### October 2022 Refresher for NCBFAA on EPA Import Programs Response to Webinar Questions

On October 31, 2022, the Environmental Protection Agency (EPA) hosted a free webinar for the National Customs Brokers and Freight Forwarders Association of America (NCBFFA). The webinar provided the NCBFAA members an overview of our import programs (TSCA, FIFRA, CAA (V&E and ODS)) and their filing requirements for entries in the U.S. Customs Border Protection (CBP) Automated Commercial Environment (ACE). This document solely answers questions raised during the October 31, 2022 webinar and the specific unique circumstances raised during that webinar. Nothing in these responses is meant to replace or revise applicable CBP or EPA guidance, regulatory provisions, the Code of Federal Regulations, the Federal Register, or statute. The EPA reserves the right to act at variance with this document, including changing any policy or guidance referenced within at any time without public notice. This document does not constitute new policy or guidance from the EPA, nor should regulated individuals expect this document to be updated to reflect any future changes in applicable law or Agency policies.

Importers and their brokers should refer to the regulations and resource materials and related Agency guidance material links provided in the Additional Resources section below. Click <a href="here">here</a> to view the October 31, 2022, webinar recording.

#### General Filing Questions and Answers (may apply to some or all import programs)

## Q1: When we file these entries and are required to include the supplier and ocean/air carrier PGA contact information, who should we specifically ask for when we request this information from the carrier and supplier if they state they do not have a POC?

A1: The importer or their authorized broker should provide the same supplier and ocean/air carrier point of contact information (provided in the notice of arrival issued by the carrier) as part of their <u>entry filing</u> submission to CBP. If the carrier or supplier does not provide a point of contact, provide the name, and contact of an employee authorized to act as an agent for the supplier(manufacturer) or carrier.

### Q2: Recently we've had a problem receiving a status message from EPA via ACE. Has this issue been resolved?

A1: EPA believes this issue has been resolved by CBP. Filers should let their CBP Client/Automated Broker Interface (ABI) representative know if they are not receiving status messages.

#### Q3: Is there a current list of EPA-regulated products by HTS number?

A3: No, there is no such list. Brokers can contact their software provider who has direct access to the latest HTS codes that have been flagged as "may be required" by EPA. For questions on whether a commodity is regulated by EPA, please check the filing tips sheets for each program on who to contact.

#### Q4: What is the EPA document Code used in DIS?

A4: The following lists the tags for any DIS images uploaded for the following EPA import programs so that EPA can view the documents in ACE. See CBP's "DIS XML Implementation Guide"

#### **Important Notes:**

1) The code, EPA07, is used with an email to DIS

2) For labels, EPA\_NON\_OBJECTION\_NOTICE is used when submitting XML via ABI to DIS.

Pesticides
EPA03 EPA\_3540\_1\_NOA
EPA04 EPA PESTICIDE

Toxic Substances EPA06 EPA\_TSCA

HFCs/ODS
EPA07 EPA\_NON\_OBJECTION\_NOTICE
EPA08 EPA IMPORT OF ODS

VNE
EPA05 EPA\_V\_E\_EXEMPTION
EPA02 EPA\_3520\_21\_IMPORT\_OF\_MOTOR\_V\_E\_O FF\_ROAD
EPA01 EPA\_3520\_1\_IMPORTER\_OF\_MOTOR\_V\_E\_ ON\_ROAD

### Q5: What is the best way to "resend" or "update" data in the EPA section when we have an "Under review" message.

A5: Importers or their authorized agents can amend (e.g., correct typos or other errors) their filings any time before CBP issues a "release" of the entry filing. However, the "Under Review" message does not typically apply to filing errors like "typos." For example, an "Under Review" for pesticide filings is sent just before a "Documents Required" is sent for Disclaim Code C and D filings. A "Documents Required" message only applies to these filings. For other programs such as ODS, HFCs, and Vehicle and Engines filings, an 'Under Review' may mean there are filing errors (which may include 'typos.')

Most filing messages are "reject" or "hold intact." A "reject" message indicates the filer 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 for ACE to process 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 to receive an "accept" and "may proceed" before the goods arrive at the Port of Entry. ACE does not allow corrections 10 days after arrival. If the importer or their authorized agent do not understand what needs to be corrected, they may contact the appropriate EPA Client/ABI Rep for assistance.

#### FIFRA Import Program Questions and Answers

EPA regional offices continue to accept completed and signed paper EPA Forms 3540-1 Notice of Arrival of Pesticides and Devices (NOA) from importers or their authorized agents via email. Filers should send a scanned image of the signed NOA to the Region and mail a hard copy with wet ink signature to the regional office. This is a temporary process and if the Agency intends to terminate the temporary

process, the regulated community will be notified at least seven days prior to terminating the temporary process.

#### Regulatory and Registration Questions

Q1: Is there an EPA e-mail address or contact number that we can provide to an importer so that they can check with EPA whether their products' claims fall within the device or pesticide definitions?

