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FEDERAL LABELING STANDARDS FOR ECONOMIC POISONS

Paul M. Ochs
U.S. Department of Agriculture, Washington, DC

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Staff Specialist, Rodenticides Evaluation
U.S. Department of Agriculture
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I have a joke too, Ed, about a student who attended college. This young man had been out all night, and when it came time for his class the next day, he stayed in bed. In the afternoon after he felt like getting up, he went over to the professor and said, "Excuse me professor, but I overslept and missed your class this morning and I'd like to know what you said." The professor thought he had him and answered, "Well, actually I didn't say anything." The student replied, "I know that, but I want to know how you said it."

The U.S. Department of Agriculture, Pesticide Regulation Division, has the responsibility of administering the Federal Insecticide, Fungicide and Rodenticide Act of 1947 as amended. The Act encompasses any substance or mixture of substances intended for- "preventing, destroying, repelling or mitigating any insects, rodents or any other vertebrate animals, nematodes, fungi, weeds, and any other forms of plants or animal life or viruses," except viruses on or in living man or other animals. These products must be registered if they are to be marketed or shipped in interstate commerce, imported or exported, or sold in the District of Columbia or any of the territories.

To obtain registration a manufacturer or formulator must submit an application, five copies of the proposed labeling, a complete statement of ingredients by percent, toxicity data, and adequate efficacy and safety data to the U.S. Department of Agriculture, Pesticides Regulation Division to support the petition. Such applications are reviewed by the appropriate scientific staffs of the Division to determine if the efficacy and safety data are adequate.

If you'll permit some indulgence, I'd like to read to you what the act says labeling is. The term labeling means all labels and other written, printed, or graphic matter: 1) upon the economic poison or device, any of its containers or wrappers, 2) accompanying the poison or device at any time, 3) to which reference is made on the label or in the literature accompanying the economic poison or device except to current official publications of the United States Department of Agriculture, Interior, Public Health Service, experiment stations, and so forth. In other words the term labeling is rather broad.

The Rodenticides Evaluation Staff, of which I'm a member, has the additional responsibility of reviewing applications for registration of products to be used out-of-doors to determine the hazard of such products to aquatic invertebrates, birds, fish and mammals. To do this we must have adequate data which

must be supplied by the manufacturer. Approximately two years ago a protocol for determining the hazard to freshwater fish was developed. Recently, we have proposed two protocols for determining the hazard to ground-feeding birds. One protocol is designed to provide an acute oral LD_{50} in mg/kg. The acute oral study, while not answering all the questions which arise concerning hazards, does provide us with a quick means of evaluating a possible hazardous chemical. The other protocol which we have proposed is a simulated field study which we feel will provide further information on the hazard to birds under actual field applications. Both protocols presently call for the bobwhite quail as the test species of choice. This species was selected because of the wide geographic distribution and availability. Both protocols can be modified to accommodate other species of gallinaecous birds, and in the future we plan to develop protocols for other groups of birds such as the insectivorous species and waterfowl.

Applications for registration are also referred to other Governmental agencies for advice in determining the extent of precautionary labeling necessary for the proposed use. These interdepartmental referrals are covered by an agreement, the purpose of which is to coordinate the activities of various governmental agencies pertaining to pesticides with special reference to registration and setting of tolerances.

Those applications which involve outdoor use are referred to the Fish and Wildlife Service, Department of the Interior, for advice regarding safety to wild mammals, birds, fish and food organisms, and habitat. Fish, wildlife, and bird toxicity data may include: (a) an LC_{50} in ppm on representative species of salt and freshwater fish, crustaceans, and aquatic invertebrates, (b) An acute oral LD_{50} in mg/kg on representative species of mammals and birds, (c) An approximate lethal dose for birds, either in ppm in the diet or mg/kg/day, derived from a 7 day feeding study, using a chemical, such a dieldrin as a reference, (d) Dermal toxicity as LD_{50} in mg/kg for representative species of mammals and birds.

A pesticide application in the natural environment may create hazards to fish, wildlife and birds when data indicate:

1.	Fish	LC_{50}	1.0 ppm
2.	Mammals	LD_{50}	50 mg/kg (acute oral)
3.	Mammals	LD_{50}	200 mg/kg (acute dermal)
4.	Birds	LD_{50}	100 mg/kg (acute oral)
5.	Birds	LD_{50}	200 mg/kg (acute dermal)

The acute oral dose figures may be adjusted later as more toxicity data and hazard relative to acute toxicity become available. The relationship of pesticides to any category of environmental hazard is modified when consideration is given to pesticide formulation, site, rate, method, and time of application or applications.

