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April 23, 2010

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

**Re: Public Availability of Identities of Inert Ingredients in Pesticides, Docket Number: EPA-HQ-OPP-2009-0635**

Dear Sir/Madam,

Thank you for this opportunity to comment on the agency's proposed rulemaking to increase public availability of the identities of inert ingredients in pesticide products. The agency is initiating this rulemaking in response to petitions submitted in 2006 by the Northwest Coalition for Alternatives to Pesticides (NCAP) and the Attorneys General of 15 U.S. States and territories. Beyond Pesticides, a supporter of the 2006 NCAP petition, has long advocated for greater transparency and full disclosure of all pesticide ingredients in order to better protect public health and the environment, as well as discourage the use of hazardous inert ingredients in pesticide formulations. Beyond Pesticides was also a co-plaintiff in the successful lawsuit Northwest Coalition for Alternatives to Pesticides et al. v. EPA (Civil Action No. 94-1100, 1996), in which the court ruled that "inert" ingredients should not be given blanket trade secret protection by EPA under the *Freedom of Information Act* (FOIA). In the case, we successfully argued that EPA must disclose inert ingredients since their secrecy from public disclosure served no proprietary interest for the chemical manufacturer. This same argument holds with respect to the product label. The agency agrees that disclosure of ingredients, especially inert ingredients would "assist consumers and users of pesticides in making informed decisions and reduce the presence of potentially hazardous ingredients in pesticides."[1]

Inert ingredients generally make up the largest percentage of a pesticide product or formulation. Most contain over 95 percent inert ingredients.[2] Unfortunately, there is a common misconception among the public that inert ingredients are physically, chemically, or

[1] USEPA. 2009. Public Availability of Identities of Inert Ingredients in Pesticides. Federal Register Vol 74, No. 245. {EPA-HQ-OPP- 2009-0635; FRL- 8803-3}
[2] Surgan, M.H and Gershon, A, J. 2000. The Secret Ingredients in Pesticides: Reducing the Risk. New York Office of the Attorney General, Environmental Protection Bureau. New York, NY

biologically inactive substances, and pose no harm. This cannot be further from the truth since many are known to state, federal and international agencies to be hazardous to human health. EPA, itself has identified over 500 chemicals used as inert ingredients that are also listed as active ingredients in other pesticide products,[3] and more than 200 inerts are considered hazardous pollutants and/or hazardous waste under federal environmental statutes.[4]Some inert ingredients are even more toxic than the active ingredients. For example, one of the most hazardous ingredients in the commonly used herbicide RoundUp is the surfactant polyethoxylated tallowamine (POEA), which is classified as an inert. Recent studies have shown that POEA causes cell death within 24 hours and is more deadly to human embryonic, placental and umbilical cord cells than the active ingredient glyphosate.[5] In other instances, an ingredient such as naphthalene, can be an inert ingredient in some products but is also an active ingredient in others. In general, inert ingredients have fallen through the cracks of the regulatory process.

The agency has decided to move forward with rulemaking to increase the availability of inert ingredients. Beyond Pesticides wholeheartedly supports this decision. In its Federal Register notice, the agency raises many valid questions, comments and options to achieve this new regulatory objective. We would like to take this opportunity to address some of those concerns below:

**Should EPA discontinue to allow the substitution of the term "other ingredients" for "inert ingredients" on product labels?**

As mentioned above, the term "inert" implies that the ingredient is inactive, without the ability to interact with other chemicals or organisms, or do any harm. This term is misleading, especially to the uninformed consumer. EPA and the scientific and environmental communities are already aware that "inert" ingredients can be associated with hazard. The use of the term "other ingredients" is more appropriate as it has the ability to distinguish these substances from "active" ingredients without giving the consumer a false sense of security that the substances are inactive, safe, or have no impact on their health or environment. Given that both active and inert ingredients are potentially hazardous, the listing should clearly indicate that many, if not all of the ingredients in the product, are hazardous.

