPA or other agency evaluations of hazard (which may or may not be in a specific exposure context).

(2) EPA could by rule establish objective criteria for determining whether to require disclosure, applying those criteria on an ingredient-by-ingredient basis. Unit II.E. of this ANPR contains an example of possible criteria.

(3) EPA could by rule list specific chemicals used as inert ingredients that would trigger a disclosure requirement. While approach number 2 would present criteria to use on a case-by-case basis, this approach would present a list of chemicals. In developing this list, EPA could use approach number 1 or 2 or a combination of both approaches to identify the individual chemicals to include on the list and would need to identify a process for revisions to the list. EPA considers the set of ingredients and categories identified in the petitions to be a useful starting point for discussion, but desires input regarding the categories and the chemicals contained within them. For example, should chemicals placed in the TRI by Congress be considered presumptively hazardous for purposes of label disclosure? In addition, EPA solicits suggestions for other hazard criteria to be used as a basis for identifying ingredients to be listed in the ingredient statement.

We support approach #1 (as advocated by the 2006 rulemaking petitions). We support this approach because it will provide the Agency with an expeditious approach to identifying hazardous ingredients that EPA can implement quickly. We recognize that many of the lists identified in the petition are static and therefore do not include ingredients that more recent evaluations have shown are hazardous. However, we support approach #1 because it will allow EPA to move forward quickly with the necessary regulatory changes. This will maximize the benefits for health and the environment that the Agency has outlined in the ANPR. EPA can also add a chemical at whatever time to any of the lists if the Agency determines that the chemical is hazardous under the statutes listed in the petition.

If EPA finds that approach #2 is either necessary or provides more protection for health and the environment then we recommend that the Office of Pesticide Programs use the criteria developed by the Design for the Environment (DfE) program (http://www.epa.gov/dfe/pubs/projects/gfcp/index.htm). The criteria are designed to identify "safer chemical ingredients"; we recommend that EPA consider ingredients that do not pass the DfE screens to be potentially hazardous and require their disclosure.

If EPA finds that approach #3 is either necessary or provides more protection for health and the environment then we recommend as above that EPA make use of the DfE criteria to identify the list of specific chemicals that would trigger a disclosure requirement.

We also recommend that EPA (if the agency is using any of the 3 approaches outlined in the ANPR) consider chemicals placed on the TRI by Congress as presumptively hazardous for purposes of label disclosure. The statutory language establishing the TRI ("The chemical is known to cause or can reasonably be anticipated to cause in humans- (i) cancer or teratogenic effects, or (ii) serious or irreversible--(I) reproductive dysfunctions, (II) neurological disorders, (III) heritable genetic mutations, or (IV) other chronic health effects. (C) The chemical is known to cause or can reasonably be anticipated to cause, because of-- (i) its toxicity, (ii) its toxicity and persistence in the environment, or (iii) its toxicity and tendency to bioaccumulate in the environment, a significant adverse effect on the environment") clearly is designed to identify hazardous chemicals.

1b. How should specific ingredients be added to or removed from the disclosure requirements? EPA could add (or remove) individual ingredients via regulation, or, at least for those categories established and amended via statute or regulation, could simply require that all ingredients in the category be subject to the disclosure requirement. EPA desires comment on both science and process implications of these two alternatives, as well as additional ideas.

We recommend that EPA adopt the simplest possible approach to identifying ingredients that are subject to the disclosure requirements, that is, the approach outlined in the two rulemaking petitions (require disclosure of all ingredients on the specified lists). We make this recommendation because the protection of public health and the environment is best served by a process for requiring disclosure of potentially hazardous ingredients that can be implemented quickly and without a large commitment of resources from the Agency. We understand that in

some cases this approach will not comprehensively incorporate current science, since some of the lists are static and have not been recently updated. However, we support this approach because we believe it is more efficient and will provide consumers with information more quickly than approaches that require a reevaluation of ingredient hazards and will require more Agency resources. We make this recommendation in the context of also recommending that EPA move forward with disclosure requirements for most or all ingredients as soon as possible.

1c. Should EPA consider the amount of an ingredient in a product in determining whether to require disclosure, and if so how?

We recommend that EPA follow the approach used on food ingredient statements and cosmetic labels. In these cases, all ingredients are listed, regardless of the amount in the product, and ingredients are listed in order of predominance, with the ingredients used in the greatest amount first, followed in descending order by those in smaller amounts.

