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Status of the Environmental Protection Agency's Review of Rodenticides

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STATUS OF THE ENVIRONMENTAL PROTECTION AGENCY'S REVIEW OF RODENTICIDES

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ABSTRACT: The EPA is currently conducting RPAR reviews on two widely used rodenticides, strychnine and Compound 1080. In addition, Registration Standards have been developed for the rodenticides warfarin and Fumarin®. The Zinc Phosphide Standard is currently under development. The author briefly explains the factors the Agency has been taking into account in reaching final resolution on these chemicals as well as outlining EPA's reregistration and RPAR programs.

I have been asked to speak to you this morning to provide a status on three rodenticides which are currently under review by the Environmental Protection Agency. These are strychnine, Compound 1080 (rodenticide uses only) and zinc phosphide. The rodenticide uses of 1080 and strychnine are being studied because of the Rebuttable Presumptions Against Registration (RPARs) issued on December 1, 1976[1], and January 13, 1977[2] respectively. Zinc phosphide is being reviewed for the development of a Registration Standard which is part of EPA's reregistration program. Since all three are used as an acute toxicant for many of the same target animals and are therefore alternatives to one another, the Agency is conducting all three reviews simultaneously. Registration Standards for two other widely used rodenticides, Fumarin®[3] and warfarin[4] and one bird repellent, 4-Aminopyridine[5], have already been issued. The RPARs for strychnine and Compound 1080 were issued because of the risk to nontarget birds and animals, including endangered species. The determination that the two rodenticides should be thoroughly investigated was based largely on laboratory LD_{50} values and on observations that nontarget animals could be at risk both from primary and secondary poisoning.[6]

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[1]41 FR 52792 (12/1/76): copies of the Position Documents 1 are available from the National Technical Information Service (NTIS), U.S. Department of Commerce, 5282 Port Royal Road, Springfield, Virginia 22161; Document #PB 80 216823

[2]42 FR 2713 (1/13/77); NTIS #PB 80 216807

[3]September, 1980; NTIS #PB 81 12812

[4]Copies of the Warfarin Registration Standard are expected in October 1981 and will be available from NTIS.

[5]September, 1980; NTIS #5AD/RS 81-00380

[6]Definitions of the risk criteria that, when met or exceeded, can trigger RPAR analyses can be found in the Federal Register of July 3, 1975 (40 CFR 162.11). These risk criteria are concerned with the following areas:

1. Acute Toxicity
2. Chronic Toxicity

(continued on next page)

Both processes, the RPAR and Registration Standards, involve a search for and evaluation of any and all relevant literature and studies. The output of the RPAR process is a set of proposed actions covering each currently registered use of the chemical. The output of the Registration Standard process is a set of criteria that define the conditions under which any pesticide containing the chemical under investigation as an active ingredient will be registered or reregistered. This includes a complete identification of "gaps" in the supporting scientific data. Registrants must commit to fill these gaps and make necessary label revisions before reregistration can occur.

The primary difference in the two processes is that in the case of the RPARs, the Agency believes that an unreasonable adverse effect to man or the environment is posed by the continued use of the chemical. Therefore, a detailed use-by-use risk/benefit analysis is undertaken and this becomes central to the decision making process. In developing a Registration Standard, a process the Agency will eventually go through for the active ingredients of all pesticides, there is no known information suggesting an unreasonable adverse effect as the Standard is developed. The Standard does not undertake an explicit risk/benefit analysis, unless of course data are discovered suggesting unreasonable adverse effects. The intent of the reregistration effort is to ensure the safety of existing pesticides and to expedite future Agency registration actions on these compounds.

In the case of the strychnine RPAR, the benefits have been defined as the increased cost of providing an equal level of control using alternative methods. Reregistration or registration of a chemical for a particular use will be allowed only if the benefits exceed the risks. This may involve maintaining the status quo or adopting certain risk reduction measures. If measures are not available or feasible such that the risks can be reduced to the point where they are exceeded by the benefits, cancellation may be proposed.

In the case of the rodenticidal uses of strychnine, four criteria were followed in developing and evaluating our regulatory options.

