American Chemistry Council | Biocides Panel

Comments on
Agency Information Collection Activities; Proposed Collection; Comment Request; Pesticide Data Call-in Program

Docket EPA-HQ-OPP-2016-0109
Submitted *via* http://www.regulations.gov

February 23, 2018

The American Chemistry Council (ACC) Biocides Panel (Panel)[1] submits the following comments on the above-referenced information collection request (ICR) regarding EPA's Office of Pesticide Programs Data Call-in (DCI) Program.[2] Panel member companies are registrants of antimicrobial products and are required to comply with EPA's DCIs to support continued reregistration of pesticide products. The Panel and its members continue to analyze the ICR as well as the revised methodologies and assumptions used in deriving the greatly increased burden estimates and may provide further input in the future.

As a preliminary matter, the Panel finds it inappropriate for the Agency to seek a reinstatement for an expired ICR that has changed significantly since its last approval. The ICR has expanded from eleven (11) to fifteen (15) individual Information Collection requests, relies on burden estimate methodologies revised in November 2015, and represents a 135% increase in total response hours from this previously approved ICR.

EPA seeks to justify the substantial increase in burden by noting that the Registration Review program is in an accelerated phase of reviews, with an October 2022 deadline. The Agency therefore has proposed a 5-fold increase in the number of DCIs issued annually under the Registration Review program. The Agency has recognized that there is a massive increase in registrant burden – now estimated at a total of over 615,000 hours at an annual cost of almost $44 million and a majority of the work in this revised estimate is due to reviews under Endangered Species Act and the Endocrine Disruptor Screening Program as well as non-target pollinator studies.[3] By the Agency's own admission, this ICR "change represents a program adjustment." Such a substantial change indicates that reinstatement of the previously approved ICR is not appropriate. Rather, EPA should submit a new ICR through the complete approval process.

---

[1] The Panel is composed of more than 50 companies that manufacture and formulate antimicrobial pesticides for use in industrial processes, material preservation, marine antifouling, industrial water treatment, public health applications and numerous other uses. The Panel focuses on the broad range of scientific, regulatory, legislative, legal and educational issues unique to antimicrobial pesticides, as well as those issues affecting all pesticide products. A list of Panel members is attached.

[2] 83 Fed. Reg. 3344 (January 24, 2018).

[3] *Id.*

The Panel has substantive concerns relating to this acceleration of the Registration Review program given the current staffing shortfalls at OPP with no additional staffing or funding increases planned. The planned 500% throughput increase can only reasonably be accomplished with staffing and funding increases. Yet, the budget does not contain these funds and OPP currently has many unfilled positions. The Agency's ability to use information effectively is one of the key considerations in approving ICRs under the Paperwork Reduction Act. EPA's ICR does not explain how it will have adequate resources to analyze and apply the new information it is requesting.

Finally, the Panel has concerns that the data used to generate the current burden estimates may be out of date. The last effort to collect prevailing wage data and industry estimates of burden for DCI response was in December 2013, as was data on testing costs from contract research organizations. An ICR submitted in 2018 should be informed by more recent data.

The Panel continues to assess the nature and amount of revised information on Data Call-ins for antimicrobial pesticides and may provide further information in the future.

PUBLIC SUBMISSION

As of: 3/1/18 2:42 PM
Received: February 18, 2018
Status: Posted
Posted: March 01, 2018
Tracking No. 1k2-91ke-zc8z
Comments Due: February 23, 2018
Submission Type: Web

Docket: EPA-HQ-OPP-2016-0109
Agency Information Collection Activities; Proposed Collection; Comment Request; Pesticide Data Call-in Program

Comment On: EPA-HQ-OPP-2016-0109-0009
Agency Information Collection Activities; Proposals, Submissions, and Approvals: Pesticide Data Call-in Program

Document: EPA-HQ-OPP-2016-0109-0019
Anonymous public comment

Submitter Information

General Comment

"I never said Russia did not meddle in the election" -- President Tiny Hands

Gee, I must have imagined all the times that President Impeachment Bait called the Russian hacking investigation a hoax. All the times he said that it was "phony." All the times he said that the Democrats concocted this story as an excuse for losing the election. All the times he said that he believed Putin when he denied the hacking.

Mind you I'm not saying that Trump is a pathological liar. Well... actually I am.

PUBLIC SUBMISSION

As of: 3/1/18 2:34 PM
Received: February 23, 2018
Status: QA_Ready
Tracking No. 1k2-91ny-voh9
Comments Due: February 23, 2018
Submission Type: Web

Docket: EPA-HQ-OPP-2016-0109
Agency Information Collection Activities; Proposed Collection; Comment Request; Pesticide Data Call-in Program

Comment On: EPA-HQ-OPP-2016-0109-0009
Agency Information Collection Activities; Proposals, Submissions, and Approvals: Pesticide Data Call-in Program

Document: EPA-HQ-OPP-2016-0109-DRAFT-0019
Comment submitted by Aaron Hobbs, President, RISE, Responsible Industry for a Sound Environment

---

Submitter Information

Organization: RISE, Responsible Industry for a Sound Environment

---

General Comment

Please see the attached document for comments from RISE.

