



## **Chemical Producers & Distributors Association**

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*VIA WWW.REGULATIONS.GOV*

Cameo G. Smoot  
Field and External Affairs Division  
Office of Pesticide Programs (7506P)  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460-0001

**RE: Pesticides; Satisfaction of Data Requirements; Procedures to Ensure Protection of Data Submitter's Rights; Proposed Rule; 75 Fed. Reg. 68297 (November 5, 2010); EPA-HQ-OPP-2009-0456.**

Dear Ms. Smoot:

The Chemical Producers & Distributors Association ("CPDA") appreciates this opportunity to comment on the above-referenced rule. We are the primary advocate on federal legislative and regulatory issues for generic pesticide registrants, adjuvant and inert ingredient manufacturers, and product formulators and distributors.

The U.S. Environmental Protection Agency ("EPA" or "Agency") proposes to revise certain provisions of the 40 C.F.R. part 152, subpart E regulations governing procedures to ensure protection of data submitters' rights under the Federal Insecticide, Fungicide, and

Rodenticide Act (“FIFRA”)<sup>1</sup> “to accommodate statutory and procedural changes that have occurred since [1984].”<sup>2</sup> Although this general housekeeping may be needed, the Agency also proposes to significantly revise section 152.84, which would result in generic registrants<sup>3</sup> having to submit a FIFRA-required “offer to pay”<sup>4</sup> at the time they file a registration application instead of the current flexible practice of submitting the offer at any time before the agency approves the application. CPDA strongly opposes this particular revision and urges EPA not to revise section 152.84 and the Agency’s long-standing policy of allowing generic registrants the flexibility they need to meet this FIFRA requirement.

### FIFRA Data Compensation and Generic Registrants

Section 3(c)(F)(iii) of FIFRA authorizes an applicant for a generic product to cite data in support of an application for registration, and authorizes EPA to “consider” that data without the permission of the original data submitter if the data are not subject to FIFRA exclusive use protection and the generic product applicant has made an offer to pay the original data submitter.<sup>5</sup> In addition, the applicant “must submit such offer to [EPA]” along with “evidence of delivery to the original data submitter of the offer.”<sup>6</sup> When citing data submitted by others, applicants may “cite all” relevant data in EPA’s possession that would support the application and make a general offer to pay relevant data submitters, or may use the “selective method” by citing specific studies that satisfy each data requirement for the application.<sup>7</sup> Congress sought to achieve through this statutory approach, an equitable balance between the financial interests of original data submitters/owners and opportunities for others to participate in the pesticide market; altering the flexible offer-to-pay submission policy is likely to upset that balance.

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<sup>1</sup> FIFRA §§ 2 et seq.; 7 U.S.C §§ 136 et seq.

<sup>2</sup> 75 Fed. Reg. 68297, 68297 (November 5, 2010).

<sup>3</sup> CPDA uses the term “generic” in these comments to refer to applicants that register products based on registrations or data owned by others, and which may be eligible for compensation under section 3(c)(F) of FIFRA. Generic registrants are also commonly referred to as “follow-on” or “me-too” registrants or applicants.

<sup>4</sup> FIFRA § 3(c)(F)(iii) uses the term “offer to compensate,” but the term “offer to pay” is the common term for this FIFRA requirement.

<sup>5</sup> The offer to pay requirement applies to all data EPA considers, without a data owner’s permission, in support of an application filed within 15 years after the data were first submitted to the Agency.

<sup>6</sup> FIFRA § 3(c)(F)(iii). Instead of submitting this documentation, EPA allows an applicant to certify on Form 8570-34 that it has copies of the offer and delivery and will submit them to EPA upon request.

<sup>7</sup> 40 C.F.R. §§ 152.95 and 152.96.