Should there be a de minimis concentration, below which a potentially hazardous inert ingredient would not be required to appear in the ingredient statement? EPA is initially inclined not to use the quantity of an inert ingredient--including any de minimis threshold--as a factor in determining what information should be disclosed. EPA is concerned that using a quantity factor could interfere with the consumers' ability to fully express their choices through informed purchasing and thereby adversely affect the potential for market-driven incentives for pesticide producers to provide products with less hazardous inert ingredients. It could also compromise the consumers' ability to limit their total exposure to a hazardous substance. In providing comments on using a quantity factor, please also provide suggestions for how EPA might address these concerns.

We recommend that EPA not identify a "de minimis" concentration below which disclosure requirements do not apply. We support the Agency's initial inclination for the reasons stated in the ANPR. In addition, we recommend that the agency not identify a de minimis concentration because the enormous amount of individual variation in susceptibility to a particular ingredient. Consider, by way of example, peanut butter, one of the many substances used as inert ingredients. For most people, the "de minimis" concentration of peanut butter would be rather large. For people who are severely allergic to peanuts, the "de minimis" concentration of concern is zero. Consider also sodium sulfite, also used as an inert ingredient. Some people are severely allergic to sodium sulfite, again requiring a "de minimis" concentration of zero. For some inert ingredients people may be exposed from a variety of products and exposure pathways, again making disclosure subject to a "de minimis" concentration unprotective of human health.

1d. Does disclosing the identities of hazardous inert ingredients on the label without further information provide consumers and users with information that is useful? EPA is soliciting comments on additional disclosure approaches to provide such information, including the effectiveness of such an approach, as well as the associated costs and benefits. EPA also seeks comment as to the possible positive or negative impacts of each such approach on the development of new pesticide products, in providing for more informed consumer decision-making, and in providing an incentive for manufacturers to use less hazardous inert ingredients.

We recommend that the agency answer this question with an unequivocal "yes." Pesticide consumers and users include individuals and institutions (such as researchers and municipalities) with the expertise to locate information about the specific hazards associated with identified ingredients. Other consumers and users can consult with experts (workplace safety managers, cooperative extension agents, physicians) to get information about identified ingredients.

EPA's experience with identifying hazardous inert ingredients in 1987 suggests that ingredients identified this way will soon be rarely used. Since they were mostly removed from pesticide products, consumers will not have to ascertain additional information about these ingredients. Furthermore, requiring listing on the label should also trigger increased disclosure in material safety data sheets, where more detailed information can be provided for all users.

We also recommend that EPA look at the growth of the market for 25(b) products as a demonstration that disclosure of inert ingredients can actually promote the development of new products, provide an incentive for manufacturers to use less hazardous ingredients at the same time that it provides for more informed consumer decision-making.

1e. Should potentially hazardous impurities be required to appear on the label? While inert ingredients are intentionally added to a product, impurities are not. See 40 CFR 158.300. Impurities are often leftover reactants from the manufacturing process, and their disclosure thus might in some cases reveal sensitive manufacturing process information. What are the pros and cons of including impurities in a disclosure requirement?

We support the Agency's desire to identify potentially hazardous impurities on product labels. However, we recommend that this process be separated from the effort to identify potentially hazardous intentionally-added ingredients. We make this recommendation because we believe that protection of human and environmental health requires that the disclosure of potentially hazardous inert ingredients proceed quickly and we are concerned that the complexities of requiring disclosure of impurities could slow down the process for the intentionally added inert ingredients.

Should impurities have a de minimis concentration threshold, even if inert ingredients ultimately do not? Note that impurities below a concentration of 0.1% are not normally reported to EPA unless the impurity is of toxicological significance. See 40 CFR 158.320. Would a 0.1% threshold make sense for impurities? How should the Agency determine which impurities need to be identified on the label?

We recommend that EPA not have a de minimis concentration for potentially hazardous impurities. This would be consistent with EPA's current policy that requires reporting to EPA about impurities with no de minimis concentration if the impurity is of toxicological significance.

2a. Are there classes of ingredients that should be identified only by the name of the class? Examples might be functional (e.g., fragrances, surfactants), a chemical class (e.g., clay, modified starch), or otherwise. When would the use of chemical classes be appropriate or inappropriate?

