

Sections 112(e) and 114 of the Copyright Act. *Id.* at 762, 767. By order dated October 23, 2009, the Judges established a period commencing November 2, 2009, and concluding on December 2, 2009, for the parties to negotiate and submit a settlement of the minimum fee issue that was the subject of the remand. On December 2, 2009, SoundExchange, Inc. and the Digital Media Association (“DiMA”) submitted a settlement regarding the statutory minimum fee to be paid by Commercial Webcasters.<sup>1</sup> Having received such a settlement, the Judges now publish for comment the proposed change in the rule that is necessary to implement that settlement pursuant to order of remand from the United States Court of Appeals for the District of Columbia Circuit.

#### List of Subjects in 37 CFR Part 380

Copyright, Sound recordings.

#### Proposed Regulations

For the reasons set forth in the preamble, the Copyright Royalty Judges propose to amend part 380 of title 37 of the Code of Federal Regulations as follows:

#### PART 380—RATES AND TERMS FOR CERTAIN ELIGIBLE NONSUBSCRIPTION TRANSMISSIONS, NEW SUBSCRIPTION SERVICES AND THE MAKING OF EPHEMERAL REPRODUCTIONS

1. The authority citation for part 380 continues to read as follows:

**Authority:** 17 U.S.C. 112(e), 114(f), 804(b)(3).

2. Section 380.3 is amended by revising paragraph (b) to read as follows:

#### § 380.3 Royalty fees for the public performance of sound recordings and for ephemeral recording.

\* \* \* \* \*

<sup>1</sup> Since the settlement does not include Noncommercial Webcasters, the Judges, on remand of the DC Circuit, will determine the minimum fee for Noncommercial Webcasters pursuant to the October 23, 2009, order. *See Order Regarding Conduct and Scheduling of the Remand Proceeding*, Docket No. 2005–1 CRB DTRA (October 23, 2009); *see also Order Denying in Part and Granting in Part Joint Motion to Modify Scheduling Order*, Docket No. 2005–1 CRB DTRA December 23, 2009. The Judges note that the proposed change is to § 380.3(b), which currently addresses the minimum fee for Commercial and Noncommercial Webcasters in a single paragraph. For sake of clarity, the Judges have proposed a new § 380.3(b)(1), which sets forth the proposed minimum fee for Commercial Webcasters per the settlement between SoundExchange and DiMA and a new § 380.3(b)(2), which sets forth the minimum fee for Noncommercial Webcasters and retains the language in the current § 380.3(b) except all references to Commercial Webcasters have been deleted.

(b) *Minimum fee*—(1) *Commercial Webcasters*. Each Commercial Webcaster will pay an annual, nonrefundable minimum fee of \$500 for each calendar year or part of a calendar year of the period 2006–2010 during which it is a Licensee pursuant to 17 U.S.C. 112(e) or 114. This annual minimum fee is payable for each individual channel and each individual station maintained by Commercial Webcasters, and is also payable for each individual Side Channel maintained by Broadcasters who are Commercial Webcasters, provided that a Commercial Webcaster shall not be required to pay more than \$50,000 per calendar year in minimum fees in the aggregate (for 100 or more channels or stations). The minimum fee payable under 17 U.S.C. 112 is deemed to be included within the minimum fee payable under 17 U.S.C. 114. Upon payment of the minimum fee, the Commercial Webcaster will receive a credit in the amount of the minimum fee against any royalty fees payable in the same calendar year.

(2) *Noncommercial Webcasters*. Each Noncommercial Webcaster will pay an annual, nonrefundable minimum fee of \$500 for each calendar year or part of a calendar year of the license period during which they are Licensees pursuant to licenses under 17 U.S.C. 114. This annual minimum fee is payable for each individual channel and each individual station maintained by Noncommercial Webcasters and is also payable for each individual Side Channel maintained by Broadcasters who are Licensees. The minimum fee payable under 17 U.S.C. 112 is deemed to be included within the minimum fee payable under 17 U.S.C. 114. Upon payment of the minimum fee, the Licensee will receive a credit in the amount of the minimum fee against any additional royalty fees payable in the same calendar year.

Dated: December 18, 2009.

**James Scott Sledge,**  
*Chief U.S. Copyright Royalty Judge.*

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 156

[EPA–HQ–OPP–2009–0635; FRL–8803–3]

RIN 2070–AJ62

#### Public Availability of Identities of Inert Ingredients in Pesticides

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Advance notice of proposed rulemaking.

