

Responding to Stop Sale Orders—Preparation is the Key

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In the last 18 months, the U.S. Environmental Protection Agency (EPA) has stepped up its Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) enforcement activities and, especially, the use of its “Stop Sale, Use, or Removal Orders” (SSUROs) against alleged misbranded pesticides. These are pesticides that EPA believes or has determined are in violation of their respective confidential statements of formula, cancelled products, and products that are distributed in violation of EPA’s supplemental distribution regulations. EPA’s regional offices can issue these orders whenever they have reason to believe that a pesticide or device violates FIFRA, or has been or is intended to be distributed or sold in violation of FIFRA. SSUROs essentially prohibit any further movement, shipment, sale, distribution, or use of the suspect pesticide product. Most important, they typically are effective immediately.

This means even the best companies that sell and distribute pesticides need to have response plans and procedures in place before a SSURO is received. The plan and procedures should address how the company will implement internal steps to respond to the order, take necessary corrective actions, and work with EPA to deal with the attendant enforcement action. In addition, a critical aspect of handling a SSURO is effectively communicating with key internal and external stakeholders, such as employees, distributors, and growers.

Many companies focus solely on dealing with the enforcement aspects of a SSURO, but the internal implementation and communication aspects can be even more important. This article outlines good procedures that, if put in place before a crisis, will help a company to assure necessary compliance, get prompt EPA

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permission for corrective actions (such as retrieving affected products from distribution channels), and manage marketplace risks.

SSURO Basics

FIFRA Section 13 gives EPA the authority to issue SSUROs. It grants the agency the power to stop the sale, distribution, shipment, movement, use, or removal of any pesticide or device that EPA's believes has been or is intended to be distributed or sold in violation of the Act. EPA may issue a SSURO to any company or person that owns, controls, or has custody of an offending product. This could be the registrant or a distributor, or both.

Typically, SSUROs are sent by certified mail, usually to the highest senior executive of the company, such as the President or CEO. They apply to all of the allegedly offending products under the recipient's ownership, control, or custody, wherever the product is located. This includes all sizes and quantities of the product, products marketed under alternate brand names, and any stocks returned to the company from its customers or other end-users. They also typically extend to all of the recipient's divisions, offices, and branches.

SSUROs immediately prohibit, upon receipt, any further movement, sale, shipping, distribution, and use of the offending product unless such activities are approved by EPA in writing. Thus, it is extremely important that once a SSURO is received, the company takes immediate steps to freeze and hold or block any further movement, shipment, or distribution of the subject product. Because it is a separate violation of FIFRA to violate a SSURO, failing to act promptly may subject the company to further enforcement exposure beyond just the alleged violation that triggered the SSURO.

SSUROs remain in effect indefinitely unless and until revoked, terminated, suspended, or modified in writing by EPA.

Elements of a Comprehensive Plan

Because SSUROs effectively stop any further commercial activities with respect to the products for which they are issued, they can have a huge, immediate impact on the supply chain. In most cases, therefore, it is imperative that a recipient take immediate action to evaluate the SSURO, correct any problems with the identified products, and get compliant product back into the channels as soon as possible, rather than seeking to assert legal defenses. Experience suggests that every pesticide registrant should have the steps outlined below in place before a SSURO is received.

1. Make Sure Likely Recipients Understand What SSUROs Are

As noted above, SSUROs usually are addressed to senior company executives. EPA expects the recipient to act as quickly as possible to implement the SSURO. It thus is vital that whoever screens their mail understands the significance of a SSURO and knows what to do when one is received. This may sound basic, but it is remarkable how often delays occur that have the effect of souring relationships with EPA and making resolution more difficult.

2. Have an Internal Team Ready to Act

A fundamental element of any plan for addressing a SSURO is identification of an internal team to assist in implementing necessary actions. This team should consist of representatives from legal, regulatory, logistics, and the commercial sides of the business. The legal representative is essential to the internal investigation of the allegations in the SSURO and to any compliance issues associated with the offending product. The regulatory representative is key to communicating with EPA's Office of Pesticide Programs and assisting with corrective actions, such as labeling, or other registration actions that require submission of amendments or notifications. Logistics come into play because the company will need to know how much of the affected product is still within its custody or control, how much is in the channels, where it is located, and eventually how it will be returned. Key people from sales/marketing need to be included to facilitate communications to the sales/marketing teams about the limitations set by the SSURO as well as external communications to distributors and end-users.

Ideally, this internal team should be designated ahead of time and be ready for activation if and when a SSURO is issued. At the very least, a single individual should be pre-identified as the person who will convene an appropriate team when events merit. All potential internal recipients of a SSURO (see point 1 above) should know at least who this person is, if not all the team members.

3. Find the Root Cause

As soon as the product is placed on hold, the internal team should start gathering facts and investigating the circumstances surrounding the SSURO. This process should be done under the direction of legal counsel. All SSUROs lay out the facts, the legal basis for EPA's determination that the product is in violation of FIFRA, and the specific, alleged violations that led EPA to issue the order. The first priority must be to determine whether the facts and conclusions in the order are accurate.

If the facts are accurate—and EPA has a pretty good record of getting facts correct—the next priority is to figure out how the violation occurred so that corrective actions can be implemented. The problem may extend beyond the product that is subject to the order, or may affect additional production runs for the same product. In either case, deciding on appropriate corrective actions depends on figuring out how the problem occurred.