Attachments

Comment

RISE

Responsible Industry for a Sound Environment

February 23, 2018

Ms. Cameo Smoot
Field and External Affairs Division (7596P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460

Submitted via Regulations.gov: EPA–HQ–OPP–2016–0109

Re: Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Pesticide Data Call-in Program; Docket ID No. EPA–HQ–OPP–2016-0109; 83 FR 3344; Jan 24, 2018.

Dear Ms. Smoot:

Thank you for the opportunity to submit comments on the information collection request for the Pesticide Data Call-in Program.

As an association representing pesticide registrants, we support CropLife America's (CLA) comments to this docket, which provide more information about the cost of data call-ins for registrants. Collecting data to support product registrations is an important but resource intensive process, and the Agency should ensure it uses accurate information when estimating the effects of policies on stakeholders. EPA's documents and policies should reflect the true costs to registrants, and registrants can provide additional information to help the Agency do this.

We appreciate your consideration of our comments and CLA's additional information, and we look forward to your response.

Sincerely,

Aaron Hobbs
President
RISE, Responsible Industry for a Sound Environment
1156 15th Street, NW
Suite 400
Washington, DC 20005
(202) 872-3860

RISE is a national not-for-profit trade association representing more than 220 producers and suppliers of specialty pesticide and fertilizer products to both the professional and consumer markets. RISE member companies manufacture more than 90 percent of domestically produced specialty pesticides used in the United States, including a wide range of products used on lawns, gardens, sport fields, golf courses, and to protect public health.

PUBLIC SUBMISSION

As of: 3/1/18 2:31 PM
Received: February 12, 2018
Status: Posted
Posted: March 01, 2018
Tracking No. 1k2-91gj-kir3
Comments Due: February 23, 2018
Submission Type: Web

Docket: EPA-HQ-OPP-2016-0109
Agency Information Collection Activities; Proposed Collection; Comment Request; Pesticide Data Call-in Program

Comment On: EPA-HQ-OPP-2016-0109-0009
Agency Information Collection Activities; Proposals, Submissions, and Approvals: Pesticide Data Call-in Program

Document: EPA-HQ-OPP-2016-0109-0018
Anonymous public comment

Submitter Information

General Comment

Wind-power facilities are threatening populations of insectivorous bats in North America, harming and killing thousands of these bats. Bats are voracious predators of nocturnal insects, including many crop and forest pests. Loss of bats in North America could lead to agricultural losses estimated at more than $3.7 billion/year. Bats play an incredibly important role in the ecosystem, eating billions of crop-destroying insects like moths and beetles, as well as mosquitoes. But The Indiana bat is a temperate, insectivorous, migratory bat. In spring, reproductive females migrate and form maternity colonies where they bear and raise their young in wooded areas.
Bats help Farmers with impacts of PESTICIDES on ecosystems,... which can be substantial ,... or other secondary effects of predation, such as reducing the potential for evolved resistance of insects to PESTICIDES and bats help suppression of forest insects. A single colony of 150 big brown bats (Eptesicus fuscus) in Indiana has been estimated to eat nearly 1.3 million pest insects each year, possibly contributing to the disruption of population cycles of agricultural pests. Man get so much from these bats and birds by pollinating plants and spreading seeds in the ecosystems.
Wind Turbines are a hazard for terrestrial and aquatic habitat for 18 animal species listed as endangered or threatened in New York State that are protected under the State Endangered Species Law and associated regulations. Ecological and economic importance of insectivorous bats in Agriculture.

PUBLIC SUBMISSION

As of: 3/1/18 2:41 PM
Received: January 25, 2018
Status: Posted
Posted: February 02, 2018
Tracking No. 1k2-914o-9vkk
Comments Due: February 23, 2018
Submission Type: Web

Docket: EPA-HQ-OPP-2016-0109
Agency Information Collection Activities; Proposed Collection; Comment Request; Pesticide Data Call-in Program

Comment On: EPA-HQ-OPP-2016-0109-0009
Agency Information Collection Activities; Proposals, Submissions, and Approvals: Pesticide Data Call-in Program

Document: EPA-HQ-OPP-2016-0109-0017
Anonymous public comment

Submitter Information

General Comment

Hi EPA,

Can you say more about your "rigorous scientific and public process"? I assume you're aware that Pruitt has attempted to subvert EPA's scientific advisory boards by banning EPA-funded researchers from serving on them. In fact the EPA is currently being sued over this.

The big picture is that President Tiny Hands not only has no use for science, he has no use for facts. All he cares about are bumper stickers, e.g. "Job Killing This" and "Wall Building That." I know it's hard to run a democracy when the President is a complete ignoramus, but presumably the EPA still has some process that's better than Ask-A-GOP-Lobbyist.

Thanks, and if you see Zinke please tell him that we just LOVE seeing his cute little flag over Interior.

