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W. A. K.

DEC 19 1974

December 16, 1974

TO: Food, Drug, and Cosmetic Chemicals Committee

SUBJECT: Poisonous or Deleterious Substances in Foods

Members:

Attached is a copy of the notice on the above subject which appeared in the December 6 Federal Register (pages 42743 - 42748).

Now Jan 28

The Legislative and Regulatory Subcommittee is to consider this proposal at its January 14, 1975 meeting. If you have any comments on it, please be sure to send them to Mr. Sunshine (copy to me) prior to this meeting.

Sincerely yours,

M. M. Hoover

M. M. Hoover, Secretary
Food, Drug, and Cosmetic
Chemicals Committee

MMH:sh

Attachment

Distribution "B"

[21 CFR Part 122]

POISONOUS OR DELETERIOUS SUBSTANCES IN FOOD

Notice of Proposed Rule Making

Elsewhere in this issue of the FEDERAL REGISTER the Commissioner of Food and Drugs is issuing proposed regulations concerning permitted levels of mercury in fish and shellfish (mollusks and crustaceans), lead in evaporated milk and evaporated skim milk, and aflatoxin in shelled peanuts and peanut products used as human foods. The Commissioner has concluded that Part 122, promulgated in an order published in the FEDERAL REGISTER of July 6, 1973 (38 FR 18096), should be expanded to deal with all poisonous or deleterious substances in food, including food-contact surfaces, pet food, and animal feed, to implement sections 402(a) and 406 of the Federal Food, Drug, and Cosmetic Act.

Section 402(a)(1) of the act provides that a food shall be deemed to be adulterated:

> If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.

Section 402(a)(2) of the act provides that a food shall be deemed to be adulterated:

> (A) If it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of secton 406, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408(a); or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409: *Provided*, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity; or (D) if it is, or it bears or contains, a new animal drug (or conversion product thereof) which is unsafe within the meaning of section 512.

Section 406 of the act permits the establishment of tolerances for added poisonous or deleterious susbtances in food; section 408 of the act permits the establishment of tolerances for pesticide chemicals in or on raw agricultural commodities; and section 409 of the act permits the establishment of tolerances for food additives.

The basic provision of the act dealing with poisonous or deleterious substances in food is section 402(a)(1) of the act, which applies to all poisonous or deleterious susbtances, whether they are naturally occurring or added. It is deliberately cumulative with the provisions relating to establishment of tolerances for food substances referenced in section 402(a)(2) of the act and was retained from the Food and Drugs Act of 1906 because its language had been construed by the Supreme Court in United States v. Lexington Mill & Elevator Co., 232 U.S. 399 (1974). See Hearings on S. 2800 Before the Senate Committee on Commerce, 73d Cong., 2d Sess. 530 (1934). Its broad scope is shown by the fact that the related provisions in sections 406, 408(a), 409(a), and 512(k) of the act exempt a substance from section 402(a)(1) only if a regulation has been promulgated under the authority of those other sections.

Section 402(a) of the act distinguishes between naturally occurring and "added" substances and sets different standards for each. Naturally occurring substances are prohibited only if they render the food "ordinarily" injurious to health. Added substances are prohibited if they "may" be injurious to health; if such substances are necessary or unavoidable, special procedures are established by which they can be regulated.

"Added" is a statutory term of art encompassing all ingredients which are not inherent and intrinsic parts of a food. The term "added" was introduced into Federal food law in the drafting of the 1906 act when the U.S. Department of Agriculture (USDA) opposed a provision defining a food product as adulterated if it was injurious to health. The Department noted that such a provision would outlaw coffee, tea, and other foods containing deleterious ingredients as natural constituents. See the testimony of the Commissioner in Hearings on H.R. 6906, H.R. 8805, H.R. 8941, and S. 5 Before A Subcommittee of the House Committee on Interstate and Foreign Commerce, 74th Cong., 1st Sess. 58 (1935). To exempt such foods containing naturally occurring deleterious ingredients, the Senate committee considering the bill in 1906 adopted the word "added." See 40 Cong. Rec. 897 (1906). Although the word chosen implies that the statute is concerned with the act of addition, the legislative history makes clear that the term seeks rather to establish a standard based upon the necessary and inherent normal condition of the food.

