SUPPORTING STATEMENT FOR AN INFORMATION COLLECTION REQUEST (ICR)

1. Identification of the Information Collection

1(a) Title of the Information Collection

TITLE: Notice of Arrival of Pesticides and Devices under section 17(c) of FIFRA.

OMB No. 2070-0020

EPA No. 0152.12

1(b) Short Characterization/Abstract

The U.S. Customs and Border Protection (Customs) regulations at 19 CFR 12.112 require that an importer desiring to import pesticides into the United States shall, prior to the shipment's arrival in the United States, submit a Notice of Arrival (NOA) of Pesticides and Devices (EPA Form 3540-1 or its Customs-authorized electronic equivalent) to the U.S. Environmental Protection Agency (EPA or Agency). Once EPA receives the NOA, EPA will determine the disposition of the shipment. Upon completing its review, the EPA response is sent to the importer of record (importer) or licensed customs broker (broker), who must present the NOA to Customs upon arrival of the shipment at the port of entry. This is necessary to ensure that EPA is notified of the arrival of pesticides and devices as required under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 17(c), and that EPA has the ability to examine such shipments to determine compliance with FIFRA.

The NOA requires the identification and address information of parties involved in the importation of the pesticide or device and information on the identity of the imported pesticide or device shipment. When the NOA is submitted to the EPA regional office having jurisdiction over the state or territory in which the port of entry is located, EPA enforcement personnel will determine whether the shipment should be released for entry upon arrival, detained for examination, or refused admission into the United States. The responsible EPA official returns the NOA to the importer or broker with EPA instructions to Customs as to the disposition of the shipment.

Upon the arrival of the shipment, the importer or broker must present the completed paper NOA to the Customs and Border Protection's port of entry. The entry information for each shipment will be handled with the NOA and Customs notifies the EPA regional office of any discrepancies, which EPA will resolve with the importer or broker. If there are no discrepancies, Customs follows instructions regarding release, detention, or refusal. If there are discrepancies, the shipment may be detained until cleared for release, or retained for examination. If EPA inspects the shipment and it appears from examination of a sample that it is adulterated, misbranded, or otherwise violates the provisions of FIFRA, or is otherwise injurious to health or the environment, the pesticide or device may be refused admission into the United States.

On February 19, 2014, President Obama issued Executive Order (EO) 13659, Streamlining the Export/Import Process for America's Businesses, in order to reduce unnecessary procedural requirements relating to, among other things, importing into the United States, while continuing to protect national security, public health and safety, the environment, and natural resources. See 79 FR 10657 (February 25, 2014). Among other directives, EO 13659 mandates that no later than December 31, 2016, International Trade Data System (ITDS) "agencies shall have capabilities, agreements, and other requirements in place to utilize the ITDS and supporting systems, such as the Automated

Commercial Environment [ACE], as the primary means of receiving from users ... the standard set of data and other relevant documentation (exclusive of applications for permits, licenses, or certifications) required for the release of imported cargo..." By that time, ACE is expected to have the operational capabilities necessary to enable users to transmit a harmonized set of import data elements, via a "single window," to obtain the release and clearance of goods. As a result, ITDS would eliminate redundant reporting requirements and facilitate the transition from paper-based requirements reporting and other procedures to faster and more cost-effective electronic submissions to, and communication among, government agencies.

To support the implementation of ITDS, EPA began collecting NOA information electronically in June 2016 through the "Emergency Processing Request for Information Collected in ITDS Pilot for Pesticide Notice of Arrival" ICR (OMB Control No. 2070-0020; EPA ICR No. 0152.11; ICR Ref. No. 201606-2070-002). This pilot was necessary for successful testing of ITDS before the December 31, 2016 deadline established in EO 13659. More specifically, the EPA requested the emergency processing of the collection of a few additional data elements in the ITDS pilot for pesticides and devices that were not covered by EPA ICR No. 0152.10.

Under the ITDS pilot, importers were given the option to electronically file the data needed for a NOA through Custom's ACE. Both the electronic and paper NOAs collect the same data that allows EPA to determine whether the pesticide or device complies with FIFRA import requirements. Electronic filings offer the benefit of providing information once to ACE thus meeting both Customs and EPA reporting requirements well in advance of the shipment's arrival in the United States. Most of the electronic filings are automatically processed, and an early indication is provided to the filer if the initial reporting requirements have been met and if the shipment can be released upon arrival at the port of entry. For those filings that do not meet the reporting requirements, automatic checks will be performed to notify the filer of errors. For filings that require non-automated checks, EPA staff can review and provide feedback notifications through ACE to the filer on what information is needed that has not been provided. Customs has since made the electronic filing option available permanently through an interim final rule published on September 30, 2016 (81 FR 67140), and effective immediately. This renewal ICR incorporates the burdens from the emergency ITDS Pilot ICR and now covers both paper and electronic filings of NOAs as a result of the interim final rule.

During this renewal of this information collection, EPA is also capturing the burden of providing the label and other supporting documentation that is currently submitted by most importers to the Agency as part of an existing voluntary practice. EPA has found that questions about a shipment can often be resolved if the label or other supporting documentation accompanies the NOA prior to the arrival of the shipment in the United States.

Respondents subject to this information collection include all importers of pesticides and pesticidal devices as defined by FIFRA.

2. Need for and Use of the Collection

2(a) Need/Authority for the Collection

This information collection activity allows Customs to fulfill its statutory obligation under FIFRA section 17(c) (Attachment A) to notify the EPA of the arrival of pesticides and pesticidal devices in the United States. A NOA must be submitted for all imported pesticides and pesticidal devices, including but not limited to those pesticides that are registered under section 3 of FIFRA and to those

that may be transferred, sold, or distributed without registration pursuant to 40 CFR 152.30, such as pesticides for which an Experimental Use Permit has been granted under section 5 of FIFRA, and pesticides for which an Exemption has been granted under sections 18 or 25(b) of FIFRA. This notification allows EPA to determine whether imported pesticidal devices and registered and unregistered pesticides comply with FIFRA. The information permits EPA to stop suspended, cancelled, misbranded, contaminated, or otherwise violative products from being imported into the country, track those that do enter, and minimize any adverse human health or environmental impact that might arise from the importation of violative products. If EPA did not collect this information, Customs and EPA would be unable to meet their statutory requirements under FIFRA. The statutory provisions set forth in section 17(c) of the FIFRA, 7 U.S.C. 1360(c), are implemented in the Customs regulations at §§ 12.110 through 12.117 of title 19 of the CFR (19 CFR 12.110–12.117) (Attachment B).

