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## Approval of Pesticides

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### Introduction

Weeds present a risk to the cultivation of agricultural crops, as they have for thousands of years. The modern use of herbicides to help control this risk began shortly after World War II, and since then numerous variations have been introduced. In the United States, herbicides are typically regulated on the federal level. Herbicides fall within the general definition of “pesticides” under the Federal Insecticide, Fungicide, and Rodenticide Act (commonly referred to as “FIFRA”). In fact, the definition of “pesticide” under FIFRA is extremely broad and includes “(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer.”<sup>1</sup> There are approximately 18,000 different pesticide products currently in use, with about 5,800 of those used in food production.<sup>2</sup>

FIFRA is administered by the Environmental Protection Agency, or “EPA”. Pesticide products that are used directly on food products are also regulated under the federal Food, Drug and Cosmetic Act, which sets tolerance levels for pesticide residue on food that is shipped across state lines or internationally.<sup>3</sup> In order to standardize the evaluation of potential pesticides, the EPA created a process to evaluate them before they are initially used in production, as well as before they are used in production for a new purpose.

This fact sheet will focus on the second process, or the evaluation of pesticides that have already been approved for use in some crops, but are trying to obtain approval for the use in additional crops. For example, edamame is a variety of immature soybean. While there are many pesticides that have been approved for commodity soybean production, edamame is considered a different crop for purposes of FIFRA. This means that pesticides must go through the approval process a second time or be reregistered in order to receive the label allowing them to be used on edamame.

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<sup>1</sup> 7 U.S.C.A. § 136 (West).

<sup>2</sup> Beech, James L., U.S. EPA, Office of Pesticide Programs, letter, November 20, 2006.

<sup>3</sup> Esworthy, Robert, Pesticide Registration and Tolerance Fees: An Overview, CRS Report, available at: <http://nationalaglawcenter.org/assets/crs/RL32218.pdf>

Because of this restriction, it is important to understand the basics of FIFRA and the approval processes that are available to get a pesticide approved for a new use.

### **Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)**

FIFRA was originally passed in 1947, but amendments to the statute in the early 1970s transformed the statute into the basic law that we recognize today.<sup>4</sup> Under this statute, the EPA is to regulate the sale and use of pesticides through registration and labeling. This is to ensure that there is a “reasonable certainty” that “no harm will result from pesticide exposure” to either humans or to the environment.<sup>5</sup> A pesticide that has been approved by EPA is limited to the uses that are specifically designated on the label. It is illegal to sell any pesticide (including herbicides) in the United States that are not registered and labeled under FIFRA. Additionally, it is illegal to use any pesticide for a purpose or in a way that is different than is listed on the label of the product.

During registration, the EPA will determine if a pesticide should be classified either as a general use pesticide or a restricted use pesticide. A general use pesticide is considered safe enough to be used by the general public as long as they are following the instructions on the label. An example of a general use pesticide is Roundup®. Restricted use pesticides, on the other hand, are considered more hazardous and may only be applied by certified users. Most states have developed programs approved by the EPA to train and certify applicators for restricted use pesticides. Arkansas, for example, licenses applicators through the Arkansas State Plant Board.

After the initial evaluation process, special review provisions in FIFRA allow the EPA to reevaluate registered pesticides. Registrants are required to submit new evidence if it suggests there may be adverse effects that prior science or technology could not detect. If the EPA determines that there may be unreasonable risks associated with a pesticide, a special review will be opened to repeat the analysis of a pesticide's risks and benefits. Registrants (i.e. makers of the pesticide) may be required to submit additional data and undertake new studies to assist with the review process. After completion of the special review, the EPA may continue the registration, amend the registration and labeling requirements, or cancel the registration altogether depending upon what is discovered in the special review.

Beyond the special review process, re-registration of older pesticides is required to ensure that they continue to meet new scientific criteria. In addition to re-registering all pesticides approved before November 1, 1984, FIFRA has also established periodic reviews with the goal that all pesticide registrations will be examined on a 15-year cycle. The 15-year review may also lead to a registration being amended or cancelled, depending on the results.