Fish, wildlife and bird toxicity data are shared commonly by the Departments of Agriculture and Interior. Nearly all registration applications are referred to the U.S. Public Health Service of the Department of Health, Education, and Welfare for advice regarding human safety. Mammalian toxicity data include

LC_{50}'s in micrograms per liter (or mg/L) as inhalation data, acute oral in mg/kg and dermal LD_{50}'s in mg/kg (24 hours exposure). A compound may be very hazardous when:

1. LD_{50}	50	mg/kg or less	(acute oral)
2. LD_{50}	200	mg/kg or less	(acute dermal)
3. LC_{50}	2	mg/1	(inhalation)

All such compounds would require the word "Danger" in a contrasting color, "Poison," and a skull and cross bones to appear on the label. The FIFRA requires that products accepted for registration bear precautionary statements which, when observed, are adequate to prevent injury to living man and other vertebrate animals, vegetation, and useful invertebrate animals. Antidote statements must also be present on the label.

Tolerance

As of December 31, 1967, to further protect the public health, all products specifying uses involving expectation of residues on food or feed at harvest must have a "finite" tolerance prior to registration. Such "finite" tolerances must be obtained by petitioning the U.S. Food and Drug Administration, Department of Health, Education and Welfare. Since the Department of Agriculture must certify that a pesticide is useful for the purpose intended, all data necessary for the establishment of a tolerance should be submitted to the Pesticides Regulation Division at the same time it is submitted to the Food and Drug Administration. Once a tolerance has been established then registration can be issued. Registration by the U.S. Department of Agriculture is effective for a period of five years from date of issuance, after which time it is cancelled or extended for an additional five years.

Enforcement

The Act prohibits the shipment in interstate commerce of products which are not registered or which are adulterated or misbranded. Again with your indulgence I'd like to read the interpretation for adulterated or misbranded products. The term adulterated shall apply to any economic poison if its strength or purity falls below the professed standard of quality as expressed on the label under which it is sold, or if any substance has been omitted wholly or in part from the article, or if any valuable constituent of the article has been wholly or in part extracted. The term misbranded shall apply to any economic poison or device if its labeling bears any statement designed or graphic representation relative thereto or to its ingredients which is false or misleading in any particular, to any economic poison if it is an imitation or is offered for sale under the name of another economic poison, if the labeling bears any reference to registration under

this act other than the registration number assigned to the economic poison, if the labeling accompanying it does not contain directions for use which are adequate and if complied with for the protection of the public, if the label does not contain a warning or caution statement which may be necessary and if complied with adequate to prevent injury, and so on. Products which are in violation of the Act may be seized and criminal action may be instituted against the shipper of such products. As a side note, according to an article which appeared in one of the Washington local papers, we apparently haven't done too well since we haven't arrested anybody or brought them to court in thirteen years.

The Rodenticides Evaluation Staff is also responsible for reviewing both efficacy data and directions for use of economic poisons submitted for registration as vertebrate animal control products.

Efficacy data required for all vertebrate animal control products and for avicides, encompasses such areas as:

1. Acute oral and acute dermal toxicity for each animal claimed.
2. Bait acceptance.
3. Percent of control or kill.
4. Primary and Secondary hazards on non-target species of birds and mammals.

Test methods acceptable as supporting these basic criteria are:

1. Laboratory cage tests
2. Field cage tests
3. Field studies

Other tests may be required depending on the action of a chemical and the claims made on the label.

A Laboratory cage test should be used to determine the acute toxicities (oral and/or dermal), species specificity, and oral or dermal secondary hazards. Acute studies must include several replications to obtain statistical significance. These tests are usually conducted under controlled environmental conditions.

Field cage tests should be conducted as a link between the laboratory, under controlled conditions, and the field, under natural conditions. In these tests determinations, such as: effects of climatic factors on the chemical, on the formulation and/or the carrier, reaction time in or on the bird, effects on groups of birds and reacceptance, should be made. Lack of positive results at this stage negate the necessity for further testing.

Field tests vary widely to their method of conduct. Generally, data from field tests include: bait acceptance, degree of control, and flock response. Data are also collected on translocation, human hazards, decontamination and effects on non-target species. Other data which may be required include physiological effects and repellency.

Any mechanical contrivance which may be used to repel or trap birds and mammals is termed a device and is not subject to registration under FIFRA. However, any collateral labeling or advertisement which may accompany the device is subject to FIFRA, and the claims made must be documented by scientific data.

It is readily apparent that much effort must be expended by both industry and government in the preparation of adequate labeling for pesticides. It is also apparent that the ultimate responsibility for proper use is with the user. Pesticide regulations relating to product labeling are fulfilled when the user reads, understands, and follows the label.

DISCUSSION:

SPITZ: You said that devices are not subject to labels, but any accompanying data is subject to a label. Does that mean a man could use a device if he is given oral instructions on how to use it, and not be subject to the regulatory agency?

OCHS: Actually the device itself, the unit, the trap, the biosonic sound device is not subject to the act. The only thing that is subject to the act is the collateral labeling, advertisement, and so forth. Let's say you own the device, you operate it, you set it up for the man, etc.; this is still your device, and it has not entered into interstate commerce. If you give it to one of your employees and he does likewise, it's still your device; it's not in interstate commerce.

SPITZ: What if I sell it?