The use of functional or chemical classes is inappropriate if the chemical is one that EPA has identified as hazardous. For broader disclosure, EPA's proposal to "promote or mandate public

availability of most or all inert ingredient identities," we recommend that functional or chemical classes be used under a limited set of circumstance: if the registrant of the product has demonstrated that the specific identity of the product is not publicly available, the ingredient identity cannot readily be determined through reverse engineering, and identification of the ingredient on product labels would cause the registrant competitive harm. If these conditions are documented by the registrant and the documentation approved by EPA, the ingredient statement on the product could include the class description rather than the specific identity of the ingredient that legitimately deserved protection as confidential business information. For example, the ingredient statement could say "surfactant" instead of the common chemical name of a surfactant that is legitimately confidential business information.

2b. Should impurities potentially appear on the label regardless of hazard? See Unit II.C.1.e., for more discussion of impurities.

As stated earlier, we support EPA's efforts to mandate label identification of impurities. We support these efforts both for inert ingredients that have already been identified as hazardous and those that have not. We recommend that this initiative be separate from the efforts to mandate identification of intentionally added inert ingredients because of the additional complexities of the impurity issue.

3a. How might consumers respond to the disclosure approaches presented previously? Would there be any difficulty in interpreting the information? How would consumers judge risks from hazardous inert ingredients that have broader environmental impacts as opposed to risks that are borne more directly by the user? What evidence exists regarding how disclosure affects consumer decisions and market outcomes in similar contexts? How should disclosure be designed to achieve better user decision-making?

We believe that general consumers will respond to disclosure of inert ingredients in much the same way that consumers respond to ingredient statements on food or cosmetics. Consumers who need to avoid particular ingredients will do so. Consumers who want assistance in understanding complex chemical names will seek out information from government agencies, educational institutions, and nonprofit organizations that specialize in these issues, physicians, researchers, or agencies with expertise in these areas. The same sources of information will be useful to consumers who wish to understand environmental impacts.

Consumers of agricultural and institutional pesticides have access to pest control advisors, extension agents, organizations that evaluate, certify, or rank pesticides and pest management practices, and researchers at land grant universities to help interpret inert ingredient information. In addition this type of consumer often has in-house expertise.

As mentioned earlier, both current experience with 25(b) products and the experience with EPA's 1987 disclosure requirements show that disclosure both removes hazardous ingredients from products and creates new markets for low-hazard products.

3b. If inert ingredients are required to be listed on the label, would consumers and users be able to weigh the risk from the listed inert ingredients against that from the active ingredients, which often pose

greater risks than the disclosed inert ingredients? What steps would assist consumers and users in taking into account all risks posed by the pesticide?

We believe that most consumers will not be concerned about weighing the risk from inert ingredients against that from active ingredients. Instead, most consumers will be concerned with either specific hazards of the individual chemicals (active and inert) and with hazards of the mixture of active and inert ingredients. Public identification of all of the ingredients will make it possible for consumers and the experts that consumers consult to make informed assessments of these hazards.

3c. What are the possible positive or negative impacts of the approaches described in Unit II.C. on the development of new pesticide products?

The increase of 25(b) products in recent years suggests, at the very least, that disclosure of inert ingredients does not hinder the development of new pesticide products. Also, the experience with cosmetics and over-the-counter drugs (both of which identify all ingredients on product labels) shows that ingredient disclosure does not hinder the development of new products.

3d. Should the concentration of ingredients be disclosed, along with their identities? How might the concentration inform the decision-making of the consumer or user? Is there sufficient benefit to consumers and users to do so? What are the interests of registrants and manufacturers of proprietary inert ingredients and proprietary mixtures of inert ingredients in concentration information?

We recommend that EPA follow the example of food and cosmetic ingredient labels, which identify ingredients in descending order of concentration, but do not provide exact concentrations. We recommend this approach because it avoids the need to determine whether the exact concentrations in a mixture are confidential business information but also provides consumers with a relative way of assessing the amount of an ingredient in a product.

