Review of Regulatory-Imposed Marketing Constraints to Repellent Development

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ABSTRACT

The purpose of this paper is to review the regulatory issues concerned with marketing repellents and to try to identify areas where changes may be needed. Repellents are covered unevenly by the various Federal and State pesticide laws. These laws were generally formulated to deal with pesticides and other highly toxic chemicals used to control "pests." However, repellents discourage pests due to their disagreeable properties rather than their toxicity. The U.S. Environmental Protection Agency has recently introduced reduced risk pesticide guidance which limits reporting requirements and hastens review. Those states that follow the Federal lead do not represent a problem. However, such states as California, Florida, and New York, that conduct their own detailed reviews, have not yet moved to adopt the Federal reduced-risk guidance and often require additional data beyond those required at the Federal level. In addition, foreign countries deal differently with repellents. Canada does not have biochemical or reduced risk guidance and therefore reviews repellents as regular pesticides. The European Union's new biocides law includes repellents and has significant information requirements. On the other hand, other countries such as New Zealand and Australia have no or minimal registration requirements for repellents. This uneven regulatory treatment makes introduction of repellents into the global market difficult.

KEY WORDS

Australia, biochemical, California, Canada, European Union, Florida, New Hampshire, New Zealand, reduced risk, repellent

INTRODUCTION

Repellents are a unique class of agents that repel pests because they are disagreeable to them. They are not covered effectively by the pesticides or biocides laws and regulations of the United States, Canada, or the European Union (EU), which are focused more on agents that exert their influence through their toxicity; hence the use of the stem word "cide." In general, repellents are

unfairly subjected to the rigorous screening reserved for pesticides and biocides which slows their review and entry into the marketplace.

This paper identifies how repellents are regulated under various National and State regulations, points out the inconsistencies and problems, and suggests possible solutions and areas where more work is needed.

REGULATION OF REPELLENTS BY THE U.S. ENVIRONMENTAL PROTECTION AGENCY

The U.S. Environmental Protection Agency's (USEPA) Office of Pesticide Programs regulates repellents under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Many repellents are naturally occurring materials, also referred to as biochemicals, that have properties which make them aversive to certain target organisms, such as capsaicin to mammals or methyl anthranilate to birds. USEPA recently exempted pheromones, another family of naturally occurring repellents, from registration under FIFRA (U.S. Environmental Protection Agency 1994). Additionally, in July 1993, EPA published guidance for reduced risk pesticides (U.S. Environmental Protection Agency 1993). This guidance reduced the information requirements, but required the submitter to discuss how the new active ingredient being registered is less toxic and has fewer deleterious environmental effects than materials previously available.

The reduced risk active ingredients are assigned an increased priority rating and therefore pass more rapidly to the top of the reviewers' stacks. The reduced data requirements also minimize the number of studies to be conducted and reviews performed. This results in a more rapid passage through the regulatory process. USEPA recently published statistics for "average" FY-94 review times in the Office of Pesticide Programs: 251 days for new active ingredients, 208 days for new biologicals, 127 days for fast-tracked, already registered active ingredients, 175 days for other already registered active ingredients, 98 days for a fast-tracked amendment, 180 days for a regular amendment, and 263 days for a new use. Repellents should be in the most rapidly reviewed category.

One potential problem is that at the present time only new active ingredients can be classified as "reduced risk." This means that an existing active ingredient for which new uses or formulations are proposed will not automatically receive the fast tracking being afforded to those associated with new reduced risk actives. This should not be difficult to correct and may require a company preparing a petition that an existing active be considered as "reduced risk" in the future.

There is also discussion that since products such as capsaicin and methyl anthranilate are heavily used as flavoring and fragrance ingredients, they should not be subject to FIFRA. In fact, a number of potential active ingredients have been specifically exempted including pheromones and vitamin hormone products (U.S. Environmental Protection Agency 1994).

REGISTRATION OF REPELLENTS BY INDIVIDUAL STATES

Most U.S. states accept the reviews of pesticide registration-related data performed by USEPA without additional investigation. For these states, registration is generally a matter of filing USEPA-approved labels and Material Safety Data Sheets and paying the registration fee. Several states, including California, New York, New Hampshire, and Florida, however, perform their own data reviews. They require submission of the original studies as well as EPA's environmental review findings. Not only do they re-review the data, they occasionally request additional studies or data, not required by the new reduced risk or biochemical reporting requirements. This lack of parallel in the State and Federal requirements occurs because the states have not updated their review processes to parallel that at USEPA. It is well-known that California requires at least a year to review the registration submission for a new active ingredient and New York is requiring 3 months from the time an application is deemed complete which adds at least 2 more months.