OCHS: If you sell it and it's in interstate commerce, then the labeling or the claims must be supported.

SPITZ: What if there are no labels? Then is it subject to the act?

OCHS: If there is no label how can it be subject to the act?

QUESTION: Does advertising constitute a label?

OCHS: According to the act, yes.

STECKEL: Do instructions constitute a label?

OCHS: Verbal instructions, as you know Jim, would be pretty hard to tie down.

STECKEL: O.K. let's say printed instructions? If they're attached to or mailed with?

OCHS: Yes, if they are meant to accompany the device, they would be considered collateral material.

SEUBERT: Did I hear you mention anything about the need for determining the rates of degradation? What are the requirements?

OCHS: Again, it gets into the area of tolerance. And on strict orders from the Director, he says, "Any product that will be used on a crop that may be used for food or feed will have to be subject to tolerances."

SEUBERT: What about latent effect; like something used on crop land when the crop isn't growing? We're personally concerned about these possibilities and are looking into it. But regulations don't take this into account.

OCHS: There is consideration given to this; yes, there is degradation. This data must be submitted prior to the establishment of a tolerance. Data must include degradation in the soil, in the leaf, and in water.

SEUBERT: Can you give us an idea of the average time required for registration research and the average cost?

OCHS: I sure can't. Large sums of money is all I can say.

LIEB: Is there any change in regulations of shipping liquid chemicals in glass?

OCHS: Not that I know of now. There is one area due to the accident in Mexico with parathion when they shipped the parathion with bread. I believe now that you cannot ship pesticides with food; you cannot store pesticides with food. But to answer whether it can or can't be shipped in glass, I don't think this is under our act; it may be under ICC regulations; I don't know.

SPEAR: Would you run quickly through the matter of experimental or temporary registration?

OCHS: An experimental permit is a temporary registration which generally lasts for one year. It is usually used to obtain data on the effectiveness of a particular chemical. There are some areas where an experimental permit is not required and, if you'll permit again, I'll read. . . "A substance or mixture of substances being put through tests in which the purpose is only to determine its value for economic poison purposes or to determine its toxicity or other properties, or where the user does not expect to receive any benefit from pest control in its use is not considered an economic poison within the meaning of Section 2-A of this act. Therefore no permit under this act is required for its shipment." There is one area which has a direct affect on this; the Food and Drug Administration will not issue a temporary tolerance if there is no temporary permit issued. Therefore if you intend to do these kind of tests, ship it interstate, eventually end up on a food crop, you must have an experimental permit, and you must have temporary tolerance from the Food and Drug Administration.

STECKEL: On reregistration, after your registration runs out, are they now asking for further data or different data than they did in the past?

OCHS: This depends on what you want to do in the way of a reregistration. If it is just that you want to maintain the present registration, no further data is required. If you want to change the formulation, then data may be required to show that additional toxicant or chemical in the formulation is necessary. If you change the formulation drastically, then I would suspect you'd better be prepared to do the whole works over again. And this has happened.

SPITZ: On what basis would a label registration be withdrawn?

OCHS: This is extremely difficult to do, really. On the basis of human hazard, primarily, registration has been withheld. In two instances I know the human hazard was so high that it was felt that the human hazard outweighed the worth of the chemical.

STECKEL: In the area of bird management what are some of the materials and devices that have to be registered?

OCHS: Anything that is an economic poison that has claims for repelling, mitigating, controlling, etc. Even your sticky repellents have to be registered. Devices also, as determined by our legal staff; again, the device itself does not come under the act, only the collateral labeling—the present interpretation says "which is shipped with," or a statement made on the label which refers to another publication which may be obtained upon writing to the company. A lot of people do this; it is perfectly all right, 1080 for one and some others. But all this collateral labeling has to be registered.

SEUBERT: You said anything that mitigates, repels, etc. is considered an economic poison. Is a surfactant considered an economic poison?

OCHS: No, under the normal terms of a surfactant. It would generally be considered an inert ingredient. However, if you make claims for a surfactant this, I would then think would be an economic poison.

SEUBERT: What if the effect is not a poisonous effect, per se?

OCHS: Well, the same would apply as with the sticky repellents.

SEUBERT: I'm not concerned now with the claims of advertising; I'm concerned just whether a surfactant is a poison, per se by definition, or if the material actually causes the demise of a bird and yet again is not a poison?

OCHS: I would think you would again come under the act, because the act spells out "to repel, control, mitigate, or prevent." I don't know how you can get any broader than that.

COMMENT: Then it is an economic poison?

OCHS: Well, the term economic poison itself is very broad. Here: "The term economic poison means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any insects, rodents, and so on."

COMMENT: Paul, then in the case of a repellent, sticky material, the label needs a formula and the active ingredients must be explained in a percentage list?

OCHS: Yes, and the acceptable chemical names for the active ingredients.

QUESTION: How do you determine the active ingredients and the inert ingredients?

OCHS: Well, in the case of the sticky repellents they are considered 100% active ingredients.