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REGISTRATION STATUS OF VERTEBRATE PESTICIDES WITH EMPHASIS ON 1080 AND STRYCHNINE

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ABSTRACT: A review of currently registered vertebrate pesticides is reported with by far the major weight given to strychnine and 1080. The author searched the Agency's label files and has listed most of those pesticides that have claims against at least one vertebrate animal.

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INTRODUCTION

The purpose of this paper is to report on the current status of those active ingredients that purport some pesticidal activity against vertebrate pests. At one time the Agency had in its files 1,583 labels on at least 85 vertebrate pesticides (Table 1). These are pesticides registered under Sections 3 and 24 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Also included were products that were used only within state boundaries prior to 1972 (i.e., Intra-State Products used under 40 CFR 162.17).

Table 1. List of chemicals that have been listed as an active ingredient on at least one vertebrate pesticide label. Note that some of these vertebrate pesticides are no longer in use or the Agency has determined they should not be considered active ingredients.

Chemical	Chemical	Chemical
Acetophenone	DDT	Phosphorus
Allyl isothiocyanate	Diphacinone	Alpha-pinene
Alpha-chlorohydrin	Diphacinone sodium salt	Pival
Aluminum phosphide	Endrin	Pival, calcium salt
4-aminopyridine (Avitrol)	Essential oils	Pival, sodium salt
Anticycin A	Fenthion	PMP
Antimony potassium tartrate	Fumarin	Polybutenes
ANTU	Fumarin, sodium salt of	Putrescent whole egg solids
Arsenious oxide (arsenic trioxide)	Geranium oil	R-55
Barium carbonate	Gophacide	Red squill
Bayluscide	Lavender oil	Rotenone
Biomet 12	Lemongrass oil	Soap
Bitrex (Benzyl diethyl ammonium)	d-Limonene	Sodium cyanide (M-44)
Blood (dried)	Lindane (bird control use only)	Starlicide
Bone tar oil (bone oil)	Magnesium phosphide	Strychnine alkaloid
Brodifacoum	Mesurol (Methiocarb)	Strychnine sulfate
Bromadiolone	Methyl bromide	Sulfaquinoxaline
Bromethalin	Methylene chloride	Talon (Brodifacoum)
Capsaicin	Methyl nonyl ketone	TFM
Carbon disulfide	Mineral oil	Thalium sulfate
Castor oil, hydrogenated	Mustard oil	Tobacco dust
Chlorophacinone	Naphthalene (repellent use only)	Tri-n butyltin
Cholecalciferol	Nicotine sulfate	Thiram
Cinnamaldehyde	Norbormide	Thymol
Citral	Ornitrol	Warfarin
Citronella oil	PA-14	Warfarin sodium salt
Coconut oil	Pardichlorobenzene	Zinc phosphide
Compound 1080		Ziram
Compound 1081		
Copper naphthenate		

Starting in 1988 the list of vertebrate pesticides started to shrink somewhat with the call-in of the intra-state products. This meant that the owners of these products were required to submit an application for a section 3 registration and the registration had to be supported by data. FIFRA, as amended in 1988, required registrants to pay maintenance fees starting in 1989. In 1989 this fee was $425 per registered product up to 50. When the total bill reaches $20,000, the registration fee drops to $100 for each additional registered product until the total bill reaches the maximum limit of $35,000. This year the maintenance fee is $1,300 per product (except the first product is $650). Section 4 of FIFRA authorizes the administrator of the Agency to adjust the maintenance fee so that the Agency will realize an aggregate amount of $14 million. If these fees are not paid, the administrator may cancel a registration "by order and without hearing." Therefore if there is a net loss in the number of registrations, the cost of the maintenance fees may increase the next year. Reregistration of vertebrate pesticides also contributed to the decline in the number of products. While the scope of data requirements was kept to an absolute minimum in order to permit Agency scientists to make judgments relevant to the safety and efficacy of a pesticide product, some registrants did not feel that the costs of data generation would justify continued registration. Registrants who are slow to submit required data can have their product registrations suspended from further sale and distribution until the required data is supplied to the Agency. Suspended products are subject to the maintenance fees!

STRYCHNINE AND 1080

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. Additionally, in February 1978 the Agency restricted products of several active ingredients, including strychnine formulations with concentrations greater than 0.50 percent, for use only 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 or exceeded for the outdoor above-ground 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.

Position Document 2/3 (PD 2/3), which detailed the Agency's decision on strychnine, was published for comments in November 1980, 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. 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 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.

The Agency has issued three Data Call-In (DCI) Notices for rodenticidal uses 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. As a result of the requirements, 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 data-gathering 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).

STRYCHNINE

In spite of efforts by EPA, USDA/APHIS/ADC, and others to facilitate the strychnine data-gathering 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 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 prehearing 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, 1989, the ALJ approved the settlement. California Department of Food and Agriculture and the California counties have cancelled all their strychnine registrations and have submitted three section 3 applications for the following target species: horned larks, crowned sparrows, and house finches.

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, kangaroo rats, marmots, hares, cotton rats, ground squirrels, moles, and pigeons, 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.

EPA sought review of the District Court's ruling by the Court of Appeals. The Court of Appeals ruled that FIFRA provides the exclusive means of cancelling pesticide registrations. However, the Endangered Species Act (ESA) contains a citizen suit provision which allows private citizens to sue EPA to seek to enjoin violations. The Court ruled that EPA's strychnine registrations constituted prohibited takings because the decision to register or to continue these registrations was critical to the resulting poisonings of endangered species. At this writing the Agency has not acted upon the Court of Appeals ruling and is considering its options.

SODIUM FLUOROACETATE (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 adversely 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 ALJ issued a preliminary decision and cancelled the product, pursuant to regulation.

In a similar action, the Agency mailed a October 4, 1988 "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 Suspend 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 was nearly complete, the Agency required only a small amount of product chemistry data to complete all the data requirements. The Agency registered Compound 1080 technical to be used only in the livestock protection collar on June 19, 1989, to USDA/APHIS/ADC. 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 ml livestock protection collar.