

Attachment D

EPA Responses to Comments from Bayer CropScience on “Information Collection Request for Notice of Arrival of Pesticides and Devices under Section 17(c) of FIFRA” (Docket EPA-HQ-OPP-2016-0122)

Comment 1: Bayer CropSciences (Bayer) believes that active ingredients (AI) and percentages of each AI should be treated as CBI for compounds imported for research and development (R&D) purposes. Because EPA requires this field and because Bayer also needs to maintain confidentiality on research materials, Bayer proposes 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. In this manner companies may provide EPA with the necessary information to facilitate import but not risk exposure of sensitive information. An associated field could be created in box 18 to allow for identification when an internal compound name is utilized. This option need not be available for registered pesticide products.

Response: As stated in the 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 a rulemaking related to filing NOAs through the ACE/ITDS system. Changes to the NOA forms to address issues such as this (to be available either through electronic or 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.

Comment 2: Bayer believes 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. An EPA NOA represents a commercial activity of the respondent, namely the importation of a product for commercial reasons (e.g. sale, manufacturing, etc.). There is no public benefit or need to disclose any of the information contained in an NOA as the public has no right under FIFRA to track the commercial operations of an individual or company. The data disclosed by the EPA for NOAs can be, and is used to calculate a company’s marketing forecasts, identify manufacturing sites for generic duplication of a company’s proprietary formulas, and evaluate a company’s import strategies and business relationships to potentially garner additional information⁴. Examples of these activities make up a substantial number of requests under the Freedom of Information Act⁵. Recognizing that such information may be disclosed to the public, Bayer has attempted to claim all its NOAs as confidential as allowed within the existing system (excepting boxes 4, 5, 6, & 7), but has been hindered from doing so by the disparate manner in which EPA regions have carried out these CBI requests. Some EPA regions accept the CBI with no questions asked, but others put the NOA under a legal review with EPA’s Office of General Council (OGC) citing transparency requirements of the current administration.

Without discussing the need to do so, the different approaches to executing a CBI request on an NOA have the practical effect of substantially delaying NOA approvals⁶, adjusting port of entry choices to account for inconsistent enforcement practices (which usually lead to increases in shipping costs), and creating delays in NOA review. 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.

Response: 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 imports 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 claims.

Comment 3: Bayer states that it has been communicated by the Agency that it will not allow for the return of goods bearing a US based EPA establishment number to be “imported” into the United States, and that such goods should bear a 98 series HS code⁷ allowing for importation of US based goods under the CBP 3311 form without the need for an NOA. In some cases these products bear a label which make them suitable for sale in the United States. EPA’s rationale is that it is too easy for an importer to use this process to import misbranded and unregistered products. While Bayer is sympathetic and appreciates this effort, business realities sometimes require the return of sold product for legitimate reasons. If a Purchaser Acknowledgement Statement (PAS) has not been filed, there should be no blanket restriction on returned goods. Additionally for returned pesticides, FIFRA clearly mandates that the NOA process be used when bringing this product into the country. This also has ramifications on whether a returned product is sold or exported on the section 7 reporting system. As EPA is seeking to increase scrutiny of these returns it is suggested that, instead of disallowing the return of goods under these circumstances, the following declarations be made, preferably on the NOA form box 19, for all goods identifying a US-based establishment number:

- a. The product is a return of goods produced in the US that do not qualify for reentry as per CBP 3311; and
- b. The product in question has not been modified or otherwise changed since export.

Response: Pesticides that are produced in the U.S., exported to a foreign market, and then subsequently returned are subject to the import requirements of FIFRA, not the general provisions provided by CBP’s regulations.

Comment 4: Bayer applauds EPA’s proposal to integrate into the customs process through use of the ABI/ACS systems. We feel that any alignment of the EPA’s data needs with data currently collected through other systems (or *vice versa*) will enhance the quality, utility and accuracy of

information collected. Additionally, integration into other systems will help harmonize enforcement and application of policies (such as CBI) not only between regions, but also between US Administrative Agencies. Bayer supports this effort, and looks forward to its implementation.

Response: As stated in the revised supporting statement, electronic filing through ACE/ITDS has been tested through a pilot since June 2016, and is permanently available through an interim final rule published on September 30, 2016. Additional rulemaking to facilitate its usage is planned for 2017.

