PESTICIDE REGISTRATION NOTICE 2000-8

NOTICE TO MANUFACTURERS, FORMULATORS, PRODUCERS, DISTRIBUTORS AND REGISTRANTS OF PESTICIDE PRODUCTS

ATTENTION: Persons Responsible for Federal Registration of Pesticides

SUBJECT: Reportability of Attorneys' Opinions and Conclusions Under 40 CFR Part 159 and FIFRA Section 6(a)(2)

EPA's regulation at 40 CFR § 159.158(a) provides that risk/benefit information subject to reporting under FIFRA section 6(a)(2) includes opinions and conclusions of certain employees and agents of registrants. Some registrants have objected to this provision because they believe it requires reporting of all opinions and conclusions of attorneys. EPA is issuing this PRN to inform registrants of EPA's opinion that an attorney's professional legal judgment is not an opinion or conclusion that is reportable under 40 CFR part 159.

I. Opinions and conclusions rendered as the professional legal judgment of an attorney are not relevant to EPA's assessment of the risks or benefits of a pesticide and are not required to be reported under part 159

Part 159 requires reporting of toxicological and ecological studies, discontinued studies, human epidemiological and exposure studies, information on pesticides in or on food, feed, or water, pesticide metabolites, degradates, contaminants, and impurities, toxic or adverse effect incidents, and failures of performance. Such information must be reported only if it meets the requirements of § 159.158, in particular, that it contains "information relevant to the assessment of the risks or benefits" of a pesticide registration. EPA's primary purpose in assessing the risks and benefits of a pesticide is to determine whether the pesticide meets the criteria for registration under section 3, chiefly, that it "will perform its intended function without unreasonable adverse effects on the environment [and] when used in accordance with commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."[1] In contrast, the attorney's professional judgment is defined in the Model Code of Professional Responsibility as the attorney's "educated ability to relate the general body and philosophy of law to a specific legal problem of a client". Model Code of Prof'l Responsibility, EC 3-5 (1980). EPA believes that the professional legal judgment of an attorney is sufficiently unlikely to contribute to EPA's

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[1]FIFRA section 3(c)(5)(C)&(D). FIFRA section 2 (bb) defines "unreasonable adverse effects on the environment" to mean:

> (1) 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, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a).

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understanding of whether a pesticide presents unreasonable adverse effects on the environment. Therefore, opinions and conclusions rendered as the professional legal judgment of an attorney, as defined in the Model Code, need not be reported under part 159.

II. Opinions and conclusions of attorneys other than the attorney's professional legal judgment can be reportable under part 159

EPA recognizes that attorneys today may perform many different types of tasks for registrants, and these tasks may result in opinions and conclusions that are not strictly the professional legal judgment of an attorney. Those opinions and conclusions may become reportable under part 159. If a person is involved in "the development, testing, sale or registration of a pesticide" or "could be reasonably expected to come into possession of information otherwise reportable," § 159.155(d) provides that any conclusion or opinion held by that person would be possessed or received by the registrant and must be reported – regardless of whether that person might also happen be an attorney.[2] Collecting information about the risks and benefits of a pesticide and obtaining reviews of data by expert consultants are activities commonly performed by persons other than attorneys, and are also activities that are very likely to produce information that is reportable under part 159. Registrants cannot shield themselves from the reporting requirements of part 159 by putting attorneys in the front lines of their information gathering apparatus.

III. Factual information upon which an attorney's professional legal judgment is based must be reported if it meets the criteria of part 159

Although opinions and conclusions rendered as the professional legal judgment of an attorney need not be reported under part 159, the factual information underlying those opinions and conclusions would be reportable if it meets the criteria of part 159. For example, while an attorney's opinions as to the legal sufficiency of an adverse effect allegation would not be reportable, the allegations themselves would be reportable pursuant to § 159.184. Where an attorney engages outside experts to review and advise on the effects of a pesticide on a registrant's behalf, the experts' opinions and conclusions may be subject to reporting.

IV. Conclusion

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[2]Section 159.155(d) provides, in part, that:
[A] registrant possesses or knows of information at the time any officer, employee, agent, or other person acting for the registrant first comes into possession of, or knows of, such information; provided that, such person performs any activities for the registrant related to the development, testing, sale or registration of a pesticide or the person could be reasonably expected to come into possession of information otherwise reportable under this part.

Opinions and conclusions rendered as the professional legal judgment of an attorney need not be reported under part 159. To the extent that the attorney engages in activities that do not necessarily call for the professional legal judgment of an attorney, the attorney's opinions and conclusions may become reportable under part 159.

This Notice is intended to give notice to pesticide registrants of EPA's interpretation of 40 CFR part 159. This Notice does not increase registrants' reporting burden.

V. Contact Information

For further information regarding part 159 and FIFRA section 6(a)(2), contact Kathryn Bouvé at: telephone number (703)305-5032, facsimile number (703)305-7670, or e-mail address bouve.kate@epa.gov.

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