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SUPPORTING STATEMENT
ENVIRONMENTAL PROTECTION AGENCY
NOTICE OF ARRIVAL OF PESTICIDES AND DEVICES (EPA Form 3540-1)
19 CFR 12.110-117

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. 0152.10

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 Form 3540-1) to the U.S. Environmental Protection Agency (EPA or Agency). EPA will review the form and determine the disposition of the shipment. Upon completing Form 3540-1, EPA returns the form to the importer of record (importer) or licensed customs broker (broker), who must present the form 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.

Form 3540-1 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 Form 3540-1 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 review the form to 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 form 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 presents the completed NOA to the Customs District Director at the port of entry. Customs compares entry documents for the shipment with the NOA and 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.

During this renewal of this information collection, EPA is revising Form 3540-1. The revisions clarify the instructions for completing the form, amend the required data items, and update the terms used on the form to be consistent with those used by Customs. 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 existing practice or on a voluntary basis. EPA has found that questions about a

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shipment can often be resolved if the label or other supporting documentation accompanies the Form 3540-1 prior to the arrival of the shipment in the United States.

Respondents subject to this information collection include all importers of pesticides and 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) to notify the EPA of the arrival of pesticides in the United States. An NOA must be submitted for all imported devices and pesticides, including but not limited to those pesticides that are registered under section 3 of the 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 the 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 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.

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 Pesticides Programs (OPP) to monitor and assure compliance with FIFRA. Customs uses this information to ensure pesticide and 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

Some of the information collected on EPA's Notice of Arrival is identical or similar to information collected on Customs' entry notice form (Form 3461, OMB Control Number 1651-0024) or entry summary form (Form 7501, OMB Control Number 1651-0022). In addition, in order to expedite the processing of shipments of pesticides and devices, EPA recommends that respondents provide EPA with a copy of either the entry notice or entry summary, or other information submitted to Customs pursuant to 19 CFR 142.3(5). This supporting documentation allows EPA to validate the information provided on Form 3540-1. The information on entry forms is collected electronically via Customs ABI/ACS. EPA does not have the ability to electronically receive this information. Respondents would plan for and gather the information submitted on Form 3540-1 as part of customary business practices. To avoid double counting of burden hours, EPA only accounts for the additional time to enter the information and submit the form.

Customs entry forms cannot substitute for the submission of EPA's notice of arrival because the entry forms are not required to be completed prior to the arrival of the shipment and hence do not meet

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the requirements of FIFRA 17 (c). Entry may be made up to 15 days after a pesticide or device arrives in the U.S. and the entry forms does not contain all of the information required in a notice of arrival. The information in a notice of arrival is necessary for EPA to determine the disposition of a shipment upon its arrival in the U.S.

As discussed in Section 5(b), EPA is currently participating in the ACE/ITDS project. When ACE becomes fully functional, it will allow for the electronic collection of the information in the Notice of Arrival. EPA is currently undertaking rulemaking to facilitate the electronic submission of Notice of Arrival information.

EPA and the United States Department of Agriculture (USDA) both regulate the importation of seeds that are genetically-engineered to express pesticidal properties (a.k.a. plant-incorporated protectants, or PIPs). During the OMB comment period, the American Seed Trade Association submitted a comment asking OMB to consider alternatives for satisfying EPA's information needs in a manner that does not duplicate USDA requirements. EPA and USDA, along with Customs and OMB, are engaged in discussions to investigate the possible overlap between regulatory requirements and business processes regarding the importation of PIP seeds. The discussions will address: 1) the status quo process and information requirements at each agency concerning the importation of PIPs, identify any specific areas of overlap, and consider the feasibility of streamlining processes and requirements which overlap; 2) the potential for rule and non-rule options for streamlining government processes and/or reporting obligations, if identified, for importers of PIP seeds; and 3) the implications for existing information collection requests approved by OMB under the Paperwork Reduction Act. The agencies will also evaluate possible streamlining of processes and requirements that may be practicable under the 'single window' concept of Customs' ACE/ITDS, which will integrate and automate the government-wide collection, use, and dissemination of international trade data.

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

Pursuant to 5 CFR 1320.8(d), EPA published a Federal Register (FR) notice on Wednesday, December 14, 2011 (76 FR 77817) announcing the proposed renewal of this information collection activity and provided a 60-day public comment period. The Agency received three comments on this ICR renewal. The comments are available in the docket for this action, and are summarize below, along with EPA's responses, which are also available in the docket.