A1: If importers are unsure whether their product is regulated under FIFRA as a pesticide or a pesticide device, the importer may submit their questions to <a href="mailto:opp-fifra\_jurisdictional\_issues@epa.gov">opp-fifra\_jurisdictional\_issues@epa.gov</a>, or may submit a request for a regulatory determination from EPA. The instructions for submitting a request and information on the associated fees can be found at <a href="https://www.epa.gov/pesticide-registration-manual-chapter-13-devices#obtain">https://www.epa.gov/pesticide-registration-manual-chapter-13-devices#obtain</a>.

**Q2:** Is there a personal exemption for importing small amounts of pesticides or pesticide devices?

A2: There is no exemption from the NOA requirement merely because a pesticide is small in quantity or volume.

Q3: Does an EPA "hold intact" status message requires merchandise be kept within the port of entry? A3: No, the "hold intact" is not restricted to keeping the merchandise within the port of entry. Merchandise can be transported to the delivery location or location of goods for examination where the merchandise must remain held intact (no distribution or movement of the goods beyond the holding location) pending EPA's determination on whether the merchandise may proceed into the commerce of the United States.

Q4: If there is a product we know is regulated under FIFRA and is not compliant, but the client did not file an NOA, how should we proceed with the filing? Should we reach out to EPA prior to filing to discuss how to remove those goods? Or file entry with a certain message set?

A4: Importers and their authorized agents are encouraged to contact the appropriate EPA official as soon as possible after learning of a non-compliant shipment, especially before filing for entry with CBP. FIFRA § 12 establishes violations that may be attributed to "any person" engaging in violative conduct, including importers or their authorized agents. 7 U.S.C. § 136j.

If the importer or their authorized agent has regulatory questions concerning pesticide or pesticide device and/or whether they are required to file an EPA NOA after reading the resource materials provided, the importer or their authorized agent should contact the appropriate EPA regional pesticide imports specialist for the state/territory for the port of entry. The EPA regional pesticide import contacts can be found at <a href="https://www.epa.gov/compliance/regional-contacts-questions-concerning-notices-arrival-epa-form-3540-1">https://www.epa.gov/compliance/regional-contacts-questions-concerning-notices-arrival-epa-form-3540-1</a>

#### Notice of Arrival of Pesticides and Devices (NOA) Filing Requirements

#### Q1: Are paper NOAs still required?

A1: Importers or their authorized agents still have the option of filing the paper EPA NOA (EPA Form 3540-1) in accordance with CBP regulations at 19 C.F.R. § 12.112. 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). Importers should note that filing an electronic NOA in ACE is not available for admissions into Foreign Trade Zones (FTZs), Customs bonded warehouses, or shipments being transported in-bond for export at this time. Therefore, in those circumstances the importer or their authorized agent must submit to EPA a completed paper NOA.

For full instructions for filing EPA NOAs, please refer to the <u>ACE Tips and Guidelines for Filing EPA</u> Pesticides.

#### Q2: How far in advance of vessel arrival should we file the NOA?

A2: EPA NOAs, whether filed by the EPA Pesticides PGA Message Set or by paper using EPA Form 3540-1, should be filed well in advance of arrival of the shipment for ample time for review and planning for the final disposition of the shipment. [Note: For ocean shipments, the NOA can be filed at least 30 days prior to arrival or when the goods are loaded on the vessel.]

#### Q3: Is there a blanket EPA Form 3540-1?

A3: No. "Blanket" NOA filings are not allowed. A separate EPA NOA must be submitted for each unique pesticide product or pesticide device in each shipment. The following scenarios illustrate this concept. For further guidance, please refer to the <u>ACE Tips and Guidelines for Filing EPA Pesticides</u>, which provides full instructions for filing EPA NOAs.

#### Scenario 1:

Separate entries will be filed for three arriving shipments of the same pesticide product. Each shipment contains two shipping containers of the pesticide product. Three NOAs must be submitted, one for each entry. An entry's NOA should be filed prior to the arrival of the first shipping container in the entry.

#### Scenario 2:

Entry will be filed for a single shipment that will include quantities of three unique pesticide products. A total of three NOAs must be filed prior to arrival, one for each pesticide product in the shipment.

### Q4: Do containers being imported for cleaning and then re-used to export a pesticide require an NOA?

A4: If the returned containers <u>do not</u> contain any pesticide residues at the time of importation into the U.S., <u>an NOA is not required</u>. Requirements for the management, reuse, and disposal of depleted containers (including refilling and repacking) are set forth at 40 C.F.R. part 165, which were promulgated in accordance with FIFRA § 19.