Comment 5: Bayer states 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. #) captured in box 5. Instead, EPA should accept the CBP country of origin within the CBP the Automated Commercial Environment (ACE) environment, which is provided based on CBP rules.

Response: EPA is in the process of harmonizing with CBP under ACE the definition of “Country of Origin” and plans to update the NOA form using the CBP 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.

Comment 6: Bayer stated that electronic integration of EPA’s NOA requirement with the existing electronic CBP database, ACE, will help reduce complexity, confusion, and data errors. Additionally, this will allow Bayer to reduce its costs in preparation and tracking of this information. Such innovative solutions are appreciated, and Bayer intends to make use of these solutions when they are available.

Response: As stated in the revised supporting statement, electronic filing through ACE/ITDS has been tested through a pilot since June 2016, and is available permanently through an interim final rule published on September 30, 2016. EPA and CBP intend to complete other revisions to the regulations to facilitate the electronic filing of NOAs in 2017, which may revise portions of the existing NOA form. Bayer is encouraged to provide comment during those efforts as well.

Comment 7: 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.

Response: 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 to facilitate a streamlined and more efficient review and approval. Much of the supporting information requested by a Regional Office reviewing a NOA will be available to EPA Regional Offices in the ACE environment.

Comment 8: Bayer indicated that some of the information requested on the NOA form are already collected to some extent. Bayer states that Import data is currently collected by US customs services, which protects most collected data as confidential business information. However, ship manifests are routinely disclosed from the port of entry and provide specific details of all shipments. This information is available through the Port Import/Export Reporting Service (PIERS). Such information is limited to the raw import Bills of Lading for all waterborne cargo vessels, and it does not cover air or land freight shipments. PIERS does not collect all fields required by the EPA NOA for pesticide registration information.

Response: Some of the information collected on EPA's NOA 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 pesticidal devices when the NOA Form is filed, EPA recommends the importer submits 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 previously collected electronically via Customs ABI/ACS is now being replaced by ACE. Filers 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 NOA because the entry forms are not required to be completed prior to the arrival of the shipment and hence do not meet the requirements of FIFRA section 17(c). Entry may be made up to 15 days after a pesticide or pesticidal 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 NOA is necessary for EPA to determine the disposition of a shipment upon its arrival in the U.S.

EPA is participating in ACE/ITDS, which will be a single window for trade to submit info to the federal government. With ACE being implemented, importers who choose to submit in ACE will no longer need to duplicate their efforts. NOAs can currently be submitted through the

ACE/ITDS, which has been available fulltime since September 30, 2016. EPA is currently undertaking additional rulemaking to facilitate the electronic submission of Notice of Arrival information. This renewal document only identifies those burdens associated with the current collection activities for both paper and electronic NOAs, and will be revised once EPA and CBP make additional revisions to the regulations in 2017.

Comment 9: Bayer states that electronic reporting and transmission would be beneficial to industry and ease both recordkeeping obligations and transmission. Additionally multiple parties could have access simultaneously, reducing redundancy. Finally, should correction or resubmission be needed, electronic communication would minimize the burden and costs to all parties and help reduce delay in the import process. As mentioned above electronic reporting would be beneficial to industry provided that confidentiality can be ensured. Bayer requests to participate in the ACE-EPA implementation effort.

Response: EPA agrees. In June 2016, EPA and Customs launched an ACE/ITDS pilot to test the submission of NOAs electronically. The electronic submission option has since been made available permanently on September 30, 2016. EPA and Customs intends to propose additional rulemaking to clarify requirements for NOAs and facilitate the implementation of ACE in 2017. Bayer is encouraged to provide comment on those rulemakings.

Comment 10: Bayer states that instructions on the NOA are clear and suggested improvements in previous comments. The primary issue at this point is the inconsistent and diverging requirements of regional EPA authorities tasked with oversight of this process. Some require labels, confidential formulas, Certificates of Authenticity, or other documents while other regions do not require this documentation. Additionally, enforcement of NOA data is inconsistent, with some regions requiring form changes for each instance in which a ship docks a day late, while others deem these variations to be a trivial irregularity. Standardization of required documents would be useful to integrate regulatory and logistics functions to more efficiently deliver the information the EPA regions require.

Response: As the EPA continues to work through ACE implementations issues with Customs, it is our goal to create greater consistency in the review and approval of NOAs throughout. EPA regional offices with oversight responsibilities may request additional information on a case-by-case basis in order to ensure compliance with FIFRA.

