

§ 180.1

40 CFR Ch. I (7-1-13 Edition)

180.1322 *Bacillus pumilus* strain BU F-33; exemption from the requirement of a tolerance.

Subpart E—Pesticide Chemicals Not Requiring a Tolerance or an Exemption from a Tolerance

180.2000 Scope.
180.2003 Definitions.
180.2010 Threshold of regulation determinations.
180.2020 Non-food determinations.

AUTHORITY: 21 U.S.C. 321(q), 346a and 371.

SOURCE: 36 FR 22540, Nov. 25, 1971, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 180 appear at 62 FR 66023, Dec. 17, 1997.

GLOSSARY

NOTE: The items in this glossary were compiled as an aid to the users of the Code of Federal Regulations. Inclusion or exclusion from this glossary has no legal significance.

APPLI = APPLICATION
C-I MET = CHOLINESTERASE-INHIBITING METABOLITES
CARB = CARBAMATES
EPWRR = EDIBLE PORTION WITH RIND REMOVED
EXC = EXCEPT
I (IN PPM COLUMN) = INTERIM TOLERANCE
INC = INCLUDING
K=CWHR = KERNEL PLUS COB WITH HUSK REMOVED
MBYP = MEAT BYPRODUCTS
MIN = MINIMUM
N (IN PPM COLUMN) = NEGLIGIBLE RESIDUES
NMT = NOT MORE THAN
NON-PER BAG/PKGD RAC = NON-PERISHABLE PACKAGED OR BAGGED RAW AGRICULTURAL COMMODITY
PPM = PART(S) PER MILLION
POST-H = POSTHARVEST APPLICATION
PRE-H = PREHARVEST APPLICATION
PRE-S = PRESLAUGHTER APPLICATION
PRODS = PRODUCTS rollert
T (IN PPM COLUMN) = TEMPORARY TOLERANCE

[41 FR 4537, Jan. 30, 1976]

Subpart A—Definitions and Interpretative Regulations

§ 180.1 Definitions and interpretations.

(a) *Administrator*, without qualification, means the Administrator of the Environmental Protection Agency.

(b) *Agency*, without qualification, means the Environmental Protection Agency.

(c) *FFDCA* means the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. 301-392.

(d) Raw agricultural commodities include, among other things, fresh fruits, whether or not they have been washed and colored or otherwise treated in their unpeeled natural form; vegetables in their raw or natural state, whether or not they have been stripped of their outer leaves, waxed, prepared into fresh green salads, etc.; grains, nuts, eggs, raw milk, meats, and similar agricultural produce. It does not include foods that have been processed, fabricated, or manufactured by cooking, freezing, dehydrating, or milling.

(e) Where a raw agricultural commodity bearing a pesticide chemical residue that has been exempted from the requirement of a tolerance, or which is within a tolerance permitted under FFDCA section 408, is used in preparing a processed food, the processed food will not be considered unsafe within the meaning of FFDCA sections 402 and 408(a), despite the lack of a tolerance or exemption for the pesticide chemical residue in the processed food, if:

(1) The pesticide chemical has been used in or on the raw agricultural commodity in conformity with a tolerance under this section;

(2) The pesticide chemical residue has been removed to the extent possible in good manufacturing practice; and

(3) The concentration of the pesticide chemical residue in the processed food is not greater than the tolerance prescribed for the pesticide chemical residue on the raw agricultural commodity.

(f) For the purpose of computing fees as required by § 180.33, each group of related crops listed in § 180.34(e) and each crop group or subgroup listed in § 180.41 is counted as a single raw agricultural commodity in a petition or request for tolerances or exemption from the requirement of a tolerance.

(g) Tolerances and exemptions established for pesticide chemicals in or on the general category of raw agricultural commodities listed in column A apply to the corresponding specific raw

Environmental Protection Agency

§ 180.1

agricultural commodities listed in column B does not apply to the general category in column A. However, a tolerance or exemption for a specific commodity in col-