**SUMMARY:** 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. This action would assist consumers and users of pesticides in making informed decisions and reduce the presence of potentially hazardous ingredients in pesticides.

**DATES:** Comments must be received on or before February 22, 2010.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2009–0635, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

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

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility’s normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

*Instructions:* Direct your comments to docket ID number EPA–HQ–OPP–2009–0635. EPA’s policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [www.regulations.gov](http://www.regulations.gov) or e-mail. The [www.regulations.gov](http://www.regulations.gov) website is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [www.regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an

electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

**Docket:** All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Kerry B. Leifer, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8811; fax number: (703) 605-0781; e-mail address: [leifer.kerry@epa.gov](mailto:leifer.kerry@epa.gov).

#### **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you engage in activities related to the registration of pesticide products. Potentially affected entities may include, but are not limited to, engaging in the formulation and preparation of agricultural and household pest control chemicals or pesticide and other agricultural chemical manufacturing (NAICS) code 32532.

You may also be affected by this action if you are a consumer or user of pesticides, or if you are exposed to pesticides.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also

be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### *B. What Should I Consider as I Prepare My Comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through [regulations.gov](http://www.regulations.gov) or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

### **II. Discussion**

#### *A. What Action is the Agency Taking?*

EPA is seeking comment on options for increasing the public availability of

the identities of inert ingredients in pesticides registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* This action is in response to two petitions filed in 2006 that identified a set of over 350 pesticide inert ingredients as hazardous and requested that EPA act to require that these inert ingredient identities appear on the labels of products that include these ingredients in their formulations (Refs. 1 and 2).

On September 30, 2009, EPA partially granted the petitions, committing to initiate rulemaking to increase the public availability of the identities of inert ingredients (beginning with this ANPR), but seeking comment on a range of options to achieve this goal (Ref. 3.)

#### *B. Background*

1. *Statutory background.* In enacting FIFRA, Congress chose to distinguish between active and inert ingredients in pesticides. Section 2(a)(1) defines "active ingredient" to include an ingredient "which will prevent, destroy, repel, or mitigate any pest." Section 2(m) defines "inert ingredient" as an ingredient which is "not active."

FIFRA does not directly regulate active and inert ingredients *per se*. Rather, by means of a registration process, the statute regulates the sale, distribution, use and labeling of the pesticide products (often referred to in shorthand as "pesticides") that contain these ingredients. An applicant who seeks to register a pesticide must demonstrate that, among other things, "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." FIFRA section 3(c)(5)(D). An applicant who seeks to register a pesticide must also submit or cite test and other data to demonstrate the safety (and in some cases the efficacy) of the pesticide. See FIFRA section 3(c)(1)(F) and 40 CFR part 158. Among other information, EPA requires a complete description of the composition of a pesticide formulation, including the identity of each active ingredient, intentionally added inert ingredient, each impurity present in an amount greater than 0.1% of the technical grade material, and each other impurity of toxicological significance.

In order to determine if a pesticide product meets the unreasonable adverse effects standard, EPA conducts risk assessments for pesticide products in accordance with guidelines developed by the National Academy of Sciences (NAS)/National Research Council (NRC). The NRC risk assessment guidelines consist of four general steps:

Hazard identification, dose-response assessment, exposure assessment, and risk characterization. In the case of an inert ingredient, information on its hazard (the ability to cause adverse health and/or environmental effects) informs the risk assessment process but by itself is not sufficient to determine the risk (the likelihood that an adverse health effect will result from exposure) associated with a particular product.

Active ingredients must be identified by name and percentage on the pesticide's ingredient statement, which is a necessary component of the pesticide product label under FIFRA section 2(q)(2)(A). By contrast, only the total percentage of all inert ingredients in the pesticide must be contained on the ingredient statement. FIFRA section 2(n)(1). There is no statutory requirement that the names of all inert ingredients be contained on the ingredient statement.

Confidentiality of information submitted under FIFRA is governed by section 10 (with additional provisions in sections 7 and 12). With certain limited exceptions, FIFRA section 10(b) bars EPA from disclosing information "which in the Administrator's judgment contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential."

Among the exceptions to confidentiality in section 10 is the requirement in FIFRA section 10(d)(1) to make safety and efficacy data available to the public. Safety and efficacy data constitute much of the information provided to EPA to support pesticide registration.

