FIFRA Import Program Requirements Webinar Frequently Asked Questions

EPA has held webinars in the past for importers and brokers on the import program requirements under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA" or "Act"). Below are questions frequently asked by the trade community about the requirements and EPA's responses. In addition to the responses provided below, importers and their brokers can refer to the <u>Tips and Guidelines for filing EPA Notice of Arrival (NOA) for Pesticides and Devices</u> ("ACE Tips and Guidelines for Filing EPA Pesticides").

Q1: In the event the Partner Government Agency (PGA) Message Set responds with an "Under review" due to a typo, can an importer or the importer's agent submit a PGA Message Set data update, or will the importer or the importer's agent have to work directly with EPA to correct such an error?

A1: Importers or their authorized agents can make corrections (e.g., typos) to their filings any time before CBP issues a "release" of the entry filing. The "Under Review" message does not typically apply to filing errors like "typos." For pesticide filings, the "Under Review" message is sent just before a "Document Required" is sent for Disclaim C and D filings. A "Documents Required" message only applies to these filings. CBP is automatically notified and will check the filing to make sure the submission includes an uploaded authentic and complete EPA-signed NOA. If the importer or their authorized agent filed correctly and EPA indicated on the signed NOA that release was appropriate, a "release" will be issued by CBP.

The majority of filing messages are "reject" or "hold intact." A "reject" message indicates the filing has not provided the information needed in one or more data fields for ACE to process the filing and the filing error is identified in the "reject" message. The importer or their authorized agent will need to provide the required data in order for ACE to <u>process</u> the filing. If the filing is complete for processing but does not provide valid information, a "hold intact" message either ACE-generated or placed by EPA will be sent. The merchandise in question is held intact pending EPA's determination on whether the merchandise may proceed into the commerce of the United States.

For making corrections to filings that receive an "hold intact" message, the importer or their authorized agent can correct the filing directly in ACE and submit a correction (CA) filing in order to receive an "accept" and "may proceed" before the goods arrive at the Port of Entry. If the importer or their authorized agent do not understand what needs to be corrected, they may contact the appropriate EPA regional import coordinator for assistance. A list of the EPA FIFRA import coordinators may be found here: https://www.epa.gov/compliance/regional-contacts-questions-concerning-notices-arrival-epa-form-3540-1. As a general rule, EPA NOAs, whether filed by Message Set or in paper form, should be filed well in advance of arrival of the shipment at the port of entry in order to allow for corrections. ACE does not allow corrections 10 days after arrival.

Q2: Can an importer or the importer's agent file an EPA NOA for pesticides arriving at any port of entry? If yes, can the importer or importer's agent file the EPA NOA electronically for pesticides arriving at any port of entry?

A2: Yes, importers or their authorized agent can file an EPA NOA for pesticides arriving at any port of entry. However, importers filing an EPA NOA using EPA Form 3540-1 (Option 1 or 2 from ACE Tips for Filing EPA Pesticides), must mail their completed form to the Regional office associated with the port of entry where the merchandise will be imported for completion by that Region. Similarly, filing a hard copy of EPA Form 3540-1 by submitting it with the shipment (Option 2) can only be done at the port of entry.

Under the electronic alternative, importers or their authorized agent can submit pesticide data required by EPA Form 3540-1 through the PGA Message Set, along with an image of the label that is on the product being imported, through ACE's Document Image System (DIS) for the port of entry where the merchandise will be imported. However, for EPA pesticide filings, you can't file electronically for all entry type through ACE.

Q3: How do importers handle the EPA producer establishment number for pesticide samples that are imported for research [testing]?

A3: FIFRA section 7(a) states that "[n]o person shall produce any pesticide subject to this subchapter or active ingredient used in producing a pesticide subject to this subchapter in any State unless the establishment in which it is produced is registered with the Administrator." Pursuant to 40 C.F.R. § 167.20(a)(3), foreign establishments that produce any pesticides for import into the U.S. are subject to this requirement. Therefore, the importer of any pesticide, whether it is registered or unregistered, must provide the address of the shipping establishment and the EPA establishment number of the establishment where the pesticide was produced as part of the EPA NOA information filed either on the Form 3540-1 or via the EPA Pesticides ACE PGA Message Set.

If the pesticide being imported is unregistered and intended for research testing, the importer must indicate whether the research testing is authorized under an experimental use permit (EUP) and include the relevant EUP number. See 40 C.F.R. § 152.30(c)(1).

If the research testing is presumed not to need an EUP pursuant to 40 C.F.R. § 172.3(b), the importer must indicate that in the EPA NOA information, describe the specific intended use of the pesticide, and submit any supportive or explanatory documentation. See 40 C.F.R. § 152.30(c)(2).

Q4: If a product is making an antibacterial claim, does that automatically make it a pesticide? For example, antibacterial soap.