3e. *Should inert ingredients be listed in order of concentration? Although specific concentrations are not provided for food products and cosmetics, the ingredients are typically listed in order of concentration as instructed at 21 CFR 101.4 and 21 CFR 701.3, respectively, under FDA regulations implementing the Federal Food, Drug, and Cosmetic Act. How might listing the inert ingredients in order of concentration inform the decision-making of the consumer and user? What would be the value of this type of listing for pesticide consumers and users? Could listing inert ingredients in order of concentration mislead consumers or users regarding the safety of the formulation?*

As stated above, we support listing of inert ingredients in order of concentration. We believe that this will provide useful information to consumers who need to avoid a particular ingredient, and also help consumers who wish to make an evaluation of the overall environmental impact of using a particular product. The widespread acceptance and use of this kind of labeling for food and cosmetics indicates that it does not mislead consumers or users. It will also enable consumers to (with the assistance of experts if necessary) consider estimates of relative concentration if they need to make a detailed assessment of a particular product.

3f. EPA has on occasion rejected pesticide labels with partial disclosure of inert ingredient identities as misleading under FIFRA section 2(q)(1)(A) on the theory that emphasizing ingredients widely considered innocuous can mislead consumers as to the overall safety of the formulation. What features of a label (or other disclosure) could help avoid this outcome?

The disclosure approach that we are recommending, disclosure of hazardous inert ingredients as an interim step followed by disclosure of most or all inert ingredients, circumvents any potential confusion caused by an approach that would allow registrants to emphasize ingredients widely considered innocuous. We also recommend that EPA continue its policy of rejecting labels that identify only ingredients most people consider innocuous.

3g. In PR Notice 97-6, http://www.epa.gov/opppmsd1/PR_Notices/pr97-6.html, EPA allowed and encouraged pesticide registrants to replace the designation ``inert ingredients'' with ``other ingredients'' on pesticide labels, because inert ingredients may in some cases be associated with hazard, and the term ``inert ingredients'' might therefore be confusing. Under a full or partial disclosure of inert ingredients, should EPA discontinue to allow the substitution of the term ``other ingredients'' for ``inert ingredients'' on product labels?

We agree with the Agency that "inert ingredients may in some cases be associated with hazard and the term 'inert ingredients' might therefore be confusing." We are not aware of problems that have been caused by PR Notice 97-6. We recommend that EPA continue with the current policy.

3h. Should inert ingredients continue to be listed in a separate location from active ingredients? Current EPA guidelines contained in the Label Review Manual specify that active ingredients be listed on the product label separately from inert ingredients. Should EPA preserve this distinction between inert and active ingredients? Should the inert ingredient listing be divided into hazardous and non-hazardous sections?

We recommend that EPA continue its current policy of listing active ingredients separately from inert ingredients. If EPA follows our recommended approach of requiring disclosure of hazardous inert ingredients as an interim step and full disclosure as a longer term step, we would support dividing inert ingredients into "other hazardous" and "other" sections, but only during the interim period.

3i. Should disclosure of the inert ingredient identities be made elsewhere than on the label, such as in accompanying labeling materials, by a registrant-operated toll free telephone system, or on an EPA-maintained website? What information would be useful to provide on a website? What other alternative ways of communicating information to users about ingredients and safety of pesticides might be effective? What are the advantages and disadvantages of such alternatives?

We recommend that disclosure of inert ingredient identities be made on the label. Consumers are accustomed to looking on labels for this information; it provides simple, quick access to the information for health professionals who are treating a pesticide-related illness; and it avoids potential confusion caused by pesticides with similar names but different ingredients or pesticides whose formulation changes.

A website or toll-free telephone system is a convenient way for additional information about inert ingredient identities (in particular the CAS Registry number) to be provided.

3j. Should unique procedures apply to products containing proprietary inert ingredients or proprietary mixtures of inert ingredients? Because registrants may not know the identity of a proprietary inert ingredient or the identities of all the ingredients in a proprietary mixture of inert ingredients, there may be confidentiality concerns when informing registrants of new requirements applying to their pesticide products, and such registrants might face additional barriers to adjusting to a disclosure requirement. In addition, manufacturers of proprietary inert ingredients and proprietary mixtures of inert ingredients might raise confidentiality and other issues that do not apply to registrants.

In the interests of creating a "level playing field" for all pesticide products, we believe that no unique procedures should apply to products containing proprietary inert ingredients or proprietary mixtures of inert ingredients.

k. Should disclosure of the identity of inert ingredients apply to all types of pesticide products or should EPA exempt certain types of products, e.g., manufacturing use products, plant-incorporated protectants, biopesticides, products intended only for use in industrial settings such as wood preservative treatment facilities, from disclosure rules?