Two commenters, CropLife America and the Chemical Producers and Distributors Association requested that EPA allow for a 45-day extension of the public comment period from February 13 to March 29, 2012. The FR notice sought public comment on the renewal of three ICRs (OMB Control No.'s 2070-0032, 2070-0020, and 2070-0060) that are currently approved under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*). The approval for two ICRs (OMB Control No.'s 2070-0032 and 2070-0060) is currently scheduled to expire on July 31, 2012, and the approval for this ICR (OMB Control No. 2070-0020) is currently scheduled to expire on August 31, 2012. The agency carefully considered these requests to extend the comment period. However, the timeframes established under the PRA to renew ICRs before they expire are such that EPA was unable to allow for an extension of the comment period. EPA's response to the request for an extension is also available in the docket for this action.

Bayer CropSciences (Bayer) also submitted comments to the public docket. EPA's response to Bayer can be found in the docket (Docket ID EPA-HQ-OPP-2011-0843); EPA is summarizing Bayer's comments and the agency's responses here. Regarding the clarity of instructions on EPA Form 3540-1,

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Bayer provided several comments. Bayer commented that EPA's definition of brand name (block 6) could be confusing because a pesticide can be relabeled and may bear multiple alternate brand names for the same registration. EPA agrees with the need for clarification. EPA will revise the instructions for block from "Brand name of the product as it appears on the label under which the pesticide or device is sold or distributed" to "Brand name of the product as it appears on the product label at the time of import."

Bayer believes that the active ingredients and percentage of each (block 7) can be redundant because this registration information can often be found online at publically available websites. EPA must rely on the information provided by the importer at the time of importation. Publically available websites may not accurately describe registration information for products in the shipment upon importation and are not used to validate the active ingredients and percentages of each. EPA is recommending that this information be provided on EPA Form 3540-1 because the agency has found in practice that it needs to validate the formulation of imported pesticides. The actual active ingredients and percentages of each in the actual shipment of an imported pesticide may vary from the percentages as registered with EPA. EPA needs to ensure that the variation is within the certified limits for the pesticide product. In addition, EPA notes that, on occasion, the incorrect EPA registration number has been provided on EPA Form 3540-1; in such cases, EPA may not rely on the EPA registration number to identify the active ingredients or percentages of each.

Bayer commented that EPA should harmonize its definition of the country of origin with Customs definition. In addition, Bayer believes that EPA's requires that the country of origin provided on the form match the EPA Producer Establishment number (block 5), and hence is redundant, since country of origin is captured in the EPA Producer Establishment Number. The definition of the country of origin provided by EPA is harmonized with Customs definition. Under 19 CFR 134.1(b), Customs definition of country of origin states in part "Country of origin means the country of manufacture, production, or growth of any article of foreign origin entering the U.S." EPA's definition for the country of origin reads "The country of manufacture, production, or formulation of the pesticide or device of foreign origin entering the United States." The EPA Producer Establishment Number and the country of origin do not have the same definition. On the product label, the EPA Producer Establishment Number is the final establishment where the product was produced prior to shipment to the U.S. The country of origin represents the country where the product was first produced. Thus, the country of origin may be, but is not necessarily captured by, the EPA Producer Establishment Number.

Bayer noted that it can provide entry numbers for shipments (block 14), but the presence of this field as a required element of EPA Form 3540-1 creates certain challenges in timing of submission to EPA. Bayer also noted that some research and development compounds are shipped in such small quantities that they qualify for customs free entry into the United States, and therefore no entry number would be needed. Making this field required under these circumstances could create an unresolvable data gap in the form. EPA recommends that all applicable blocks on the NOA form be completed when submitting the form to EPA. The entry number is the primary data element that allows EPA to identify and communicate with Customs about a specific shipment. EPA will consider incomplete forms and resolve data gaps on a case-by-case basis.

Bayer believes that all data contained on EPA Form 3540-1 should be considered confidential and covered by confidentiality provisions of FIFRA with the exceptions of the information provided in blocks 4,5, 6 & 7. EPA notes that all the information provided on the form, with the exception of that in blocks 4, 5, 6, &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

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claiming as CBI. 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 claims.