2(b) Practical Utility/Users of the Data

The information is used by EPA regional pesticide compliance and enforcement staff, the Office of Enforcement and Compliance Assurance (OECA), and the Office of Pesticide Programs (OPP) to monitor and assure compliance with FIFRA. Customs uses this information to ensure pesticide and pesticidal device products admitted to the U.S. have been reviewed by EPA for compliance. The absence of an accompanying NOA is, under Customs regulations, grounds for refusal of entry into the United States.

3. Non-Duplication, Consultations, and other Criteria.

3(a) Non Duplication

The information collection currently involves a partial duplication if filing with a paper NOA. Much of the identifying information collected on a paper NOA is identical or similar to information collected on Customs' entry notice form (Form 3461, OMB Control Number 1651-0024).

Under the existing regulation, the NOA must be submitted to EPA prior to arrival so that EPA can assess whether the shipment complies with FIFRA and provide recommendations about the disposition of the shipment to Customs when shipment arrives on the NOA form and returns it to the importer. The importer then includes the NOA with other shipment paperwork for presentation to Customs at the port. On the other hand, entry forms are to be presented only when a shipment will make entry, which can occur up to 15 days after a pesticide or device arrives in the U.S., and the entry forms do not contain all of the information required in a notice of arrival.

EPA began collecting the NOA information in June, 2016, as part of an ITDS pilot necessary for successful testing of the ACE system (Attachment C). Electronic NOA filings have streamlined the information collection and eliminated the duplication seen in paper NOA forms. Respondents' use of ACE to file import paperwork electronically enables respondents to electronically populate certain identifying information once in the system, and have that information available for pre-population on the electronic NOA. Customs codified the availability of both paper and electronic NOA filing options through an interim final rule on September 30, 2016 (81 FR 67140), making electronic reporting a permanent option for filing. Importers are encouraged to continue or start filing NOAs electronically to eliminate duplication. In addition to the interim final rule, EPA is undertaking rulemaking to facilitate the electronic submission of NOA information and to update the existing regulations, which is expected to be completed in 2017. This renewal document specifically identifies those burdens associated with the current collection activities and paper and electronic forms that are currently available. As additional

rulemakings are completed to update the data elements required in an NOA, this ICR will be revised to incorporate those changes.

3(b) Public Notice Required Prior to ICR Submission to OMB

Pursuant to 5 CFR 1320.8(d), EPA published a notice in the Federal Register (FR) on Friday, April 15, 2016 (81 FR 22261) announcing the proposed renewal of this information collection activity and provided a 60-day public comment period. The Agency received comments from one commenter (Bayer CropSciences, or Bayer) on this ICR renewal. The comments are available in the docket for this action, and are summarized below, along with EPA's responses, which are also available in the docket (Attachment D).

Bayer commented that active ingredients (AI) and percentages of each AI should be treated as CBI for compounds imported for research and development (R&D) purposes. Bayer stated that because EPA requires this field and because Bayer also needs to maintain confidentiality on research materials, Bayer proposed that when a numbered compound code or other internal methodology is used, the translation for this code be provided in box 19 which can be claimed as CBI. Bayer suggested that in this manner companies may provide EPA with the necessary information to facilitate import but not risk exposure of sensitive information. They felt that an associated field could be created in box 18 to allow for identification when an internal compound name is utilized, and this option need not be available for registered pesticide products.

In response, as stated in the original supporting statement, some information presented in a NOA may not be claimed as CBI, pursuant to FIFRA section 7(d) and labeling requirements for pesticides/devices at 40 CFR 156.10; specifically, the EPA registration number, the producer establishment number, the brand name of product, and the active ingredients and percentages of each active ingredient. While EPA believes that Bayer's comment has potential merit regarding R&D compounds, this renewal ICR is intended to reflect the estimated burden hours and cost associated with the existing NOA form and is not intended to make specific changes to the existing form. EPA is currently working with Customs to develop additional rulemaking related to filing NOAs through the ACE/ITDS system. Changes to the NOA forms to address issues such as this (to be available through both electronic and paper versions) may be considered as part of that rulemaking process, not through this ICR renewal. After completion of the rulemaking, EPA will issue a rule-related ICR that will revise this ICR and associated forms. EPA encourages Bayer to provide this concern as part of that rulemaking.

Bayer stated that all data contained on a NOA form should be considered confidential and covered by confidentiality provisions of FIFRA with the exceptions of the information provided in blocks 4, 5, 6, and 7. Bayer continues to advocate for automatic identification of NOA information as completely confidential, but in the absence of this determination would ask that EPA consistently apply their CBI standards to all respondents, and exempt NOA CBI requests from additional review by OMB or OGC.

In response, EPA notes that all of the information provided on the NOA form, with the exception of the information in blocks 4, 5, 6, and 7, may be claimed as CBI by respondents, and if claimed as such, would be covered by the confidentiality provisions of FIFRA. EPA needs to know what information the respondent is claiming as CBI and importers must substantiate exactly what informational fields in the paper version of the NOA should be considered "FIFRA CBI" with the exception of fields 4, 5, 6, and 7. EPA believes that the current requirement to indicate clearly in block 16 what information is to be considered CBI provides respondents with flexibility in making CBI

November 13, 2017 claims.

Bayer stated that on the NOA form, in Box 11: *Country of Origin*, the definition of country of origin differs between US Customs and US EPA, which is one source of confusion which has led to delays in import. These definitions should be harmonized to prevent delays from either the EPA or US Customs. Specifically, EPA need not separately require a Country of Origin because that information is already provided in the US EPA Registered Establishment number (EPA Est. No.) captured in box 5. Instead, EPA should accept Customs' country of origin within the Automated Commercial Environment (ACE) environment, which is provided based on Customs rules.

