UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 24, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: **Response to Comments** Received on Proposed Renewal of the Information Collection Request Entitled: "Application for New and Amended Pesticide Registration" (EPA ICR No. 0277.17, OMB Control No. 2070-0060); Solicited on June 15, 2015 (80 FR 34153).

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TO: Angela Hofmann, Director
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Pursuant to 5 CFR 1320.8(d), in proposing to renew this ICR, the EPA published a **Federal Register** Notice (80 FR 34153; June 15, 2015) providing a 60-day public comment period. The Agency received comments from two registrants: the American Chemical Council's Biocides Panel (ACC, or the Panel) and Bayer CropScience LP (Bayer). This memorandum summarizes the comments and provides the Agency's responses, which are summarized in unit 3(b) of the ICR.

1. **ACC Comments.** In general, ACC commented that it believes the EPA has significantly underestimated the Paperwork Reduction Act (PRA) burden associated with this information collection activity.

Comment 1: The Panel states that the activity categories (Type A, B, and C) do not capture amendments to applications that require the submission of data. Further, the Panel asserts that the EPA has assumed that no data are required for Type B applications and that the Agency only estimated the burden for notifications that require no data in estimating the burden for Type B applications.

EPA Response: As described in unit 4(b)(i) of the ICR, Type B activities involve a registrant or applicant assembling and submitting an application for registration of a new or amended product that contains a currently registered active ingredient. Under Type B applications, the Agency has included a range of actions, including those which require the submission of product specific data. Generally, "Type B" activities involve less data and complexity than "Type A" activities; nevertheless, "Type B" activities include label amendments (which may require data) and notifications (which do not require data). Estimates for the paperwork burden and the costs of data generation associated with new AIs and new products are discussed in this unit 6(b) of the ICR. Tables 4A-B represent the average overall

submissions. EPA estimates that there are very few type B applications that require data and that these account for a small portion of the cost and burden associated with this information collection. The majority of data required for registration of new uses are limited to residue chemistry studies, which are already required to be submitted to EPA under FFDCA to establish a new tolerance for food/feed use. Data submitted to establish tolerance limits are covered under the Tolerance ICR (OMB Control No. 2070-0024), and therefore not discussed in this ICR.

Comment 2: The Panel believes that there is not a full accounting of the burden associated with increased data requirements under 40 CFR part 158W. The Panel further comments that for antimicrobials there is greater need for consultations with the EPA and the development of new approaches because existing test guidelines are inapplicable.

EPA Response: The commenter is referring to the data requirements in the final rule promulgated in 2013 (78 FR 26936), which consolidated data requirements for antimicrobial pesticides in 40 CFR Part 158W. That final rule included an amendment to the existing ICR to account for new burden attributed to that final rule. In drafting the renewal for this ICR, EPA reviewed and updated the information collection activities and related burden estimates as present in unit 6 of the ICR.

The Agency estimates test costs using cost estimates collected from various independent labs, with the most recent update occurring in 2013. Those estimates were used for the final rule and are also used in this ICR. The Agency also notes that it previously responded to the Panel's comments on the costs associated with the 2013 final rule, and refers the reader to the docket for that rulemaking (docket ID EPA-HQ-OPP-2008-0110) for a complete discussion of the Panel's comments and EPA's responses.

In particular, the 2013 final rule does not mandate any consultation to determine the data required or test protocol used to develop data for a particular antimicrobial product. EPA did not intend for the references to consultations in the test notes of the proposed rule to impose mandatory consultation requirements; neither did EPA intend the consultation references as a means of establishing a different standard for determining if a study is triggered. The 2013 final rule addresses this and there is no longer any misunderstanding of the voluntary nature of consultations, which have always existed.

Comment 3: The Panel states that the EPA has not addressed the significant amount of additional paperwork and costs associated with developing and obtaining approval of testing protocols since no approved testing procedures existed for several of the data requirements in the 2013 final rule. In addition, the Panel maintains that the Agency's clearly stated intent is to require approvals under Federal Food, Drug, and Cosmetics Act (FFDCA) Section 408 for the vast majority of antimicrobial pesticide uses, which will require significant paperwork and be an economic burden associated with preparation of petitions and the establishment of tolerances.

