



Chemical Producers & Distributors Association

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April 23, 2010

VIA EPA Docket

Kerry B. Leifer
Registration Division
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington DC 20460-0001

Re: Public Availability of Identities of Inert Ingredients in Pesticides: Advance Notice of Proposed Rulemaking; 74 Fed. Reg. 68215 (December 23, 2009); Docket No. EPA-HQ-OPP-2009-0635

Dear Mr. Leifer:

The Chemical Producers & Distributors Association (“CPDA”) appreciates this opportunity to comment on the above-referenced document (“ANPR”), in which the U.S. Environmental Protection Agency (“EPA” or “Agency”) sets forth two options “for increasing the public availability of the identities of inert ingredients in pesticides registered under the Federal Insecticide, Fungicide, and Rodenticide Act (‘FIFRA’).”¹ Option 1 would mandate disclosure only of potentially hazardous ingredients, and Option 2 would promote or mandate disclosure of most or all inert ingredient identities, regardless of hazard. EPA also solicits ideas

¹ FIFRA §§ 2 *et seq.*; 7 U.S.C. §§ 136 *et seq.*



for alternative approaches, both regulatory and non-regulatory, and responses to numerous related questions. CPDA does not support placement of inert ingredient identities on pesticide product labels, particularly for non-hazardous² inert, and may support some form of disclosure of “hazardous” ingredients after these are further defined by the Agency.

CPDA is the primary advocate on federal legislative and regulatory issues for generic pesticide registrants, adjuvant and inert ingredient manufacturers, and product formulators and distributors. We represent over \$7 billion worth of pest control products used on food, feed, and fiber crops and in non-crop segments of the pesticide industry. Accordingly, we have a vital interest in EPA’s proposed enhanced disclosure of inert ingredients in pesticide products. We are particularly concerned about EPA’s failure to articulate clearly why almost 40 years of Agency safety determinations under FIFRA are deficient and now must be supplemented by disclosure based on concerns about “the fair and efficient functioning of the market” and “market-driven incentives” that are unrelated to FIFRA’s statutory requirements.

INTRODUCTION

We³ believe the ANPR is premature and should be republished when the Agency has gathered the necessary information to support inert ingredient disclosure rulemaking consistent with the mandates of FIFRA. Specifically, EPA should develop reliable information to respond to the following recommendations:

- EPA states in its problem statement that a market failure has occurred leading to registered pesticide products that are more “hazardous than is efficient” and that rulemaking is needed to correct this failure. EPA has provided no evidence to support this premise. Therefore, the Agency should collect the information and develop the analyses needed to support the presumption that the lack of inert ingredient disclosure has resulted in a market failure.
- EPA has not demonstrated it has the authority under FIFRA to impose a “hazard-based” labeling regime on top of the current “risk-based” statutory regime and require disclosure of inert ingredients on the label of a registered pesticide product. Therefore, the Agency should reevaluate its convoluted interpretation of FIFRA statutory support for implementing a transparency policy.

² We note that neither FIFRA nor its implementing regulations define the terms “hazard” or “hazardous,” and we therefore use those terms in these comments solely to distinguish some inert ingredients from others for discussion purposes.

³ These comments are the result of a collaborative effort between CPDA and CropLife America and therefore, are substantially similar to those submitted by CropLife America.



- EPA acknowledges that there is “*no definition of hazardous inert ingredients in FIFRA.*”⁴ Therefore, the Agency must first define hazardous inert ingredients, as appropriate under the terms of FIFRA, and then appropriately (a) determine what incremental risk may be posed by the presence of that ingredient in a pesticide product and (b) determine the most appropriate vehicle to inform the consumer of that risk.

Our comments are organized under the following topics in support of these recommendations. Appended is supporting documentation that responds in detail to several of the questions raised in the ANPR.

- EPA’s premise that the market has failed and regulatory action is needed to correct the market and provide net social benefit is unsupported;
- EPA’s interpretation that inerts disclosure can be required under FIFRA on the basis of “hazard” rather than risk is incorrect; and
- The ANPR lacks the needed clarification from EPA on the appropriate hazard and risk criteria for requiring disclosure of inert ingredients on the pesticide label.

COMMENTS

UNJUSTIFIED RELIANCE ON MARKET EFFICIENCIES TO REQUIRE DISCLOSURE OF INERT INGREDIENTS UNDER FIFRA

The Agency believes the “problem” that will be solved through rulemaking is one of market failure; specifically, 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.*”⁵ EPA’s description of alleged market failure includes no supporting evidence. The Agency provides no rationale that would support any correlation between market “efficiency” and inert ingredients. Nor does the Agency provide any evidence that the “*current lack of information about inert ingredients interferes with the fair and efficient functioning of the market.*” In sum, the Agency offers no evidence to conclude that there has been a market failure and that label disclosure of inert ingredients will correct undefined market inefficiencies and/or market failure. Therefore, there is not a sufficient legal or economic ground for regulation, but fortunately EPA’s presumptions can be reformulated as testable hypotheses.

⁴ ANPR at 68219.

⁵ ANPR at 62818.



Regulation can both promote economic and social welfare and lead to significant economic and social costs. It is therefore unlikely that the case for regulation on grounds of “market failure” can be convincingly made on an *a priori* basis. EPA must provide evidence that the lack of information on inert ingredients has resulted in the failure of a regulated market. If EPA is correct that current informational asymmetry leaves consumers worse off than they would be given complete inert disclosure, then it must be true that EPA’s registration program has somehow failed. Consumers, EPA implies, do not trust the Agency’s scientific and economic determinations, and they need the disclosure of both active and inert ingredients in order to perform their own risk/benefit analyses. This implies that EPA’s registration program has little or no economic value to consumers because consumers do not trust the Agency’s determinations and believe that it has allowed unsafe products on the market. But the foundation of EPA’s registration program is the conviction that only EPA has the expertise to *process* information into a risk/benefit analysis in order to authoritatively discern whether the proper use of a pesticide product has more social benefits than social costs. Consumers presumably rely on this determination in lieu of reams of technical information, which even if provided is difficult and expensive to interpret correctly.

