

Generic Questions from Exporter Notification Letter

- **Am I required to produce a Foreign Purchaser Acknowledgement Statement (FPAS) for a proprietary material that is not registered with the EPA, but will not be used in the U.S.? I think this product is considered to be an antimicrobial. Should it be registered?**

Yes, proprietary materials that are used as antimicrobials are considered pesticides, and the export of an unregistered pesticide is subject to the FPAS requirement.

- **I manufacture and export a device that does not require an EPA registration. Is the export of this device, which is not registered for use in the U.S. but can be sold in the U.S., regulated under FIFRA Section 17(a)? Do I need an FPAS?**

No, [pest control devices](#) are not subject to the Foreign Purchaser Acknowledgement Statement (FPAS) requirement, but are subject to production reporting requirements and labeling requirements. See 40 CFR 167 and 168.65(a).

“Every exported pesticide, device, and active ingredient used in producing a pesticide... must bear a label or labeling which meets the requirements of FIFRA section 17(a)(1).”

- **If I export an EPA registered product and send a copy of the EPA-approved label and a copy of the foreign approved label with the shipment, am I compliant with FIFRA 17(a)? Does the use of the foreign label, written in their official language, which has not been reviewed by the EPA, deem my product an unregistered pesticide?**

If you are exporting an EPA registered product, then you are compliant with FIFRA 17(a) as long as the EPA approved label is either attached to the immediate product container or accompanies the product at all times as supplemental labeling. EPA does not review labels developed for selling the product in other countries.

For more information, please see [40 CFR 168.65, Pesticide export label and labeling requirements](#), especially paragraph (c)(1).

Please see [40 CFR 156 for the labeling requirements for registered products](#).

- **If my unregistered chemicals, some of which are used as inert ingredients, are sold in the U.S. and overseas, am I required to include the statement, “Not Registered for use in the United States” on the label? Are there instances when this statement is not required?**

No, the label statement is not required on packaging for inert ingredients alone. Products that consist of only inert ingredients do not have to be registered and are not subject to FIFRA 17(a). The statement is only required on the labels of unregistered pesticide products that are exported.

- **Are inert ingredients required to be registered?**

No, inert ingredients are not required to be registered.

- **Letters were sent to our foreign establishments in addition to domestic establishments. Is there a circumstance where a foreign establishment would need to file a FPAS?**

No. If a foreign establishment received the letter of June 24, 2010, it was in error.

- **Who sends the copy of the FPAS statement to the appropriate official of the government of the importing country?**

EPA sends the Foreign Purchaser Acknowledgement Statement and a notice of export to the government of the importing country.

- **What is the scope of the streamlining process for FPAS submission referenced in the letter?**

EPA is developing new procedures that will enable the submission and transmission of the Foreign Purchaser Acknowledgement Statements electronically. The new procedures will be announced on EPA's web site, in the Office of Pesticide Program's electronic newsletter, and in another direct mailing to pesticide production establishments. [Sign up for the electronic newsletter](#) to receive the announcement and other pesticide news.

- **Does EPA have concerns about the time delay in Foreign Purchaser Acknowledgement Statement reporting and input into the EPA database?**

The timing for Foreign Purchaser Acknowledgement Statement reporting and input into the EPA information system are based upon available resources.

- **What brought about this notice? Was FDA involved in the process that brought about this notice?**

This notice was a result of an audit by EPA's Office of Inspector General. The Food and Drug Administration (FDA) was not the direct subject of this audit. However, one aspect of the audit involved potential pesticide residues on imported foods, and to that extent, FDA was involved in relevant data review. Since the FDA is responsible for enforcing U.S. pesticide residue tolerance (maximum legal residue) levels, any new information related to the import of foods that may contain unregistered pesticide residues will be provided to FDA.

- **What is the scope of the labeling clarifications referenced in the letter?**

The labeling changes are not substantive; they distinguish statements that relate to unregistered products from those that relate to registered exported pesticides.

- **Does “unregistered pesticide” refer to an unregistered formulation which has no uses in the U.S., or does it also include unregistered uses of registered formulations?**

It refers to both. Because registration is specific to uses, “unregistered pesticide” refers to unregistered uses of any pesticide formulation, regardless of whether or not the formulation is registered for other uses in the United States.

- **I have several disinfectant registrations in Canada, products that are manufactured in Canada and distributed only in Canada. If I import the finished disinfectant products into the U.S. and then ship to our Canadian customers from our warehouse in the States, would an FPAS be required?**

Yes, this situation is covered by [PR Notice 99-1, *Import of Unregistered Pesticides Intended for Export*](#).

- **If I want to manufacture Canadian disinfectants at our EPA-registered facility in the U.S., and ship them directly to our Canadian customers would an FPAS be required?**

Yes, this is considered an export of an unregistered product from the United States.

- **If the disinfectants I manufacture are chemically very similar to those registered in the U.S. by EPA and make virtually the same efficacy claims as EPA-registered disinfectants, are these products considered to be unregistered? Is an FPAS required?**

If EPA has not reviewed and assigned a pesticide registration number to the pesticide products you manufacture, then yes, they are unregistered and require the submission of Foreign Purchaser Acknowledgement Statements if they are exported from the United States.

- **Are Work-In-Progress products (those that are not labeled with the final label before being shipped, and will be labeled with the final label in the country where they are being shipped) considered unregistered products for the purpose of the foreign purchaser acknowledgement statement?**

The requirement for Foreign Purchaser Acknowledgement Statements apply to any “unregistered pesticides,” regardless of the terms manufacturers might use internally to describe their products, such as “Work-In-Progress products.” If your products are pesticides and are unregistered, then the requirements for submission of Foreign Purchaser Acknowledgement Statements apply.

