OUTLOOK FOR RODENTICIDES AND AVICIDES REGISTRATION

JAMES O. LEE, JR., Chief Staff Officer, Rodenticides Evaluation Staff, Pesticides Regulation Division, Agriculture Research Service, United States Department of Agriculture, Washington, D.C.

ABSTRACT: The history of pesticide regulations is presented. Major emphasis is on federal regulations. The evaluation of avicides and rodenticides is discussed and related to regulations. Currently registered avicides and rodenticides are described along with a listing of efficacy criteria requirements. The future of registration of avicides and rodenticides is projected.

Federal legislation relating to pesticide use in the United States dates back to 1910 with passage of the Federal Insecticide Act. This consumer protection from substandard or fraudulent products was considered sufficient for the next 37 years.

In 1947, Congress passed the Federal Insecticide, Fungicide, and Rodenticide Act. The FIFRA superseded the earlier legislation and was designed as a regulatory measure. Under the Act any product considered an "economic poison" must be registered with the U.S. Department of Agriculture before it may be marketed in interstate commerce.

The FIFRA defines an economic poison as any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any insects, rodents, nematodes, fungi, weeds, and other forms of plant or animal life or viruses, except viruses on or in living man or other animals, which the Secretary shall declare to be a pest, and any substance or mixture of substances intended for use as a plant regulator, defoliant or desiccant.

The Act brought rodenticides and rodent repellents under Federal law for the first time. The shortcomings of the Act, as related to the definition of "rodent," were soon obvious but it was not until 1961 that vertebrate animals other than rodents were included.

Pesticide registrations are handled by the Pesticides Regulation Division of USDA's Agricultural Research Service. The manufacturer is required to furnish statements of the composition of the product, the names of the crops on which it is to be used, the specific conditions under which it is to be applied as well as safety and efficacy data.

Application for registration of economic poison under the Act may be made by a manufacturer, seller, shipper, or distributor.

Coverage of the 1947 Act was extended by the Nematocide, Plant Regulator, Defoliant, and Desiccant Amendment in 1959. Since 1960 these materials have been covered by the Amendment and registration requirements have been applied.

On December 20, 1961, a "Notice of Proposal to Declare certain Forms of Plant and Animal Life and Viruses to be Pests" was published in the Federal Register. This proposal was in accordance with authority granted to the Secretary of Agriculture under the basic law, wherein he is empowered to declare as pests forms of life not specifically named in the law.

This proposal was included in Regulations for the Enforcement of the FIFRA as amended August 29, 1964.

This declaration of pests includes:

Mammals - including but not limited to dogs, cats, moles, bats, wild carnivores, armadillos, and deer;

Birds - including but not limited to starlings, English sparrows, crows, and blackbirds;

Fishes - including but not limited to the jawless fishes such as the sea lamprey, the cartilaginous fishes such as the sharks, and the bony fishes such as the carp;

Amphibians and reptiles - including but not limited to poisonous snakes;

Aquatic and terrestrial invertebrates - including but not limited to slugs, snails, and crayfish;

Roots and other plant parts growing where not wanted;

Viruses - other than those on or in living man or other animals.

Public Law 88-305, added in 1964, eliminated the "registration under protest" section which permitted the sale of an unregisterable product when a protest was filed. The amendment also specified that pesticide labels must bear a federal registration number. Other provisions related to conspicuous label precautions, and the removal of unwarranted safety claims from labels.

Supplementing the 1947 Act and its amendments and regulations is the Federal Food, Drug and Comestic Act of 1938. This Act requires that tolerances be established for pesticide residues in foods.

The Miller Amendment to the Food, Drug and Comestic Act, passed in 1954, provided that any raw agricultural commodity may be condemned as adulterated if it contains a residue of any pesticide chemical, the safety of which has not been formally exempted, or which is present in excessive amounts. The Amendment gives the Secretary of Health, Education, and Welfare the power to establish residue tolerances.

The FIFRA and the Food, Drug and Comestic Act, as amended, are interrelated by law and in practical operation. Most manufacturers file for registration and petition for a tolerance or an exemption from tolerance specification simultaneously.

The "Delaney Clause" of the FDCA, which stipulates that no material capable of causing cancer may under any condition be permitted in food, also affects pesticides registration.

Most states have pesticide registration laws specifying certain controls over distribution and sales of pesticides in intrastate commerce, as well as use and application laws governing the substances themselves.

Modeled after the Federal Insecticide, Fungicide, and Rodenticide Act, the Uniform State Pesticide Act has been adopted in more or less similar form by 47 of the 50 states.

State application and use laws differ greatly. Various states have regulations regarding licensing provisions, use of pesticides, and inspection of equipment.

It is obvious that current pesticide regulation legislation has cleared many hurdles. Paralleling this torturous path has been the development of vertebrate animal control chemicals.

The mammal control chemicals in use at the time of the initial federal pesticide legislation were limited to strychnine, arsenic, barium carbonate, thallium sulphate, phosphorus, sodium and calcium cyanide, carbon disulphide, and red squill. Strychnine alkaloid was the primary predatory animal control agent. Thallium sulphate and strychnine alkaloid were basic to field rodent control. Calcium cyanide and carbon disulphide were the only burrow fumigants. Strychnine sulphate, arsenic, barium carbonate, thallium sulphate, phosphorus, and red squill were primary commensal rodent control chemicals.

The mammal control features of sodium fluoroacetate (compound 1080) had been uncovered by 1946. Red squill was being fortified by this time. Zinc phosphide was being used as a replacement for thallium in many instances.