EPA makes pesticide product registration decisions based on risk, not hazard. FIFRA requires a risk-based safety determination that considers the hazard associated with a specific use, placed in context with the exposure associated with that use. The disclosure of an ingredient identified as a “hazard” on a list under a different regulatory statute does not provide added or valuable information on the safety or risk associated with the use of a product containing some trace amount of that ingredient. In fact, it is *irrelevant* to the potential risk and safety of the product for its registered use. More specifically, the disclosure of “hazardous” inerts cannot improve consumer decision-making because hazard, even objectively defined, is not a synonym for risk. In an attempt to use this information to avoid purchasing a “hazardous” chemical a consumer may, in fact, use or combine substitute products that *increase* environmental and human health risk and potentially create unexpected new risks, such as promoting accelerated pest resistance or reducing the level of public health protection offered by pest control products. It is also plausible *a priori* that consumers would respond to mandatory disclosure by incorrectly inferring that inert ingredients are risky when in fact they are not. EPA noted in the ANPR that they have in the past rejected as misleading labels voluntarily bearing the names of inert ingredients on the theory that consumers could misconstrue the overall safety of the product as determined by the Agency.⁶

The Agency asserts that because of the presumed market failure, “*pesticide products may contain levels of hazardous ingredients that are higher than society wants or needs and/or people may use a pesticide product or combination of products that lead to more adverse health*

⁶ ANPR at 68221.



*or environmental outcomes than would otherwise occur.”*⁷ However, the Agency offers no empirical evidence supporting the claim that pesticide products pose greater human health or environmental risk than they would if inert ingredients were disclosed. EPA must quantify and monetize the social human and environmental health benefits expected to result from the removal of “hazardous” inert ingredients singularly from pesticide products – that is, taking into account exposure from other sources.

EPA assumes that there will be net benefit from input substitution as some inert ingredients are deselected and disappear from the pesticide market, but the Agency offers no empirical evidence to support this assumption. The Agency notes that “[I]f 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,”⁸ implying (a) that industry does not have incentive to innovate unless consumers force them to do so through selective “avoidance” purchasing and (b) that disclosure will lead to net beneficial market-driven incentives for producers of pesticide products. However, the Agency also acknowledges that disclosure might negatively impact innovation – a market *disincentive* – then promptly dismisses this consideration by stating it “believes” there are circumstances where this would not occur. If pesticide products are deselected for reasons unrelated to their efficacy, use and safety, and innovation is stifled due to lack of incentive, then the results of this Agency action will create market inefficiencies.

Needed Agency Analyses:

EPA must first verify the existence of a material market failure. If hypothesis tests of market failure fail, it is impossible for new disclosure regulations to provide greater social benefits than social costs. Further, the existence of a material market failure is merely a *necessary* condition for regulation, for EPA then would be required to objectively analyze each of the regulatory actions under consideration to ascertain whether it is expected to actually deliver actual net social benefits.

EPA thus must also show by credible objective empirical evidence that consumers would make materially different choices *if only inert ingredients were disclosed*. Unless this is so, it is impossible for a disclosure rule to yield *any* social benefits, much less net social benefits after accounting for social costs. As OMB’s Circular A-4 states: “*Even though the market may supply less than the full amount of information, the amount it does supply may be reasonably adequate and therefore not require government regulation*” (p. 5).

EPA contends that a future inert disclosure rule would lead to significant changes in product formulation. Thus, any rulemaking that might follow this ANPR is presumptively

⁷ ANPR at 68218.

⁸ ANPR at 68218.



economically significant pursuant to Executive Order 12,866 and major pursuant to the Congressional Review Act. It is likely that a significant number of small entities would experience disproportionate effects, so EPA also has a statutory obligation to perform a rigorous Regulatory Flexibility Analysis (RFA). If, in fact, the action is economically significant, the agency must also conduct the regulatory impact analysis (RIA) required under EO 12,291. In an RIA, the Agency must (a) state the need for the proposed regulatory action; (b) examine alternative approaches to the problem (including taking no action); (c) quantify benefits and costs and value them in dollar terms (where feasible); and (d) evaluate the findings on benefits, costs, and distributional effects. The RIA also should provide information on the *market imperfections that necessitate regulatory action* and should discuss how, if promulgated, the regulatory proposal would improve the way the market functions and produce better results than no regulatory change, taking into account the possibility that regulation fails to achieve its stated goals.⁹

It is clear, therefore, that the Agency will need to conduct a full economic analysis of all the potential social welfare risks and benefits for each potential option to regulate disclosure. This includes, but is not limited to: the potential reduction in real environmental and human health risk; the loss of use of currently registered safe pesticide products; the cost of ingredient and product substitution; and the financial impact of incentives or disincentives for innovation in the industry. The analysis must be conducted before proposing regulation.

LACK OF FIFRA AUTHORITY TO REQUIRE BROAD DISCLOSURE OF NON-HAZARDOUS INERT INGREDIENTS

EPA's fundamental legal obligation under FIFRA is to register pesticide products based on a determination that uses of those products in accordance with requirements set forth on the product label will not result in "*unreasonable adverse effects to the environment.*"¹⁰ This determination reflects Congress' mandate that authorized uses of pesticides must represent a balance between the acceptable risk of using each pesticide product and the benefits society receives from that use. Significantly, Congress also recognized the need to balance protection of proprietary information and public access to certain information related to pesticide products by requiring EPA to make case-by-case determinations about what information submitted to the Agency should be available to the public and what information should not be available.¹¹

⁹ Guidelines for Performing Regulatory Impact Analysis. EPA-230-01-84-003. United States Environmental Protection Agency, Office of Policy Analysis. Washington, DC 20460. December 1983.

¹⁰ FIFRA §3(c)(5)(A). Although the definition of "unreasonable adverse effects" includes a cost-benefit analysis, the ANPR by contrast includes conclusions based on vague assumptions of market efficiency that go far beyond any FIFRA requirement.

¹¹ FIFRA §10. Such information must meet standards for trade secrets or commercial or financial information.



The pesticide registration process has long provided extensive protection of trade secrets and confidential business information (“CBI”), including information about inert ingredients in product formulations. The current statutory framework for protecting inert ingredients from unfettered disclosure reflects the balance Congress established between promoting innovation (to encourage investments in research and development of safer and more efficacious products) and providing users with information needed to make informed purchasing decisions and to use products safely. However, EPA’s Option 2 would upset this important balance by requiring or promoting broad disclosure of inert ingredient identities, which is neither required by FIFRA¹² nor consistent with the congressionally mandated balanced approach to regulating pesticides.

FIFRA section 10 provides clear provisions for the protection of CBI, including inert ingredient information, which gives users information necessary to make informed decisions about product use and safety while also protecting proprietary rights. This congressional balancing of interests and compromise “*is intended to protect the secrecy of . . . the confidential formula of a formulated product...*”¹³ a compromise embodied in the statutory language of section 10 that cannot be nullified administratively by an EPA regulation.