PUBLIC SUBMISSION

As of: 3/1/18 2:50 PM
Received: February 23, 2018
Status: QA_Ready
Tracking No. 1k2-91o0-lfwh
Comments Due: February 23, 2018
Submission Type: Web

Docket: EPA-HQ-OPP-2016-0109
Agency Information Collection Activities; Proposed Collection; Comment Request; Pesticide Data Call-in Program

Comment On: EPA-HQ-OPP-2016-0109-0009
Agency Information Collection Activities; Proposals, Submissions, and Approvals: Pesticide Data Call-in Program

Document: EPA-HQ-OPP-2016-0109-DRAFT-0020
Comment submitted by Gerret Van Duyn, Regulatory Lifecycle Manager, Bayer CropScience LP

Submitter Information

Organization: Bayer CropScience LP

General Comment

Dear Sir / Madam,

Please find attached comments offered by Bayer on EPA's proposed ICR for planned DCIs. We appreciate the opportunity to comment and welcome any follow up discussions if there are questions or concerns.

Best Regards,

S. Gerret Van Duyn
Regulatory Lifecycle Manager

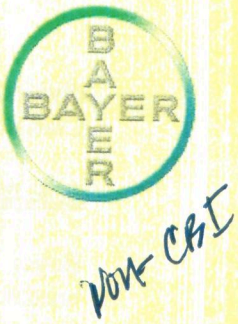
Attachments

Comment CBI Version

The attachment is restricted to show metadata only because it contains confidential business information data

Comment

Bayer CropScience



Non-CBI

February 23, 2018

U.S. Environmental Protection Agency
Docket Center (EPA/DC) (28221T)
1200 Pennsylvania Avenue NW
Washington, DC 20460-0001

Submitted via Online Portal

Re: Agency Information Collection Activities; Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Pesticide Data Call-in Program FIFRA Section 3 (40 CFR 158): EPA ICR No. 2288.03; OMB Control No. 2070-0174; Docket Number EPA-HQ-OPP-2016-0109

Bayer CropScience
RTP
P. O. Box 12014
RTP, NC 27709
Tel 919 549-2000

These comments are submitted by Bayer CropScience (Bayer) in response to the Environmental Protection Agency (EPA) request for comment on burdens placed on industry to comply with data requirements mandated by the Federal Insecticide Fungicide and Rodenticide Act (FIFRA)[1]. Bayer is the subgroup of Bayer AG responsible for the agricultural business, one of the world's most innovative crop science companies with advanced seed germplasm and protective seed treatments, as well as agricultural insecticide, herbicide and fungicide products that provide valuable protection to crops. Bayer also has a broad portfolio of non-agricultural pest control products for use in many settings, including insect, weed and plant disease pest control in and around homes, and in gardens, parks and many types of recreational areas. All of these products have been registered under rules and regulations administered and enforced by EPA. For this reason we welcome the opportunity to share details relating to the costs of data required by EPA to fulfill the statutory registration standard under FIFRA.

As per EPA's federal register notice[2], comments are solicited related to EPA's methodology, assumptions and the resulting estimate of the paperwork burden associated with Data Call-Ins (DCIs) as per FIFRA 3(c)(2)(B). We are pleased with the agency's efforts to capture the various burdens and the detail in which such efforts are categorize, described, and explained. Bayer offers both specific comments on the methodology and figures used, as well as request clarification on the meaning of parts of the DCI as currently written. Our comments are

[1] As per FIFRA 3(c)(2)(b) as implemented in 40 CFR 158
[2] 83 FR 3344

divided into three parts: ICR Methodology, EPA Assumptions and Request for Further Clarification.

ICR Methodology

Bayer offers comments on EPA's selected methodology for calculating the overall burden of the ICR in question. These comments are meant to address the process of formula development, versus the assumptions made to provide the needed variables and largely deal with exclusions made to what contributes to the overall burden.

Burden should reflect activities prior to issuance of the formal DCI

To prepare a DCI for scheduled registration review, the EPA provides a vehicle by which public participation can help inform the agency of issues of concern, or address data gaps or other concerns already known by the agency. This comes in the form of the "Problem Formulation" where EPA solicits public input on its preliminary review of the available data vs. the requirements of the registration standard. If a study is missing or out of date, due to advances in scientific understanding, or new risks previously unknown to the agency, additional data would be ordered in the DCI to address agency concerns. In addition to this formal process, significant effort is expended by registrants in discussions with the agency[3] as it conducts this process.

Under EPA's methodology, the burden associated currently begins with the issuance of the DCI itself when the data is known, and is directly related to conduct of the studies, their associated paperwork, and collaboration efforts between registrants. Therefore it is concluded that the burden calculation does not account for "pre-DCI" effort on behalf of registrants to provide input to agency to identify what will actually be requested in the formal DCI[4].

Using the recent DCI for imidacloprid as an example, the EPA issued its environmental problem formulation some 2 years before the issuance of the actual DCI. During this time, Bayer invested heavily in discussions with the EPA and the resulting work products to help address its concerns through the submission of risk evaluations, studies related to EPA's preliminary problem formulation, as well as significant time in discussions with the agency for how their needs could be addressed, what the studies would look like, and understanding the desired outcome EPA required in order to meet the Registration

CBI [redacted]

[3] Primarily data generating registrants

[4] As referenced in EPA-HQ-OPP-2016-0109-0010; see Non-Duplication section in 5(b) stating, "*The Agency maintains files on all pesticide chemicals, which includes all correspondence and information/data submitted. Before any DCI is issued, these files are referenced to determine whether the necessary data are already on hand, thereby eliminating duplicative data requests.*" An example of this activity can be found at EPA-HQ-OPP-2008-0844 during EPA's announcement of registration review and publication of the problem formulation at EPA-HQ-OPP-2008-0844-0003.