Some of the products identified in this question (manufacturing use products, products intended only for use in industrial settings) have the potential to expose employees who work at the manufacturing or industrial facility and disclosure of inert ingredients will provide significant assistance to worker health and safety efforts. Some have the potential to expose employees during transport. In addition, as with the previous question, creating a level playing field is best accomplished by having uniform disclosure requirements for all pesticides.

3l. What form of ingredient identity should appear on the label? There are a variety of ways to identify an ingredient, such as Chemical Abstracts Service (CAS) name, CAS Registry Number, trade name, and common chemical name (of which there may be several). Which form would be most useful to consumers and users of pesticides? See 40 CFR 156.10(g) for requirements regarding common names for active ingredients, and Pesticide Registration (PR) Notice 97-5: Use of Common Names for Active Ingredients on Pesticide Labeling, http://www.epa.gov/opppmsd1/PR_Notices/pr97-5.html, for Agency policy and guidance.

We recommend that the common chemical name designated as the "EPA Registry Name" in the Agency's Substance Registry Services database be the name that is used on the label. As stated earlier, we also support the development of a web site that identifies CAS Registry Numbers in addition to the common chemical names. This would allow use of common names, which is easier for consumers, but also provide a standard reference for determining which common name to use, if there was more than one.

3m. How would a non-regulatory approach, such as voluntary disclosure of inert ingredients by pesticide registrants, affect consumer decisions and market outcomes? What would be the advantages and

disadvantages of voluntary disclosure versus required disclosure in considering the issues noted in items a. through l. of this unit?

Voluntary disclosure would be able to affect consumer decisions and market outcomes only to the extent that all (or almost all) ingredients are disclosed on individual product labels and disclosure occurs for all (or almost all) products. Past experience with voluntary initiatives suggests that this is unlikely to occur. A regulatory approach is the simplest way to provide the "level playing field" for registrants mentioned earlier. It is also the simplest way to be sure that health professionals have quick, efficient access to inert ingredient information when necessary for treating a patient. We are also concerned that voluntary disclosure could lead to the disclosure of ingredients such as water and without the disclosure of ingredients that pose health or environmental hazards, resulting in misleading labels.

3n. What lead time should be given before the effective date of any regulatory changes, and should there be any special process for approving new labels? Registrants and manufacturers of proprietary inert ingredients/proprietary mixtures of inert ingredients may wish to reformulate rather than continue with a formulation where potentially hazardous ingredients are listed in the ingredient statement. Since EPA normally requires acute toxicity data on each new formulation of a pesticide, any large-scale movement toward reformulation of pesticides could result in a significant amount of additional animal toxicity studies. Further, the logistics of widespread label change or possible product reformulation may present special challenges for EPA, States and the regulated community. What procedures would minimize disruption? Are there alternatives to requiring the testing of products reformulated to eliminate hazardous inert ingredients?

We recommend that the lead time for the effective date of any regulatory changes related to disclosure of hazardous inert ingredients be as short as possible (60 – 90 days) because these ingredients have already been identified as hazardous. We recognize that the lead time for full (or nearly full) disclosure will necessarily be longer. This is why we urge the Agency to move forward with disclosure of hazardous inert ingredients as an interim step.

We also recommend that the Agency adopt policies to encourage registrants to reformulate to remove hazardous ingredients. One such policy could be expedited approval of the new formulation. Another policy could be to allow the registrant to use the "21st Century" toxicology testing methods advocated by the National Academy of Sciences to reduce the need (and expense) of animal testing.

3o. Are there other regulatory approaches that may promote the use of less hazardous inert ingredients that might be considered in lieu of inert ingredient disclosure? For example, what would be the potential impacts on consumers, pesticide manufacturers, and the general public if EPA were to limit or prohibit the use of any hazardous inert ingredient in a pesticide product?

We support EPA's efforts to limit or prohibit the use of hazardous inert ingredients in pesticide products. However, we recognize that any such limit or prohibition would likely be a lengthier process than label disclosure. Therefore we recommend that the Agency move forward with disclosure of hazardous inert ingredients while limits or prohibitions are in process.

Sincerely,

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El Comite de Apoya a Los Trabajadores Agricolas
The Farmworker Support Committee
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