If the returned containers <u>do</u> contain pesticide residues at the time of importation into the U.S., <u>an NOA is required</u>. FIFRA §17 and CBP-promulgated regulations set forth at <u>19 C.F.R. §§ 12.110-12.117</u> require that any importer of a "pesticide" (including any amount of pesticide, whether registered or unregistered) subject to FIFRA file a NOA prior to arrival of the shipment. If the returned containers contain unregistered pesticide or unregistered pesticide residue, they may only be imported if the shipment meets the criteria of one of the exceptions in <u>40 C.F.R. § 152.30</u> permitting the transfer, distribution or sale of unregistered pesticides (e.g., transfer between registered establishments; distribution or sale under an experimental use permit; transfer solely for export; distribution or sale under an emergency exemption; or, transfer for disposal in accordance with FIFRA § 19 or EPA order). If the unregistered pesticides or pesticide residues are being imported solely for the purpose of formulation or packaging for subsequent export to a foreign purchaser, the import must meet the conditions set forth in FIFRA § 17(a) which have been interpreted by the EPA in <u>Pesticide Registration Notice (PRN) 99-1: Import of Unregistered Pesticides Intended for Export</u> (Mar. 1, 1999) (<a href="https://www.epa.gov/pesticide-registration/prn-99-1-import-unregistered-pesticides-intended-export">https://www.epa.gov/pesticide-registration/prn-99-1-import-unregistered-pesticides-intended-export</a>).

Q5: What happens when we have an entry that has been issued a may proceed but the importer receives a notice from EPA requesting additional information about the product when the importer already distributed the product? What are the steps the filer should take to stay compliant?

A5: The importer or their authorized agent should contact the appropriate EPA regional pesticide imports contact for the state/territory for the port of entry. The EPA regional pesticide import contacts can be found at <a href="https://www.epa.gov/compliance/regional-contacts-questions-concerning-notices-arrival-epa-form-3540-1">https://www.epa.gov/compliance/regional-contacts-questions-concerning-notices-arrival-epa-form-3540-1</a>

**Q6:** If the importer files the NOA with EPA, is there any action the broker needs to take for NOA? A6: Importers are independently responsible for determining whether they have any FIFRA obligations. However, both the importer and broker are responsible for ensuring they are meeting the Federal laws and regulatory requirements governing imports and exports of pesticides and pesticide devices. Upon entry of a shipment of pesticides or pesticide devices into the U.S., and concurrent with the filing of the entry documentation, CBP must be in receipt of a completed NOA, which includes **EPA's signature and recommended disposition** with respect to the shipment.

**Q7:** Is the NOA required at the arrival on US soil or arrival at the port of clearance?

A7: "Arrival" refers to when the shipment (regardless of mode of transportation) physically crosses into the United States territory, which includes Foreign Trade Zones.

Q8: What information is required for importing an unregistered R&D pesticide, and what information is required when importing an unregistered pesticide for export?

A8: FIFRA prohibits the importation of unregistered pesticides unless they are exempt from FIFRA regulation, or the import meets one of the exceptions set forth at 40 C.F.R. § 152.30.

Importers are independently responsible for determining whether an exception in section 152.30 applies to their proposed import and they must provide documentation to EPA to support that determination. The EPA regional import coordinator where the pesticide shipment is to arrive will determine, on a case-by-case basis, what kind of information, and how much, is necessary.

#### <u>Unregistered research pesticides</u>:

40 C.F.R. § 152.30(c) sets forth the conditions for the lawful import of unregistered research pesticides, specifically (1) unregistered pesticides for which an experimental use permit (EUP) has been obtained, and (2) unregistered pesticides for which an EUP is not required in accordance with the provisions of 40 C.F.R. § 172.3. If an importer believes it meets the conditions of one of those exceptions and is filing a NOA form, it may check either box 18c or 18d, whichever is applicable, and submit its supportive documentation as an addendum to the NOA form. A duly delegated officer of the importing company, not the broker, should sign the NOA form and the addendum. If the importer files the EPA NOA information electronically using the Pesticides ACE PGA Message Set in ACE, it should use Program Code PS3 with no Disclaim Code, and upload to DIS the documentation that shows which exception in 40 C.F.R §152.30 applies.

Generally, the information included with your paper or electronic NOA should always include an image of the on-product label and all labeling. For a research pesticide, the supportive information submitted should include each of the following:

1. A description of the intended experimental use of the pesticide and where the use will take place (e.g., laboratory tests, field trials) (see 40 C.F.R. section 172.3(b)(1));

- 2. A statement that the producer, applicator, or any other person conducting the research does not expect to receive any benefit in pest control from the pesticide's use (see 40 C.F.R. § 172.3(b)(2);
- 3. A projected date of completion for the experimental use;
- 4. The research pesticide's ultimate destination and the specific points of distribution en route to that destination;
- 5. The plan for disposing of unused stocks of the research pesticide; and
- 6. A statement that the label provided is a true and correct representation of the label that will accompany the research pesticide throughout its distribution in the U.S.

#### <u>Unregistered pesticides intended solely for export:</u>

FIFRA § 17 and 40 C.F.R. § 152.30(d) set forth the conditions for the lawful import of unregistered pesticides for the sole purpose of export that an importer must satisfy. Section 17(a) allows distribution (and importation) of an unregistered pesticide or active ingredient only if the pesticide or active ingredient are intended solely for export and have been prepared or packaged according to the specifications of the foreign purchaser. Section 17(c) of FIFRA establishes requirements pertaining to the importation of pesticides and devices. These requirements are implemented through regulations promulgated by the U.S. Customs and Border Protection (CBP) at 19 C.F.R. § 12.112 - 12.117 and regulations promulgated by EPA at 40 C.F.R. § 152.30(d). The regulations at 40 C.F.R. § 152.30(d) establish conditions that must be met to lawfully transfer, sell, or distribute unregistered pesticides. For additional information, see EPA's Pesticide Registration Notice (PRN) 99-1, Import of Unregistered Pesticides Intended for Export, which can be found at <a href="https://www.epa.gov/pesticide-registration/prn-99-1-import-unregistered-pesticides-intended-export">https://www.epa.gov/pesticide-registration/prn-99-1-import-unregistered-pesticides-intended-export</a>.