Bayer asked EPA to clarify whether the EPA Establishment Number is required for movement of unregistered pesticides between establishments operated by different producers. EPA agrees with the need for clarification. EPA will revise the instructions for block 17 from:

“Location of Goods for Examination after Importation: Enter the physical address of the location of goods for examination after importation. In the case of unregistered pesticides products imported between establishments operated by the same producer, enter the EPA establishment number for importing registered establishment.”

to:

“Location of Goods for Examination after Importation: Enter the physical address of the location of goods for examination after importation. In the case of unregistered pesticides products imported between establishments operated by the same or different producer(s), enter the EPA establishment number for importing registered establishment.”

Bayer asked EPA to give consideration to capital investments made to comply with the notice of arrival requirement, and should include information considering potential impacts on commerce and business as a result of delays in shipment from resolving issues arising in the NOA process. EPA Form 3540-1 is available as a pdf document, and can be completed, printed, and stored using office technology and technology systems that are required for the routine and usual functioning of a company. In addition, this ICR renewal does not require new capital investments to acquire and install new systems. With regards to impacts on commerce and business as a result of delays in shipment from resolving issues arising in the NOA review process, EPA acknowledges that these are real costs associated with the regulation of the importation of pesticides. EPA makes every effort to resolve issues in a timely and efficient manner. Costs incurred during the review process, however, are not part of the burden of collecting, generating, or providing information that is the subject of this ICR.

Bayer also noted that, in its experience, the submission of supporting information along with the EPA Form 3540-1 is not voluntary. Bayer noted that documentation requests for supporting information are inconsistent between EPA regions, are time consuming and can lead to additional delays or issues with the notice of arrival review process for reasons unrelated to the notice of arrival or human health and safety. Bayer would ask that if such practices are to be normal that they not be given a “voluntary” designation but rather be officially incorporated and standardized as part of the notice of arrival process. In its response to Bayer, EPA noted that although §17(c) provides authority for the U.S. Government to require companies to provide information that is necessary to ensure that a pesticide shipment is in compliance with FIFRA, consistent with the purposes of the Paperwork Reduction Act, information should only be requested when needed. Supporting information is needed in some cases and not others. The recommendation to provide the supporting information with EPA Form 3540-1 prior to arrival is based on EPA’s experience that importers have learned that supplying supporting information expedites the notice of arrival review process. The decision to request supporting information for an imported pesticide, if the information not provided voluntarily by the importer, is made on a case-by-case basis by the regional office, depending on the unique circumstances of surrounding the importation of the pesticide product. If an importer believes that it is more efficient to routinely submit supporting information, that company may incorporate such submission into its standard business operations without necessity of a Government requirement.

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EPA has since re-considered Bayer's comment. As stated above, the agency maintains that information should only be requested when needed. In practice, a copy of the product label submitted by the importer is routinely reviewed by regional staff as part of the notice of arrival process; the label, however, is not reviewed in every instance. The agency also recognizes that it may be more efficient for importers to submit the label with the NOA, rather than supply the label later in the review process upon receiving a request from EPA. Hence, EPA is including the label as a recommended data item in the standard NOA package and accounting for the respondent burden of submitting the label to EPA as part of current practice.

3(c) Consultations

As part of preparation of this ICR renewal, EPA contacted representatives from importers and brokers 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 that participated in the consultation process, and a summary of the consultations is provided in the docket for this action.

Regarding clarity of instructions, two representatives, Bayer and Syngenta, asked EPA to clarify the instructions for submitting EPA Form 3540-1 and for completing blocks on the form designated as self-explanatory. For this ICR Renewal, EPA has clarified the instructions for submitting the form and for completing all data elements.

In addition, Bayer asked EPA to provide direction on EPA Form 3540-1 regarding what should be done if the shipment is delayed or there is a carrier change after the form has been filed and approved (and therefore the entry date or shipper is incorrect). Bayer also asked whether direction could be placed on the form as to how much advance notice EPA would like a form received by. If the information on EPA Form 3540-1 changes after it has been submitted and approved, EPA recommends that the importer contact the Region having jurisdiction of the state/territory of the port of entry where the shipment will arrive. Further, EPA recommends that the importer submit the form prior to the arrival of the pesticide or device at the port of entry. EPA leaves the exact timing of the submission of the notice of arrival to the importer's discretion. Syngenta asked for clarification on net quantities and units of measure requirements. Due to the variety of packaging, EPA provides importers with discretion when reporting net quantities and units of measures. On the revised Form 3540-1, EPA provided clarification that the net weight is the net weight as identified on the product label of the pesticide or device on the immediate container, not including the wrapper or other packaging materials.

