

Residue Tolerances For Aquatic Herbicides¹

J. G. CUMMINGS

Chief, Chemistry Branch, Registration Division
U. S. Environmental Protection Agency
Washington, D.C. 20460

ABSTRACT

Events in the late 1960s leading to development of a mechanism for sanctioning aquatic pesticide usage by the federal agencies are described. Procedures for obtaining pesticide residue tolerances in potable water, irrigated crops, and fish, under the Federal Food, Drug and Cosmetic Act (FFDC) and registration procedures under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) are discussed. Data requirements include residue studies and toxicology data. The relationship between tolerances set under the FFDC Act for residues in potable water from purposeful addition and the Drinking Water Standards promulgated by the Environmental Protection Agency is clarified.

INTRODUCTION

It might be well to consider for a moment the development of aquatic-use pesticide petitions, in the hope that we can expedite such future petitions, and at the same time, to acknowledge the persistence and tenacity of the U. S. Army Corps of Engineers in pursuing the tolerance for the amine salt of (2,4-dichlorophenoxy)acetic acid (2,4-D amine) for use in their waterhyacinth [*Eichhornia crassipes* (Mart.) Solms.] control program. The tolerances

proposed by the Corps for potable water, fish, and shellfish are now under final administrative review and will be announced shortly.² Other pending aquatic-use petitions are briefly listed in Table 1.

HISTORY

The first question one might ask is, "Why do we need this tolerance regulation under the Federal Food, Drug and Cosmetic Act (FFDC Act) to sanction a successful program which has been ongoing for many years?" To answer this, we have to look back about 6 or 7 years when the federal agencies which were engaged in large scale aquatic weed control programs began to be concerned about their operations. Pressures were being brought to bear from a number of sources:

1. The Federal Working Group on Pest Control requested that the Tennessee Valley Authority, Bureau of Reclamation, and Corps of Engineers obtain the sanctions of the federal regulatory agencies for continuation of their aquatic pest control operations.
2. Some Departments, notably the Department of the Interior, issued directives that only registered pesticide uses could be employed in Department programs.
3. Certain local action groups were questioning whether

¹Paper presented at Research Planning Meeting, U. S. Army Corps of Engineers, Charleston, South Carolina, 22 to 25 October 1975.

²The tolerances were published in the Federal Register 16 December 1975.

TABLE 1. PETITIONS FOR AQUATIC USES CURRENTLY UNDER AGENCY REVIEW OR IN ABEYANCE^a (22 OCTOBER 1975).

Pesticide	Petitioner	Use	Status
Diquat (6,7-Dihydrodipyrro[1,2-a:2',1'-c]pyrazinediium (salt)	Corps Eng.	Ponds, lakes, slow moving water	active review
Endothal (3,6-Endoxohexahydrophthalic acid)	Pennwalt	Lakes, ponds, irrigation ditches, canals	active review
Glyphosate (N-Phosphonomethyl)glycine)	Monsanto	Irrigation water	active review
2,4-D (2,4-Dichlorophenoxyacetic acid)	TVA	Watermilfoil, TVA system	abeyance ^b
2,4-D, BEE (Butoxy ethanol ester of 2,4-D)	Corps Eng.	Hyacinths, ponds, lakes, slow moving water	abeyance
Silvex (2,2,4,5-Trichlorophenoxy) propionic acid	Corps Eng.	Hyacinths, ponds, lakes, slow moving water	abeyance
Dichlobenil (2,5-Dichlorobenzonitrile)	Thompson-Hayward	Farm ponds, fish farming, other bodies under control of user	abeyance
Dalapon (2,2-Dichloropropionic acid)	Bur. Recl.	Irrigation ditch bank	abeyance
Fenac (2,3,6-Trichlorophenylacetic acid)	Amchem	Flowing and nonflowing water, lakes & ponds with low exchange	withdrawn

^aAquatic herbicides for which tolerance or exemption regulations have been issued: Basic copper carbonate, copper triethanolamine, basic copper sulfate, xylene, simazine (2-chloro-4,6-bis(ethylamino)-s-triazine), and 2,4-D amine salt (ponds, lakes, and ditch bank use).

^bAbeyance—petition for tolerances has been denied pending submission of supplemental information.

the resulting pesticide residues in public drinking water supplies were safe. There were lawsuits brought against federal agencies because of pesticide treatments in aquatic sites.