Inert ingredients are accorded unique disclosure treatment under FIFRA. Although FIFRA requires disclosure of the total percentage of the inert ingredients in a product, Congress chose not to require public disclosure of the names and/or percentages of each individual inert ingredient.¹⁴ Therefore, EPA’s broad disclosure initiative for inert ingredients appears to be an effort to increase “transparency” through rulemaking, and not a mandated FIFRA requirement. Under section 3(c)(5) of FIFRA, an inert ingredient may not be included in a pesticide unless EPA finds that the pesticide does not impose an unreasonable adverse effect on the environment. Accordingly, an inert ingredient in an approved pesticide could not, by definition, pose an unreasonable risk of adverse effect, and therefore the Agency has no statutory basis for disclosing its identity, except perhaps in very rare circumstances. For this reason, EPA’s ANPR is in plain contravention of FIFRA.

We are very concerned about EPA’s apparent disregard for the express provisions of FIFRA section 10 that generally protect trade secrets and confidential business information, and provides special protection for inert ingredients. Congress placed great importance on the necessary balance of product innovation (via data protection, trade secret, and CBI provisions) and public access to information, and phrased section 10 in a manner that prohibits EPA from disclosing CBI and/or inert ingredient information unless EPA makes case-by-case

¹² ANPR at 68217. (EPA concedes in the ANPR that “There is no statutory requirement that the names of all inert ingredients be contained on the ingredient statement.”).

¹³ Senate Agriculture Committee Report at 23.

¹⁴ Congress amended section 10 of FIFRA in 1978 to provide for mandatory disclosure of most pesticide health and safety data, but deliberately provided for non-disclosure of the identity and quantities of inert ingredients unless disclosure is necessary to protect against an unreasonable risk.



determinations that certain criteria have been met. Thus, the identity of an inert ingredient cannot be disclosed unless the Agency determines under section 10(d)(1)(C) that disclosure is necessary “to protect against an unreasonable risk of injury to health or the environment.” We are aware of EPA’s interpretation of the scope of this section of FIFRA,¹⁵ and do not agree with that interpretation. EPA’s interpretation does not nullify the significant FIFRA requirements the Agency must meet. In addition, broad disclosure of inert ingredients would involve the expenditure of significant Agency resources merely to implement a misdirected transparency policy that disrupts a carefully crafted congressional statutory scheme.

Congress gave applicants for pesticide registrations the express right to declare as trade secrets or CBI any information submitted to the Agency, including inert ingredient information. EPA must protect this information unless the Agency determines that it does not merit protection under FIFRA.¹⁶ In addition, section 10 requires EPA to refrain from disclosing any information that a data submitter designates as CBI, until the submitter has the opportunity to challenge the Agency’s disclosure decision in a court of law.¹⁷

Despite these express FIFRA mandates, the ANPR suggests a radical expansion of the limited section 10 authority granted to EPA to disclose inert ingredient information. Section 10(d)(1)(C) unambiguously limits the Agency’s authority to disclose inert identities and percentage quantities only to disclosures that are “*necessary to protect against an unreasonable risk of injury to health or the environment.*” The Agency makes this risk-based determination through its decision to register a product, a decision that is based on extensive expert review of considerable amounts of scientific data, including data on inert ingredients. EPA’s decision to register a product is based on a legal finding that it will not result in an “unreasonable adverse effect” when used in accordance with the requirements and limitations set forth on a label.¹⁸

LACK OF DEFINITION OF “HAZARD” OR “HAZARDOUS” CRITERIA UNDER FIFRA AND CONFUSION OVER HAZARD AND RISK

As we note in footnote 2, the term “hazard” is not defined in FIFRA, and is used only in the context of “imminent hazard” that justifies cancellation proceedings and restricted use classification.¹⁹ In contrast, the primary FIFRA provision protecting inert ingredients from disclosure requires EPA to disclose the identity or quantity of an inert ingredient only to protect

¹⁵ ANPR at page 68217.

¹⁶ FIFRA §10(a) and 40 CFR §2.307.

¹⁷ FIFRA §10(c).

¹⁸ FIFRA §3(c)(5)(D).

¹⁹ FIFRA §2(I) (cancellation); FIFRA § 3(d)(1)(C)(i) (restricted use).



against an unreasonable risk of injury.²⁰ FIFRA does not use “hazard” in any context related to disclosure of inert ingredients.

“Hazard” and “risk” are not synonymous either in law or in fact or in practical application to regulatory programs. Whether a “hazard,” such as toxicity or combustibility, presents a “risk” is dependent on the nature of the hazard, concentration of the hazard in the product, potential for exposure under reasonably expected use conditions, type of possible exposure, quantity of exposure, and duration of the exposure. EPA makes pesticide product registration decisions based on risk, not “hazard.” Nevertheless, the Agency proposes to confuse the public by creating a new regulatory regime in which hazard would be qualitatively defined independent of risk for the purpose of disclosing the identities of inert ingredients. EPA would ignore risk even though it is the statutory criterion that is the foundation for the Agency’s registration decisions under FIFRA. EPA’s pesticide registration program is premised on the belief that the Agency’s scientific expertise, ability to process voluminous information into a risk/benefit analysis, and make focused health and safety decisions is superior to decisions about safe use of pesticides based on disjointed information from multiple sources in the marketplace. Therefore, EPA’s proposed partial abdication of FIFRA health and safety decisions has significant potential to undermine public confidence in the Agency’s expertise in risk assessment.

Few inert ingredients would merit listing on a pesticide label based on FIFRA risk concerns due to the small concentrations in products. An acknowledged exception to this statement would be for known allergens. We support users being appropriately warned on the product label when such allergens are used as inert ingredients, even at very low concentrations or in very small amounts because of the potential severity of human reactions. However, this would involve relatively few pesticide products, including for example, the use of peanut butter as a component of an insect bait station, or use of peanut hulls as the carrier for some granular formulations of home garden pesticides.

