Bayer CropScience

June 14, 2016

Office of Pesticide Programs (OPP)
Regulatory Public Docket (7502P)
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

RE: Comments to Docket ID Number: EPA-HQ-OPP-2016-0122; Information Collection Request for Notice of Arrival of Pesticides and Devices under Section 17(c) of FIFRA.

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Dear Sir or Madam:

Bayer CropScience LP (Bayer) is submitting comments to EPA's *Federal Register* publication dated April 15, 2016 regarding proposed changes to the EPA Notice of Arrival of Pesticides and Devices form (NOA)[1]. Bayer appreciates EPA's efforts to continue to streamline and improve on their regulatory practices to carry out their duties while continuing to make the process more efficient and less burdensome for respondents. Bayer is providing comments in this letter only regarding the NOA process in the docket ID number specified above.

Bayer is one of the largest agricultural chemical producers in the world. With manufacturing facilities all over the world, the pesticide importation process is of great importance to Bayer's operations. Due to specific manufacturing time frames and intense competitive pressure in the marketplace, Bayer's utilization of open international trade is essential to providing high quality products to the market place at a reasonable cost. Bayer's compliance with all requirements of sovereign nations is part of this cost, and processes which delay or detain shipments of goods used in manufacturing and commerce can represent a significant disruption to operations. We applaud the resources EPA commits to the execution of their duties, and efforts to help reduce the complexity and confusion that sometimes arises.

In its *Federal Register* publication, EPA has requested for comments on its Information Collection Activities (ICR) which is to be submitted to the US Office

[1] 81 FR 22261-22262

of Management and Budget (OMB) for approval. Specifically, EPA is requesting information on:

Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.

Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

Enhance the quality, utility, and clarity of the information to be collected.

Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

Bayer will address these requests in the order requested.

Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.

Bayer believes that the Agency is unnecessarily limiting respondents' ability to provide information in several areas in which an alternative collection process could achieve more accuracy overall with less burden on both the agencies and respondents. Specifically:

Box 7: *Active Ingredients and percentage of each should be treated as CBI for compounds imported for research and development purposes*: Bayer has faced several import challenges recently because of the difficulty of redacting the listing of active ingredients of experimental compounds and mixtures. The agency has at times refused entry of R&D compounds and formulations due to the use of laboratory codes or other non-IUPAC recognized nomenclature to identify the product compound. Because EPA requires this field and because Bayer also needs to maintain confidentiality on research materials, it is 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. 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.

Box 16. *Confidential Business Information (CBI) designation*: It is Bayer's position that **ALL** data contained on a NOA form is confidential and covered by confidentiality provisions in FIFRA[2], with the exception of boxes 4, 5, 6, & 7[3]. 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 information[4]. Examples of these activities make up a substantial number of requests under the Freedom of Information Act[5]. 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 approvals[6], 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.

EPA Establishment Numbers on Returned Goods: Finally, 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

[2] FIFRA Sec. 10(b)

[3] This position was last communicated to the agency in its letter dated 9/25/2009 to Kent Johnson Esq. in EPA OGC Region 7 Office as part of the 07-RIN-00405-09 claim against Bayer records.

[4] In fact, FIFRA 10(b) states, "…the Administrator **shall not** make public information which…contains or relates to trade secrets or **commercial** or financial information…" (emphasis added)

[5] Examples of such requests are: EPA-R9-2016-003269, EPA-R4-2013-002719 and EPA-R10-2016-001581

[6] In conversations with EPA Region 2, it was communicated that approval of CBI claims on NOAs by OGC may result in delays ranging from several weeks to potentially a month or more based upon transmission, review, and return times starting with the date of receipt of the NOA.

should bear a 98 series HS code[7] 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)[8] 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.

Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

Bayer does not question the accuracy of the estimates provided by EPA, based upon the figures that are provided in its supporting statement[9].

Enhance the quality, utility, and clarity of the information to be collected.

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.

Specifically to the NOA form, in Box 11: *Country of Origin,* The definition of country of origin differs between US Customs and US EPA,[10] which is one source of confusion which

[7] Due to cooperative agreement between CBP & EPA which flag certain HS codes as requiring a NOA to be filed. A 98 series HS code is not one of those codes.
[8] See 40 CFR 168.75
[9] EPA-HQ-OPP-2016-0122-0002

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.

Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

As stated above, 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.