EPA Response: Although not available in final form at the time the final rule was issued in 2013, EPA subsequently issued final test guidelines for use in generating data for antimicrobial products, and provided final test guidelines and related guidance for Tier 2 testing expectations under the endocrine disruptor screening program (EDSP). As indicated in the 2013 final rule, registrants could use available draft guidelines in the interim, and were encouraged to consult with EPA if they had any concerns or questions.

In unit 6 of the ICR, EPA added the cost of scientific study data and used a conservative estimate to derive the cost. As described in unit 6(b) for the ICR, the EPA used a methodology which assumes that

pesticide registrants generate all of the data as specified in the CFR without any changes, and that none of the data is waived. Since a registrant would never be required to provide all of the data identified in 40 CFR part 158, the resulting estimate is conservative.

With regard to the approval of test protocols or variations to test guidelines, while the EPA acknowledges that protocol development as it relates to certain data requirements is a critical step at which point the Agency and the applicant can benefit from discussions, for most studies the EPA has included the cost of protocol development in test cost estimates that are used to calculate the burden in this ICR. In order to determine estimated test costs, several independent laboratories are asked to identify the minimum and maximum cost for each guideline study based on a set of predetermined protocols that are provided to them. Understanding that the lab costs could vary considerably based on the study protocol chosen by the lab, the EPA often establishes two protocols, a high cost protocol and a low cost protocol, for each guideline in order to bracket the costs. For some larger studies, the EPA's estimate may or may not be consistent with the cost incurred for a particular registration action – which it is not expected to be anyway. Based on the information provided by the commenter, the Agency does not have enough information to update a particular study to account for different protocol development costs. The EPA further notes that the burden associated with tolerance petition process and the establishment of tolerance exemptions is accounted for in a separate ICR (OMB No. 2070-0024, Tolerance Petitions for Pesticides on Food/Feed Crops and New Inert Ingredients). If the reference to FFDCA section 408 was meant to cite the endocrine disruptor screening program under section 408(p), EPA notes that the burden associated with EDSP orders is addressed in separate ICR(s). Test guidelines for EDSP Tier 1 screening and Tier 2 testing are now available, with the same flexibility provided in terms of proposing alternative methods.

Comment 4: The Panel comments that the EPA did not account for the burden of submitting the official data evaluation record (DER) for data submissions.

EPA Response: The Agency assumes the comment refers to its offering of respondents the option of including pre-populated DER templates with study reports. The EPA's DER templates are revised versions of OECD's format, and largely harmonized for compatibility with PMRA templates. Pre-populated DER templates are mutually acceptable and can be easily divided among countries. The Agency does not maintain a record of how many of these pre-populated DERs it has accepted. However, the ICR provides burden estimates that are inclusive of the preparation and submission of study material.

Comment 5: The Panel notes that the Agency appears to assume that large amounts of the associated paperwork are handled by clerical staff, and that the vast majority of registrants of antimicrobial pesticides are small companies that do not employ a dedicated team of clerical staff to handle pesticide registrations.

EPA Response: The EPA notes that there are two sources of paperwork associated with this information collection, paperwork for submitted pesticide applications and paperwork for data generation. The Agency assumes approximately 20%, 30%, and 15% of the paperwork burden is attributed to clerical staff for type A, B, and C applications, respectively. As discussed below, Type B applications are less likely to involve submission of data. Therefore, the methodology assumes that relatively fewer technical staff hours are required to submit type B applications, resulting in a higher percentage of clerical hours relative to the total burden. For data generation, the EPA assumes 15% of the total paperwork burden is attributed to clerical staff. While EPA acknowledges that many antimicrobial pesticide registrants are small companies and that small companies may not have

dedicated clerical staff, the Agency notes that the burden for type A, B, and C applications is an average over the applications of each type, independent of the size of the applicant. The EPA further notes that large companies, which are more likely to employ dedicated clerical staff, generally submit a larger portion of applications of each type than smaller companies. In addition, it is unclear whether this applies only to antimicrobial registrants and which activities warrant consideration of being reassigned from clerical to technical. Since such a reassignment would affect the distribution of the burden hours and the estimated costs that are used in the methodology to estimate burden hours for the data generation activities, EPA did not make an adjustment to the current ICR. The Agency is, however, interested in discussing this further with the registrants and in the context of developing a revised ICR at the next renewal cycle, using the 3 years from approval of this ICR to explore alternatives.

Comment 6: The Panel believes that the assumption that paperwork accounts for 35% of a study cost significantly underestimated the time involved for management and technical personnel in the planning, to gather/create information, and in the compile/review stages.

