



# The Role of BEAD In Pesticide Regulation

## Introduction

The United States Environmental Protection Agency (EPA) has been charged by Congress through various Acts with protecting human health and improving the quality of the environment. As a regulatory agency in the executive branch, EPA creates and implements Rules and Regulations carrying out these Acts.

The Office of Pesticide Programs (OPP) of the EPA is responsible for regulating the use of pesticides to ensure that they will not pose unreasonable adverse risk to human health or the environment. All pesticides which are sold and distributed in the U.S. must be registered by EPA. Each pesticide product must bear a label which identifies the product, describes how the product should be used, and provides appropriate precautionary and safety information. OPP's responsibilities to ensure a safe food supply, as well as a healthy environment, overlap with those of the U.S. Department of Agriculture, the Department of the Interior, and the Food and Drug Administration.

Pesticide regulation is administered through two primary authorities: the *Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA) and the *Federal Food, Drug and Cosmetic Act* (FFDCA). Pesticide regulation under FIFRA requires the Agency to balance *risks* to human health and the environment against the *benefits* to the economic and social aspects of society. Real or potential risks to man and the environment are the result of the interaction of two factors: the *toxicity* of the chemical or biological agent and the degree to which people and the environment are *exposed*. Benefits describe how well a pesticide prevents negative impacts to public health, industry, or agriculture. Pesticides can benefit society by controlling pests that cause or carry human or animal diseases (e.g., bacteria in cooling water systems or toilet bowls); cause environmental damage (e.g., gypsy moths in forests); foul industrial materials (e.g., bacteria and fungi in paint or fuels); or reduce food production (eg., weeds, diseases, insects).

The Biological and Economic Analysis Division (BEAD) is comprised of agricultural scientists, chemists, economists, information management specialists, microbiologists, policy analysts, statisticians, and toxicologists. BEAD provides data and analyses to support pesticide product registration decisions and supports the development of regulations, policies, guidance, and initiatives affecting pesticide regulation.



## Support For Pesticide Registration Decisions

### Compile Pesticide Use Information

One of the basic functions of BEAD is to provide scientists throughout OPP with data concerning what is being treated (crops, equipment, premises), why it is being treated (what pests are being controlled), how the pesticide is applied (application equipment, application timing, safety precautions, application limitations), and the quantity of pesticide used (application rates, area or number of units treated, number of applications per season or year, total pesticide applied per season or year). This pesticide use information is used by OPP to: 1) determine data requirements for pesticide registration, 2) estimate human and environmental exposure to a pesticide for risk analysis, and 3) conduct benefits and economic analyses for various regulatory actions.



## **Provide Input To Specific Regulatory Actions**

### ***Conditional Registration***

A registrant may request a conditional registration based on preliminary data while a full product registration is still pending. In addition to requirements concerning risk, one of the requirements for some conditional registrations is that the Agency finds that the proposed use of the pesticide is in the public interest. BEAD assists in this effort by analyzing: 1) if there is a need for the pesticide product which is not being met by other currently available pest control methods, and 2) if use of the proposed product would result in significant benefits to the product users and to society.

### ***Emergency Exemptions***

In an emergency situation, FIFRA, Section 18 allows EPA to grant petitioners a limited exemption from the requirement to federally register a pesticide product prior to its use on a specific site. BEAD evaluates the pest situation described by the petition to determine if a specific site meets the definition of an "emergency" as defined by EPA's regulations, and to determine if the requested pesticide would avert the significant economic losses directly attributed to the emergency condition.

### ***Reregistration***

EPA periodically reviews pesticides which are already registered to determine if the data supporting these registrations meet current standards. Amendments to FIFRA in 1988 specify a five-phase process with a nine year deadline for the complete review (reregistration) of products registered prior to 11/1/84. The main role of BEAD in the reregistration process is to define the currently registered use practices for each pesticide. To this end, BEAD is developing an electronic database which captures pesticide use information from product labels. This summary of currently registered uses, application methods, and limitations is used to determine reregistration data requirements and to define exposure to pesticides as part of a risk analysis. BEAD also plays a key role in maintaining vocabulary terms for electronic databases and printed material which describe pesticides and their use in order to facilitate communication, interpretation, and database retrieval.

