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October 6, 2011

**Via Electronic & U.S. Mail**

Lisa Jackson, EPA Administrator
United States Environmental Protection Agency
Office of Pesticide Programs
401 M Street, S.W.
Washington, DC 20460

**Re: Disclosure of Pesticide Inert Ingredients**

Dear Administrator Jackson:

On behalf of the Center for Environmental Health, I write to support EPA's proposed actions to require the disclosure of pesticide inert ingredients on product labels pursuant to its authority under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq*.[1] Specifically, EPA should either require the disclosure of inert ingredients that EPA has already identified as "hazardous" or require the disclosure of all inert ingredients, as proposed in EPA's Advanced Notice of Proposed Rulemaking ("ANPR"). *See Public Availability of Identities of Inert Ingredients in Pesticides*, 74 Fed. Reg. 68215 (Dec. 23, 2009). Contrary to the comments of industry groups, ample authority supports the proposed actions.

As detailed further below, FIFRA provides EPA with broad authority to require disclosure of hazardous inert ingredients, as well as all inert ingredients on pesticide labels. Section 10 of FIFRA, which prohibits the disclosure of trade secrets or other confidential business information (collectively "CBI"), does not block the proposed actions, as claimed by industry commentators. It provides no *per se* exemption for the disclosure of inert ingredient information. Further, notwithstanding the fact that inert ingredient information is routinely claimed as CBI, EPA can and should determine that as a class such information is not entitled to confidential treatment. Even if some inert ingredient information is legitimately CBI, however, EPA has the authority to exempt it from CBI treatment by determining that its disclosure is "necessary to protect against an unreasonable risk of injury to health or the environment." Finally, while all of the above supports the disclosure of all inert ingredients, whether hazardous or not, EPA has additional grounds for specifically compelling the disclosure of known hazardous inert ingredients in pesticides, which EPA should immediately require.

[1] Hereinafter, all "§" references are to FIFRA, unless otherwise noted.

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**A. EPA May Require Disclosure of Inert Ingredient Identities on Product Labels.**

FIFRA does not affirmatively require the disclosure of all ingredients in a pesticide; only the disclosure of "active" ingredients is explicitly required. An active ingredient is defined as "an ingredient which will prevent, destroy, repel, or mitigate any pest." § 2(a). "Inert ingredient" means "an ingredient which is not active." § 2(m). Whereas a product label's ingredient statement must contain "the name and percentage of each active ingredient," it only need disclose "the total percentage of all inert ingredients in the pesticide." § 2(n).

EPA, however, has broad authority to require additional disclosure of information regarding inert ingredients, such as their identities and relative concentration levels, under FIFRA. Indeed, EPA has already acted pursuant to that authority by authorizing the Administrator to "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." *See* 40 C.F.R. § 156.10(g)(7); 40 Fed. Reg. at 28252. The legal basis for adopting this regulation is summarized in the ANPR:

> When [40 C.F.R. § 156.10(g)(7)] was promulgated . . . 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).

ANPR, 74 Fed. Reg. at 68217 (emphases added).

EPA's "basic obligation" of "determining the risks which may be posed by a pesticide" and "control[ling] an unreasonable risk" is manifest in FIFRA's statutory scheme. FIFRA prohibits the sale and distribution of a pesticide, unless it meets certain safety criteria for registration. § 3(a). Such criteria include that the pesticide "will perform its intended function without unreasonable adverse effects on the environment," and "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." § 3(c)(5)(C), (D). In addition, FIFRA imposes a continuing duty on registrants to submit to EPA new information "regarding unreasonable adverse effects on the environment" not considered in the initial registration decision. § 6(a)(2). For those pesticides not registered or otherwise approved under FIFRA, EPA is empowered "[t]o the extent necessary to prevent unreasonable adverse effects on the environment" to limit by regulation their "distribution, sale, or use in any State." § 3(a). *See also New York State Pesticide Coal., Inc. v. Jorling*, 874 F.2d 115, 117, 119 (2d Cir. 1989) (noting FIFRA's intent to "'protect man and his environment' from the deleterious effects of [pesticides]" (quoting S. Rep. No. 92-838, p. 1 (1972)).