### Timing of an Offer to Pay

FIFRA is silent on when offers to pay must be submitted during the application process. Section 3(c) of FIFRA addresses procedures related to registration and states only that EPA can “consider,” in support of an application, data submitted by others if the data are eligible for compensation and the applicant has made an offer to pay. EPA addressed this silence 26 years ago when it promulgated a rule governing when materials must be submitted to the Agency.<sup>8</sup> In section 152.84 of subpart E of this rule EPA states:

“All information required by this subpart should be submitted with the application, but may be submitted at any later time prior to EPA’s approval of the application. The Agency will not approve any application until it determines either that the application is not subject to these requirements or that all required materials have been submitted and are acceptable.” (emphasis added)

Moreover, the Preamble to the rule provided EPA’s unequivocal interpretation that section 152.84 allowed flexible submission of required components of an application:

“Section 152.84 therefore provides that applicants may submit materials required by this subpart at any time before registration is granted. The Agency will not delay the review of other information pertinent to the application pending receipt of lists and certification statements, but will not approve the registration until they are received.”<sup>9</sup> (emphasis added)

In mid-2002, EPA revisited this policy when it was made aware of EPA staff inconsistently applying the policy. CPDA and others expressed their concerns about changes to this policy through letters to EPA and in meetings with Agency staff, including the Office of General Counsel. In November of 2002, EPA published draft guidance (“Notice”)<sup>10</sup> on how to comply with data citation regulations “to clarify the obligations of data citers.”<sup>11</sup> EPA also advised applicants relying on cited data that they “must assure that the offer-to-pay letters they provide to data submitters satisfy EPA’s regulatory requirements as provided in [subpart E].”<sup>12</sup> However, the Agency expressly

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<sup>8</sup> 49 Fed. Reg. 30884 (August 1, 1984). Procedures to Ensure Protection of Data Submitters’ Rights.

<sup>9</sup> Id. at 30897.

<sup>10</sup> 67 Fed. Reg. 68866 (November 13, 2002); See Draft PR Notice 2002-XXXX.

<sup>11</sup> Notice at p. 2.

<sup>12</sup> Id. at p. 1.

declined to address the issue of when offers to pay must be submitted, stating that the Notice:

“...does not address the issue of when offers-to-pay must be made or when documentation demonstrating that offers-to-pay have been made must be submitted to the Agency. EPA expects to issue guidance on this related issue through a separate means.”<sup>13</sup>

The Agency never issued this guidance, never issued the draft Notice, and has continued to follow the 1984 flexible offer-to-pay policy.

Thus, for 26 years EPA has used this flexible policy when processing generic product applications, with no apparent hindrance to the registration process or obstruction of data submitters' compensation rights. Obviously, allowing applicants to decide when to submit an offer to pay during the application review process has resulted in a long-term workable balance of the needs of EPA, data submitters, and generic product applicants. Nevertheless, EPA now proposes to upset this balance by eliminating this equitable flexibility.

#### EPA Should Not Change the 1984 Policy on the Timing of Offer-to-Pay Submissions

EPA offers two reasons for revising section 152.84 to eliminate a generic product applicant's option to submit an offer to pay “at any time prior to EPA's approval of the application.” First, the Agency states that it “believes the primary rationale” for section 152.54 submission flexibility is the waiting period for data gap certification letters, and asserts that “EPA identified the 60-day waiting period for data gap certification letters as the primary example”<sup>14</sup> of why submission flexibility was needed, but which EPA now says is unnecessary because these letters are no longer required. However, EPA mischaracterizes the Agency's former statement, which simply used the 60-day waiting period as an example (a “notable example”) and not as the “primary rationale” for the submission flexibility.

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<sup>13</sup> Supra, note 10 at p. 68868.

<sup>14</sup> Supra, note 2 at p. 68300.

Second, EPA asserts that FIFRA section 33(f)(4)(B)<sup>15</sup> requires it to determine, during a PRIA II 21-day application completeness screen, whether an application contains “all the necessary forms, data, draft labeling...,” including those required by subpart E, and the Agency must reject applications not containing all subpart E information and forms. CPDA disagrees with EPA’s assumption that the PRIA II 21-day screen requires that all forms, data, and draft labeling be submitted when an application is first submitted. Section 33(f)(4)(B) authorizes EPA to determine the contents of a complete application, but that section does not compel EPA to require an offer to pay to be part of the 21-day completeness determination. EPA understood this to be the case when the Agency used its discretion under section 33(f)(4)(B) to develop the worksheet for conducting PRIA II 21-day content screens for registration applications in 2009.<sup>16</sup> The Agency noted in footnote B of the worksheet that:

“[a] policy on documentation of offers to pay is still being developed, however, for [“me-too” or “fast track” fee categories] an application without the necessary authorizations of offers to pay will be placed into [other categories with slightly elevated fees and review time]. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency’s decisions.”