Though FIFRA section 10(d)(1) is important to public understanding of the risks and benefits of specific pesticides, the provision is sometimes misunderstood in its effect on the confidentiality of inert ingredients. Section 10(d)(1) excludes three categories of information from the mandatory disclosure requirement for health and safety data:

(A) manufacturing or quality control processes, (B) methods for testing, detecting, or measuring the quantity of inert ingredients, and (C) the identity or percentage quantity of inert ingredients.

The FIFRA section 10(d)(1)(C) exclusion for inert ingredient information has been taken by some to mean that any disclosure of inert ingredients is prohibited by statute, regardless of whether the information meets the confidentiality test in FIFRA section 10(b), but in fact the information must meet the FIFRA section 10(b) standard in order to be eligible for confidential treatment. See *Northwest Coalition for*

*Alternatives to Pesticides (NCAP) v. Browner*, 941 F. Supp. 197, 201 (D.D.C. 1996).

FIFRA section 12(a)(2)(D) provides authority for limited disclosures of confidential information, such as to medical professionals for evaluation and treatment purposes.

2. *EPA treatment of inert ingredient identities.* Even with the limitations on confidentiality in section 10 of FIFRA, EPA is required by its confidentiality regulations at 40 CFR part 2, subpart B to protect information claimed as confidential until and unless the Agency makes a final determination that the information is not entitled to confidentiality. Moreover, under certain circumstances, if EPA possesses information for which an affected business might be expected to assert a confidentiality claim if it knew EPA proposed to disclose it, EPA must contact the submitter regarding any possible confidentiality claims prior to public release of the information. See 40 CFR 2.204(c)(2); 2.201(d).

Inert ingredient identities are often claimed as confidential by pesticide applicants and registrants. In addition, registrants often include in pesticide formulations proprietary inert ingredients or proprietary mixtures of inert ingredients whose identities are not disclosed to the registrants by the manufacturers of these products. The complete chemical identities of proprietary inert ingredients and proprietary mixtures of inert ingredients are reported to EPA by the manufacturers rather than by the registrants, and EPA normally does not disclose these identities to the registrants.

Therefore the identities of inert ingredients are often difficult for pesticide users and other interested persons to obtain. Pesticide registrants may in certain circumstances be willing to provide such information directly to those who ask for it, and EPA, when necessary, provides inert ingredient information to medical professionals treating persons in connection with exposure to a pesticide in accordance with FIFRA section 12(a)(2)(D), as discussed previously. Nonetheless, the identities of inert ingredients in pesticides are not as a matter of course available to consumers in the way that, for example, cosmetic ingredients are disclosed.

In some cases, however, EPA has determined that in order to meet the requirements of FIFRA certain inert ingredient identities must be disclosed on the labels of products in which they are present. In 1975, EPA promulgated 40 CFR 156.10(g)(7), which provides

that "[t]he Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment." When the provision was promulgated (originally as 40 CFR 162.10(g)(7)), EPA discussed the provision as implementing "the Administrator's basic obligation under the amended 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 Administrator is authorized by the amended FIFRA to: (1) Deny registration or cancel an existing registration, (2) classify the pesticide for restricted use, or (3) require specific label statements." (40 FR 28252, July 3, 1975).

Additionally, in 1987, EPA published a **Federal Register** notice (52 FR 13305, April 22, 1987) announcing "certain policies designed to reduce the potential for adverse effects from the use of pesticide products containing toxic inert ingredients." This notice announced, among other things, that the identities of "inerts of toxicological concern," otherwise known as List 1 inert ingredients, would be required to be listed on pesticide labels. Approximately 50 ingredients were put onto List 1, based on data demonstrating "carcinogenicity, adverse reproductive effects, neurotoxicity or other chronic effects, or developmental toxicity (birth defects)" as well as "ecological effects and the potential for bioaccumulation." The notice also indicated that EPA intended to require the registrants of products containing List 1 ingredients to generate additional data to support the continued registration of the products. After publication of the notice, most List 1 ingredients disappeared from pesticide formulations. The notice created additional categories of inert ingredients, including List 2 ingredients, "which the Agency believes are potentially toxic and should be assessed for effects of concern. . . . Many of these inert ingredients are structurally similar to chemicals known to be toxic; some have data suggesting a basis for concern about the toxicity of the chemical."