FIFRA therefore empowers EPA to "impos[e] the necessary regulatory requirement to adequately control an unreasonable risk." *See* 40 Fed. Reg. 28242, 28252 (July 3, 1975). Specifically, it is authorized to "prescribe regulations to carry out the provisions of [FIFRA]," which "shall take into account the difference in concept and usage between various classes of pesticides . . . and *differences in environmental risk and the appropriate data for evaluating such risk*." § 25(a)(1) (emphasis added). This includes the discretion to determine the "appropriate data" for "evaluating [environmental] risk" to be included on a pesticide label. *Id*. EPA could reasonably conclude that inert ingredient identities, including the identities of hazardous ingredients, should be included on label statements to enable consumers to make informed choices in evaluating such risks.[2] In addition, EPA has broad authority to promulgate "guidelines specifying the kinds of information which will be required to support the registration of a pesticide," which encompasses the discretion to specify whether registrants must include inert ingredient information on a pesticide label. §3(c)(2)(A).

This authority complements FIFRA's mandate that, except as provided by section 10 regarding the disclosure of CBI, EPA "shall make available to the public the data called for in the registration statement together with such other scientific information as the Administrator deems relevant to the Administrator's decision" after registering a pesticide. § 3(c)(2)(A). Registration statements must include the complete formula of a pesticide, including inert ingredient information. § 3(c)(1)(D). The duty to make public all information supporting a registration decision, including inert ingredient information, strongly supports EPA's authority to compel disclosure of inert ingredient information on product labels.

Inert ingredients present an "unreasonable risk," because their effects are largely untested and unknown and yet there is potential for significant harm, as will be further discussed later in section C. Thus, FIFRA authorizes EPA to "adequately control" this risk by requiring label disclosure of these ingredients.

[2] FIFRA does not paternalistically see EPA as the exclusive arbiter of acceptable risk level as some commentators claim. FIFRA's requirements that EPA shall disclose to the public various data concerning environmental risk (*e.g.*, § 3(c)(2)(A); § 10(d)(1)) contemplates that the public play an important role in ensuring that such risks are properly assessed and empowers consumers to determine acceptable levels of risk for themselves. Indeed, the Supreme Court has recognized that in the context of FIFRA, "public disclosure can provide an effective check on the decision-making processes of EPA and allows members of the public to determine the likelihood of individualized risks peculiar to their use of the product." *See also Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1016 (1984) (citing H.R. Rep. No. 95–343, p. 8 (1977) (remarks of Douglas M. Costle); S. Rep. No. 95–334, p. 13 (1977)).

## B. FIFRA's Restriction on Disclosing CBI Does Not Preclude Disclosure of Inert Ingredient Information.

### *1. Disclosure of inert ingredient information is not "per se" prohibited.*

Section 10 of FIFRA, which prohibits the disclosure of trade secrets or other confidential business information (collectively "CBI"), does not block the proposed actions. Section 10 only prohibits the disclosure of 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." § 10(b). This provision is "subject to the limitations in subsection (d)." *Id*. In relevant part, subsection (d) commands that all safety and efficacy information[3] "shall be available for disclosure to the public" with the caveat that this subsection "does not authorize the disclosure of any information that . . . discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide." § 10(d)(1)(C). Some commentators have misconstrued this caveat as a *per se* prohibition on inert ingredient information. But subsection (d) simply limits and defines the boundaries of what information may be claimed as CBI. In essence, then, such claims do not apply to safety and efficacy information but may apply to inert ingredient information. *See Disclosure of Reviews of Pesticide Test Data*, 50 Fed. Reg. 48833 (Nov. 27, 1985) ("data described by . . . section 10(d)(1)[(C)] . . . *may* be entitled to protection from disclosure as [CBI]" (emphasis added)).

