2,4-D/TOX 315 (62)

Releasable

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[PP 2E1293/7E1980/P197; PH-FRL-1968-1]

2,4-D; Proposed Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This notice proposes that a tolerance be established for the pesticide 2,4-D (2,4-dichlorophenoxyacetic acid). This proposal was submitted by the Interregional Research Project No. 4 (IR-4). This amendment will establish a maximum permissible level for residues of 2,4-D on apricots at 5 parts per million (ppm) and millet grain at 0.5 ppm and millet forage and straw at 20 ppm.

DATE: Comments must be received on or before November 27, 1981.

ADDRESS: Written comments to: Donald R. Stubbs, Emergency Response Section, Registration Division (TS-767C), Environmental Protection Agency, 401 M Street, SW, Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Donald Stubbs, (703) 557-7123 at the above address.

SUPPLEMENTARY INFORMATION: The Interregional Research Project No. 4 (IR-4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903, has submitted to EPA pesticide petition PP 2E1293 on behalf of the IR-4 Technical Committee and the Agricultural Experiment Station of California, and PP 7E1980 on behalf of the IR-4 Technical Committee and the Agricultural Experiment Stations of Colorado, Kansas, Minnesota, Nebraska, Nevada, and North Dakota.

The petitions requested that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act propose the establishment of a tolerance for residues of 2,4-D (2,4-dichlorophenoxyacetic acid) from application of its dimethylmine salt in or on the raw agricultural commodity apricots at 2 ppm (PP 2E1293) and the establishment of tolerances for residues of 2,4-D and its metabolite 2,4-dichlorophenol (2,4-DCP) in or on the raw agricultural commodities millet grain at 0.5 ppm and millet forage and straw at 20 ppm (PP 7E1980). Later PP 2E1293 was amended to propose a tolerance of 5 ppm in or on apricots. It was also later determined that tolerances in millet grain, straw and forage should be in terms of 2,4-D *per se* rather than in terms of parent plus metabolite.

The data submitted in the petitions and all other relevant material have been evaluated. The pesticide is considered useful for the purposes for which the tolerances are sought. The toxicological data considered in support of the proposed tolerances for residues of 2,4-D, dimethylamine salt, on apricots at 5 ppm included a two-year rat feeding study (using 2,4-D acid) with a no-observed-effect level (NOEL) of 1,250 ppm, a two-year chronic feeding study in dogs (using 2,4-D acid) with a NOEL of 500 ppm, and a 3-generation rat reproduction study of 1500 ppm (2,4-D acid) which showed no reproductive impairment but did suggest slight toxicity to weanlings at 100 ppm. Several teratology studies are positive but have NOEL's for fetotoxicity at 25 mg/kg (of dimethylamine salt) and 40 mg/kg (of 2,4-D acid) for terata in the rat and hamster respectively; the margin of safety for teratogenicity for the proposed use on apricots is approximately 2400.

The toxicological data considered in support of the proposed tolerances for residues of 2,4-D and its metabolite 2,4-DCP in or on millet grain at 0.5 ppm and millet forage and straw at 20 ppm included acute rat oral lethal dose (LD_{50}) studies of 2,4-D, its sodium salt, and various esters at levels ranging from 300 mg/kg of body weight (bw) to about 640 mg/kg bw; a 22-week cattle feeding study with a NOEL of 50 mg/kg bw; a 32-week rat feeding study with minimal changes at 1,000 ppm; a 113-day rat feeding study with a NOEL of 300 ppm; a 90-day dog feeding study with a NOEL of 400 ppm; a rat reproduction study with a NOEL of approximately 100 ppm; a two-year dog feeding study with a NOEL of 500 ppm; and a two-year rat feeding study with a NOEL of 1,250 ppm.

Toxicological data gaps for the proposed tolerances are a second mammalian species oncogenicity study and a new reproduction study. Desirable data which are lacking from the petitions to support the proposed tolerances and uses are a dermal absorption study with the dimethylamine salt and a teratology study with the 2,4-D metabolite, 2,4-dichlorophenol. The data gaps that exist are presently being filled by industry.

The Agency initiated a review of the available information on the potential health effects of 2,4-D. Based on the results of this review, EPA concluded that (a) the currently available information on the potential adverse health effects of 2,4-D does not support a regulatory action to remove 2,4-D products from the market, (b) information from scientifically valid studies does not indicate that the continued use of 2,4-D poses an imminent hazard or unreasonable adverse effect when used according to label precautions and directions for use, and (c) the Agency should act quickly and vigorously to obtain better toxicological information on 2,4-D.

The technical preparation of 2,4-D contains a nitroso contaminant. The Agency has calculated that nitrosamine residues in millet grain and straw would be less than 1 part per billion (ppb), which is not considered to be a significant health hazard in this use pattern.