Comment 11: Bayer maintains significant information technology infrastructure for accounting, import/export logistics and in all manufacturing plants tied to providing information for the NOA. While these systems support several functions, it is incorrect that there are no capital costs to Bayer associated with this activity.

Response: EPA Form 3540-1 is currently available as a PDF document and electronically through ACE/ITDS 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. This ICR renewal does not require new capital investments to acquire and install new systems and does not create added or new capital investments outside of what has been assessed for the ACE.

Comment 12: Bayer estimates its own expense in completion of the form to be 650 hours per year. The current process for completion is:

- Receive shipping documentation from foreign shipper
- Determine appropriate EPA regulation>TSCA or FIFRA. If FIFRA,
- Identify port of entry using shipping docs (box 12)>this determines EPA regional office to file NOA
- Complete NOA form using 2014 document version,
 - o *2 regions allow electronic NOA filing (Region 6/TX, Region 9/CA)>comparable time taken to enter NOA data in the designated online portal.*
 - o *All other regions follow the standard process, requiring hardcopy documentation.*
 - o Request entry number from Customs broker, include on NOA form. Region 2 requires dummy 7501 which must be provided to us by Customs broker
 - o Prepare any additional documentation required by designated regional office. Region 2 requires a pro forma invoice, Regions 4, 7 required addendum letters, Regions 6 and 9 require a guideline statement (similar to USDA 1114)
- Review EPA label to determine if respective data fields are accurate (EPA Reg #, EPA Est #, CBP origin marking). If label is questionable, follow up with Label Graphics and KIM teams for further review.
- Save pdf copy of NOA in our archive system, by product and entry number (or IT # for FTZ).
- Print 2 copies of NOA form, 1 cover letter, 1 copy of additional documentation, and EPA label to submit to regional office; secondary copies of the aforementioned docs are printed and retained in entry folder.
- Create mailing label to submit NOA to regional office, and return mailing label to send back to importer or Customs broker. We have had a few instances of where EPA will hold NOA until they receive a return mailing envelop, because they do not want to pay postage.
- Received approved hardcopy from EPA either directly to team or by Customs broker. Once entry complete, Imports team scans copies of entry docs (including NOA) to SharePoint as convenience/information copies.

Bayer also estimates an additional 30-60 minutes per NOA that are questioned by EPA, including research, review, and response to agency...timetable depends upon receipt of information from other teams. This may take longer, spanning into 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.

According to Bayer, NOA review/approval times are dependent upon the regional office, with most regions take an average of approx. 3-5 business days to review and approve. However, certain regions may take 2-3 weeks to approve considering high NOA volumes they process. We advise our customers that NOA processing time can take approx. 1 week to receive an approved NOA. Assuming the NOA is filed upon customs entry, this adds and associated 5 days of storage and other costs. 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.

Response: EPA believes that the additional burden per 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 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, another representative indicated that EPA's estimate may be off the first few times a company completes a NOA, but were otherwise accurate once NOAs become routine. Therefore, EPA is maintaining that the burden to complete a NOA is approximately 0.43 hours per response. EPA expects that much of the burden and delay outlined by Bayer should be alleviated as the use of ACE becomes routine. EPA intends on reexamining whether burden reductions have occurred during the next renewal.

Comment 13: In the event of delays in the import process, Bayer could expect expenses dealing with the storage and holding of samples. Such charges are somewhat dependent upon the type of shipment and include:

- For courier / sample type of shipments
 - o \$20 - 30 per shipment per day for
- For ocean containers
 - o \$100 - 300 per day
 - o An additional \$100+ per day if goods sit at the rail ramp

Air freight is even more expensive than ocean containers but costs were not immediately available at the time comments were submitted.

Response: As ACE becomes fully operational, importers will be encouraged to submit the required NOA for pesticide shipments via ACE to avoid anticipated delays. If importers choose to continue to utilize the paper submission of NOAs, they must ensure that all supporting documentation is present along with the NOA and that the NOA is completed truthfully and accurately, with no missing data elements, to avoid potential delays and the associated costs with those delays. EPA has addressed the potential costs of delays for the paper submissions of NOAs in Table 6 of the supporting statement, but expects this to occur for less than 5% of all paper NOAs submitted. EPA expects this to be minimal once ACE is fully implemented and becomes routine.