- Pesticides Home

- Regulating Pesticides Home
- Registration
- Reevaluation: Pesticide Review
- Pesticide Product Labels
- Pesticide-Producing Establishments
- Laws and Regulations
- International Activities
- Adverse Effects Reporting
- Storage & Disposal
- Restricted & Canceled Uses
- Pesticide Tolerances
- Registration Information Sources

Electronic Submissions for Registering Pesticide Products

Current as of April 14, 2009

Resources

- Data Requirements for Pesticide Registration
- Templates for Use in Developing Pesticide Study Documents
- Web-distributed labeling

Before manufacturers can sell pesticides in the United States, EPA must evaluate the pesticides thoroughly to ensure that they meet federal safety standards to protect human health and the environment. EPA grants a "registration" or license that permits a pesticide's distribution, sale, and use only after the company meets the scientific and regulatory requirements.

Applications for a new or amended pesticide registration must include the appropriate EPA forms. These forms are available for download from the Pesticide Registration Kit Web page. This page also contains information on preparing a application submission and points of contact for additional assistance.

Depending on the nature of the application, supporting data may be required as part of the submission. These scientific (or "data") requirements are set out in 40 Code of Federal Regulations (CFR) FR 158. The documents that are submitted to fulfill the data requirements are commonly called "studies."

Applications for new or amended registration must also be accompanied by draft labeling that meets the regulatory requirements set out in 40 CFR 152.50. Further information on labeling requirements is available in the "Label Review Manual, Chapter VI. Label Submission Requirements".

The entire contents of a submission supporting an application for new or amended registration, experimental use permits, tolerance petitions, and supplemental distributor applications may be submitted in electronic format as described below. At this time submissions that support reregistration or registration review are **not** eligible for electronic submission. Also not currently eligible for electronic submission are supplemental information submitted at Agency request, FIFRA 6(a)(2) submissions, submissions of data as a condition of registration, and notifications.

The Office of Pesticide Programs now has a new Electronic Confidential Statement of Formula (e-CSF) application. This application has been designed as a stand alone application to support the implementation of Pesticide Registration Information SysteM (PRISM) and is available from the website. Read more about the e-CSF application.

On this page:

For questions or assistance with the PRISM e-Submission or e-CSF application, please refer to the contact information below.

PRISM e-Submission and e-CSF Application Help

Support Hours: 8:00 am - 4:00 pm Eastern Time, Monday through Friday

Phone Number:

- Robert Schultz - 703-308-8186

E-mail Address: OPP_e-Submission_Help_Desk @epa.gov

e-CSF Application

Getting Started

To get started with the e-CSF process, download the application to your computer's desktop, open the application, and begin entering information about a CSF. Each section of the application corresponds to a section in the EPA Form 8570-4. Once the e-CSF form has been completed, it may be saved as PDF and XML documents. **The e-CSF process requires an ink signature - electronic signatures are not acceptable. Please be sure to sign the e-CSF form where appropriate and incorporate the signed page into the PDF document to be submitted electronically.**

- Download the e-CSF application (30 MB, ZIP file)
- e-CSF User Guide (57 pp, 2.1 MB, About PDF)

About the e-CSF

The Confidential Statement of Formula (CSF) form (EPA Form 8570-4) is used to identify the complete chemical composition of each pesticide so it can be evaluated for registration under the Federal Insecticide, Fungicide, and Rodenticide Act. This form is designed for reporting the ingredients used in the formulation of a pesticide product and must be completed and submitted with each application for new registration of a pesticide and application for amended registration if the revision involves a formula change.

To progress towards the e-Gov Initiatives, the Office of Pesticide Programs has designed an application that allows for the ability to submit data currently available on the CSF form in an electronic file format to reduce the reliance on paper as part of the Paperwork Reduction Act. Data entry requirements associated with the current paper-based process will also be reduced. This new capability will be referred to as electronic CSF (e-CSF). The e-CSF application allows for a streamlined paperless-like process, improved access to critical decision documents, as well as enhancing availability of information to both internal and external stakeholders. It supports the following functional areas:

- CSF Form Generation; and
- Data Entry.

The application will reside on the users computer and will contain all necessary logic and data fields for the CSF form. The form will be saved as an XML file and can also be saved as a PDF if the user chooses. The XML file will later be parsed for import into PRISM. The application will collect and store specific information needed to facilitate the e-CSF process. This information will primarily consist of chemical formulation information for the CSF. The CSF will be entered by the user, and will focus on additional formula information, inert chemical, weight, density, viscosity, etc. The user will have the ability, to update and/or edit CSF information.