**Should EPA mandate disclosure only of potentially hazardous ingredients or mandate disclosure of all ingredient identities?**

[3] Cox,C. and Surgan, M. 2006. Unidentified Inert Ingredients in Pesticides: Implications for Human and Environmental Health. *Environ Health Perspect*; 114(12): 1803–1806.
[4] Abrams, R., 1991. Attorney General *The Secret Hazards of Pesticides: Inert Ingredients*.New York State Department of Law
[5] Benachour, N. and Seralini, G.E. 2009. Glyphosate Formulations Induce Apoptosis and Necrosis in Human Umbilical, Embryonic, and Placental Cells. *Chem. Res. Toxicol.* 22 (1): 97–105

EPA is considering two approaches for inert ingredient disclosure. The first is to disclose only inerts that may be hazardous, while the other approach is to disclose all inert ingredients. The agency should require the disclosure of ingredients that are considered hazardous on product labels at this time. The agency has the legal authority to do this and to do it now without any risk of a successful legal challenge from those in the chemical industry still arguing for secrecy of hazardous product ingredients. By focusing on hazardous inerts, the agency can move expeditiously in accordance with judicial findings.

In order to do this, we encourage the agency to utilize established lists, as recommended by the petitioners in their 2006 petition.[6] This ensures that the agency can move quickly to identify hazardous inerts on product labels. While we maintain that hazardous inert ingredients should not be formulated in pesticide products, disclosing these ingredients to complete disclosure can be done quickly and painlessly.

Transition to Full Disclosure

Beyond Pesticides believes that only ***full*** disclosure on ***all*** pesticide products, including plant incorporated protectants, truly fulfills the mission to provide consumers with the information they need to make informed decisions that impact their health and that of their environment. Underlying disclosure, and public right to know the ingredients that are in pesticide products, is the assumption by the public that all the ingredients have been subject to full testing. Beyond Pesticides believes that in a public policy context, differentiating between hazardous and non-hazardous ingredients could potentially confuse public understanding of the hazardous nature of the overall formulation. Therefore, we believe that EPA should ultimately seek to evaluate the complete formulation of pesticide products and disclose all the ingredients in pesticide formulations.

To the extent that EPA seeks, through the new rulemaking, to "reduce the presence of potentially hazardous ingredients in pesticides,"[7] the agency should strive to reduce and eliminate hazardous inert ingredients from pesticide products and not to simply identify them on a product label. Although disclosure of ingredients is helpful to informing the public, there still exists the false notion in the consumer marketplace that products would not be available if they were harmful or not fully tested and reviewed. In fact, the EPA registration number on pesticide products implies an "approval" by the agency and suggests that the product is 'safe.' Language on the label that clearly indicates the nature of the review, with all its limitations, is the only truly fair disclosure. A full disclosure of ingredients accompanied by a fair characterization of the limits of the agency review and assessment will help to move the pesticide industry to safer products.

[6] Petition of Northwest Coalition for Alternatives to Pesticides, Et Al., To Require Disclosure of Hazardous Inert Ingredients o n Pesticide Product Labels. 2006. Available at http://www.epa.gov/opprd001/inerts/

[7] USEPA. 2009. Public Availability of Identities of Inert Ingredients in Pesticides. Federal Register Vol 74, No. 245. {EPA-HQ-OPP- 2009-0635; FRL- 8803-3}

Total disclosure of all active and inert ingredients on all pesticide products will also help consumers identify and/or avoid substances that may *not* be associated with hazard, but may possibly lead to allergic reactions or asthma attacks. For example, newer pesticide products on the market that are considered least-toxic may contain many botanical and essential oil ingredients to which many people may have allergic responses. Disclosing all ingredients ensures that the public has the information it needs to avoid not only hazardous chemicals, but also seemingly less hazardous ones that may cause harm.