4. Proposed amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) would make it an offense to use a pesticide in a manner other than as described on registered labels.

At about this time, the federal "user" agencies approached the federal regulatory agencies and pointed out that the use of aquatic herbicides was essential in carrying out their responsibilities. They asked for the establishment of a mechanism by which sanction of the regulatory agencies could be obtained.

DEVELOPMENT OF POLICY

Two federal statutes did offer some means of a formal assessment of safety. The major difficulty was, that the Pesticide Amendment of the Federal Food, Drug and Cosmetic Act was designed to set legal residue tolerances for agricultural uses on raw agricultural commodities and not in water; and the Federal Insecticide, Fungicide and Rodenticide Act controlled only the shipment and use of pesticides. After much study, the legal groundwork was laid for a workable procedure. Basic to this was a finding that potable water was a processed food within the meaning of the FFDC Act, and that a pesticide residue contributed to potable water from purposeful use was a Food Additive within the meaning of Sect. 409 of the Act. A tolerance under the FFDC Act became prerequisite for registration. In August 1970 the USDA Pesticide Regulation Division announced that registration for aquatic uses would be cancelled unless tolerances were obtained. The policy was officially endorsed at the highest levels of Departmental authority by the Secretaries of Agriculture, Interior, and Health, Education and Welfare in a statement in the Federal Register of 3 March 1970 in which it was agreed that tolerances for pesticides in water should be established under the FFDC Act.

DATA REQUIREMENTS

Having ascertained that legal tolerances for potable water could be established, the Food and Drug Administration, (EPA and later the Environmental Protection Agency) set about developing the data requirements which would be necessary. Agency spokesmen presented data requirements at meetings of the professional societies (Weed Science Society of America, American Fisheries Society). Simply stated the requirements were: If the prescribed use is such that there is a reasonable expectation of residues in potable water, fish or shellfish, irrigated crops, or in meat, milk, eggs, it would be necessary for the user agency to conduct residue studies to show what levels are to be expected in these commodities. Toxicology data are required to show that the predicted levels are safe for human consumption.

Fortunately, the federal agencies were using herbicides on which the long term toxicology work had been com-

pleted to support existing tolerances on crops. The agencies were not so fortunate with respect to the residue data which were available. Pesticide manufacturers would ordinarily carry this burden, but in general declined the task on the grounds that their return on research expenditures would not justify the investment. The implied message was that the government is the primary user of aquatic herbicides, therefore it was the public agency's responsibility to generate the residue data. It must be noted however, that certain manufacturers did make data available to the petitioning Agency and provided valuable cooperation.

Why the need for residue data? The most obvious answer is that the residue information is used to gauge the extent of exposure to the public so that risks may be evaluated. The need also derives from certain inherent principles in the FFDC Act. The first is that the tolerance set for a chemical in a food should be no larger than is necessary to accomplish the intended effect; secondly that the tolerance should reflect the residue levels likely to occur in the food; and last, that an analytical method to enforce the tolerance must be available.

The research required to establish the identity and magnitude of residues from agricultural uses on crops are fairly straightforward. The research required to show the level and identity of residues which can result in irrigated crops, fish, shellfish, meat, milk, eggs, and potable water at a given point in time after an aquatic pesticide use is enormously complicated. The EPA, as a regulatory agency, was unable to furnish the user agencies with precise experimental protocols, and on the other hand, the user agencies lacked the considerable experience and expertise necessary in the preparation of successful petitions for tolerances. This combination of circumstances led to many frustrating experiences and delays, which hopefully are behind us as experience is gained on both sides.

It is most important to understand that the more tightly circumscribed the aquatic use, the less residue research is required. For example, the Bureau of Reclamation petition for 2,4-D tolerances was more simple to prepare than the one submitted by Corps of Engineers; this occurred because the Bureau's specialized use of 2,4-D in the western irrigation systems excluded consideration of fish, shellfish, and livestock. The Corps of Engineers' petition for 2,4-D in waterhyacinth control in impounded or slowly moving waters did present the possibility of residues in fish, shellfish, meat, milk, and eggs and therefore required extensive data (including metabolism studies) on the residues occurring in these commodities. It follows then, that the Food Additive Regulation which established a tolerance of 0.1 ppm in potable water at the request of the Bureau of Reclamation would specifically restrict the pesticide usage to the programs of the Bureau and cooperating agencies in the western irrigation districts. Similarly, the regulation issuing in response to the Corps of Engineers proposal will limit the usage to hyacinth control by the Corps or other official agencies as specified in the petition.

