



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460**

**OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION**

**May 5, 2023**

**MEMORANDUM**

**TO:** Anita Pease; AD Division Director  
Madison Le; BPPD Division Director  
Charles Smith; RD Division Director

**FROM:** Edward Messina; OPP Director

**SUBJECT:** PRIA 5 – Approach for Renegotiation of PRIA Due Dates Going Forward

The Pesticide Registration Improvement Act of 2022 (PRIA 5) was enacted on December 29, 2022, and among other things updated the pesticide registration service fee tables in FIFRA Section 33(b)(3)(B) and made those fee tables effective 60 days after enactment of the law, or February 27, 2023. The law also contained many other important changes. One of which concerns the conditions around which – under PRIA 5 – renegotiations are to be conducted. In order for OPP to move forward in its implementation on this aspect of PRIA 5 collectively, I am sharing this memo which outlines the office's framework for renegotiating actions under PRIA 5. If staff have not already introduced this practice into their registrant interactions, this approach is to be adopted immediately within the registering divisions.

Historically, EPA has often sought to renegotiate PRIA due dates due to lack of resources for staff to adequately complete the assessment or in a situation where data may be needed for EPA to make a determination on an action. As a result, the PRIA renegotiation rate has climbed in recent years, with many actions having been renegotiated multiple times. Accordingly, the on-time complete measure results of 97-99% have not accurately conveyed the percentage of PRIA actions completed within the original PRIA due date, considering the duration of time and/or number of times a PRIA action was renegotiated or delayed.

### **Changes to Renegotiation Under PRIA 5**

Specifically, PRIA 5 amended the language of FIFRA Section 33(f)(5)(B) and (C) to read:

**(B) EXTENSION BY NEGOTIATION OR MUTUAL AGREEMENT.** — The Administrator, acting solely through the Director of the Office of Pesticide Programs, and the applicant may mutually agree, in writing, to extend a decision time review period under this subsection if—

(i) there is new or additional data or information from the applicant that is necessary for the Administrator to make a decision on the application that cannot be made available within the original decision time review period; or

(ii) a public comment period associated with the application generates significant comments that cannot be addressed within the original decision time review period.

**(C) PRIORITY.** — Once a decision time review period for a covered action described in subsection (b)(3)(B) is missed or extended, the Administrator shall make any action on the application a priority.

It is important to note that one of the basic principles of renegotiation — that all such agreements must be in writing and mutually agreed-upon by both EPA and the applicant — was not changed by PRIA 5. Neither EPA nor an applicant can unilaterally renegotiate a PRIA due date. However, this statutory language calls for several important changes to the renegotiation process.

First, PRIA 5 specifies that any renegotiation agreement on EPA's part must be taken by the Office Director (OD) of OPP. The potential for renegotiation can continue to be managed by OPP staff during review of PRIA actions in accordance with the new PRIA 5 conditions but all renegotiation agreements between EPA and applicants must be signed by the OPP OD.

Second, pursuant to PRIA 5, the decision time review period for applications may be renegotiated only under certain specified circumstances, described above in FIFRA Section 33(f)(5)(B)(i) and (ii). Prior to PRIA 5, there were no conditions whereby EPA and an applicant could agree to an extension of the PRIA due date. The limitations enacted by PRIA 5, discussed in more detail below, will result in fewer PRIA actions being eligible for renegotiation. For many actions, this will result in the registration action not being completed by the PRIA due date.

Third, if the PRIA due date is missed or extended, in accordance with Section 33(f)(5)(C) of FIFRA, EPA must prioritize review of that application. While PRIA 5 did not delineate any specific steps that EPA must take to “prioritize” its review, there are several considerations to keep in mind. If, for example, the PRIA due date is extended due to the need for additional data from the applicant, EPA might prioritize the review to complete the assessment of the data and

make a decision on the application within the renegotiated PRIA due date. Alternately, if the PRIA due date for an action has been missed, EPA should continue working on the action to reach a decision, as soon as practicable. OPP is still developing a process for prioritization, which may involve providing a projected completion date to applicants after the missing of a PRIA due date. We will develop the functional definition of this provision through upcoming PRIA Bi-weekly Meetings and other venues. It is important to note that “a decision on the application” includes both granting the application, but also a determination that EPA cannot grant the application. For actions in which EPA determines — within the original PRIA due date — that it cannot grant the application or that the application otherwise does not meet the standard for registration under FIFRA, the Agency considers its obligations under PRIA to be complete. Accordingly, such applications that EPA cannot grant are not subject to prioritization under FIFRA Section 33(f)(5)(C).

Though not a renegotiation, a footnote exists for specific categories throughout the PRIA fee tables which allows the decision review time to be extended for endangered species assessment one-time only for up to 50% of the decision review time-period. That extension is not subject to the same restrictions discussed below but is contingent upon EPA finalizing guidance to registrants regarding analysis necessary to support EPA review of outdoor uses of pesticide products under the Endangered Species Act and providing written notification to the applicant prior to completion of the preliminary technical screen.