3. *Petitions for disclosure of inert ingredients.* In August 2006, EPA received two similar petitions, one from a group of 22 non-governmental organizations (NGOs) and the other from the Attorneys General of 15 U.S. States and territories. These petitions identified inert ingredients that were contained within the categories listed later in this section, which the

petitioners stated were indicators that the inert ingredients met the standard for 40 CFR 156.10(g)(7) and should therefore be required to be listed on pesticide labels. The NGO petition argued, among other things, that disclosing inert ingredients that may be hazardous "is in the public interest by supporting the public's ability to make informed consumer decisions, enabling faster and more accurate medical diagnoses after exposure to pesticides, and providing an incentive for manufacturers to use less toxic ingredients." Similarly, the state petition stated that "EPA should require that pesticide product labels disclose the identity of all hazardous ingredients used in the formulation of the product, for whatever purpose they are used in that product, in order to adequately protect the public and fulfill the purposes of FIFRA." Following are the categories specified in the petitions:

- Organic pesticide active ingredients listed in 40 CFR part 455, Table 1, in conjunction with section 304 of the Clean Water Act (CWA).
- Inert ingredients on List 2.
- Extremely Hazardous Substances - Emergency Planning and Community Right-to-Know Act (EPCRA) section 302(a).
- Chemicals on the Toxics Release Inventory (TRI)--EPCRA section 313.
- Chemicals regulated under section 6 of the Toxic Substances Control Act.
- Listed and characteristic wastes regulated under the Resource Conservation and Recovery Act and EPA regulations at 40 CFR part 261, including F, P, and U wastes.
- Chemicals regulated under CWA section 311: Discharges to navigable waters or adjoining shorelines.
- Chemicals regulated under CWA section 307: Pretreatment standards for indirect dischargers whose waste water passes through publicly owned treatment plants.
- Chemicals regulated under Clean Air Act (CAA) section 112: Hazardous air pollutants.
- Chemicals regulated under CAA section 112(r): Substances known to cause death, injury, or serious adverse effects to human health or the environment.
- Chemicals regulated under CAA section 202(a): Motor vehicle pollutants.
- Chemicals designated as hazardous mixtures consistent with section 101(14) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).
- Chemicals designated under CERCLA section 104(i)(2) as priority list chemicals.

- Chemicals subject to the Occupational Safety and Health Administration's (OSHA) Occupational Safety and Health Standards at 29 CFR part 1910.

- Chemicals contained in the American Conference of Governmental Industrial Hygienists' Threshold Limit Values for Chemical Substances and Physical Agents in the Work Environment (see <http://www.acgih.org/TLV/PolicyStmnt.htm>).

On September 30, 2009, EPA partially granted the petitions by committing to initiate rulemaking to broaden the public availability of inert ingredient identities but reserving the scope and details of such rulemaking. The Agency agrees with the petitioners that inert ingredient disclosure should be greatly increased (EPA's policy considerations are discussed in this document), and believes that rulemaking is the most practical and efficient means to bring about such disclosure. Because there remain a number of significant questions regarding the scope and nature of such disclosure, as well as the means by which such disclosure should be achieved, and because the changes involved will require significant input from persons that could be affected by such a rule, the Agency is initiating this rulemaking via an ANPR.

4. *Current efforts to increase public availability of the identities of ingredients in consumer products.* EPA's efforts to increase public availability of the identities of ingredients in consumer products build on the substantial work done by the Inert Disclosure Stakeholder Workgroup (IDSW) which has helped shape the Agency understanding of the complex nature of inert disclosure issues. In 1999, the Pesticide Program Dialogue Committee (PPDC, established under the Federal Advisory Committee Act to advise EPA regarding pesticide matters) approved the establishment of the subgroup, the IDSW, a diverse workgroup of members from public health, environmental, industry, academic and state government organizations, as well as EPA, to create proposals for submission to the PPDC regarding enhanced disclosure to the public of information about inert ingredients in pesticides products. (This examination was spurred in part by earlier petitions from essentially the same groups of petitioners regarding disclosure of inert ingredients.)

The IDSW compiled a final report in 2002 (Ref. 4). This report helped the Agency identify target audience groups and their informational needs regarding inert ingredients, documented several different proposals to enhance inert

disclosure, and published position papers covering topics such as reverse engineering, response to medical emergencies, ingredient information readily available to the medical community, identification of inert ingredients, and labeling changes. The final report also discusses other Federal regulatory schemes for handling the confidentiality of ingredient information implemented by the Food and Drug Administration, OSHA, and the Consumer Product Safety Commission.

The IDSW discussions and final report continue to inform the Agency as EPA contemplates rulemaking to increase public availability of inert ingredients.