To define “hazard,” EPA proposes to rely on lists of chemicals deemed “hazardous” in accordance with criteria specified in other statutes or to devise new “objective criteria” for mandating (or not) disclosure of inert ingredients. However, both of these approaches to defining “hazardous” inert ingredients for purposes of disclosure are likely to provide pesticide users with misleading information for choosing among pesticide products with different inert ingredients when risk, not hazard, is the relevant consideration in assessing safe use of pesticides under FIFRA. There is no reason to believe that the majority of consumers would correctly discern the difference between hazard and risk, and every reason to believe that consumers would be misled to believe that *hazard* and *risk* mean the same thing. EPA’s evaluations and approvals of inert ingredients for use in pesticide products now take into account very

²⁰ FIFRA §10(d)(1)(C).



conservative estimates of the exposure component of the risk equation, including contributions from exposure to such ingredients from their use in non-pesticidal products. For example, several inert ingredients recently completing tolerance reassessment were reapproved subject to percentage limitations in the pesticide product formulations. This underscores the importance of EPA conducting a case-by-case reevaluation of the risk imposed by “hazardous” inert ingredients in pesticide formulations.

EPA asserts that, “*under FIFRA section 2(bb), any risk from hazardous ingredients, however small, should in general be less reasonable that 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.*” It is unclear how the Agency draws this conclusion when “hazardous” ingredient remains undefined while risk is fully evaluated. Again, this underscores the need for the Agency to conduct a risk assessment on each potentially hazardous ingredient in the concentrations found in the pesticide product to confirm the premise of “less reasonable.”

In order to proceed with any rulemaking on inerts disclosure, the Agency will first need to develop and clarify the appropriate criteria by which to classify inert ingredients as “hazardous” under FIFRA, and then develop criteria by which these ingredients will be evaluated in the risk assessment of the pesticide product under the approved uses conditions.

CONCLUSIONS AND RECOMMENDATIONS

We are concerned about this proposed action to graft a hazard-based disclosure requirement premised on market concerns onto a mature FIFRA regulatory program founded on risk-based decision-making. Therefore, we does not support the mandatory or voluntary, full or partial disclosure of inert ingredients on pesticide product labels at this time.

EPA must first verify the existence of a material market failure. If hypothesis tests of market failure fail, it is impossible for new disclosure regulations to provide greater social benefits than social costs and the rulemaking must be abandoned. Further, the existence of a material market failure is merely a *necessary* condition for regulation, for EPA then would be required to objectively analyze each of the regulatory actions under consideration to ascertain whether it is expected to actually deliver actual net social benefits.

EPA must plan now to perform the RFA and the RIA required for economically significant rules and to ensure that this is done rigorously and objectively. These analyses must document the material market failure that the Agency intends to solve.



Chemical Producers and Distributors Association

EPA has not established that clear statutory authority exists for increasing the disclosure of either “hazardous” inerts or all inerts, over the level of disclosure that exists today. In fact, we believe that such authority does not exist, and that FIFRA expressly and clearly protects inert information from disclosure. The ANPR admits that partial disclosure is misleading and therefore impermissible. The current registration and labeling procedures adequately inform users of the risk of using the pesticide products, including the inert ingredients they contain.

We wish to thank the Agency for consideration of our comments. As EPA has not yet formally proposed a rule for altering current inert disclosure requirements for pesticide products, we trust the Agency will remain receptive to on-going submissions of public comments. If we find or develop additional information that we believe would be helpful to the Agency in developing an approach to inert ingredient disclosure, we will provide it to you with the request that it be placed in the public docket.

Sincerely,

Susan Ferenc, DVM, Ph.D.

President



Response to Questions in the ANPR

EPA poses several direct questions in the ANPR which we address in detail in here. Our answers adhere to the basic opinions and positions stated in the main body of this document. We have attempted to provide answers to the selected questions where our expertise will most inform the Agency in its rulemaking process. Time has not allowed us to provide comprehensive responses to all questions, and we believe some questions are premature or irrelevant to this rulemaking process. Our decision not to respond to some questions in the ANPR should not be interpreted as acceptance or approval of any process or content in those questions, or in support of full or partial disclosure of inert ingredients on the label of pesticide products.

Reverse engineering and formulation identity

EPA asks several questions in the introduction to Option 2 in Unit II.C.2, which begins on page 68220 of the ANPR. The questions in this portion are not numbered in the ANPR.

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

No. Our products are generally safe from reverse engineering, especially with respect to the identity and concentration of surfactants and other additives. Some chemicals, such as solvents, can be determined fairly easily. Other components, such as identifying a type of clay, can present more of a challenge. Characterization of a material that is a single chemical at a high concentration is not as challenging. Characterization of chemicals that are mixtures and present at low concentration is almost impossible. Characterization of chemical components is also more difficult as their molecular weight increases.

Current analytical techniques can identify some, but not all, of the components in a pesticide formulation with a reasonable certainty. Given the points made above, the components most likely to be identified are single components (i.e., not polymers) present in the formulation at a concentration of 5% or higher and of molecular size of 500 g/mole or less. However, it requires the use of multiple techniques by competent analytical chemists, and there are limitations to detecting subtle changes and differences among inert ingredient molecules. The challenge also increases depending on the formulation type and the complexity of the inerts used. A standard formulation with above average concentrations of only three or four inerts has a higher susceptibility to “reverse engineering” than the same formulation in a dilute form. A formulation with inerts at low concentrations is more difficult to address due to limits of detection and the addition of diluents. Also, mixtures of closely related inert ingredients can further complicate



analysis, making it difficult to determine specific identities and precise ratios. These subtle differences in formulation components and ratios can significantly affect the performance of the end product in terms of efficacy, stability, ease of use, and cost.

Any “reverse engineering” analysis is only representative of a particular production batch of the product currently on the market. With multiple registrations and subtly different formulations in use for different market conditions, the task of tracking these by “reverse engineering” is further complicated. Therefore, reverse engineering can occur in theory but does have limitations in discovering the level of detail needed to accurately duplicate a registered pesticide formulation.

- b. *Do they believe that their own products are safe from reverse engineering due to the limits of analytical techniques or prohibitive cost?*

Given the current limitations on inert disclosure and the protections afforded by the confidentiality of the Confidential Statement of Formula (CSF), the pesticide and inert industry’s well- trained analytical, organic synthesis, and formulation chemists all agree that pesticide formulations cannot be reverse engineered to the degree that two end use formulations would have identical chemical compositions or identical performance characteristics. These chemists would be the most capable group to reverse engineer an exact chemical pesticide formulation composition and the most likely group to try to do it, but they universally agree that it cannot be done. Identifying some components present in a complex chemical mixture does not produce a formula for recreating the mixture.

Most inert ingredients used in pesticide formulations are not identified in common industry reference sources (such as the Farm Chemical Handbook 2000). Development of analytical methods for these inert ingredients, for reverse engineering would be prohibitively expensive. Even if technically achievable, such methods would not be capable of identifying pesticide formulations to a point at which they would produce exactly comparable chemical compositions. Thus, “reverse engineering” is not wholly achievable.