### **Circumstances Allowing for Renegotiation of PRIA Actions**

While many PRIA actions that would previously have been eligible for renegotiation will not meet the criteria for renegotiation under PRIA 5, others will.

More rarely, and perhaps more simply, where EPA intends to issue a proposed decision for public comment (*e.g.*, new active ingredient, first residential use, etc.), and where EPA receives “significant” public comments, renegotiation may be permissible. In order to justify renegotiation of these actions, EPA must determine that it cannot respond to the significant public comments before the original PRIA due date. Such determinations will be made on a case-by-case basis, and factors to consider may include the following:

- The public comment period ending close to the original PRIA due date;
- A large number of significant public comments received;
- Complexity of comment(s) is such that EPA requires additional time to respond;
- Response to significant comment(s) requires EPA to take some additional step, such as remodeling the ecological risk assessment with new or different inputs based on comments received, which would require more time than remaining before the PRIA due date.

More regularly, EPA staff will encounter questions of whether a PRIA action may be renegotiated based on the need for additional data to complete the review. If, during its PRIA review of an action, EPA discovers that it cannot make the required FIFRA determination with the information submitted as part of the applicant's package, the Agency often requires the applicant to submit the additional materials needed.<sup>1</sup> This is often accomplished through "75-day letters" issued to applicants pursuant to 40 C.F.R. § 152.105, which allows for administrative withdrawal of applications that are not completed within the specified time period. In order to justify renegotiation of these actions, EPA must determine that the new or additional information is necessary for the Agency to make a decision on the application, and also that the new or additional information cannot be submitted before the original PRIA due date. As with public-comment based renegotiations discussed above, determinations as to whether renegotiation is appropriate will be made on a case-by-case basis, and factors to consider may include the following:

- Can OPP make the required FIFRA determination with the materials submitted in the applicant's package, including that all 40 CFR Part 158-required data requirements are satisfied?
- If the current contents of the applicant's package do not support the PRIA action, can OPP make a determination that it cannot grant the application (or, in other words, would start a denial process if the applicant requested) or that the application otherwise does not meet the standard for registration under FIFRA?
- How much time would the applicant need to submit data that OPP needs to make a FIFRA determination combined with how much time OPP would need to review it?

In the coming weeks, OPP will continue working to design an appropriate metric that aligns with the legal language of PRIA 5. This standard set of metrics will consistently track across OPP, within divisions, and across PRIA categories or groups of categories. In concept, it could involve tracking on-time completions, as well as our progress in terms of reducing completion times for all and discrete PRIA categories and certain covered activities, such as new active ingredients, new uses, and new products. Under PRIA 5, renegotiations are largely reserved for situations where the registering divisions cannot make FIFRA determinations due to missing data or the need for clarification on existing data. PRIA renegotiations will not be requested based on lack of registering division resources or late receipt of assessments and reviews from the science divisions and teams. These new restrictions will change how OPP tracks our work and will result in a reduction in the renegotiation rate and likely an increase in the number of missed or extended PRIA due dates. It is important to note that this change is for the better, as it will more accurately reflect the length of time needed to complete actions submitted under a given PRIA category.

---

<sup>1</sup> To the extent practicable, OPP must determine whether an application is complete or whether additional data or information is needed from an applicant within the preliminary technical screening under FIFRA Section 33(f)(4)(B)(iv).

I appreciate the continued hard work from everyone in OPP over the years in this area. While we continue to strive to meet PRIA statutory timeframes, we understand that some actions will be missed or extended for various reasons. We realize this is a significant change in how we have been regularly operating, which will require adjustments for many of us. For instance, some staff may have performance elements in their PARS agreement regarding on-time completion rates. Considering the direction, we intend to take on measuring the length of time to complete registration actions for discrete PRIA categories, we will need to reconsider these types of performance elements and develop more meaningful measures to better manage our resources. Although these changes are being required by statute, from discussions with our stakeholders, I believe they will help alleviate the need for repetitive renegotiations by our staff and allow more time to work on reviewing applications; be responsive to registrants' expectations; and provide a more accurate portrayal of EPA's performance on PRIA actions.

We intend to engage all levels of the organization for input on how best to implement these changes to improve the efficiency of the organization and the employee experience. Along these lines, we intend to set up town hall type meetings to hear your concerns and ideas, and to answer questions you may have. We realize there are still many remaining questions on what these changes mean and how they are to be implemented. I commit to you that the process for modifying and enhancing our processes will be collaborative and iterative. To help with this transition, questions that you may have or that you receive from a registrant can be sent to Steve Schaible at [schaible.stephen@epa.gov](mailto:schaible.stephen@epa.gov).

Cc: Michael Goodis, Deputy Director of Programs  
AD Branch Chiefs  
BPPD Branch Chiefs  
RD Branch Chiefs  
Stephen Schaible, PRIA Coordinator