5. *Problem statement.* EPA believes that the lack of information available to consumers and users about the inert ingredients in pesticide products results in a market failure that causes pesticide products to contain inert ingredients that are more hazardous than is efficient. Consumers may prefer to use pesticide products with non-hazardous inert ingredients. In general, however, pesticide producers currently do not publicly disclose the identities of inert ingredients. Consequently, consumers cannot base their decisions about which pesticides to use or whether the pesticides contain hazardous inert ingredients. If this information were available, it could influence consumers' decisions on which pesticides to purchase and use. Moreover, if consumers prefer pesticides without hazardous inert ingredients, their ability to choose such pesticides would create incentives for producers of pesticide products to offer products without hazardous inert ingredients. The current lack of information about inert ingredients interferes with the fair and efficient functioning of the market by adversely affecting consumers' ability to exercise individual choice or express preferences and thus the market-driven incentives for producers and suppliers of pesticide products. As a result, pesticide products may contain levels of hazardous ingredients that are higher than society needs or wants and/or people may use a pesticide product or combination of products that lead to more adverse health or environmental outcomes than would otherwise occur.

In this section, the use of the term "consumer" is not intended to limit this discussion to individuals purchasing or using pesticide "consumer products" that are marketed for residential use but also includes consumers of other kinds of pesticide products such as those used in agricultural and institutional settings. As such, the term goes beyond the usual point-of-sale consumer to include a

wide range of individuals, entities and organizations that purchase or use different kinds of pesticide products. This wide range of consumers, represent a complex and diverse range of knowledge and understanding about pesticides. Consumer knowledge is not limited to an individual's understanding of specific chemicals. Such knowledge may be supplemented via training, websites or other independent sources of pesticide information. In addition, purchasers or users of pesticides for agricultural and institutional settings often rely on organizational knowledge and preferences to inform their decisions.

There is an overall societal benefit from individual choice. This is one reason that legislation has favored informing consumers about products in commerce through product labeling. For example, the Fair Packaging and Labeling Act, 15 U.S.C. 1450 *et seq.*, states that "Informed consumers are essential to the fair and efficient functioning of a free market economy." (Ref. 6). When consumers are knowledgeable about the product choices available to them, they are better able to compare the products and vote with their pocketbook by selecting that product which best satisfies their needs and/or preferences. For example, consumers of pesticide products may have specific preferences related to reducing potential exposures to chemicals due to allergies or concerns over potential hazards to human health or the environment.

Increased public disclosure of inert ingredients in pesticides, particularly hazardous inert ingredients, could enable consumers and users of pesticides to make more informed decisions when choosing or using pesticide products. It could also 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 (e.g., using a pesticide containing a specific inert ingredient where a person with a known sensitivity to that ingredient might be exposed to the product, or where the inert ingredient might adversely affect non-target organisms).

By interfering with the consumers' ability to fully express their preferences through informed purchasing, the lack of information on inert ingredients in pesticide products also adversely affects the potential for market-driven incentives for pesticide producers to provide products that better meet the needs and/or preferences of the

consumer. For example, where consumers that have a preference for pesticide products with less hazardous inert ingredients are able to fully express that preference, pesticide producers have a market-based incentive to select less hazardous inert ingredients for the product formulations.

Ultimately, by enabling more informed consumer choices, disclosure of inert ingredients in pesticides, particularly hazardous inert ingredients, may lead the market to provide more product choices that could reduce overall exposures to potentially hazardous chemicals. For example, public disclosure of the presence of a potentially hazardous inert ingredient in a specific pesticide formulation may lead to less exposure to that hazardous inert ingredient because consumers will likely choose products informed by the label and pesticide producers will likely respond by producing products with less hazardous inert ingredients. The ability of public disclosure of information as a market-driver to reduce the use of potentially hazardous chemicals has been demonstrated by publication of the TRI under EPCRA section 313 (Ref. 5).

On the other hand, mandatory inert ingredient disclosure could have potential negative effects on innovation in the pesticide market. Producers of pesticides invest in developing formulations that are effective. Public disclosure of ingredients could give competitors the ability to "free ride" on another company's investment in research and development required to bring a pesticide product to the market. The presence of such "free riders" could deter further investments needed to bring new, improved products to the market in the future. However, as discussed in Unit II.C.2., the Agency believes a closer examination of those circumstances under which confidentiality of inert ingredient identities is necessary for preserving manufacturers' returns to research and development investments will reveal situations where public availability of inert ingredient identities may occur without significant detriment to innovation in the pesticides market.