EPA is therefore correct that "information must meet the FIFRA section 10(b) standard in order to be eligible for confidential treatment" and may require the disclosure of any inert ingredient information which does not meet the 10(b) standard. ANPR, 74 Fed. Reg. at 68217. Its rulemakings consistently employ this interpretation. Safety and efficacy information "that has not been designated by the submitter as [information disclosing the identity or percentage quantity of any deliberately added inert ingredient of a pesticide] is not entitled to confidential treatment and may be disclosed to the public without further notice to the submitter." 40 C.F.R. § 158.33(d)(1). Information so designated, however, "is entitled to confidential treatment *only to the extent provided by FIFRA sec[tion] 10(b)* . . . and [the regulations providing how CBI is claimed and determined]." *Id*. *See also id.* § 158.33(d) ("Information that is not *entitled to be protected as confidential in accordance with FIFRA sec[tion] 10(b)*, this section and with EPA confidentiality regulations at 40 CFR part 2, subpart B [providing how CBI is determined], may be released to the public . . .").

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[3] Safety and efficacy information includes "information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism." § 10(d)(1); 40 C.F.R. § 158.33(a)(2).

Commentators have also misconstrued subsection (d) as not authorizing the disclosure of inert ingredient information "unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment" as the only circumstances under which such information may be released. § 10(d)(1)(C). Once again, this provision operates only as a "limitation" on subsection (b)'s reach. If the Administrator has first made this determination with respect to certain inert ingredient information, that information is not subject to confidential treatment under subsection (b). But if the information does not meet the subsection (b) standard for confidential treatment in the first place, this determination is not a necessary condition for inert ingredient information to be released. *See Northwest Coalition for Alternatives to Pesticides v. Browner ("NCAP")*, 941 F. Supp. 197, 201 (D.D.C. 1996) ("FIFRA § 10 does not prohibit the disclosure of inert ingredients in the absence of the Administrator's judgment").

The rest of section 10 supports this interpretation, referring to the prohibition on disclosure provided by subsection (b) but omitting to mention any supposed prohibition on disclosure of inert ingredient information provided by subsection (d). Subsection (e) provides that "[i]nformation *otherwise protected from disclosure under subsection (b) of this section* may be disclosed to contractors with the United States and employees of such contractors" under certain specified conditions. § 10(e) (emphasis added). It makes no similar exception for inert ingredient information purportedly protected by subsection (d) specifically, though such information could be "necessary for the satisfactory performance by the contractor of a contract with the United States." *Id*. Similarly, subsection (f) only imposes penalties for unauthorized disclosure by a federal employee of "material the disclosure of which is prohibited by *subsection (b)* of this section" and does not mention a prohibition provided by subsection (d). § 10(f) (emphasis added). These provisions' silence with respect to subsection (d) indicates that the only prohibition on disclosure is provided by subsection (b), and that any information that does not meet the confidentiality standard of subsection (b) is subject to disclosure.

In sum, section 10(d)(1) does not contain a "*per se*" prohibition on the disclosure of inert ingredient information, and the disclosure of inert ingredient information is not limited to circumstances under which the Administrator first determines that such disclosure is necessary to protect against an unreasonable risk to health or the environment. Only if inert ingredient information meets the standard for CBI under section 10(b) must this condition be met to require its disclosure. If it is not CBI, it can be disclosed.

### *2. EPA can and should determine that certain inert ingredient information as a class is not CBI.*

The fact that inert ingredient identities are routinely claimed as CBI is not a bar to requiring their disclosure. EPA currently does not require any upfront substantiation of these claims, and commentators and case law have demonstrated that certain inert ingredient information generally does not meet the standard for CBI under section 10(b). Indeed, EPA has

the authority to find that as a class, certain types of inert ingredient information do not meet the standard for CBI. This includes:

- the common name of the ingredient (which does not necessarily reveal the precise chemical identity or trade name);
- the name of any ingredient disclosed on a Material Safety Data Sheet ("MSDS");
- the chemical abstract number ("CAS number") for the ingredient; and
- the relative concentration of the ingredient, in descending order, from highest to lowest percentage quantity (but not the specific percentage quantity).