Anticoagulant rodenticides began appearing on the market in 1950. Warfarin, fumarin, pival and diphacinone are the most familiar of these chemicals. Anticoagulant baits represent about 90 per cent of the current rodenticide market.

Rodenticides are continuing to evolve in four basic directions. Emphasis is being placed on the use of familiar rodenticides in new situations as indicated by the petition now under consideration for the use of zinc phosphide in Hawaiian sugar cane. Research in the area of acutely toxic rodenticides has produced a promising candidate in 5-chlorophenynl silatrane. Modification of concepts in rodenticides has led to some interesting experimental work with a stabilized red squill. A great deal of time has been expended in research on candidate chemosterilants. Results of this research show some promise. However, some

basic problems, such as palatable baits to act as carriers for the active ingredient, are yet to be solved.

The future of rodenticides is greatly dependent upon the continued interest and the need of the people involved in vertebrate pest control. The support of industry and governmental agencies in fulfilling the minimum basic requirements for registering rodenticides is also important. The following minimum basic requirements for registering rodenticides are those which have been developed by the USDA. These criteria do not infringe upon requirements of FDA as related to tolerances in or on food or feed however some parallelism may be obvious.

The efficacy criteria of USDA are presented as a classic laboratory and field study design. Laboratory studies must provide concrete information on the candidate rodenticide in areas of physical-chemical properties, acute oral toxicities, mode of action, secondary hazards and hazards to non-target species.

Laboratory studies designed along standardized, acceptable lines must include single cage tests, group tests, and maze tests for special claims.

Field studies must include testing in various geographic regions on target species. These tests must be acceptable in design and include pre- and post-treatment population surveys, test and control areas, and emphasize rodenticide effects on the target population.

Avicides, while not demanding professional interest as early historically as rodenticides, have followed a similar basic pattern of evolution. A good many of us are familiar with the initial mechanical methods of bird control as characterized by the scarecrow along with the use of firearms, firecrackers, carbide exploders, sticky bird repellents and dynamite in roosts. Earlier references indicate people being stationed in crop fields during critical periods and attempting to keep birds away by any method available.

As people and birds came into more open conflict, not only in agricultural but also in urban and suburban areas, it became obvious that more attention must be focused on the bird problem.

Baiting techniques were developed and attempts were made to combine these techniques with bait materials specific for the pest bird. As with rodenticides highly toxic materials like thallium sulfate, 1080, and strychnine were used initially but the hazards associated with the use of these materials soon became obvious.

Label limitations like "For Professional Use Only" were instrumental in reducing hazards. Of these more commonly recognized highly toxic chemicals only strychnine has been accepted for USDA registration. English sparrows and feral pigeons are the target animals for this registration pattern.

The professional bird control field has maintained a high interest level in highly toxic chemicals. Endrin and fenthion solutions for use in artificial perches were developed as one tool, while 4-amino pyridine (Avitrol) and 3-chloro-p-toluidine hydrochloride (Starlicide) maintained the interest in baiting techniques. The "Avitrol" and "Starlicide" approach indicated an interest in very specific bait materials while using the minimum level of active ingredient.

Minimum levels can be accomplished by incorporating the active ingredient with each particle of bait or by blending a prepared concentrate with untreated grain.

The outlook for avicides seems to be radiating in three general directions. Some emphasis is being placed on the use of avicides in or on food or feed. The temporary permit for "Avitrol" use in field corn, supported by the necessary work in establishing a tolerance and acceptable chemical analytical method, is one example.

Basic concepts in bird control were modified and re-evaluated to formulate sodium fluoride for use in bird control. This re-evaluation produced increased interest in highly toxic compounds with emphasis placed on varied modes of action. Wetting agents and "Starlicide" are examples of bird control chemicals with varied actions.

Research in the area of bird chemosterilants has resulted in the registration of 20, 25-diazacholestenol dihydrochloride (Ornitrol) for use in suppressing feral pigeon populations. The type of research which produced "Ornitrol" is now being applied to other pest birds.

The outlook for avicides registration can be categorized by the mode of action of the avicide. This action in turn determines the minimum basic requirements for registering avicides.

Again, as with rodenticides, basic requirements for registering avicides are approached from the laboratory and field study viewpoint. The laboratory studies with dermal repellents must produce data which indicate physical-chemical properties of the candidate material as well as acute oral toxicities, subacute oral toxicities, acute dermal toxicities, and subacute dermal toxicities.

Field studies should be designed on the test-control area concept, include pre- and post-treatment target population surveys, and show control success. If advanced field studies are in order, then these advanced studies should be conducted in a variety of geographic areas. Field studies should show the length of time treatment is effective and any variety in control success.

The following are registration requirements for oral toxicants used in bird control.

A. Laboratory studies
   1. Physical chemical properties.
   2. Acute oral toxicities.
   3. Sub-acute oral toxicities.
   4. Acute dermal toxicities.
   5. Sub-acute dermal toxicities.
   6. Cage tests.
      a. Single and multiple animal.
      b. Bait preference.
      c. Critical acceptance times.
      d. Bait stability.
   7. Secondary hazards.
   8. Hazards to non-target species.
   9. Specificity.
   10. Mode of action.

B. Field studies
   1. Preliminary
      a. Pre- and post-treatment population levels.
      b. Control success.
      c. Flock effect.
   2. Advanced
      a. Geographic areas on target species.
      b. Variety in control success.
      c. Significance in replications.

Most of the criteria listed above for dermal repellents and oral toxicants are also applicable as registration requirements for chemosterilants. However, data should also be submitted on specificity, reversibility, sex effected, and hazards to non-target species when dealing with chemosterilants.