Regarding the frequency of submission and the review process, Syngenta noted that EPA will not grant blanket notice of arrivals for multiple shipments arriving in defined period of time. EPA is not contemplating granting blanket notices at this time. Bayer noted that some Regions require justification of CBI claims, which can take several weeks to resolve. EPA notes that during review of a notice of arrival, EPA regional staff may on occasion raise a question regarding confidentiality claims, but the Agency does not delay approval of a shipment based on such claims.

Regarding the burden estimates, the respondent representatives provided a range of estimates for the burden hours required to complete EPA Form 3540-1. The estimates provided range from 0.18 hrs to 3.85 hrs. EPA believes that an estimate of the burden per NOA calculated by averaging the estimate provided by the consultants would over-estimate the burden per response. The respondents included burden estimates of activities that are customary and usual, and hence, according to OMB guidance, would not be included in EPA burden calculation. EPA contacted by phone a representative from the

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brokerage firm Norman Jensen, which provided an estimate of 3.85 hours per shipment. The representative indicated that their estimate represented a “worst case scenario” for a shipment with multiple pesticide products that would require the submission of multiple NOAs. Upon subtracting the burden associated with customary and usual activities and taking into account that EPA calculates the burden per NOA, the estimate provided by Norman Jensen is consistent with EPA’s estimate.

For this ICR renewal, EPA increased the burden from .3 hrs to .43 hrs per response, on average, as discussed in section 6(f) below. This change in burden hours per response is a result of changes to the data items on Form 3540-1, and well as an accounting of the burden of voluntarily submitting certain information. EPA’s estimate of the burden hours represents an average. Some respondents will spend less time and others more time than the estimated average.

EPA appreciates the comments provided during the consultation period. These communications permit an exchange of issues, problems and solutions on many issues.

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.

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

If information on Form 3540-1 is declared sensitive or confidential, it cannot be released to the public. Certain information on Form 3540-1 (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 Confidential Business Information (CBI). Other information (EPA Registration Number and Producer Establishment Number, the brand name of product, and active ingredients and percentages of each) may not be claimed as CBI pursuant to FIFRA section 7(d) and labeling requirements for pesticides/devices at 40 CFR § 156.10.

Confidential data submitted to EPA is handled in accordance with the provisions of the FIFRA 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.

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 business 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, devices are the same, except where indicated below.

a. Currently approved 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 and complete address of broker or agent (19 CFR 12.112)
- name and complete address of importer or consignee (19 CFR 12.112)
- name and 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, entry date (19 CFR 12.113)
- carrier (19 CFR 12.113)
- location of good for examination after importation (19 CFR 12.115)

b. Revisions to the data items

EPA is revising the following minor changes to the data items on EPA Form 3540-1 under this information collection:

- Requiring the complete address of the carrier (19 CFR 12.113). Currently, only the name is required. This information allows EPA to contact the carrier, if necessary, to resolve issues arising in the NOA review, and it assists EPA in identifying a shipment when coordinating review of the shipment with Customs.
- Adding the email and phone numbers to the address information required for the importer, broker, shipper, carrier, and consignee (19 CFR 12.112). The complete address will be defined to include the physical address, telephone number (including cellular or mobile telephone), and email address. Email and phone number facilitate communications with

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parties involved in importing a pesticide or device, with the goal of resolving issues quickly and avoiding delays

- Changing the entry date to anticipated entry date (19 CFR 12.113)
- Adding the recommendation that respondents importing an unregistered pesticide provide additional information, including the intended use and a description of why the product is being imported into the United States, in the remarks. Providing this information voluntarily on Form 3540-1 will expedite EPA's review of the Notice of Arrival.
- Adding the recommendation that respondents of registered pesticides list the active ingredients and percentage of each. Most respondents already voluntarily provide this information. For unregistered pesticides, this information provides the identity of the active ingredient in the pesticide product. For registered pesticides, this information allows EPA to verify that the chemical composition of the pesticide product being imported matches the chemical composition as a condition of the registration of the product in the United States. This addition is accounting for current practice.
- Including the product label 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 CBP Officers take appropriate precautionary measures when handling these shipments at the port. This addition is accounting for current practice.
- Adding the recommendation that respondents include supporting documentation, such as a material safety data sheets, 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 addition is accounting for current practice.

