

Process Improvements in the Pesticide Program

Improvements in Information Management and Labeling

Internet Applications

The EPA has created new Internet applications to promote transparency and public participation to allow users to easily find information. The [Pesticide Product Labeling System \(PPLS\)](#), [Chemical Search](#) and [Inert Finder](#) use modern Web technology to dynamically display pesticide chemical data and links to other important resources.

Pesticide Product Labeling System

The Pesticide Product Label System (PPLS) provides a collection of pesticide product labels (Adobe PDF format) that have been approved by the EPA under Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Newly redesigned, PPLS allows a user to search for labels by product name, company name, or EPA Registration Number. PPLS contains more than 170,000 current and historical labels, all of which are available in text-searchable PDFs. Not included in the previous version, product transfer information helps a user understand the story of a particular pesticide product. The redesigned Pesticide Product Labeling System can be accessed on the Internet at <http://www.epa.gov/pesticides/PPLS>.

Chemical Search

Chemical Search allows a user to easily find the pesticide chemical or active ingredient that they are interested in by using an array of simple to advanced search options. Chemical Search provides a single point of reference for easy access to information previously published in a variety of locations, including various EPA Web pages and Regulations.gov.

Chemical search contains the following:

- More than 20,000 regulatory documents (including fact sheets, regulatory decision documents and science reviews)
- Links to over 800 dockets in Regulations.gov
- Links to pesticide tolerance (maximum residue level) information found in the e-CFR
- A variety of Web services providing easy access to other scientific and regulatory information on particular chemicals from other EPA programs and federal government sources

Chemical Search provides the user with multiple search options. A user may enter a chemical name, a corresponding Chemical Abstracts Service registry number (CAS Number), or an EPA Pesticide Chemical code. A user may also access several chemical lists for easy access to commonly requested information. Chemical Search can be accessed on the Internet at <http://www.epa.gov/pesticides/chemicalsearch>.

InertFinder

InertFinder is an online database for searching substances used as inert ingredients in pesticide products. InertFinder is searchable by chemical name or CAS Registration Number, and provides information on the approval status of substances used as inert ingredients for use in food, nonfood and fragrance-use pesticide products. Also featured in InertFinder are advanced search and sort capabilities, giving users further control of search results. Links to the e-CFR for inert ingredients that are approved for food use are displayed so users may directly visit the e-CFR for limit and use information. Users are able to further manipulate data by exporting search results into various standardized formats. The InertFinder can be accessed on the Internet at <http://www.epa.gov/pesticides/inertfinder>.

Electronic Submission and Document Retention

The EPA is using information technology to improve the efficiency of the pesticide registration program and to reduce the paperwork burden on both the agency and the public.

In July 2008, the EPA's Office of Pesticide Programs announced it would receive pesticide submission packages in electronic form or e-Registration submissions following a pilot project conducted in FY 2007. The Agency published a *Federal Register* Notice and provided [guidance](#) on the Web. The types of applications currently being accepted electronically are Section 3 New Applications, Section 3 Amendments, Experimental Use Permits, Petitions for Tolerances, and applications for Supplemental Distributor Products. The agency also established an e-Submission Help Desk in May 2008 to assist applicants with their questions about formatting their e-submission and to provide step-by-step direction to ensure the validity of the submission.

As described in the FY 2010 PRIA Annual Report, the e-Submission Module of the Agency's tracking system, Pesticide Registration Information System (PRISM) supports the processing of the documentation required for pesticide applications. Traditionally, this paperwork has been submitted in hardcopy form. The E-Submission initiative helps EPA move toward a more paperless environment. The information exchange from industry to EPA is based on a harmonized XML schema adapted from Canada's Pest Management Regulatory Agency. This harmonization ensures that a submission package submitted to one participating regulatory agency can likewise be submitted to any of the other participating agencies, thus increasing standardization and decreasing the burden on pesticide applicants. Once the package is received by EPA, its contents are parsed and validated, thereby promoting data quality. The data submitted are then used to pre-populate data entry screens in an effort to save processing time and decrease the burden on EPA. Finally, the e-Submission module is fully integrated with PRISM's core data repository for registration information and its document management repository. When the incoming package has been processed, the data and documents are seamlessly blended into other PRISM components (Document Management Workflow) for processing within the pesticide program. PRISM was enhanced to accept electronic registration (e-Registration) documents to make these documents available on-line at any time to the multiple users simultaneously processing registration actions. E-Submission/e-Registration will improve processing times, data quality and completeness; reduce data entry and the number of data entry iterations; and improve document management. In addition, the EPA is actively working with OECD to develop a common, globally accepted standard for the transport of electronic data to various international regulatory authorities. By conforming to a single standard, registrants will

have to produce only one submission package for submission to multiple countries, reducing time and resources required for multinational submissions.

For FY 2011, OPP received 513 e-submission application packages. A total of 5369 documents (such as forms, correspondence, study reports, and labels) were associated with these 513 packages out of a total of 4483 application packages submitted.