The investigation should also include gathering information to determine the scope of the problem, such as how much affected product remains within the control or custody of the company; how much product is in the distribution channel; and where the product is located. The company must have this information if it needs to move affected product for rework or disposal while the SSURO is in place, since Agency authorization may be required. **The first inclination of most companies is to retrieve affected product from the distribution channels, but this typically is not allowed under SSUROs.** Instead, the only way to remove product from the distribution channel after the SSURO is received is to get permission from EPA. Once again, failure to understand the rules in advance, and retrieving product without permission, can substantially increase a recipient's penalty exposure.

4. Take Steps to Implement the SSURO

Upon receipt of the SSURO, a company should immediately convene its internal team and take action to “freeze” in place all product within its ownership, custody, or control, wherever it is located. It is rarely in a recipient’s interest to delay compliance while legal rights and obligations are assessed.

As an initial step, the product subject to the SSURO should be physically segregated from other products in inventory and marked to indicate that it is subject to an order and cannot be moved, shipped, or distributed until further notice. It is important that this happen immediately and effectively, because the SSURO is typically effective upon receipt and prohibits any movements, removal, sale, or distribution of the product from that point forward until the SSURO is lifted or EPA grants permission to move the product. The company’s potential penalty exposure thus can be substantially increased if its procedures for implementing the SSURO allow product to get shipped or moved after the SSURO is in place.

Although it sounds like a simple exercise, there have been a number of situations where companies have failed to effectively place a timely hold on products subject to a SSURO, as a result of which further shipments were made. Because companies are required to keep all pesticide shipping and distribution records under FIFRA Section 8 and EPA’s implementing regulations at 40 C.F.R. Part 169 for two (2) years, this activity will almost certainly come to light. Indeed, companies that intentionally ship or move product in violation of the SSURO are subject to potential criminal enforcement for “knowing” violations of FIFRA. Having a plan in place before an SSURO is received and implementing it in a timely manner should inoculate a recipient against such charges.

5. Develop a Strategy

If investigation shows the SSURO was issued on the basis of an error of fact, EPA must immediately be contacted and efforts initiated to have the order rescinded. In most cases, however, companies find that the facts and allegations in the SSURO are largely accurate. Thus, the internal team should develop a strategy for implementing corrective actions and lifting the order. If the violation involves misbranding, corrective actions will include correcting the labeling on all products that are packaged and labeled going forward. This may require simply ordering new labeling stock and packaging, and determining how to correct and work with existing labeling stock. In some situations, however, submission of a labeling amendment or notification to EPA may be required. In either case, all newly produced material should be labeled and packaged with the correct labeling, at a registered establishment, to avoid further allegations of violation.

A second part of the strategy must address existing product that is within the control and custody of the company and in distribution channels. Any relabeling, repackaging, or formulation adjustments must be done at an EPA establishment registered under FIFRA Section 7. Thus, even if the product can be reworked, it may need to be shipped to a registered establishment where the rework process will occur. This is another common area of confusion. **Doing any rework at a location that is not an EPA-registered establishment can create another violation and attendant enforcement issue. And, relabeling includes simple label corrections or restickering.** A number of companies have been subject to enforcement action for directing

field personnel or distributors to make label corrections in the field. This generally is not allowed, unless the location where the labeling or restickering occurs is an EPA-registered establishment.

In addition, the EPA-registered establishment number for wherever labeling or repackaging occurs must be added to the label. EPA requires that the last EPA-registered establishment where the product was formulated, labeled, or packaged be the establishment listed on the labeling. This detail is often overlooked and has resulted in additional penalty assessments against some companies. In light of these considerations, in most cases the best strategy is to obtain EPA approval for shipping all existing product to an EPA-registered establishment designated by the company for relabeling or rework. This is often the same establishment that originally packaged and labeled the product. This process starts with a request to EPA's Office of Enforcement and Compliance Assurance (OECA). The request should be in writing and include (1) the purpose for which the movement is requested; (2) an accounting of the quantities of product to be moved, including location(s) and container sizes; (3) the destination location to which the product will be moved. OECA will review the request and determine whether to permit the movement of the product. If OECA grants the request, it will issue a letter or amended SSURO that provides for the movement of the product. **No product should be moved until the letter or amended SSURO is received from EPA.**

6. Implement a Communication Plan

One final aspect for effectively handling SSUROs is to develop a communication plan. This aspect is often overlooked but is equally as important as all the other elements noted above. The communication plan should have two tracks to be effective. The first should address internal communications to sales/marketing teams and others within the company that need to understand the SSURO, and how existing product in distributor's hands will be addressed. The second track should address external communications to distributors and growers/end-users.

For internal communications, there should be a coordinated message to the sales/marketing teams about the hold on further sales and distribution of the product. Employees who have regular contact with distributors should also be instructed on how to answer common questions likely to be received from distributors about the hold and when product will be available again. External communications should be focused on providing pertinent information to distributors and end-users/growers. Communications about the SSURO should be clear, factual, and not confusing. The company may need to implement a series of communications for the channel. Initially, the company will want to inform and educate regarding the product hold. Further communications will become necessary to inform the external stakeholders about returning existing product once the process for addressing the SSURO is further along and EPA has granted permission to retrieve product for rework or replacement. All communications should be reviewed by the internal team responsible for handling the SSURO and by the company's legal counsel before they are issued.

Understanding and implementing these elements and the other steps noted above will help to assure that the company handles a SSURO as effectively as possible and minimizes both its enforcement exposure and its marketplace risks.