- c. *To what extent do patents or other public sources of information provide this kind of information?*

Only to a very limited extent. The fact that formulation identity, as an aspect of trade secrecy, is important to competitive advantage is demonstrated by reviewing the general content of patent filings and descriptions. Numerous compositional patents reveal classes of chemistry but not 100% of the actual composition. In these cases, the composition and process are deemed significant and released for patent purposes. Otherwise, the information is not patented and is



held as a trade secret. Trade-secrets are valuable because a company does not need to release 100% composition.

- d. Are there types of products or ingredients where reverse engineering is more or less likely to be performed or successful?*

Possibly. The identity of some solvents may be relatively easily determined for specific formulation types. For example, water is, by definition the solvent or diluent in a product identified as a soluble liquid formulation. The other inert ingredients in a soluble liquid formulation may include surfactants to improve wetting and spreading, and performance additives such as crystal inhibitors and sequestrants, which are very difficult or impossible to reverse engineer. However, most inert ingredients that might be identified qualitatively are not considered easy to quantitate. Quantitative analysis requires standards and validated methods. Accurate quantitative analysis is very difficult for the complex matrices presented by pesticide formulations due to extraction issues and analytical interferences. Quantitation within an order of magnitude is generally a reasonable expectation of analysis.

Analytical standards for many inert ingredients may be very difficult to prepare. Nonionic surfactants and polymers, are major inert ingredients, and the analytical standards of an ethoxylated castor oil, for instance, are not available. For example, the standard of an ethoxylated castor oil is created using castor oil raw material used as the feedstock for ethoxylation is typically 87% ricinoleic acid (a natural fatty acid), the other 13% is natural varying in composition from one batch to the next. To truly identify the ethoxylated castor oil used in a specific pesticide formulation, analytical standards would be needed for all of the various ethoxylate polymer chains plus the variations of the castor oil feed stock. Constructing a comprehensive matrix would be virtually impossible. But, it is precisely those exact, subtle variations and ratios that are the key to the performance of the pesticide formulations, and thus their commercial value. These could not be determined by reverse engineering, but having the advantage of inert disclosure would certainly make the “copying job” easier and would erode the competitive and commercial value of a proprietary formulation.

- f. Do other countries disclose this information and if so under what circumstances?*

In general, other countries do not disclose the identity of inert ingredients. Canada does require disclosure of select inert ingredients. For example, Canada requires disclosure of known food allergens, such as peanut shells are used as carriers for certain granular pesticides formulations.

- g. Are there classes or sectors where the identities of inert ingredients are generally known among competitors?*



No. Disclosure is of substantial harm even when the technology is generally known. Millions of dollars are spent by the registrant even on “known” technologies in order to develop robust products that meet customer quality criteria. Publishing this information would allow competitors to not invest in this research, and in fact is a disincentive to conducting such research at all. The harm of disclosure is done via disclosure of the inert identity, not the supplier of the chemical, as many suppliers sell the same (or similar) chemicals.

- h. 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?*

Confidentiality plays a major role, both as an incentive for innovation and in promoting competition through formulation technologies and product quality. The confidentiality of a formulation gives the inventor a period of time to recoup his investment in developing an improved formulation. In off-patent products, competition is stimulated by the development of unique formulations with specific properties that aid or enhance the simplicity of application, weathering, mixing, or product safety.

Disclosure of the specific inert ingredients or even chemical class of inert ingredients provides a shortcut to a competitor for getting into the marketplace, thus giving him an advantage over the company that invested resources in development of the new formulated product.

Declaring confidentiality (under either option)

EPA solicits comment on the following issues, which apply to both of the options presented on disclosure. In Unit II.C.2 (p. 68221), EPA asks the following questions that appear in the ANPR text but are not itemized:

- a. Should EPA 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?*

No. Pesticide registrants consider all the ingredients, other than the active ingredient, to be subject to the confidentiality provided by FIFRA Section 10(b). When the composition of the test substance (i.e., the product formulation) is disclosed in a specific report (i.e., the confidential statement of Formula (CSF), EPA Form 8570-4), it is placed in a confidential appendix according to the guidance provided by Pesticide Registration Notice 86-5. EPA’s long-standing filing practices for such information further confirm its understanding of the confidential nature



of the information on the CSF. As a matter of general practice, a registrant would include a cover letter claiming confidentiality of the information on a revised CSF submitted subsequently to the Agency.

Should a specific claim of confidentiality for a CSF be in doubt, it is still entitled to the same level of confidential treatment by the Agency. The EPA form 8570-4 does not carry the citation to 40 CFR §2.203, required by that section along with other conditions, notifying the submitter that specific and separate claims of confidentiality for the various items of information on the form are necessary to prevent automatic disclosure of the information. By the very name of the form (“Confidential Statement of Formula”), “any business which, although it has not asserted a claim, might be expected to assert a claim if it knew EPA proposed to disclose the information ...” (40 CFR §2.204(b)(2)(i)). Thus EPA would be obligated to pursue verification of the claims prior to releasing the information.

- b. Should EPA require 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?*

No. If the Agency believes that existing measures are not sufficient to assert industry’s claim of confidentiality for the composition of technical and end-use pesticide products, then specific procedures should be established to ensure that the identity and amount of each individual ingredient in that product remains confidential. The status of a company’s confidentiality claims changes over time, so pre-declaration of this is not appropriate. The competitive advantage based on the product’s composition is not known at the time of application for registration. Substantiating each item of information on the CSF is an arduous, expensive, and time-consuming task. In all likelihood, the Agency is unlikely to review that information, even if it is submitted, because of the effort and resources involved. Outside requests and needs for the information are relatively few in number, and do not justify requiring the information up front. For urgent or emergency needs, EPA has the mechanisms under the law to disclose the information to appropriate parties.

EPA might consider having registrants simply check a box to claim confidentiality for specific inert ingredients, without having to provide further substantiation of the claim unless and until a legitimate request for the information is received by the Agency. The registrant could declare which ingredients they are not interested in maintaining as confidential (such as water or fertilizer) simply by not checking the box. In the past, if a registrant decided that the identity of a certain ingredient may be disclosed, industry proposed this be accomplished by the disclosure of the functionality of the inerts in combination with specific chemical names, as appropriate to the issue or concern at hand.



- c. 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?*

This type of certification is achieved through the CSF. See the answer to the previous question. If a legitimate need for further up-front substantiation of confidentiality is established, EPA could revise the CSF (with the required opportunity for public input and OMB review), instructing the registrant on disclosing the identity and amount of each individual component, and how to assert confidentiality under the pertinent laws and regulations.