**Should potentially hazardous impurities be required to appear on label?**

Yes. Should an ingredient, whether active or inert be associated with a hazardous substance considered to be an impurity (unintentional and sometimes inseparable leftover reagent or product during synthesis of active or inert ingredient), then the public has a right to know that small amounts of a hazardous impurity(s) is contained in a product. Exposure to hazardous substances, even at low concentrations, is a serious human health issue. The scientific community is discovering that even low-dose exposures can have long-term and harmful effects on human health, especially the health and development of infants and children.[8] The agency normally receives information on impurities with concentrations ≥ 0.1% according to 40 CFR 158.320. The agency must therefore disclose reported or known impurities of toxicological significance regardless of concentration. However, while we support the listing of hazardous impurities, this process should not detract or interfere with the disclosure of inert ingredients. Inert ingredients must ultimately be disclosed whether they are associated with impurities or not. If an inert is in fact associated with a hazardous impurity, the process of listing this substance should be a secondary and separate matter.

The agency is uncertain of how to identify impurities on product labels. Similar to food labels with statements such as, "*manufactured in a facility that processes eggs, wheat*, *soy, peanuts,*" which serves as a warning to consumers with egg, wheat or peanut allergies (Food Allergen Labeling and Consumer Protection Act of 2004), so too can EPA place a disclaimer on product labels with similar language to acknowledge impurities. Example, "*this product contains chemical impurities that may be hazardous to your health:* <name of impurity(s)>." This statement can be placed below the list of active and inert ingredients.

**Should inert ingredients be listed in order of concentration? Should concentrations be disclosed? What form of ingredient identify should be used? Where should inert ingredients be listed?**

[8]Haviland JA, et al. 2009. Long-term sex selective hormonal and behavior alterations in mice exposed to low doses of chlorpyrifos in utero. *Reprod Toxicol* doi:10.1016/j.reprotox.2009.10.008; Weiss, B., Amler, S. and Amler, R. 2004. Pesticides. *Pediatrics* 113;1030-1036; Greenlee**,** A.R., Ellis, T.M. and Berg, R.L. 2004. Low-dose Agrochemicals and Lawn Care Pesticides Induce Developmental Toxicity in Murine Preimplantation Embryos. *Environ Health Perspect* 112:703-709;

In an effort to maximize product label space and harmonize ingredient listing with other label systems, e.g. Cosmetics under FDA regulations,[9] inert ingredients can be listed in order of predominance (concentration) and without stating concentrations. This would allow the consumer to readily understand pesticide product labels, as the public is already familiar with this format.

In order to accommodate easy consumer understanding, inert ingredients should be identified by their common names. Where there are multiple common names, the most recognizable/widely used in the U.S. should be utilized. 40 CFR 156.10(g). If the substance does not have a common name, its chemical name should be used or its Chemicals Abstract Service (CAS) number. The CAS system is widely used in the U.S. and by EPA and other federal, medical and emergency agencies. Ingredients should only be listed by common name or chemical name. Using chemical or functional classes (eg surfactant or preservative) to identify an ingredient(s) defeats the purpose of having full disclosure of ingredient identities and should not be considered.

Listing all the ingredients on the product label is the desired and most convenient method for the consumer to find product information. Inert ingredients should be listed in the same location (directly below active ingredient list) as the active ingredients. This way, consumers understand that there is one place to find the entire list of product ingredients.

Removal of label information and use instructions from the product raises safety concerns about consumer product choice and label compliance. Requiring consumers to source product information electronically, via telephone or elsewhere, adds an unnecessary extra step for consumers who might already be confused by the relative hazards and uses of products. With agency enforcement against non-compliance with product labels already limited, these approaches will further reduce compliance with the label instructions. Persons without access to the internet or telephone would also be adversely affected disproportionately.

**How would disclosure impact the market, development of new pesticide products and incentive for manufacturers to use less hazardous inert ingredients?**

Consumers are increasingly becoming conscious of the chemicals that are in the products they buy, whether it is lead in children's toys or bisphenol A in baby bottles. Public disclosure of all ingredients on pesticide products leads to greater consumer understanding, and informed decision-making results from knowing the chemicals to which one is exposed. This growing consumer awareness and desire for healthy, eco-friendly products drives the marketplace. Beyond Pesticides receives many calls and emails daily from consumers looking for least-toxic pesticide alternatives. This is a reflection of a growing awareness that is beginning to significantly drive the marketplace as consumers demand safer products. Disclosing inert ingredients, including hazardous ones, creates market incentives for manufacturers to reformulate their products to include the safest ingredients, resulting in a better informed,

[9] 21 CFR 201; 21 CFR 701.3

healthier public.

