Chapter Eleven
RECALLS

Table of Contents

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AUTHORITY

No regulation currently exists under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for the mandatory recall of products. The effectiveness of a recall action, therefore, is contingent on the cooperation of the involved party. Section 19(b) of FIFRA contains authority for mandatory and voluntary recall of products if the registration of a pesticide has been suspended and canceled under section 6. The Regulations to implement section 19 have been proposed, however they have not been codified.

Statutory/Regulatory Requirements

If the registration of a pesticide has been suspended and canceled under section 6 of FIFRA, and if the Administrator finds that recall of the pesticide is necessary to protect health or the environment, the Administrator shall order a recall of the pesticide.

Voluntary Recall [Section 19(b)(2)]

If, after determining that a recall is necessary, the Administrator finds that voluntary recall by the registrant and others in the chain of distribution may be as safe and effective as a mandatory recall, the Administrator shall request the registrant of the pesticide to submit, within 60 days of the request, a plan for the voluntary recall of the pesticide. If such a plan is requested and submitted, the Administrator shall approve the plan and order the registrant to conduct the recall in accordance with the plan unless the Administrator determines, after an informal hearing, that the plan is inadequate to protect health or the environment.

Mandatory Recall [Section 19(b)(3)]

If, after determining that a recall is necessary, the Administrator does not request the submission of a plan under section 19(b)(2), or finds such a plan to be inadequate, the Administrator shall issue a regulation that prescribes a plan for the recall of the pesticide. A regulation issued under this paragraph may apply to any person who is or was a registrant, distributor, or seller of the pesticide, or any successor in interest to such a person.

Recall Procedure [Section 19(b)(2)]

A regulation issued under this section 19(b)(2) of FIFRA may require any person that is subject to the regulation to:

- Arrange to make available one or more storage facilities to receive and store the pesticide to which the recall program applies, and inform the Administrator of the location of each such facility.
- Accept and store at such a facility those existing stocks of such pesticide that are tendered by any other person who obtained the pesticide directly or indirectly from the person that is subject to such regulation.
- On the request of a person making such an offer, provide for proper transportation of the pesticide to a storage facility.
- Take such reasonable steps as the regulation may prescribe to inform persons who may be holders of the pesticide of the terms of the recall regulation and how those persons may tender the pesticide and arrange for transportation of the pesticide to a storage facility.

Contents of Recall Plan [Section 19(b)(5)]

A recall plan established under this subsection shall include:

- The level in the distribution chain to which the recall is to extend, and a schedule for recall.
- The means to be used to verify the effectiveness of the recall.

Special Considerations

The voluntary/mandatory statutory recall provision was added to FIFRA in 1988 and relates only to pesticides suspended or cancelled under section 6. Voluntary or mandatory recalls provide the most expeditious means of removing pesticides from channels of trade and may continue to be used for these purposes. Failure to comply with a voluntary/mandatory recall will result in the issuance of a stop sale, use, or removal order to the consignees of the pesticide in question.

OBJECTIVES

The voluntary recall program is designed to remove any violative product (such as an ineffective antimicrobial pesticide) from the market as expeditiously as possible. Recalls will be initiated in all cases in which the available information indicates that the product is (1) potentially hazardous when used as directed, or (2) ineffective for the purpose(s) claimed. A product will be considered for recall when, among other things, its use as directed would likely result in the following:

- Economic or physical injury to the user or handler of the product.
- Injury to animals or plants where direct application is made.
- Injury resulting from illegal residues.

- Injury to fish or wildlife.
- Other adverse effects on the environment.

A recall may be made after the cancellation by EPA of a product due to lack of existing tolerance, environmental damage caused by a pesticide's labeled uses, or EPA actions taken under the Food Quality Protection Act (FQPA) of 1996 during a pesticide's registration or re-registration, such as cancellation due to harm to workers, or human health risk analysis.

PROCEDURES

Process

The following summarizes the steps in the recall process:

- Identify the violation and develop evidence to support the violation and the hazard presented.
- Prepare a complete description of the material to be recalled and the level in the distribution chain to which the recipient will be requested to remove the product.
- Prepare and issue the recall.
- Monitor the quantities from each location returned.
- Monitor the disposition of all returned material.