Actions of the USDA after enactment of the 1906 act demonstrate that all contamination was regarded as "added." In 1914, the USDA announced that it had been investigating the presence of lead and arsenic in food, noting that such contaminants were "usually introduced into such products through the use of impure raw materials or from the apparatus or utensils employed in the processes of manufacture." The announcement further stated that "this bureau holds that food containing arsenic or lead, added in any manner, is adulterated, in that it contains an added poisonous or deleterious ingredient which may render the product injurious to health." U.S. Department of Agriculture, Bureau of Chemistry, Service and Regulatory Announcements 312–313 dated June 23, 1914.

[1] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044.

Throughout the hearings leading to the 1938 act, it remained clear that substance was "added" within the meaning of the statute whenever it was not inherent in nature, and not just when it was purposefully added. Thus, in explaining a proposed provision equivalent to the present section 402(a)(1) of the act, which removed the 1906 act's limitation to added ingredients, the Commissioner testified that the effect of eliminating the reference to added ingredients was to include deleterious ingredients "normal to the food product." Hearings on S. 2800, supra, at 528. The Commissioner's examples of added substances clearly included environmental and industrial contaminants. One example given of food containing an added poisonous substance was sugar contaminated by smoke from a nearby smokestack. Lead pipes, lead manufacturing equipment, and lead containers were also identified as sources of added poisonous substances. Hearings on H.R. 6906, supra, at 59–60; Hearings on S. 1944 Before a Subcommittee of the Senate Commerce Committee, 73d Cong., 2d Sess. 25, 27 (1933). The Commissioner testified at one point that some added poisonous or deleterious substances were "more or less universal," and at another time that "[t]here are very few things * * * in which you will not find contaminating products in some small degree." Hearings on S. 1944, supra, at 18; Hearings on H.R. 6906, supra, at 59. This emphasis on the ubiquity of added poisonous or deleterious substances clearly demonstrates that the term was understood to include all food contaminants.

The legislative history also identifies examples of foods naturally containing poisonous or deleterious substances and thus not subject to the "added" provisions of section 402(a)(1) of the act. These examples are Burma beans, which contain a glucoside that yields prussic or hydrocyanic acid; rhubarb, which contains oxalic acid; and coffee and tea. See Hearings on S. 1944, *supra*, at 17; Hearings on S. 2800, *supra*, at 29; Hearings on H.R. 6906, *supra*, at 58. Except for substances whose deleterious nature is inherent to the natural state of the food, and thus similar in origin to these examples, all poisonous and deleterious components are "added" within the meaning of the act. Moreover, when a naturally occurring poisonous or deleterious substance is increased to abnormal levels through mishandling or other intervening act, it is "added" to the extent of such increase.

Judicial decisions have recognized that the scope of the "added" provisions of the law extends to all poisonous or deleterious substances not inherently a component of the food. In United States v. 1,600,800 Pounds of White Corn, Civil No. T–4173 (D. Kan., Dec. 18, 1970), the court held that aflatoxin in corn was an added poisonous or deleterious substance within the meaning of the act since aflatoxin is not a natural constituent of corn. In *United States v. 1200 Cans, Pasteurized Whole Eggs*, 339 F. Supp. 131, 136 (N.D. Ga. 1972), the court recognized that salmonella in eggs is an added poisonous or deleterious substance.

Section 406 was included in the 1938 act to permit the establishment of tolerances for added poisonous or deleterious substances which are required in the production of food or otherwise cannot be avoided by good manufacturing practice. A limitation may be placed upon such substances to the extent necessary for the protection of the public health. Although formal tolerances under section 406 have not been used by the Food and Drug Administration, except for the tolerance for PCB's published in the FEDERAL REGISTER of July 6, 1973 (38 FR 18096), informal action levels have frequently been utilized to implement this provision of the law and a number of those action levels exist today. In the past, such action levels have been issued through press releases and other public announcements but have not been published in the FEDERAL REGISTER or codified as regulations.