In response, EPA is in the process of harmonizing with Customs under ACE the definition of "Country of Origin" and plans to update the NOA form using the Customs definition once this process is completed through rulemaking. EPA will also need both the Country of Origin information and the EPA Establishment No. where the pesticide was last "produced" as that term is broadly defined under FIFRA. This change will occur when ACE is implemented and the regulations are revised, with additional revisions planned for 2017.

Bayer noted that, in its experience, the submission of supporting information along with the NOA is not voluntary. It has been the experience of Bayer that such submissions are not treated by the requesting regions as voluntary. Failure to submit a product label, customs entry form, pro-forma invoice, guidance statement, R&D certificates, or any of the other "voluntary" documents results in denial of entry of the shipment to the United States. In addition, the documentation requests are inconsistent between EPA regions, are laborious and time consuming for the industry, and tend to create delays for reasons unrelated to the NOA or human health and safety. Additionally, individual EPA regions use the NOA screen for a variety of other enforcement checks, such as supplemental labeling or EPA Registered Establishment reporting compliance. These practices are also inconsistent between regions, with some EPA regions conducting systematic relabeling mandates to alter shipments and issuing fines for conduct that does not constitute an infraction in a different geography. Bayer proposes that EPA clarify the requirements and harmonize enforcement standards among the regions.

In response, EPA's experience shows that importers typically submit the recommended/voluntary information in an effort to facilitate an expedited review of the NOA submission. The label and other voluntary information allows EPA to easily verify compliance with FIFRA labeling requirements and may help EPA to quickly resolve issues with a shipment. The label also communicates information that may help Customs Officers take appropriate precautionary measures when handling these shipments at the port. By providing this information upfront, importers have found that providing this information is more efficient than addressing questions or document requests from EPA later in the process, which can delay entry and increase costs and burden. If an importer believes that it is more efficient to routinely submit the supporting information, that company may incorporate such submissions into its standard business operations to facilitate a streamlined and more efficient review and approval.

In practice, a copy of the product label submitted by the importer is routinely reviewed by EPA regional staff as part of the notice of arrival process; the label, however, is not reviewed in every instance. The decision to request supporting information for an imported pesticide, if the information is not provided voluntarily by the importer, is therefore made on a case-by-case basis depending on the unique circumstances surrounding the importation of the pesticide product. For example, a request for additional information by EPA Regional offices is more likely to occur when the importation is not a routine import of a registered pesticide product. Therefore, consistent with the purposes of the

Paperwork Reduction Act, EPA maintains that this information should only be requested when needed and continues to identify the label and other supporting documents as recommended data items in the standard NOA package. However, to account for Bayer's experience that this information has not been treated as voluntary in all instances by EPA Regions, EPA assumes in Section 6 of this Supporting Statement that all NOA submissions will include the recommended/voluntary information to ensure that it has accounted for the associated burdens. Much of the supporting information requested by a Regional Office reviewing a NOA will be available to EPA Regional Offices in the ACE environment, reducing the need for some of these requests.

Bayer also provided comments to the docket that were in response to the consultation process discussed in 3(c). Those comments are discussed in 3(c).

3(c) Consultations

As part of the preparation of this ICR renewal, EPA contacted three stakeholders seeking feedback on the notice of arrival information reporting requirements and processes, as well as an assessment of the burden estimates associated with this information collection. The list of companies contacted in the consultation process, and a summary of the consultations is provided in the docket for this action (Attachment E). Two of the three representatives (Bayer and Nisso America) responded to EPA's consultation request.

Both Bayer and Nisso America supported EPA's efforts to offer electronic filing of NOAs and stated that NOA instructions were clear. Bayer, however, suggested that burden hours and delays by EPA reviewers on the paper NOA can increase burden and costs on importers, by as much as 30-60 minutes per NOA. Bayer also stated that this may take longer, spanning up to 1-3 business days, depending upon level of research required and key personnel availability. Assuming a follow up rate of 5%, this adds another 65 – 130 hours of burden to the process. Bayer also stated that NOA review/approval times are dependent upon the regional office, with most regions taking an average of approximately 3-5 business days to review and approve, but certain regions may take 2-3 weeks to approve considering high NOA volumes they process. Bayer stated that they advise their customers that NOA processing time can take approximately one week to receive an approved NOA. Bayer stated that assuming the NOA is filed upon customs entry, this adds and associated 5 days of storage and other costs. Bayer also suggested that if filed early (before entry) this presents this problem associated with customs entry numbers and increases the number of NOAs questioned and the likelihood of refiling due to changes in the delivery date, carrier or other NOA fields.

EPA disagrees with this assessment because the Agency believes that the additional burden per paper NOA identified by Bayer is an overestimate of the amount of time required to complete a NOA. EPA's estimate of the burden hours represents an average. Some respondents will spend less time and others will spend more time than the estimated average. While the higher estimates provided by Bayer may be true for the first few instances in which a company submits a paper NOA, EPA believes that as repetitive filings occur and business practices improve over time, the cost and time to complete a NOA will be reduced. During the consultation period, Nisso America indicated that EPA's estimate may be off the first few times a company completes a paper NOA, but were otherwise accurate once paper NOAs become routine and that all pertinent costs have been accounted for by EPA. Therefore, EPA is maintaining that the burden to complete a NOA is approximately 0.43 hours per response. EPA also expects that much of the burden and delay outlined by Bayer should be alleviated as the use of electronic NOA filings through ACE becomes routine. However, as EPA gathers data on electronic filing over the course of the next few years, EPA intends to reexamine whether burden reductions have occurred during the next renewal.

3(d) Effects of less frequent collection

This collection represents the minimum collection frequency possible to comply with statutory requirements, which is that the Agency be notified of the arrival of each shipment into the United States so that each imported shipment may be evaluated, and if necessary, refused. In addition, if a shipment that should have been refused is allowed entry, the information collection enables the federal government to track the movement and distribution of those shipments within the United States, and to minimize any potential adverse human health or environmental impact that might arise. Collecting this information less frequently or not at all would not only violate a statutory mandate, but would hamper mission-critical objectives of EPA and Customs.

