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Steve D. Palmateer

Environmental Protection Agency

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Status of Strychnine, Compound 1080, and Registered Alternatives'

Steve D. Palmateer

Abstract.--This paper reveals the current regulatory status of 1080 and strychnine relevant to data call-in actions, administrative hearings, and litigation outside of FIFRA. All strychnine prairie dog claims are cancelled as well as all label claims requiring a tolerance. The 1080 technical is cancelled and all rodenticide uses have been issued a notice of intent to deny.

The Rebuttable Presumption Against Registration (RPAR) notice (now called Special Review), for 1080 and strychnine was published in the FEDERAL REGISTER of December 1, 1976. The presumption was against all outdoor above-ground uses of strychnine and all uses of Compound 1080. Three other actions by the Federal government should be noted. In March 1972, Executive Order 11643 was issued. This order prohibited the use of all toxicants, including strychnine, for control of predators on Federal lands or in Federal programs. In the same year, the Environmental Protection Agency (the Agency) cancelled the registrations of thallium sulfate, cyanide, strychnine, and Compound 1080 for predator control. Additionally, in February 1978, the Agency restricted products of several active ingredients, including strychnine formulations with concentrations greater than 0.50 percent, for use by certified applicators. The criteria influencing the restriction for strychnine were significant acute oral toxicity, apparent hazards to nontarget species, and the results of use and accident history.

The RPAR criteria that were determined to have been met exceeded for the outdoor aboveground uses of strychnine and all uses of Compound 1080 were: 1) acute toxicity to mammals and birds, and 2) significant reduction in populations of nontarget organisms and fatalities to members of endangered species.

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Biologist, Registration Division,
Office of Pesticide Programs, EPA
Washington D.C. 20460

Position Document 2/3 (PD 2/3), which detailed the Agency decision on strychnine, was published for comments in November 1980 for strychnine and in June 1983 for Compound 1080. In these documents, EPA proposed cancellation of many of the uses for both of these vertebrate pesticides or at least modification in terms of use. As you might expect, the Agency received numerous comments on the PD 2/3 documents. The most common criticism was that the Agency had very little definitive data to support its conclusions. The Agency felt that its worldwide literature search had yielded enough data to provide a basis for concern about potential risks to nontarget organisms. Also, as clearly required under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the responsibility for establishing the safety and efficacy of both of these vertebrate pesticides rests with the registrant and not with the Agency. A complete data base for both strychnine and 1080 had not been generated, in large part because of the uncertain registration status of the pesticides.

Therefore, EPA has issued three Data Call-In (DCI) Notices for strychnine and two for Compound 1080. EPA required that all products be supported by data necessary for registration under section 3. These actions were taken under the authority of FIFRA section 3(c)(2)(B) based on the determination that the additional data were needed to support the continued registration of both strychnine and Compound 1080 products.

The Agency required product chemistry, environmental fate chemistry, toxicology, and wildlife and aquatic organism testing. The Agency also requested the development of tolerances for these products if there is foliar contact of the pesticide with a food or feed crop, uptake of the pesticide in a food or feed crop from the soil,

or direct contact of the pesticide with a livestock animal (e.g., dermal contact or ingestion of treated bait), in which case the application is a food use, and food use requirements **will apply**. Under these circumstances, a petition for tolerance or a petition for exemption from the requirement of a tolerance is required to support registration. All registrants revised their labels to reflect nonfood uses to avoid the tolerance requirement.

EPA reviewed the data requirements very carefully before issuing the DCI documents. EPA feels that the requirements were kept to an absolute minimum to avoid unnecessary data-gathering costs and yet at the same time to provide adequate data in order to make a scientific regulatory judgment about the risks and benefits of Compound 1080 and strychnine. Several registrants requested waivers and/or postponement of data requirements and presented persuasive rationales why the waivers should be granted enabling the Agency to grant these requests.

In October 1985 and again in October 1987, EPA sent a group of its scientists and other staff to public meetings in Denver, Colorado, to explain why the data were needed, how the data should be generated, and describe the standard format for data submitted under FIFRA. The Agency also sent its vertebrate pest biologists to a meeting of the strychnine registrants held in conjunction with the Thirteenth Vertebrate Pest Conference in Monterey, California in March 1988. The most important development at this meeting was the formation of the strychnine datagathering consortium headed by the U.S. Department of Agriculture Animal and Plant Health Inspection Service, Animal Damage Control (USDA/APHIS/ADC). From the beginning of the strychnine consortium, the Agency has attempted to be helpful to the group (e.g., supplied names and addresses of all strychnine registrants, clarified many of the data requirements, reviewed hundreds of protocols, and made hundreds of determinations of data applicability from one registrant to another). USDA/ APHIS/ADC personnel were a particularly fortunate choice by the consortium to be the lead as they have quickly learned the EPA regulatory process and have kept the data-gathering costs to a minimum. In particular, we would like to single out two of the USDA's Denver personnel, Edward Schafer and Kathleen Fagerstone, who have been proficient and professional in their transactions with EPA.

data requirements. Notices of Intent to Suspend were sent to 99 companies with a total of 383 products suspended with the California Department of Food and Agriculture (CDFA) and many California counties holding about 250 of the strychnine registrations.