The determination that certain information is not CBI need not be made on a case-by-case basis. Under EPA's general regulations concerning CBI, *see* 40 C.F.R. § 2.201 *et seq*., EPA routinely initiates class-based determinations as to whether certain categories of information are CBI. *See e.g.*, *Greenhouse Gas Reporting Rule*, 76 Fed. Reg. 30782, 30788 (May 26, 2011); *Disclosure of Reviews of Pesticide Data*, 50 Fed. Reg. 48833, 48834 (Nov. 27, 1987). All information submitted to EPA under FIFRA is also subject to such class-based determinations. 40 C.F.R. § 2.307(b), (c); *id*. § 158.33(b)(1).[4] Specifically, "[a] class determination may state that all of the information in the class . . . [f]ails to satisfy one or more of the applicable substantive criteria, and is therefore ineligible for confidential treatment." *Id*. § 2.207(c)(3). The substantive criteria for confidential treatment, in relevant part are:

- "The information is not, and has not been, reasonably obtainable without the business's consent by other persons (other than governmental bodies) by use of legitimate means . . . "
- "The business has satisfactorily shown that disclosure of the information is likely to cause substantial harm to the business's competitive position."

*Id*. § 2.208 (c), (e)(1). These criteria also apply to CBI claimed under FIFRA section 10(b). *Id*. § 158.33(d)(2).

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[4] Such a class-based determination may be made where:

(1) EPA possesses, or is obtaining, related items of business information;

(2) One or more characteristics common to all such items of information will necessarily result in identical treatment for each such item under one or more of the provisions in this subpart, and that it is therefore proper to treat all such items as a class for one or more purposes under this subpart; and

(3) A class determination would serve a useful purpose.

40 C.F.R. § 2.207(a).

The fact that inert ingredient information can be "reasonably obtain[ed] without the business's consent" through reverse engineering precludes any determination that it is CBI. "The feasibility of 'reverse engineering' is germane to the question whether information is in the public domain (and thus whether a showing of competitive harm can be made)." *See NCAP*, 941 F. Supp. at 202. Ingredient identities can be readily discovered through reverse engineering at relatively low cost and within reasonable time frames. *See* Comments of the State Attorneys General on ANPR at 8 (April 22, 2010) (demonstrating that "qualitative deformulation to determine the inert ingredients in pesticides is both highly feasible and commercially available," and that "[i]nformation sufficient to replicate a commercial formulation can be determined at reasonable cost and within reasonable time periods"); Comments of NCAP on ANPR at 2 (undated letter from Caroline Cox to Kerry Leifer) (noting deformulation of herbicides was "neither difficult nor expensive"). *See also NCAP*, 941 F. Supp. at 202 (finding that defendant failed to establish genuine issue of material fact "as to the economic feasibility of identifying the common names and CAS numbers of inert ingredients through 'reverse engineering'").

Moreover, the identities of hazardous ingredients in pesticides are also "reasonably obtainable." Such information is routinely disclosed on publicly available Material Safety Data Sheets that chemical manufacturers are required to produce to EPA under the Emergency Planning and Community Right to Know Act ("EPCRA"), 42 U.S.C. §§ 11021(a), (c)(2), 11044 and the Occupational Safety and Health Administration's Hazard Communication Standards. 29 C.F.R. § 1910.1200(g).[5]

For all of these reasons, moreover, inert ingredient information is not "likely to cause substantial harm to the business' competitive position." 40 C.F.R. § 2.208 (e)(1). Because "the information at issue is publicly available through other sources [or otherwise reasonably obtainable], no showing of competitive harm can be made." *See NCAP*, 941 F. Supp. at 202.

But even if some of this information were neither publicly available nor "reasonably obtainable" through reverse engineering, its disclosure would still not cause harm to a business' competitive position. Common chemical names, CAS numbers, and relative ingredient concentrations, in descending order, do not reveal trade secrets. A "trade secret" is "a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Id*. at 201-202, quoting *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C. Cir. 1983). In *NCAP*, neither the EPA nor the business claiming a CBI exemption under FOIA "demonstrated . . . that the common name and CAS numbers of inert ingredients [were] trade secrets." *Id*. at 202. This was "general identifying

[5] In limited situations, manufacturers that demonstrate supportable trade secret claims may exclude the identity of the chemical ingredient and identify a generic class instead. 42 U.S.C. § 11042(a)(1); 29 C.F.R. § 1910.1200(i). These claims must be substantiated before the information can be excluded from the MSDS. *See* 42 U.S.C. § 11042(b). In such cases, pesticides label could disclose the generic class instead of the specific ingredient identity.