EPA Response: The approach developed that assumes the paperwork burden accounts for 35% of a study cost is based on numerous sources of information including agency expertise, consultation with industry and the OMB examiner, specific public review and comment opportunities, and repeated review in the context of the various Agency information collection activities that adopted this methodology. This methodology allows the Agency to consider the potential variation in paperwork burdens for different kinds of studies, reflecting that there is likely to be more paperwork burden related to a more complex study. Previously, the standard approach was to use a single burden estimate for each paperwork activity that might occur when generating data, and using that as an average burden estimate for all studies, regardless of study complexity. Another alternative approach considered was to only account for the study costs, as non-burden hour costs, and to only estimate burden for the submission activities. Although it is not a perfect methodology, EPA believes that it is a reasonable approach for incorporating potential variations in the paperwork burdens associated with conducting the study, which is also the consensus of the commenters who have participated in the reviews of that method.

Comment 7: The Panel is concerned that this ICR does not consider the need for preparation of petitions for tolerance and for the risk assessments that are involved in many new and amended applications for antimicrobial pesticides.

EPA Response: As indicated previously, although the paperwork burden for the residue studies under part 158 are covered by this ICR, the paperwork burden for the tolerance petition process is not included in the estimates for this ICR. The tolerance petition process is covered in a separate ICR under OMB No. 2070-0024, Tolerance Petitions for Pesticides on Food/Feed Crops and New Inert Ingredients. The EPA acknowledges that – although not required to do so – some companies submit risk assessments with their applications. EPA believes that many companies may conduct such assessments as part of their product stewardship programs. However, since the submission of a risk assessment is not required under the data requirements in 40 CFR part 158, EPA is unable to predict such events, or otherwise capture potential burden.

Comment 8: The Panel notes that the EPA has not fully identified or addressed the significantly increased burden or the method of data population for the proposed electronic Confidential Statement of Formulation (e-CSF), also referred to as the Confidential Statement of Product Specification (e-CSPS).

EPA Response: The discussion in unit 3(e) of this ICR (the *Electronic submissions* sub-section) has been updated to more fully describe both the anticipated overall burden decrease and the recent changes in the electronic data submission portal. To summarize, the EPA began offering a new, fully electronic system for pesticide application through the Pesticide Submission Portal (PSP)[1] in September, 2015. The PSP leverages the Agency's existing Central Data Exchange (CDX) to provide a secure method of submitting information entirely online. CDX does require initial user registration, for which the paperwork burden estimate is covered under "*Cross-Media Electronic Reporting Rule*" ICR, OMB No. 2025-0003; EPA No. 2002.26. As far as potential burden increase resulting from using the e-CSPS versus the existing CSF, the Agency has quantitatively described the reasoning in unit 3(e) of this ICR.

Overall, the EPA expects fully electronic form submissions to reduce the burden of exchanging and keeping records while minimizing errors and eliminating the need for multiple data entries across forms. The Confidential Statement of Product Specifications (CSPS) form is intended to provide an optional, fully electronic alternate to the Confidential Statement of Formula, or CSF (EPA Form 8570-4). The proposed joint form (CSPS) is a combined and harmonized version of the CSF form and Canada's Statement of Product Specification Form (SPSF). The harmonized form reflects a baseline level of information already submitted to either agency in the registration application. While there are some differences between PMRA and EPA information requirements, many CSPS data elements are overlapping. Some data elements on the form are specific to EPA or PMRA requirements, and PMRA requirements that do not overlap with EPA's will not be required for a US registration application. For the current ICR renewal, the EPA has assumed that most submissions would still be paper-based. As industry's experience with the electronic version of the form is evolving, the EPA anticipates that it will have sufficient information to address the burden of electronic submission of the e-CSPS in future ICR renewal cycles.

2. **Bayer Comments.** In general, Bayer contends that the EPA significantly underestimated the burden associated with pesticide registration actions due to the following considerations: 1) The EPA underestimated labor rates; 2) The EPA excluded many relevant parts of the 158 data requirements and additional activities related to creation of documents required to meet the completeness check for a submission for pesticide registration, including required label information; 3) The EPA did not include capital investment, maintenance, and operational costs necessary to take advantage of its digital information investments as well as the omission of capital investments that R&D companies with internal laboratory capacities make to keep their facilities "state of the art"; and 4) the EPA underestimated of the average cost of regulatory studies.

