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Comments from the Natural Resources Defense Council on the EPA Proposed Rule to increase public availability of the identities of the inert ingredients in pesticide products

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Supported by:

Alaska Community Action on Toxics (Pam Miller)
Citizens' Environmental Coalition, Albany NY (Barbara Warren)
Clean Water Action (Lynn Thorp)
Environmental Cancer Initiative, Karmanos Cancer Institute (Michael Harbut, MD, MPH)
Farmworker Association of Florida (Jeannie Economos)
Glynn Environmental Coalition, Georgia (Daniel Parshley)
Green Science Policy Institute (Arlene Blum, Ph.D.)
Institute for Agriculture and Trade Policy (David Wallinga, MD, MPA)
Kentucky Environmental Foundation (Elizabeth Crowe)
Northwest Atlantic Marine Alliance (Boyce Thorne-Miller)
Northwest Coalition for Alternatives to Pesticides (Aimee Code)
OMB Watch (Brian Turnbaugh)
Oregon Toxics Alliance (Dona Hippert)
Pesticide Action Network North America (Karl Tupper)
RAMP (Rochesterians Against the Misuse of Pesticides) (Judy Braiman)
Sciencecorps, Lexington, MA (Kathleen Burns, Ph.D.)
TEDX (The Endocrine Disruption Exchange) (Theo Colborn, Ph.D.)

In response to two petitions seeking disclosure of selected inert ingredients on pesticide labels, based on hazard, EPA is initiating rulemaking to increase public availability of the identities of the inert ingredients in pesticide products. We applaud EPA for taking this action as it will surely assist consumers and users of pesticides in making informed decisions and reduce the presence of potentially hazardous ingredients in pesticides.

On its webpage announcing this proposed rule, EPA provides the following definitions and explanations:[1] Pesticide products contain both "active" and "inert" ingredients. The terms "active ingredient" and "inert ingredient" have been defined bythe Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §136, et seq, since 1947.

- An active ingredient is one that "will prevent, destroy, repel, or mitigate any pest", or is a plant regulator, defoliant, desiccant or nitrogen stabilizer. 7 U.S.C. §136(a). By law, the active ingredient must be identified by name on the label together with its percentage by weight.
- An inert ingredient means any substance (or group of structurally similar substances if designated by the Agency), other than an active ingredient, which is intentionally included in a pesticide product. Inert ingredients play a key role in the effectiveness of a pesticidal product. For example, an inert ingredient may serve as a solvent, allowing the pesticide's active ingredient to penetrate a plant's outer surface. In some instances, inert ingredients are added to extend the pesticide product's shelf-life or to protect the pesticide from degradation due to exposure to sunlight. Pesticide products can contain more than one inert ingredient, but current federal law only requires that the total percentage of inert ingredients be labeled on the pesticide product; it does not require that these ingredients be individually identified by name or percentage on the label.

Summary:

We fully support this proposed rulemaking to increase public disclosure of hazardous inert ingredients for pesticide products. We hope that this is an interim step, to be followed by a regulatory requirement for disclosure of all inerts, whether classified as hazardous or not, and all impurities in pesticide products. We applaud EPA for taking this step to improve public awareness, public transparency, consumer education, and public health protection.

Specific response:

[1] EPA webpage on Rulemaking Underway Related to Disclose of All Pesticide Ingredients (accessed 2-21-2010) http://www.epa.gov/opprd001/inerts/

Below is our response to selected questions that EPA posed in the advance notice of proposed rulemaking (ANPR).

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 a rule requiring full disclosure of all hazardous inerts if the inert ingredient appears on specified lists, as described by approach #1 above, and 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. This will maximize the benefits for health and the environment that the Agency has outlined in the ANPR.

