

Request for a Non-Substantive Change to an Existing Approved Information Collection

(EPA ICR No. 0277.17; OMB Control No. 2070-0060)

I. Introduction

EPA is requesting OMB approval for a non-substantive change to the currently approved ICR to account for the new PRIA 4 fee-for-service category, M009. The amended PRIA 4 statute was passed in March 2019. This non-substantive change request is to provide interim Paperwork Reduction Act (PRA) coverage until EPA can revise the “Application for New and Amended Pesticide Registration” ICR to include these categorical actions during its renewal cycle starting this month (August 2019).

II. Description of Non-Substantive Changes

What Information Collection Request (ICR) is EPA changing?

- **ICR Title:** Application for New and Amended Pesticide Registration
- **ICR Numbers:** EPA ICR No. 0277.17; OMB Control No. 2070-0060
- **ICR Expiration Date:** September 30, 2020

What are the changes that EPA is making to this collection of information?

EPA is responding to the new M009 category resulting from an amendment to the PRIA 4 statute passed in March of 2019. This category, entitled “Non-FIFRA Regulated Determination: Applicant initiated, per product,” allows applicants to pay a fee to receive an EPA determination of whether FIFRA registration is required for a proposed product. These determinations include, but are not limited to, determinations for treated articles exemptions, 25(b) minimum risk pesticides, pesticide active ingredients and pesticidal device(s). Requests for determinations are submitted to the Agency at the discretion of the applicant.

EPA is currently defining the scope of this new PRIA category in order to draft informational materials that will direct applicants regarding the information that companies could submit to support a determination. The Agency anticipates revising the ICR to include the burden and costs associated with the collection of information resulting from the M009 category.

Did EPA consult with stakeholders about this approach?

The amended PRIA 4 statute included the addition of the M009 category. Due to this new category, EPA is now statutorily obligated to respond to applicants' determination requests upon fee payment. Once a request is submitted and payment is received, EPA has four months to respond to the applicant with a determination. Prior to PRIA category M009, EPA was not mandated to respond to similar requests within a specific time. The creation of this category ensures applicants who pay a fee, receive a determination on their product within the four-month time-frame. EPA will consult stakeholders regarding the new category and proposed informational materials during the ICR comment period in the next three months as part of the ICR renewal cycle.

Will this change impact the annual ICR burden estimate?

EPA anticipates a minimal PRA burden increase resulting from this new category. In order to receive a determination, applicants must pay a fee of \$2,363. Some companies may qualify for up to a 75% small business fee waiver. Since this category only came into existence after PRIA 4 was passed in March 2019, there are insufficient data and no baseline information to analyze the real impact the new category will have on the Agency's ICR burden. EPA will revise the ICR during its current renewal cycle with data that's generated from the maturation of the program.

What is the expected non-paperwork impact of this change?

The new PRIA 4 category, M009, is expected to save both the agency and applicants time and resources by defining the parameters needed for an EPA determination. Informational materials that will be included in the Section 3 ICR renewal are currently being drafted by the Agency. These materials are expected to reduce the burden on applicants by defining the specific information needed by the EPA to respond to the applicants' determination request within the specified time-frame. Previously, the Agency would receive periodic requests for these determinations; however, since there was no EPA guidance or fee structure in place, applicants may have submitted inadequate or unnecessary data. The inconsistent information submitted often required EPA to contact the companies to request additional information or clarification of submitted information in order to make a determination on the product, resulting in delays. The information requested to support the M009 applications is anticipated to streamline the determination process for these specific applicant requests. To date, the Agency has received **six** applications submitted under PRIA category M009.