Comment 1: With regard to the labor rates, Bayer indicated that the EPA's burden calculation for data generation should closely mirror the costs of the basic R&D companies who conduct this data and bear nearly all of the data development costs for the industry as a whole. In this regard, they request that the EPA modify the burden calculation to reflect that data generation costs should be related to "technical" personnel only, that the managerial and clerical personnel rates should only apply to administrative or submission activities, and that the EPA acknowledges and includes the cost of capital investments and facility overhead through the use of a labor rate supplied by Bayer.

EPA Response: EPA believes that the Agency's methodology for calculating the paperwork burden associated with data generation already addresses the request by Bayer. As explained in unit 6(b) of the

[1] http://www.epa.gov/pesticides/electronic-submission-now-available-pesticide-applications-september-1-2015.

ICR, the EPA assumes that the total paperwork burden to conduct a study is 35% of the estimated total test cost as charged by an independent laboratory. The 35% of test cost is then disaggregated into managerial (20%), technical (65%), and clerical (15%) labor categories. The disaggregation is based on EPA's assumption that the paperwork burden associated for data generation mostly involve the technical staff to perform the tests, with fewer activities related to management and clerical staff. In particular, the activities identified for clerical staff are clearly those associated with administrative functions like typing cover letters, preparing packages, making copies, mailing submissions, maintaining files of submissions and related correspondence. It is unclear if Bayer's comment meant that these administrative functions are no longer performed by clerical staff, and are instead being performed by technical staff; and whether this is now the new norm for most registrants.

In addition, the EPA accounts for a portion of the cost of capital investments and facility overhead through its fully loaded labor rates. The EPA's overhead cost formulas may or may not sufficiently account for companies like Bayer that maintain their own in-house laboratories. The EPA also believes a portion of the cost of capital investments and facility overhead are captured in the test costs gathered from laboratories. The EPA assumes that these laboratories incorporated into their test costs some portion of capital investments and overhead to maintain their facilities. The EPA uses the Bureau of Labor Statistics wage rates because they represent an average across the pesticide industry. Based on a lack of information of the applicability of Bayer data to the broader industry, the EPA does not have sufficient information to change the estimated industry wage rates in the ICR. It is important to note that agencies are only required to account for those burden hours and costs – including any capital investment costs – that are reasonably associated with the information collection activity.

Comment 2: Bayer commented that the EPA excluded many 158 data requirements and additional activities from its burden calculation. In particular, Bayer believes that the EPA excluded the costs of archiving data required under 40 CFR 158 from burden calculation for this ICR as well as the costs of residue studies supporting "Tolerance petitions."

EPA Response: The burden and costs from archiving data as required under 40 CFR 158 is covered by a separate ICR (see OMB Control No. 2070-0028, Recordkeeping Requirements for Producers of Pesticides under Section 8 of FIFRA). That information collection includes the paperwork burden associated with the storage of study documents developed in accordance with Good Laboratory Practice Standards.

Likewise, the paperwork burden for tolerance petitions is not included in the estimates for this ICR because they are covered in a separate ICR (see OMB No. 2070-0024, Tolerance Petitions for Pesticides on Food/Feed Crops and New Inert Ingredients). However, in that ICR, the EPA does not include the paperwork costs of studies required under 40 CFR 158, i.e., the cost of residue data, which EPA has chosen to include in this ICR in order to avoid double counting.

Comment 3: Bayer commented that the EPA excluded the costs of label development activities, disclosure of the label to the public, and data generation in support of product performance data requirements under 40 CFR 158.400(e). Bayer indicated that EPA should include the paperwork burden of providing required information to potential users and the public through the pesticide product label. The commenter requests that the EPA add the burden and cost of preparing and submitting the required information for the label, and of providing the label to the public on the product.

EPA Response: Prior to submitting comments, Bayer inquired by email if the Agency can provide supporting documentation for a statement in unit 3(e) of the draft supporting statement, concerning general OMB guidelines for third party disclosure requirements for labeling information for pesticide products. The Agency has revised relevant sections of this ICR, including unit 3(e), to clarify the basis for the conclusion that the third party disclosure provision does not apply to displaying specific product information on pesticide labeling; it is therefore not a collection of information that requires estimated burden to be included in this ICR. The EPA has posted Bayer's request and our response email in the docket (**Attachment L**).

