FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)

PESTICIDES EXPORT POLICY

QUESTIONS AND ANSWERS

ISSUES: SUPPLEMENTAL LABELING;
EFFECTIVE DATE;
REGISTRATION STATUS FOR LABELING PURPOSES;
FOREIGN PURCHASER ACKNOWLEDGEMENT STATEMENTS;
CONFIDENTIALITY

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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 five issues: (1) the allowance for "label" statements to be attached to shipping containers instead of immediate product container labels; (2) the effective date of the labeling requirements of the rule; (3) the requirement that unregistered products labeling include the statement "Not Registered For Use In the United States of America;" (4) the need for foreign purchaser acknowledgement statements to be submitted in connection with the exportation of unregistered pesticides; and (5) the extent that certain information submitted in accordance with FIFRA section 17 will be treated as confidential business information.

SUPPLEMENTAL LABELING

1. Would a shipment be considered to be in compliance with the labeling requirements of the rule if the product container had all of the necessary foreign requirements and all additional U.S. labeling requirements were met by supplemental labeling?

   As stated in the rule at 40 CFR 168.65(c)(2), supplemental labeling, when used, must be attached to the shipping container at all times when the product is shipped or held for shipment, and must meet all FIFRA requirements not met by the immediate product label. It is permissible, therefore, for some of the labeling needs to be met by the immediate product labeling, i.e., the label which meets foreign labeling requirements, with the remainder to be met through supplemental labeling. The foreign label is still considered to be part of the product labeling, and cannot include false or misleading claims, misrepresent the product, or otherwise violate misbranding provisions under the statute. Note that the product label and supplemental labeling must complement each other to provide full coverage of FIFRA labeling, including the multilingual labeling needs. Note, finally, that copies of all labels or labeling used to comply with FIFRA must be maintained as stated at 40 CFR 169.2(h)(2).

2. When supplemental labeling is used, can one label be used per pallet, or must each carton or drum be separately labeled?

Supplemental labeling used to meet pesticide export label requirements must be attached to each smallest divisible shipping container of a given pesticide product. In the case that cartons or drums are secured to a pallet such that they will not be separated from the pallet during shipment, it is permissible to attach supplemental labeling to the pallet load. An example would be where a pallet of cartons has a wrapper (e.g., shrink-wrap) which contains all of the cartons on the pallet. However, if cartons or drums are loosely stacked on a pallet so that they could be separated during shipment, each drum or carton must be labeled.

3. What are the type size/label size requirements for various cautionary statements, etc. with regard to supplemental labeling?

Under FIFRA, a product is considered to be misbranded if any information required to appear on the label or labeling is not "prominently placed...with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling)...as to render it likely to be read and understood..." The EPA's rule does allow FIFRA-required label statements for export pesticide products to be present in the form of supplemental labeling as defined in the rule. This allowance does not address the actual content or nature of the required label statements. Those requirements are addressed elsewhere under FIFRA labeling regulations. FIFRA labeling regulations at 40 CFR 156.10 provide a minimum of 6-point type size for any FIFRA-required label text. This would certainly apply to any text used to meet label requirements, whether attached to the immediate container or attached to the shipping container as supplemental labeling. These regulations also state that warning and caution statements must be grouped together on the label with sufficient prominence relative to other text and material to make them unlikely to be overlooked under customary conditions of purchase and use. Also, minimum text size requirements are given at 40 CFR 156.10(h)(1)(iv), relative to label size. These requirements apply to supplemental labeling when supplemental labeling is used to meet label requirements.

4. Is it acceptable to include the U.S. required labeling with shipping papers?

   The rule allows certain statements which normally must be attached to the immediate product container to instead be attached to the shipping container. While it is acceptable to include such labels or labeling with the shipping papers, they must also be attached to the immediate product container and/or the shipping container as required.

5. Is the establishment number required to be present on all labeling, including that on the immediate product container and the shipping container (i.e. supplemental labeling)?