3(e) General Guidelines

The only PRA-imposed guideline in 5 CFR 1320.6 that is exceeded in this collection is the recordkeeping retention period. Any record required to be made, kept, and rendered for examination and inspection by Customs under 19 CFR 163.2 shall be kept for 5 years.

3(f) Confidentiality

Confidential data submitted to EPA is handled in accordance with the provisions of the FIFRA Confidential Business Information (CBI) security manual. This manual contains instructions to physical security measures; CBI copying and destruction procedures; transfer of CBI materials within EPA to contractors or to other government offices; computer security; CBI typing procedures; and internal office procedures. The manual dictates that all CBI must be marked or flagged as such, only authorized Agency personnel may be permitted access to CBI, all CBI must be kept in secure (double-locked) areas, and all CBI marked for destruction must be cleared by a Document Control Officer.

If information in the NOA is declared sensitive or confidential, it cannot be released to the public. Certain information in NOAs (e.g., names and complete addresses, along with unit size, quantity, total net weight, country of origin, port of entry, entry number, and anticipated entry date) may be claimed as FIFRA CBI.

However, other information presented in a NOA may not be protected as confidential pursuant to FIFRA section 7(d), labeling requirements for pesticides/devices at 40 CFR 156.10, and misbranding provisions in FIFRA section 2(q), specifically:

- EPA Registration Number.
- EPA Establishment Number.
- Brand name of product.
- Active ingredients and percentages of each.

3(g) Sensitive Questions

Not applicable. No information of a sensitive or private nature is requested in the information collection activity.

4. The Respondents and Information Collected

4(a) Respondents/North American Industry Classification System (NAICS) Codes.

Respondents to this information collection are pesticide importers, which includes many types of business entities ranging from Commercial and Institutional Building Construction (NAICS 236220) to Pesticide and Other Agricultural Chemical Manufacturing (NAICS 325300) and even Public Administration: Executive Offices (NAICS 921110). Other industries and institutions that import pesticides include Agriculture, Forestry, Fishing and Hunting (Sector 11), Wholesale Trade, (Sector 42). The majority of responses come from businesses that fall under NAICS code 325300.

4(b) Information Requested

(i) Data items, including record keeping requirements

The data items that must be submitted for registered pesticides, unregistered pesticides, and pesticidal devices are the same, except where indicated below.

a. Required data items.

All data in this ICR that is recorded and reported is required by FIFRA Sections 3, 7, and 17, and 19 CFR Part 12.

Provide notification of:

• Name, complete address, phone number, and email address of broker or agent (19 CFR 12.112)

• name, complete address, phone number, and email address of importer or consignee (19 CFR 12.112)

- name, address, phone number, and email address of shipper (19 CFR 12.112)
- EPA registration number (19 CFR 12.111 and FIFRA Sec. 3)
- EPA producer establishment number (19 CFR 12.112 and FIFRA Sec. 7)
- brand name of product (19 CFR 12.112 and FIFRA Sec. 17(c))
- active ingredients and percentage of each (19 CFR 12.112 and FIFRA Sec.17(c))
- unit size, quantity, and total net weight (19 CFR 12.112 and FIFRA Sec. 17(c))
- country of origin (19 CFR 12.112)
- port of entry, entry number, anticipated entry date (19 CFR 12.113)
- name, complete address, phone number, and email address of the carrier (19 CFR 12.113)
- location of good for examination after importation (19 CFR 12.115)

b. Recommended/voluntary data items

In addition to the required data items identified in section 4(b)(i)(a), EPA recommends that the following data items be included with the submission of a NOA under this information collection:

- When importing an unregistered pesticide, provide the CAS No. or PC code for the active ingredients in Box 7. The CAS No. and PC code is a unique identifier of the chemical ingredient or substance. Brokers and importers sometimes provide CAS # or PC code because it is faster and more reliable than the chemical name. If the chemical name of the active ingredient for an unregistered pesticide is unknown, it can delay the NOA approval processing.
- Any additional information, including the intended use and a description of why the product is being imported into the United States (Box 18 on EPA Form 3540-1 (Attachment F)) or information in the remarks (Box 19 on EPA Form 3540-1). EPA recommends that importers of unregistered pesticides provide this information to help expedite EPA's review of the NOA. Electronic filers will be able to provide this information through ACE.
- A copy of the product label that is affixed to the imported pesticidal device and pesticide product as part of the standard NOA package. The label allows EPA to verify compliance with FIFRA labeling requirements and may help to resolve issues with a shipment. The label also communicates information that may help Customs Officers take appropriate precautionary measures when handling these shipments at the port. This recommendation is accounting for current practice and can be provided through paper or electronic filing.
- Supporting documentation, such as a material safety data sheets (MSDS), Customs forms 7501 or 3461 other information submitted to Customs pursuant to 19 CFR 142.3(5), that may assist EPA in evaluating the shipment. The Customs entry forms allow EPA to verify that the

information submitted on an NOA is accurate. The MSDS provides EPA inspectors with information about the proper handling of the shipment when an inspection is required. This recommendation is accounting for current practice and can be provided through paper or electronic filing.

(ii) Respondent Activities

- Read instructions
- Plan activities-CBP
- Gather information
- Enter information on Form 3540-1 or its Customs-authorized electronic equivalent and submit the information, including the label, to EPA prior to arrival of pesticide or pesticidal device product
- Respond to questions if further inquiries are made by EPA
- If using the paper Form 3540-1, after it is reviewed and signed by EPA, provide to Customs
- Plan and review information for accuracy
- Store, file, and maintain the information

CBP means "Customary and Usual Business Practice;" during the course of normal and prudent business operations, a respondent would plan activities for this information collection, arrange for the collection, review the information for accuracy, and arrange to maintain or store the information detailed under 4(b) above. The information to be kept is generally information that prudent businesses would maintain.