A	B
Alfalfa	<i>Medicago sativa</i> L. Subsp. <i>sativa</i> , (alfalfa, lucerne); <i>Onobrychis viciifolia</i> Scop. (sainfoin, holy clover, esparcet); and <i>Lotus corniculatus</i> L. (trefoil); and varieties and/or hybrids of these.
Banana	Banana, plantain.
Bean	<i>Cicer arietinum</i> (chickpea, garbanzo bean); <i>Lupinus</i> spp. (including sweet lupine, white sweet lupine, white lupine, and grain lupine). <i>Phaseolus</i> spp. (including kidney bean, lima bean, mung bean, navy bean, pinto bean, snap bean, and waxbean; <i>Vicia faba</i> (broad bean, fava bean); <i>Vigna</i> spp. (including asparagus bean, blackeyed pea and cowpea).
Bean, dry	All beans above in dry form only.
Bean, succulent	All beans above in succulent form only.
Blackberry	<i>Rubus eubatus</i> (including bingleberry, black satin berry, boysenberry, Cherokee blackberry, Chesterberry, Cheyenne blackberry, coryberry, darrowberry, dewberry, Dirksen thornless berry, Himalayaberry, hullberry, Lavacaberry, lowberry, Lucretiaberry, mammoth blackberry, marionberry, nectarberry, olallieberry, Oregon evergreen berry, phenomenalberry, rangerberry, ravenberry, rossberry, Shawnee blackberry, and varieties and/or hybrids of these).
Broccoli	Broccoli, chinese broccoli (gia lon, white flowering broccoli).
Cabbage	Cabbage, Chinese cabbage (tight-heading varieties only).
Caneberry	<i>Rubus</i> spp. (including blackberry); <i>Rubus caesius</i> (youngberry); <i>Rubus loganbaccus</i> (loganberry); <i>Rubus idaeus</i> (red and black raspberry); cultivars, varieties, and/or hybrids of these.
Celery	Celery, Florence fennel (sweet anise, sweet fennel, finocchio) (fresh leaves and stalks only).
Cherry	Cherry, sweet, and cherry, tart.
Endive	Endive, escarole.
Fruit, citrus	Grapefruit, lemon, lime, orange, tangelo, tangerine, citrus citron, kumquat, and hybrids of these.
Garlic	Garlic, great headed; garlic, and serpent garlic.
Lettuce	Lettuce, head; and lettuce, leaf
Lettuce, head	Lettuce, head; crisphead varieties only
Lettuce, leaf	Lettuce, leaf; cos (romaine), butterhead varieties
Marjoram	<i>Origanum</i> spp. (includes sweet or annual marjoram, wild marjoram or oregano, and pot marjoram).
Melon	Muskmelon, including hybrids and/or varieties of <i>Cucumis melo</i> (including true cantaloupe, cantaloupe, casaba, Santa Claus melon, crenshaw melon, honeydew melon, honey balls, Persian melon, golden pershaw melon, mango melon, pineapple melon, snake melon); and watermelon, including hybrids and/or varieties of (<i>Citrullus</i> spp.).
Muskmelon	<i>Cucumis melo</i> (includes true cantaloupe, cantaloupe, casaba, Santa Claus melon, crenshaw melon, honeydew melon, honey balls, Persian melon, golden pershaw melon, mango melon, pineapple melon, snake melon, and other varieties and/or hybrids of these.)
Onion	Bulb onion; green onion; and garlic.