A4: No, not all products for which antibacterial claims are made are pesticides as defined and regulated under FIFRA. Pursuant to FIFRA section 2(u), a "pesticide" is defined, in part, as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any <u>pest</u>..." (underline added). Pursuant to section 2(t), the term "pest" means "(1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other

living animals) which the Administrator declares to be a pest under [section 25(c)(1)]" (underline added). Products meeting these definitions are regulated by EPA under FIFRA.

Products not meeting these definitions may be regulated by other agencies, for example, the Food and Drug Administration (FDA). Examples of products with antimicrobial uses regulated by FDA include cosmetics, beverages, processed food, drugs, and animal feed. For a more detailed description of the claims and uses of antimicrobial products that would be regulated by EPA, FDA or another agency, or by more than one, see Chapter 18 of the EPA's Pesticide Registration Manual. For assistance determining whether a cleaning product is a pesticide, see the EPA webpage: Determining If a Cleaning Product Is a Pesticide Under FIFRA

Q5: We are a Customs Broker in the Northern Border environment with a short timeframe to process shipments before the freight arrives for clearance. If we need to have EPA-signed NOAs to upload in DIS, are the importers able to submit EPA NOAs for a product and have it cover a blanket period of imports?

A5: No. "Blanket" NOA filings are not allowed. A separate EPA NOA must be submitted for each pesticide product or pesticide device in each shipment. If the importer is importing the same type of pesticide product in three separate shipments, e.g., one arriving Monday, one arriving Tuesday, and one arriving Wednesday, the importer or their authorized agent must file one EPA NOA for each day's shipment (three total EPA NOAs). 19 CFR 12.113(a). Note also that if the importer is importing two different kinds of pesticide products in one shipment, the importer or their authorized agent must submit two EPA NOAs (completed and signed by the importer) for EPA to determine if the import is compliant prior to that shipment arriving in the United States. Please refer to the ACE Tips and Guidelines for Filing EPA Pesticides, which provides full instructions for filing EPA NOAs.

Q6: If a product shipment is refused entry into the United States and must be exported or destroyed, how much time does the importer have to export or destroy the shipment?

A6: CBP regulations at 19 C.F.R. § 12.114 state that, "[t]he port director will cause the destruction of any shipment refused delivery and not exported by the consignee within 90 calendar days after notice of such refusal of delivery." Importers or their authorized agent should contact their CBP client representatives regarding the disposition of a refused shipment as soon as possible after refusal of entry.

Q7: What program code should be used in filing a disclaim code for pesticide imports?

A7: Determining which Government Agency Program Code to select will depend on whether the merchandise is a pesticide, pesticide device, or other regulated product. The available Government Agency Program Codes are:

PS1 – Registered pesticides PS2 – Pesticide – Devices¹

¹ FIFRA-regulated pesticide devices pursuant to FIFRA Section 2(h).

PS3 - Pesticides - Other²

Disclaim Codes are used to indicate the reason a filer has not filed a full PGA Message Set (constituting an EPA NOA) in ACE. The possible reasons and associated Disclaim Codes are:

A = product is not regulated by this agency

C = data filed through other agency means

D = data filed through paper

In general, if an importer has determined an NOA is not required to import its merchandise, then Disclaim Code A may be selected. Using Disclaim Code A indicates to EPA and CBP that the importer has determined the merchandise in question is not intended for use as a pesticide or a pesticide device, or is a pesticide exempt from the requirements of FIFRA, and thus the EPA NOA filing requirement does not apply. Note that the improper use of Disclaim Code A on products for which the importer is required to file an EPA NOA may result in the issuance of a Notice of Redelivery of the merchandise to the port for export and may result in an enforcement action against the importer or their authorized agent by either CBP and EPA or both.

There may be a scenario where merchandise's HTS code is flagged in ACE³ as a pesticide (EP5) that may be regulated by EPA, even in cases where the importer has determined that the merchandise is not a pesticide or pesticide device that requires an EPA NOA. In that circumstance, the importer or their authorized agent is required *to file a partial EPA PGA Message Set*, including the Government Agency Code, Government Agency Program Code, and Disclaimer Indicator, but not required to enter a full PGA Message Set. This partial PGA Message Set will not constitute an EPA NOA. In this scenario where the merchandise is not a FIFRA-regulated pesticide or pesticide device, the filer may select Government Agency Program Code PS3, and Disclaim Code A.

In any Disclaim Code A filing, the importer is advised to check whether a TSCA filing is required for import of the merchandise. Contact information for determining TSCA filing requirements in the <u>ACE</u> Tips for Filing EPA TSCA.