In addition to submitting a completed EPA NOA and a copy of the on-product label of the unregistered pesticide product being imported, importers must provide documentation sufficient to show that the product is intended solely for export, a foreign purchaser has been identified, and the product is prepared and packaged according to the specifications of the foreign purchaser. This may be satisfied by submission of:

- A completed Foreign Purchaser Acknowledgement Statement (FPAS), and
- Documentation that identifies the foreign purchaser, the foreign purchaser's product specifications, and the product is intended solely for export.

Or submission of documentation that shows:

- The product is intended solely for export,
- Identifies the foreign purchaser, and
- The product is prepared and packaged according to the specifications of the foreign purchaser.

If an importer believes it meets the conditions of the exception set forth at 40 C.F.R. § 152.30(d) and is filing a NOA form, it may check and complete box 18e and submit its supportive documentation as an addendum to the NOA form. A duly delegated officer of the importing company, not the broker, should sign the NOA form and/or the addendum. If the importer files the EPA NOA information electronically using the Pesticides ACE PGA Message Set in ACE, it should use Program Code PS3 with no Disclaim Code, and upload to DIS the documentation that shows the import meets 40 C.F.R. §152.30(d).

More information on exporting unregistered pesticides and FPAS requirements can be found at <a href="https://www.epa.gov/compliance/importing-and-exporting-pesticides-and-devices#export">https://www.epa.gov/compliance/importing-and-exporting-pesticides-and-devices#export</a>.

#### **Devices Questions**

#### Q1: Does a "part" of a device need an NOA?

A1: If a component or part is being imported as a replacement part or incorporated for further manufacturing and is intended for a pesticidal purpose, it's likely FIFRA regulated if the part is integral to the function of the device. For example, if there is a UV bulb that is being imported as a replacement for a UV air purifier, it may be considered a device, which would require an NOA; EPA would consider claims being made on any labeling and/or intent.

Q2: What constitutes a device? There are some examples of devices that are often overlooked / missed. Trade has run across flea combs/sonic rodent deterrents ...both of which do not flag EPA. A2: A device is an instrument or contrivance that is intended to destroy, repel, trap, or mitigate any pest, including but not limited to rodents, molds, viruses, and bacteria. See FIFRA § 2(h) and 40 C.F.R. § 152.500. While a pesticide incorporates a substance to achieve its pesticidal purpose, a device works through physical or mechanical means (such as electricity, light, sound, or glue). Examples of devices may include water or air filters, ultraviolet light systems, ozone generators, and sound generators. For

more examples, please see Chapter 13 of the EPA's Pesticide Registration Manual (<a href="https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices">https://www.epa.gov/pesticide-registration-manual-chapter-13-devices</a>) and Pesticide Devices: A Guide for Consumers (<a href="https://www.epa.gov/pesticides/pesticide-devices-guide-consumers">https://www.epa.gov/pesticides/pesticide-devices-guide-consumers</a>).

EPA regularly reviews and works with CBP to set 'may be required' flags in ACE for merchandise with HTS codes that may be regulated by EPA (e.g., pesticides (EP5)). Any HTS codes EPA may come across as part of our compliance monitoring review of pesticide or pesticide device shipments are reviewed internally to determine whether an HTS code not currently flagged for EPA falls within the Agency's regulatory purview. Brokers should contact their software provider directly for the latest codes from ACE. If you encounter an HTS code that is not flagged for pesticides or pesticide devices that should be flagged, please contact EPA.

### Q3: Is there an avenue for prototype pesticide/pesticide device products to be imported (i.e., testing purposes) despite it being not registered with EPA.

A3: The lawful avenue for importing unregistered pesticides intended for research or testing purposes is described above at Q&A number 8 of the Notice of Arrival (NOA) Filing Requirements section.

Pesticide devices are regulated by EPA but does not need to be registered with EPA. It does not matter whether a pesticide device is being imported for research or non-research purposes; in any case, if the product meets the definition of a pesticide device set forth in section 2(h) of FIFRA, it may be imported if a NOA is filed prior to arrival and it complies with all FIFRA requirements applicable to devices, including being produced in an EPA registered establishment.

### Q4: Are filters that are only used for filtering/capturing waste from animal environments subject to FIFRA?

A4: Products not intended for a pesticidal purpose are not regulated under FIFRA. A filter intended for pesticidal purposes that incorporates a substance is a pesticide, and a filter intended for a pesticidal purpose that does not incorporate a substance is a device, and both would be subject to FIFRA.