### ***Special Reviews***

Special Review is a process where the registration of a currently registered pesticide is re-examined in light of data which indicate that there *may* be unacceptable risks associated with the pesticide's use. The goal of the

Special Review process is to reduce the risks posed by a pesticide to an acceptable level while taking into consideration the benefits provided by the use of that pesticide. In conducting the benefits analysis for this process, BEAD identifies: 1) what alternative pest control methods could legally substitute for the pesticide undergoing Special Review, and 2) the economic impact to pesticide users and consumers (not to the pesticide registrants) that would occur if these alternative pest control methods were used instead of the pesticide undergoing Special Review. For example, with a pesticide used to control an agricultural pest, the Agency is required to take into account the impacts on production and prices of agricultural commodities, retail food prices, and other effects on the agricultural economy. Utilizing this benefits analysis, EPA can determine which pesticide risk reduction measures should be taken (such as the imposition of use restrictions, reduction of application rates, or cancellation of all or some uses).

### ***Waivers***

A registrant may request that EPA waive certain data required as part of the registration process due to financial hardship that would adversely affect the registrant's ability to produce the pesticide. A waiver may be granted where the financial hardship outweighs the need for the data. BEAD analyzes a registrant's ability to pay for the development of the necessary data based on the registrant's financial capabilities.

### ***Pesticide Tolerances***

A pesticide tolerance is the legal level of a pesticide that may remain in or on a food or feed crop. Pesticide use information provided by BEAD is used by OPP when setting tolerances. BEAD also maintains the database of tolerances set by OPP. Tolerances are updated monthly and are made publicly available through both the Government Printing Office (GPO) and EPA.

### ***Validate Analytical Laboratory Methods***

BEAD operates pesticide labs located in Beltsville, Maryland and Bay St. Louis (Stennis Space Center), Mississippi. These labs have unique capabilities in the areas of food, product, and/or environmental chemistry.

The Analytical Chemistry Lab (ACL) evaluates analytical pesticide detection methods for foods and fibers to make sure they are suitable for enforcement monitoring. This internationally recognized work is essential to registration and/or reregistration decisions.

Each method that is tested by ACL allows a chemist to isolate, identify, and measure the concentration of a known chemical or material. ACL also evaluates product chemistry methods to make sure they are suitable for determining the concentration of pesticide active ingredients in technical and end use formulations. More recently, this lab has started a preregistration testing program for antimicrobial methods and products.

The Environmental Chemistry Lab (ECL) evaluates soil and water testing methods to determine if they are suitable for generating data for environmental fate, exposure, and ecological effects studies used to support pesticide registration and/or reregistration decisions. ECL has highly specialized and internationally recognized capabilities to identify and measure extremely small amounts of pesticide contaminants (such as dioxins). ECL is currently using that capability to determine the amounts of dioxins in specific pesticide products that are widely used around the home.

The Microbiology Laboratory participates in collaborative efforts with the Association of Analytical Chemists (AOAC) to improve efficacy test methods for antimicrobial products of public health significance (e.g., those used in hospitals, drinking water, swimming pools). The lab also provides support for compliance and enforcement actions by conducting Good Laboratory Practice and laboratory data audits.

BEAD's pesticide labs provide technical support to the State Enforcement Laboratories in order to identify and measure inadvertent pesticide residues for misuse cases. They also supply the states with reference standards for calibrating their instruments and for determining the known quantity of the pesticide. Finally, the labs provide technical assistance to the EPA and State enforcement labs by giving them methods from EPA files, helping them solve problems with specific methods, and assisting in conducting laboratory audits.

## **Development Of Regulations, Policies, Guidance, And Initiatives**

OPP develops regulations, policies, guidelines, and guidance to ensure implementation and enforcement of statutory requirements regarding pesticides. Examples include regulations for pesticide storage and disposal, guidance for developing state management plans for

groundwater protection, and policies regarding registration of reduced risk ("safer") pesticides. OPP also provides recommendations, data and analyses, and testimony support for new or amended legislation affecting FIFRA as well as other legislation affecting pesticides (such as FFDCA and the Clean Water Act). Finally, OPP undertakes a number of special projects such as the harmonization of data requirements among international pesticide regulations or the reduced pesticide use/risk initiative.