Section 408 was added to the act in 1954 to permit the establishment of tolerances for pesticide chemicals in or on raw agricultural commodities. This provision of the law was administered by the Food and Drug Administration (FDA) until the establishment of the Environmental Protection Agency (EPA) in 1970.

In 1958, Congress enacted the Food Additives Amendment, which affected the legal status of some of the contaminants previously regulated only as added poisonous or deleterious substances. The legislation was basically in two parts: first, a broad definition of "food additive" and a general prohibition of food additives not demonstrated to be safe; and second, a procedure by which the use of safe food additives could be approved. This two-part approach was the congressional answer to what was identified as a "dual problem." See H.R. Rep. 2284, 85th Cong. 2d Sess. 1 (1958). The first part of the problem was that under section 402(a)(1) and (2)(A) of the act, the burden is on the Government to show that a food substance is poisonous or deleterious. As the House Commerce Committee noted, "to prove an untested substance poisonous or deleterious may require approximately 2 years or more of laboratory experiments with small animals and during this period the Government cannot prevent the use of such a substance in food." The amendment therefore shifted the burden of proof in enforcement actions brought against food containing poisonous or deleterious substances to the food manufacturer.

The definition of "food additive" established in section 201(s) of the act is not limited to intentional additives. The breadth of the language in section 201(s) of the act includes any food substance, and excludes only those substances which cannot reasonably be expected to become a component of food. The statutory definition thus includes what are referred to as "incidental additives" as well as "intentional additives". See H.R. Rep. No. 2284, supra, at 3. Any added poisonous or deleterious substance in food, unless accidental and unforeseeable or specifically exempted by section 201(s) of the act, is a food additive. A food naturally containing a poisonous or deleterious substance becomes a food additive if it is not generally recognized as safe and is added to other food or undergoes processing. Food-packaging material may also contain food additives. The broad scope of section 201(s) of the act has been judicially recognized in United States v. Ewig Bros. & Co., Nos. 73–1008, 73–1454 (7th Cir., Aug. 28, 1974), and United States v. City Smoked Fish Co., Civil No. 33989 (E.D. Mich. 1970, 1972) in which DDT in smoked fish was held to be a food additive. The court in United States v. Articles of Food, 370 F. Supp. 371 (E.D. Mich. 1974), held that substances migrating from pottery plates are food additives.

The Food Additives Amendment of 1958 was also intended to rectify the second part of the dual problem which was that "present law entirely prohibits the use of these additives even if their use at safe levels would advance our food technology and increase and improve our food supplies." H.R. Rep. 2284, supra, at 1–2. Section 409 of the act was enacted to permit issuing a regulation prescribing the conditions under which an additive may be safely used. Before any such regulation can be issued, the statute requires that the safety of the food additive be demonstrated. The statute also requires that the food additive accomplish a physical or other technical effect and requires the regulation to restrict use of the food additive to the lowest level necessary for that purpose.

When the Food Additives Amendment of 1958 was enacted, the provisions of section 406 of the act were not repealed. Although all added poisonous or deleterious ingredients are food additives, except when they appear in food accidentally and unforeseeably or are exempted under section 201(s) of the act because they are otherwise regulated under the act, the tolerance-setting provisions of section 406 of the act were left intact to deal with those unavoidably added poisonous or deleterious ingredients that could not meet the high standards for issuance of a regulation under the authority of section 409 of the act. A number of added poisonous or deleterious substances, which are also food additives within the meaning of section 201(s) of the act, are unavoidable but cannot meet the requirements for a section 409 regulation because their safety cannot be demonstrated and because they serve no functional purpose. A prominent example is lead, which was one of the contaminants most frequently mentioned in the legislative history of the 1938 act and one of the prime contaminants with which section 406 was enacted to deal. Lead cannot be the subject of a food additive regulation under section 409 of the act even at trivial levels because it serves no functional purpose. Section 406 of the act, therefore, remains in force to control the use of such substances, since there would otherwise be no statutory means available to recogniz

their unavoidability and to exercise reasonable control over their presence.