Option 1 (List potentially hazardous inerts)

In Unit II.C.1, EPA included a list of 5 questions, labeled *a* through *e*, with this option. Those questions are answered below:

- a. How should the list of potentially hazardous ingredients be identified?*

EPA must first define “hazardous” and establish objective criteria whereby a chemical would be identified as “hazardous” and then establish objective criteria for determining whether to require disclosure of “hazardous” ingredients on an ingredient-by-ingredient basis. This approach was used for List 1 inerts. The Toxics Release Inventory (TRI) lists, for example, contain concentration triggers which include an exposure aspect, however these trigger concentrations need to be validated for pesticide exposure scenarios. In developing objective criteria, the most appropriate types of hazard criteria are those that are pertinent to the formulated product, which excludes acute toxicity end points. Formulated products are tested as mixtures for acute effects, and label warning statements reflect these hazards. Inclusion of acute effects would be misleading to the user. In addition, EPA has the ability to review and make approval decisions for inert ingredients based on chronic mammalian data. Therefore, disclosure of inerts with chronic mammalian effects would be of limited benefit to the user.

Evaluation of the hazard of a chemical used in a FIFRA setting must be placed in the context of its use. EPA is in the unique position to conduct such an evaluation since the Agency has developed the scientific expertise to evaluate the safety of materials used in pesticide formulations. A series of test methods are identified in 40 CFR Part 158 to quantify the toxicity (hazard) of chemicals and the formulation in which they are delivered to the consumer. These tests provide data by which EPA may assess whether an introduced formulation ingredient presents an additional hazard in the end use product. In addition, EPA uses the results of these tests to compare hazard to exposure in a process that evaluates the risk associated with use of the pesticide under variable, relevant scenarios. Consequently, for virtually all circumstances, the role and risk of an inert ingredient is fully evaluated and understood.



The specific lists referenced in the ANPR are not of value for pesticide assessment purposes and do not consider use in the appropriate context. Many of the materials identified are allowed as food additives and therefore are not an issue for mammalian safety. Other lists are based on notification of release of waste and purposes not pertinent to pesticide use. It makes no sense to include materials from other regulatory “lists” that are not approved for use in pesticide formulations. It is important that any characterization of an inert as “hazardous” be done under the rigors of product and risk assessment that are established by FIFRA, which take into account dose, exposure and exposure frequency. EPA states that such review would be tedious, yet as a part of each registration action, every end use product formulation is supported by this same process of testing, hazard assessment and risk analysis.

b. How should specific ingredients be added to or removed from the disclosure requirements?

EPA conducts a series of risk assessments when considering a petition proposing to establish a tolerance or tolerance exemption for an inert ingredient. The determination of “hazardous” and a hazard threshold (concentration in the final formulation over which a hazard would be expressed) should be made during the review of the data supporting such a petition. The process for inclusion of the identity of a newly proposed inert should support the disclosure requirements for all products that contain that inert, not just the first product registration that includes the new inert. A similar evaluation should be used when considering if a chemical should be added to the list of approved non-food use ingredients. A process for removal of a ‘hazardous’ classification from a chemical should consider supporting data to show that the hazardous classification is not applicable. Ingredients should be added to a list only after hazard is confirmed and removed when new data show that the ingredients are not hazardous. When new data becomes available, it should be used in the tolerance review process and inert approval process. The new data should be subject to FIFRA GLP and Data Quality Act criteria.

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? In providing comments on using a quantity factor, please also provide suggestions for how EPA might address these concerns.

EPA already applies a *de minimis* paradigm in its risk assessments on inerts approved for food use.

The setting of a *de minimis* level should be determined by EPA and be based on realistic exposure scenarios. The risk posed by a pesticide when used in accordance with label directions



is assessed for each and every pesticide registered by the EPA. During the evaluation process, hazard and exposure are considered for all labeled use scenarios. A safety determination is made and a use is registered when the risk is found to be acceptable. Thus, the statutes require a safety determination that considers the hazard associated with a specific use, placed in context with the exposure associated with that use. Just as hazard alone is not the single determining factor when evaluating an active ingredient against the FIFRA standard, neither is hazard the sole standard for the evaluation of intentionally added inert ingredients.

Outside of FIFRA-regulated products, there are numerous examples of chemicals that, in their pure form, may be considered corrosive or toxic, but because of concentration or use patterns, they are safely added to commonly used products. Examples include sodium fluoride in toothpaste, sodium hypochlorite in bleach and household cleaners, and alcohols in shampoos. A clear distinction should be maintained in regulating what could “potentially” be a hazardous ingredient and what is confirmed as a hazardous ingredient at the concentration found in the final formulation and considering the labeled use pattern of the pesticide.

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

No. It can be difficult to correlate hazard with chemical name, especially for the general consumer. It would be much more useful to communicate the actual pertinent hazard associated with the inert, but within the context of the formulation and the use of the product. A possible exception to this is communication of the presence of allergens (such as peanut hulls).

A list of ingredients contained in a pesticidal product does not in itself provide sufficient or useful information by which a consumer can make an “informed decision.” An informed decision would require scientific and professional expertise to evaluate the large amount of complex data used for risk assessment. Decisions based simply on a listed ingredient are susceptible to conflicting and incorrect secondary safety assessments developed by organizations that either do not have this expertise or are not fully informed on the intricacies of the data and risk assessment. Quality control of the information input may be weak and the tools are open to misuse by organizations that may wish to influence consumer purchasing decisions for reasons other than public safety. Conflicting standards derived from secondary assumptions will only further confuse the public, especially when the possible standards could range from simple hazard-based cut-off criteria to relatively complex computer models that attempt to evaluate and rank different hierarchies of risk. Such independently developed indices are problematic and create contentions, because they undermine and erode public confidence in the more sophisticated and better validated EPA assessment and approval process.



We emphasize that all the ingredients of pesticide products, both active and inert, currently must be selected from lists approved by EPA for the intended uses. Inerts approved for food use pesticide products are already screened for possible hazard and a tolerance action is taken only when appropriate. Inerts not on the current lists are not relevant for the disclosure issue. Again, risk is not presented by hazard alone. Most lists from other statutes are based on environmental releases of contaminants, not the intentional use of a highly regulated, intentionally designed pesticide end-use product. The approval of such products depends upon a safety determination of proposed uses, where consideration is given to all sub-populations that may be exposed, with special consideration to groups that may be particularly susceptible, such as infants and children. The Agency should focus on developing more effective communication strategies to ensure the public that protection goals for the consumer and for the environment are being met regarding the safety of registered products. It is the Agency's mission to ensure these protection goals are met.