One of the primary objectives of the e-CSF application is to be able to provide the first step to a paperless process. The application incorporates design considerations that allow for future interfaces to the e-PRISM interface. The future of e-CSF is the integration into the e-Submission portal. By leveraging open standards like XML, e-CSF can provide the means for transferring and importing data, in a more efficient manner.

Top of page

New XML format for e-submissions

The e-Submission initiative is helping EPA move toward a more paperless environment. The information exchange from industry to EPA is based on a harmonized XML schema used by Canada's PMRA, which has been adapted by EPA. This harmonization assures industry that a documentation package submitted to one participating regulatory agency can likewise be submitted to the other participating agency, thus increasing standardization and decreasing the burden on industry.

Information submitted to EPA in the XML schema format will improve data quality and allow for a more efficient pesticide registration process.

Instructions for e-submissions using the XML schema

The e-Submission XML Guidance Document provides instructions to create and submit files containing digitized versions of their submission documents (i.e., studies, labels, and forms) using Pest Management Regulatory Agency (PMRA) e-Index Builder or by using a XML file creation application (i.e., Notepad,, Microsoft Word, etc.)

- e-Submission XML Guidance Document for Pesticide Registration Packages (PDF) (51 pp, 451k, About PDF)
- Sample XML schema (36k, ascii txt - RTF)

Top of page

Studies

Before sending an electronic submission that will include one or more studies, contact Teresa Downs (downs.teresa@epa.gov), 703-305-5363 to request a set of 'root' MRIDs (Master Record Identifiers). A MRID is unique eight-digit number assigned to each study submitted to EPA. The first six digits are referred to as the 'root' MRID. In the case of non-electronic data submissions, MRIDs are assigned by EPA upon receipt. In the case of electronic data submissions, the MRIDs are assigned to each study by the registrant using the root MRID provided by EPA. The first MRID always ends in '00' and must be assigned to the transmittal document that describes the purpose of the submission and lists all of the included studies by title and MRID. MRIDs ending in '01' through '99' are available for assignment to supporting studies. If a submission includes more than 99 studies EPA will provide two or more root MRIDs as needed. List studies on the transmittal document in MRID order without any breaks in sequence. Do not use MRIDs from the same root MRID for different submissions. Print the MRID ending in '00" on the upper right corner of page one of the transmittal document. Print each study's MRID on the upper right corner of the title page (page one).

EPA has established Adobe Portable Document Format (PDF) as the

standard file format for the electronic submission of required studies, using compact disks as the transport medium. Adobe Acrobat allows OPP reviewers to easily navigate within and among studies and related supplemental files, perform full text searches, annotate text and tables, export data to other software for analysis, extract and edit text and tables, and view and print text and tables in a variety of ways.

- Specifications for Creating a PDF Version of Study Reports (PDF) (10 pp, 291k, about PDF)

  This document provides detailed instructions on how to convert study reports to PDF for electronic submission. It includes information about file formats, naming conventions, fonts, conversion options, and guidance on bookmarking and hypertext linking. The document is modeled after similar guidance developed by the Food and Drug Administration (FDA).

- Software Settings for the Creation of PDF Files for Electronic Study Submission (PDF) (16 pp, 352k, about PDF)

  This document provides details regarding the appropriate settings of various software products used in the creation of PDF files. Included are instructions for Adobe® Acrobat® Distiller, Microsoft® Word, and Corel® Wordperfect®.

- Adobe Acrobat Distiller Job Options for electronic studies (3k)

  This file supplies a ready-to-use Job Options file for use with Adobe® Acrobat® Distiller. Save this file in the *"Acrobat 5.0\Distillr \Settings*" folder under the Adobe folder on your local hard drive.

Top of page

Guidance on Study Formatting

- Suggested Format for Acute Toxicity Studies (PDF) (5 pp, 155k, about PDF)

This document suggests the format for study reports for acute toxicity studies. One format is appropriate for oral, dermal, primary eye irritation, and skin irritation studies. Slightly different formats are appropriate for acute toxicity - inhalation and skin sensitization study reports. It also indicates where PDF Bookmarks and links should be used.

- Suggested Format for Reporting Sub-Chronic and Chronic Toxicity Studies

  This document suggests the format for sub-chronic and chronic study reports. It also indicates where PDF Bookmarks and links should be used.