Determining whether a product is subject to FIFRA requirements is made on a case-by-case basis. The specific composition of a product, its intended use(s), and the claims made for it must all be examined to determine whether the product is regulated by FIFRA at all, and if so, whether it is regulated as a pesticide or as a device. If an importer is unsure whether their product is a pesticide, device, or not regulated under FIFRA, the importer can submit a request for a regulatory determination by using PRIA MOO9. Instructions for submitting the request can be found at <a href="https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices#obtain">https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices#obtain</a>. Because PRIA M009 sets forth a fee-for-service application process for requesters to seek formal determinations on whether FIFRA jurisdiction covers particular products, EPA generally does not provide informal answers outside of that process.

#### Q5: Is an air filter for a car engine regulated under FIFRA?

A5: Products not intended for a pesticidal purpose are not regulated under FIFRA. A filter intended for pesticidal purposes that incorporates a substance is a pesticide, and a filter intended for a pesticidal purpose that doesn't incorporate a substance is a device, and both would be subject to FIFRA.

Determining whether a product is subject to FIFRA requirements is made on a case-by-case basis. The specific composition of a product, its intended use(s), and the claims made for it must all be examined to determine whether the product is regulated by FIFRA at all, and if so, whether it is regulated as a pesticide or as a device. If an importer is unsure whether their product is a pesticide, device, or not regulated under FIFRA, the importer can submit a request for a regulatory determination by using PRIA MOO9. Instructions for submitting the request can be found at <a href="https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices#obtain">https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices#obtain</a>. Because PRIA M009 sets forth a fee-for-service application process for requesters to seek formal determinations on whether FIFRA jurisdiction covers particular products, EPA generally does not provide informal answers outside of that process.

Q6: How does a medical device manufacturer know if a filter (used in a medical device) needs to be reported? Does FDA reporting negate need to declare this as an EPA regulated antimicrobial?

A6: A NOA is required for pesticides and devices that fall under FIFRA § 2(h) and FIFRA§ 2(u). FIFRA § 2 defines "device", "pest," and "pesticide" (see FIFRA §§ 2(h), 2(t), and 2(u)). The Agency issued regulations to help determine what products or substances meet those definitions, and whether a given pesticide is regulated by FIFRA. See 40 C.F.R. Part 152, Subparts A and B.

There are products that may meet both the FIFRA definition of device (regulated by EPA) and the device definition under the Federal Food, Drug, and Cosmetic Act (FFDCA) (regulated by FDA). Such products are dually regulated by FDA and EPA (e.g., ventilator filters, devices used to treat Continuous Positive Airway Pressure (CPAP) accessories, air purifiers, or UV light devices used in FDA-regulated healthcare settings). Depending on the specifics of the product, it may be regulated as a device or require registration as a pesticide.

If an importer is unsure whether their product is a pesticide, device, or not regulated under FIFRA, the importer can submit a request for a regulatory determination by using PRIA MOO9. Instructions for submitting the request can be found at <a href="https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices#obtain">https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices#obtain</a>. Because PRIA M009 sets forth a fee-for-service application process for requesters to seek formal determinations on whether FIFRA jurisdiction covers particular products, EPA generally does not provide informal answers outside of that process.

#### Q7: Are LED bulbs considered devices under FIFRA and if so, do they need a PGA msg set?

A7: Pursuant to section 2(h) of FIFRA, any LED bulbs intended for a pesticidal purpose that do not contain a pesticidal substance are subject to FIFRA as devices. Therefore, submission of an NOA is required.

Importers or their authorized agents may submit NOA information using EPA Form 3540-1 or electronically via CBP's ACE system. EPA NOAs, whether filed by the EPA Pesticides PGA Message Set or by paper using EPA Form 3540-1, should be filed well in advance of arrival of the shipment for ample time for review and planning for the final disposition of the shipment.

#### TSCA Import Program Questions and Answers

#### **Article Questions**

#### Q1: Please provide more examples of what qualifies as an "Article"?

A1: EPA has a fact sheet for its Chemical Data Rule (CDR) about imported articles that has additional examples. See <a href="https://www.epa.gov/chemical-data-reporting/tsca-chemical-data-reporting-fact-sheet-imported-articles-2020">https://www.epa.gov/chemical-data-reporting/tsca-chemical-data-reporting-fact-sheet-imported-articles-2020</a>. 19 CFR 12.120(a) defines "article." Note 19 CFR 12.121(b) states that a specific rule or order can require TSCA import certification for components of articles; however, only the Formaldehyde Rule currently has the import certification requirement. Also, although a TSCA import certification is not required, the import of certain articles is still regulated by TSCA. Please also see related Questions 2, 6, and 7 below.

# **Q2:** During the presentation, did EPA say a pen would get a TSCA positive because of the ink? A2: Yes. While a pen is considered an article and any chemicals that comprise the pen body are not subject to reporting, the ink in the pen is not considered to be part of the article because it is intended to come out of the pen for it to be used. Any chemicals in the ink require a positive TSCA import

certification.