CBI [redacted]

Due to the extreme nature of the imidacloprid DCI burden, a representative "pre-DCI" effort of other DCI's recently received by Bayer can be found in table 1[6].

Table 1 – Regulatory Management incurred by molecule between issuance of Problem Formulation & DCI

Molecule	Preliminary Work Plan Issued	DCI Issued	DCI Number	Hours of Burden (Regulatory Management[7])
Ethofumesate	4/11/2016	3/9/2017	GDCI-110601-1697	[redacted]
Tebuconazole	1/11/2016	9/14/2017	GDCI-128997-1598	[redacted]
Oxadiazon	12/19/2014	9/26/2016	GDCI-109001-1502	[redacted]
Deltamethrin	3/31/2010	Multiple	Multiple[8]	[redacted]
Trifloxystrobin	3/21/2013	1/24/2014	GDCI-129112-1342	[redacted]
Bromoxnil	3/27/2013	1/24/2014	Multiple[9]	[redacted]

CBI

Following the definition of burden as cited by the agency[10], it is felt these costs are appropriate to be included. A simple average of the recent DCIs in Table 2 results in 581 hours of "pre-DCI" burden, all of which was derived from scientific and regulatory staff (*i.e.* technical labor). Due to the very real burdens of discussions, planning, commenting and coordinating even before the issuance of a DCI, it is requested that an additional 581 hours per DCI of burden be reflected as an increase associated with data generation.

Use of Clerical Labor Rates:

EPA uses the Bureau of Labor Statistics for NAICS labor code 325300[11] as the source of its unloaded hourly rate. The following categories are used for Management, Technical & Clerical:

Management: *11-0000, Management Occupations*
Technical: *19-0000, Life, Physical, and Social Science Occupations*
Clerical: *43-0000, Office and Administrative Support Occupations*

---

[5] Total DCI burden is 24,545 hours for a registration review DCI (item #6) as per EPA-HQ-OPP-2016-0109-0012 table 5

[6] Hours derived from Bayer internal R&D timesheets

[7] In this case, management activities include but are not limited to administrative response, protocol development, agency meetings, consortia development, report writing, and other paperwork burdens; figures derived from Bayer internal R&D timesheets and labor tracking systems.

[8] GDCI-097805-899 on 8/5/2013; GDCI-097805-1100 on 6/18/2015; GDCI-097805-1210 on 6/18/2015;

[9] GDCI-035301-1347, GDCI-035301-1348, GDCI-035301-1349 all on 1/24/2013, and GDCI-035301-1347 on 5/28/2014

[10] 5 CFR 1320.3(b)(1); "*Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency...*" Specifically, Bayer points to the sections under (b)(1)(i), (v), (vii), and (ix) as reflective of the review of EPA's problem formulation, reviewing the data submitted and if any additional data exists which may address concerns or if concerns are warranted, and the subsequent comments, risk assessments, and data submitted as part of the notice & public comment period and subsequent discussions on whether such information addresses the concerns, or if not how such concerns can be addressed resulting in the DCI itself.

[11] Found at http://www.bls.gov/oes/current/naics4_325300.htm

In reviewing these labor categories, we find that the use of the three different categories of labor is inappropriate for data generators who, by far, assume the primary burden of DCI compliance[12]. As such, labor patterns and costs should align more closely with the companies who actually develop and submit the requested information rather than respondents whose burden is restricted to completing a few forms and sending a promise of compensation to companies[13] who actually incur the costs[14].

In previous comments[15]on the 158 data requirements, Bayer comments on the use of "clerical" wages in data development, stating:

> *"One additional point of consideration to the agency would be that as systems grow more complex, simple "clerical" labor will not be sufficient to properly utilize systems to provide the agency with the necessary information needed, resulting in a higher skill set needed for companies which is, of course, more financially burdensome."*

Recognizing this developing trend of an increasing technical and skilled workforce it is recommended that the Agency's ICR completely remove the clerical portion of the labor calculation and replace the 15% of the time allocated to clerical staff to technical staff instead. This is in line with previous Bayer comments[16] and we feel it continues to warrant consideration by the agency in this case as well. EPA's previous response to Bayer's request was that application of clerical time was for administrative tasks, specifically[17]:

> *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.*

Bayer reinforces and clarifies that it has no such personnel doing the specific tasks listed above. Regulatory managers, scientists and technical information specialists conduct these tasks, which is in alignment with EPA's exclusion of postage[18] as a recognition that submissions are very often made electronically and not *via* hardcopy paper submission[19]. Additionally, files are maintained by trained personnel to integrate them into the

---

[12] In this instance, data generators primarily refers to Basic R&D companies; while some generic manufacturers do conduct data the vast majority of the data generation is conducted by the original registrant. In Bayer's case, almost 100% of studies needed for molecules initially registered by Bayer were conducted by Bayer with no other DCI respondent volunteering or offering to conduct the needed data.