information about inert ingredients," which does not reveal the "recipe" or formulation for the pesticide. *See id*. (noting EPA and business defendant had "conceded that disclosing the common name of an inert ingredient may not reveal exactly which one of a class of ingredients sharing the same common name is used in a particular pesticide"). Further, rarely does revealing a common name or CAS number result in competitive injury. *Id*. at 203-205 (noting that "in general the CAS number does not disclose the 'trade name' of an ingredient" and finding that in multiple instances defendants failed to show that disclosure of CAS numbers and common names would result in competitive injury). The same can be said for identifying the relative concentrations of inert ingredients in descending order, which does not reveal specific ingredient proportions that would reveal the formula.

Thus, given that inert ingredient information is already publicly available and can be reverse engineered, and that its disclosure is not likely to result in substantial harm to a businesss' competitive position, EPA can determine that common chemical names, CAS numbers, and relative ingredient concentrations in descending order, each as a class does not constitute CBI. Such a determination would thereafter enable EPA to require that common chemical names and relative ingredient concentrations must be disclosed on pesticide labeling and that inert ingredient CAS numbers for each pesticide must be disclosed in a public database.[6]

Even if there are exceptional instances in which such information is properly CBI, legitimately claimed CBI can still be protected. When requesting notice and opportunity for comment on a class determination that CAS numbers, common chemical names, and relative concentrations of all ingredients in descending order, do not qualify as CBI, EPA would make clear to affected businesses that this would be the opportunity for them to substantiate existing CBI claims. *See* 40 C.F.R. § 2.204(e)(4); 76 Fed. Reg. at 30788 (using same procedure for making class determination as to confidentiality of certain categories of greenhouse gas emissions data reported to EPA).[7] If it turns out that there are some cases where businesses can

[6] In *NCAP v. Leavitt*, the court held that inert ingredient information cannot be disclosed through a blanket rulemaking because the statute contemplated a case-by-case determination of whether "disclosure is necessary to protect against an unreasonable risk of injury." Tr. of Oct. 12, 2004 hearing at 62-63 (D.D.C. Case No. 00-2483). The *Leavitt* decision did not directly address, however, whether EPA could make a blanket determination that certain types of inert ingredient information do not constitute CBI. To the extent that *Leavitt* holds that *NCAP* does not control in the context of whether EPA can require disclosure of inert ingredients through rulemaking, *Leavitt* overlooks *NCAP*'s express holding that FIFRA section 10 "does not prohibit the disclosure of inert ingredients in the absence of the Administrator's judgment," such that FOIA's Exemption 3 (allowing withholding of information that another federal statute prohibits from disclosure) did not apply to inert ingredient information. *See NCAP*, 941 F. Supp. at 201.

[7] A proper showing of substantiation would demonstrate that the ingredient identity has not been disclosed to others under nonconfidential conditions, it has been guarded as confidential, it is not required to be made available to the public under any Federal or State law, it is not readily discoverable through reverse engineering, and identification of the ingredient on product labels is

properly substantiate CBI claims, EPA could make an exception for the disclosure of such ingredients. It could require that inert ingredient information be disclosed in labeling and in a public database as described above, unless the registrant or applicant has claimed the information as CBI and it has been properly substantiated and found to be CBI pursuant to section 10(b).[8]

### C. EPA May Find that the Disclosure of Inert Ingredients Is Necessary to Protect Against an Unreasonable Risk of Injury.

Even if some inert ingredient information is CBI, EPA has the authority to compel disclosure of all inert ingredients, if EPA determines that disclosure is "necessary to protect against an unreasonable risk of injury to health or the environment." *See* section B(1) above. This determination need not be made on a case-by-case basis, given that all inert ingredients pose an "unreasonable risk," because the chronic, synergistic, and cumulative effects of these ingredients in combination with active ingredients or other factors are unknown. The disclosure of inert ingredient identities is necessary to protect against these risks.

