

chemical residue" under FFDC section 201(q)(3) and are therefore exempt from regulation under FFDC section 402(a)(2)(B) and 408. These substances are subject to regulation by the Food and Drug Administration as food additives under FFDC section 409.

(a) Inert ingredients in food packaging impregnated with an insect repellent when such inert ingredients are the components of the food packaging material (e.g., paper and paperboard, coatings, adhesives, and polymers).

(b) [Reserved]

[63 FR 10720, Mar. 4, 1998]

§ 180.5 Zero tolerances.

A zero tolerance means that no amount of the pesticide chemical may remain on the raw agricultural commodity when it is offered for shipment. A zero tolerance for a pesticide chemical in or on a raw agricultural commodity may be established because, among other reasons:

(a) A safe level of the pesticide chemical in the diet of two different species of warm-blooded animals has not been reliably determined.

(b) The chemical is carcinogenic to or has other alarming physiological effects upon one or more of the species of the test animals used, when fed in the diet of such animals.

(c) The pesticide chemical is toxic, but is normally used at times when, or in such manner that, fruit, vegetables, or other raw agricultural commodities will not bear or contain it.

(d) All residue of the pesticide chemical is normally removed through good agricultural practice such as washing or brushing or through weathering or other changes in the chemical itself, prior to introduction of the raw agricultural commodity into interstate commerce.

§ 180.6 Pesticide tolerances regarding milk, eggs, meat, and/or poultry; statement of policy.

(a) When establishing tolerances for pesticide residues in or on raw agricultural commodities, consideration is always given to possible residues of those pesticide chemicals or their conversion products entering the diet of man through the ingestion of milk, eggs, meat, and/or poultry produced by ani-

mals fed agricultural products bearing such pesticide residues. In each instance an evaluation of all available data will result in a conclusion either:

(1) That finite residues will actually be incurred in these foods from feed use of the raw agricultural commodity including its byproducts; or

(2) That it is not possible to establish with certainty whether finite residues will be incurred, but there is a reasonable expectation of finite residues; or

(3) That it is not possible to establish with certainty whether finite residues will be incurred, but there is no reasonable expectation of finite residues.

(b) When the data show that finite residues will actually be incurred in milk, eggs, meat, and/or poultry, a tolerance will be established on the raw agricultural commodity used as feed provided that tolerances can be established at the same time, on the basis of the toxicological and other data available, for the finite residues incurred in milk, eggs, meat, and/or poultry. When it is not possible to determine with certainty whether finite residues will be incurred in milk, eggs, meat, and/or poultry but there is a reasonable expectation of finite residues in light of data reflecting exaggerated pesticides levels in feeding studies, a tolerance will be established on the raw agricultural commodity provided that appropriate tolerances can be established at the same time, on the basis of the toxicological and other data available, for the finite residues likely to be incurred in these foods through the feed use of the raw agricultural commodity or its byproducts. When it is not possible to determine with certainty whether finite residues will be incurred in milk, eggs, meat, and/or poultry but there is no reasonable expectation of finite residues in light of data such as those reflecting exaggerated pesticide levels in feeding studies and those elucidating the biochemistry of the pesticide chemical in the animal, a tolerance may be established on the raw agricultural commodity without the necessity of a tolerance on food products derived from the animal.

(c) The principles outlined in paragraphs (a) and (b) of this section will also be followed with respect to tolerances for residues which will actually