5. The Information Collected - Agency Activities, Collection Methodology, and Information Management.

5(a) Agency Activities

EPA regional personnel reviews the submitted information for accuracy and completeness and maintains files of the NOA for inspection and targeting. If all information is complete and accurate, the Agency reviewer signs and returns the form to the importer. An incomplete NOA may require additional follow-up in order to determine the disposition of the pesticide or pesticidal device shipment. EPA regional personnel also work with Customs agents at the port of entry to resolve discrepancies between information submitted in a NOA and Customs entry documents.

5(b) Collection Methodology and Management

The information collected is produced by all importers as part of Customary and Usual Business Practice, as described above. This collection request concerns the entry and submission of this information using either EPA Form 3540-1 (Attachment F) or its Customs-authorized electronic equivalent. The currently approved version of EPA Form 3540-1 is included in the docket for this action.

NOA information is currently entered once onto Form 3540-1 (if submitting through paper), signed, and submitted to EPA. Form 3540-1 is reviewed by EPA, and, if approved, signed by the EPA reviewer. The form is then returned to the importer for submission as a shipping document to accompany the shipment upon its arrival at the U.S. port of entry. Customs inspectors compare Form 3540-1 with entry documents for the shipment of pesticides or pesticidal devices and notify the

Administrator of any discrepancies.

As discussed in previous sections, EPA is also participating in an interagency initiative known as the ITDS. ITDS is the organizational framework for Customs and more than 40 participating government agencies to integrate import requirements into a modernized, upgraded ACE, which is being designed by Customs to process imports and exports. The goal of ITDS is to make the federal government's compliance monitoring of international trade less burdensome and more efficient by integrating and automating the government-wide collection, use, and dissemination of international trade data. Under the ITDS concept, agencies harmonize their data requirements with Customs, thereby eliminating redundancies and minor definitional differences.

EPA has been working with Customs to integrate into the ACE system the Agency's six import regulatory programs, including the current process for notification of arrival of pesticides and pesticidal devices. EPA anticipates that most importers will choose to submit the NOA electronically in the ACE system as importers become familiar with the system, and that the NOA process will be done fully electronically and almost instantaneously among importers, EPA, and Customs for most shipments of pesticides or pesticidal devices. However, the paper EPA Form 3450-1 will continue to be available for use by importers.

Part of the effort to ensure that the U.S government meets the December, 2016, deadline involved testing the ITDS system or ACE. Customs tested the new technology by conducting pilots under the National Customs Automation Program (NCAP). EPA has worked with Customs to launch NCAP pilots for imported pesticides, with the information collection activities approved under the ICR entitled, "Emergency Processing Request for Information Collected in International Trade Data System (ITDS) Pilot for Pesticide Notice of Arrival" (OMB Control No. 2070-0020; EPA ICR No. 0152.11; ICR Ref. No. 201606-2070-002) (Attachment C). Under the pilot, electronic filings offer the benefit of providing information once to ACE, thus meeting both Customs and EPA reporting requirements well in advance of the shipment's arrival in the United States. Most of the electronic filings are automatically processed, and an early indication is provided to the filer if the initial reporting requirements have been met and if the shipment can be released upon arrival at the port of entry. For those filings that do not meet the reporting requirements, automatic checks will be performed to notify the filer of errors. For filings that require non-automated checks, EPA staff can review and provide feedback notifications through ACE to the filer on what information is needed that has not been provided. Customs has since made the electronic reporting option available fulltime through an interim final rule published on September 30, 2016 (81 FR 67140).

5(c) Small Entity Flexibility

The burden of this information collection is minimal and affects all importers. It cannot be reduced and still meet requirements outlined in Section 2(a). The information collection does not disproportionately impact small businesses, because the information requested is gathered during "customary and usual business practices."

5(d) Collection Schedule

A Notice of Arrival submission is required on each occasion that a pesticide or pesticidal device shipment arrives for entry in the United States.

6. Estimating the Burden and Cost of the Collection.

6(a) Estimating Respondent Burden

In calculating the respondent burden, EPA estimates that, on average, importers will submit 38,000 responses to this information collection annually during this renewal ICR. This estimate is based on a projected increase in the number of NOAs EPA receives. For the last renewal, EPA estimated the annual number of responses at 35,000. EPA received approximately 36,000 NOAs in 2013, 39,000 in 2014, and 38,000 in 2015. If this trend continues, EPA anticipates that over the next three years, EPA will receive, on average, 38,000 NOAs annually. This indicates an increase of about 3,000 additional NOAs received per year since the last renewal.

In estimating the burden per response, EPA assumes that all importers will include a copy of the product label as part of current practice and will voluntarily submit other supporting documents to EPA as part of the NOA. In addition, EPA assumes importers of unregistered pesticides will voluntarily provide information regarding the intended use of the product, as well as a description of why the product is being imported. Therefore, all potential burden (both required and recommended/voluntary information) for both registered and unregistered pesticide imports has been accounted for in these burden estimates, and may represent a slight overestimation of actual paperwork burden.

On average, the burden associated with this information collection activity is approximately 0.43 hours (26 minutes) per response. This estimate is based on an average response time across all response types. The response time includes an estimated average of 4 minutes of managerial time, 9 minutes of technical time and 13 minutes of clerical time, which is broken down approximately as follows:

- 4 managerial and technical minutes to read and hear any instructions.
- 4 minutes of technical and clerical time to gather information, including the label or supporting information.
- 5 managerial and technical minutes to process, compile and review information.
- 5 technical and clerical minutes to complete the form and attach the label.
- 4 clerical minutes to mail the form.
- 4 clerical minutes to file the form and supporting information.

Because EPA recommends that importers of unregistered pesticides voluntarily supply information about the intended use and an explanation of why the product is being imported, the responses types have been divided into two types. The number of respondents expected annually for each response type is exhibited in Table 1.