EPA believes in the value of transparency to consumers and users of pesticides, above and beyond those issues pertaining to potentially hazardous inert ingredients. EPA is also mindful of potential "label clutter," i.e., the inclusion of so much information in the labeling of a product that it becomes difficult for a user to find the relevant information necessary to use the pesticide safely, effectively, and legally.

The Agency therefore wishes to explore what avenues are available to maximize the public availability of inert ingredient identities generally. In addition to the policy considerations raised in the discussion in Unit II.C., EPA is specifically interested in comments on the relationship of inert ingredient labeling to the fair and efficient functioning of the market.

### C. Possible Approaches

EPA is considering two general types of 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. Each approach has variations and issues associated with it. Further, EPA solicits ideas for alternative approaches, both regulatory and non-regulatory.

1. *Require the identities of potentially hazardous inert ingredients to be listed on pesticide labels.* This approach involves identifying a set of potentially hazardous inert ingredients and amending labeling regulations in 40 CFR part 156 to require that pesticides containing those ingredients list them in the ingredient statement. There are a number of issues that would need to be resolved in order to implement this option; EPA solicits comment on these issues:

a. 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.

b. 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.

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

d. 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.

e. 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? 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?

2. *Require all or most inert ingredients to be listed on pesticide labels.* In addition to the hazard-based disclosure discussed previously, EPA is also interested in broader availability of inert ingredient identities. Many consumer products, such as food products and cosmetics and, to an increasing extent, other household products, disclose some information about their ingredients. The Agency believes that consumers and users of pesticides should have comparable kinds of ingredient information available to them about pesticides as they do regarding many other, often less hazardous products. Such information assists consumers in making informed choices.

Requiring disclosure of all inert ingredients would be possible if inert ingredients as a class were not entitled to confidential treatment under FIFRA section 10(b). Though confidentiality is normally determined on a case-by-case basis, see *NCAP v. Browner*, 941 F. Supp. 197 (D.D.C. 1996), EPA desires input on an issue pertinent to the confidentiality of inert ingredients in general. Among the factors in determining eligibility for confidential treatment is whether competitors could reverse engineer the product to obtain the information on their own, without undue cost. Though this question is itself normally answered on a case-by-case basis, EPA solicits comment regarding whether analytical techniques have increased in accuracy and

decreased in cost to the extent that essentially complete analysis of competitors' products is now both routinely performed and successful when attempted in the pesticide industry.

Do registrants and inert ingredient manufacturers know (or can they easily find out) what is in their competitors' products? Do they believe that their own products are safe from reverse engineering due to the limits of analytical techniques or prohibitive cost? To what extent do patents or other public sources of information provide this kind of information? Are there types of products or ingredients where reverse engineering is more or less likely to be performed or successful? Are there characteristics of a formulation (e.g., concentration of certain ingredients) that can make reverse engineering economically infeasible? Do other countries disclose this information and if so under what circumstances? When commenting on this issue please distinguish qualitative analysis (determining which ingredients are present) from quantitative analysis (determining the concentrations of ingredients). In addition, bear in mind the distinction between disclosure of the chemical name of an inert ingredient and disclosure of the identity of a particular vendor of the ingredient. Please also comment upon whether these questions would be answered differently for impurities.

Are there classes or sectors where the identities of inert ingredients are generally known among competitors? The Agency assumes that there would be no substantial competitive harm from the disclosure of inert ingredients where the technology is generally known among competitors. EPA solicits comment on these questions.

EPA is not only seeking input from knowledgeable persons regarding the factors that influence whether competitors are aware of one another's formulations, but is also challenging registrants and inert ingredient manufacturers to reexamine their own assumptions about the competitive landscape for their products. What role does confidentiality of inert ingredient identities play today in product competitiveness? Are there sectors of the industry where this role is enhanced or diminished?

Even to the extent that particular inert ingredients are entitled to confidential treatment under FIFRA section 10(b), EPA can amend its regulations to increase the public availability of inert ingredient identities. As discussed previously, Agency practice results in sparse disclosure of inert ingredient

identities because there is seldom a clear indication up front of which ingredient identities are claimed as confidential. Where specific identities are not claimed as confidential by the registrant or inert ingredient manufacturer, EPA could make the information public without further analysis. EPA therefore solicits comment regarding whether the Agency should require the identities of all inert ingredients (and perhaps impurities) to be specifically claimed as confidential upon submission to the Agency, such that in the absence of a confidentiality claim the name will be required to appear on the label (or elsewhere) as discussed in Unit II.C.3.i.). EPA also solicits comment on requiring that all confidentiality claims for inert ingredient identities be accompanied by a substantiation of the confidentiality claim in order to help ensure that the confidentiality claims have substance. See 40 CFR 2.204(e)(4) for EPA's standard substantiation questions. If EPA were to require up-front substantiation of confidentiality claims, what kinds of information in addition to the questions in 40 CFR 2.204(e)(4) would be of value to assess the merits of a confidentiality claim for inert ingredient information?

