Make my day! - Registrant gets court to order EPA to cancel their product

Industry stakeholders won a major victory Jan. 28 when Judge Ellen Huvelle of the U.S. District Court for the District of Columbia ruled EPA could not circumvent FIFRA's cancellation procedures in its actions regarding 10 rodenticide active ingredients (see story, Page 1). Jim Aidala, former Assistant Administrator of EPA's Office of Chemical Safety and Pollution Prevention, delves into the background of the case and assesses its wider implications, including possible next steps for EPA and other stakeholders.

Reckitt Benckiser is a manufacturer of a variety of household cleaning and pesticide products, including rodenticides, sold widely under the D-Con brand. In recent years Reckitt Benckiser has formulated rodenticide products using what is known as a "second-generation" anti-coagulant, brodifacoum. The term second-generation refers to the lack of resistance in rodents, which has developed in some cases to earlier, "first-generation" anti-coagulant products, such as warfarin.

In May 2008, EPA issued a Risk Mitigation Decision for brodifacoum (and nine other rodenticide active ingredients). Concerning the use of brodifacoum, the decision described EPA's rationale for removing its use from household consumer products, and as such, EPA declared it would consider any products sold after June 2011 as "misbranded" under FIFRA. Registrants of brodifacoum products, including Reckitt Benckiser, had been meeting with EPA for an extended period discussing the use of brodifacoum as a household rodenticide and whether reports of accidental or unintended exposures by children or non-target animals warranted further restrictions or removal from the marketplace. The decision in May 2008 articulated EPA's concerns with brodifacoum and other second-generation products as the basis for wanting to declare any such products sold after June 2011 as misbranded.

FIFRA authorizes EPA to take a variety of different actions to ensure that statutory requirements are met. In the situation where EPA concludes that a pesticide no longer meets the standard for registration, the law allows EPA to seek to "cancel" the pesticide's registration (or in the case where EPA might conclude an imminent hazard exists, EPA can "suspend" the registration) through a formal administrative proceeding. FIFRA also allows EPA to stop the sale of products that it concludes are misbranded due to labels that EPA claims are false or misleading, among other reasons.

In this situation, where EPA informed registrants that their products would be considered misbranded after a certain date, Reckitt (among other registrants) contended that the appropriate tool for EPA was to propose to cancel its FIFRA registrations. A cancellation order would allow the affected registrants the opportunity for an evidentiary hearing as proscribed under the law to rebut EPA conclusions that the product's risks were excessive or otherwise unacceptable under FIFRA. The declaration to consider products misbranded after a certain future date was seen by the registrants as a way to have EPA effectively cancel the product without using the appropriate cancellation mechanism, because the threat of EPA enforcement action against anyone who sold the products after a certain date would likely cause sales to vanish. The lack of a cancellation order would also prevent the registrants from being able to use the cancellation administrative process publicly to rebut EPA's conclusions.

Cancellation hearings can be protracted and resource intensive as they are a full evidentiary hearing where the entire decision-making record must be developed *de novo*. Subpoenas can be issued, and witnesses for the government and registrant are subject to discovery and cross-examination. In the past, some cancellation hearings have taken many years and great expense in time and resources. They are generally considered to be an option that both EPA and the registrant in question hope to avoid due to the time and expense involved. Although there are thousands of registered pesticides, and over time, hundreds have been removed from the market, relatively few cases have resulted in cancellation hearings to resolve a dispute between EPA and a registrant. Avoidance of cancellation hearings is also not seen as a partisan affair; both Democratic and Republican administrations have been criticized for the practice (the rodenticide case here was initiated under the Bush administration in 2008).

In this case, however, Reckitt sought a judicial order for EPA to issue a cancellation order in lieu of its decision that brodifacoum products would be considered misbranded. Reckitt contended that the misbranding option would allow a challenge only after the market for its product had evaporated, which is not what FIFRA calls for in a case where there is a significant disagreement between the registrant and EPA.

Reckitt has stated in the past that brodifacoum does not present excessive risks, citing, among other things, that the vast majority of accidental exposures do not cause any significant harm. Reckitt also argues that hospitalizations and serious injury are relatively infrequent, especially given the millions of applications of these products used each year. And brodifacoum products, under EPA's approach, would only be available if used by a professional applicator, which would price the availability of the product out of reach for most lower-income users who are among those who are the most in need of rodent control. EPA claims to have considered all of these arguments and nonetheless concluded that brodifacoum should be more restricted.

Who is correct is not the point; Reckitt's argument was that cancellation proceedings were the way EPA should propose its restrictions and that a cancellation order, not a threat of misbranding, was the appropriate statutory instrument.

In this case, the court ruled that Reckitt was correct — the misbranding threat was equivalent to a cancellation order but EPA used the wrong tool; it should issue a cancellation order instead. This will allow Reckitt the rights and opportunities to challenge the cancellation order using the FIFRA administrative procedures.