#### *1. Significant data gaps exist in the understanding of pesticides' effects and inert ingredients.*

In order to register a pesticide, EPA must determine that the pesticide "will perform its intended function without unreasonable adverse effects on the environment," and "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." § 3(c)(5)(C), (D). Whether a pesticide causes "unreasonable adverse effects" turns upon a cost-benefit analysis, considering data submitted by the pesticide registrant. Unreasonable adverse effect means " any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." § 2(bb)(1). This determination is based on data submitted by the registrant, and EPA has broad authority to specify the kinds of information required to support the registration. *See* § 3(c)(2).

Under the current data submission requirements, however, significant informational gaps inhibit the full understanding of a pesticide's adverse effects on health or the environment. While EPA requires a number of tests and various data concerning a product's safety to be submitted, for many of these tests, EPA does not require testing with the actual product formulation, but with the active ingredient only. Only two out of the 19 medium- and long-term toxicity tests - assessing effects of the most significant concern, such as cancer, developmental and reproductive

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likely to cause the registrant substantial competitive harm. *See* 42 U.S.C. § 11042(b) (upfront substantiation showing required under EPCRA).

[8] In any case, for all future data submissions, EPA should require that all CBI claims must be substantiated upfront, given that inert ingredient information will rarely ever qualify as CBI. *See* n.7 above; 40 C.F.R. § 174.9(b) (requiring upfront substantiation of CBI claims for plant-incorporated protectant submissions).

problems, and genetic damage - must be conducted with the pesticide formulation to support the registration of an end use product. 40 C.F.R. § 158.500. The rest are conducted with the active ingredient, and in one case the test substance is discretionary. *Id*.

This is despite the fact that studies indicate that inert and active ingredients combined can have synergistic effects, resulting in more harmful effects than the individual ingredients alone would cause. *See* Caroline Cox & Michael Surgan, *Unidentified Inert Ingredients in Pesticides: Implications for Human and Environmental Health*, 114 ENVIRONMENTAL HEALTH PERSPECTIVES, 1803, 1805 (2006). Inert ingredients can even increase the likelihood of exposure by reducing the efficacy of protective skin and clothing and increasing persistence and dispersal in the environment. *Id*. at 1804-1805. However, in most cases, the effects are truly unknown, and thus, pesticides may be registered before the effects of their formulations or inert ingredients on health and the environment are fully understood.

***2. Disclosure of inert ingredient identities is necessary to protect against an unreasonable risk.***

Disclosure of inert ingredients on pesticide labeling is necessary to protect against the unknown chronic and synergistic effects of pesticides, which are potentially significant. Whether a risk is unreasonable depends on various factors, though FIFRA does not specifically define what factors should be considered in what is "an unreasonable risk" under section 10(d)(1).

One factor that should be considered is the extent to which there is certainty about a product's safety, i.e., whether its safety is known or unknown. For example, in the context of the FDA's approval of medical devices, the lack of data on a product's efficacy or safety is relevant to assessing whether the product poses an unreasonable risk to the consumer. *See Lake v. United States Food and Drug Admin.*, 1989 WL 71554, at *3 (E.D. Pa. 1989) ("When there is no valid scientific evidence of efficacy, *and the risks are unknown*, the risk is unreasonable."). While "risk" means "*possibility* of loss or injury," *see* Merriam-Webster Dictionary, entailing no certainty of injury, "unknown risk" here refers not to the uncertainty of an individual organism in being "hit" by a known potential harm as a result of exposure (e.g., 1% chance of cancer) – but that there is no sense of how probable any harm is (0% chance of cancer vs. 1% vs. 50%?).

The statutory scheme for the Toxic Substances Control Act ("TSCA") similarly acknowledges that some risks of injury are unreasonable, although not proven or certain to occur. The *possibility* of harm is enough to warrant the imposition of controls on a chemical substance, if EPA finds that "there is a reasonable basis to conclude that the . . . chemical substance . . . presents or will present an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2605(a). The legislative history for this provision explains:

> This standard for taking action recognizes that factual certainty respecting the existence of an unreasonable risk of a particular harm may not be possible and the

> bill does not require it. Further, regulatory action may be taken even though there are uncertainties as to the threshold levels of causation.