The specified lists used to identify hazardous chemicals, including inert ingredients, should include the following lists already identified in the petition of the Northwest Coalition for Alternatives to Pesticides et al.:[2]

CAA § 202A - Clean Air Act § 202(a) – National Emissions Standards Act

CAA § 112 – Clean Air Act § 112

CERCLA §101(14) - Comprehensive Environmental Response, Compensation, and Liability Act – all chemicals primarily identified in Clean Water Act §

[2] Petition of the NCAP et al. to Require Disclose of Hazardous Inert Ingredients on Pesticide Labels (2006). Available at http://www.epa.gov/opprd001/inerts/petition_ncap.pdf

311(b)(4) and § 307(a), Clean Air Act § 112, and Resource Conservation and Recovery Act § 3001

CWA § 311 – Clean Water Act § 311(b)(2)(A)

PAI – Organic Pesticide Active Ingredients – Clean Water Act § 304

EPA Pretreatment Standards- Clean Water Act § 307

RCRA Appendix VII – Resource Conservation and Recovery Act Appendix VII to 40 C.F.R.§ 261

RCRA Appendix VIII – Resource Conservation and Recovery Act Appendix VIII to 40 C.F.R. § 261

RCRA F Waste – Resource Conservation and Recovery Act list of hazardous wastes from nonspecific sources pursuant to RCRA § 3001

RCRA P Waste – Resource Conservation and Recovery Act list of acutely hazardous commercial products that when disposed of become acute hazardous wastes pursuant to RCRA § 3001

RCRA U Waste – Resource Conservation and Recovery Act list of commercial chemical products that when disposed of become hazardous wastes pursuant to RCRA § 3001

CERCLA §104(i)(2)- Priority List of Hazardous Substances

EPCRA 302A – Title III of Superfund Amendments and Reauthorization Act, also known as the Emergency Planning and Community Right-to-Know Act of 1986

Toxic Release Inventory (TRI)

TSCA § 6 Unreasonable Risk – Toxic Substances Control Act § 6

OSHA – Toxic and Hazardous Substances List

ACGIH - American Conference of Governmental Industrial Hygienists' Threshold Limit Value for Chemical Substances and Physical Agents in the Work Environment.

In addition to the above lists, we recommend that EPA also include the following authoritative lists to identify hazardous chemicals:

California Proposition 65, OEHHA

Toxic Release Inventory (TRI), EPA

Integrated Risk Information System (IRIS), EPA

RCRA Waste Minimization Priority Chemicals (WMPC), EPA

CERCLA/SARA § 313 PBT list of persistent bioaccumulative toxic chemicals, EPA

Report on Carcinogens, National Toxicology Program, NIEHS

All Group 1, 2a, and 2b chemicals identified by the International Agency for

Research on Cancer (IARC), World Health Organization

Any chemical listed on any one or more of the above lists should automatically be considered a hazardous chemical and required to be disclosed.

Chemicals should be disclosed according to their chemical names, and also the unique CAS Registry Number (CASRN) associated with that chemical. Although chemicals can be described in many different ways (molecular formula, structure, generic name, trade name, etc.) only the CASRN is unique and specific to only one substance regardless of other descriptors for that substance. Governmental agencies worldwide use CASRNs to track substances, giving it easy and reliable validation and international recognition.

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.

So long as a chemical is considered to be hazardous by any authoritative body, including but not limited to those listed above, then it should be subject to disclosure requirements. Chemicals should be added to the disclosure requirements if they are added to any of the above lists, and could be removed if they are no longer considered hazardous by any authoritative bodies including the lists above.

We suggest that future rulemakings of this nature require full disclosure of inert chemicals that are identified on authoritative lists as being persistent, bioaccumulative, and toxic (PBTs).

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

No, the amount of the ingredient in a product should not determine whether or not it should be disclosed as an ingredient. For many hazardous chemicals there is no known "safe" level of exposure for a diverse population. This is especially relevant to individuals who are uniquely sensitive to the chemical, allergic to the chemical, or susceptible to harm because of age, health status, life stage, or other factors. Reproductive toxicants such as lead or mercury, even at very low levels, have been shown in animal studies to cause permanent irreversible damage to the developing brain. Human data support these findings. Other reproductive toxicants, carcinogens, mutagens, immunotoxicants, and endocrine disrupting chemicals may also have no "safe" exposure level for sensitive or vulnerable individuals. Consumers have a right to make informed choices about the products they purchase and use, particularly for those that contain hazardous ingredients. Further, determining a "safe" or acceptable level of exposure for many inert chemicals will lead to unacceptable delay's in disclosure.

1d. Does disclosing the identities of hazardous inert ingredients on the label without further information provide consumers and users with information that is useful?