Type of Response	Number of Responses	Percent of Total (%)	Burden Hours per Response
Registered Pesticides and Pesticidal Devices	26,600	70	0.40
Unregistered Pesticides	11,400	30	0.50

Table 1: Estimated Average Annual Number of Responses, by Type

device product 0.40 hours (i.e., 24 minutes) per response to read instructions, complete form, and submit information to EPA and Customs, for a total of 10,640 hours annually. Respondents submitting a NOA for unregistered pesticides will require 0.50 hours (i.e., 30 minutes) for these activities, or 5,700 hours annually. The annual burden hours per response type are found by multiplying the annual number of responses for each response type, times the estimated burden per response for that type. The paperwork burden estimates represent the average burden and costs. Some respondents will spend less time and others more time than the average estimated. The total estimated respondent burden to comply with this information collection is 16,340 hours annually.

Since the option to file NOAs electronically is new to many importers, the burden estimates in this renewal assumes that companies will submit the NOA using paper Form 3450-1, which EPA believes overestimates the burden to submit a NOA electronically. Over time, EPA expects that the burden to file NOAs will decrease as electronic NOA filings become a part of standard business practice. These burden reductions will be reevaluated as the ACE system is fully implemented and will be reflected in future renewals of this ICR once EPA has data on the frequency of electronic and paper filings.

6(b) Estimating Respondent Costs

The methodology for calculating the wage rates in this renewal of the ICR has been updated to be consistent with the method for wage calculation for all ICRs managed by the Office of Pesticide Programs (OPP). The current wage estimates are based on latest wage data, 2014 data accessed online in 2016. The calculation of the wage rates (Attachment G) use base wage data for each sector and labor type for an *Unloaded wage rate* (hourly wage rate) and calculates the *Loaded wage rate* (unloaded wage rate + benefits) and the *Fully loaded wage rate* (loaded wage rate + overhead) based on that data. Fully loaded wage rates are used to calculate respondent and Agency costs.

Unloaded Wage Rate: Wages are estimated for labor types (management, technical, and clerical) within applicable sectors. The Agency uses average wage data for the relevant sectors available in the National Industry-Specific Occupational Employment and Wage Estimates from the Bureau of Labor Statistics (BLS) (see http://www.bls.gov/oes/current/oes_nat.htm).

Sectors: The specific North American Industry Classification System (NAICS) code and website for each sector is included in that sector's wage rate table in Attachment G. Within each sector, the wage data are provided by Standard Occupational Classification (SOC). The SOC system is used by federal statistical agencies to classify workers into occupational categories for the purpose of collecting, calculating, or disseminating data (see http://www.bls.gov/oes/current/oes_stru.htm)

Loaded Wage Rate: Unless stated otherwise, all benefits represent 46% of unloaded wage rates, based on average rate of benefits for all civilian non-farm workers (see http://www.bls.gov/news.release/ecec.t01.htm).

Fully Loaded Wage Rate: OPP multiplies the loaded wage rate by 50% (EPA guidelines 20-70%) to get overhead costs. Since the majority of NOAs are submitted by firms in NAICS code 325300 (Pesticide and Other Agricultural Chemical Manufacturing), hourly wage rates for this sector were used to calculate respondent burden. The fully loaded hourly wage rates for management, technical, and clerical occupations for NAICS 325300 are \$124.02, \$73.37, and \$41.70, respectively. See Attachment G for labor wage calculations.

Table 2 shows the estimated respondent burden and cost for submitting a NOA, including a label and other supporting documents, for registered pesticide and pesticidal devices. For these products, EPA estimates the burden per response to be 0.40 hours.

Collection Activities	Management (hours) ¹	Technical (hours) ¹	Clerical (hours) ¹	Total (hours)	Cost (\$)
	\$124.02/hr	\$73.37/hr	\$41.70/hr	· · ·	
Read or hear any instructions	0.01	0.05	-	0.06	4.91
Plan activities	-	-	-	-	0.00
Create information	-	-	-	-	0.00
Gather information, including label and supporting information (both					
mandatory and recommended/voluntary information)	-	0.02	0.03	0.05	2.72
Process, compile, review information for accuracy	0.02	0.05	-	0.07	6.15
Complete written forms	-	0.04	0.04	0.08	4.60
Record, disclose, or display information	-	-	0.07	0.07	2.92
Store, file, or maintain information	-	-	0.07	0.07	2.92
TOTAL BURDEN ²	0.03	0.16	0.21	0.40	\$24.22

Table 2: Respondent Burden and Cost per Response: Registered Pesticides and Pesticidal Devices

¹ Hourly wages rates are fully loaded wage rates based on NAICS 325300 - Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturing from U.S. Dept. of Labor, Bureau of Labor Statistics, 2014 data, Accessed March 2016. See Attachment G for wage calculations.

² Totals may not sum due to rounding.

The estimated total annual burden for registered pesticides and pesticidal devices is shown in Table 3. The total annual burden is estimated to be 10,640 burden hours, at a cost of \$644,161. The burden and cost per response is multiplied by the number of responses to get total annual respondent burden and cost, respectively.

Table 3: Total Annual Respondent Burden and Cost: Registered Pesticides and Pesticidal Devices

Information	Burden Per	Cost Per	Responses	Annual	Total
Collection	Response	Response	Per Year	Burden	Costs
Notice of Arrival for Registered Pesticides and Pesticidal Devices	0.40 hrs	\$24.22	26,600	10,640	\$644,161

Table 4 shows the estimated respondent burden and cost for submitting a NOA, including a label, supporting documents, and intended use information, for unregistered pesticides. For these responses, EPA estimates the burden per response to be 0.50 hours.

Collection Activities	Management (hours) ¹	TechnicalClerical(hours)1(hours)1		Total (hour)	Cost
	\$124.02/hr	\$73.37/hr	\$41.70/hr	(nour)	(\$)
Read or hear any instructions	0.02	0.05	-	0.07	6.15
Plan activities	-	-	-	-	0.00
Create information	-	-	-	-	0.00
Gather information, including					3.87
label and supporting information	-	0.03	0.04	0.07	
Process, compile, review					6.15
information for accuracy	0.02	0.05	-	0.07	
Complete written forms	-	0.04	0.04	0.08	4.60
Record, disclose, or display					8.05
information	-	0.07	0.07	0.14	
Store, file, or maintain information	_	-	0.07	0.07	2.92
TOTAL BURDEN ²	0.04	0.24	0.22	0.50	\$31.74

Table 4: Res	oondent Burden	and Cost per	r Response:	Unregistered Pesticides
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¹ Hourly wages rates are fully loaded wage rates based on NAICS 325300 - Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturing from U.S. Dept. of Labor, Bureau of Labor Statistics, 2014 data, Accessed March 2016. See Attachment G for wage calculations.