(ii) Respondent Activities

- Read instructions on reverse side of Form 3540-1
- Plan activities-CBP
- Gather information
- Enter information on Form 3540-1 and submit Form, including the label, to EPA prior to arrival of pesticide or device product
- Respond to questions if further inquires are made by EPA
- Submit Form 3540-1, after it is reviewed and signed by EPA, to Customs and Border Protection
- 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.

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

5(a) Agency Activities

EPA regional personnel review Form 3540-1 for accuracy and completeness of the submitted information and maintain 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 device shipment. EPA regional personnel also work with Customs agents at the port of entry to resolve discrepancies between information submitted on Form 3540-1 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 the Form 3540-1.

In addition to the revisions of the data items discussed in 4(b), EPA is proposing the following changes to Form 3540-1 to improve the information collected and review process for importers:

1. Change “Broker” to “Licensed Broker” in Block 1 and “Importer” to “Importer of Record” in Block 2. EPA is also removing the term “Agent” in Blocks 1, 19 and 20. These changes will improve the form’s consistency with the terminology used by Customs.
2. Include in the Instructions for completing Form 3549-1 and in the Remarks (Block 19) a recommendation that a copy of the label be submitted with the NOA.
3. Include in the Instructions for completing Form 3540-1 a recommendation to the importer to voluntarily provide all information, including supporting documentation, at the time of submission of Form 3540-1 to EPA prior to the arrival of the shipment in the United States in order to expedite the review of the pesticide or device shipment.
4. Include in the instructions for the Remarks in Block 19 a reminder that respondents can voluntarily submit additional information. Pesticides or devices without an EPA registration number often require consultation between the EPA reviewer and the respondent and many respondents are not aware they can submit additional information.
5. Clarify the instructions for Blocks 3, 4, 5, 6, 7, 11, 13, 16 and 17. EPA has closely followed EPA and Customs regulatory provisions in proposing these changes.
6. Add instructions for Blocks 1, 2, 8, 9, 10, 12, 14, 15, and 18. The added instructions primarily provide information for those respondents not familiar with importing pesticides and devices, and clarify the information that is needed for those who are familiar with import requirements. EPA has closely followed EPA and Customs regulatory provisions in proposing these changes.

The currently approved version and revised versions of EPA Form 35401-1 are included in the docket for this action. In addition, EPA revised the instructions based on comments received during the first comment period. The final revised version is also in the docket.

NOA information is entered once onto Form 3540-1, 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

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pesticides or devices and notify the Administrator of any discrepancies.

EPA is currently participating in an interagency initiative known as the International Trade Data System (ITDS). 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.

ITDS is the organizational framework for Customs and more than 40 participating government agencies to integrate import requirements into a modernized, upgraded Automated Commercial Environment (ACE), which is being designed by Customs to process imports and exports. EPA is currently 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 devices. In the future, EPA anticipates that most importers will submit the notice of arrival electronically in the ACE system, and that the notice of arrival process will be done electronically and almost instantaneously among importers, EPA, and Customs for most shipments of pesticides or devices.

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 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 35,000 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 25,000. In 2010, EPA received approximately 27,000 NOAs and in 2011, EPA received approximately 30,000 NOAs. If this trend continues, EPA anticipates that over the next three years, EPA will receive, on average, 35,000 NOAs annually. EPA believes that the increase in NOAs may be due, in part, to the changing nature of the pesticide industry. As pesticide manufacturers have adjusted to the global economy, they may have shifted some of their manufacturing to overseas locations.

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:

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- 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 for each response type is based on the number of each type of response, exhibited in Table 1.

Table 1: Number of Responses by Type

Type of Response	Number of Responses	Percent of Total (%)	Burden Hours per Response
Registered Pesticides and Devices	24,500	70	0.40
Unregistered Pesticides	10,500	30	0.50

As discussed above, importers must submit EPA Form 3540-1 prior to the arrival in the United States of a shipment of a pesticide or device. 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 with Form 3540-1. 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.

EPA estimates it will take respondents submitting a NOA for a registered pesticide or device product 0.40 hours per response to read instructions, complete form, and submit information to EPA and Customs, for a total of 9,800 hours annually. Respondents submitting a NOA for unregistered pesticides will require 0.50 hours for these activities, or 5,250 hours annually. The annual burden hours per response type are found by multiplying the annual number of responses per response type times the burden per response. The paperwork burden estimates represent the average 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 15,050 hours annually.