BEAD provides a broad variety of support to OPP ranging from basic pesticide use data previously described to typical cultural practices, individual industry profiles, and detailed impact analyses of proposed regulations and policies. Impact analyses vary in scope and provide vital information for decision makers. The scope of many of these analyses is mandated by Executive Order or statute. The primary mandates are outlined below.

### **Regulations And Policies Executive Order 12866**

E.O. 12866 establishes procedures to be followed by agencies and the Office of Information and Regulatory Affairs (OIRA) in reviewing and promulgating regulations. An objective of the E.O. is to enhance planning and coordination with respect to both new and existing regulations and to ensure that agencies tailor regulations to impose the least burden on society. A key principle of E.O. 12866 charges agencies with assessing both the costs and the benefits of the intended regulation and alternatives in order to choose the best alternative action being considered and to insure that the benefits of the intended action justify the costs.

BEAD has the primary responsibility of conducting the benefit-cost analysis of proposed regulatory actions being developed by OPP. This helps OPP choose the best alternative action and to determine if a regulatory action is deemed to have "significant" economic impacts as defined by the E.O. If so, a more extensive analysis is required. The analysis of costs should include: 1) the direct cost both to the government in administering the regulation and to businesses or others in complying with the regulatory requirements, and 2) any adverse effects on the functioning of the economy. An analysis of the benefits anticipated includes the promotion of the efficient functioning of the economy and private markets, the enhancement of health and safety, and the protection of the natural environment.

## Regulatory Flexibility Act

The Regulatory Flexibility Act mandates that if a regulation will have "a significant economic impact on a substantial number of small entities," the Agency generally must perform a Regulatory Flexibility Analysis (RFA) that explores options for minimizing those impacts. The Act establishes that agencies shall endeavor to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals.

BEAD attempts to provide a profile of affected entities in terms of size and evaluates the impacts imposed on small entities to determine the extent of the impacts and whether or not they are disproportional relative to impacts on larger entities. Reasonably feasible and effective alternatives to the proposed regulation are also analyzed.

## Paperwork Reduction Act

The Paperwork Reduction Act controls the paperwork burden on the public by requiring agencies to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB) prior to any collection of information from the public. Information collection may take the form of written or oral questions as well as data reporting regulations. The Paperwork Reduction Act requires the public to participate in the Federal paperwork review process.

BEAD's role is to provide estimates of the burden both on the information respondent and on the Agency. Burden is estimated based on the hours required to fulfill collection of the information. BEAD disaggregates estimates of total annual reporting and record keeping burden for each collection of information into discrete components applicable to each separate collection of information. The actual costs to be incurred by the respondent and the Agency due to the information collection request are estimated based on the burden hours.

## Guidance And Initiatives

### Registration Data Requirements And Testing Guidelines

40 CFR Part 158 is the regulation which prescribes which data are required to support the registration of a pesticide. This includes data used to determine both the risks and the benefits of a given pesticide. The Pesticide

Assessment Guidelines is a document which explains in greater detail how the tests required by this regulation should be conducted. BEAD is currently revising a portion of both the data requirements and the guidelines to include additional testing on comparative product performance, that will improve the quality of data used by EPA to assess pesticide benefits.

## Pesticide Use/Risk Reduction

The Pesticide Use/Risk Reduction Initiative, announced in June 1993, is a joint effort of the United States Department of Agriculture, the United States Food and Drug Administration and EPA to reduce the use of pesticides that pose unreasonable risks to humans and the environment. Through a coordinated strategy, the federal government is committed to work with all affected interests (including commodity organizations, public interest groups, federal, state and local government agencies, researchers and industry representatives) to develop a plan which reduces the risks posed by pesticides while maintaining cost-effective pest control methods. As part of this initiative, BEAD serves as the lead organization in the Office of Pesticide Programs, coordinating OPP's activities in support of the initiative. This includes coordinating EPA's efforts with those of USDA and FDA, providing pesticide usage data, conducting economic and biological analyses of policy options and meeting with affected interests to identify opportunities for the reduction in pesticide use and risk.

Need additional information write or call:  
U.S. Environmental Protection Agency  
401 M St., SW (7503W)  
Washington, DC 20460  
(703) 308-8200