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Sent: Friday, September 10, 2004 12:35 PM
Subject: Section 18 'Emergency Exemption' Proposed Rule Published For Comment

Action: EPA has issued for public comment a proposed rule that would streamline the application and review process for pesticide emergency exemptions (i.e., "Section 18's"). These proposed revisions to the 'Section 18' (see below) emergency exemption process are meant to streamline and improve the emergency exemption process by reducing the burden to both applicants and the EPA; hence **decisions could be made quicker by EPA**. It would also use **"significant economic loss" as the basis for an emergency** to make decisions more equitable. Comments must be received on or before November 2, 2004; see proposed rule for all the details @ <http://epa.gov/EPA-PEST/2004/September/Day-03/index.html>.

EPA provides that the revisions would allow applicants for emergency exemptions to:

1. generally re-certify that emergency conditions continue in the second and third years for certain repeat requests, thus **eliminating the need for annual documentation**; and
2. use a **loss-based approach** to substantiate the "significance of economic losses" (the most commonly used criterion for demonstrating an emergency condition) rather than a comparison of revenues under the emergency to historical variations in revenues.

Background: The United States Environmental Protection Agency (EPA) regulates pesticides under broad authority granted in two major statutes, the Federal Insecticide, Fungicide & Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA). These statutes were subsequently amended by the Food Quality Protection Act (FQPA) of 1996. Under **Section 3** of FIFRA, EPA can register pesticides for use throughout the United States. This type of Federal pesticide registration is commonly called a "Section 3". However, EPA can authorize limited use of unregistered pesticides, or pesticides registered for other uses to address emergencies and special local needs.

Under the authority of **Section 18** of FIFRA, EPA can allow State and Federal agencies to permit the unregistered use of a pesticide in a specific geographic area for a limited time if emergency (or in some cases crisis) pest conditions exist, and that use of the product will be protective of human health and the environment. This type of Federal pesticide registration is commonly called a "Section 18" emergency exemption and is granted to State and Federal agencies. Currently, EPA authorizes emergency exemptions (except quarantine exemptions) for no longer than 1 year. Some exemptions may subsequently be approved again, 1 year at a time. It has been found to be a time-consuming and burdensome process. The proposed revision allows applicants to submit applications that would allow applicants to incorporate by reference all information submitted in a previous application, instead of submitting a complete re-application and supporting documentation. The proposed revisions do not affect the risk side of the assessment and decision.

The current Section 18 Emergency Exemptions are published online @ <http://www.pestmanagement.rutgers.edu/NJinPAS/PesticideRegistration/NJ18s.htm>

Sources:

1. Federal Register: September 3, 2004 (Volume 69, Number 171)[[Proposed Rules]][Page 53866-53879] <http://epa.gov/EPA-PEST/2004/September/Day-03/index.html>.
2. Press Advisory - EPA's latest developments; News for release: (Washington, D.C. - September 1, 2004)
3. EPA's background document, "Section 18s Program and Proposed Reforms," @ www.pestmanagement.rutgers.edu/NJinPAS/PesticideRegistration/Section%2018s%20Program%20and%20Proposed%20Reforms.pdf details proposed changes to the Section 18 process.
4. RCE New Jersey Pesticide Registration webpage: www.pestmanagement.rutgers.edu/NJinPAS/PesticideRegistration/NJregistrations.htm

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