The acceptable daily intake (ADI), based on the two-year dog feeding study (NOEL of 500 pm, 12.5 mg/kg bw) and using a 100-fold safety factor, is calculated to be 0.1250 mg/kg of body weight (bw)/day. The maximum permitted intake (MPI) for the 60-kg human is calculated to be 7.5 mg/day. The theoretical maximum residue contribution (TMRC) from existing tolerances for a 1.5-kg daily diet is calculated to be 0.9033 mg/day. The current action will utilize 0.12 percent of the ADI. Published tolerances utilize 12.04 percent of the ADI.

The nature of the residues is adequately understood and an adequate analytical method (gas-liquid chromatography) is available for enforcement purposes. The established tolerances in eggs, meat, milk, and poultry are adequate to cover the existing and proposed uses of 2,4-D. There are presently no actions pending against the continued registration of these chemicals.

Based on the above information considered by the Agency, the tolerances established by amending 40 CFR Part 180 would protect the public health. It is proposed, therefore, that the tolerances be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this notice in the Federal Register that this rulemaking proposal be referred to an Advisory Committee in

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accordance with section 408(e) of the Federal Food, Drug, and Cosmetic Act.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating both the subject and the petitions and document control numbers, "[PP 2E1293/7E1980/P197]." All written comments filed in response to these petitions will be available for public inspection in the office of Donald Stubbs from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays.

As required by Executive Order 12291, EPA has determined that this proposed rule is not a "Major" rule and therefore does not require a Regulatory Impact Analysis. In addition, the Office of Management and Budget (OMB) has exempted this regulation from the OMB review requirements of Executive Order 12291 pursuant to section 8(b) of that Order.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-534, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

(Sec. 408(e), 68 Stat. 514 (21 U.S.C. 346a(e)))

Dated: October 14, 1981.

Douglas D. Campt,

Director, Registration Division, Office of Pesticide Programs.

PART 180—TOLERANCE AND EXEMPTIONS FROM TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

Therefore, it is proposed that 40 CFR 180.142 be revised by reformatting the commodities in an alphabetized columnar listing, adding a new explanatory sentence relating to the apricot tolerance and alphabetically inserting the raw agricultural commodity apricots in paragraph (a), and alphabetically inserting the raw agricultural commodities millet forage, millet grain, and millet straw in paragraph (b) to read as follows:

§ 180.142 2,4-D; tolerances for residues.

(a) Tolerances are established for residues of the herbicide, plant regulator, and fungicide 2,4-D (2,4-dichlorophenoxyacetic acid) in or on raw agricultural commodities as follows:

Commodity	Parts per million
Apples	5
Apricots	5
Citrus fruits	5
Pears	5
Potatoes	0.2
Quinces	5

(1) The tolerance on apricots also includes residues of 2,4-D (2,4-dichlorophenoxyacetic acid) from the preharvest application of 2,4-D dimethylamine salt to apricots.

(2) The tolerance on citrus fruits also includes residues of 2,4-D from the preharvest application of 2,4-D isopropyl ester and 2,4-D butoxyethyl ester and from the postharvest application of 2,4-D alkanolamine salts and 2,4-D isopropyl ester to citrus fruits.

(b) Tolerances are established for residues of 2, 4-D at:

Commodity	Parts per million
Barley, grain	0.5
Barley, straw	20
Blueberries	0.1
Corn, fodder	20
Corn, forage	20
Corn, fresh, sweet (K+CWHR)	0.5
Corn, grain	0.5
Cranberries	0.5
Grapes	0.5
Grass, hay	300
Grasses, pasture	1,000
Grasses, rangeland	1,000
Millet, forage	20
Millet, grain	0.5
Millet, straw	20
Oats, forage	20
Oats, grain	0.5
Rice	0.1
Rice, straw	20
Rye, forage	0.5
Rye, grain	0.5
Sorghum, fodder	20
Sorghum, forage	20
Sorghum, grain	0.5
Sugarcane	2
Sugarcane, forage	20
Wheat, forage	20
Wheat, grain	0.5

(1) *Salts.* Residues on all the above may result from application of 2, 4-D in acid form, or in the form of one or more the following salts:

(i) The inorganic salts: Ammonium, lithium, potassium, and sodium.

(ii) The amine salts: Alkanolamines of the ethanol and isopropanol series), alkyl (C-12), alkyl (C-13), alkyl (C-14), alkylamines derived from tall oil, amylamine, diethanolamine, diethylamine, diisopropanolamine, dimethylamine, N,N-dimethyl-linoleylamine, N,N-dimethyloleyamine, ethanolamine, ethylamine, heptylamine, isopropanolamine, isopropylamine, linoleylamine, methylamine, morpholine, octylamine, oleylamine, N-oleylamine, N-oleyl-1,3-propylenediamine, propylamine, triethanolamine, triethlamine, triisopropanolamine, and trimethylamine.