§ 180.1

40 CFR Ch. I (7–1–13 Edition)

A	B
Onion, bulb	Bulb onion; garlic; great headed garlic; serpent garlic; Chinese onion; pearl onion; potato onion; and shallot, bulb.
Onion, green	Green onion; lady's leek; leek; wild leek; Beltsville bunching onion; fresh onion; tree onion, tops; Welsh onion; and shallot, fresh leaves.
Peach	Peach, nectarine
Pea	<i>Cajanus cajan</i> (includes pigeon pea); <i>Cicer</i> spp. (includes chickpea and garbanzo bean); <i>Lens culinaris</i> (lentil); <i>Pisum</i> spp. (includes dwarf pea, garden pea, green pea, English pea, field pea, and edible pod pea). [Note: A variety of pesticide tolerances have been previously established for pea and/or bean. Chickpea/garbanzo bean is now classified in both the bean and the pea categories. For garbanzo bean/chickpea only, the highest established pea or bean tolerance will apply to pesticide residues found in this commodity.]
Pea, dry	All peas in dry form only.
Pea, succulent	All peas in succulent form only.
Pepper	All varieties of pepper including pimento and bell, hot, and sweet pepper.
Radish, oriental, roots	<i>Raphanus sativus</i> var. <i>longipinnatus</i> (roots and tops), including Chinese or Japanese radish (both white and red), winter radish, daikon, lobok, lo pak, and other cultivars and/or hybrids of these.
Radish, oriental, tops	<i>Raphanus sativus</i> var. <i>longipinnatus</i> (roots and tops), including Chinese or Japanese radish (both white and red), winter radish, daikon, lobok, lo pak, and other cultivars and/or hybrids of these.
Rapeseed	<i>Brassica napus</i> , <i>B. campestris</i> , and <i>Crambe abyssinica</i> (oilseed-producing varieties only which include canola and crambe.)
Raspberry	<i>Rubus</i> spp. (including bababerry; black raspberry; blackcap; caneberry; framboise; frambueso; himbeere; keriberry; mayberry; red raspberry; thimbleberry; tulameen; yellow raspberry; and cultivars, varieties, and/or hybrids of these).
Sorghum, grain, grain	<i>Sorghum</i> spp. [sorghum, grain, sudangrass (seed crop), and hybrids of these grown for its seed].
Sorghum, forage, stover	<i>Sorghum</i> spp. [sorghum, forage; sorghum, stover; sudangrass, and hybrids of these grown for forage and/or stover].
Squash	Pumpkin, summer squash, and winter squash.
Sugar apple	<i>Annona squamosa</i> L. (sugar apple, sweetsop, anon), and its hybrid <i>A. squamosa</i> L. x <i>A. cherimoya</i> M. (atemoya). Also <i>A. reticulata</i> L. (true custard apple).
Squash, summer	Fruits of the gourd (<i>Cucurbitaceae</i>) family that are consumed when immature, 100% of the fruit is edible either cooked or raw, once picked it cannot be stored, has a soft rind which is easily penetrated, and if seeds were harvested they would not germinate; e.g., <i>Cucurbita pepo</i> (i.e., crookneck squash, straightneck squash, scallop squash, and vegetable marrow); <i>Lagenaria</i> spp. (i.e., spaghetti squash, hyotan, cucuzza); <i>Luffa</i> spp. (i.e., hechima, Chinese okra); <i>Momordica</i> spp. (i.e., bitter melon, balsam pear, balsam apple, Chinese cucumber); <i>Sechium edule</i> (chayote); and other cultivars and/or hybrids of these.
Sweet potato	Sweet potato, yam.
Tangerine	Tangerine (mandarin or mandarin orange); clementine; Mediterranean mandarin; satsuma mandarin; tangelo; tangor; cultivars, varieties, and/or hybrids of these.
Tomato	Tomato, tomatillo.
Turnip tops or turnip greens	Broccoli raab (raab, raab salad), hanover salad, turnip tops (turnip greens).

A	B
Wheat	Wheat, triticale.

(h) Unless otherwise specified in this paragraph or in tolerance regulations prescribed in this part for specific pesticide chemicals, the raw agricultural commodity or processed food to be examined for pesticide residues, shall consist of the whole raw agricultural commodity or processed food.

(1) The raw agricultural commodity bananas, when examined for pesticide residues, shall not include any crown tissue or stalk.

(2) Shell shall be removed and discarded from nuts before examination for pesticide residues.

(3) Caps (hulls) shall be removed and discarded from strawberries before examination for pesticide residues.

(4) Stems shall be removed and discarded from melons before examination for pesticide residues.

(5) Roots, stems, and outer sheaths (or husks) shall be removed and discarded from garlic bulbs and dry bulb onions, and only the garlic cloves and onion bulbs shall be examined for pesticide residues.

(6) Where a tolerance is established on a root vegetable including tops and/or with tops, and the tops and the roots are marketed together, they shall be analyzed separately and neither the pesticide residue on the roots nor the pesticide residue on the tops shall exceed the tolerance level, except that in the case of carrots, parsnips, and rutabagas, the tops shall be removed and discarded before analyzing roots for pesticide residues.

(7) The crowns (leaves at the top of the fruit) shall be removed and discarded from pineapples before examination for pesticide residues.

(8) The term *lima beans* means the beans and the pod.

(9) The term *peanuts* means the peanut meat after removal of the hulls.

(10) For processed foods consisting primarily of one ingredient and sold in a form requiring further preparation prior to consumption (e.g., fruit juice concentrates, dehydrated vegetables, and powdered potatoes), the processed food to be examined for residues shall

be the whole processed commodity after compensating for or reconstituting to the commodity's normal moisture content, unless a tolerance for the concentrated or dehydrated food form is included in this part. If there exists a tolerance for a specific pesticide on the processed food in its concentrated or dehydrated food form, for the purpose of determining whether the food is in compliance with that tolerance, the processed food to be examined for residues shall be the whole processed commodity on an "as is" basis.

(i) The term *pesticide chemical* shall have the meaning specified in FFDC section 201(q)(1), as amended, except as provided in §180.4.