[13] Referring to an offer to pay as described in 40 CFR 152 Subpart E

[14] As evidenced by EPA's current methodology – see EPA-HQ-OPP-2016-0109-0012 table 6 where EPA calculates the burden to Data Generators to be $127,308,461 *vs.* $4,069,109 for all other categories

[15] See EPA-HQ-OPP-2015-0332-0005

[16] See EPA-HQ-OPP-2015-0332-0026 – *"As such the 15% of clerical work should be classified as technical not clerical. This is applicable more to "Type A" activities than "Type B" which could be classified as more clerical as the amount of data submitted to support these activities are significantly lower although the administrative paperwork is the same or similar."*

[17] See EPA-HQ-OPP-2015-0332-0026

[18] See EPA-HQ-OPP-2016-0109-0010: *"Mailing costs for DCIs are not included in the estimates below as electronic submissions are now accepted, and it is typical practice for registrants to submit data using this method."*

[19] Bayer has been conducting submissions in this manner for over 15 years

electronic submission systems but also to maintain compliance with regulatory requirements as applicable[20].

Realizing smaller entities and generic market participants do not as often develop data in house and frequently cite primary registrant data, the use of clerical labor categories may be appropriate as the burden is exclusively administrative. As such, Bayer makes its request only for "data generator" class of respondents.

Bayer makes the request that the Agency adjust its methodology to reclassify the 10,872 hours of "clerical" burden[21] and convert them with an equal number of technical hours and the corresponding labor rate.

Requirement of Data Pursuant to the Toxic Substances Control Act (TSCA)

In its description of the ICR, EPA references the need to collect data as codified under TSCA[22]. In reviewing the guideline tables, it is unclear to Bayer what data would be needed from TSCA which could not be addressed under FIFRA. As per 40 CFR 158.75, EPA may ask for whatever data it feels is necessary to assess the risk of a pesticide in pursuit of its legal mandate[23], with or without a DCI.

Collection of data pursuant to TSCA is inappropriate and creates regulatory confusion. Bayer strongly objects to even the appearance of combining regulatory statutes and requirements between FIFRA and TSCA on the grounds that:

1. TSCA specifically exempts any substance regulated under FIFRA from regulations promulgated to carry out the legislative purposes of TSCA[24].
2. Juxtaposition of regulatory statutes creates confusion amongst registrants and the public. When the EPA, seeking to review a pesticide under the standards of FIFRA, unintentionally coveys a TSCA data requirement it is making a determination related to the definition of a chemical as a pesticide. This creates the opportunity for interested parties to disagree about what standards should be applied (and are already available) to assess the risk of a chemical. EPA's experiences with litigation under The Clean Water Act[25] and the Endangered Species Act[26] are examples of such misunderstandings.

---

[20] *E.g.* 40 CFR 169 and 40 CFR 160

[21] As per listed hours burdens for data development activities in EPA-HQ-OPP-2016-0109-0012 table 5

[22] 40 CFR part 790-799; Specifically: Part 795 - Provisional Test Guidelines; Part 796 - Chemical Fate Testing Guidelines; Part 797 - Environmental Effects Testing Guidelines; Part 798 - Health Effects Testing Guidelines; Part 799 - Identification of Specific Chemical Substance and Mixture Testing Requirements

[23] See EPA-HQ-OPP-2015-0332-0029; "*EPA acknowledges the collection of data pursuant to its authority under 40 CFR 158.75 and that this is an appropriate collection in lieu of the formal DCI process.*"

[24] TSCA Sec. 3(2)(B)(ii)

[25] E.g. *Headwaters, Inc. v. Talent Irrigation Dist., 243 F.3d 526, 529 (9th Cir. 2001)* or *League of Wilderness Defenders v. Forsgren, 309 F.3d 1181, 1185 (9th Cir.2002)*

[26] E.g. *Ellis v. Housenger, Case No. 13-cv-01266-MMC, 2017 U.S. Dist. LEXIS 70107 (N.D. Cal. May 8, 2017)* or *Center for Biological Diversity (CBD) and Save Our Springs Alliance (SOSA) v. EPA (Case No: 1:04-Cv-00126-Ckk, 2004)*

Bayer requests the agency remove its burdens associated with collecting data pursuant to FIFRA OR stipulate that these data are requested pursuant to FIFRA guidelines with no reference to 40 CFR 790-799.

Burden should be Inclusive of "Voluntarily" Submitted Studies

EPA in its burden calculation makes efforts to acknowledge the numerous contributions made to the agency's efforts to assess the risks and address concerns of the agency in what it refers to as "Voluntary" data submissions. These submissions are loosely defined by EPA as data submitted to the agency by the registrant absent a formal DCI[27]. Bayer requests the agency consider these as part of the burden of the process of DCI satisfaction & development. More broadly, as discussed further below, Bayer also asks the agency to use a more accurate term for these studies. A more accurate term for such data would be "registrant-initiated" or "proactive" submissions.