   The rule specifically states at 40 CFR 168.65(c)(1) that any required label or labeling statement not met on the immediate container may be met through supplemental labeling. Although the establishment number is required under FIFRA to be placed on the product label (i.e., the label attached to the immediate product container), EPA will not treat statements placed on supplemental labeling attached to the shipping container as violations of the requirement. Hence, the establishment number may be placed in supplemental labeling as provided in the rule instead of on the product container label.

EFFECTIVE DATE

6. Will EPA formally extend the April 19, 1993 effective date for labeling requirements?

   No. The labeling requirements went into effect on April 19, 1993, as stated in the policy. EPA believes that sufficient time was provided by the 60 day post publication effective date to enable exporters to achieve compliance with the new requirements.

7. Must existing stocks of pesticides be relabeled to comply with the new requirements?

   Yes, all products distributed or sold on or after the effective date of the rule must be labeled to meet the new requirements. Note, however, that where supplemental labeling is used to meet product label requirements, it should not be necessary to modify immediate product container labels. Also, except where a product's shipment triggers new requirements under the policy, such as in the case where multilingual labeling is required, there would not be a need to make labeling changes, provided that the product was already in compliance with the previous rule.

REGISTRATION STATUS FOR LABELING PURPOSES

8. Define what EPA considers to be a registered pesticide for the purposes of the labeling requirements.

   EPA considers a pesticide intended for export to be a registered product when it meets the provisions in 40 CFR 168.65(b)(1)(iii)(A). Briefly, the pesticide must be registered under FIFRA section 3, and the EPA approved label, which must be one that would be in full compliance with FIFRA if used to distribute the product in the United States, must be either on or attached to the immediate product container or the shipping container of the pesticide at all times. No statements appearing on the product labeling may add new uses or claims or contradict in any way the approved section 3 labeling. Further, the exported pesticide must have the same composition as the EPA registered product except that exporters may make certain modifications to the color and fragrance of a registered product. Finally, exporters can make the labeling and packaging changes as described in 40 CFR 152.46(b) without rendering the product unregistered for the purposes of this provision.

   All other exported products must contain the labeling statement "Not Registered for Use in the United States of America".

9. Is it permissible to modify the label statement, "Not Registered for Use in the United States of America"?

Under 40 CFR 168.65(b)(1)(iii), unless an exported product is registered under FIFRA section 3 the statement, "Not Registered for Use in the United States of America" must be present on the product's labeling. This statement must be present verbatim and appear in English and in the appropriate foreign languages of each country of destination. However, under 40 CFR 168.65(b)(1)(iii), EPA has determined that it will be acceptable for an exporter to modify this label statement provided that the additional information is an accurate clarification of the registration status of the product in the U.S. If the language is misleading or misrepresents the registration status of the product in the U.S., the product will be considered misbranded.

EPA has been asked to react to several proposed modified label statements. Examples of the specific proposals cited were "Not Registered for Use in the United States of America in this type of packaging"; "Not Registered... for Commercial Reasons"; and "Not Registered... on Crops Other Than ....(list of U.S. registered uses)". EPA does not believe that it is possible to pre-approve the language of all contemplated modifications because, in order to determine whether the language would be acceptable, it must be considered in the context of the product to be exported.

In general, any additional language that is added to the statement "Not Registered for Use in the United States of America" must be factual and specific. Consequently, EPA finds that the statement "Not Registered for Use in the United States of America for Commercial Reasons" would not be acceptable as it is too general. Conversely, EPA believes that it would be within the intent of 40 CFR 168(b)(1)(iii) to modify the "Not Registered..." statement, where applicable, with a statement that reads, "Not Registered for Use in the United States of America Unless in Child Resistant Packaging".