Recalls

A recall is conducted to prevent serious problems in the future. It is essential that the recall action be followed up by a visit to the company involved and that cooperating State officials be notified. The remainder of this section details the monitoring procedures to be followed by the inspectors in this type of recall.

Levels of Recalls

The level of recall refers to the point in the distribution chain from which the product is to be recalled. The determination of that point is based on the potential hazard, use pattern, and distribution pattern of the product. The levels of recall can extend to the following:

- Pesticide products under the registrant's control.
- Products in the chain of distribution not under the control of the registrant.
- User-level recalls will be requested only in cases in which there is a very serious hazard to human health or the environment.

Notification to the Company

EPA will send the company headquarters a notification requesting a recall. The letter must include:

- A brief summary of why EPA is requesting a recall.
- A request that the company provide EPA with the amount and location of product that is being recalled (if it is known).
- A request that the company inform EPA of all steps taken in connection with the recall and provide an accounting of the amount that was actually recalled.

Additionally, EPA may provide draft recall letters for the company to send to their primary and secondary distributors and for those distributors to send to their customers. A draft "Recall Effectiveness Checklist" may also be included for customers to fill out and return to their dealers.

The company is encouraged to contact EPA and discuss the notice. In urgent cases, EPA will initially notify the company by telephone and/or facsimile.

Inspection Procedures

After the company has received notification of recall from EPA, an inspector will be assigned to monitor the recall. The inspector may receive the recall notification. In some instances, the inspector may receive a strategy for monitoring the recall. The inspector will always receive a copy of the recall agreement between the registrant(s) and the EPA. In those instances where a strategy has not been provided, the Regional Supervisor and the inspector must develop their own strategy before proceeding. Each recall is unique. The inspector must review and understand the terms of the recall. An initial visit to the firm must be planned to occur about 30 days after the date of the recall letter. The 30-day time period provides adequate time for the company to respond to the notice and decide upon a course of action.

Initial Visit to Company

The inspector must review the progress of the recall with the responsible company official and obtain copies of documents, records, and correspondence used by the company in the recall. If the inspector discovers that the terms of the recall are not being met (e.g., failure to notify distributors as required), the inspector must document the noncompliance. This may be accomplished by photocopying appropriate documents or taking statements from knowledgeable persons.

Follow-Up to Recall

The inspector may conduct interim visits to the company or receive status reports from the company to document how the recall is proceeding.

Follow-up After Completion of Recall

Upon receiving information from the company that all available product has been located and either returned or other appropriate action taken, the Regional EPA Pesticide Supervisor may institute procedures to visit a selected number of consignees to determine the effectiveness of the recall. Each consignee visited must be asked whether the firm received a recall letter, whether any of the product in question was on hand and, if so, if the company complied with the recall letter. Document as appropriate.

Reporting

All inspection reports must be provided to the Regional Supervisor for evaluation and a summary of the inspection reports must be forwarded to EPA Headquarters.

Initial Recall Report

The initial visit report must be a narrative which reflects the company's efforts to implement the recall and will include:

< When appropriate, a list of consignees to whom the recall letters were mailed and the date(s) sent.

< Any documentation obtained during the visit.

Interim Reports

Interim reports must be submitted on: (1) a regular basis as required by the compliance strategy, and (2) whenever any new information becomes available.

Final Recall Reports

The Final Recall Report is the inspector's narrative summarizing actions taken by the company and must be submitted as soon as the recall is completed. This report must include the following information:

< Name of the product being recalled.

< EPA Reg. No. of the product being recalled.

< Batch number(s) of the product being recalled.

< Name, address, and contact for the company that received EPA's letter requesting the recall of the product.

< Action taken by the company, such as:

- Number of consignees the company had and number of consignees they contacted.
- Actual amount of the product the company distributed to consignees.
- Amount of products the consignees still have in their control.
- Number of consignees that returned product.
- Total amount of product returned for all of the consignees.

- What the company did with the product (Did they dispose of it or reuse it?).

< Which consignees the inspector visited; dates of inspections; and documented discrepancies.

Follow-Up Reports at Consignees

These reports of effectiveness must be included as attachments to the final recall report.