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Lyle A. Crosby
Rodent and Predator Control Division, Wyoming Department of Agriculture, Cheyenne, WY

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CURRENT STATUS AND POTENTIAL REGISTRATIONS OF COMPOUND 1080 AND STRYCHNINE FOR RODENT CONTROL

Lyie A. Crosby, Rodent and Predator Control Division, Wyoming Department of Agriculture, Cheyenne, WY 82002

Abstract: On December 1, 1976, the Environmental Protection Agency applied Section 6 of the Federal Insecticide, Fungicide, and Rodenticide Act, "Administrative Review", in determining that the use of products containing strychnine, for above ground application to control several rodent species, met specific cancellation criteria outlined in 40 CFR 162.11. Position Document 4 (the final Agency decision), published on September 30, 1983, proposed to cancel registrations of strychnine products for above ground use to control prairie dogs and required label modification for confined use on ground squirrels. The final decision was challenged by several parties who requested a formal hearing which was granted by the EPA. This request temporarily stayed the EPA decision to cancel registrations. A formal hearing has not yet been held, pending negotiations for a settlement agreement by the parties to this action. The use of Compound 1080 for rodent control has undergone the same administrative review as strychnine with similar conclusions drawn. Position Document 4, published in July of 1985, proposed to cancel current intrastate registrations by December 31, 1985. However, current application and bait concentrations may continue for use in ground squirrel control while Section 3 registration data are being developed. Bait treatment levels may not exceed 0.02% 1080 in the California Condor Range: if the 0.02% concentration is not effective, data must be submitted to establish the lowest effective concentration.

Introduction

RPAR Action by the EPA

The Rebuttable Presumption Against Registration (RPAR) notice for strychnine was published in the Federal Register on December 1, 1976. The presumption was against all outdoor, above-ground uses of strychnine.

The RPAR criteria that were determined to have been met or exceeded for the outdoor above-ground uses of strychnine are:

1) Acute toxicity to mammals and birds, and
2) Significant reduction in populations of nontarget organisms and fatalities to members of endangered species.

Position Document 4 (PD4: the final Agency decision), published on September 30, 1983, proposed cancellation of strychnine for control of prairie dogs, deer mice, meadow mice, chipmunks and marmots on rangeland, pastures and cropland and modification of other registrations. The Agency proposed to continue registrations for control of ground squirrels, marmots around rock piles, jackrabbits around airports and porcupines on nonagricultural sites.

The Agency indicated that label modifications for use to control ground squirrels and several other rodent and bird species were necessary. The Agency also concluded that additional data to determine the lowest effective dose rates were needed.

The states of Wyoming and South Dakota, the American Farm Bureau, Wyoming and South Dakota Farm Bureaus, and the USDA, et aL, challenged the final decision by requesting a hearing which was granted by the EPA. A prehearing conference was held in Kansas City, Missouri on March 4, 1984, at which the parties in this action expressed preference on locations to present witnesses and settled other procedural matters.

In addition to other changes in this case, on August 27, 1984, the U.S. Fish and Wildlife Service (USFWS) Department of the Interior (DOI). was granted persmission to intervene as an active party in the strychnine action.

In its motion to intervene, the USFWS stated that There were adequate survey techniques to determine whether black-footed ferrets inhabit particular areas. Thus, it would be possible to conclude with some certainty that ferrets are not present and therefore strychnine could be safely used in certain areas."

Additional meetings which were held following the USFWS intervention and which included data on black-footed ferrets, surveys, etc. led to improved communications and settlement efforts between the parties. These meetings specifically addressed black-footed ferret surveys and related factors important to arrangements for settling these issues without conducting a formal hearing.

Discussion of several significant issues will appear in the settlement if an agreement is reached, and I believe an agreement to settle will occur.

The significant items are:

1) Strychnine products used for prairie dog and ground squirrel control will be classified as restricted-use pesticides.
2) Black-footed ferret surveys will be required prior to the application of strychnine-treated bait
3) A permit system to be implemented will require the landowner and/or applicator to present proof of an adequate survey for black-footed ferrets prior to the purchase of strychnine- treated bait

The compromises that evolved in efforts to settle these issues without a formal hearing may not be palatable to some people: however, it is my opinion that they are workable and will permit registrations that are acceptable and functional for continued prairie dog and ground squirrel control.