The public could be aided in their choices by EPA communications and education programs that clarify labeling safety factors and their meaning. For example, what is the significance of signal words (CAUTION, DANGER, and WARNING) on product labels? Educating the public on how these signal words are derived and why they are used would help them with their choices in the marketplace. Education is key to understanding the label and properties of a finished formulation. Typical consumers will not know the relevance of a particular chemical or chemical class, regardless of hazard, without further information. The Agency, with help from the registrant community, could develop the appropriate communication forum to disseminate information related to inert ingredients, their functions in formulations, the potential hazards, etc.

Since implementation of the Food Quality Protection Act in 1996, EPA has enhanced its risk assessment process through the development of a sophisticated testing regime accompanied by methodologies to evaluate risk to both the environment and the population, with special consideration for infants and children. The scientists within the Agency have the expertise to conduct safety evaluations of the intended uses of a pesticide formulation according to formally established guidelines and uniform standard operating principles. The general consuming public, however, does not have the expertise to conduct such an evaluation, nor do they have consistent guidance on how to approach such a task in order to arrive at an independent and reliable safety evaluation.

The EPA exists to perform the function of risk assessment and risk management on behalf of the consumer of pesticide products. To address concerns about pesticide formulation additives, EPA should develop communication and outreach tools that educate the public on regulatory procedures, instill confidence in the user community, and assure the public that the risks associated with a pesticide have been fully evaluated.



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

No. Impurities are fully evaluated in the toxicity testing programs for registration and tolerance setting process and their disclosure gives no meaningful new information to the consumer. As in the case of ingredients intentionally added to a pesticidal formulation, the mere presence of a “hazardous” impurity does not constitute an unacceptable risk. As noted in the ANPR, all impurities of toxicological significance in the technical grade active ingredient are disclosed to the EPA. In addition, a detailed description of the manufacturing process is also disclosed to the Agency in order for the Agency to independently evaluate if an impurity of concern could potentially occur. Because impurities of toxicological concern will be regulated based on potential risk, their mere presence is not an issue. In rare instances, EPA has regulated certain manufacturing impurities by setting stringent but risk-based limitations on the concentration of such impurities in final products. In absence of the tremendous set of data and assessments supporting the limits that are set, simply identifying an impurity as “present” even at a trace amount will likely be misunderstood by the public.

The technical grade of the active ingredient is used as the test substance to generate most of the mammalian and environmental toxicity data required by 40 CFR Part 158 (studies requiring use of radio-labeled test substance are an exception, for example), and as such it contains the profile of impurities that would ultimately be associated with the final formulations registered. There is sufficient existing guidance for dealing with impurities of toxicological concern. The active ingredient and the full range of materials obtained by the specified manufacturing process are tested in the toxicity assays. All labeling of the final product includes consideration of precautions and personal protective equipment (PPE) that might be required for any impurity of concern. In addition, the concentrations of these impurities usually make them very minor components of the final mixture. In certain cases, data are generated on specific impurities to ensure that the hazards associated with the presence of the material are fully considered in the evaluation process.

Accordingly, the risk assessment process takes into full account not only the risks associated with use of the active ingredient, but also risks associated with impurities created by the manufacturing process. As such, the current regulations ensure that the safety determination is protective and that no disclosure is necessary or meaningful for the consumer.

A negative associated with disclosing an impurity is that the identity of impurities can give competitors access to confidential business information that could lead to the discovery of the manufacturing process of the active ingredient. This is one reason that impurity data is considered highly confidential information. Furthermore, there does not appear to be any value



to the consumer to have this information on the label. It could be a distraction from the critical information already there concerning precautions and PPE.

Option 2 (List all or most inerts)

In conjunction with this option, we address the following two numbered questions EPA poses in Unit II.C.2 of the ANPR:

- 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?*

Although we do not agree with the premise that label disclosure of inert ingredients is justified, we agree from a purely communications viewpoint that functional names are less confusing.

- b. *Should impurities potentially appear on the label regardless of hazard?*

No. This would not give the consumer any useful additional information and could cause great confusion. It would also complicate response to emergencies, forcing a response unit to sort through superfluous information and not focus on the full warning and protection statements already on the label. Impurities are included as part of the test material when registration data are generated and the hazard classification of the technical and end use materials reflect the presence of these impurities. Alternatively, the identity of impurities can often provide insight to the manufacturing processes used for a given product. Such information is specifically protected from disclosure under FIFRA §10(d)(1)(A): “This paragraph does not authorize the disclosure of any information that ... discloses manufacturing or quality control processes ...”

Common Issues

Many elements relate to both options and some have been addressed in the above sections of our comments. For clarity, however, the 15 EPA questions, labeled “a” through “o” in Unit II.C.3, are addressed individually below.

- a. *How might consumers respond to the disclosure approaches presented previously? Would there be any difficulty in interpreting the information?*

It is highly unlikely that a consumer could make an accurate interpretation of hazard based on chemical name. Listing names does not indicate the concentration, function or potential “hazards” associated with inert ingredients in pesticide products. Overall acute hazard information of the formulation is already included on the existing label. However, additional



information, separate from labeling, that gives the reasons for the specific warning statements connected to an end use product would be helpful to a consumer. For example, an explanation of why a material is labeled “danger” would be helpful to a consumer who is selecting PPE.

Because EPA has developed the scientific expertise and methodology to thoroughly evaluate data submitted on pesticidal products, the Agency is uniquely qualified to make a safety determination. In contrast, consumers would find individual interpretation difficult, particularly when presented with apparently conflicting labeling. For example, if a formulation carried the precautionary statement “Caution” but an ingredient was listed on the same label as “hazardous,” how is the consumer aided in their choice? Disclosure should be designed to inform, not confuse or overwhelm the consumer.

Even though EPA notes in the ANPR that the term “consumer” is more inclusive than the traditional definition of that term, a clear definition of “consumer” is needed. Pesticide products sold to the crop protection and specialty pest control industries are handled by knowledgeable, trained, and most likely certified “users.” However, homeowner-use products may warrant limited disclosure if the product contains confirmed hazardous or allergenic ingredients.