(2) *Esters.* Residues on all the above may result from application of 2,4-D in acid form, or in the form of one or more of the following esters: amyl (pentyl), butoxyethoxypropyl, butoxyethyl, butoxypolyethylene glycol butyl ether, butoxypropyl, butyl, dipropylene glycol isobutyl ether, ethoxyethoxyethyl, ethoxyethoxypropyl, ethyl, ethoxypropyl, isobutyl, isooctyl (including, but not limited to, 2-ethylhexyl, 2-ethyl-4-methyl-pentyl, and 2-octyl), isopropyl, methyl, polyethylene glycol 200, polypropoxybutyl, polypropylene glycol, propylene glycol, propylene glycol butyl ether, propylene glycol isobutyl ether, tetrahydrofurfuryl, and tripropylene glycol isobutyl ether.

(c) Tolerances are established for negligible residues of 2,4-D from application of its dimethylamine salt to irrigation ditch banks in the Western United States in programs of the Bureau of Reclamation, U.S. Department of the Interior; cooperating water user organizations; the Bureau of Sport Fisheries, U.S. Department of the Interior; Agricultural Research Service, U.S. Department of Agriculture; and the Corps of Engineers, U.S. Department of Defense. Where tolerances are established at higher levels from other uses of 2,4-D on the following crops, the higher tolerance applies also to residues from the irrigation ditch bank use cited in this paragraph. The established tolerances follow:

Commodity	Parts per million
Avocados	0.1(N)
Citrus fruits	0.1(N)
Cottonseed	0.1(N)
Cucurbits	0.1(N)
Forage grasses	0.1(N)
Forage legumes	0.1(N)
Fruiting vegetables	0.1(N)
Grain crops	0.1(N)
Hops	0.1(N)
Leafy vegetables	0.1(N)
Nuts	0.1(N)
Pome fruits	0.1(N)
Root crop vegetables	0.1(N)
Seed and pod vegetables	0.1(N)
Small fruits	0.1(N)
Stone fruits	0.1(N)

(d) A tolerance is established for residues of 2,4-D sodium salt and alkanolamine salts (of the ethanol and isopropanol series), calculated as 2,4-D (2,4-dichlorophenoxyacetic acid) as follows:

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Commodity	Parts per million
Asparagus	5

(e) A tolerance is established for residues of 2,4-D from application of its alkanolamine salts (of the ethanol and isopropanol series) as follows:

Commodity	Parts per million
Strawberries	0.05

(f) Tolerances are established for residues of 2,4-D from application of its dimethylamine salt for water hyacinth control in ponds, lakes, reservoirs, marshes, bayous, drainage ditches, canals, rivers and streams that are quiescent or slow moving in programs conducted by the Corps of Engineers or other Federal, State, or local public agencies. Where tolerances are established at higher levels from other uses of the dimethylamine salt of 2,4-D on crops included within these commodity groups, the higher tolerances also apply to residues from the aquatic uses cited in this paragraph. The established tolerances follow:

Commodity	Parts per million
Crops in paragraph (c) of this section	1.0
Crop groupings in paragraph (c) of this section	1.0
Fish	1.0
Shellfish	1.0

(g) [Reserved]

(h) Tolerances are established for residues of 2,4-dichlorophenoxyacetic acid (2,4-D) and/or its metabolite, 2,4-dichlorophenol (2,4-DCP) in food products of animal origin as follows:

Commodity	Parts per million
Cattle, fat	0.2
Cattle, kidney	2
Cattle, meat	0.2
Cattle, mbyp (exc. kidney)	0.2
Eggs	0.05
Goats, fat	0.2
Goats, kidney	2
Goats, meat	0.2
Goats, mbyp (exc. kidney)	0.2
Hogs, fat	0.2
Hogs, kidney	2
Hogs, meat	0.2
Hogs, mbyp (exc. kidney)	0.2
Horses, fat	0.2
Horses, kidney	2
Horses, meat	0.2
Horses, mbyp (exc. kidney)	0.2
Milk	0.1
Poultry	0.05
Sheep, fat	0.2
Sheep, kidney	2
Sheep, meat	0.2
Sheep, mbyp (exc. kidney)	0.2

(i) A tolerance is established for residues of 2,4-D from applications of its dimethylamine salt or its butoxyethanol ester for Eurasian Watermilfoil control in programs conducted by the Tennessee Valley Authority in dams and reservoirs of the TVA system as follows:

Commodity	Parts per million
Fish	1.0

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