It is confusing to have the agency put the fact it receives data supportive of its DCI process but then immediately label such data as "not a DCI" and therefore not relevant to the ICR. Additionally, we feel EPA does not capture the full value of a voluntary submission as evidenced by experiences with the Imidacloprid DCI. In 2015 alone at the request of EPA, Bayer submitted 67 studies without a formal DCI adding[28] an [redacted] many of which have appeared in citations of preliminary pollinator risk assessment published by EPA. Even for those studies not directly cited by EPA, the burden of the collection still exists as neither EPA nor Bayer knew for certain which studies would address or inform concerns of the agency.

CBI

Bayer requests that this issue be studied further to be considered as part of all future ICRs reflective of FIFRA data requirements. An update to EPA's 2013 burden conference with industry would be an appropriate forum to provide input.

EPA Assumptions

In this section Bayer offers comments on EPA's assumptions informing its methodology for calculating the overall burden of the ICR in question. These comments are meant to highlight challenges to EPA's ICR calculations which originate from the variables selected to be used in EPA's methodology.

Non-guideline studies are a significant burden

EPA utilizes a variety of internal and external sources to derive the estimated costs of studies. A big part of this process is analyzing pricing for studies from contract laboratories to set a baseline cost. This methodology may be appropriate for the estimation of well understood and time tested research to answer known questions about the risks associated with compounds in general. However, this methodology lacks

[27] Or other statutory obligation such as a Sec. 3 filing, petition for tolerances or adverse effects reporting

[28] As per EPA confirmatory data request letters; studies refer to submissions with root MRID numbers 497662, 496027, and 496482

consideration of the additional cost associated with more complex research inherent in the innovation process, and particularly when novel research is needed to address questions which are less well understood.

For example, in recent years EPA has placed significant emphasis on pollinator safety, and indeed many of these studies which are part of a great number of DCIs are now listed in Appendix E. When these studies first were required, it was Bayer who worked on and consulted with the agency to develop methodologies and protocols on a great deal of this research. Using EPA's proposed labor rates and percentages, [redacted]. Taking, EPA's assumption of 35% of study cost as burden, this results in a paperwork burden of [redacted]. This compares to the 24,545 hours of effort of identified by EPA, representing a [redacted] increase in burden. These learnings will apply to other compounds in this class of chemistry but serves as a model for molecules facing "novel" or "new" challenges.

CBI

Bayer asks that EPA recognize this increased burden which is caused by an ever evolving knowledge of the compounds and our environment and advances in scientific technology. Appreciating that once these issues are addressed the respective burden will decrease as industry becomes more efficient, **Bayer proposes that the agency apply a 100% increase in burden for all Registration review DCIs[29] for each unique class of chemistry[30] for which a DCI will be issued over the next 3 years divided amongst all the DCIs expected to be issued.**

For example, of the 663 DCI planned to be issued, 184 will be registration review DCIs. Should 5 different classes of chemistry be represented, Bayer advocates for an increase in each DCI burden to be:

24,545 hours x 5 chemistry classes = 122,725 hours / 184 DCIs = 667 hours increased burden per DCI

<u>Request for Further Clarification</u>

For some issues, Bayer is unclear how the agency defines or interprets terms and concepts in its calculations. In these circumstances, Bayer requests additional clarification which will inform future reviews and policy, and appreciates EPA's further efforts to explain these concepts.

<u>Data for Non-Hazard Components of Assessment</u>

In describing the authority for its collection, the EPA cites the need to comply with the statutory registration standard as the justification for collection of the needed data. In reviewing this ICR it is unclear how EPA accounts for burden as it is assessing the

---

[29] 24,545 hours according to Table 5 of EPA-HQ-OPP-2016-0109-0012

[30] A full index of all registration review DCIs to be issued is unavailable, so a specific burden calculation could not be provided. If the provided example does not clarify the request appropriately, we would be happy to discuss with the agency in more detail.

"economic, social, and environmental....benefits of the use of any pesticide[31]." In the event of previous assessments, such as EPA's review of benefits of seed treatments on soybeans[32], the data used was primarily publically available, resulting in the burden being primarily on the agency rather than the registrant. Such an exercise would not be as well understood to Bayer, and of which the agency would have a greater understanding. Still, it would be a topic to see in greater detail in future ICRs for data considered by the agency.

Bayer requests the agency comment on how this or future ICRs could reflect the burdens generated by its assessments of economic, social and environmental benefits of pesticide use.

DCI classification of studies submitted at request of EPA without a DCI

In addition to the significant effort prior to the issuance of a DCI, data generators often submit numerous studies to address agency concerns proactively and therefore reduce overall DCI burdens. The agency partially accounts for these activities by listing such submissions as voluntary but assigns a minimal role to the development of this information.

This request for clarification was brought to light by the agency's frequent practice of formally or informally requesting data outside of the DCI process. It is recognized the agency may ask for any data, guideline or otherwise, as per 40 CFR 158.75. The instance of this practice which garnered the most recent attention by Bayer is the EPA's request for data submitted outside the United States pertaining to Imidacloprid in 2015[33] which resulted in the submission of an additional 67 volumes of data submitted at the agency's request. However, in its comments on the Imidacloprid summary document[34] as well as the EFED Problem formulation[35], Bayer made the presence of information useful to the agency known, which was subsequently requested by the agency and also submitted in addition to the DCI and EPA's 2015 request resulting in an additional 52 volumes of research being provided to the agency (bringing the total to 119). There are other "pre-DCI" submissions as well[36] covering publications, public research and proprietary data.