EPA Pesticide Registration Policy

Current EPA policy indicates that Section 5 Experimental Use Permits (EUPs) should not be issued unless the applicants intend to provide data for a full Section 3 registration and have expressed that intent by submitting Section 3 Registration requests concurrently with EUP applications.

The EPA has recently issued "Data Call In's" for a number of pesticide registrations for which the Agency has determined that it has insufficient data to support registration. These specific EPA data requirements for "End Use" products and certain Technical Products" may require registrants to conduct additional tests to maintain registrations.

The EPA has, within the last year, identified specific criteria which must be met to secure and maintain pesticide registrations. By examining the specific criteria which must be met, potential registrants are able to establish whether a registration can be achieved,

determine data needed and whether a registration is economically feasible.

Control of Local Rabies Epizootics

Since 1972, the states of Wyoming and Montana have requested and received numerous Section 18 Emergency exemptions to apply strychnine-treated eggs for control of local rabies epizootics in striped skunks. However, in 1985 when agencies in these states again requested exemptions for this purpose they were informed by the EPA that strychnine had not been effective in the past for control of rabies or local populations of rabies vectors. In fact, the EPA further stated in the Federal Register notice of May 17, 1985, that the use of strychnine for this purpose may prolong rabies outbreaks.

The EPA stated further that both states had historically requested and had been granted Section 18 exemptions for this purpose and had not attempted to apply for Section 5 Experimental Use Permits or Section 3 registrations. However, the primary reason the states had not applied for Section 5 EUPs or Section 3 registrations was that the EPA had not provided specific criteria for these purposes. Also, the cost of research to meet unknown criteria and data requirements can be prohibitive. In addition, the EPA had been willing to grant such exemptions prior to its recent change in policy.

Another important factor in denial of these requests was stated in EPA notice PR 84-2 (Appendix A), issued on April 20, 1984, which established a new EPA policy on Section 18 Emergency Exemptions and Section 24C Special Local Needs registrations. This new policy regarding Section 18 exemptions and the use of a previously cancelled pesticide presents a slightly different situation. In this case, the applicant must demonstrate that there are significant new data, including information developed following the cancellation, if the Administrator is to reconsider the cancellation. The reconsideration of a cancelled pesticide also requires a hearing under 40 CFR 164, Subpart D.

Following EPA's Federal Register notice of intent to deny such requests, the states of Wymoning and Montana resubmitted requests for Section 18 exemptions, and requested emergency hearing waivers. The states also agreed to perform the research to develop the required data and **to** submit Section 3 registration applications. As a consequence. Section 18 exemptions were granted to Wyoming and Montana agencies on November 6, 1985 to apply strychnine-treated eggs for control of local populations of striped skunks where rabies has been confirmed by laboratory analysis. The purpose of these control efforts is to reduce exposure of people and domestic animals to rabies vectors.

In conclusion, registrations of strychnine and Compound 1080 in the future appear feasible, if applicants can meet the additional registration data requirements identified by the EPA.

Appendix A

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

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PR NOTICE 84-2 **PCSTicioes AMO TOXIC suasTA^ces**

NOTICE TO MANUFACTURERS, FORMULATORS
AND REGISTRANTS OF PESTICIDES

ATTENTION: Persons Responsible for Federal Registration ofc' Pesticides

SUBJECT: EPA Policy Regarding the Use of Section 18 Emergency Exemptions and Section 24(c) State Issued Special Local Need Registrations

PURPOSE

The purpose of this Notice is to notify all pesticide registrants that the Office of Pesticide Programs (OPP) is taking steps to assure that the section 18 Emergency Exemption and section 24(c) Special Local Need programs do not oecome vehicles for the circumvention of section 3 registrations by reviewing State submissions to assure conrormance with acceptance criteria. For registrants* information, this notice summarizes the Agency's acceptance criteria used to evaluate State submission*

SCOPE

In 1982, OPP conducted an audit of the programs for emergency exemptions and special local need registrations, and concluded that these programs are valuable to users if employed properly. Both EPA and the State Lead Agencies are taking measures to ensure that these programs do not become vehicles for early marketing of pesticide's which have not yet progressed through the normal registration process. All section 18 requests and section 24(c) registrations will be reviewed according to the criteria set forth in this Notice and 40 CFR Part 162 du&part D and 40 CFR Part 166.