#### TSCA Reporting and Disclaim Questions

### Q1: Please clarify, if a product is flagged for TSCA but is regulated by FDA, this means that the TSCA can be disclaimed, correct?

A1: The answer is it depends. Some products that are regulated by FDA are also regulated by EPA under TSCA. Others are not. See TSCA § 3(2)(B)(vi). Generally, if the product is both clearly regulated by FDA and it is imported solely for a TSCA-excluded use (e.g., a drug or a medical device under the FFDCA), then filing a Disclaim is ok. If the product is also being imported for a TSCA use, then a positive import certification is required. See 19 C.F.R. § 12.121(a)(1). If the import is not clearly regulated by FDA, but its imported use is solely for an FDA covered use then a negative TSCA import certification is required. See 19 C.F.R. § 12.121(a)(2).

#### Q2: Please advise when a disclaimer code B can be used for TSCA.

A2: Please see <u>ACE Tip for Filing EPA TSCA</u>, page 2 Disclaims for ACE "B = data is not required per agency guidance (Disclaim Code B is for ODS and TSCA Section 13 certifications only- call the <u>TSCA hotline</u> to determine if this applies. **This Disclaim Code is not allowed for TSCA Title VI certifications.**)

Q3: Please explain EPA guidance on TSCA reporting for Foreign Trade Zone (FTZ) admissions and FTZ entries.

A3: As discussed in the August 21, 2019 preamble to the Technical Amendment to the Formaldehyde Rule, 84 FR 43521 "Foreign merchandise admitted into an FTZ constitutes 'imported merchandise which has not been properly released from Customs custody in the Customs territory.' (See 19 CFR 146.1). EPA notes that FTZs are not considered customs territory for purposes of customs laws (including TSCA section 13 import certification) but are considered customs territory for purposes of other federal laws (see 19 U.S.C. 81c and general note 2 of the Harmonized Tariff Schedule of the United States). Any composite wood products or finished goods containing composite wood products must, therefore, be labeled upon importation to be admitted into an FTZ. Prior to release from CBP custody at a port of entry, a TSCA Section 13 import certification is required for all regulated composite wood products, component parts fabricated using composite wood products, and finished goods fabricated using composite wood products (see 19 CFR 12.121(a)(3)(i))." Similarly, any chemical substance admitted to a FTZ must be compliant with TSCA and prior to release from CBP custody at a port of entry, a TSCA Section 13 import certification is required.

### Q4: Some importers are completing the negative/positive chemical certification for composite wood importations, is this acceptable to EPA?

A4: No. While the positive TSCA import certification language is the same for chemical substances and composite wood products subject to TSCA Title VI, per <u>ACE Tip for Filing EPA TSCA</u> only a positive TSCA import certification or Disclaim Code A is allowable to composite wood products subject to TSCA Title VI.

### Q5: Can furniture that contain a piece of plywood made in 1920-1950 be disclaimed or negative declaration?

A5: Disclaim Code A may be used only if the imported furniture falls outside the scope and applicability or the TSCA Title VI regulations. Under 770.1(c), Subparts B, C, and D of 40 CFR part 770 do not apply to the following: (1) Any finished good that has previously been sold or supplied to an end user, an individual or entity that purchased or acquired the finished good in good faith for purposes other than resale. For example, subparts B, C, and D of this part do not apply to antiques or secondhand furniture. Thus, Disclaim Code A may be used for this piece of furniture if it has previously been sold or supplied to an end user, an individual or entity that purchased or acquired the finished good in good faith for purposes other than resale. For other scenarios, compliance with 40 CFR Part 770 and a positive TSCA import certification may be required, so please consider contacting the TSCA Hotline.

### Q6: Can EPA provide more details where no TSCA certification is required (positive or negative)? Would you give an example of chemical substances "as parts of articles"?

A6: No TSCA import certification (positive or negative) is required when:1) imported Chemical substances or mixtures are as parts of articles, unless import certification is required by a specific rule under TSCA. 19 CFR 12.120(a) defines "article."; 2) Chemical substances are otherwise clearly identified as a product excluded from TSCA; or 3) Commodities are imported under HTS codes flagged for TSCA as potentially subject to the Formaldehyde Standards for Composite Wood Products final rule but are not composite wood products subject to the rule. Note, when no TSCA certification is required, a Disclaim code may be required.

Clink <u>here</u> to see EPA's fact sheet for its Chemical Data Rule (CDR) about imported articles that has additional examples..

### Q7: If I import a used vehicle which contains fluids, does the importer have to file a TSCA certification to cover the fluids?

A7: Yes, only for the fluids that are intended to be released and have an end use or commercial purpose separate from the vehicle. Consistent with EPA's interpretation found in the Inventory Reporting Regulations of Dec. 23, 1977 (42 FR 64583), in the Agency's response to Comment 21, which includes the text below, fluids in a vehicle would be considered part of an article unless the fluids were intended to be released (e.g., windshield washing liquid) and have an end use or commercial purpose separate from the vehicle:

"Chemical substances or mixtures will be considered to be imported as part of an article, if the substance or mixture is not intended to be removed from that article and has no end use or commercial purpose separate from the article of which it is a part.....For example, transformer fluids in transformers, lighter fluids in cigarette lighters, and crankcase oil in automobiles are not intended to be removed from the articles of which they are a part and have no commercial purpose separate from these articles."