In previous comments to the agency[37], EPA responded to questions regarding recent requests for data outside the normal DCI process to be used as "confirmatory data" or

---

[31] Costs are determined by the safety data submitted as part of the initial registration under FIFRA 3(c)(1)(F) and validated by the registration review process already captured herein.

[32] As published in 79 FR 63118 (Docket # EPA-HQ-OPP-2014-0737)

[33] See letters dated 2/27/2015, 6/4/2015 and 10/4/2015 received from PRD titled, "*Imidacloprid: Request for Studies Conducted by Bayer CropScience not previously submitted to the Environmental Protection Agency.*" At the time, requests were verbally referred to as "confirmatory data" in discussions with the agency.

[34] EPA-HQ-OPP-2008-0844-002

[35] EPA-HQ-OPP-2008-0844-003

[36] *E.g.* MRID numbers 47647900, 47725300, 47726500, *etc.*

[37] EPA-HQ-OPP-2015-0332-0005

otherwise to inform the risk assessment during registration review[38]. At the time, Bayer interpreted EPA's statement to mean EPA acknowledged the collection of data pursuant to its authority under 40 CFR 158.75 was appropriate in lieu of the formal DCI process. In reviewing the agency's comments further it is now seen that the agency was referring to the collection of such data as part of a new application process since the issue at the time was the information collection pursuant to section 3 registration. This was not Bayer's concern at the time, and as such additional clarifying questions were submitted[39] which received no response. Bayer again asks for clarification on the following questions as they relate to information requested by the agency as part of a review process not captured by a formal DCI:

1. Is data requested informally (pursuant to 40 CFR 158.75 or otherwise) captured in this ICR, which may or may not be harmonized with EPA's study guidelines and,
2. How does the agency account in its burden calculation for data requested informally?

Bayer is interested in furthering the transparency of this process not only for its own interests but also so the public may see the fruits of EPA's efforts and understand why some information is incorporated into the risk assessment in lieu of others.

Clarification of General Information Collection Groups

EPA divides DCI responsibilities into multiple production groups, specifically confirmatory data, chemical-specific data, product-specific data, and voluntary data. Bayer would like further definition and clarification of these IC groups.

Confirmatory Data – This data is identified as needed to confirm assumptions in the agency's risk assessment.

1. Is data collected through Generic or Product-specific DCIs (or both)?

Chemical-specific data – This data is identified as information necessary to determine whether the registration can continue in effect without change, or if modifications to the registration will be necessary to reduce risks of concern. Such data needs are determined by a chemical or active ingredient level and are used for making all decisions regarding that chemical or active ingredient

1. Is data collected through Generic or Product-specific DCIs (or both)?
2. In what ways is this data different than confirmatory data?

Product-specific data – This data is identified as information related to end-use products, which registrants are required to submit specific to the product as formulated and sold (including, but not limited to, acute toxicity, product chemistry studies, and product-specific labeling).

1. Are burdens associated with data developed to create EPA-approved labels[40] accounted for?

---

[38] EPA-HQ-OPP-2015-0332-0026; Response to comment #7 where EPA states, "*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.*"

[39] EPA-HQ-OPP-2015-0332-0029

[40] Meaning compliant with 40 CFR 158.400(e)

Voluntary data – This data is characterized as data registrants (and other interested parties) have voluntarily submitted to EPA that was not specifically required or requested, but nonetheless data or information that the registrant wanted EPA to consider in making its decisions

1. What is EPA's definition of "specifically required?" Does this mean required by a formal DCI?

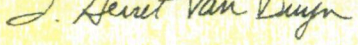
Other Comments

Bayer's other comment related to data submission is EPA's use of the term "voluntary." EPA labels studies submitted for a reason other than an explicit regulatory mandate[41] or DCI response as "voluntary." A great number of times, these studies are submitted at the request of the agency but no DCI is issued due to the burden and time it takes for EPA to issue a DCI. Registrants such as Bayer frequently submit data pro-actively, in the absence of a formal DCI, and in fact EPA relies heavily upon registrants' willingness to do so. Data submitted in the absence of a DCI are routinely relied upon by EPA and are frequently required to support a given registration decision under FIFRA. EPA's use of the label "voluntary" can be misunderstood by the commercial arbitrators who are tasked with deciding data-compensation disputes under FIFRA. Follow-on registrants now often argue in such proceedings that any data labeled as "voluntarily" submitted can never be eligible for data compensation, even where the follow-on used the cite-all method (which encompasses all relevant data in EPA's files).

Bayer desires a collaborative relationship with EPA in which any concerns may be expressed and addressed proactively and efficiently. However EPA's use of imprecise terminology such as "voluntary" in describing substantive data submissions may inadvertently make it more difficult for Bayer to enforce its rights under FIFRA. We request that EPA discontinue the use the term "voluntary" when referring to data submitted outside the context of a formal DCI. Instead, Bayer suggests a more accurate term, such as "registrant Initiated" or "proactive" data submissions.