Currently, under section 25(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), pesticide products granted the status of "minimum risk pesticides" must disclose all ingredients (active and inert) and they must be listed on the label. Many of these ingredients are generally recognized as safe, such as corn oil, rosemary or clove oil. The full disclosure required for 25(b) products has not negatively affected the market for these products. In fact, it has grown tremendously in recent years. For instance, CedarCide Industries, a small pesticide manufacturing company that produces essential oil-based products reported $2.5 million in revenue in 2008, and increased its revenue one and a half times in 2009 to approximately $4 million from online-only retail sales, and now the company is looking to expand its production capabilities.[10]

Consumers voluntarily pay significant price premiums to acquire goods perceived to be 'green,' 'natural' or 'organic.'[11] Many large pesticide manufacturers have already seen this shift in marketplace and have created so-called 'green' or 'natural' product lines to satisfy consumer demand. In fact, companies are scrambling to generate competitive advantages by proving their 'green' credentials, and back up their green rhetoric with improved environmental performance.[12] For example, Scotts Miracle-Gro has a new 'EcoSense' product line with soybean oil as an active insecticide ingredient; S.C. Johnson has 'Nature's Source' line of cleaning products, along with other manufacturers such as Clorox® (GreenWorks). Other smaller brands such as EcoSmart and CedarCide have created least-toxic pesticide products that have enjoyed great success. Many of these brands already disclose most of their ingredients, regardless of section 25(b) status. This, coupled with a growing organic market, offers opportunities and challenges for formulators to develop and market products compatible with organic standards and consumer expectations.

As a result of these current trends, the agency can rest assured that disclosure of inert ingredients would not negatively impact the market, cause competitive harm, hamper the development of new products, nor provide any disincentive for manufacturers to produce less hazardous products. In fact, with public knowledge of product ingredients, manufacturers can depend on being held accountable for making a transition to less hazardous ingredients.

**Conclusion**

[10] Isensee, B. (2010, January , 22) Keeping bugs at bay: Switch to direct sales helps natural pesticide company swat competition. Houston Business Journal. Available at: http://www.bizjournals.com/atlanta/othercities/houston/stories/2010/01/25/smallb1.html?s=industry&b=1264395600^2772831&page=2

[11] Katz, B. (2009, November, 20). Shoppers going green despite struggling economy. Reuters http://www.reuters.com/article/idUSTRE5AJ2HL20091120; Hamilton, S.F. and Zilberman, D. 2006. Green markets, eco-certification, and equilibrium fraud. J. of Environ. Econ. and Man..52(3):627-644.

[12] Peattie, K and Ratnayaka, M. 1992. Responding to the green movement. Industrial Marketing Management, 21(2):103-110.

Public disclosure of inert ingredients serves the public interest by allowing consumers to make well-informed decisions regarding the products they use. The agency must press ahead with this rulemaking to ensure that consumers are better protected from hazardous substances. Beyond Pesticides urges EPA, with the above suggestions and recommendations, to expedite the process to make way for full disclosure of hazardous product ingredients and not be deterred by those in opposition. It has become increasingly clear over the last couple of decades that registrants and manufactures of pesticide products derive no real economic benefit from the secrecy of their products' ingredients and would not be adversely impacted by the agency's decision. While competitors may reverse engineer each others' products to determine their ingredients, the only segment of society being left in the dark about the ingredients in pesticide products are those who use them. Manufacturers are acutely aware of the changing marketplace shifting toward more eco-friendly, least-toxic products, and have already begun to accommodate consumer demand. With the disclosure of inert ingredients, the agency can help advance the elimination of hazardous substances from consumer goods and better protect human health and the environment.

Thank you for moving ahead quickly to disclose all pesticide ingredients.

Sincerely,

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