Imported used vehicle intended for scrap and not to be used as a vehicle would not likely qualify as an article because it no longer has an end use function dependent in whole or in part upon its shape or design during the end use.

Q8: If we file a TSCA certification, can we Disclaim Pesticides if the HTS flags for both and vice versa? A8: The answer depends on the product's intended use. Some products may have both TSCA, and FIFRA uses and require filing both a positive TSCA import certification and NOA. Others are solely intended for pesticidal purposes or for nonpesticidal purposes. Generally, if an importer files a positive TSCA import certification for a chemical substance being imported for a TSCA use, and the importer determines they do not need to file an EPA NOA, they can file Disclaim Code A (not regulated by this Agency). Using Disclaim Code A indicates to EPA and CBP that the importer has determined, after reviewing FIFRA and its implementing regulations, that 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. If the product is clearly excluded from TSCA (e.g., its use is solely as a pesticide and a NOA was filed), then it may be disclaimed for TSCA.

**Q9:** We often have shipments of plastic toys that are flagged for TSCA. Can we Disclaim these items? A9: Yes, if the toys are not a covered article regulated under a specific rule or order requiring TSCA import certification for components of articles. Contact the TSCA Hotline for more information. If in this scenario, the toy is imported under HTS code 95030000 and flagged for TSCA for the Formaldehyde Standards for Composite Wood Products final rule, a Disclaim Code A for program code TS1 may be filed.

#### CAA – Vehicles and Engines Import Program Questions and Answers

#### **Regulatory Questions**

Q1: During the presentation, EPA mentioned electric vehicles require EPA reporting? If so, which boxes should be checked on the 3520-1/3520-21?

A1: Yes, that is correct. Electric motor vehicles are required to be certified by EPA and are required to be declared upon importation, unless the importer is their OEM who is the holder of the EPA certificate. In declaring EPA-certified electric motor vehicles for importation, use Code B in the 3520-1 form. Note that the term "motor vehicles" pertains to vehicles that are for transporting persons or property on a street or highway. Electric vehicles not designed for use on public roads and highways do

not need to be certified by EPA or declared. Examples include electric go karts, electric ATVs, electric boats, electric forklifts, electric cherry pickers and electric golf carts.

#### Q2: Are electric golf carts regulated by EPA?

A2: Electric golf carts are not regulated by EPA, so they do not need to be declared. EPA realizes some states allow golf carts to be licensed for road use, but such use is not sanctioned by EPA.

#### Q3: Are natural gas full house generators regulated by EPA? Are they regulated if new?

A3: Natural gas-fired whole house generators have internal combustion engines regulated by EPA; therefore, they are required to be declared, regardless of whether they are new or used.

#### Q4: Is there a regulatory reference for the unit to engine EPA 1 year lag time?

A4: Yes, there is. See 40 C.F.R § 1068.105

#### Filing Requirement Questions

#### Q1: What are the filing requirements for electronic cars?

A1: Filing for electric cars is no different than for any other cars. If the cars are EPA-certified, use Code B in the EPA form 3520-1 (ACE Doc ID 942). If the vehicles are subject to an exemption or exclusion, use that code in the 3520-1.

#### Q2: Do electric forklifts require EPA filing?

A2: No, electric forklifts did not require an EPA filing. Only electric motor vehicles (meaning vehicles for use on public roads) need to be declared for EPA.

#### Q3: Do watercraft require EPA filing?

A3: If the watercraft is powered by an internal combustion engine (ICE), that engine is regulated by EPA and so the entry must be declared.

### Q4: Is an EPA filing required for an electric vehicle model entering on a carnet for testing and a car show?

A4: If the electric vehicle is a motor vehicle (meaning it is designed for use on public roads), it must be declared. It must be either EPA-certified or otherwise eligible for an exemption or exclusion from EPA regulation. Testing and display exemptions require EPA letters of approval before importation occurs.

### Q5: Are cars purchased oversees that over 25 years old, still functional, and will be used on the road/highways etc. regulated by EPA and require filing?

A5: Cars are regulated by EPA, regardless of their origin or age. If they are over 21 years old, they can be imported using the Code E exemption, but they still must be declared.

#### **Exemption Questions**

### Q1: Are there current 3520-21 exemptions for stationery ICEs imported for use in remote areas, such as in the Alaska wilderness?

A1: There are no exemptions for the use of any equipment just because it is to be used in remote areas. If it is in the territory of the United States, it must meet EPA requirements.

### Q2: Is there an exemption for prototype vehicles imported solely for testing and evaluation purposes that may travel on highway to point of testing?

A2: If a vehicle is imported under an approved testing exemption, the exemption may allow for limited road use. The importer should request such use in the application for an exemption.

#### CAA – Ozone Depleting Substances and AIM Act – Hydrofluorocarbons

No questions were submitted for this program overview during the webinar.