The burden and cost of preparing and submitting the label information to EPA are included in this ICR as part of the burden for preparing the application package that is submitted to obtain a registration. EPA reviews the product label as part of the licensing/registration process for pesticides. The label on a pesticide package or container and the accompanying instructions are a key part of pesticide registration because the label provides critical information about how to handle and safely use the pesticide product and avoid harm to human health and the environment. To promote an understanding of the pesticide labeling process and approaches for how labels should generally be drafted, EPA developed a Label Review Manual for EPA personnel that is now also available to registrants, state regulatory agencies and the public.

In 2014, EPA initiated the SmartLabel Pilot in an effort to make pesticide label information easier to find and the approval of pesticide labels more efficient, and is working with pesticide registrants to pilot an electronic label system. As part of the SmartLabel pilot, nine pesticide registrants are developing and submitting pesticide labels to EPA through a fully electronic system, instead of as paper or PDF files. Goals of the SmartLabel system include making label information more quickly available to the public in an easily searchable format; making the label approval process more efficient by creating standardized label sections for all pesticide labels; and allowing for easier and quicker comparison of previous label versions without losing the necessary flexibility to make a label appropriate for each product.

Of course, EPA will consider each label on its own merits and will consider deviations from existing policy in labeling under the appropriate provisions of FIFRA and its implementing regulations.

The ICR does not, however, include estimated burden and costs for providing the pesticide label on each product so as to disclose use and safety information to potential users and the general public. The use of the pesticide label to accomplish this disclosure, is not a collection of information as defined by the PRA and OMB implementing regulations (5 CFR 1320.3(c)(2)). This determination was made by OMB in the context of implementing the 1995 PRA amendments and related OMB final regulations of 1995. In general, OMB explained that the new 3rd party disclosure provision added to the PRA in 1995 was not intended to require agencies to estimate burden for the required disclosure of important health and safety information on product labels, in particular if the label or language for the label is specifically provided by law (e.g., the Surgeon General warnings required to be on the labels of alcohol or tobacco products), or required to be approved by an agency (e.g., EPA labels on pesticide products or PCB containing transformers).

It is also important to note that whenever EPA revises a regulation to require new, revised or additional labeling, the costs associated with that new or revised mandate are assessed as part of that rulemaking package, including the full cost of submitting the application to amend a registered product's label, as applicable. When the Agency issues guidance (usually in the form of a PR Notice) that establishes new

or significant revisions to non-binding policies or guidance that involve labeling, the Agency considers whether that guidance or policy might impact existing estimates for burden and costs as part of the process used for developing that guidance or policy. In both those cases, the public has an opportunity to review requirements or draft guidance and policies and any accompanying assessment of burden and cost before it is finalized.

Comment 4: Bayer asserts that the EPA has not included capital investment, maintenance, and operational costs necessary to take advantage of its digital information investments. Bayer notes that the costs of capital investments in facilities, information technology infrastructure, and other innovations are captured in fully loaded wage rages and did not request additional burden specifically on this topic provided that the higher labor rates they proposed are reflective of these investments.

EPA Response: As discussed above, while the wage rates the EPA uses may not be as high as those Bayer proposes, the Agency believes it has appropriately captured capital investments through fully loaded wage rates and test cost estimates. In addition, not all capital investments, maintenance or operational costs are part of the information collection. Since including such costs do not affect the burden hour estimates, without additional information to tie investments directly to the information collection activities of this ICR, EPA did not make an adjustment to the current ICR. The Agency is, however, interested in discussing this further with the registrants and in the context of developing a revised ICR at the next renewal cycle, using the 3 years from approval of this ICR to explore alternatives.

Comment 5: Bayer requests that the burden of data generation and application for plant incorporated protectants (PIPs) also be included.

EPA Response: PIPS and the related burden and costs for the information collection activities covered by this ICR are included in the calculation for the Biopesticides and Pollution Protection Division (BPPD) in unit 6 of this ICR. There is also a separate ICR for PIPs that covers the information collection activities associated with PIPs CBI substantiation and adverse effects reporting (See OMB Control No. 2070-0142 (EPA ICR No. 1693), Plant-Incorporated Protectants; CBI Substantiation and Adverse Effects Reporting).