Although EPA prefers that an offer to pay be included with the initial application, the Agency has nevertheless structured the worksheet to accommodate flexibility in submitting offers to pay for certain generic end-use products.

Despite the 26-year history of the current offer to pay submission policy causing no apparent problems for EPA, and after multiple Agency reexaminations of the policy, EPA now proposes to terminate by rule the ability of generic registrants to submit offers to pay at any time during the application review process. The Agency has provided neither credible reasons for this action nor demonstrated that this submission flexibility has adversely affected the Agency’s ability to timely register generic products or interfered with data compensation rights of data submitters.

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<sup>15</sup> Section 33 was added to FIFRA by the 1996 Pesticide Registration Improvement Renewal Act (PRIA II).

<sup>16</sup> EPA, PRIA 2 – 21-Day Content Screen Review Worksheet (2009).

The Agency's ability to conduct science reviews is not limited in any way by allowing applicants to submit offers to pay throughout the application review process. However, unnecessarily denying applicants the option to do so makes them vulnerable to significant increased costs to register their products. EPA is well aware of aggressive filing of petitions to deny generic registrations in the past, and although the number of unjustified petitions filed has decreased after PRIA, the option to file them remains. An applicant's option to delay submitting an offer to pay provides an opportunity to minimize the chance of having to defend this costly interference with a registration application.

Even more burdensome is having to involuntarily engage in arbitration early in the application process. The Agency is also well aware of this method of disruption. Once an offer to pay has been submitted and the required 90-day period has passed, a data submitter can initiate binding arbitration, possibly subjecting an applicant to significant and unfair costs to register a product. If a science review raises uncertainties involving "substantially similar" determinations and related data issues, this is likely to occur before data compensation needs to be addressed. An applicant may, in some instances, decide not to register a product for reasons unrelated to data submitters and data compensation. If that applicant involuntarily becomes involved in arbitration early in the process, significant costs could be unjustly incurred even if that registration effort is abandoned later in the process for reasons unrelated to the arbitration.

The bottom line is that EPA will not approve an application until offers to pay have been made. However, that approval is not related to or based upon the Agency's important and mandatory comprehensive science review and subsequent "no unreasonable adverse effects" determination needed for approval. Only after that determination does the offer to pay become important, and EPA is required to ensure a valid offer to pay has been made. This is simply an administrative function EPA performs under FIFRA, which does not specify when EPA must perform it. Nevertheless, the time of submitting an offer to pay can be of little importance or of great importance to an applicant, and the degree of importance is an application-by-application determination. Consequently, CPDA strongly opposes EPA's proposed change to section 152.84, and

recommends that the Agency not eliminate this important flexibility policy in the registration process.

#### Recommended Alternate Procedure for Submitting Offers to Pay

If EPA decides that section 152.84 must be revised, CPDA recommends that the Agency use a two-step procedure that would ensure data submitters receive adequate notice of intent to file an application for a generic registration and also preserve the ability of applicants to submit offers to pay at any time before applications are approved. The regulation would specify that a PRIA II completeness determination requires proof that a “Notification of Intent to File an Application” had been provided to all relevant data owners prior to filing the application. This proof would be included with the initial application. Upon EPA’s determination during the application review process that the cited data are acceptable to support an application, and so notifies the applicant, the applicant would then tender the offers to pay and file the Certification with Respect to Citation of Data. This equitable and balanced approach would provide applicants with a means of minimizing problems, such as obstructive and costly arbitration, and would ensure data submitters have notice of an application and the opportunity to challenge it through a petition to deny.

#### Conclusion

CPDA urges EPA to continue the flexible submission policy for offers to pay and not revise section 152.84 as proposed. Neither FIFRA nor PRIA require that offers to pay be submitted at the time an application is first filed with EPA, and EPA’s long-standing policy of allowing this flexibility is consistent with Congress’ balanced statutory scheme for protecting data submitters’ investments while allowing cost-effective opportunities for generic registrants to participate in the pesticide market. Generic registrants have relied on this flexibility to timely obtain registrations at reasonable cost for the past 26 years, and EPA has not demonstrated any compelling reason for abandoning this policy. If EPA does decide to adopt its proposed change, CPDA recommends that the Agency use the two-step approach described above, which would ensure the concerns of generic registrants and data submitters are equitably addressed as Congress intended.