Thus, there is nothing in the language of section 402(a)(2)(A) of the act to prevent issuance of a regulation under section 406 of the act for an added poisonous or deleterious substance that is also a food additive and for which no food additive regulation has been or can be promulgated. Section 402(a)(2)(A) of the act deems a food adulterated "if it bears or contains any added poisonous or added deleterious substance (other than one which is * * * (ii) a food additive * * *) which is unsafe within the meaning of section 406". If the parenthetical exception had been meant to prohibit issuance of section 406 tolerances for food additives, the exception would have been placed in section 406 of the act. Instead, the language of section 406 of the act allowing the Secretary of Health, Education, and Welfare to promulgate tolerances remains in full effect. Section 406 of the act must, of course, be read as having equal force and effect as the other parts of the statute.

The parenthetical exception was placed in section 402 of the act, the section dealing with the legal definitions of adulteration, rather than in section 406 of the act, the authority to promulgate tolerances, because the intention was to exempt a food additive from the provisions of section 406 of the act once a section 409 regulation has been promulgated. The parenthetical exception is thus similar to the language in sections 406, 408(a), 409(a), and 512(k) of the act granting an exemption from section 402(a)(1) of the act if a regulation under one of those sections is in effect.

The correctness of that interpretation is confirmed by the language of the proviso in section 402(a)(2)(C) of the act. That proviso creates an exemption from the food additive provisions of the act for a pesticide in a processed food under certain circumstances. In doing so, the proviso refers to both sections 406 and 409 of the act. A reference to section 406 of the act would obviously not have been necessary to exempt a substance from the provisions of the act applicable to food additive if the language of section 402(a)(2)(A) of the act made the provisions of section 406 of the act inapplicable to food additives. Instead, because the proviso deals with a situation in which no section 409 regulation will be issued, the reference to section 406 of the act is necessary to afford complete exemption.

Similarly, when a tolerance for an unavoidable pesticide cannot be issued under the criteria of section 408 of the act, section 406 is available to control its use. Under the Executive Order establishing it, the EPA promulgates tolerances under sections 406, 408, and 409 of the act for pesticides in or on food, and the FDA is then responsible for enforcing those provisions.

The Commissioner proposes to establish procedures for controlling all poisonous or deleterious substances. Basic reliance on the provisions of section 409 for regulating use of such substances remains unchanged, and regulations issued under that authority are set forth in 21 CFR Part 121. However, when a food contaminant is unavoidable but cannot be approved under the criteria of section 409 of the act, a formal procedure is being proposed to control its use under authority of sections 306, 402(a), and 406 of the act.

When a tolerance is established under the provisions of section 406, the act requires it to be set at the level necessary for the protection of the public health taking into account the extent to which the substance cannot be avoided and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

At times it will not be appropriate to establish a formal tolerance. The Commissioner is not required to establish a tolerance for every added poisonous or deleterious substance, as is indicated by the language of section 406 of the act recognizing that an adulteration charge can be made under section 402(a)(1) of the act when no tolerance is in effect. Section 306 of the act has long been interpreted to permit the Food and Drug Administration to establish action levels in implementing the adulteration provisions of the act. See United States v. Goodman, 486 F. 2d 847 (7th Cir. 1973); United States v. Thriftimart, Inc., 429 F.2d 1006, 1011 (9th Cir. 1970); United States v. 1500 Cases More or Less, Tomato Paste, 236 F. 2d 208, 211–12 (7th Cir. 1956); United States v. 449 Cases Containing Tomato Paste, 212 F. 2d 567, 572–73 (2d Cir. 1954); United States v. 133 Cases of Tomato Paste, 22 F. Supp. 515, 516 (E.D. Pa. 1938); cf. United States v. Ewig Bros. & Co., supra.

When the factors required to be considered prior to promulgation of a section 406 tolerance are rapidly changing, it would be inappropriate to set such a formal tolerance. The procedures required by section 406 of the act, including a public hearing and requirement of substantial evidence to support the tolerance, contemplate ample evidence to consider, and a relatively stable situation where the evidence will be of more than transient significance and where the tolerance eventually promulgated will be appropriate for a relatively long period of time. For example, if industrial practices are improving so quickly that the extent to which the substance is unavoidable changes significantly from year to year, there is little justification for use of section 406 procedures. Similarly, if toxicological data are scanty or conflicting, but additional data are being developed, it would serve no good purpose to labor over an assessment of the existing data in a public hearing while ignoring the prospects of additional studies. The Commissioner therefore concludes that the structure and criteria of section 406 of the act indicate it is to be used primarily in relatively static circumstances.