Another example of a statement which EPA believes could be acceptable would be a statement that reads, "Not Registered for Use in the United States of America on [list all crops/uses appearing on the label of the exported product, for which there is no approval under FIFRA]". It will not be acceptable, however, for exporters to make modifications to the "Not Registered" statement which obscure

or conceal the fact that a product may be unregistered in the U.S. due, even in part, to risk concerns. Thus, the statement "Not Registered For Use In the United States of America on [list all crops/uses appearing on the label of the exported product, for which there is no approval under FIFRA]" would not be acceptable when an applicant has failed to develop data necessary to support registration of the use in the U.S. after EPA requested such data to be submitted to evaluate a possible environmental or health concern, or where a registrant has deleted the bulk of the U.S. uses following the expression by EPA of risk concerns.

FOREIGN PURCHASER ACKNOWLEDGEMENT STATEMENTS

10. Under what specific circumstance is a foreign purchaser acknowledgement required?

Export shipments of all pesticides are subject to the FPAS requirement except those pesticides which are registered under FIFRA Section 3 or sold under an existing stocks provision per FIFRA Section 6(a)(1). An unregistered pesticide product exported only for research and development purposes is subject to the PAS requirement but would not be treated as subject to that requirement in the event that it meets the criteria at 40 CFR 168.75(b)(5).

It should be noted that the requirements to obtain a FPAS as described under 40 CFR 168.75 are independent of the requirements under 40 CFR 168.65 for labeling.

For example, under 40 CFR 168.65(b)(1)(iii), the statement "Not Registered For Use In the United States of America" is to appear on all exported pesticides which are not registered under FIFRA Section 3. This provision also describes a limited set of circumstances under which it would be acceptable to modify a registered product without triggering the requirement to provide the "Not Registered" labeling statement. 40 CFR 168.75(b) contains a description of a different set of limited circumstances under which it would be acceptable to export an unregistered pesticide without obtaining a FPAS.

Exporters are advised to recognize that there are differences in the way that the PAS requirements and label requirements are to be administered. Modification of the label of a domestically registered product to include an additional use would render the product "unregistered" for the purpose of 40 CFR 168.65. The labeling statement "Not Registered for Use in the United States of America" would be required. Under 40 CFR 168.75, as long as the new use is within the same general use pattern as those already approved under FIFRA and the exporter meets the additional applicable requirements articulated in this section, an FPAS would not be necessary.

11. What is the appropriate format for FPAS submissions?

EPA does not currently have a reporting form or required format for FPAS submissions . Any format that an exporter chooses to develop will be acceptable as long as the required information can be clearly identified by EPA. If a portion of the FPAS submission is sent to EPA in a language other than English, -- for example, the explanation of the U.S. requirement to the foreign purchaser -- then an English translation of that material must also accompany the statement.

12. Will EPA allow the submission of FPAS's obtained via electronic media (e.g. telex, fax)?

It will be acceptable for exporters to submit fax copies of a foreign purchaser's signature. However, telex's or other electronic media where a purchaser's signature cannot be transmitted will not be acceptable.

13. Must a FPAS be obtained in connection with each shipment of an unregistered pesticide?

Exporters may meet the requirements of 40 CFR 168.75 by complying with one of the two procedures (per-shipment or annual) which EPA has developed in connection with the FPAS notification requirement. Under the per-shipment reporting procedure exporters must obtain and submit a FPAS in connection with each shipment of each unregistered pesticide. The procedure for per-shipment

reporting is explained at 40 CFR 168.75(c)(2)(i). Under the annual reporting procedures, exporters obtain and submit an FPAS once annually for the first shipment of each unregistered product shipped to a purchaser in a foreign country, and a year-end summary of the shipments for the year. The full requirements under this option are set out at 40 CFR 168.75(c)(2)(ii).

14. Can a purchaser's acknowledgement statement be obtained for more than one product at a time?

Yes. It is permissible to obtain the purchaser's acknowledgement for more than one product in one acknowledgement communication. However, all of the required information, particularly, each product and respective active ingredient(s) and destination(s), must be presented in a clear and understandable format.