There is an initiative underway between USEPA and the State of California Department of Pesticide Regulation to see whether they can accept each other's acute toxicity data reviews; a Memorandum of Understanding (MOU) has already been signed (California Department of Psticide Regulatåon and U.S. Environmental Protection Agency 1994). In this case, a registration package would be filed with the State at the same time it is filed with USEPA, and together they will decide who will review which sections and share the results. Currently, State registrations cannot be filed until after the Federal process is completed. If differences of opinion result from the parallel reviews, the MOU calls for discussion among the reviewing toxicologists followed by, if necessary, arbitration.

Recently a problem was experienced with the State of New Hampshire's Department of Agriculture, Division of Pesticide Control, which reviewed the new active ReJeX-iT® MA containing the avian repellent methyl anthranilate. Because of its intended use as a bird control agent, they immediately classified the material as "Prohibited-Limit Use," the same level of protection given to animal poisons. This classification means that ReJeX-iT can only be applied by trained applicators who have obtained a "special permit." New Hampshire experts totally ignored the product's very low toxicity and already high human exposure levels as a common flavoring and fragrance ingredient. Petitions have had to be filed to have the material re-reviewed and reclassified as "General Use."

Dealing with the states is also difficult because of the wide variety of requirements. Presently, there are seven different filing dates for State registrations and the fees per product range from no fee in Alaska to $300 in New York and Louisiana. They also differ on Experimental Use Permits, sales tracking, what label changes they require and when they should be submitted, etc.

REGULATION OF REPELLENTS IN CANADA

At the present time, Canada does not publish guidance exempting or reducing the reporting burden for biochemicals or for reduced risk products under their Pest Control Products Act and its implementing regulations (Environment Canada 1994). The average review time is about 2 years, but the submitters of a registration for methyl anthranilate were recently told that they could be assured of a more rapid review because of the demand for this product and its low toxicity. Part of the dialog between the United States and Canada concerning joint review of pesticide registrations needs to focus on materials, such as repellents, for which the United States supports submission of a reduced data set but Canada does not.

At the present time, the registration submission requirements for repellents in Canada are more laborious than they are in the United States due to the inclusion of an obligatory economic impact section in the filing and the lack of a reduced data requirement. They also require more copies of most of the materials because they have decentralized the review process across a number of agencies. In April of this year, Canada moved to improve coordination by establishing the Pesticide Management Regulatory Agency under Health Canada. The review, however, is still carried out at multiple locations, and the impact on registrant communication is not yet clear.

Problems similar to those with several U.S. states conducting independent reviews can be experienced with the Canadian provinces which also require separate registration of pest control materials.

REGULATION OF REPELLENTS IN THE EUROPEAN UNION

Until last year, regulation of repellents in Europe was accomplished under the pesticide laws and regulations of the various countries. For the last several years, the Commission of the European Union has been working on a new Council Directive Concerning the Placing of Biocidal Products on the Market. When this is ratified, all of the member countries will have 2 years to bring their laws into harmonization with the EU Directive. It will probably be adopted in early 1996. Under the proposed Directive, repellents represent one of the classes of regulated substances. Accompanying guidance has specifically excluded contact repellents (Frost and Hansen 1994).

Annex 1 to the Biocides Directive contains a list of active ingredients that are currently used in Europe. A separate testing scheme has been proposed for each class of biocides. Two of the issues remaining to be finalized in the Directive are the lack of a stepped testing plan with triggers for invoking more intensive testing and the lack of a waiver process. At the present time, the proposed European requirements are singularly rigorous. They will greatly increase the cost of registration and the time required to acquire the necessary data.

Under the new Directive, application can be made to a single member country or to that country and the EU as a whole. A central clearinghouse for information will probably be set up similar to that for new chemical substances registration which will collect and distribute submitted

data and the initial member country reviews. The EU has already adopted uniform labeling of toxic substances which may have to be expanded to cover biocides.

REGULATION OF REPELLENTS IN OTHER COUNTRIES

There are other countries which require data submission similar to those discussed above, and there are those that essentially exempt repellents from evaluation under their pesticides laws. For example, Australia waives active ingredient review, but requires data submission for end use products. New Zealand, on the other hand, totally ignores repellents and only maintains a formatted label on file and requires no supporting data submission.

CONCLUSION

Much effort is therefore required to research and comply with the widely varying regulations governing repellents. This affects the cost of bringing a product to market as well as the length of time between development and full marketing. The extent to which standardization can be accomplished, such as the efforts just beginning between the Canadian Pesticide Management Regulatory Agency and USEPA and the State of California and USEPA, are to be lauded. It is hoped that similar efforts might be possible among states, provinces, and member countries. The following should be high priorities for regulatory reform:

- Incorporate USEPA reduced risk pesticide language into the pesticide regulations of the individual states.
- Initiate dialogue between USEPA and the European Union to harmonize the requirements regarding repellents.
- Support USEPA work with the Canadian Pest Management Agency to develop harmonized regulations on repellents and reduced risk pesticides.
- Expedite the studies underway between USEPA and Canada and the State of California to facilitate joint reviews.
- Work with USEPA to find additional ways to expedite reviews and issuing of exemptions from tolerance for reduced risk pesticides, including repellents.

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