Bayer CropScience

February 13, 2012

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-2011-0843; 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 December 14, 2011 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] 76 FR 77817 - 77820

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 requesting information in several areas from respondents although the agency has invested significant resources in generating systems which make this information available to the public. Specifically:

- Box 6: *Brand Name of Product*: The proposed definition for box 6 is, "Name of the product as it appears on the label under which the pesticide or device is sold or distributed." Because a pesticide can be relabeled, and may bear multiple alternate brand names for the same registration this could cause confusion. It is suggested that this definition be replaced with: "Name of the product as it appears on the product label at the time of import." This definition is much clearer, and could help avoid any misunderstandings related to alternate brand names under which the product is marketed.
- Box 7: *Active Ingredients and percentage of each*: Because a mandatory field of the NOA form is the EPA Registration Number (box 4) this information can be redundant with registration information found online[2]. This field has practical application for unregistered compounds being imported for manufacturing or research purposes, but not for registered products.

[2] *Via* NPIRS located at: http://ppis.ceris.purdue.edu/npublic.htm or through EPA web resources such as PPLS located at: http://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1:1587292055406690

- Box 11: *Country of Origin*: The definition of country of origin differs between US Customs and US EPA[3] 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 customs. For the EPA definition requires that the country of origin match the US EPA Registered Establishment number (EPA Est. #) captured in box 5. As the country is captured in the EPA Est. # itself this information is redundant.
- Box 14. *Entry Number*: Bayer can provide entry numbers for shipments, but the presence of this field as a required element of the NOA form creates certain challenges in timing of submission to the EPA. Shipments submitted for entry cannot be submitted sooner than 7 days prior to arrival at the port of entry as per customs regulations[4]. Additionally, freight shipped by air cannot file for customs entry until the plane has physically taken off from a foreign airport[5] to avoid errors in the carrier, arrival date, etc., practically resulting in a 24 hour availability of the customs information for EPA's use prior to a decision on the NOA being needed by the respondent. From a business process point of view, it makes no sense to submit an NOA to EPA sooner than customs filing occurs, as the NOA would be awaiting import application so that EPA could compare this document to the customs 7501 application form data. Additionally, some research and development compounds are shipped in such small quantities that they qualify for customs free entry into the United States[6], and therefore no entry number would be needed. Making this field required under these circumstances could create an unresolvable data gap in the NOA form.
- 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[7], with the exception of boxes 4, 5, 6, & 7[8]. 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

[3] 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)).

[4] See instructions for filing at: https://help.cbp.gov/app/answers/detail/a_id/214/~/filing-an-formal-entry-(for-goods-valued-at-$2000-or-more)

[5] See definition for "Departure" in 19 CFR 122.49a

[6] Sec. 321(a)(2)(C) of the Tariff Act of 1930 as amended, codified in 19 CFR 10.

[7] FIFRA Sec. 10(b)

[8] 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.

and business relationships to potentially garner additional information[9]. Examples of these activities make up a substantial number of requests under the Freedom of Information Act[10]. 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 (exempting out 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[11], adjusting port of entry choices to account for inconsistent enforcement practices (which usually lead to increases in shipping costs), and delays in having NOAs reviewed and returned. 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 from additional review by OMB or OGC for the NOA.

- Box 17. *Location of Goods for Examination after Importation*: EPA requests the EPA Est. # for movement of unregistered pesticides between the same producer. Bayer would ask that EPA clarify if this is also a requirement for movement of unregistered pesticides between establishments operated by different producers as allowed by the regulations[12], or in any other circumstance.

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. However, Bayer would like to identify that these estimates are based upon data collected by EPA from respondents who have invested capital to develop systems to handle the volume of NOAs appropriate to their business. In the case of Bayer, the company has invested capital to create, track, adjust, and archive NOAs in the form of databases, hardcopy archives, file servers, and other such devices. This capital cost is not captured by EPA in their calculation as per their supporting documentation[13]. Without such investments the time commitment to process such NOAs would increase, which is a field captured by

[9] 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)

[10] Examples of such requests are: 10-FOI-00232-10, 10-RIN-00312-09, 09-FOI-00327-10, 04-FOI-00426-10

[11] 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.

[12] As per 40 CFR 152.30(b)

[13] EPA Supporting Statement section 6(b)(ii) and 6(b)(iii)

EPA. Additionally, EPA does not present data concerning the amount of time and effort to resolve potential conflicts that arise from data in the NOA process. While each instance will have its own time commitment depending on the severity of the issue, Bayer estimated to the agency in its initial data collection that each delay, on average, resulted in 1-2 working days of time to resolve the issue. This is internal time only, with no consideration given to storage costs, fees, and other costs as a result of the shipment being delayed in port. These estimates were not provided to EPA during their data collection phase, as they are impossible to estimate due to the number of variables involved in such an estimate (*e.g.* days on the dock, size of the shipment, time of import, etc.). Bayer would ask that EPA give consideration to capital investments made to comply with the NOA requirement, and include information considering potential impacts on commerce and business as a result of delays in shipment.

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.

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 customs database will help reduce complexity, confusion, and data errors. Additionally, this will allow Bayer to reduce its costs in preparation and tracking of this information. Short of full integration with Customs, Bayer supports initiatives such as the electronic NOA application system used in EPA Region 6. Such innovative solutions are appreciated, and used when 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 considered by the requesting region to be voluntary. Failure to submit a product label, customs entry form, pro-forma invoice, guidance statement,

R&D certificates, or any of the other requested documents will result in denial of entry of the shipment to the United States. Such documentation requests are inconsistent between EPA regions, and are time consuming and can lead to additional delays or issues with the NOA process for reasons unrelated to the NOA or human health and safety. Additionally, the EPA uses the NOA screen for a variety of other enforcement checks such as supplemental labeling or EPA Registered Establishment reporting compliance. These additional compliance questions arise in the form of issue such as removal of required Global Harmonized System (GHS) labeling for factories in the European Union or confirmation that production not yet reported will be reported on the following year's 3540-16 form. Such "add on" enforcement practices are not under the NOA process, but are within EPA jurisdiction to conduct. These practices are extremely inconsistent between regions with some EPA regions not considering them to be an issue (*e.g.* GHS labeling) while others are conducting systematic relabeling mandates to alter shipments and fining respondents for exactly the same "offense." 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 NOA process.

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,

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