

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

(EPA ICR No. 0227.22; OMB Control No. 2070-0060; Application for New and Amended Pesticide Registration)

## **I. Introduction**

### ***Why is EPA Requesting a Non-Substantive Change?***

The existing, approved ICR, entitled “Application for New and Amended Pesticide Registration.”

## **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. 0227.23; OMB Control No. 2070-0060

### ***What is the current status of this ICR?***

This ICR was approved on March 23, 2021.

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

In September 2015, the EPA started offering the Pesticide Submission Portal (PSP), a fully electronic alternative as an option for submitting registration forms electronically, as well as the ability to sign and submit confidential information using Central Data Exchange (CDX) technology. The development of a web-based submission portal is a critical step in the realization of EPA’s long-term vision for secure data exchange between registrants and the Agency.

EPA can now make available the option for electronic reporting for the Confidential Statement of Formula (CSF) which will allow users to access information already stored in the data system to partially complete their submissions so that the data would not need to be reentered for every submission. The software would perform error checks and validations, flagging issues that registrants may need to address before being permitted to advance to the next step in a given submission. This technology is expected to provide significant improvement in data accuracy by reducing common errors such as mathematical calculations. The electronic software would also greatly enhance registrants’ ability to correctly designate information for pesticide product types and for food use applications (e.g., with antimicrobial and inert ingredients). Once an eCSF has been created, registrants will be able to copy the file and use it to make modifications or alternate formulations.

The existing CSF is currently submitted only on paper, and as a result, no structured data are collected. Any time a change is needed, some of the common data must be reentered and resubmitted on a different form. As most CSF forms submitted to EPA are modifications to previously submitted versions, adopting the proposed electronic reporting option is anticipated to result in significant time savings for the applicant and the Agency.

***Did EPA consult with stakeholders about this approach?***

As part of the most recent ICR renewal process, EPA noted that the eCSF was still in development but will seek to provide an optional, fully electronic alternative to the Confidential Statement of Formula, or CSF (EPA Form 8570-4). EPA welcomed input from stakeholders on the movement towards electronic reporting and use of the PSP application.

***Will this change impact the annual ICR burden estimate?***

This change will not increase the annual ICR burden estimate. It is not mandatory for stakeholders to take advantage of this electronic reporting option. This action will not change the scope or content of submissions, nor would it prescribe a format.

The burden associated with CDX registration is covered by another approved ICR (OMB control no. 2025-0003 and ICR No. 2002.07). EPA estimates that this 73% of CSF submitters are already registered in CDX and already use the PSP for other purposes. In most cases, these entities are pesticide registrants.

Those that choose to submit electronically may experience some savings related to postage and materials (paper, ink, etc.). Because the electronic reporting option is both time-limited and voluntary, these cost savings are likely to be *de minimis*. Although there will be additional burden in establishing the eCSF file, subsequent submissions will be faster because of the saved data.

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

There is no expected non-paperwork impact of this change.

***How does a temporary electronic reporting option help EPA properly perform Agency functions necessary to comply with legal requirements and achieve program objectives?***  
An individual or entity wanting to obtain a registration for a pesticide product must submit an application package consisting of information relating to the identity and composition of the product, proposed labeling, and supporting data (or compensation for others' data) for the product, as outlined in 40 CFR part 158.

All registrants, "Types A, B, and C" are required to submit CSFs with their pesticide registrations. For example, all "Type A" applications for new active ingredients are required to submit administrative forms, product labeling, a CSF, and full complement of physical chemistry, toxicology, environmental fate, ecological effects, worker

exposure, residue chemistry, environmental chemistry, and product performance data. "Type B" activities include a range of actions from Fee-for-Service to the less involved label amendments and notifications. The items that must be submitted or cited in this application include product specific data, administrative forms, product labeling, and a CSF. For "Type C" activities the registrant must provide a "reduced risk" rationale document addressing risk reduction parameters described in PR Notice 97-3. The items required to be submitted in applications for "reduced risk" chemicals include generic data, product specific data, administrative forms, product labeling, and a CSF. Administrative forms also usually include the application for registration, data compensation form, a data matrix, the CSF, and copies of the complete labeling.

All registration actions are entered into the Office of Pesticide Program's Information Network (OPPIN) and EPA's internal database Salesforce to track progress toward registration. Registration actions accompanied by data (e.g., products containing new active ingredients or new uses) are also entered into the database to track progress toward registration. Once a product has been registered, pertinent status information regarding the product is revised in the tracking database. The system contains the following types of information: new or amended product registrations, suspensions, cancellations, product active ingredients, product uses, use deletions and preapplication determinations. EPA maintains official registration file jackets, in which copies of the application, EPA's reviews, registration approvals, correspondence, label, the CSF and other related information are all retained. This electronic reporting option will allow for faster and more efficient processing of registrations for EPA to carry out its functions under FIFRA Section 3.

There were 7,292 FIFRA Section 3 registration actions annually, on average, during the years 2015-2017. These included an average of 205 "Type A" activities, 7,082 "Type B" activities, and 5 "Type C" activities.

***Will EPA consider a permanent electronic reporting solution for CSF?***

Yes, EPA is considering the development of a longer-term electronic reporting solution. As part of considering and developing a long-term solution, EPA will determine whether it is necessary to amend to the CSF requirement at 40 CFR 158 to ensure submissions conform with the requirements of 40 CFR 3. EPA is in the process of conducting outreach amongst stakeholders in order to identify ways in which electronic reporting and standardization of format can maximize efficiency and burden reductions for both the Agency and stakeholders.