Disclosure of hazardous ingredients to consumers can drive consumers' towards products that contain fewer or no hazardous ingredients. This creates a market space for the introduction of reduced risk products. For example, the FIFRA 25(b) program has successfully registered many minimum risk pesticides as alternatives to more hazardous ones that are being removed from the market. Disclosure of all hazardous ingredients, including inerts, in pesticide products is a critical component of educating the public to make purchasing choices that reduce their exposure to hazardous chemicals and will promote safer products.

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?

Impurities in pesticides can be hazardous, such as toxic solvents, chlorinated compounds, and acids that are the byproduct of chemical synthesis. It is difficult to comment here on the specific chemical nature of the impurities since at this time that information is not publicly available. We support requiring that potentially hazardous impurities be disclosed on product labels. Some of the impurities may be reproductive toxicants, carcinogens, mutagens, immunotoxicants, and endocrine disrupting chemicals that have no safe exposure level for sensitive or vulnerable individuals. Consumers have a right to make informed choices about the products they purchase and use, particularly for those that contain hazardous ingredients. However, so that this rule to require disclosure of hazardous inert ingredients that are intentionally added to products is promulgated as quickly as possible, we suggest that the regulation of impurities (along with inerts that are not already listed as hazardous) be considered under a separate rule-making.

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?

No, there are no chemical classes that should be used instead of identifying the specific chemical identity. Consumers have a right to make informed choices about the products they purchase and use, particularly for those that contain hazardous ingredients.

In rare cases where a registrant is able to justify a legitimate claim of confidential business information (CBI) with regard to the specific chemical identity of an inert ingredient, disclosure of the chemical class may be appropriate. However, such claims

should precisely identify what information is requested to be kept confidential, and should be accompanied by full justification and documentation in writing, with a time-limited period for which the request is being made. To make this functional, EPA will have to specify what fulfills the requirements for a justifiable CBI claim, including the documentation that must accompany such a claim. EPA will have to review claims in a timely manner. EPA will have to determine acceptability on a case-by-case basis. EPA could consider imposing a processing fee for each CBI claim submission, to cover its costs to review claims in a timely manner, and also as a disincentive to submit frivolous claims. All accepted CBI requests should be time-limited to not more than five years, after which disclosure should occur by default, unless a new request is submitted and a new determination is made by EPA. If a CBI claim is rejected by EPA then EPA should require disclosure of the chemical ingredient. Health and safety information and the chemical identity associated with such information should never be protected by CBI claims. The identity of the registrant or submitter of the information should never be withheld. Workers and workplace representatives should have access to all available information, whether or not it is CBI protected, for any substance or mixture used in their workplace, or to which workers, contractors, or the public could be exposed during work. Other governments, including State, regional, tribal, or international, should be given access to CBI protected information, with appropriate arrangements made to protect legitimate and approved CBI claims.

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

We support rulemaking to disclose all impurities on product labels, regardless of hazard. Consumers have a right to make informed choices about the products they purchase and use. However, we do not want consideration of impurities to delay implementation of this initiative to require disclosure of all hazardous inert ingredients.

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 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 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 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. Consumers of institutional pesticide products have similar resources and often have in-house expertise.

Both current experience with 25(b) products and the experience with EPA's 1987 disclosure requirements show that disclosure encourages manufacturers to remove hazardous ingredients from products, and it creates new markets for reduced-risk products.

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 policies will not work reliably. An enforceable, regulatory requirement to disclose inert ingredient is the only effective and only acceptable approach. Past EPA voluntary initiatives have been marginally effective at best, and more often have been failures.

For example, EPA's HPV Challenge, initiated in 1998, was designed to get companies to voluntarily submit hazard data on high production volume (HPV) chemicals that are produced or used in the U.S. at over 1 million pounds annually. After over 4 years, only 60% of the chemical profiles were completed, and over 300 chemicals were "orphaned" with no companies that would volunteer to supply data on them. Further, the manufacturers often submitted poor quality data, as determined by a report from the Environmental Defense Fund.[3] Meanwhile, over 600 additional chemicals are produced or used at over 1 million pounds annually that have yet to be subjected to a rigorous scientific review.

