

UNDERSTANDING THE BIOPESTICIDE REGISTRATION PROCESS AT EPA

Prepared by

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The purpose of this information is to give an outline of the registration process and some guidance concerning some of the actions necessary to successfully register a biopesticide at EPA. It is geared mainly toward new registrants, but the process is very detailed and beyond the scope of this report. Without properly formatted information, your submission literally will not get through the front door. There are many regulations and forms concerning the registration process which are listed on the EPA website:

<http://www.epa.gov/pesticides/biopesticides>.
<http://www.epa.gov/pesticides/registrationkit/>
<http://www.epa.gov/opprd001/forms/> .

The active components of the product must be chemically identified, or in the case of microbial products, the organism must be clearly identified and the active component must be shown to be responsible for the pesticide activity. Mixtures of products of unknown composition or unknown organisms can not be registered. Even if characterized, mixtures of several active components or several organisms can be difficult and costly to register. Most successful products involve a single active component. The main types of data include information on the manufacturing and characterization of the product, toxicology/safety data, environmental safety data, and product performance. In order to have the best chance of registering your new biopesticide, IR-4 recommends that registrants:

1. Have a well characterized microbial or biochemical product that has good efficacy against the targeted pests and supports label claims.
2. Strongly consider the assistance of a consultant. IR-4 can also act as a consultant for minor use products containing a new active ingredient for which there is interest by public sector researchers (University, USDA, Extension) in having the product available to the agricultural community. The first step in obtaining IR-4 assistance is to contact the Biopesticide Coordinator and have a public sector scientist fill out a Biopesticide Clearance Request Form. IR-4 generally does not work with previously registered active ingredients. A list of private consultants is also available at the EPA website <http://www.epa.gov/pesticides/biopesticides>.

If the product is microbial, and your consultant believes you have adequate preliminary information, arrange for a pre-registration meeting. If you believe the product fits within the definition of a biochemical (see PR Notice 97-3), it must first be formally classified by EPA prior to initiating a pre-registration meeting. The two most important factors in biochemical classification are that the product must be of natural origin and that it must have a non-toxic mode of action against the target pest. Do not assume that a natural product is a biopesticide. A more complete description of the requirements for biochemical classification and a list of previously approved products are on the EPA website. In general, the type of information required includes product identification, properties, how the product is to be used, and human

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7. Within about one month, you will receive two screening notices from document processing desk. The first states the application is received and assigns an identifying EPA File Symbol. The second addresses whether or not the application is in compliance with PR Notice 96-5 formatting requirements. This letter includes a copy of your cover letter and transmittal document, and states that your submission has either met 86-5 formatting and Master Record Identification Numbers (MRID) have been assigned to the submitted studies, or that your submission is not in compliance and lists the specific deficiencies. If you do not receive this letter, contact Mr James Hollins (703) 305-5761 at the document processing desk. You can also call BPPD since they send out the deficiency letters. It is important to retain both letters because you will need to refer to the EPA File Symbol and MRID numbers if amendments to the volumes are needed. MRID numbers are the proper way to reference previously submitted documents, rather than resubmitting the actual information.
8. Your package will be forwarded from the document processing desk to the Biopesticide Division and assigned to a Regulatory Action Leader (RAL). About two weeks after you receive the letters from document processing , contact the Biopesticide Division to find out the name and telephone number of the of the RAL. Contact the RAL on a monthly basis to find out the status of your review and if any additional information is needed. Alternatively, your consultant may also be doing this for you. A good consultant knows the proper balance between keeping track of your submission versus becoming an irritation to the RAL. There may be a few periods of intense exchange on a particular issue and your consultant should inform you what the issue is. Excessive contacts can be counterproductive and costly. It is suggested that the timeline in the Path of Submission Review be used as a means by which to gauge the progress of your submission.

The Path and Review Process of a Biopesticide Submission at EPA/BPPD

What affects the speed of the process?

Quality of the submission including clarity, completeness and compliance. Sound scientific rationale is especially important for waivers.

Complexity of the review and subsequently the number of reviewers and re-views needed.

Need for unforeseen revisions, modifications or invalid studies due to not following study protocols.

Timeliness and completeness of registrant responses to requests for additional information.

The registrants or their representative's ability to remain in close contact with the RAL without being intrusive.

Lengthy disagreements with EPA over data requirements, which delay initiation of a required study or unfruitful attempts at data bridging.

Receipt of independent and well supported comments in the public docket require a response, thereby increasing the required time.

The type of submission (new active ingredient -ai, me too, re-registration, new product with old ai, etc) .

Each submission is unique. The shorter range in the registration timelines in the following table assumes no corrections, and an easily reviewable product of relatively high importance to the agricultural community and the public.

For further information contact:

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Path of Submission Review for a New Active Ingredient at BPPD

STEPS

TIMELINE(Months)

	Elapsed time
<p>1. <u>Screening-Front End Processing</u></p> <ul style="list-style-type: none"> a) Submission is pin punched and logged in at document processing desk. File Symbol assigned. b) Checked for 86-5 compliance and MRID numbers assigned and letter sent to registrant. c) Submission scanned onto a CD. d) Forwarded to BPPD. e) Logged into BPPD. f) Forwarded to Microbial or Biochemical Branch Chief. g) Regulatory Action Leader (RAL) assigned. 	1-1.5
<p>2. <u>Submission Review</u></p> <ul style="list-style-type: none"> a) RAL and or Science reviewer does pre-screen. b) Data and waivers go to primary science review and data evaluation record is written. c) RAL prepares and sends for publication FR Notice of Receipt for a new active ingredient and FR Notice of Filing for a tolerance or tolerance exemption petition. d) Secondary science review and risk assessment performed and forwarded to RAL. e) Possible repeat of steps B and C resulting in letter of deficiency or acceptance. 	3 7-9 7-9 8-9 8-10
<p>3. <u>Regulatory Coordination, Management Review and Regulatory Decision</u></p> <ul style="list-style-type: none"> a) RAL compiles materials to create public docket. b) Federal Register (FR) Final Rule Notice for tolerance or tolerance exemption pre-signature approval. c) RAL drafts Biopesticide Regulatory Action Document (BRAD), Plain English Fact Sheet (PEF) and FR Final Rule Notice. d) BRAD, PEF, and FR Final Rule Notice reviewed by science reviewers, PEF coordinator and Branch Chief. e) Pending editing and agreement on items on step 3d, documents are forwarded to the Office of General Counsel (OGC). f) OGC comments reviewed and incorporated and possible repeat of steps d and e. g) Typeset FR Final Rule notice checked. h) Internal EPA Decision Document. i) Published in Federal Register as a Final Rule. 	9-11 9-12 11-16 12-17 13-18 13-19 14-20 14-20
TOTAL ELAPSED TIME	15-21