H.R. Rep. No. 94-1341 (1976). *See also Chemical Manufacturers Ass'n v. U.S. EPA*, 859 F.2d 977, 986 (D.C. Cir. 1988) (noting that TSCA's standard that a chemical "will present an unreasonable risk" is "arguably is less rigorous" than a "more-probable-than-not finding"). The Federal Food and Drug Administration has also disapproved marketing of products, despite lacking conclusive evidence of their ability to cause harm. *See e.g.*, *Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present An Unreasonable Risk*, 69 Fed. Reg. 6788, 6826 (Feb. 11, 2004).

While in these two latter contexts risk may be deemed unreasonable *despite* the uncertainty of its existence, and not necessarily *because* of such uncertainty, as we propose, the practical effect of each approach is the same: precautions are taken in the face of uncertainty of risk. This precautionary approach should similarly apply in the context of requiring pesticide label disclosures of inert ingredients, and to a certain extent, EPA's labeling regulations already reflect that approach. EPA may require the disclosure of inert ingredient names on product labels if it "determines that such ingredient(s) *may* pose a hazard to man or the environment." 40 C.F.R. § 156.10(g)(7) (emphasis added)

The consideration of additional factors is also relevant in assessing whether the risk is "unreasonable." EPA can compel disclosure of inert ingredient information that is CBI if it "has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment." § 10(d)(1). Thus, whether a risk is unreasonable is also assessed in light of the costs and benefits of disclosure.[9]

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[9] Unlike in *Lake* (the medical device example above) or in the context of registration, where the issue is whether use of the product should be allowed, the question is not whether the risk of injury is unreasonable in light of the costs and benefits of *allowing its use*. That balancing has already occurred in the registration decision, an entirely different calculus than the one posed by section 10(d)(1). Therefore, it is not correct, as some critics have claimed, that EPA cannot find that disclosure of the inert ingredients of all pesticides already registered is necessary to protect against an unreasonable risk, because EPA has already determined that the pesticide will not cause "unreasonable adverse effects."

Further, EPA is on a much shorter leash when it comes to denying registration than with respect to requiring disclosure of inert ingredients. EPA "shall" register a pesticide if it finds that "*when used in accordance with widespread and commonly recognized practice it will not generally cause* unreasonable adverse effects on the environment," *see* § 3(c)(5)(D) (emphasis added), where "unreasonable adverse effects" is defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." § 2(bb).

As explained above, virtually no pesticides are subject to full testing of their formulations, and there is thus an unknown risk as to the long-term effects of all pesticides and the synergistic effects of inert ingredients in combination with other ingredients. This information gap is compounded by the difficulty in tracing chronic effects to a single source. More significantly, there is also a potential for enormous cumulative harm with other environmental pollutants and destructive practices, but the actual effects and extent of harms are unknown. *See* Comments of Science and Environmental Health Network ("SEHN") on ANPR at 9-12 (April 23, 2010). Thus, notwithstanding the fact that EPA must determine that a pesticide will not cause "unreasonable adverse effects" on human health or the environment before it can be registered, the full risks of registered pesticides are truly unknown, resulting in a potential for significant harm to the public and environment from the use of such pesticides.

Clearly, having the public assume the unknown but potential risk of catastrophic environmental harm is unreasonable, given the fact that disclosure could protect against that risk, at negligible cost. Disclosure would facilitate and encourage public and scientific assessment of those ingredients, acting as an independent check on EPA's own incomplete assessments. Indeed, "public disclosure can provide an effective check on the decision-making processes of EPA and allows members of the public to determine the likelihood of individualized risks peculiar to their use of the product." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1016 (1984), citing H.R.Rep. No. 95–343, p. 8 (1977) (remarks of Douglas M. Costle); S. Rep. No. 95–334, p. 13; *see id*. at 1015 (rejecting reasoning that health and safety data had no public value because FIFRA's registration process and labeling requirements "provided the public with all the assurance it needed that the product is safe and effective").