Comments regarding voluntary submission of supporting documentation for NOAs

EPA has solicited comments on its practice for submission of "voluntary" supporting information for submitted NOAs. 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.

[10] Customs definitions vary depending on the type of inputs, country of manufacture, and/or the primary value of the product. See US Customs Marking rules under 19 CFR 102, Article 401 of the Tariff Act of 1930 (19 USC 1304) or any number of unilateral trade agreements which may alter the definition (*e.g.* North American Free Trade Agreement (NAFTA)).

For additional details, Bayer references its comments dated April 8, 2015[11] on general regulatory improvement at EPA

Additionally, the EPA requests details as per the Consultation for OPP ICR form[12] requesting the following information:

Publicly Available Data

Is the data that the Agency seeks available from any public source, or already collected by another office at EPA or by another agency?

To some extent, 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)[13].

If yes, where can you find the data? (Does your answer indicate a true duplication, or does the input indicate that certain data elements are available, but that they don't meet our data needs very well?)

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.

Frequency of Collection

Can the Agency collect the information less frequently and still produce the same outcome?

Electronic reporting and transmission, as stated earlier, 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.

Clarity of Instructions

The ICR is intended to require that respondents provide certain data so that the Agency can utilize them.

[11] EPA-HQ-OA-2011-0156-0179 see pages 4 – 8 for NOA and import related topics
[12] OMB No. 2070-0020, EPA No. 0152.11
[13] See: https://en.wikipedia.org/wiki/PIERS:_The_Port_Import/Export_Reporting_Service

Based on the instructions (regulations, PR Notices, etc.), is it clear what you are required to do and how to submit such data? If not, what suggestions do you have to clarify the instructions?

Instructions on the NOA are clear and suggested improvements are addressed in the comments above. 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.

Do you understand that you are required to maintain records?

Are there forms associated with this process? Do you use them? Are they clear, logical, and easy to complete?

Bayer maintains records as required under 40 CFR 169.

Electronic Reporting and Record keeping

The Government Paperwork Elimination Act requires agencies make available to the public electronic reporting alternatives to paper-based submissions by 2003, unless there is a strong reason for not doing so. One such reason is that, at the present time, the Agency is unable to ensure the security of CBI that might be transmitted over the Internet.

What do you think about electronic alternatives to paper-based records and data submissions? Current electronic reporting alternatives include the use of web forms@/XML based submissions via the Agency's Internet site and magnetic media-based submissions, e.g., diskette, CD-ROM, etc. Would you be interested in pursuing electronic reporting?

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.

Are you keeping your records electronically? If yes, in what format?

What benefits would electronic submission bring you in terms of burden reduction or greater efficiency in compiling the information?

Records are being kept both in hardcopy and electronic formats with a desire to convert completely to electronic records where allowed by law. Electronic recordkeeping would better allow for cross connection with other systems to quickly retrieve and report information contained in multiple documents.

Burden and Costs

Are the labor rates accurate?

Bayer refers to comments submitted by Bayer in response to EHA-HQ-OPP-2015-0332-0001[14].

The Agency assumes there is no capital cost associated with this activity. Is that correct?

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.

Bearing in mind that the burden and cost estimates include only burden hours and costs associated with the paperwork involved with this ICR (e.g., the ICR does not include estimated burden hours and costs for conducting studies), are the estimated burden hours and labor rates accurate? If you provide burden and cost estimates that are substantially different from EPA's, please provide an explanation of how you arrived at your estimates.

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,
    - *2 regions allow electronic NOA filing (Region 6/TX, Region 9/CA)>comparable time taken to enter NOA data in the designated online portal.*
    - *All other regions follow the standard process, requiring hardcopy documentation.*
    - Request entry number from Customs broker, include on NOA form. Region 2 requires dummy 7501 which must be provided to us by Customs broker

[14] 80 FR 34153

    - 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.

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.

Are there other costs that should be accounted for that may have been missed?

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
    - $20 – 30 per shipment per day for
- For ocean containers:

- $100 – 300 per day
- 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.

Bayer appreciates this opportunity to provide input and guidance as to how EPA's practices impact our business. We appreciate any consideration that can be made to attempt to reduce the regulatory burden on companies involved in the importation of pesticides, and look forward to EPA's continued innovation into measures which will increase their efficiency. Should EPA desire additional follow-up or details regarding any of our questions here, please do not hesitate to contact me at any time.

Best Regards,

S. Gerret Van Duyn

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