When it is not appropriate to promulgate a tolerance under section 406, it may nevertheless still be appropriate to take some formal regulatory action to control use of a substance. In such circumstances, the Commissioner will consider promulgating an action level under authority of sections 306, 402(a), and 406 of the act.

Such action levels are similar to a formal tolerance in basis and effect. In setting an action level, the Commissioner considers evidence indicating when the presence of an added poisonous or deleterious substance may render food injurious to health, which is the standard in section 402(a)(1) of the act. In addition, the Commissioner takes into account the question of its unavoidability, a policy embodied in section 406 of the act. Thus, an action level is based on the same criteria as a tolerance, except that an action level is temporary until the appearance of more stable circumstances makes a formal tolerance appropriate.

Particular problems are raised with respect to the use of pesticides, which frequently result in environmental contamination. Tolerances under section 406 of the act may be issued by EPA which allow for residues of pesticides in food, even though the pesticide itself is not registered by EPA for use with that particular crop.

An action level may also be established for a pesticide for which the EPA has not issued a tolerance under section 406 of the act. Because of their joint pesticide responsibilities under the act, the EPA and the FDA agree that both agencies have definite roles in respect to action levels for pesticides. Since action levels are an exercise of enforcement discretion, and since FDA is responsible for enforcement under the Executive Order establishing EPA, FDA is responsible for determining when an action level for a pesticide should be established and issuing such actions levels as regulations. Since action levels are similar to a formal tolerance in basis and effect, and since EPA has the expertise to establish pesticide tolerances, EPA is responsible for determining, upon request from FDA, the appropriate level at which a pesticide action level is to be set.

Such tolerances or action levels properly recognize the problem of environmental contamination caused by drift of a pesticide from one area to another, or the persistence of the chemical in the environment over a period of time. In no instance, however, does any such action level or tolerance itself authorize use of any pesticide on a food crop for which it has not been registered by EPA. Except in the limited instances discussed below, no action level or other administrative action will be taken to permit the sale of food contaminated with a pesticide that has been used in any manner other than in strict accordance with the label directions approved by EPA.

The establishment of a tolerance or an action level does not authorize use of the particular poisonous or deleterious substance involved, or mean that any product containing up to that level of contamination is necessarily a lawful

product. The failure to comply with the requirements of section 402(a)(4) of the act, which prohibits the preparation, packaging, or storage of food under insanitary conditions, is a separate violation of the act, even if the food itself does not violate any tolerance or action level for added poisonous or deleterious substances. Similarly, blending a contaminated food with a noncontaminated food, to produce a final product that falls within a tolerance or action level, is unlawful under the act and is prohibited by the proposed regulations.

The proposed principles and procedures set forth in Part 122 apply equally to imported food. Any food additive or pesticide intentionally used in or on imported food must be the subject of a regulation issued under section 408 or 409 of the act. Unavoidable added poisonous or deleterious substances may be the subject of a tolerance or action level issued under Part 122.

Because of enforcement practicalities, tolerances and action levels for imported food must be the same as for domestically produced food, although levels of unavoidable contamination may differ from country to country. For example, some pesticides are approved for use abroad because of conditions which justify their use, but are not registered for use in this country because those conditions do not exist here. In such a case, a regulation issued by EPA under section 408 or 409 of the act would apply to any food on which the pesticide was intentionally used. A tolerance may be issued by EPA or an action level by FDA, however, to be applied to food unavoidably contaminated by the pesticide. That tolerance or action level will be set at a uniform level for all food, including domestic food. The establishment of the tolerance or action level would not authorize any use of the pesticide in this country, however.

The Commissioner intends to issue, by publication in the FEDERAL REGISTER, all existing action levels for unavoidable poisonous or deleterious substances as regulations in Part 122. In the interim, these publicly known action levels will continue in effect. Although the Commissioner intends to issue as regulations all new action levels as well, circumstances may require use of informal action levels pending issuance of final regulations. Such informal action levels will continue to be announced to the public.