In addition to general pesticide registrations, FIFRA authorizes procedures for temporary registrations, minor use registrations, experimental use registrations, special local registrations, and emergency use registrations. Special local use registrations allow states to add permissible

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<sup>4</sup> Schierow, Linda-Jo, Pesticide Law: A Summary of the Statutes, CRS Report, available at: <http://nationalaglawcenter.org/assets/crs/RL31921.pdf>

<sup>5</sup> Schierow, Linda-Jo, Pesticide Law: A Summary of the Statutes, CRS Report, available at: <http://nationalaglawcenter.org/assets/crs/RL31921.pdf>

uses to pesticide labels for special local needs within a state. This paper will address the general registration process and special local needs registrations as it relates to edamame production.

### **General Approval Process under FIFRA**

Section 3 of FIFRA controls the registration process for new active ingredients, products or new uses of a previously registered product for all pesticides that are used within the United States. Pesticides that have not been approved under FIFRA or those that have had their approval revoked because of a later review can be manufactured in the United States. However, they must be shipped to other countries and cannot be sold or used within the United States.

At the beginning of the registration process the pesticide manufacturer must submit a wide variety of information. This information will include the proposed uses for the pesticide, the application rate, the scientific data on toxicity and the effect that the pesticide will have on the environment. The various categories of information required include the product's chemical makeup (i.e. product chemistry); environmental fate; residue chemistry; dietary and non-dietary hazards to humans; and hazards to domestic animals and nontarget organisms.<sup>6</sup> The pesticide applicants must also supply technical information describing the product's active and inert ingredients, manufacturing or formulating processes, information to be included in the label, and physical and chemical characteristics.<sup>7</sup>

Not only does the product testing have to be conducted by the manufacturer of the pesticide, but the results from the tests must be turned over to EPA for further review. The data is then used to determine whether there is an unreasonable risk to the environment or to human health. Pesticides used in food crops, including crops that will be used for animal feed, include another level of scrutiny. For intended uses that include food crops, the EPA also has the authority under the federal Food, Drug, and Cosmetic Act to determine at what levels the pesticide is safe for human consumption (this is called the "tolerance" level). This tolerance must be set before any food crop pesticide can be approved. After the EPA has reviewed the scientific evidence the data will be made available for scientific review.

Once a pesticide is approved for registration, the EPA will specify the approved uses, whether the pesticide is of general use or restricted use, how and where it may be used, and how it must be stored and disposed of. All of this information is required to fulfill the labeling component of FIFRA. Additionally, this data will be provided with the pesticide when it is sold within the United States.

### **24(c) Registration under FIFRA**

FIFRA provides for several alternative approval processes, including the 24(c) "special local needs" exception. This exception allows the state entity in charge of enforcing FIFRA to register an additional use for a pesticide in addition to those already found on the label. A "special local need" is defined as "an existing or imminent pest problem within a state for which the state lead agency, based upon satisfactory supporting information, has determined that an appropriate

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<sup>6</sup> 40 CFR Part 158.

<sup>7</sup> 40 CFR Part 158.

federally registered pesticide product is not sufficiently available.”<sup>8</sup> This alternative registration by the state agency is subject to EPA review and the EPA is responsible for overseeing the general program.

In order for a “special local need” to be recognized the following factors must be met:

1. There is a special local need for the use within the State;
2. The use is covered by necessary tolerances, exemptions or other clearances under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 346 *et seq.*), if the use is a food or feed use;
3. Registration for the same use has not previously been denied, disapproved, suspended or cancelled by the Administrator, or voluntarily cancelled by the registrant subsequent to
4. issuance by the Administrator of a notice of intent to cancel that registration, because of health or environmental concerns about an ingredient contained in the pesticide product, unless such denial, disapproval, suspension or cancellation has been superseded by subsequent action of the Administrator; and
5. The registration is in accord with the purposes of FIFRA.<sup>9</sup>

In addition to these factors, the state agency must follow other guidelines laid out under 24(c). One of the provisions within 24(c) holds that *state* determinations on the registration of a pesticide that has a “special local need” are recognized as a *federal* registration within 90 days unless EPA objects.<sup>10</sup> As a result of this specific window, the EPA must respond to these registrations quickly if they want to further review the new pesticide or pesticide use. This is one reason why this form of registration is much faster than the general registration process.

