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U.S. EPA

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REGISTRATION STATUS OF VERTEBRATE PESTICIDES WITH EMPHASIS ON 1080 AND STRYCHNINE

STEVE D. PALMATEER, Insecticide-Rodenticide Branch, Registration Division, Office of Pesticide Programs, U.S. Environmental Protection Agency, Washington D.C.

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.

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.

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Chemical</th>
<th>Chemical</th>
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<tbody>
<tr>
<td>Acetophenone</td>
<td>DDT</td>
<td>Phosphorus</td>
</tr>
<tr>
<td>Allyl isothiocyanate</td>
<td>Diphenacinone</td>
<td>Alpha-pinene</td>
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<tr>
<td>Alpha-chlorohydrin</td>
<td>Diphenacinone sodium salt</td>
<td>Pival</td>
</tr>
<tr>
<td>Aluminum phosphide</td>
<td>Endrin</td>
<td>Pival, calcium salt</td>
</tr>
<tr>
<td>4-aminoypyridine (Avitrol)</td>
<td>Essential oils</td>
<td>Pival, sodium salt</td>
</tr>
<tr>
<td>Anticyan A</td>
<td>Fenithion</td>
<td>PMP</td>
</tr>
<tr>
<td>Antimony potassium tartrate</td>
<td>Fumarin</td>
<td>Polybutenes</td>
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<tr>
<td>ANTU</td>
<td>Fumarin, sodium salt of Geranium</td>
<td>Putrescent whole egg solids</td>
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<tr>
<td>Arsenious oxide (arsenic trioxide)</td>
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<td>R-55</td>
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<tr>
<td>Barium carbonate</td>
<td>Gophamide</td>
<td>Red squill</td>
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<tr>
<td>Bayluscide</td>
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<td>Rotenone</td>
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<td>Biomet 12</td>
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<td>Soap</td>
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<td>Bitemx (Benzyl diethyl ammonium)</td>
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<td>Sodium cyanide (M-44)</td>
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<tr>
<td>Blood (dried)</td>
<td></td>
<td>Staricide</td>
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<tr>
<td>Bone tar oil (bone oil)</td>
<td></td>
<td>Strychnine alkaloid</td>
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<tr>
<td>Brodifacoum</td>
<td></td>
<td>Strychnine sulfate</td>
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<tr>
<td>Bromadiolone</td>
<td></td>
<td>Sulfafurazoximine</td>
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<tr>
<td>Bromethalin</td>
<td></td>
<td>Talon (Brodifacoum)</td>
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<tr>
<td>Capsaicin</td>
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<td>TFM</td>
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<tr>
<td>Carbon disulfide</td>
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<td>Thallium sulfate</td>
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<td>Castor oil, hydrogenated</td>
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<td>Tobacco dust</td>
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<tr>
<td>Chlorophacinone</td>
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<td>Tri-n butyltin</td>
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<tr>
<td>Cholecalciferol</td>
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<td>Thiram</td>
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<tr>
<td>Cinnamaldehyde</td>
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<td>Thymol</td>
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<tr>
<td>Citral</td>
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<td>Warfarin</td>
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<tr>
<td>Citronella oil</td>
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<td>Warfarin sodium salt</td>
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<tr>
<td>Coconut oil</td>
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<td>Zinc phosphate</td>
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<tr>
<td>Compound 1080</td>
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<td>Ziram</td>
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<tr>
<td>Compound 1081</td>
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<tr>
<td>Copper naphthenate</td>
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<tr>
<td>Naphthalene (repellent use only)</td>
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<tr>
<td>Nicotine sulfate</td>
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<td>Norbornide</td>
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<tr>
<td>Ornithol</td>
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<td>PA-14</td>
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<tr>
<td>Parachlorobenzene</td>
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</table>
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minimum in order to permit Agency scientists to make
judgments relevant to the safety and efficacy of a pesticide
the scope of data requirements was kept to an absolute
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
evaluations 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 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 order. 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.