15. Is an exporter's initial decision on whether to report under the per-shipment or annual basis binding?

The requirements of 40 CFR 168.75 may be met by submitting FPAS information on either a per-shipment or annual basis. The two reporting systems are described at 40 CFR 168.75(c)(2). All applicable exports must be covered by a FPAS that meets the new requirements of 40 CFR 168.75 as of June 1, 1993. At that time, exporters must be in compliance with one or the other of these two options for a given product, purchaser and destination.

EPA will permit an exporter who has begun to comply with 40 CFR 168.75 through one of the reporting methods and subsequently determines that they would prefer to report under the other method, to switch its reporting system. However, EPA strongly encourages an exporter to continue the same reporting system for the entire calendar year reporting period. If an exporter switches from one reporting system to the other in the middle of the year, EPA advises the exporter to submit a letter to the Agency explaining its intent to change reporting systems. When changes are made at the beginning of the calendar year reporting period, no separate notice is required.

There are several reasons why EPA encourages exporters to stay with one reporting option for a complete year. First, exporters are reminded that the ultimate users of the FPAS submissions are officials in the country of destination. Therefore, EPA believes that it would be useful for these foreign officials to be able to anticipate the kind of information that they can expect to receive through FPAS reporting. If an exporter's plans with respect to their preferred reporting option are known, foreign officials can anticipate the quantity and timing of the information that they will receive from EPA. The other major reason that EPA expects exporters to utilize one of the reporting systems for a calendar year is that this will facilitate more accurate record-keeping for the submissions and greater clarity in terms of ensuring an exporter's compliance with this requirement.

CONFIDENTIALITY

16. What is the purpose of the class determination contained in the export policy?

The export policy contains a legal discussion known as a Class Determination (58 FR 9078) that examines the releasability under the Freedom of Information Act (FOIA) of a particular set of information reported by exporters in each FPAS. Specifically, the Class Determination explains that EPA does not consider the country of destination as reported in a FPAS to be confidential business information.

This discussion informs affected businesses and the public of EPA's position on the manner in which FPAS submissions that have been marked by the exporter as "FIFRA Confidential Business Information" will be handled for this set of information under the FIFRA.

This decision was reached after a review of the issue that revealed that information on the country of destination for exported pesticides was already available through several public sources.

17. May businesses make any claims of confidentiality on FPAS submissions?

Yes. Exporters that submit FPAS's to EPA may assert a claim of confidentiality. However, in addition to the Class Determination, EPA issued a Federal Register notice on January 12, 1990 (Volume 55 FR No. 9 Page 1261) relevant to the confidentiality of the producer and product name for exported pesticides. This notice explained that EPA would no longer consider information submitted on FPAS's relating to the product, active ingredient and the producer as FIFRA confidential business information. This section 7 information is publicly available.

18. Will FPAS information submitted for research and development pesticides be transmitted to foreign officials?

Under the export policy, unregistered research and development pesticides are subject to the FPAS requirement unless the intended use is such that it would be exempted from this reporting as described in 40 CFR 168.75(b)(5). Because the Agency is sensitive to the potential competitive disadvantage a business might realize following the release of information relevant to new areas of chemistry or innovative practices that an exporter is in the process of researching, EPA has indicated that the chemical identity of research pesticides may be coded on both the product label and the FPAS. If the exporter opts to use such coded information in the FPAS reporting, however, an attachment that clearly identifies the product must also accompany the submission to EPA. Such attachments may be claimed as FIFRA Confidential Information and will not be released to foreign officials through the notification process by the Agency.

19. For reporting under the annual summary method, will this kind of FPAS submission be released under the Freedom of Information Act (FOIA)?

The reporting option that an exporter chooses to use for the FPAS requirement does not affect whether the information could be subject to public release under FOIA. Thus, annual summaries and per-shipment FPAS submissions would both be subject to release under FOIA in accordance with the procedures of 40 CFR 2.