Implications

EPA in recent years has been accused by some registrants of seeking to eliminate or impose severe restrictions on pesticides while avoiding the time and expense of the cancellation procedures. In a case involving an insecticide used on corn and other field crops, carbofuran, EPA chose to revoke the tolerance using the revocation procedures under the Federal Food, Drug and Cosmetic Act (FFDCA) instead of first cancelling the pesticide's registration under FIFRA. Some

A View from the Field

critics of this EPA path believe this was another recent attempt by the agency to avoid the FIFRA cancellation procedures. That case is being challenged under the provisions of FFDCA, but the fundamental criticism revolves over what are the appropriate ways for EPA and the registrant to resolve a dispute over the safety of a registered pesticide. In the case of carbofuran and using the FFDCA procedures, critics also note that the risk-benefit calculus required under FIFRA is avoided.

Critics of this EPA behavior cite that it is Congress that has intentionally made it difficult to remove a product from the market, in part at least, due to the significant burdens placed on a registrant to get to the market initially. The costs and requirements for registration are substantial, so this argument goes, so the removal of a registration should not be a matter of a declaration on the part of EPA. EPA has an array of tools to reassure the public that public health and the environment are being protected, and the public expects that such protection is not hindered or delayed by administrative or procedural hurdles once EPA has concluded an unreasonable harm is occurring. The dispute is what appropriate procedures are called for when there is a fundamental disagreement over whether a registered pesticide no longer meets the standard for continued sale and use. Typically, EPA calls for restrictions or elimination of a registered product are based on new data or interpretation of data on the part of EPA. Affected registrants want to ensure that if there is a dispute over the meaning of any new information or the application of a new policy or interpretation, there will be ultimately an objective forum to help determine whether the new EPA conclusion is warranted by scientific information and the law.

In the Reckitt case, EPA may appeal the ruling and continue to defend its use of the misbranding threat. It is less clear, if the decision stands, if EPA will issue a cancellation order or seek to negotiate an alternative set of restrictions with the registrants. The larger question will remain whether this will lead to less EPA reliance on paths other than cancellation or if it will encourage registrants to insist more firmly on cancellation procedures when there is a significant dispute over a pesticide's registration status.

At the same time, if EPA is made to rely on cancellation proceedings before imposing significant restrictions on a registered pesticide, environmental critics of FIFRA's procedures and risk-benefit standard are likely to accelerate their reliance on non-FIFRA avenues to seek restrictions on pesticides. Most notorious in recent years is the emergence of litigation under the Endangered Species Act, which does not have risk-benefit considerations and is based on a statute not authorized by the agriculture committees of Congress. Similarly, the Clean Water Act also has the potential to affect pesticide use as recent litigation has imposed water permit requirements for certain pesticide applications. Over time, this could result in a need for Congress to more clearly define what law and federal program is to have primacy when imposing requirements on pesticide use.

ABOUT OUR AUTHOR

James V. Aidala has been vice president of policy and government affairs at Bergeson & Campbell, P.C. since 2003. Immediately prior to his current position, he was president of JSC Inc., a Washington, D.C.-based consulting firm specializing in FIFRA and TSCA regulatory matters (2001-2003). He is a former Assistant Administrator for what is now EPA's Office of Chemical Safety and Pollution Prevention (OCSPP), (2000-2001) and a former Associate Assistant Administrator for OCSPP (1993-2000). He has held various positions with the U.S. House of Representatives, the U.S. Senate, the Congressional Research Service, and the Wallace Institute for Alternative Agriculture. He is also a founding member of the Capitol Steps, a Washington, D.C. political satire musical group first organized in 1981 and now heard regularly on National Public Radio .

Upcoming Events

Inherently Safer Chemical Processes: The Use of Methyl Isocyanate at Bayer CropScience - Feb. 9

The National Research Council's project on Inherently Safer Chemical Processes: The Use of Methyl Isocyanate at Bayer CropScience is holding its initial meeting, Feb. 9-10, at the National Academies' Keck Center, 500 5th St. NW, Washington, D.C. Only parts of the Feb. 9 proceedings will be open to the public. Topics to be presented during the public session include: an overview of the scope of the study; an overview of the Bayer CropScience facility in Institute, W. Va.; and an overview of assessments of inherently safer chemical processes. Registration is required to attend. For more information about the project, including a link to register for the meeting, go to: *www8.nationalacademies.org/cp/meetingview.aspx?MeetingID=4956*

Codex Pesticide Residues Committee - Feb. 24

The Pesticide Residues Committee of the Codex Alimentarius Commission (Codex) is meeting from 1 p.m. to 3 p.m. on Feb. 24 at EPA's offices located at One Potomac Yard, 2777 South Crystal Drive (Room S-7100) in Arlington, Va. According to USDA's Food Safety and Inspection Service, the objective of the meeting "is to provide information, receive public comments on agenda items and draft United States positions that will be discussed at the 43rd Session of the Codex in Beijing, China, April 4-9." For more information contact Doreen Chen-Moulec, U.S. Codex Office, at (202) 205-7760 or *Doreen.Chen-Moulec@fsis.usda.gov*, or go to: *www.fsis.usda.gov/News_&_Events/NR_012611_01/index.asp*

Society for Chemical Hazard Communication Spring Meeting - March 26-30

The Society for Chemical Hazard Communication is holding its annual spring meeting March 26-30 at the Marriott Seattle Waterfront Hotel, 2100 Alaskan Way, Seattle, Wash. Sessions on the preliminary agenda include: "Industry Stakeholder Perspective on Green Chemistry;" "GHS Implementation - A Company Perspective;" and "Prop 65 Risk Assessments." For more information, find the meeting at *www.schc.org*

