FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)

PESTICIDES EXPORT POLICY

QUESTIONS AND ANSWERS

ISSUES: RESEARCH AND DEVELOPMENT PESTICIDES;
ACTIVE INGREDIENT CONCENTRATIONS

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U.S. Environmental Protection Agency

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The following questions and answers are intended to assist in compliance with the Environmental Protection Agency's February 18, 1993 rule (58 FR 9062) regarding the exportation of pesticides. This guidance addresses the issue of FIFRA applicability to exported research and development pesticides, and the effect of active ingredient concentrations on registration status. This guidance only addresses the obligations of exporters under the pesticides export rule, and is not intended to address legal obligations under any other rule or statute.

RESEARCH AND DEVELOPMENT PESTICIDES

1. Under what circumstances is an exporter of a pesticide that is being exported solely for research and development (R&D) purposes subject to the requirements of the pesticide export rule?

   The requirements of the pesticide export rule apply to all types of exported pesticides. However, EPA will not treat as a violation of FIFRA either the exportation of an unregistered pesticide for which no Foreign Purchaser Acknowledgement Statement (FPAS) has been submitted or the exportation of any pesticide which is not labeled according to FIFRA requirements, provided that the exporter can substantiate that the pesticide is being exported solely for the purpose of conducting R&D and can also substantiate that the R&D activities are to be performed within a laboratory or:

   a) The product's use would not involve land uses of more than 10 acres or the product would not be used on or affect food or feed crops intended for consumption;

   b) The product's use would not involve aquatic uses of more than 1 acre or involve water used for irrigation, drinking or recreation or the product would not be used on or affect plants or animals taken for food or feed from such waters; and

   c) The product's use would not involve tests on animals intended for food or feed.

   These are similar to the criteria in 40 CFR 172.3 for determining whether an experimental use permit is required for field research in the United States.

   Notwithstanding the above, those research and development microbial pesticides for which notification would be required prior to outdoor release if the testing were performed in the United States have to meet the labeling requirements of the export rule in order to be legally exported for tests involving outdoor release.

   If an exporter is required to obtain an FPAS before exporting an R&D pesticide, for example, the use involves greater than 10 acres, then the exporter should refer to Q&A # 4, below, to obtain information regarding intracompany shipments.

2. Are analytical samples of pesticides or radio-labeled pesticides subject to EPA's rule on exported pesticides?

   Yes. However, because analytical samples of pesticides and radio-labeled pesticides are typically tested under conditions below the criteria discussed in the response to question 1, they therefore would not have to comply with the export rule in most cases.

3. How can the required labeling, with translations, be placed on small vials containing a milligram sample?

   In the case that a small quantity of substance is subject to FIFRA labeling requirements and is packaged in an immediate container which is too small to be practically labeled, the labeling requirements for exported pesticides may be met through the use of attached supplemental labeling as described at 40 CFR 168.65(c).

   Where supplemental labeling is used, it must be securely attached to the immediate product container or the shipping container of the pesticide, device or active ingredient at all times when it is shipped or held for shipment.

4. For the FPAS requirement, please define the term "purchaser". In the case of shipment of an unregistered pesticide to a subsidiary or parent company, must a FPAS still be obtained?

   For purposes of the export rule, the term "purchaser" includes the person at the foreign site who procures or receives the exported pesticide, whether or not through a financial transaction. Because the intent of the FPAS requirement is to inform foreign governments of shipments of unregistered pesticides to their countries, the obligation to obtain the acknowledgement associated with this receipt or purchase must be carried out regardless of whether the shipment is to take place in connection with non-commercial or commercial purposes. The FPAS obligation would extend, for example, to shipments between a parent and subsidiary company.

5. Are the use criteria at 40 CFR 168.75(b)(5) based on the shipment of a certain product to a particular country or shipment of the product to a country for a particular use pattern?

   The export rule explains that shipments of a research pesticide to different purchasers and different countries or final destinations will be evaluated separately. Further, shipments in a different calendar year will be evaluated independently.

   It is EPA's intention that applicability of FIFRA requirements to the exporting of R&D pesticides be as consistent as possible with domestic shipment of such products. Thus, EPA considers the application limits presented at 40 CFR 168.75(b)(5)(i) to be applicable to uses against different pests or pest complexes. As stated at 40 CFR 168.75(b)(5)(iii) the exporter must be able to demonstrate that this actually is the case. Separate applications

against a particular pest or pest complex are considered to be cumulative toward reaching the application limits of section 168.75(b)(5)(i).

6. Does the export rule affect the responsibilities of an exporter of an R&D pesticide to provide EPA with production information per the requirements of FIFRA Section 7?

   The export rule does not alter a producer's obligation under section 7.

ACTIVE INGREDIENT CONCENTRATIONS

7. Many foreign countries require that the minimum concentration of an ingredient is to be presented on the label. For this same information, EPA requires the ingredients to be identified through the use of the nominal concentration of the product. If an exported product is labeled to meet the foreign required minimum concentration, and has the U.S. registered label (including the nominal concentration) attached in order to qualify as "registered", would the product be considered either unregistered or misbranded?

   No. When the label placed on the immediate product container differs from the U.S. registered label which is attached as supplemental labeling only in the manner of declaration of the percent active ingredient (i.e., minimum concentration vs. nominal concentration), the product will not need to be labeled with the statement "Not Registered For Use In the United States of America."

   EPA believes that it can determine compliance by comparing the certified limits in the statement of formula, required to be kept under FIFRA section 8, with the labeling. If the minimum concentration listed on the foreign label is within the certified limits, the export product labeling would be considered to be in compliance.

8. What labeling information would be required in the case of a product whose composition has been modified by decreasing the percentage of active ingredient and replacing it with a List 4 inert ingredient?

   Pursuant to 40 CFR 168.75(b)(4), pesticide exporters who are also the product's manufacturer may decrease the percentage of active ingredient by addition to this material of a List 4 inert ingredient without triggering the requirement to obtain a FPAS. In such instances the Agency has been asked to clarify the impact of this modification on the labeling requirements contained in the export rule. Note, however, that 40 CFR 168.75(b)(4)(ii) indicates that exporters of pesticides used in public health settings are not relieved from the obligation to obtain a FPAS if the product's percentage of active ingredient is decreased.

The Agency intended that these sort of minor composition modifications could also be made to a product without triggering the "Not Registered..." labeling statement under 40 CFR 168.65(b). However, the codified text inadvertently failed to achieve this goal. Since this was not the Agency's intention, EPA plans to propose an amendment to the export rule to address this issue. Until such an amendment is codified, EPA does not intend to pursue enforcement action against persons who fail to apply the "Not Registered..." statement to exported registered pesticides if the composition has been modified by the registrant to decrease the percentage of active ingredient by the addition of a List 4 inert ingredient.