EMERGENCY EXEMPTIONS

When a state determines that emergency conditions exist, section 18 authorizes EPA to grant an exemption from certain requirements of FIFRA. An emergency situation may exist when:

1. A pest outbreak has occurred or is about to occur and no pesticide for the particular use or alternative method of control is available to eradicate or control the pest; and

2. Significant economic oc health problems will occur without the'use of th^ pesticide; and

3. The time available £rora the discovery or prediction o£ the pest outbreak is insufficient for a pesticide to be registered for the particular use.

There are three types of emergency exemptions: specific exemptions 9 quarantine-public health exemptions, and crisis exemptions•

OPP Policy Regarding Emergency Exemptions

There are many repeat requests for emergency exemptions (same chemical/site/pest) each year. The Agency is concerned that section 18 may be used as a substitute for registration under section 3. The Office of Pesticide Programs will closely review emergency exemption requests for continued use of a pesticide on the same pest at the same site. Continued authorization of such uses will depend on adequate justification of a continual or recurring emergency situation, an analysis of potential risks and evidence of active pursuit of the registration under section 3

With respect to exemption requests for the use of multiple pesticides to deal with the same emergency situation, it is EPA^ policy not to grant emergency exemptions for the use of multiple pesticides containing different active ingredients to control the same pest on the same site. Lack of essentiality is a key factor in section 18 actions. In granting an emergency exemption for one pesticide, the emergency condition necessitating the need for a second pesticide would no longer exist, i.e., there would be an effective alternative to mitigate the original emergency condition. Also, reviewing multiple requests for the same emergency is inefficient since these resources could be more productively devoted to other emergency situations. Only under unusual circumstances, such as variable efficacy of pesticide unregistered alternatives, or when sufficient supplies o£ one pesticide are not available to meet the entire emergency need, will EPA consider granting exemptions for multiple pesticides, It is the responsibility of the requesting agency to demonstrate that special circumstances exist which would warrant an emergency exemption for the use of multiple pesticides for the same pest on the same site.

In situations where the justification for an emergency exemption request is the lack ot registered pesticides, the Agency will apply the-following in determining the validity of such requests: in instances when the pest is new at the site or was not previously a critical problem, such requests may constitute a valid emergency. On the other hand, an emergency would not normally be considered to exist when a new crop is introduced in an area where there are no Federally registered pesticides to control anticipated pests.

SPECIAL LOCAL NEEDS (SLN) PESTICIDE REGISTRATIONS

Section 24(c) permits States, upon request, to register additional uses of federally-registered pesticides to meet the needs of special local pest problems. OPP reviews SLN registrations to determine if the following criteria have been met:

1. The existence of an established tolerance which will support the registration which is 'for a food/feed use registration. Assurance that there are no geographical restrictions on the tolerance that may affect the registration.

2. Proper labeling for the registration is present.

3. For food crop products 9 a determination that all inert ingredients have proper clearance.

4. The registration is not for a product/use that has been denied, disapproved, cancelled or is currently subject to a suspension order.

5. Data, when necessary, have been submitted to support the registration.

6« The product does not contain an active ingredient that is not currently contained in a federally-registered pesticide.

ADDITIONAL INFORMATION

Questions on this Notice relating to the Emergency Exemption (section 18) program may be directed to Donald Stubbs, Registration Support and Emergency Response Branch at (703) 557-1192. Questions relating to the State registrations issued under section 24(c) should be directed to the appropriate product Manager in the Registration Division.

Edwin L. Johnson

Edwin **L<. Johnson,** Director
Office of pesticide Programs.