Disclosure would thus promote informed consumer choice and discourage registrants from using potentially toxic chemicals in their formulations, while encouraging the development of safer alternatives, resulting in the reduced use of potentially toxic pesticides overall. *See* Comments of SEHN at 15-23. The cost of disclosure, however, would be minimal. As discussed above, many inert ingredient identities are already publicly available, most are obtainable through reverse engineering, and the disclosure of common names and CAS numbers would not result in substantial competitive harm.

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Section 10(d)(1), however, permits EPA to disclose CBI-protected inert ingredient information if disclosure is "necessary to protect against an unreasonable risk of injury to health or the environment," which is not defined, but which is much broader than "effect[s]" "generally cause[d]" "when used in accordance with widespread and commonly recognized practice." (The fact that "unreasonable risk" as used in section 10(d)(1) is left undefined and that it is not the same as the definition of "unreasonable adverse effects" also indicates that they are different inquiries.) Moreover, while the latter language suggests registration should be denied to protect against an actual known risk of injury ("adverse effects") "cause[d]" by the pesticide (based on the data submitted to EPA and known at the time), the language of section 10(d)(1) indicates that disclosure may be used more broadly to protect against any "unreasonable" risk, even if its existence is uncertain.

Moreover, in light of the fact that EPA does not require full testing of pesticides before registration and apparently lacks the capacity to conduct testing on its own, disclosure of inert ingredient identities is *necessary* to protect against these risks. It is also a modest measure for controlling this risk, compared to the burdens that full testing before registration would place on applicants.

Finally, *NCAP v. Leavitt* does not preclude a blanket determination that disclosure of inert ingredient identities is necessary to protect against an unreasonable risk. While *Leavitt* held that this is a case-by-case determination, the court did not consider the rationale that because there is uncertainty as to the chronic and synergistic effects of *all* pesticides, as well as their cumulative effects, and in light of the fact that disclosure can protect against that risk at minimal cost, the failure to disclose presents an unreasonable risk of injury to health and the environment. *See* Tr. of Oct. 12, 2004 hearing at 62-63 (D.D.C. Case No. 00-2483). However, even where this determination must be made on a case-by-case basis, those instances should be rare. Most inert ingredient information can already be disclosed because it is not CBI. *See* section B(2) above.

In sum, given that the costs of disclosure are negligible in comparison to its benefits, having the public otherwise bear the unknown risks of potentially harmful pesticides is "unreasonable" and contrary to FIFRA's intent to protect the public from harmful pesticides.

### *3. Additional Factors Support the Disclosure of Hazardous Inert Ingredients.*

Having the public bear the risk presented by formulations of unknown and untested chronic, synergistic and cumulative effects is even more unreasonable when the formulation contains known hazardous inert ingredients. As the ANPR recognizes:

> [F]ormulations 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 [found] 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.

74 Fed. Reg. at 68222. This less favorable cost/benefit ratio is attributable to the greater health and environmental costs that known hazardous ingredients pose, compounding the unreasonable risk presented by formulations of unknown and untested chronic, synergistic and cumulative effects. And as noted above, having the public bear the potentially enormous health and environmental costs of known hazardous ingredients is plainly unreasonable, where disclosure could protect against that risk at slight cost.

Not surprisingly, then, EPA has already allowed some disclosure of hazardous inert ingredients by authorizing the Administrator to "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." *See* 40 C.F.R. § 156.10(g)(7); *Inert Ingredients in Pesticide Products*, 52 Fed. Reg. 13305, 13307 (April 22, 1987) (requiring label disclosure of certain inert ingredients listed as chemicals of "toxicological concern"). Moreover, the court in *Leavitt* recognized that such a determination is a case-specific determination that the ingredient poses an "unreasonable risk" within the meaning of section 10(d)(1). Tr. of Oct. 12, 2004 hearing at 63-64. Because EPA has already determined that a number of chemicals are hazardous – and thus "may pose a hazard to man or the environment" – EPA can immediately act to require the disclosure of those ingredients under § 156.10(g)(7) and FIFRA section 10(d)(1). Such action would be a significant initial step towards ensuring that the public and environment are protected from potentially harmful pesticides.

Thank you for your time in considering these comments, and we look forward to your response.

Sincerely,

Wendy Park
Associate Attorney

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