

Federal Registration Of Herbicides

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The Pesticides Regulation Division of the United States Department of Agriculture administers the only Federal law dealing directly with pesticide products in interstate commerce.

All products intended for use against weeds, i.e., any plant growing where it is not wanted, are defined as herbicides under the Federal Insecticide, Fungicide, and Rodenticide Act. Interstate shipment of such products requires compliance with this law.

In addition to herbicides, the term "economic poison" is defined to include any substance or mixture of substances intended for use as: Insecticides, Fungicides, Rodenticides, Nematocides, Germicides, Plant Regulators, Plant Defoliants, Plant Desiccants and products intended for use against Amphibians, Reptiles, Birds, Fish, or Mammals.

This Act requires that all products intended for use as economic poisons be properly labeled and registered with our Division prior to entry into interstate commerce.

To obtain registration and be able to legally ship a pesticide product in interstate commerce, a manufacturer must submit an application, copies of his proposed labeling, a statement of complete composition of the product, and if requested, adequate data to support the proposed use. He would not be required to submit complete data to support a use pattern for which data has already been submitted and found adequate.

Applications for registration are reviewed with three basic questions in mind. These are:

I. Will the product be effective for the purposes claimed in the labeling and can it be used effectively without causing damage to the crop or property to which it is applied?

The effectiveness of certain herbicides for controlling water hyacinth is well established. This factor is not a bar to registration for these herbicides. Of course, a new or little known chemical proposed for this use would have to be supported by effectiveness data.

In addition to simply being effective, the proposed use must be relatively free from adverse side effects. A formulation proposed for use in controlling weeds in citrus groves would not be acceptable if the directed use caused significant damage to the trees.

II. Does the product label bear precautionary statements which are adequate, when complied with to prevent injury to the user and other persons or beneficial animals which may be exposed?

The Federal Act requires that products accepted for registration must bear such precautionary labeling. It further provides that regulated products must not be, to a significant degree, injurious to beneficial forms of life when used as directed or in accordance with commonly recognized practice.

The precautionary labeling requirements and the toxicity of many of the aquatic herbicides are also well known. Products like 2-4-D have been handled and used safely for many years.

We have interpreted this to mean that proposed directions for use must be practical and likely to be understood and followed by the user of the product.

The extent of precautionary labeling required depends on the nature and toxicity of the proposed product and the potential hazard involved. For example, those products which are highly toxic as described by regulation (Section 362.8) either by ingestion, skin absorption, or inhalation are required to bear extensive precautionary statements, including: The skull and crossbones, the word POISON (in red on a clearly contrasting background), the signal word DANGER, the statement "KEEP OUT OF REACH OF CHILDREN," and an antidote statement. All of this must appear on the front panel of the label, while other required warnings and cautions may be placed elsewhere on the label. Remember that the greater the requirements for precautionary labeling the more important it becomes that it be carefully read and followed.

Regulations for the enforcement of the Federal Act (CFR Title 7, Chapter III part 362) require that specified warning statements appear on the front panel or that part of the label displayed under customary conditions of purchase. Additional precautions other than the required signal word (DANGER, WARNING, or CAUTION) and the statement "KEEP OUT OF REACH OF CHILDREN" may be placed on another part of the label if some reference to its location is made in the vicinity of the signal word.

Our Division has benefited greatly by being able to consult experts in other Government agencies in determining the extent of precautionary labeling necessary and the safety of the proposed use.

Applications involving the use of aquatic herbicides are referred to the Fish and Wildlife Service of the Department of the Interior for their advice regarding safety to fish and other beneficial wildlife.

III. Does the proposed use of the product involve food? I do not believe water has been legally defined as food; however, we cannot logically consider the treatment of potable water as a nonfood use.

Products with directions for use on food or feed are registered on the basis of finite tolerances or exemptions from the need of tolerances to cover any residues likely to result from the directed use. In the past, we have accepted such uses when adequate residue data were submitted to show that the directed use would not result in detectable residues on harvested food or feed. Although, this was satisfactory in most cases, the development of more sensitive analytical methods often invalidated these "no-residue" acceptances. This sometimes resulted in food seizures and made it necessary for us to cancel or amend the registered use pattern. Indemnification programs whereby farmers have been paid for milk or other condemned commodities because of pesticide residues result in from the directed use have resulted.

In an effort to resolve this problem our Division and the Food and Drug Administration requested that the

"no-residue" and "zero tolerance" concepts be reviewed by a committee appointed by the National Academy of Sciences of the National Research Council. After a thorough study, the committee submitted a report in June of 1965, with several recommendations for changes. The committee felt that the zero tolerance and no-residue concepts were scientifically and administratively untenable and should be abandoned. It recommended instead that pesticides be registered on the basis of negligible residues or permissible residues.

This report was thoroughly evaluated by the two agencies and a joint USDA-HEW statement was published in the Federal Register on April 13, 1966. This action abandoned the "no-residue" and in most cases the "zero tolerance" concept of registering pesticides in favor of registrations based on finite tolerances. We do not register products for a new use in a manner reasonably expected to leave residues in or on food in the absence of a finite tolerance.

Applications for registration of products involving directions for the use of herbicides or other economic poisons in potable waters are not acceptable for registration in the absence of a finite tolerance to cover residues likely to result from the directed use.

If either the Food and Drug Administration of the Department of Health, Education, and Welfare or the agency within the Department of the Interior with legislative responsibility for the purity of drinking water would set legal tolerances or standards to cover residues from herbicide use, we could accept such uses. Then, and only then, can we register 2-4-D or other herbicide products for controlling water hyacinths in potable waters.

We will continue to work closely with all interested parties in an effort to solve the many problems encountered in the control of pests. We are all consumers and the responsibility for promoting the advancement of the health and well being of the American people rest equally with all public servants.