Number of FY 2011 e-Submissions Compared to Paper Submissions

	Number e-Submission Packages	Number of Documents	% of all e-Submissions rejected*	Number Paper Application Packages	% e-Submissions of Total
1st	143	1438	17%	938	15%
2nd	108	721	18%	862	12%
3rd	148	2099	31%	1029	14%
4th	114	1111	18%	1654	7%

*E-submissions were rejected because the XML file submitted could not be accepted into EPA's data systems.

As a result of scanning documents and storing e-Registration documents in Documentum, OPP currently has a Documentum library of over 255,381 documents available electronically, an increase of 35,059 documents from FY 2010. Documents stored in the library consist of studies, forms, letters, and labels.

Electronic Label Review

Acknowledging the agency's efforts in this area, Congress required the EPA [under PRIA 2, FIFRA Section 33(k)(2)], to report the number of label amendments reviewed using electronic means and to make recommendations for electronic submission and review of labels, including process improvements to further enhance the procedures used in electronic label review. The agency's specifications and procedures for submitting electronic submissions (including electronic labels) can be found at:

<http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm>.

FY 2011 represents the second full year that the agency's tracking systems have been recording statistics regarding submission and review of electronic labels. A summary of this information is presented below:

FY 2011 Labels Submitted*			
Type of Product	# of labels submitted	# of e-labels	% electronic labels
Antimicrobial	1521	99	7
Biopesticide	403	42	10
Conventional	4,814	1,366	28
Total	6,738	1,507	22

FY 2011 Labels Reviewed*		
Type of Product	# of labels in e-format	% of e-labels reviewed electronically
Antimicrobial	95	33
Biopesticide	26	4
Conventional	644	25
Total	765	25

*Note: The number of labels *submitted* versus the number of e-labels *reviewed* should not be compared to each other since they may count different labels. Labels are usually not reviewed until all studies submitted with an action have been reviewed. Therefore, labels submitted in FY 2011 may not be reviewed until a later year. Conversely, label reviews completed in FY 2011 may have been submitted in earlier year.

Conclusions:

- 1) Of approximately 6,740 labels submitted to the EPA in FY 2011, 22% included an electronic label. This is a slight increase from the 15% submitted in FY 2010.
- 2) Of the label actions completed by the EPA in FY 2011 that included an electronic label, 25% were reviewed electronically. This is a slight decrease from the 33% reviewed electronically in FY 2010. This may be due to problems with the text comparison software. Text comparisons using the latest deployed version of Adobe Acrobat are more difficult to interpret than that using the previous version. The agency is investigating alternative software solutions.

Labeling Consistency

The agency formed a cross-program Labeling Consistency Committee in FY 2005 to address broad labeling issues and to oversee revisions to the [Label Review Manual \(LRM\)](#). The LRM provides guidance to EPA staff on reviewing labels. A Label Review Manual Team was formed to revise and update the LRM, completed in 2009. In 2010, EPA began to solicit comments on the LRM from State pesticide regulatory agencies and the general public. State agencies collect comments through the working committees of the State FIFRA Issues Research and Evaluation Group (SFIREG) and send them directly to the committee. Public comments, primarily from pesticide registrants, are received through a [Web-based discussion forum](#). Since the agency has requested comments on one or two chapters of the LRM at a time, the process of evaluating comments and making edits on all 18 chapters will likely extend through 2012. The purpose of asking for comments is to seek clarification of language, improved examples and needed updates to make the LRM more useful to both EPA and other stakeholders.

The Committee developed a [Web site](#) to communicate its activities and to address the public's general labeling policy questions forwarded through the Web site's e-mail address (OPP_labeling_consistency@epa.gov), a major activity of the committee. The committee receives about 75 to 100 questions per year, with close to 500 questions since the site began. Answers to questions of general interest are posted, but all questions receive a direct response.

The committee from time to time publishes issue papers on its Web site. For example an issue paper on [chemigation](#) (PDF, 6pp, 63.8kb) was made available for comment in December 2008, and in October of 2011 a paper on the use of the term “non-crop areas” on labels was issued for a 60 day comment period. The site is also used to publish compact summations of selected policies that might otherwise be difficult for interested parties to locate, for example, the [agency's policy on warranty and disclaimer statements](#).

To further promote consistency in labeling and conformity with guidance, the EPA has undertaken a number of label training initiatives. In June 2010, the EPA made available its [Pesticide Label Review Training Web application](#) to the public on its pesticides Web site. Through a series of modules, users can learn the basics of pesticide labeling, and links are provided to resources for more detailed information, particularly in the relevant sections in the Label Review Manual. In September 2011, the Pesticide Program hosted a workshop on label quality issues and the principles of good labeling that was attended by 60 representatives of agricultural pesticide registrant companies, as well as EPA staff and state regulators. A similar workshop focusing on consumer products is being planned for April 5-6, 2012.