A decade after the limp-along HPV Challenge, EPA initiated another voluntary scheme, the Chemical Assessment and Management Program, or ChAMP. The program was initiated in 2009, promising to assess over 6,000 chemicals by 2012, over one-third of them already in high production volume. Already, the poor or questionable quality of submitted data and the lack of transparency of the program have been strongly criticized by Environmental Defense Fund scientists in a series of blog reports called, "ChAMP: Not exactly a heavyweight."[4]

Another failed voluntary chemical program initiated by EPA was the Voluntary Children's Chemical Evaluation Program (VCCEP) pilot, which was begun in 1998 with the stated goal of gathering information from industry for citizens on the effects of

[3] Low Marks for Voluntary Chemicals Program: New report on HPV Challenge reveals missed deadlines, data quality concerns. Report by Environmental Defense Fund. July, 2007. Available at: http://www.edf.org/article.cfm?contentID=6641

[4] ChAMP: Not exactly a heavyweight. Blog by Richard Denison, Ph.D. April 20, 2009. Available at: http://blogs.edf.org/nanotechnology/2009/04/20/champ-not-exactly-a-heavyweight/

chemicals in the home and marketplace. VCCEP asked chemical manufacturers and importers to voluntarily provide information on the health effects, exposure, risk, and data gaps regarding their chemicals. The program was launched in 2000, and by 2006 only 23 chemicals had been selected for review, and only nine meeting reports were publicly available. This slow pace leaves thousands of chemicals un-assessed that are commonplace in homes, schools, and playgrounds where children may be exposed. In June 2006 the program was reviewed and strongly criticized by the Children's Health Protection Advisory Committee (CHPAC) for its inability to meet its stated goals.[5] In a public letter to the EPA Administrator, the Committee cited structural flaws and the voluntary nature of the program as problematic.

In 2008 the CHPAC sent another letter to the EPA Administrator, this time criticizing both the VCCEP and ChAMP programs, specifically noting the voluntary nature as particularly problematic. The expert advisory committee recommended that EPA use its statutory authorities to require companies to provide chemical hazard information.[6]

In addition to our distrust of voluntary chemical management programs, we are skeptical of the chemical industries' interest in timely public disclosure of the hazards of their products. In the past, industries have downplayed the health risks of asbestos, lead, vinyl chloride, and other toxics, only to have those chemicals cause devastating occupational and public health injuries and even deaths. Richard Smith, an editor for the *British Medical Journal* for 25 years, noted that "overall, studies funded by a company were four times more likely to have results favorable to the company than studies funded from other sources."[7] In *Doubt Is Their Product: How Industry's Assault on Science Threatens Your Health*, David Michaels, now Administrator of OSHA, documented how ichemical manufacturers attempt to influence regulatory agencies so as to avoid regulation of their products.[8] For example, in December 2005, the EPA slapped chemical manufacturer DuPont with the largest administrative penalty in its 35-year history for failing to submit to EPA more than 20 years of data on birth defects and other harmful effects from its Teflon-related perfluorochemicals.

In summary, only an enforceable regulatory requirement to disclose hazardous inert ingredients will be effective and publicly acceptable. Voluntary programs are not acceptable. We look forward to future rulemakings that require disclosure of inert

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[5] Letter from Melanie Marty to Administrator Johnson regarding the Voluntary Children's Chemical Evaluation Program (2006) http://yosemite.epa.gov/OCHP/OCHPWEB.nsf/content/6302006.htm/$file/6302006.pdf

[6] Letter from Melanie Marty to Administrator Johnson regarding Chemicals Assessment and Management Program; Voluntary Children's Chemical Evaluation Program (2008) http://yosemite2.epa.gov/ochp/ochpweb.nsf/content/12182008_2.htm

[7] Smith R, "Medical journals are an extension of the marketing arm of pharmaceutical companies," *PLoS Medicine* 2, no. 5 (2005):e138. http://kurse.fh-regensburg.de/kurs_20/kursdateien/inko/2005-05-17PLoSSMITH.pdf

[8] Michaels D., *Doubt Is Their Product: How Industry's Assault on Science Threatens Your Health* (New York: Oxford University Press USA, 2008).

ingredients that have not been classified as hazardous (although they may be hazardous) as well as impurities.

Jennifer Sass, Ph.D.
Natural Resources Defense Council
Washington, DC

Email: jsass@nrdc.org
Tel: 202-289-2362