Finally, the Commissioner recognizes that there may be some circumstances where it will be in the public interest to permit the marketing of food that is contaminated with a poisonous or deleterious substance, even though the contamination may have occurred through unlawful or other avoidable misuse of the substance and thus the food would not be eligible for a tolerance or action level. This would occur where a large amount of food is contaminated, resulting in a substantial adverse impact on the national food supply, and all available toxicological data indicate that no significant health hazard is involved. Accordingly, the proposed regulations provide a public procedure whereby, under such circumstances, the Commissioner may permit the marketing of such food, as an exemption from the usual rules that would be applicable. Any such exemptions would be limited to a single occurrence and would be decided on an ad hoc basis after public consideration of the issues involved.

The proposal also prescribes a method of issuing regulations to deal with foods containing naturally occurring poisonous or deleterious substances. Where appropriate, the Commissioner may identify foods which, because of their inherent components, are deemed to be adulterated within the meaning of section 402(a)(1) of the act. These regulations would, of course, not constitute a complete list of such foods.

In the FEDERAL REGISTER of September 23, 1974 (39 FR 34172), the Commissioner consolidated existing regulations on substances prohibited from use in food in a new § 121.106 (21 CFR 121.106). Prohibited food additives will continue to be listed in Part 121, and Part 122 will be used only to identify foods prohibited even when not used as food additives. Since neither of these lists is exhaustive, the appearance of a food or of a poisonous or deleterious substance on one of the lists while not on the other does not constitute a determination that it should not appear on the other.

In addition, the proposal creates a method whereby interested persons can petition the Commissioner to establish a tolerance, action level, or other regulation under this part. Petitions adequately supported would be published in the FEDERAL REGISTER for comment.

No action is proposed for polychlorinated biphenyls (PCB's) (21 CFR 122.10) except recodification as § 122.100. The renumbered section is set forth in its entirety as part of the revision for the convenience of the reader. Additionally, paragraph (a)(9) of that section was stayed by an order published in the FEDERAL REGISTER of August 24, 1973 (38 FR 22792).

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 306, 402(a), 406, 408, 409, 701(a), 52 Stat. 1045–1046 as amended, 1049, 1055, 68 Stat. 511 as amended; 72 Stat. 1785–1788 as amended; 21 U.S.C. 336, 342(a), 346, 346a, 348, 371(a)) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes that Part 122 be revised to read as follows:

PART 122—POISONOUS OR DELETERIOUS SUBSTANCES IN FOOD AND FOOD-PACKAGING MATERIAL

Subpart A—Definitions and Procedures

Sec.
122.3 Definitions.
122.4 Establishment of regulations.
122.5 Petitions.
122.6 Added poisonous or deleterious substances.
122.7 Unavoidability.
122.8 Exemptions.

Subpart B—Tolerances for Added Poisonous or Deleterious Substances

122.100 Polychlorinated biphenyls (PCB's).

AUTHORITY: Secs. 306, 402(a), 406, 408, 409, 701, 52 Stat. 1045–1046 as amended, 1049 1055–1056 as amended, 68 Stat. 511, as amended; 72 Stat. 1785–1788 as amended (21 U.S.C. 336, 342(a), 346, 346a, 348, 371).

Subpart A—Definitions and Procedures

§ 122.3 Definitions.

(a) "Act" means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms contained in section 201 of the act are applicable to such terms when used in this part.

(c) A "naturally occurring poisonous or deleterious substance" is a poisonous or deleterious substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other handling or contamination.

(d) An "added poisonous or deleterious substance" is a poisonous or deleterious substance that is not a naturally occurring poisonous or deleterious substance. When a naturally occurring poisonous or deleterious substance is increased to abnormal levels through mishandling or other intervening act, it is an added poisonous or deleterious substance to the extent of such increase.

(e) "Food" includes human food, substances migrating to food from food-contact articles, pet food, and animal feed.

§ 122.4 Establishment of regulations.

(a) When appropriate under the criteria of § 122.6, a tolerance for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in Subpart B of this part under the provisions of section 406 of the act. A tolerance may be established at the level of zero.

