



No. 37: Section 25(b) Pesticides: Minimum Risk?

Amy E. Brown, Ph.D., Coordinator
Elizabeth Ingianni, M.S., Program Assistant
Pesticide Education and Assessment Programs
Orig. 2001; Last rev. July 2012

BACKGROUND

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires that all pesticides (insecticides, fungicides, herbicides, rodenticides, etc.), with very limited exceptions, must be registered with the U.S. Environmental Protection Agency (EPA) before they can legally be sold or used in the United States. In 1996, the Agency exempted from this requirement certain pesticides considered to pose “minimum risk” to humans and the environment, provided the products satisfy certain conditions. These products were exempted based in part on their minimal risk status and in part as an effort by EPA to reduce the cost and regulatory burden on businesses so that the Agency could focus its limited resources on pesticides that pose a greater risk.

Products identified as exempt under Section 25(b) do not require EPA label approval, do

not undergo review by the Agency, and have no label requirements for an EPA Registration Number, an EPA Establishment Number, any signal word, or any personal protective equipment (PPE). Pesticide Registration Notice 2000-6 states that “EPA does not review or issue notices of exemption for products which meet the conditions for exemption.” Section 25(b) pesticides are required to have a *tolerance* (the maximum amount of pesticide residue that can legally remain in food or feed at harvest) established if they are intended for use in or on foods, food crops, food contact surfaces, or animal feeds, unless they are exempt from a tolerance under other regulations.

The lack of a requirement for any review before placing a pesticide product, even of minimal risk, on the market evokes some concerns in those who are responsible for developing programs that regulate pesticides and/or educate pesticide users.

CONDITIONS OF EXEMPTION

Identification of active and inert ingredients

EPA developed a list of active ingredients and a list of inert ingredients that could be considered minimum risk. In order to qualify for the exemption from registration, the product must contain only all active ingredients and inert ingredients from these two lists. The lists may be accessed on EPA's website as follows:

- Active ingredients acceptable in 25(b) products
www.epa.gov/oppbppd1/biopesticides/regtools/25b_list.htm
- Inert ingredients acceptable in 25(b) products
www.epa.gov/opp001/inerts/section25b_inerts.pdf

Pest control claims

Pesticides for which the label claims to control a microorganism that causes human disease, or control a pest that vectors or transmits human disease, are not eligible to be considered minimum risk pesticides. This is because the Agency has determined that pesticides used for protection against human diseases should undergo a full spectrum of testing, and thus should not be exempt as the minimum risk pesticides are.

Acceptable statements

- "Controls ticks"
- "Controls mosquitoes"

Unacceptable statements

- "Controls ticks that can carry Lyme disease"
- "Controls mosquitoes that may transmit West Nile virus"

Safety claims

Section 25(b) products may not carry label statements that imply that the pesticide is recommended or endorsed by EPA or any other agency of the federal government.

Acceptable statements

- "Safe for children and pets"
- "Natural way to control pests"

Unacceptable statements

- "Recommended by EPA as safe."
- "It is a violation of federal law to use this product in a manner inconsistent with its labeling."

STATE REGULATIONS

Each state has its own statutes and regulations concerning pesticide registration and regulation. States are not required to permit the sale of a Section 25(b) product simply because it meets EPA's stated conditions for minimum risk exemption. About half of the states, including Maryland, do not recognize this exemption and, as a result, require that all 25(b) products be registered with Maryland Department of Agriculture's State Chemist Section as pesticides.

Maryland regulations require applicators use or recommend only those pesticides that are registered with Maryland Department of Agriculture's State Chemist Section. If there is no EPA Registration Number listed on a product label, an applicator must call the State Chemist's Section (**410-841-2721**) to determine if the product has been registered in Maryland.

ISSUES

- Because no EPA registration number appears on Section 25(b) product labels, these products cannot be identified or tracked, and their labels can change without notice or review.
- Unless an applicator is familiar with all of the active and inactive ingredients that can be classified as 25(b) products, it is not possible to know whether a product that does not bear an EPA registration number is, in fact, a 25(b) product and exempt from the requirement, or simply an illegal pesticide.
- In some states, labels that do not bear an EPA registration number and/or a signal word are, by definition, considered misbranded and illegal.
- Label statements are inconsistent and claims can be very confusing. Not all claims have been substantiated.
- In some states, including Maryland, businesses that apply pesticides must have at least one certified applicator, regardless of whether they use restricted or only general use pesticides. Because 25(b) products in Maryland are treated no differently than other pesticides, firms that apply only 25(b) products must still have at least one certified applicator.
- Ingredients are not subject to verification, and there are no resources for routine laboratory sample analysis. Most state regulatory labs are not equipped to test for many organics (e.g., essential oils), and thus cannot verify many of the ingredients in 25(b) products.
- Certain claims, as identified above, are illegal even for 25(b) products. Yet without the requirement for label reviews or approval by EPA, it is difficult to ensure that manufacturers and distributors are following this requirement. For instance, one product found in the marketplace carried the following label statement, which is clearly illegal and misleading: “So safe the Environmental Protection Agency exempted it from herbicide regulation.”
- The label is the primary principle in pesticide education. Educators teach that pesticide ingredients are reviewed prior to registration, and that labels are developed on the basis of information submitted to EPA, yet this is not true for 25(b) products. As specified above, labels of 25(b) products are not allowed to claim that use inconsistent with the label is a federal violation because this implies that a federal agency has reviewed or approved the label.
- The lack of requirements for signal words and PPE implies that safety and exposure minimization are not of concern for these 25(b) products, yet some of the listed approved ingredients are known to pose potential risks to human health if exposure is high enough. For example, a Material Safety Data Sheet (MSDS) for eugenol states “Eugenol is irritating to eyes. Repeated contact may cause allergic dermatitis.” The label for this 25(b) product, however, merely states “Safe around people and livestock.”
- Risk depends on both the toxicity of a substance and one’s exposure to it. However, label statements such as “Safe for children and pets” may mislead the public into disregarding this principle.

- Educators teach that the labeled rate of pesticide application must be followed strictly. One 25(b) product label states “If you choose, you can use twice the recommended rate for even better control...” This contributes to consumer confusion and may influence users to believe that application of other pesticides at nonlabeled rates is acceptable.

SUMMARY

A minimum risk pesticide may be a good choice for certain pest situations. However, the user should be aware of the difficulty of knowing whether a product that does not bear an EPA registration number is truly one that EPA would consider a minimum risk pesticide as opposed to a product that does not bear the registration number because it is an illegal product. When handling or applying minimum risk products, users should still observe good safety practices to avoid any possible adverse effects on health (their own, their families’ or the general public’s) and/or on the environment.

SOURCES

Mulkey, Marcia. 2000. Pesticide Registration (PR) Notice 2000-6. Notice to manufacturers, formulators, producers, and registrants of pesticide products. EPA Office of Pesticide Programs. 10 pp.

Schulze, Larry. 2001. Section 25(b) pesticide labels: Background, challenges and possible solutions. University of Nebraska - Lincoln. American Association of Pesticide Safety Educators. March 15, 2001. PowerPoint presentation.

US. Environmental Protection Agency. Active Ingredients Exempted Under 25(b) of the Federal Insecticide, Fungicide, & Rodenticide Act. Minimum Risk Pesticides.
www.epa.gov/opp00001/biopesticides/regtools/25b_list.htm#activeingredients