1. The ability to control each target rodent species was not to be taken away if at all possible.
2. The proposed actions are determined by the existence of risks, not the absence of benefits.
3. The use of an alternative method of rodent control must not increase the risk related to the benefits.

   A. Oncogenic
   B. Mutagenic
3. Other Chronic Effects
   A. Reproductive
      (1) Fetotoxicity
      (2) Teratogenicity
   B. Spermatogenicity
   C. Testicular Effects
   D. Neurotoxicity
   E. Others
4. Significant reduction in wildlife, reduction in endangered species, and reduction in nontarget species.
5. Lack of emergency treatment or antidote.

4. Any proposed risk mitigating and risk reducing measures, including the use of alternatives, must be economically feasible and viable.

The basis for the first criterion, retaining the ability to control the target rodent pest, arose from an examination of the rebuttals to the RPAR notice and a detailed benefit analysis. Although accurate figures were not provided for the amount and value of cropland, rangeland and non-agricultural site damage caused by birds and animals, the comments and analysis made the need for some controls obvious.

For some uses of strychnine the relatively small amount of bait used and the absence of any figures showing damage prevention meant that the benefits might be considered as negligible. The small amount of usage also implies, however, little potential for exposure and, therefore, little potential for risk. In the absence of data, definite, quantifiable comparisons were not possible. This need for a qualitative analysis formed the basis for the second criterion, that an absence of measurable benefits was not grounds for a proposed action.

Because an RPAR is an intensive examination of the risks and benefits of some or all uses of a single pesticide, the focus of the examination is such that the risks and benefits of alternatives are presented mainly as comparisons to the subject chemical. As mentioned earlier, the benefits of strychnine were presented as the increased costs of using alternatives. Similarly, the risks of alternatives were presented as being either greater than, equal to, or less than the chemical under investigation. In some cases, rough quantitative comparisons were possible, but in most instances, the relationships were qualitative. The purpose of the type of analysis is simply to help form a basis for developing and evaluating possible regulatory options. From this analysis, the Agency is able to predict whether an alternative is worse than the chemical being studied, in keeping with the third criterion.

Having determined that the ability to control target pests was not to be taken away, the Agency's proposed actions attempt to ensure that de facto cancellation does not occur. This de facto cancellation would arise if the alternative or use modification were too expensive to use or if no one would use the chemical because the restrictions on the use were just too much trouble, or virtually impossible to comply with. For these reasons, the Agency established the fourth criterion, that the proposed action had to be economically feasible and viable.

What were the Agency's main concerns after analyzing the risks and benefits of strychnine and the alternatives? We were concerned that we lacked data as to whether the proposed risk reduction measures would lessen the efficacy of the pesticide. We were concerned with the lack of quantitative data on benefits and risks. We were especially concerned as to whether our actions would comply with the Endangered Species Act.

In the ideal situation, just the right amount of bait with just the right active ingredient concentration is distributed in a way that all the bait is eaten by the target pests and that the animal consumes no more active ingredient than is absolutely necessary to kill it. If this happens, no risk of primary poisoning of nontarget animals would be possible and the risk of secondary poisoning would be minimized.

Unfortunately, in our investigation we could not find any data that we could use to establish the lowest efficacious active ingredient concentration and dosage combination for strychnine. The option the Agency chose in the case of strychnine was to try to elicit information from users and registrants to try to come as close as possible to the optimum of the lowest efficacious level. In the case of strychnine we selected from the myriad of currently registered labels the one with the lowest active ingredient concentration. Parenthetically, for compound 1080, the range of concentrations on the registered labels is not as great as with strychnine.

The important point is that, in the case of strychnine, our goal was to obtain data, regardless of the format, that would help us come as close as possible to the lowest efficacious level. At this point, our actions are only proposed and we are willing to alter our decisions if we are given data showing that the proposed levels will not be efficacious.

The other use modifications that concerned us were those that were designed to protect endangered species. Although the purpose of the RPAR was to determine if strychnine could continue to be used without killing nontarget animals, we realized that without cancellation, some nontarget kills are inevitable. We concluded that, given the benefits, these nontarget kills were acceptable as long as the numbers were minimized. This decision did not apply to endangered species.

