

**Monsanto Response to EPA ICR No. 0161.11, Consultation Questions
September 16, 2008**

Attn: Docket ID No.: EPA-HQ-OPP-2008-0255

(1) Publicly Available Data

(1) Is the data that the Agency seeks available from any public source, or already collected by another office at EPA or by another agency?

Not to our knowledge.

(2) If yes, where can you find the data?

(2) Frequency of Collection

Can the Agency collect the information less frequently and still produce the same outcome?

Not to our knowledge.

(3) Clarity of Instructions

(1) The ICR is intended to require that respondents provide certain data so that the Agency can utilize them.

(1) Based on the instructions (regulations, PR Notices, etc.), is it clear what you are required to do and how to submit such data?

Yes, we believe the expectations and instructions are clear on the requirements. We appreciate that the export policy governing the export of unregistered pesticides has been constant since 1993. In that way, except for the need to train new personnel on the requirements, the experienced personnel are already familiar with the policies and procedures.

(2) If not, what suggestions do you have to clarify the instructions?

Even though we believe the instructions are already fairly clear, questions and confusion over specific requirements still arise somewhat frequently.

One frequent question or concern is about why, when the pesticide material is identical in chemical composition to a U.S. registered product, the label must still contain the phrase “not registered for use in the United States of America.” When individuals do not have an understanding of what it really means to obtain a registration under FIFRA section 3, is there a simple instruction that can address this question?

Another question or concern that takes additional time to clarify is the exemption for research and development pesticide shipments. Although documentation supporting research use may be available and may be adequate, it may not all exist in a single location or in a readily retrievable fashion. As a result, the Foreign Purchaser Acknowledgment Statement (FPAS) may be submitted in cases where it is not really required. In those cases, foreign governments would also be somewhat misled regarding the quantities and purposes for which research pesticides were being imported.

Because Monsanto chooses to comply with the option of an annual summary report of export shipments when the FPAS is submitted prior to the first shipment in a calendar year, we suggest that some additional instructions might clarify or avoid end-of-year problems. Due to long lead times required to prepare material for an ocean shipment (manufacturing lead times for made-to-order products, delivery to port from the plant or warehouse, booking activities, etc.), the export process has to begin several weeks in advance of the intended date of export. When the intended date of export may get delayed by any of a variety of causes (weather, overbooked vessels, trucker strikes, damaged cargo, etc.), there are times in a business when the intended date of export in a given year does not occur until after calendar year-end. The steps for bringing a delayed shipment back to the manufacturing plant, or trying to stop a shipment from going out on the next vessel while waiting for the new year FPAS to arrive, are costly due to the amount of manual intervention required, are not practical, and may be very difficult. Perhaps the Agency could clarify or provide some comment on how businesses who choose the annual summary option might avoid the end-of-year problem of unintentional noncompliance. For example, how long before the beginning of a new year or the first shipment in a new year can the FPAS for the following year be submitted?

Finally, one suggestion that might clarify the instructions would be a definition of the term "foreign purchaser." In a large global company like Monsanto, pesticide material is frequently shipped from location to location, all within the company and without a formal financial transfer of monies at the time of shipment. Monsanto believes that the intent of the policy is to make the appropriate officials aware of the registration status of the labeled pesticide product, rather than concern itself with whether or not the product is exchanged for money. For example, R&D material or material to be used for a product promotion, exported without the expectation of financial payment in order to obtain it, would still require the FPAS if other exemptions did not apply.

(2) Do you understand that you are required to maintain records?

Yes. As stated in the supporting statement for the ICR, "Records of shipment and confirmation of research intent must be maintained and made available for inspection and copying by EPA for two years following the exportation of the pesticide."

(3) Considering that there is no required submission format, is it difficult to submit information in ways that are clear, logical and easy to complete?

No.

(4) Regarding the any [specific program] forms, do you use them? Are they clear, logical, and easy to complete?

Monsanto has used the same template document for completing the FPAS that it originally developed several years ago. The use of this template form makes the completion of the FPAS easy for Monsanto customers and is consistent from year to year. If a different or specific form would be developed and required by EPA, especially to enable electronic reporting and transmission of information to EPA, Monsanto would support making any necessary changes.

(4) Electronic Reporting and Record keeping

The Government Paperwork Elimination Act requires agencies make available to the public electronic reporting alternatives to paper-based submissions by 2003, unless there is a strong reason for not doing so. One such reason is that, at the present time, the Agency is unable to ensure the security of CBI that might be transmitted over the Internet.

(1) What do you think about electronic alternatives to paper-based records and data submissions? Current electronic reporting alternatives include the use of "web forms"/XML based submissions via the Agency's Internet site and magnetic media-based submissions, e.g., diskette, CD-ROM, etc. Would you be interested in pursuing electronic reporting?

Are you keeping your records electronically? If yes, in what format?

Yes, Monsanto keeps records electronically and would be interested in pursuing electronic reporting. At the present time, typically the FPAS will be received by email as a pdf file. Monsanto could more quickly and easily submit this electronic file to EPA if it were not necessary to print and copy the file in order to mail a paper copy to EPA.

(2) Although the Agency does not offer an electronic reporting option because of CBI-related security concerns at this time

(1) Would you be more inclined to submit CBI on diskette than on paper?

Monsanto would not be more inclined to submit CBI on regular computer diskettes than on paper. However, Monsanto would be happy to work

with the Agency to pursue the use of alternate means that could be made available to securely submit CBI in electronic form to the Agency's Internet site.

(3) What benefits would electronic submission bring you in terms of burden reduction or greater efficiency in compiling the information?

Monsanto believes that electronic submission has the potential to reduce the burden of submitting the information and that the information would be more efficiently compiled and transferred. Greater efficiency could be realized if foreign customers were able to simultaneously submit the FPAS to EPA as well as to Monsanto.

Monsanto again wishes to express appreciation for the convenience that was provided to submit this response to the Agency by email.

(5) Burden and Costs

(1) Are the labor rates accurate?

Monsanto does not have an opinion about the accuracy of the labor rates, and assumes that they are correct.

(2) The Agency assumes there is no capital cost associated with this activity. Is that correct?

Yes, we believe this would be correct.

(3) Bearing in mind that the burden and cost estimates include only burden hours and costs associated with the paperwork involved with this ICR, e.g., the ICR does not include estimated burden hours and costs for conducting studies, are the estimated burden hours and labor rates accurate? If you provide burden and cost estimates that are substantially different from EPA's, please provide an explanation of how you arrived at your estimates.

We do not have an opinion on the accuracy of the estimated burden hours and labor rates, and assume they are correct.

(4) Are there other costs that should be accounted for that may have been missed?

Monsanto invests some labor to monitor and to upgrade the export ordering and shipping software systems to maintain compliance with the pesticide export policy. Within the past year, specific steps were taken to add control points to the ordering and shipping process which will prevent an order from being completed, or an export shipment to take place unless the necessary FPAS has been submitted for the current year. Designing and coding system checks, continually updating and maintaining major system software (SAP) with an accurate and current list of

approved materials, countries, and customers, is costly and requires computer technology experts to be involved with compliance efforts.