If an importer or their authorized agent is filing for entry by uploading an image of an EPA-signed NOA Form 3540-1 in ACE (Option 1 in the Tips for Trade), then Disclaim Code C and whichever Program Code applies to the products should be selected. If filing for entry by sending a physical paper EPA-signed NOA Form 3540-1 with the import shipment, then Disclaim Code D (Option 2 in the ACE Tips for Filing EPA Pesticides) and whichever Program Code applies to the products should be selected.

Q8: During the presentation, EPA noted a negative TSCA certification is no longer needed for pesticide shipments, but the presentation covered TSCA in general. Can EPA clarify if a TSCA certification is no longer needed for both "positive" and "negative" or is it just the negative TSCA certification that is no longer needed?

<u>code-agency-program-cross-reference</u>

² FIFRA-regulated pesticides that are not registered with EPA and chemicals which can be used as pesticides, but which are not imported for such use and are not shown on the Index of Pesticide Products located in the Environmental Protection Agency's handbook entitled Recognition and Management of Pesticide Poisonings.

³ See CBP's ACE Agency Tariff Code Reference Guide at https://www.cbp.gov/document/guidance/agency-tariff-

A8: Effective March 21, 2017, the negative TSCA certification is no longer needed when filing an EPA NOA for a pesticide or pesticide device. A positive TSCA certification is still required for a TSCA chemical substance, in accordance with regulations at 19 CFR 12.118-12.127 and 127.28(i).

Q9: When disclaiming TSCA on a pesticide product, should the importer or importer's agent use disclaim code B or A?

A9: File a Disclaim Code B. For more guidance, contact the TSCA hotline (202-554-1404 or tscahotline@epa.gov) to determine if a positive or negative TSCA certification is needed. If a TSCA certification is not required, the hotline can help the importer, or their authorized agent determine which disclaim code is appropriate.

Q10: In the past, our client has imported water filters that have been determined to be regulated by EPA, but these shipments have never been flagged in ACE for EPA Pesticides requiring an EPA NOA. Should we contact EPA to ask questions on requirements for water filters?

A10: Importers are responsible for determining whether their products are regulated by EPA. ACE is not designed to perform a full product review for each entry filing or to recognize each HTS code that could be associated with a FIFRA-regulated product.

Water filters that are intended for use against microbial, bacterial, or other pests as defined by FIFRA are regulated by EPA. Some may be regulated as pesticides and some as pesticide devices. Products that incorporate a substance to achieve their intended pesticidal effect are pesticides, e.g., products containing an antimicrobial (germ-killing) or bacteriostatic (slowing or inhibiting growth of germs) agent. Products that remove or filter pests by physical or mechanical means are pesticide devices. More information is provided at the links below:

<u>Pesticide Registration Manual: Chapter 4 – Additional Considerations for Antimicrobial Products</u> <u>Pesticide Registration Manual Chapter 13 – Devices</u> <u>Pesticide Devices – A Guide for Consumers</u>

The importer or their authorized agent may also contact the EPA regional office having jurisdiction over the port of entry where the shipment is to arrive. The EPA pesticide import contacts can be found at https://www.epa.gov/compliance/regional-contacts-questions-concerning-notices-arrival-epa-form-3540-1.

Q11: Do In-bond shipments (Transportation & Exportation from Mexico to Canada for example) require EPA NOA filing?

A11: Yes, an EPA paper NOA is required. "In-bond" shipments that have "arrived" in the United States, i.e., have been imported, and are in transit through the United States to another country meet the definition of "to distribute or sell" under FIFRA. The importer or their authorized agent must submit an EPA paper NOA for the shipment prior to arrival to the United States.

Q12: When will EPA/ACE go into effect for all ports?

A12: Filing through ACE to satisfy EPA NOA requirements is currently available in all ports of entry. On September 30, 2016, CBP amended the FIFRA import regulations at 19 C.F.R. part 12 to include the

option of filing an electronic alternative to the paper NOA form with entry information via ACE. See 81 Fed. Reg. 67,140 (Sept. 30, 2016).

Q13: EPA Region 2 (New York) still requires a paper NOA be submitted. When will they use DIS?

A13: Importers or their authorized agents have the option of filing the paper EPA NOA (EPA Form 3540-1) or its electronic alternative in ACE. Filers can submit supporting documentation and a paper EPA-signed NOA through ACE's DIS by uploading an electronic version of these document (i.e. PDF or JPEG). All EPA Regions, including Region 2, allow filing an EPA NOA either by paper or the electronic alternative in ACE. Please refer to the ACE Tips and Guidelines for Filing EPA Pesticides, which provides full instructions for filing EPA NOAs.

Filings for most, but not all, entry types can be accomplished through ACE. If the importer or their authorized agent is unclear on how to best file, contact the appropriate EPA regional pesticide imports contact for the state/territory where the shipment is to arrive.

Q14: Is there a list to find out what products fall under pesticides?