#### **Import Program Resources**

Additional resources and background information on each import program is provided below.

#### **Current Published Filing Tips and Guidelines for Trade**

- Ozone Depleting Substances (ODS)
   https://www.cbp.gov/document/publications/ace-tips-filing-epa-ods
- Hydrofluorocarbons (ODS currently)
   <a href="https://www.cbp.gov/document/fact-sheets/ace-tips-filing-epa-hfcs">https://www.cbp.gov/document/fact-sheets/ace-tips-filing-epa-hfcs</a>
- Vehicles and Engines (VNE)
   <a href="https://www.cbp.gov/document/publications/ace-tips-filing-epa-vehicles-engines">https://www.cbp.gov/document/publications/ace-tips-filing-epa-vehicles-engines</a>
- Pesticides/Devices (PS1, PS2, PS3)
   https://www.cbp.gov/document/publications/ace-tips-filing-epa-pesticides
- Toxic Substances (TS1)
   <a href="https://www.cbp.gov/document/publications/ace-tips-filing-epa-tsca">https://www.cbp.gov/document/publications/ace-tips-filing-epa-tsca</a>

#### **FIFRA Import Program**

- June 6, 2018, EPA Webinar for NCBFAA on ACE filing of Pesticide Imports at https://www.youtube.com/watch?v=vYvgFUDFkZg
- <a href="https://www.epa.gov/compliance/regional-contacts-questions-concerning-notices-arrival-epa-form-3540-1">https://www.epa.gov/compliance/regional-contacts-questions-concerning-notices-arrival-epa-form-3540-1</a> (also where you can download EPA Form 3540-1)
- <u>Devices (Pesticide Registration Manual: Chapter 13)</u> (including regulatory determinations information)
- FAQs of the FIFRA Import Program
- EPA Responses to Webinar FAQs (previous webinars)
- <u>CBP and Trade Automated Interface Requirements (CATAIR) EPA Supplemental Guidelines</u> (February 12, 2019)
- Overview of Requirements for Pesticide Registration and Registrant Obligations (Pesticide Registration Manual: Chapter 1)
- Additional Considerations for Biopesticide Products (Pesticide Registration Manual: Chapter 3)
- Additional Considerations for Antimicrobial Products (Pesticide Registration Manual: Chapter 4)
- Compliance Advisories and Enforcement Alerts
  Index: https://www.epa.gov/enforcement/compliance-advisories-and-enforcement-alerts

- Types of Pesticide Ingredients
- Pesticide Devices: A Guide for Consumers
- Minimum Risk Pesticides Exempted from FIFRA Registration
- Determining if a Cleaning Product is a Pesticide Under FIFRA
- Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136-136y
- CBP Regulations Applicable to Pesticides and Devices, 19 C.F.R. §§ 12.110-12.117
- EPA Regulations Applicable to Pesticides Programs, 40 C.F.R. parts 150-189

#### TSCA Import Program and Import Resources

- Import and Export Requirements under the Toxic Substances Control Act (TSCA).
  - Compliance Guide for the Chemical Import Requirements of the Toxic Substances Control Act
  - TSCA Section 13 Import Compliance Checklist (does not include TSCA Title VI)
- Resources and Guidance Materials for the Formaldehyde Emission Standards for Composite
   Wood Products Rule
  - Importers, distributors, and retailers
  - Harmonized Tariff Schedule Codes
- Tips for Trade when filing an EPA TSCA Certification in ACE.
- <u>Customs and Trade Automated Interface Requirements (CATAIR)</u> EPA Supplemental Guidelines (TSCA on pages 155-172)
- The TSCA Hotline can answer general questions about import-export requirements: 202-554-1404 (or e-mail: TSCA-Hotline@epa.gov)

#### **CAA – Vehicles and Engines Import Program Resources**

- <a href="https://www.epa.gov/importing-vehicles-and-engines">https://www.epa.gov/importing-vehicles-and-engines</a>
- <a href="https://www.epa.gov/ve-certification/information-about-family-naming-conventions-vehicles-and-engines">https://www.epa.gov/ve-certification/information-about-family-naming-conventions-vehicles-and-engines</a>
- https://www.epa.gov/sites/default/files/2013-09/documents/nonroadengines-0609.pdf
   https://www.epa.gov/compliance-and-fuel-economy-data/annual-certification-data-vehicles-engines-and-equipment

### CAA – Ozone Depleting Substances and AIM Act – Hydrofluorocarbons

- Fact Sheet for Importers of HFCs:
  - https://www.epa.gov/system/files/documents/2021-11/hfc-allocation-rule-importer-requirements-fact-sheet.pdf
- Tips Sheet for Filing HFC Imports in ACE:
  - https://www.cbp.gov/document/fact-sheets/ace-tips-filing-epa-hfcs
- Tips Sheet for Filing ODS Imports in ACE:
  - https://www.cbp.gov/document/publications/ace-tips-filing-epa-ods
- If you have a question about a shipment or whether it is an HFC or ODS, please contact: HFCAllocation@epa.gov