² Totals may not sum due to rounding.

The estimated total annual burden for unregistered pesticides is shown in Table 5. The total annual burden for unregistered pesticides and pesticidal devices is estimated to be 5,700 burden hours, at a cost of \$361,874.

Information Collection	Burden Per Response	Cost Per Response	Responses Per Year	Annual Burden	Total Costs
Notice of Arrival for					
Unregistered	0.50 hrs	\$31.74	11,400	5,700	\$361,874
Pesticides					

(ii) Other Costs

EPA acknowledges that delays of shipments resulting from resolution of issues arising in the NOA process may result in real costs incurred by the importer. While these costs are not part of the paperwork burden associated with this information collection activity, EPA is providing an estimate of costs that may arise. During the last renewal cycle (EPA ICR No. 0154.10), EPA consulted with 5 importers/brokers and asked them estimate the costs associated with delays due to resolving issues arising in the NOA review process. The respondents provided estimates that include storage, broker fees, container demurrage after free time, and additional freight and storage charges, as follows:

Table 6: Other Costs

Other Costs ¹	Estimated cost per day
Storage	\$264
Broker Fees	\$106
Container Demurrage	\$132
Additional Freight	\$317

During the last renewal cycle, one importer also indicated that there is a market loss of \$6,500 per day associated with delays. On average, it takes from one to five days to resolve an issue related to an NOA. EPA has not attempted to confirm these estimates. In many instances, if the importer submits the paper NOA prior to the arrival of shipment at the port of entry or files the NOA electronically with the filing of the entry documentation via any Customs-authorized electronic data interchange system, issues can be resolved quickly with no associated costs incurred.

EPA estimates that delays occur for less than 5% of all paper NOAs submitted to EPA and that as few as 2.5% to 5% of shipments are held at the port annually due to resolving issues associated with the NOA review. In many instances, if the importer has submitted a paper NOA prior to the arrival of shipment at the port of entry, issues can be resolved quickly and there is a little likelihood that delays and associated costs will be incurred. EPA expects delays to be minimal for electronic filings, but the Agency is unable to determine this until electronic filings become more routine.

6(c) Estimating Agency Burden

EPA estimates that, in total, 10 FTEs across EPA regional offices are allocated for processing data submitted under this information collection. The estimated number of federal government FTEs (full time equivalents) needed to process and review NOAs on an annual basis was increased from the previous estimate of 8 to 10. The number of EPA FTEs was estimated upward to 10 based on input from EPA regional offices and the increase in the number of NOAs received annually in comparison to the previous renewal cycle. To estimate the Agency burden hours for this ICR, the number of FTEs, 10, was multiplied by the number of workday hours in a year, 2,080 hours (52 weeks multiplied by 40hrs/week), to get a total of 20,800 Agency burden hours.

¹ The prices from the previous ICR were updated using the Consumer Price Index (CPI). Inflation rate based on CPI, All Urban Consumers, U.S. City Average, Series ID: CUSR0000SA0; change from June 2011 to June 2015.

Table 7: Agency Burden Estimate

	Total Burden Hours
FTEs (full time equivalents)	10 FTEs
Workday hours per FTE	2,080 hours
Total Workday Hours Annually	20,800 hours

6(d) Estimating Agency Costs

The methodology for calculating the wage rates in this renewal of the ICR has been updated to be consistent with the method for wage calculation for all ICRs managed by the Office of Pesticide Programs (OPP). The previous ICR used the 2011 annual salary for a federal employee at the GS-13, Step 1 level (\$71,674 annually, or \$34/hr, \$74/hr when fully loaded). This ICR uses the fully loaded hourly (flh) wage rate for technical staff in the federal government (\$77,272, \$37/hr, \$82/flh) to represent the wage rates for relevant Agency staff.

The current wage estimates are based on the most recent 2014 wage data, accessed online in 2016. The calculation of the wage rate uses base wage data for each sector and labor type for an *Unloaded wage rate* (hourly wage rate) and calculates the *Loaded wage rate* (unloaded wage rate + benefits) and the *Fully loaded wage rate* (loaded wage rate + overhead) based on that data.

Fully Loaded Wage Rate: OPP multiplies the loaded wage rate by 50% (EPA guidelines 20-70%) to get overhead costs. NAICS code 999100 for the Federal Government was used to calculate hourly wage rates for the Agency. The fully loaded hourly wage rates for management, technical, and clerical occupations for NAICS 999100 are \$124.09, \$81.53, and \$46.42, respectively. See Attachment G for labor wage calculations.

Table 7 shows the total cost of federal government labor for processing NOA forms. At a fully loaded annual wage rate of \$169,589 per FTE annually, the total annual cost of 10.0 FTEs to the federal government is approximately \$1.7 million.

Data Category	Value	
Fully Loaded Annual Rate (\$/year per FTE) *	\$169,589	
Total EPA FTEs	10	
Total Federal Government Labor Costs\$1,695,890		
* For calculation of Fully Loaded Annual Rate from base salary, see Attachment G		

Table 8: Federal Government (Agency) Labor Costs

In addition to labor costs, there are direct costs of printing instructions and reporting forms. In the previous ICR renewal, this cost was estimated at \$70,482. Adjusting for inflation using the Consumer Price Index, the direct cost of processing NOA forms for this ICR renewal is estimated at \$74,438.² Updating the number to account for the increase in NOAs, the value for this renewal is \$76,352.

