

LEGISLATION AND REGULATIONS

Proposed residue tolerances and operating procedure under Miller Amendment announced by FDA

PROPOSED REGULATIONS to establish pesticide residue tolerances for fruits and vegetables, and the proposed operating procedure for application for residue tolerances have been announced by the Food and Drug Administration. The proposed regulations will become official after 60 days if no interested parties file exceptions.

The proposed tolerance regulation establishes tolerances for 26 pesticides in common use based on the scientific data presented at the hearings held in 1950 under section 406 of the Food and Drug Act. The operating procedure proposed in the second regulation outlines the program to be followed in application for pesticide residue tolerances. The proposed procedure is the result of the Miller Amendment (Public Law 518) which became law July 22 of this year.

The table of tolerances gives the name of the pesticide, the amount of tolerance to be allowed and the food crops to which these tolerances apply. Under the proposed regulation fruits and vegetables can be distributed in interstate commerce only if residue present on the commodity does not exceed that established by the FDA.

Zero Tolerances Established

The proposed regulations provide zero tolerances on nine types of insecticides: Calcium cyanide, dinitro-*o*-sec.-butylphenol, dinitro-*o*-cresol, hexaethyl tetraphosphate, tetraethyl pyrophosphate, hydrocyanic acid, mercury compounds, nicotine and nicotine compounds, selenium, and selenium compounds. Under the regulation no fruits or vegetables containing detectable residues of these pesticides can be transported in interstate commerce.

The zero tolerance will probably not have any appreciable effect on agricultural usage of some of these pesticides, calcium cyanide and hydrocyanic acid for example, which are dissipated so rapidly after application that they are not ordinarily present at the time commodities are shipped.

Some of the other zero tolerances, mercury and nicotine compounds for example, may require a modification of some existing practices.

The proposed tolerances announced

by FDA were based on the 1950 pesticide tolerance hearings and technological advances of the past 4 years were not considered in these residue tolerances. Under the operating procedure proposed to meet the provisions of the Miller Amendment recent scientific data can be filed in application for a new tolerance.

The zero tolerance will probably be proposed by FDA in situations where it is believed that any amount of the residue, however small, would be unsafe for consumers or where there is insufficient data to establish a safe tolerance.

In a number of cases the evidence presented in the 1950 hearings was not sufficient to provide a basis for establishing tolerances. Applications for tolerances for these pesticides and any others which have been developed since 1950 will be processed under the Miller Amendment.

Operating Procedure

The proposed operating procedure based on the Miller Amendment would:

1. Set up exemptions for a group of common pesticides which are entirely safe when properly used on growing crops. These are: common copper compounds (except those containing arsenic); petroleum oils; pyrethrum, rotenone, and four synergists used to

enhance their effects; ryania, and sabadilla. The latter two, like pyrethrum and rotenone, are insecticides derived from plants. The exemptions do not apply when this group of materials is used at time of harvest or after harvest.

2. Establish operating procedures and fees to make administration of the new law self-supporting. The proposed application fee for a new tolerance is \$500 and for extending a tolerance to additional crops, \$140.

3. Set up procedure for the appointment by the Department of experts selected by the National Academy of Science to committees to advise the Department in regard to controversial scientific questions arising in the establishment of tolerances. The cost of an advisory committee would be paid by the person requesting that it be appointed.

Under the new law the Secretary of Agriculture is required to certify whether a pesticide chemical is useful in agricultural production before the Secretary of Health, Education, and Welfare is required to act upon a petition to set up a tolerance for that chemical. All economic poisons (pesticide chemicals) which move interstate must be registered by the U. S. Department of Agriculture under the Federal Insecticide, Fungicide, and Rodenticide Act of 1947 and labeled according to that law.

The new Miller Amendment to the Federal Food, Drug, and Cosmetic Act makes the Secretary of Health, Education, and Welfare responsible for protecting the public health from foods exposed to dangerous amounts of pesticide chemicals.

Pesticides Tolerances Proposed by FDA

Pesticides	Tolerance in Parts Per Million	Pesticides	Tolerance in Parts Per Million
Aldrin	0.1	2-Heptadecyl glyoxalidine	5
Benzene hexachloride	5	Lead arsenate	7 (of combined lead) except on citrus
Calcium arsenate	3.5 (of combined As ₂ O ₃)		1, citrus
Copper arsenate	3.5 (of combined As ₂ O ₃)	Magnesium arsenate	3.5 (of combined As ₂ O ₃)
DDT	7	Methoxychlor	14
2,4 - Dichlorophenoxy acetic acid	5	Naphthalene acetic acid	1
Chlordan or heptachlor	0.1	Parathion	1
Dicyclohexamine salt of dinitro-O-hexylphenol	1	Phenothiazine	7
Dieldrin	0.1	Sodium arsenate	3.5 (of combined As ₂ O ₃)
EPN	3	Tartar emetic	3.5 (of combined Sb ₂ O ₃)
Ferbam	7	TDE	7
Fluorine compounds	7 (of combined fluorine)	Texaphene	7
		Zineb	7
		Ziram	7