Bayer appreciates this opportunity to provide input into the regulatory process to help make regulations more efficient and less burdensome on all parties while still providing the same level of protection and inspiring public confidence. Should the agency wish to discuss any specific provisions of our proposals further we would be pleased for the opportunity to do so.

Sincerely,



Gerret Van Duyn
Bayer CropScience LP
Regulatory Lifecycle Manager

[41] Such as 6(a)(2) as implemented under 40 CFR 159

PUBLIC SUBMISSION

As of: 3/1/18 2:54 PM
Received: February 23, 2018
Status: QA_Ready
Tracking No. 1k2-91o1-stqj
Comments Due: February 23, 2018
Submission Type: Web

Docket: EPA-HQ-OPP-2016-0109
Agency Information Collection Activities; Proposed Collection; Comment Request; Pesticide Data Call-in Program

Comment On: EPA-HQ-OPP-2016-0109-0009
Agency Information Collection Activities; Proposals, Submissions, and Approvals: Pesticide Data Call-in Program

Document: EPA-HQ-OPP-2016-0109-DRAFT-0021
Comment submitted by Janet E Collins, Ph.D., R.D., Executive Vice President, Science and Regulatory Affairs, CropLife America (CLA)

Submitter Information

Organization: CropLife America (CLA)

General Comment

CLA appreciates the opportunity to provide input on the Pesticide Data Call-in Program as requested in the docket (EPA-HQ-OPP-2016-0109).

Janet E Collins, Ph.D., R.D., CFS
Executive Vice President
CropLife America

Attachments

Comment

23 February 2018

Ms. Cameo Smoot
Field and External Affairs Division (7596P)
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460–0001

via Regulations.gov: **EPA–HQ–OPP–2016–0109**

Re: Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Pesticide Data Call-in Program; Docket ID No. EPA–HQ–OPP–2016-0109; 83 FR 3344; Jan 24, 2018.

Dear Ms. Smoot:

Established in 1933, CropLife America (CLA) represents the developers, manufacturers, formulators and distributors of crop protection chemicals and plant science solutions for agriculture and pest management in the United States. CLA's member companies produce, sell and distribute virtually all crop protection and biotechnology products used by American farmers. CLA represents interests of its member companies by, among other things, monitoring legislation, federal agency regulations and actions and litigation that impact the crop protection and pest control industries, and participating in such actions when appropriate. CLA is committed to working with the U.S Environmental Protection Agency (herein EPA or the Agency), as the primary federal agency responsible for the regulation of pesticides, to encourage practical, risk-based regulation of its members' products.

On August 23, 2017, EPA opened the docket (EPA-HQ-OPP-2016-0109) for a 60-day comment period on its Information Collection Request (ICR) and its "Pesticide Data Call-in Program." On January 24, 2018, EPA re-opened the docket [(Docket ID No. EPA-HQ-OPP-2016-0109) "Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Pesticide Data Call-in Program," for an additional 30 days. CropLife America and its members continue to evaluate the ICR and the significant changes proposed.

As noted in the Federal Register Notice [(83 FR 3344) FRN], the pesticide registration process is data rich and requires extensive resources to accomplish registration review under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Registrant requirements for data collection under FIFRA are extensive, and as described in the FRN include several iterations of data review and registrant consultation, and significant industry resources. CLA requested a further extension of the comment period on February 21, 2018, but the request was not granted by OMB.

As CLA member registrants review their historic submissions, and the mandatory requirements outlined for the future ICR under FIFRA, registrants will provide detail on specific pesticide active ingredient data requirements and resources needed.

CLA members constitute a significant portion of the respondents for the actions covered by this ICR, and have a wealth of experience and background to offer in evaluating the proposed changes. Further, CLA members are greatly impacted by the increased data, and other resource requirements.

Given the significant projected added costs to registrants, CLA also may provide added comment on labor rates used in the cost estimates; omission of consideration of all expenses other than personnel costs; and estimates of level of effort for individual actions covered by the ICR such as the DCI response for registration review of a specific pesticide active ingredient.

Concluding Remarks

CropLife America appreciates the need to collect and report resource requirements for registration and registration review under FIFRA, and we appreciate the opportunity to provide relevant information to assist in the capture of realistic estimates of resource requirements. CLA members intend to provide specific information on their experiences and resource requirements for registration and registration review of their individual active ingredients.

Thank you for the opportunity to provide input on this important program review. CLA and its members continue to welcome the opportunity to work with EPA and other federal agencies in pursuit of reliable and relevant registration and registration review- we will continually provide information to assist in capturing the resource requirements for the industry under FIFRA.

Should you have any questions or wish to discuss these comments, please contact me directly by email (jcollins@croplifeamerica.org) or directly (+1-202-833-4474).

Thank you for your consideration of these comments.

Respectfully,

Janet E Collins

Janet E Collins, Ph.D., R.D.
Executive Vice President, Science and Regulatory Affairs