- **Can we send the FPAS to a U.S. address for a product that will be exported, or must we send it to the foreign address? If we get an email address, can we submit by email, and receive the acknowledgement by email?**

No, the Foreign Purchaser Acknowledgement Statements must be signed by the foreign purchaser in the country of import. Email submission options are being considered as part of

the new electronic reporting system, but are not accepted currently.

- **What are the label specifications for unregistered pesticides? Does the “Not Registered for Use in the U.S.” statement have to have a certain type, size, or placement? Can the label say “Made in the U.S?”**

There are no type or size specifications in the regulation, but the statement must be prominently displayed in English and the appropriate foreign language. EPA does not review and approve labels for unregistered pesticides, but you are welcome to refer to the [requirements for registered products in 40 CFR 156 \(iii\)](#) as guidance. You are not prohibited from using “Made in the U.S.” on the label, since the label will already include the name and address of the registered production establishment.

- **I have a pesticide product that was voluntarily cancelled. Under the terms of the cancellation order EPA has allowed 24 months to sell off existing stocks of the product. Does the Foreign Purchaser Acknowledgement Statement apply when the period of selling off existing stocks expires, or before hand?**

The FPAS requirement applies to any pesticide that is not registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). When EPA cancels a registration, the continued sale of existing stocks (i.e., product that was already made but had not yet been sold) is a condition specified in the cancellation order. Although this sale is permitted under FIFRA, the pesticide itself is technically unregistered, so export of such existing stocks would require a Foreign Purchaser Acknowledgement Statement.

- **Is there an FPAS form or template that I should follow? What are the required data elements that should be included?**

EPA has not published a FPAS form or template. However, [40 CFR 168.75](#) states:

(1) *Contents of the purchaser acknowledgement statements.* The purchaser acknowledgement statement must include the following information in a format that is clearly understandable:

- (i) Name, address, and EPA identification number, if applicable, of the exporter.
- (ii) Name and address of the foreign purchaser.
- (iii) Identity of the product and the active ingredient(s), including:
 - (A) The Chemical Abstract Services (CAS) Registry number for each active ingredient.
 - (B) The chemical nomenclature for each active ingredient as used by the International Union of Pure and Applied Chemists (IUPAC).

(C) Other known chemical or common names; or if the export involves a research product, a code name or identification number that can be used by EPA to identify the product from the exporter's records. If a code name or identification number is used, additional information must be attached to the certification statement submitted with the purchaser acknowledgement statement which will enable EPA to identify the product. This attached information may be claimed as confidential, and EPA will not forward this information with the purchaser acknowledgement statement to foreign governments.

(iv) If known or reasonably ascertainable, the country or countries of final destination of the export shipment, *i.e.*, where the exported pesticide is intended to be used, if different from the country of the foreign purchaser's address.

(v) A statement that indicates that the foreign purchaser understands that the product is not registered for use in the United States and cannot be sold in the United States.

(vi) The signature of the foreign purchaser.

(vii) The date of the foreign purchaser's signature.

- **If I occasionally ship small quantities of unregistered pesticides overseas to support client registration efforts in those countries, for research purposes only, am I still required to obtain a Foreign Purchaser Acknowledgement Statement?**

Your exports may be considered to be “Research and Development” products, which are exempt from the Foreign Purchaser Acknowledgement Statement regulation, though there are other reporting requirements. Please see [40 CFR 168.75](#) and scroll down to (b)(5) *Research and development products* to determine if your product meets the specifications for an R&D product.

- **Does FIFRA 17(a) apply to those that import unregistered pesticides only to repackage and export?**

Yes, a Foreign Purchaser Acknowledgement Statement must be filed. [PR.99-1, Import of Unregistered Pesticides Intended for Export](#) covers this situation and specifies that the requirements of 17(a) must be met.

- **How does EPA define the term “pesticide?”**

Pesticide is defined by statute. See the [online definition of the term “pesticide”](#) for more information.

- **What is meant by “export?” Outside of the state? Outside the U.S.?**

Export is not defined in federal pesticide law. EPA uses the term to describe the sale or distribution of a pesticide or device from a location in the U.S. to a location in another country. Shipping to U.S. territories or to other states is not considered “exporting.”

- **What EPA address do I use to submit the FPAS?**

The FPAS can be sent to either of the following addresses:

1. By US Postal Service:

US Environmental Protection Agency
Office of Pesticide Programs (7506P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460
Attention: Foreign Purchaser Acknowledgment Statement

2. By Commercial Courier:

US Environmental Protection Agency
Office of Pesticide Programs (7506P)
2777 S. Crystal Drive
Arlington, VA 22202
Attention: Foreign Purchaser Acknowledgment Statement

- **Does EPA accept electronic submissions of the FPAS, such as a pdf? If so, what email address do I send it to?**

EPA does not accept electronic Foreign Purchaser Acknowledgement Statement submissions at this time, but a new electronic submission system that will accommodate the pdf format is under development. The new procedures will be announced on EPA’s web site, in the Office of Pesticide Program’s electronic newsletter, and in another direct mailing to pesticide production establishments. [Sign up for OPP’s electronic newsletter](#) to receive the announcement and other pesticide news.

- **Do I need to submit FPAS documentation retroactively?**

No.

- **How often do I need to submit the FPAS to EPA (monthly, annually, per-shipment)?**

Foreign Purchaser Acknowledgement Statements can either be submitted per-shipment to EPA or after the first submission, annually to EPA. For more information, please see [40 CFR 168.75](#) and scroll down to (c)(2) *Reporting option*.