A14: No, EPA does not maintain a list of substances or products that would meet the definition of a pesticide as defined under FIFRA. However, EPA does maintain three searchable databases of *registered* pesticide products at this link: Search for Registered Pesticide Products. The importer or their authorized agent may review the below resources for the statutory definition and regulatory criteria used to determine whether a product is a pesticide requiring registration under FIFRA:

<u>Pesticides</u>
Basic Information about Pesticide Ingredients

Q15: Is an EPA NOA required for sample materials?

A15: Yes, if the sample material is intended for use as a pesticide or pesticide device, then it is regulated by FIFRA, and an EPA NOA is required (unless the pesticide is exempt from regulation, e.g., a minimum risk pesticide). This is true for registered and unregistered pesticides. There is no exemption from the NOA requirement merely because a pesticide is in a sample size or small in quantity or volume.

The importer or their authorized agent may contact the EPA regional pesticide import coordinator for the state/territory where the shipment is to arrive with any specific questions. The EPA regional pesticide import contacts can be found at https://www.epa.gov/compliance/regional-contacts-questions-concerning-notices-arrival-epa-form-3540-1.

Q16: If there is a CBP release but not an EPA release, can we move the freight to the importer's premises just like an FDA shipment? If so, is there a distance restriction from the entry port?

A16: According to CBP's ACE Cargo Release/PGA Message Set Glossary, which can be found at this link, "[a] "CBP Release" message indicates that CBP has determined that the merchandise may be released from CBP custody. All merchandise released by CBP is released conditionally, as it is subject to recall through the issuance of a Notice of Redelivery. Merchandise that is regulated by one or more PGAs may not proceed into U.S. commerce until CBP releases the merchandise and all PGAs that regulate the merchandise have issued a may proceed message." Regarding the question of whether there are any

"distance restrictions from an entry port," while close proximity is encouraged, there is no specific requirement.

Q17: Can we get clarification on filing the EPA Pesticides ACE PGA Message Set if we transmit the PGA data elements? Why do we need to submit screenshots of the EPA PGA information through DIS?

A17: The importer or their authorized agent does not need to submit screenshots of the EPA Pesticides ACE PGA data elements. To file an electronic EPA NOA through ACE, the importer or their authorized agent should simply type into the screens provided in their software and transmit what is referred to as the PGA Message Set and upload an image of an on-product market label (final printed label) to DIS (tagged as EPA04-Pesticide Label). For more detail on how to file, the importer or their authorized agent should refer to their software provider's training and guidance, and the ACE Tips for Filing EPA Pesticides document and the FAQs links within the document.

Q18: If we import only chemicals, can we just file a TSCA statement (negative or positive) as appropriate for all our imports?

A18: If the importer's chemical imports do not meet the definition of pesticide or pesticide device, then filing an EPA NOA is not required. Contact the TSCA hotline at tsca-hotline@epa.gov to determine whether a positive or negative TSCA certification is needed. Other regulatory agencies, such as FDA, may also have import requirements for chemicals.

Q19: We have a question about the TSCA statement. Do we still have to retain a TSCA statement for our files, but a hard copy does not have to be submitted in DIS with an NOA?

A19: The TSCA statement is part of the entry record. According to 19 C.F.R. § 163.4, recordkeeping provisions, the importer maintains records for five (5) years from the date of entry, if the record relates to an entry. Contact CBP for any other questions/information regarding recordkeeping requirements.

Q20: Must the importer or their authorized agent submit a PGA Message Set filing if an HTS code is not flagged for pesticides or pesticide devices?

A20: Yes. Pursuant to CBP requirements, the importer or their authorized agent's filing software *must allow* for a filing to be made whether or not an HTS code is flagged [EP5]. Importers are independently responsible for determining whether they have any FIFRA obligations or obligations under any other Federal law. If the goods are pesticides or pesticide devices, the filing is required. Importers or their authorized agents should check with their software provider if they are having a problem.

Q21: What LED products would be regulated as pesticides under FIFRA? We had an LED light strip Harmonized Tariff Schedule of the United States (HTSUS) number get flagged as a possible EPA3 [Note: EPA3 is not a valid flag. The EP3 flag is for a Vehicle and Engine Declaration. An EPA03 is a tag for an image in DIS so EPA can see it. The HTSUS code flag for a Pesticide or Pesticidal Device is [EP5]].

A21: LED lightbulbs packaged solely for use as lightbulbs are not subject to FIFRA. LED lightbulb products that make claims that the bulb is part of a pesticidal device intended to trap, destroy, repel or mitigate a pest, may be considered a pesticide device that is regulated by FIFRA. If the importer believes their product was flagged as FIFRA-regulated [EP5] but is not FIFRA-regulated, then the importer or their

authorized agent may follow the filing procedure outlined in Answer 7 above. Check the following website for additional information on pesticide devices: <u>Pesticide Devices: A Guide for Consumers</u>