Fifty-six of the registrants (including CDFA acting as agent for 37 California counties) requested a hearing to avoid suspension. A pre-hearing was held in San Francisco, California, on November 30, 1988 at which the Agency and the affected registrants agreed to attempt an out-of-court settlement. On February 14, 1989, the final settlement document was mailed to all affected strychnine registrants and by March 2, 1989 all parties had signed the agreement. On March 10, 1980, the AII approved the settlement.

Several significant label claims have been eliminated as a result of the DCI Notices and/or litigation. Under terms of the settlement, strychnine products may not contain label directions for any food or feed use. Specifically, general broadcast applications of strychnine products are not allowed around food or feed crops. You should be aware that the Agency considers pasture and rangeland a feed use as a pesticide may be ingested by livestock and transported into milk or meat. The significant label target species claims eliminated are house mice, prairie dogs, and porcupines. However, there are still label claims for pocket gophers, microtus, kangaroo rats, marmots, hares, cotton rats, moles, pigeons and several bird species, although some of these species may be required to be dropped in the near future depending on whether registrants decide to produce supporting data.

In a related strychnine action on April 11, 1988, the United States District Court for Minnesota issued an injunction against the above-ground uses of strychnine. The court ordered that EPA temporarily cancel all above-ground uses. Therefore, on May 4, 1988 the Agency sent a letter to all strychnine registrants apprising them of the Minnesota court's April 11, 1988 decision and enclosed with this same letter a copy of the court order. On September 30, 1988, the Agency mailed to all registrants a copy of a notice of temporary cancellation signed by the EPA Administrator. This notice was issued by EPA to avoid a contempt citation. The notice did not rely on the authority of FIFRA but on the enforcement authority of the District Court in Minnesota under its own order. Under this proposal, registrants, distributors, and users of strychnine would be subject to contempt of court proceedings if they did not comply with the order.

STRYCHNINE

In spite of a efforts by EPA, USDA/APHIS/ADC and others to facilitate the strychnine datagathering process, it became apparent in October 1988 that the strychnine data requirements were not going to be satisfied in a timely manner. Therefore, on October 6, 1988, the Agency sent Notices of Intent to Suspend to all strychnine registrants for failing to submit product chemistry and/or failing to show significant progress towards satisfying the wildlife safety-efficacy

1080

In October 1988, the Agency also determined that it was not going to receive the data requested for both the 1080 technical products and the end-use products. Therefore, on October 4, 1988 the Agency mailed a Notice of Intent to Cancel the one Compound 1080 technical product.

This product had a conditional registration which required submission of satisfactory data to satisfy the requirements of the November 22, 1985 DCI Notice.

Several 1080 user groups felt they were adversely affected by the cancellation notice and requested a hearing to contest the cancellation. The Agency requested an accelerated decision based on failure of the Compound 1080 technical manufacturer to submit the data in a timely manner and the failure of the same registrant to comply with the Agency's December 17, 1987 offer to extend the data requirement due dates. The petitioners raised the issue of economic loss to farmers and ranchers and that the cancellation would affect the public health. The Administrative Law Judge (ALJ) ruled in favor of the Agency on the fact that none of the petitioners had challenged the basis of the notice of cancellation. On February 21, 1989, the AIJ issued a preliminary decision and cancelled the product, pursuant to regulation.

In a similar action, the Agency mailed a October 4, 1984 "Intent to Deny Applications for Federal Registration of 1080" to 19 California counties and to the Colorado Department of Agriculture in addition to a Notice of Intent to Susrc'nd to Klamath County, Oregon. At this writing, the Agency has not mailed denial notices to either the California counties or to the Colorado Department of Agriculture.

USDA/APHIS/ADC has submitted an application for registration of a Compound 1080 technical product to be used only in the 1080 livestock protection collar. Since the data base for the 1080 collar use is nearly complete, the Agency is requiring only a small amount of product chemistry data to complete all the data requirements. To date, Montana Department of Livestock, Wyoming Department of Agriculture, South Dakota Department of Agriculture, New Mexico Department of Agriculture, USDA/APHIS/ADC, and Ranchers Supply of Alpine, Texas have registered the 30 M.livestock protection collar.

The Agency has registered several new use patterns for old chemicals. These new use patterns include zinc phosphide and chlorophacinone baits for pocket gopher control, and has greatly expanded the sites and pest claims for 1339 as a gull toxicant.

A new DCI Notice has been issued for warfarin as a followup to the Warfarin Registration Standard issued in September 1981. The warfarin DCI requires very little new data as the registrants will be requested to submit or cite previously submitted data. All registrants will be requested to make label changes. Also, at this point, the data base for zinc phosphide products is not complete and EPA may have to take administrative action to expedite the submission of data on this compound.