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 wage estimates are based on 2010 wage data. 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 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

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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 D. 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 44% 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 \$120.28, \$60.85, and \$37.11, respectively. See Attachment D for labor wage calculations.

Table 2 shows the estimated respondent burden and cost for submitting EPA Form 3540-1, including a label and other supporting documents, for registered pesticide and devices. For these products, EPA estimates the burden per response to be 0.40 hours.

Table 2: Respondent Burden and Cost Per Response: Registered Pesticides and Devices

Collection Activities	Management (hours)	Technical (hours)	Clerical (hours)	Total (hours)	Cost (\$)
	\$120.28	\$60.85	\$37.11		
Read or hear any instructions	0.01	0.05	-	0.06	4.25
Plan activities	-	-	-	-	-
Create information	-	-	-	-	-
Gather information, including label and supporting information	-	0.02	0.03	0.05	2.33
Process, compile, review information for accuracy	0.02	0.05	-	0.07	5.45
Complete written forms	-	0.04	0.04	0.08	3.92
Record, disclose, or display information	-	-	0.07	0.07	2.60
Store, file, or maintain information	-	-	0.07	0.07	2.60
TOTAL BURDEN	0.03	0.16	0.21	0.40	21.14

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, May 2010. See Attachment C for wage calculations.

² Totals may not sum due to rounding.

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The estimated total annual burden for registered pesticides and devices is shown in Table 3. The total annual burden is estimate to be 9,800 burden hours, at a cost of \$517,887. 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 Devices

Information Collection	Burden Per Response	Cost Per Response	Responses Per Year	Annual Burden	Total Costs
Notice of Arrival for Registered Pesticides and Devices	0.40 hrs	\$21.14	24,500	9,800 hrs	\$517,887

Table 4 shows the estimated respondent burden and cost for submitting EPA Form 3540-1, 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.

Table 4: Respondent Burden and Cost Per Response: Unregistered Pesticides

Collection Activities	Management (hours)	Technical (hours)	Clerical (hours)	Total (hours)	Cost (\$)
	\$120.28	\$61.85	\$37.11		
Read or hear any instructions	0.02	0.05	-	0.07	5.45
Plan activities	-	-	-	-	-
Create information	-	-	-	-	-
Gather information, including label and supporting information	-	0.03	0.04	0.07	3.31
Process, compile, review information for accuracy	0.02	0.05	-	0.07	5.45
Complete written forms	-	0.04	0.04	0.08	3.92
Record, disclose, or display information	-	0.07	0.07	0.14	6.86
Store, file, or maintain information	-	-	0.07	0.07	2.60
TOTAL BURDEN	0.04	0.24	0.22	0.50	27.58

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, May 2010. See Attachment C 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 devices is estimate to be 5,250 burden hours, at a cost of \$289,593.

Table 5: Total Annual Respondent Burden and Cost: Unregistered Pesticides

Information Collection	Burden Per Response	Cost Per Response	Responses Per Year	Annual Burden	Total Costs
Notice of Arrival for Unregistered Pesticides	0.50 hrs	\$27.58	10,500	5,250 hrs	\$289,593

(ii) Estimating Capital and Operations and Maintenance Costs.

Not applicable.

(iii) Capital Start-up vs. Operating and Maintenance Costs

Not applicable.

(iv) 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. 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	Estimated cost per day
Storage	\$ 250
Broker Fees	\$ 100
Container Demurrage	\$ 125
Additional Freight	\$ 300

One importer 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 had submitted the NOA prior to the arrival of shipment at the port of entry, issues can be resolved quickly with no associated costs are incurred.

EPA estimates that delays occur for less than 5% of all NOA 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 the 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.

6(c) Estimating Agency Burden and Cost

EPA estimates that in total 8.0 FTEs across EPA regional offices are allocated for processing data submitted under this information collection. The estimated number of federal government FTEs needed to process and review EPA Form 3540-1 on an annual basis was increased from the previous estimate of 3.57 to 8.0. The number of EPA FTEs was estimated at 8.0 based on input from EPA regional offices. The increase reflects more accurate estimates of the federal government burden for processing NOAs.

The annual salary for a federal employee at the GS-13, Step 1 level (\$71,674) is used as the base wage; no adjustment for locality is made because employees that process NOA forms work in several different localities. After adjusting the salary to account for the cost of benefits and overhead, the fully

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loaded annual rate is \$154,386; calculations are shown in Attachment D.