Our goal is to allow the use of strychnine while precluding the possibility of jeopardizing the existance of an entire endangered species. Obviously, the easiest way to insure this is through a cancellation. However if the use is only prohibited in those areas where endangered species exist, the major uses could continue with only geographical restrictions. The problem was to prohibit the use in a manner that was both enforceable and realistic. In some cases, the ranges of these species are rather well defined, but not in terms of political boundaries. In other cases, the ranges were either not well defined or were not known.

In an effort to elicit more precise information and to establish a starting point for discussion, we proposed in the case of strychnine a prohibition of use in those counties that encompassed the ranges of the endangered species. This philosophy included the black-footed ferret, but, since the ferret could be in any county that contains prairie dogs, we proposed cancellation for prairie dog control.

What did we ultimately propose for strychnine? We retained all major uses and standardized the labels. We proposed cancellation of the minor uses and the use of strychnine for prairie dog control. We proposed geographically restricted use if endangered species are jeopardized. These are all proposed actions which were scrutinized by our scientific advisory panel in a public meeting and on which many of you have commented. We are now looking carefully at all these comments before reaching a final decision.

I have focused primarily on strychnine since the Agency has already set forth its proposed action in September 1980. The proposed action (PD 2/3) on Compound 1080 for rodent control uses has not yet been issued although the analysis and regulatory options are currently in final internal Agency review. However, much of what we learned in the strychnine proceedings will be applicable to the 1080 (rodenticide uses) RPAR. There is considerable

interest in any action the Agency might take on any of these materials and we have received much comment including some intriging possibilities for resolution short of cancellation. One of these that will be of major consideration in the final strychnine decision is the use of a precontrol survey of the area in which the material is to be used to check for the existence of endangered species.

An additional range of possibilities short of cancellation is available to the Agency given the fact that the Federally registered uses of all three rodenticides are classified for restricted use and that the states and other governmental institutions exercise oversight in the use of these materials. Further, these persons, typically professionals by training and experience, are available to consult with the users in any additional use restrictions which might be imposed on these materials. These professionals are quite aware of the acute toxicity to humans presented by these materials and know of the problems which would occur to nontarget animals and birds if the label restrictions are not carefully adhered to.

The availability of zinc phosphide will be very important in our decision-making for Compound 1080 as it was for strychnine, particularly for the prairie dog control use. Some comments received as part of the strychnine RPAR have addressed the efficacy and cost of zinc phosphide. These questions will have to be addressed in relative terms, compared to strychnine and Compound 1080.

As I stated at the beginning, zinc phosphide is in the Registration Standard process. The review and evaluation of all relevant studies and papers has been completed, and we are in the process of deciding what conclusions can be drawn and if additional studies are needed. The question of efficacy is not a part of this registration standard. The information that we will obtain from the intensive review of the zinc phosphide literature will be related only to the risks. This information combined with the information in the comments on strychnine and Compound 1080 will give as complete a risk/benefit picture for zinc phosphide as possible.

The strychnine position document was for a proposed action, and once required comments are received, we will finish preparation of the final position document. The rodenticide 1080 PD 2/3 has not yet been issued but when it is, it will be for a proposed action and comments will be solicited.[7] The thoroughness and equity of the Agency's final decision will be highly dependent on the comments we receive from persons like yourselves who are practitioners in animal control. I assure you that the Agency wants and needs any data you can provide including your reaction to the viability of our proposed regulatory actions. It is people like yourselves who use these materials and know what is and is not practical in a field situation.

In the beginning, I said that all three rodenticides had to be considered together, and that to ignore one would not give a complete picture. The decision that the Agency will make will also have three elements, none of which can be ignored -- data, timing and viable regulatory actions.

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[7]When issued the proposed decision will be published in the Federal Register. A limited number of copies of the supporting document will be available and can be obtained by writing: Director, Special Pesticide Review Division, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460. A status report on all RPAR and Registration Standards is issued periodically and may be obtained by writing to the above address.