(j) The term *negligible residue* means any amount of a pesticide chemical remaining in or on a raw agricultural commodity or group of raw agricultural commodities that would result in a daily intake regarded as toxicologically insignificant on the basis of scientific judgment of adequate safety data. Ordinarily this will add to the diet an amount which will be less than 1/2,000th of the amount that has been demonstrated to have no effect from feeding studies on the most sensitive animal species tested. Such toxicity studies shall usually include at least 90-day feeding studies in two species of mammals.

(k) The term *nonperishable raw agricultural commodity* means any raw agricultural commodity not subject to rapid decay or deterioration that would render it unfit for consumption. Examples are cocoa beans, coffee beans, field-dried beans, field-dried peas, grains, and nuts. Not included are eggs, milk, meat, poultry, fresh fruits, and vegetables such as onions, parsnips, potatoes, and carrots.

(l) The term *tolerance with regional registration* means any tolerance which is established for pesticide residues resulting from the use of the pesticide pursuant to a regional registration. Such a tolerance is supported by residue data from specific growing regions

for a raw agricultural commodity. Individual tolerances with regional registration are designated in separate subsections in 40 CFR 180.101 through 180.999, as appropriate. Additional residue data which are representative of the proposed use area are required to expand the geographical area of usage of a pesticide on a raw agricultural commodity having an established "tolerance with regional registration." Persons seeking geographically broader registration of a crop having a "tolerance with regional registration" should contact the appropriate EPA product manager concerning additional residue data required to expand the use area.

(m) The term *pesticide chemical residue* shall have the meaning specified in FFDCA section 201(q)(2), as amended, except as provided in §180.4.

(n) The term *food commodity* means:

(1) Any raw agricultural commodity (food or feed) as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act (FFDCA); and

(2) Any processed food or feed as defined in section 201(gg) of the FFDCA.

[36 FR 22540, Nov. 25, 1971]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §180.1, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 180.3 Tolerances for related pesticide chemicals.

(a) Pesticide chemicals that cause related pharmacological effects will be regarded, in the absence of evidence to the contrary, as having an additive deleterious action. (For example, many pesticide chemicals within each of the following groups have related pharmacological effects: Chlorinated organic pesticides, arsenic-containing chemicals, metallic dithiocarbamates, cholinesterase-inhibiting pesticides.)

(b) Tolerances established for such related pesticide chemicals may limit the amount of a common component (such as As_2O_3) that may be present, or may limit the amount of biological activity (such as cholinesterase inhibition) that may be present, or may limit the total amount of related pesticide chemicals (such as chlorinated organic pesticides) that may be present.

(c)(1) Where tolerances for inorganic bromide in or on the same raw agricultural commodity are set in two or more sections in this part (example: §§180.123 and 180.199), the overall quantity of inorganic bromide to be tolerated from use of the same pesticide in different modes of application or from two or more pesticide chemicals for which tolerances are established is the highest of the separate applicable tolerances. For example, where the bromide tolerance on asparagus from methyl bromide commodity fumigation is 100 parts per million (40 CFR 180.123) and on asparagus from methyl bromide soil treatment is 300 parts per million (40 CFR 180.199), the overall inorganic bromide tolerance for asparagus grown on methyl bromide-treated soil and also fumigated with methyl bromide after harvest is 300 parts per million.

(2) Where tolerances are established in terms of inorganic bromide residues only from use of organic bromide fumigants on raw agricultural commodities, such tolerances are sufficient to protect the public health, and no additional concurrent tolerances for the organic pesticide chemicals from such use are necessary. This conclusion is based on evidence of the dissipation of the organic pesticide or its conversion to inorganic bromide residues in the food when ready to eat.

(d)(1) Where tolerances are established for both calcium cyanide and hydrogen cyanide on the same raw agricultural commodity, the total amount of such pesticides shall not yield more residue than that permitted by the larger of the two tolerances, calculated as hydrogen cyanide.

(2) Where tolerances are established for residues of both *O,O*-diethyl *S*-[2-(ethylthio)ethyl] phosphorodithioate and demeton (a mixture of *O,O*-diethyl *O*- (and *S*-) [2-(ethylthio)ethyl] phosphorothioates) on the same raw agricultural commodity, the total amount of such pesticides shall not yield more residue than that permitted by the larger of the two tolerances, calculated as demeton.

(3) Where tolerances are established for both terpene polychlorinates (chlorinated mixture of camphene, pinene, and related terpenes, containing 65-66 percent chlorine) and toxaphene