

US EPA ARCHIVE DOCUMENT

Estimating the Data Generation Costs for Registration of a New Conventional Pesticide Active Ingredient

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OPP receives requests and inquiries from both internal (Agency) and external stakeholders regarding the estimated costs associated with registering new [conventional] pesticide active ingredients. In an effort to help the Program respond to these requests, the following estimates were developed, along with an explanation as to how these estimates were developed.

The specific data (studies) and information EPA requires in order to make regulatory decisions regarding the licensing of pesticide products as required under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) are specified in the U.S. Code of Federal Regulations, 40 CFR Part 158. The costs associated with conducting these studies were developed by surveying representative independent laboratories with experience conducting the tests. Consequently, actual costs for a pesticide manufacturer/registrant for a given study may vary.

Applications to register new (conventional pesticide) active ingredients vary on a case-by-case basis depending upon the intended use sites and use patterns – thus, this information is not representative of all such registrations and includes some limitations and assumptions. There are six broad use categories used in the data requirements tables (in 40 CFR Part 158) to include: terrestrial outdoor uses, aquatic outdoor uses, greenhouse uses, forestry uses, residential outdoor uses, and indoor uses of all types. Those six broad use categories are further subdivided into 12 general use patterns which are the basis for data requirements established by a use pattern. The 12 general use pattern groups used in the data requirements tables are: terrestrial food crop use; terrestrial feed crop use; terrestrial nonfood crop use; aquatic food crop use; aquatic nonfood use; greenhouse food crop use; greenhouse nonfood crop use; forestry use; residential outdoor use; residential indoor use; indoor food use; and, indoor nonfood use. Descriptors are used in the data tables as a general indication of the applicability of a data requirement, such as: R (required), CR (conditionally required), and NR (not required).

For purposes of this effort, it was assumed that all studies listed in 40 CFR Part 158 as R (required) and those listed as NR (not required) would be needed 100 percent and 0 percent of the time, respectively. For those studies listed as CR (conditionally required), it was assumed that the study would be required 50 percent of the time. Average test costs were determined by multiplying test costs by test frequency; and, the costs were summed for each use pattern for each data category. Since total costs provided are averages for various use patterns, the actual cost for a specific registration (dependent upon use patterns, etc.) may differ. Please see Table 1 for a summary of the total average cost for the 12 use patterns. Terrestrial food and feed are combined.

Table 1. Total Average Cost of Conventional Pesticide Testing By Use Pattern

Terrestrial	Food or Feed	\$9,919,000
	Nonfood	\$7,983,000
Aquatic	Food	\$8,978,000
	Nonfood	\$6,890,000
Greenhouse	Food	\$6,422,000
	Nonfood	\$4,679,000
Forestry		\$7,441,000
Residential	Outdoor	\$7,095,000
	Indoor	\$4,287,000
Indoor	Food	\$6,016,000
	Nonfood	\$4,339,000

Source: EPA data, 40CFR,part158