Table 7 shows the total cost of federal government labor for processing NOA forms. At a fully loaded annual wage rate of \$154,386 per year, the total annual cost of 8.0 FTEs to the federal government is approximately \$1.24 million.

Table 7: Federal Government (Agency) Labor Costs

Data Category	Value
Fully Loaded Annual Rate (\$/year per FTE) *	\$154,386
Total EPA FTEs	8.00
Total Federal Government Labor Costs	\$ 1,235,086
* For calculation of Fully Loaded Annual Rate from base salary, see Attachment C	

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 \$60,947. Adjusting for inflation using the Consumer Price Index, the direct cost of processing NOA forms for this ICR renewal is estimated at \$62,390.¹ Updating the number to account for the increase in NOAs, the value for this renewal is \$70,482.

Table 8 combines the labor costs and direct costs to the federal government of processing Notice of Arrival forms. The total cost is approximately \$1.3 million per year, assuming an average of 35,000 Notice of Arrival forms are processed each year.

Table 8: Total Agency Costs

Data Category	Value
Total Federal Government Labor Costs	\$ 1,235,086
Total Federal Government Direct Costs	\$ 70,482
TOTAL AGENCY COSTS	\$ 1,305,568

6(d) Bottom Line Burden Hours and Cost

(i) Respondent Burden

The total annual respondent burden hours for this ICR are estimated at 15,050 hours. The total annual respondent cost for this ICR is estimated to be \$807,480.

¹ Inflation rate based on Consumer Price Index, All Urban Consumers, U.S. City Average, Series ID: CUSR0000SA0; change from June 2008 to June 2011.

Table 9: Total Annual Respondent Burden and Costs

Information Collection	Responses Per Year	Burden Per Response (hours)	Annual Burden (hours)	Total Costs
Notice of Arrival for Registered Pesticides and Devices	24,500	0.40	9,800	\$517,887
Notice of Arrival for Unregistered Pesticides	10,500	0.50	5,250	\$289,593
Total Annual Respondent Burden			15,050	\$807,480

(ii) Agency Burden

The total annual agency burden for this ICR is estimated to be 8.0 FTEs. With direct costs, this would result in a total annual agency cost of \$1,305,568.

Table 10: Total Annual Agency Burden and Costs

Information Collection	Responses Per Year	Annual Burden (FTEs)	Total Costs (Labor plus Direct)
Notice of Arrival	35,000	8.0	\$1,305,568

(iii) Bottom Line Burden and Cost

Table 11: Bottom Line Burden Hours and Cost

	TOTAL	
	Hours/FTEs	Costs
Respondent Burden Estimate	15,050 Hours	\$807,480
Agency Burden Estimate	8.0 FTEs	\$1,305,568

6(f) Reasons for Change in Burden

There is an increase of 7,550 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 and an increase in the burden hours per response. The annual number of NOAs submitted to EPA increased from 25,000 for the previous ICR renewal to 35,000 for this ICR renewal. The average burden hours per response will change from 0.30 hours for the previous ICR renewal to 0.43 hours for this ICR renewal. This change in burden hours per response is a result of changes to the data items on Form 3540-1, and 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 new 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.

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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.

6(g) Burden Statement

The total annual public respondent burden for this collection of information is estimated to be 15,050 hours. The annual respondent burden for the collection of information associated with the submission of EPA Form 3540-1 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-2011-0843, which is available for online viewing at www.regulations.gov, or in person viewing at the OPP Docket in the EPA Docket Center, EPA 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-2011-0843 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.

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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-2011-0843**. These attachments are available for online viewing at www.regulations.gov or otherwise accessed as described in section 6(f) of the supporting statement.

- Attachment A:** 7 U.S.C. 136o - Section 17 of the Federal Insecticide, Fungicide, and Rodenticide Act. Available online at the US House of Representatives' [US Code website](#)
- Attachment B:** 19 CFR 12.110-117. Available online at the National Archives and Records Administration's [Electronic CFR Website](#)
- Attachment C:** Work Sheets used to Calculate Labor Costs
- Attachment D:** Summary of Consultations
- Attachment E:** EPA Form 3540-1
- Attachment F:** Public Comment Received from CropLife America
- Attachment G:** Public Comment Received from Chemical Producers and Distributors Association
- Attachment H:** Public Comment Received from BayerSciences LP