The application for “special local need” breaks down into two applications. First, interested parties in the state must submit an application to the state agency in charge of administering FIFRA. These interested parties might include producers, co-ops or producer associations. In Arkansas the appropriate agency is the Arkansas State Plant Board (ASPB). The interested parties must completely fill in a form DP-21<sup>11</sup>, submit a complete product label in a PDF format if the product is new to Arkansas or the label has been changed since the product was last registered in Arkansas, and submit a \$250 registration fee. Once this has been successfully submitted to the ASPB, it will work in conjunction with the University of Arkansas Cooperative Extension Service “to determine if a need actually exists, that the applicant meets all federal requirements for registration of a pesticide, that the requested use of the pesticide has not been previously denied, suspended, or cancelled by the EPA, and the product’s efficacy data supports the claims made for it.”<sup>12</sup> If these standards are met, the label will be approved.

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<sup>8</sup> 40 CFR Part 162.151.

<sup>9</sup> 40 CFR Part 162.152.

<sup>10</sup> Guidance on FIFRA 24(c) Registrations, Office of Pesticide Programs, February 9, 1996, retrieved on August 14, 2012, available at: <http://www.epa.gov/opprd001/24c/>.

<sup>11</sup> Available at: <http://plantboard.arkansas.gov/Pesticides/Pages/CommonlyUsedForms.aspx>

<sup>12</sup> Pesticides, Arkansas State Plant Board, retrieved on August 21, 2012, available at: <http://plantboard.arkansas.gov/Pesticides/Pages/PesticideRegistration.aspx>.

After a complete application package is successfully submitted to the state agency, the state agency will begin to prepare the second application, which is then sent to the EPA. To apply for the special local needs regulation the state agency should send in a completed 24(c) notification package.<sup>13</sup> The package should include a Notification of State Registration form, a cover letter that explains why a special local needs registration is necessary under the circumstances, and a copy of the labeling that has been approved by the state.<sup>14</sup> If the pesticide has never been registered before, the state must provide a Confidential Statement of Formula along with the application. Further, if the pesticide is different from any currently approved formulas or if a similar product has been denied, disapproved, canceled, or suspended, the state must also include an Unreasonable Adverse Effects Determination Statement.<sup>15</sup> Once EPA receives the complete package (which should be sent within 10 days of the effective date) the 90 day window of review begins for EPA.<sup>16</sup>

## Conclusion

Pesticide registration, both for new pesticides registered under the general application process and under 24(c), is a very common practice. In fact, EPA processed more than 1,500 registrations and re-registrations during the 2009 fiscal year.<sup>17</sup> While EPA has the authority to enforce the provisions of FIFRA this responsibility is typically delegated to a state agency (in Arkansas, the State Plant Board). When it comes to approving a pesticide for use in a given state, both the EPA and the state agency in charge of pesticide regulation have levels of authority. The EPA can approve pesticides for some states, but not others, and the states can request registrations that will affect pesticide usage in that state, but no other. The special local need registration is one example of the back and forth relationship between the EPA and the state agency to approve pesticides for uses that might not be economically feasible if the manufacturer of the chemical tried to include the new use on the label by having the product reregistered.

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<sup>13</sup> Guidance on FIFRA 24(c) Registrations, Office of Pesticide Programs, February 9, 1996, retrieved on August 14, 2012, available at: <http://www.epa.gov/opprd001/24c/>.

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<sup>15</sup> Guidance on FIFRA 24(c) Registrations, Office of Pesticide Programs, February 9, 1996, retrieved on August 14, 2012, available at: <http://www.epa.gov/opprd001/24c/>.

<sup>16</sup> Guidance on FIFRA 24(c) Registrations, Office of Pesticide Programs, February 9, 1996, retrieved on August 14, 2012, available at: <http://www.epa.gov/opprd001/24c/>.

<sup>17</sup> Esworthy, Robert, Pesticide Registration and Tolerance Fees: An Overview, CRS Report, available at: <http://nationalaglawcenter.org/assets/crs/RL32218.pdf>