Comment 6: Bayer believes that the EPA does not adequately account for the costs to generate the required studies. Bayer requests that the total burden of new A.I. development be increased by at least 100% above current levels (from $8.97 million to $17.94 million) representing real world examples and conservative tabulation of the EPA's own standard costs demonstrating the inadequacy of the value provided.

EPA Response: EPA believes that Bayer's method of calculating the burden of new A.I. development overestimates the cost because it appears that Bayer simply added the cost of all tests for each of the science disciplines (ecological effects, environmental fate, health effects, product chemistry, and residue chemistry) without regard to the use patterns. In estimating cost for data generation, the EPA first estimated the cost for each use pattern, and then averaged over the use patterns. As reflected in 40 CFR 158, the use patterns the EPA used are terrestrial (food, feed, nonfood), aquatic (food, nonfood), greenhouse (food, nonfood), forestry, residential (indoor, outdoor), indoor (food, nonfood), and industrial uses (the parenthesis represent further granulation, e.g., a greenhouse food use is considered separately from greenhouse nonfood use).

Data may or may not be required for a particular use pattern, as indicated in the data requirement tables. Further, in order to generate the paperwork burden and costs from those estimated test costs, the EPA applied its methodology, which assumes that the burden for the information collection activities represents 35% of the estimated test costs. The EPA does not believe Bayer performed a similar operation, based on the description of their method provided in the comment. Because of these differences, the EPA believes Bayer's estimates for the total burden of new A.I. development substantially overestimate the paperwork burden and costs associated with the data generation activities covered under this ICR.

Comment 7: Bayer notes that the EPA has, of late, requested data submitted to other regulatory agencies outside the United States. Bayer believes that, should the Agency require such information, it should invoke its authority under FIFRA 3(c)(2)(B) to call in additional data.

EPA Response: The EPA acknowledges that it has requested such data from applicants on occasion. In such cases, data submitted to other regulatory agencies outside the U.S. is useful to gather a more complete picture of the risks associated with such pesticides. The agency believes that it is appropriate to use its authority under 40 CFR 158.75 to request such data, if available, at the time of application, rather than waiting to issue a DCI afterwards.

The EPA continues its work-sharing efforts with Canada, Australia, the European Union, and Japan through global and joint reviews. While EPA makes independent registration decisions, the Agency shares the study reviews and works toward harmonizing its regulatory decisions with other national authorities.

Comment 8: Bayer requests that the Agency expand the ePRISM system to allow for submission of data in connection with Data Call-In (DCI) actions under 3(c)(2)(B) so that these benefits and enhancements can be applied to all data provided to the agency.

EPA Response: As of February, 2015, the EPA has started accepting electronic submission for DCI actions through the PSP.[2] The ICR has been updated to include an expanded discuss of the Agency's efforts to work with registrants and other stakeholders to develop and pilot electronic submission tools, which are now included in this ICR for OMB approval to use more broadly.

Comment 9: Bayer believes the EPA could more accurately calculate the total burden imposed on the Agency in fulfilling its regulatory obligations by adding the following two factors: the budget allocated by Congress to EPA for the Office of Pesticide Programs and, the total sum of PRIA fees collected in a calendar year.

EPA Response: The EPA disagrees. PRIA fees cover only a portion of the Agency work on covered pesticide registration activities. The remaining costs are expected to be paid from annual appropriations. In addition, the budget for OPP extends beyond the registration activities covered in this ICR. The EPA believes its current method that draws on data from the Time and Attendance Information System (TAIS) appropriately and accurately captures the Agency burden for activities covered under this ICR. In addition, the Agency uses this method for capturing burden for nearly all of its information collection requests, and believes maintaining this method would provide consistency and transparency across all program activities, and avoids the potential for double counting.

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[2] http://www.epa.gov/pesticides/phase-2-pesticide-submission-portal-expanded-functionality-electronic-submission.

Comment 10: Bayer requests that the EPA clarify whether fees collected under PRIA are considered to be a burden on industry and a data cost. While Bayer considers them to be a very real burden, if the EPA has otherwise classified these data costs, Bayer would appreciate clarification of where and what they have been classified as.

EPA Response: The EPA agrees that the PRIA fees are a cost to industry, and that the activities associated with estimating and submitting the fees qualify as an information collection activity under the PRA and has captured those activities and related burdens and costs in a separate ICR (See OMB Control Number 2070-0179 (EPA ICR No. 2330), titled: Pesticide Registration Fees Program).