- Study Report Templates

  These report templates suggest the format for study reports submitted to the EPA. These report profiles supercede the study report templates previously listed on this site. The previously listed templates were modelled off of the same Agency Data Evaluation Record (DER) templates as the new study profile templates, therefore, much of the information is the same except for minor formatting changes.

  PDF document requirements for bookmarks, links, and special concerns:

  - **Bookmarks should be included for each level of heading** as seen in the outline structure of the template. Bookmarks to individual tables are not needed.
  - **Links should be included only when the submitted document is a full study report**, and most useful when referencing specific data, such as a specific test animal identified as a concern in the summary.
  - **Before creating the final PDF file** -- when creating tables please use the inherent table features of the source software. Do not use tabs or other methods to create the look of a table's columns and rows. Consider including larger tables as attachments in Lotus 123, Word, or comma separated ASCII files.

Top of page

Guidance on Supplemental Files/Review Aids

- **Environmental Fate and Effects Studies**
  - Avian Reproduction Studies
  - Terrestrial and Aquatic Plant Studies
  - Aquatic Toxicity Studies (PDF) (7 pp, 78k, about PDF)
    - Oyster Shell Deposition
    - Daphnia Life Cycle
    - Fish - Early Life Stage
    - Fish - Full Life Cycle
  - Surface Water and Ground Water Field Studies and Monitoring Data

- **Supplemental Data Files Supporting Chronic Toxicology Studies**
  - Chronic/Subchronic Toxicity Studies (PDF) (20 pp, 347k, about PDF)
  - Developmental Neurotoxicity Studies (PDF) (34 pp, 567k, about PDF)
  - Prenatal Developmental Toxicity Studies (PDF) (18 pp, 329k, about PDF)
  - Multi-generation Reproduction Studies (PDF) (32 pp, 470k, about PDF)

Top of page

Current Guidance - Labels

The use of electronic labels will help to increase EPA review efficiency and improve the quality of labeling. Electronic labels in text .PDF format will allow EPA to:

- compare new versus old versions of labels thus quickly identifying changes and
- easily mark-up labels with any required label revisions.

The submission of electronic labels by registrants is voluntary but strongly encouraged.

For basic guidance on the paperwork and procedure used to register a pesticide product see "Registering Pesticides" on EPA's website.

For an **initial application** (new product or amendment of an existing product), registrants should submit 1) all the required paperwork, 2) a text .PDF label on a CD-ROM, and 3) a signed certification with respect to label integrity (see below). The electronic label must be a text .pdf (not image) and must be named using the filename syntax in the guidance below.

For a **resubmission** of a revised label in response to EPA comments, the text .PDF may be emailed directly to the EPA staffer or Product Manager as directed in the label review. Alternately, the resubmission may be prepared as a paper label plus a text .pdf e-label on a CD-ROM plus the certification form and sent via courier to EPA. However, do not send revised labels by both email and paper mail.

The documents below provide more detailed guidance regarding submission of electronic labels:

- Full Specifications for Text .PDF Electronic Labels (PDF) (12 pp, 151k, about PDF)

  Detailed specifications on how to compose, create, and submit text .PDF electronic labels to EPA.

- Condensed (Critical) Specifications for Text .PDF Electronic Labels

  Short list of critical specifications for creating text .PDF electronic labels (extracted from full specifications).

- Frequent Questions - Electronic Labels

  Answers to common registrant questions concerning electronic labels.

- Certification with Respect to Label Integrity (fill and print .RTF) (5k, RTF)

  This certification must be included with the submission of an electronic label on a CD-ROM accompanying a paper application (new product or amendment). The certification is not needed when resubmissions (corrected labels) are sent via email. The certification states that the paper and electronic versions of the

label are identical. Download, fill out, print, and sign the form.

- Adobe Acrobat Distiller Job Options - for electronic labels (3k)

  This file presets the EPA recommended Adobe Acrobat settings to create text .PDF labels using Adobe® Acrobat® Distiller®. Save this file under " C:\Program Files\Adobe\Acrobat 7.0\Distillr \Settings" (or similar). The file works with Adobe® Acrobat® Distiller® 5.0 or above.

Top of page

Contacts For More Information

- **Studies** - Teresa Downs (downs.teresa@epa.gov), 703-305-5363
- **Labels** - Tom Harris (harris.thomas@epa.gov), 703-308-9423

Top of page