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Pesticide Registration

Assembly of Electronic Packages and Discs

There are three methods by which companies can assemble the e-Submission Packages:

- Use the new Pesticide Submission Portal (PSP) within the Central Data Exchange (CDX) Network described in "A"
- Use the e-Dossier Builder method is based on the use of a "builder" application described in "B" below.
- Use the standard e-Submission XML format as described in "C" below.

Email Milestone Tracking Notification: All methods have been further modified to include an additional field to provide email address. This field is necessary to support PRIA and other electronically accepted packages now Milestone Tracking email message functionality.

A. Pesticide Submission Portal (PSP)

Pesticide Submission Portal (PSP) application to allow registrants to electronically submit pesticide application packages to EPA. PSP is accessed through EPA's Central Data Exchange (CDX) Network and requires user registration. For registrants currently submitting CDs or DVDs using the e-Dossier downloadable tool or their own builder tools using EPA's XML guidance, they may use the portal and forego the courier costs to send to EPA. PSP allows registrants to create and submit packages electronically. Applications for pesticide registration can be submitted electronically, including forms, studies, and draft product labeling. Applicants need not submit multiple electronic copies of any pieces of their applications. In PR Notice 2011-3, EPA made clear that the requirement to submit multiple copies of data is applicable only to paper submissions. Similarly, EPA interprets the requirement to submit five copies of draft labeling in 40 CFR 152.50(e) to apply only to applications made on paper. As electronic submissions are easily reproducible, EPA will accept electronic applications containing one copy of all the required elements.

We encourage electronic submissions for the following regulatory actions:

- Product Registration – Section 3
 - New pesticide active ingredients
 - New pesticide products containing already-registered pesticide active ingredients
 - Incident reporting (FIFRA 6(a)(2) submissions)
 - Amendments to registered pesticide products.
- Experimental Use Permit – Section 5

- Petitions for food tolerance
- Distributor products
- Notifications
- Inert Ingredient Request
- Pre-Application

A package created within PSP consists of all documents and metadata required by EPA to properly process the package. Additionally, users may also upload and submit packages created in the e-Submission XML format, method C or the EPA e-Dossier Builder format, method D.

- CDX Registration User Guide – Version 1.0
- OPP Pesticide Submission Portal (PSP) User Guide – Version 1.0

B. e-Dossier Builder method

The e-Dossier Builder method uses a “builder” software application to assist the user in the creation of the electronic package. The resulting .zip file produced by the e-Dossier Builder should be copied onto a disc (CD/DVD) to submit to us. Unlike the XML method, the e-Dossier Builder method does not require manual editing of XML and, instead, allows the user to fill in a series of fields and attach the required files. The Builder does the rest.

- e-Dossier Builder 2.1 (1 pg, 1 MB) (executable file)
- Guidance Document - Version 2.2

Note: The .zip and XML files produced by the e-Dossier Builder are unique and not related to the XML guidance provided below. Please do not attempt to make any edits to the e-Dossier Builder output based on the XML guidance from method C. Doing so may result in an electronic package that we cannot use.

C. XML format for e-submissions

The XML method of information exchange from industry to EPA is based on a harmonized XML schema used by Canada's Pest Management Regulatory Agency (PMRA), which we have adapted. This harmonization assures industry that a documentation package submitted to one participating regulatory agency can also be submitted to the other participating agency, increasing standardization and decreasing the burden on industry.

Instructions for e-submissions using the XML schema method

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 e-Index Builder or by using a XML file creation application (i.e., Notepad, Microsoft Word, etc.)

For study files, use the file naming convention of study guideline number, MRID number. For example 850.120.12345600

- e-Submission XML Guidance Document for Pesticide Registration Packages - Version 4.6
- Update to e-Submission Guidance including instructions for Dossier-formatted submissions
- Sample XML schema (36k, ascii txt - RTF)

E-submission Tools

- Pesticide Submission Portal within Central Data Exchange (CDX) Network
- e-CSF application
- Guidance on study formatting and supplemental information
- Guidance on labels
- EDSP information - “How to submit info in response to Orders”, MRIDs, guidance and other resources
- Contacts for more information
- Pesticide Submissions Portal (PSP) Frequently Asked Questions

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