EPA also notes some policy tension between the two approaches: Hazard-based disclosure is intended to reduce the prevalence of hazardous ingredients by highlighting their presence, and to the extent that the Agency achieves a broader (non-hazard-based) disclosure of inert ingredients, that highlighting would be absent. By knowing the ingredients in a product, motivated users and consumers could research the hazard, but this information would not be readily apparent simply from the ingredient list. EPA would appreciate comment on the interaction between these policy objectives.

The following issues apply to broad public availability of inert ingredient identities:

a. 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? Note that EPA is considering allowing substitution of fragrances in a formulation without requiring the reporting of the individual fragrance ingredients which comprise the fragrance, provided that the ingredients are on the Fragrance Ingredient List and that the fragrance meets concentration and other conditions in EPA's Fragrance

Notification Program such as was described as part of the Pesticide Fragrance Notification Pilot Program (<http://www.epa.gov/opprd001/inerts/fragrancenote.pdf>).

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

3. *Common issues.* EPA also solicits comment on the following issues, which apply to both hazard-based and non-hazard-based disclosure:

a. 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?

b. 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?

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

d. 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?

e. 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?

f. 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?

g. In PR Notice 97-6, [http://www.epa.gov/opppmsd1/PR\\_Notices/pr97-6.html](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?

h. 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?

i. 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?

j. 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.

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?

l. 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](http://www.epa.gov/opppmsd1/PR_Notices/pr97-5.html), for Agency policy and guidance.

m. 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?

n. 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?

o. 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?

#### *D. What is the Agency's Authority for Taking this Action?*

The authority to require public availability of potentially hazardous inert ingredients (on the ingredient statement or elsewhere) 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). 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 section 3(c)(5)(C). Under FIFRA section 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." The FIFRA section 2(bb) definition thus highlights cost/benefit comparisons pertaining to use of a particular pesticide in the consideration of its eligibility for registration.

While there is no definition for hazardous inert ingredients in FIFRA (and this document asks for comment regarding how to define such ingredients for the purpose of this rulemaking), hazardous inert ingredients can in general be described as those that may pose physical hazards (e.g., flammability, explosibility), health hazards (i.e., adverse acute/chronic health effects), or environmental hazards (e.g., adverse ecological effects, persistence, bioaccumulation). Use of any pesticide will involve some exposure to persons and the environment, and if the formulation contains potentially hazardous inert ingredients there will be some exposure to those ingredients, and therefore some level of risk resulting from this exposure. And though EPA reviews data regarding the entire formulation to ensure that this risk of a particular pesticide is not unreasonable, 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. Therefore, under FIFRA section 2(bb), any risk from hazardous ingredients, however small, should in general be less reasonable than the risk from a formulation not containing potentially hazardous ingredients, even though the risk from a particular formulation is not itself unreasonable so that the registration standard is met.

EPA solicits comment on the contribution to risk from hazardous inert ingredients. For example, are there situations where the presence of a particular hazardous inert ingredient results in a lower application rate than could be achieved through the use of a less hazardous ingredient?

EPA could address relative levels of risk on a case-by-case basis via label reviews, approvals of specific formulations, or even cancellation under FIFRA section 6 where appropriate, but such actions 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." 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.

As to requiring public availability of inert ingredients on a basis other than hazard, EPA has such authority where inert ingredient identities are not subject to claims of confidentiality or where such information is not entitled to confidential treatment under law.

#### *E. Suggested Hazard Criteria*

The following are the suggested hazard criteria as discussed in Unit II.C.1.a. that could be used as a basis for identifying ingredients to be listed in the ingredient statement.