The EPA is frequently asked why it is necessary to publish a separate regulation covering each agency's use of 2,4-D. Or, put another way, why the established tolerance

of 0.1 ppm for 2,4-D in potable water doesn't provide an umbrella for registration of general aquatic uses of 2,4-D. The foregoing comparison of the two petitions provides the answer. It would be virtually impossible to design a set of experiments to show residues which could result in various foods from the multiplicity of aquatic sites where 2,4-D can be effectively used. The policy of prescribing in the regulation what agency is to supervise the treatments and the conditions of use was adopted partly in order to reduce the research effort required of the petitioner. Also, the Food Additive Amendment requires [Sec. 409(a)(2)] that the regulation prescribe the conditions under which the additive may be safely used. It is anticipated that the present Food Additive Regulation (§ 123.110, CFR Vol 40) for 2,4-D in potable water can be consolidated when sufficient data are available to support more general use.

A final word of advice to prospective petitioners for aquatic uses would be appropriate. This concerns the restrictions associated with the use. The practicality of such usage restrictions is a most important consideration. For example, toxicology considerations may limit the tolerance to some level that cannot be achieved without a holding period before the water can be used. Such restrictions require that the body of water is entirely under the control of the user agency. It should also be pointed out that when proposing restrictions (e.g. - "do not take fish for 2 weeks," or "do not use water for domestic purpose for 2 weeks"), the user agency assumes the responsibility that such restrictions are practical and can be enforced. As a corollary, the pesticide treatments should not be made on bodies of water where the use restrictions cannot be enforced.

FOOD ADDITIVE TOLERANCES AND DRINKING WATER STANDARDS

Some confusion might be allayed by a discussion of the relationship between the tolerances for potable water set under authority of Sec 409 of the FFDC Act by EPA and the "National Interim Primary Drinking Water Regulations," established pursuant to sections 1412, 1414, 1415 and 1450 of the Public Health Service Act as amended by the Safe Drinking Water Act of 1974, (PL 93-523) also administered by EPA. Standards for maximum contaminant levels for certain pesticide chemicals, (including 2,4-D at 0.1 ppm) have been established under the Safe Drinking Water Act (§ 141.12, CFR, Title 40). The only pesticide

chemical at this time with a common tolerance or standard under both Acts is 2,4-D. Liaison has been established between the Office of Water Programs, EPA, and the Office of Pesticide Programs, EPA to assure uniformity of the criteria issuing from the respective Offices.

While there would appear to be some overlapping of responsibilities between the two functions, there are important differences. The Food Additive tolerances conform to the legislative philosophy of the authorizing amendment; namely, that the regulations are intended to control a useful and purposeful addition of a chemical to foods, that the residue level permitted in the food shall be no higher than necessary to accomplish the intended effect, that the regulation shall specify the conditions of use, and that an analytical method is available to enforce the regulation. The initiative for a Food Additive tolerance is assumed by the proponent of the use (usually the manufacturer but in the case of potable water, more typically a federal agency), and the burden of proof lies with the petitioner. Enforcement action could be taken if necessary by the FDA under Sec 402(a)(2)(c) of the FFDC Act which provides that a food is adulterated unless the added substance is covered by a Food Additive regulation. However, no federal enforcement actions have been found necessary to date on community water supplies and it is likely that any enforcement action taken would be by local public health authorities using the Food Additive tolerances as a guideline.

The Interim Primary Drinking Water Regulations are essentially a revision of the Public Health Service Drinking Water Standards, but differ in that the former are enforceable while the latter were, for the most part, merely guidelines. While the promulgation of the Drinking Water Regulations was directed by an Act of Congress, the selection of constituents to be controlled was initiated by the Agency. Selection was based on three general criteria: (1) the constituent must appear in drinking water, whether naturally or by act of man, with some frequency and at levels of health significance; (2) the constituent must present a hazard to the health of consumers; and (3) the constituent must be capable of being measured at the levels of concern. When the Interim Primary Drinking Water Regulations become effective in June, 1977, there must be monitoring at the local level, and any necessary enforcement action is to be taken by the State if the State has primary enforcement responsibility. If such is not the case, the EPA will assume enforcement responsibility.