Under this question a, EPA also included additional questions which we have chosen not to respond to:

- *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?*

Frankly, we don’t know the answers to these questions, because it is not clear that disclosure would influence or achieve any of these ends. Our opinions on the subject perhaps differ substantially from those of the Agency and many others likely to comment on the ANPR. We believe that the current regulatory scheme for inert ingredients serves the public quite well, providing effective products to protect agriculture, property, and public health at reasonable cost and without unreasonable adverse effects. The only related research on this subject that we are aware of is the Consumer Labeling Initiative conducted by EPA in the mid 1990s, which gave results conflicting with some of EPA’s market-based premises in the ANPR. Accurate, reliable answers to the above questions will require painstaking, objective market research on the part of the Agency. The answers are fundamental to the support (or lack thereof) for EPA’s market-based “problem statement” in the ANPR, advanced as the primary rationale for pursuing the



rulemaking exercise. The ANPR elicits responses only from self-selected responders, providing only anecdotal information and biased opinions, however fervent they may be. It cannot substitute for the necessary objective research that is essential, if EPA continues to believe and maintain that “market failures” have occurred and are the reason that rulemaking on inert disclosure is necessary.

- 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?*

No, consumers would not be able to weigh any potential incremental risk posed by an inert because they have not been provided the information required to make this determination. Lists of chemicals do not facilitate the consumer’s understanding of risk based on exposure. The determination of risk as a function of exposure and hazard requires more scientific information and expertise than a typical consumer would have. However, if a material could cause an allergic reaction, its identity may provide useful information to the consumer. See Canadian approach to allergen listing.

The danger of mandatory listing of inert ingredients is that the information will be misinterpreted and/or misunderstood. Consumers may deselect certain products based on faulty assumptions about individual ingredients, which could both increase overall risk by selecting an inappropriate product and/or lead to improper use of the best tools for the target pest, possibly also contributing to pest resistance. A great deal of public education would be necessary to overcome this problem, and it is unlikely that the needed level of understanding would be achieved. Consequently, EPA must be cautious in assuming that consumers will obtain and properly use ingredient information.

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

Unique formulations are frequently used in marketing strategies for active ingredients that are no longer protected by patent. Many companies obtain a large portion of their revenue from off-patent products, which represent a significant investment in unique formulation technologies. If the identity of inert ingredients in a specific product is listed on the label, competitors can much more easily copy the product, and investigation of new “safer” inert ingredients or formulations will be discouraged. Disclosure is likely to undermine the incentive to invest in conducting innovative research.



- d. Should the concentration of ingredients be disclosed, along with their identities? What are the interests of registrants and manufacturers of proprietary inert ingredients and proprietary mixtures of inert ingredients in concentration information?*

As we stated previously, listing ingredients is not useful to the consumer. Information on concentration does not add any useful information to the safety warnings and specific PPE already listed on the label. The concentration of an inert may be considered confidential information since the specific concentration is often related to a specific physical property that is desired for the final mixture. Increasing or decreasing the concentration of the inert in the final formulation is related to the properties it imparts to the final product. Safety of the final formulation is subsequently evaluated by the toxicity tests required for registration.

Additional questions under this question *d* are not addressed.

- e. Should inert ingredients be listed in order of concentration? Could listing inert ingredients in order of concentration mislead consumers or users regarding the safety of the formulation?*

As we stated previously, listing ingredients is not useful to the consumer. Information on concentration does not add any useful information to the safety warnings and specific PPE listed on the label. The label signal word and instructions for precautions already take this information into account. Listing ingredient concentrations other than allergens provides no useful information to consumers because they are not adequately prepared to interpret potential risks of chemicals. That is EPA's responsibility as the regulator, under both FIFRA and FFDCA.

Additional questions included under question *e* are not addressed here for the reasons expressed under question *a* above.

- *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?*
- 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?*



Again the Agency needs to better assure the public that they (EPA regulators) have the expertise to evaluate all risks associated with the use of the pesticide product. As we have stated before, the information on identity of the inert ingredients may be misleading and overwhelming, which could distract from communication of any actual risks via information currently on the label.

- g. *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?*

The term “inert ingredient” as defined in the pesticide statutes has a specific meaning in the context of pesticide regulations, and should remain unchanged. We recognize that the use of the term “inert” has connotations beyond the specific definition of those regulations. We would agree that the Agency could substitute the use of the term “other” ingredients on product labels, with the caution that statutory reference to “inert ingredients” continues to confer its existing meaning.

- 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.*

Active and inert ingredients should continue to be treated as they are now and located separately on the product label, without change to the distinction among ingredients.

- 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?*

The focus of the pesticide label should be in communicating clear directions and conditions under which the application can be made, in accordance with the risk management parameters used to mitigate potential risks as indicated by the Agency’s product-specific risk assessments. In this way, unintended consequences to the environment or to human health can be avoided because the user is clearly informed.

Supplemental information related to inert and active ingredients in formulations could be maintained on registrant websites, an EPA website, or another communication venue. Using these alternate resources as communication tools would allow additional detail and clarity to be thoroughly addressed for the public, which would put the disclosed information in context and better inform the consumer. The space limitations on a product label, and the challenge of



communicating complex data in capsular statements, makes the label an inappropriate communication tool for this type of information. Additional avenues to obtain the desired information already exist and include phone numbers listed on the label connecting the user to a given company or third party representatives (for example, poison control centers) who are equipped to answer very specific questions and address consumer concerns. Another option would be to provide this information upon request using a standard format.

m. What would be the advantages and disadvantages of voluntary disclosure versus required disclosure?

As the Agency notes in “f” above, it has rejected labels that voluntarily list inerts as “misleading” under FIFRA, and would therefore have to resolve this conflict prior to proposing a voluntary approach. EPA would need to provide substantial guidance for a voluntary program. EPA would need to ensure some uniformity for voluntary disclosure which in turn would ensure usefulness and meaning when employed.

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?

The necessary regulatory approaches are already in place. All ingredients found in pesticide products, both active ingredient and inert, must pass the scrutiny of EPA and be found to meet human health and environmental safety standards mandated by Congress. This includes a the formulated end-use product, which is supported by a robust dataset and a thorough safety assessment that considers the intrinsic hazards of the chemicals in the formulation and the potential exposures that may result when used as directed on the pesticide label. One safety standard applies to both active ingredients and the other formulants. Should the combination of hazard when examined in the context of exposure result in an unacceptable risk, EPA places limits on use of the product necessary to reduce the risk, declines to register the questionable uses of the product, or takes the necessary steps to remove the product or specific uses from the market. Any criteria for confirming or listing the hazard of an inert ingredient should be established using the standard scientific methods now employed.