##### **Physical Hazards**

- Extremely flammable or combustible
- Explosive
- Pyrophoric
- Strong organic peroxide
- Strong oxidizer

##### **Health Hazards**

###### *Acute Toxicity*

- Acute oral, dermal, and/or inhalation toxicity study resulting in assignment to EPA Toxicity Category I (40 CFR 156.62)



- Skin corrosion
- Eye damage
- Strong skin and/or respiratory sensitizer

#### Mutagenicity

- Known to induce heritable germ cell mutations in humans
- Positive result(s) from *in vivo* heritable germ cell mutagenicity tests in mammals

#### Carcinogenicity

- Known or presumed human carcinogen
- Classified as: Group 1 or Group 2 by the International Agency for Research on Cancer (IARC); having evidence of carcinogenic activity by the National Toxicology Program (NTP) and/or the Environmental Protection Agency (EPA); and/or a Category I Potential Carcinogen by the Occupational Safety and Health Administration (OSHA)

#### Reproductive and Developmental Toxicity

- Known or presumed human reproductive or developmental toxicant
- Clear evidence of adverse effects on reproductive ability or capacity and/or development of the offspring in peer-reviewed experimental animal studies

#### Target Organ/Systemic Toxicity

- Causes hepatotoxicity, nephrotoxicity, neurotoxicity, hematopoietic effects, immunotoxic effects, pulmonary toxicity, thyroid toxicity, cutaneous toxicity or other specific target organ/systemic toxicity in peer-reviewed experimental animal studies at doses below 50 mg/kg/day

#### Environmental Hazard

- Highly toxic to avian and mammals (acute oral toxicity <50 mg/kg) based on peer-reviewed studies
- Highly toxic to aquatic organisms at concentrations of 1 ppm or below based on peer-reviewed studies
- Highly toxic in avian dietary studies (<50 ppm) based on peer-reviewed studies
- Very slow biodegradation (<30% degradation in >28 days) in an EPA Office of Prevention, Pesticides and Toxic Substances (OPPTS) Harmonized Test Guideline Test 835.3110, Organisation for Economic Co-operation and Development (OECD) Guideline Test 301, or equivalent for biodegradability
- Partition coefficient (n-octanol/water) value (P) of log P  $\geq 4$  in OPPTS Harmonized Test Guideline 830.7550, OECD Guideline 117, or equivalent study
- Fish Bioconcentration Factor (BCF) of  $\geq 1,000$  in OPPTS Harmonized Test Guideline 850.1730 (draft), OECD Guideline 305, or equivalent study

- Class I/Class II Ozone-depleting Substance or High Global Warming Potential Gas

### III. Statutory and Executive Order Reviews

Under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993), this action was submitted to the Office of Management and Budget (OMB) for review. Any changes to the document that were made in response to OMB comments received by EPA during that review have been documented in the docket as required by the Executive Order.

Since this document does not impose or propose any requirements, and instead seeks comments and suggestions for the Agency to consider in possibly developing a subsequent proposed rule, the various other review requirements that apply when an agency imposes requirements do not apply to this action. Nevertheless, as part of your comments on this document, you may include any comments or information that you have regarding the various other review requirements.

In particular, EPA is interested in any information that would help the Agency to assess the potential impact of a rule on small entities pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*); to consider voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note); to consider environmental health or safety effects on children pursuant to Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997); or to consider human health or environmental effects on minority or low-income populations pursuant to Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income

Populations" (59 FR 7629, February 16, 1994).

The Agency will consider such comments during the development of any subsequent proposed rule as it takes appropriate steps to address any applicable requirements.

### IV. References

1. Petition of New York, et al., 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, August 2006.

2. Petition of Northwest Coalition for Alternatives to Pesticides, et al., To Require Disclosure of Hazardous Inert Ingredients on Pesticide Product Labels, August 2006.

3. EPA's Response to Petitions Requesting Disclosure of Inert Ingredients, September 30, 2009, <http://www.epa.gov/opprd001/inerts/petitionresponse.pdf>.

4. Final Report to the Pesticide Program Dialogue Committee on the Activities of the Inert Disclosure Stakeholder Workgroup, March 2000 through April 2002, <http://www.epa.gov/oppfead1/cb/ppdc/inert-finalreport.html>.

5. How Are the Toxics Release Inventory Data Used? -- Government, business, academic and citizen uses. EPA-260-R-002-004 (May 2003), [http://www.epa.gov/TRI/guide\\_docs/pdf/2003/2003\\_datausepaper.pdf](http://www.epa.gov/TRI/guide_docs/pdf/2003/2003_datausepaper.pdf).

6. Fair Packaging and Labeling Act, 15 U.S.C. 1450 *et seq.* <http://www.fda.gov/RegulatoryInformation/Legislation/ucm148722.htm>.

#### List of Subjects in 40 CFR Part 156

Environmental protection, Pesticides and pests.

Dated: December 14, 2009.

**Lisa Jackson,**  
Administrator.

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