With electronic NOAs, EPA estimates an additional \$5,000 in annual operations and maintenance costs to the federal government. These costs are associated with the electronic NOA

² Inflation rate based on Consumer Price Index, All Urban Consumers, U.S. City Average, Series ID: CUSR0000SA0; change from June 2011 to June 2015.

reference file that will be sent from the Pesticide Registration Information System to Customs via EPA's Central Data Exchange and received in ACE. There will be cost reductions from switching to electronic NOAs in the form of reduced printing costs and review time. These cost reductions will be estimated as the ACE system is implemented and will be reflected in future updates of this ICR.

Table 9 combines the labor costs and direct costs to the federal government of processing Notice of Arrival forms. The total cost is approximately \$1.8 million per year, assuming an average of 38,000 Notice of Arrival forms are processed each year.

Data Category	Value
Total Federal Government Labor Costs	\$1,695,890
Total Federal Government Direct Costs	\$76,352
Total Federal Government Operations and Maintenance Costs	\$5,000
TOTAL AGENCY COSTS	\$1,777,242

Table 9: Total Annual Agency Costs

6(e) Bottom Line Burden Hours and Cost

(i) Respondent Burden

The total annual respondent burden hours for this ICR are estimated at 16,340 hours. The total annual respondent cost for this ICR is estimated to be \$1,006,034.

Information Collection	Responses Per Year	Burden Per Response (hours)	Annual Burden (hours)	Total Costs
Notice of Arrival for				
Registered Pesticides	26,600	0.40	10,640	\$644,161
and Pesticidal Devices				
Notice of Arrival for				
Unregistered	11,400	0.50	5,700	\$361,874
Pesticides				
Total Annual	Respondent B	urden	16,340	\$1,006,034

Table 10: Total Annual Respondent Burden and Costs

(ii) <u>Agency Burden</u>

The total annual agency burden for this ICR is estimated to be 10 FTEs. With direct costs, this would result in a total annual agency cost of \$1,772,242.

Information Collection	Responses Per Year	Annual Burden* (hours)	Total Costs (Labor plus Direct & O&M)
Notice of Arrival	38,000	20,800	\$1,777,242

(iii) Bottom Line Burden and Cost

	TOTAL		
	Hours	Costs	
Respondent Burden Estimate	16,340	\$1,006,034	
Agency Burden Estimate	20,800	\$1,777,242	

Table 12: Bottom Line Burden Hours and Cost

6(f) Reasons for Change in Burden

There is an increase of 3,870 hours in the total estimated respondent burden compared with the currently approved ICR burden. This increase is a result of an increase in the annual number of NOAs submitted. The annual number of NOAs submitted to EPA increased from 35,000 for the previous ICR renewal to 38,000 for this ICR renewal. The average burden hours per response remained unchanged from the previous ICR renewal of 0.43 hours per response. This estimate of burden hours per response takes into account past changes to the data items on the NOA, as well as an accounting of the burden of submitting certain information voluntarily or as part of current practice. Specifically, this burden estimate accounts for the burdens related to providing a copy of the label as well as complete contact information, including a telephone number and email addresses, for the shipper, importer of record, licensed broker, carrier and ultimate consignee when supplying name and address information. In addition, EPA is accounting for the burden of voluntarily providing supporting documentation for registered and unregistered pesticides, active ingredients and percentage of each for registered pesticides, as well as intended use information for unregistered pesticides. The annual burden increase represents an adjustment.

Labor costs for respondents and the Agency increased as a result of changes in the wage rates made to: a) reflect current wage rates and b) to make the methodology for calculating wage rates consistent with other OPP ICRs. The new wage estimates incorporated higher estimates for benefits and overhead than were used in the past.

EPA expects that the burden hours and costs to file NOAs will decrease as electronic NOAs become a part of standard business practice. These cost reductions will be estimated as the ACE system is fully implemented and will be reflected in future updates of this ICR once EPA has data on the number of electronic and paper filings received by the Agency.

6(g) Burden Statement

The total annual respondent burden for this collection of information is estimated to be 16,340 hours. The annual respondent burden for the collection of information associated with the submission of a NOA is, on average, 0.43 hours per submission. This estimate includes the time for reviewing instructions, maintaining the data needed, and completing and reviewing the collection of information. The Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The Agency has established a public docket for this ICR under Docket ID No. EPA-HQ-OPP-2016-0122, which is available for online viewing at www.regulations.gov, or in person viewing at the OPP Docket in the EPA Docket Center, William Jefferson Clinton (WJC) West, Rm. 3334, 1200 Pennsylvania Ave, NW, Washington DC. This docket facility is open from 8:30 a.m. to 4:30 p.m.,

Monday through Friday, excluding legal holidays. The OPP Docket telephone number is (703) 305-5805.

You may submit comments regarding the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden, including the use of automated collection techniques. Submit your comments, referencing Docket ID No. EPA-HQ-OPP-2016-0122 and OMB Control No. 2070-0020, to (1) EPA online using www.regulations.gov (our preferred method), or by mail to: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mailcode: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and (2) OMB by mail to: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW, Washington, DC 20503.

ATTACHMENTS TO THE SUPPORTING STATEMENT

Attachments to the supporting statement are available in the public docket established for this ICR under docket identification number **EPA-HQ-OPP-2016-0122**. These attachments are available for online viewing at <u>http://www.regulations.gov/</u> or otherwise accessed as described in section 6(f) of the supporting statement.

Attachment A:	7 U.S.C. 1360 - Section 17 of the Federal Insecticide, Fungicide, and Rodenticide Act. Available online at the US Government Publishing Office's <u>website</u> .
Attachment B:	19 CFR 12.110-117. Available online at the US Government Publishing Office's <u>Electronic CFR Website.</u>
Attachment C:	Emergency Processing Request for Information Collected in the ITDS Pilot for Pesticide Notice of Arrival (OMB Control No. 2070-0020; EPA ICR No. 0152.11). Available online at http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201606-2070- 002
Attachment D:	EPA Response to Comments from Bayer CropScience on "Information Collection Request for Notice of Arrival of Pesticides and Devices under Section 17(c) of FIFRA."
Attachment E:	Summary of Consultations.
Attachment F:	EPA Form 3540-1 (Paper Form)
Attachment G:	Work Sheets used to Calculate Labor Costs