(b) When appropriate under the criteria of § 122.6, an action level for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in Subpart C of this part to define the level of contamination at which a food will be deemed to be adulterated under section 402(a)(1) of the act. An action level may prohibit any detectable amount of the substance in food.

(c) A regulation may be established in Subpart D of this part to identify a food containing a naturally occurring poisonous or deleterious substance which will be deemed to be adulterated under section 402(a)(1) of the act. These regulations do not constitute a complete list of such foods.

§ 122.5 Petitions.

The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may issue a proposal to establish, revoke, or amend a regulation under this part. Any such petition shall include an adequate factual basis to support the petition, shall be in the form set forth in § 2.65 of this chapter, and will be published in the FEDERAL REGISTER for comment if it contains reasonable grounds for the proposed regulation.

§ 122.6 Added poisonous or deleterious substances.

(a) Use of an added poisonous or deleterious substance, other than a pesticide chemical, that is also a food additive will be controlled by a regulation issued under section 409 of the act when possible. When such a use cannot be approved under the criteria of section 409, or when the added poisonous or deleterious substance is not a food additive, a tolerance or action level may be established pursuant to the criteria established in paragraphs (b) and (c) of this section. Use of an added poisonous or deleterious substance that is also a pesticide chemical will ordinarily be controlled by a regulation issued under section 406, 408, or 409 by the U.S. Environmental Protection Agency (EPA). When such a regulation has not been issued, an action level for an added poisonous or deleterious substance that is also a pesticide chemical may be established at a level specified by EPA pursuant to the criteria established in paragraph (c) of this section.

(b) A tolerance for an added poisonous or deleterious substance in any food may be established when the following criteria are met:

(1) The substance cannot be avoided by good manufacturing practice.

(2) The tolerance established is sufficient for the protection of the public health, taking into account the extent to which the presence of the substance cannot be avoided and the other ways in which the consumer may be affected by the same or related poisonous or deleterious substances.

(3) No technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance established. Examples of changes that might affect the appropriateness of the tolerance include anticipated improvements in good manufacturing practice that would change the extent to which use of the substance is unavoidable and anticipated studies expected to provide significant new toxicological or use data.

(c) An action level for an added poisonous or deleterious substance in any food may be established when the criteria in paragraph (b) of this section are met, except that technological or other changes that might affect the appropriateness of the tolerance are foreseeable in the near future. An action level shall cease to be enforced and shall be revoked when a tolerance for the same substance and use has become effective.

(d) Tolerances will be established under authority appropriate for action levels as well as under authority appropriate for tolerances. In the event the effectiveness of a tolerance is stayed pursuant to section 701(e)(2) of the act by the filing of an objection and request for hearing, the order establishing the tolerance shall be deemed to be an order establishing an action level until final action is taken upon such objection.

§ 122.7 Unavoidability.

(a) Tolerances and action levels in this part are established at levels based on the unavoidability of the poisonous or deleterious substance concerned and do not establish a permissible level of contamination where it is avoidable.

(b) Compliance with tolerances and action levels does not excuse failure to observe either the requirement in section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act that food may not be prepared, packed, or held under insanitary conditions or the other requirements in this chapter that food manufacturers must observe current good manufacturing practices. Evidence obtained through factory inspection indicating such a violation renders the food unlawful, even though the amounts of poisonous or deleterious substances are lower than the currently established tolerances or action levels. The manufacturer of food must at all times utilize quality control procedures which will reduce contamination to the lowest level currently feasible.

(c) The mixing of a food containing a poisonous or deleterious substance in an amount above the tolerance or action level with another lot of food is not permitted and renders the final food unlawful regardless of the amount of poisonous or deleterious substance in the final food.

§ 122.8 Exemptions.

(a) The Commissioner may exempt from regulatory action and permit the marketing of any food that is unlawfully contaminated with a poisonous or deleterious substance if:

(1) He determines (i) based upon all available scientific evidence, that the food is safe for consumption and (ii) that destruction or diversion of the food involved would result in a substantial adverse impact on the national food supply.

(2) Such determination is published as a proposal in the FEDERAL REGISTER, with time for public comment whenever feasible. The time permitted for comment shall depend upon the degree of urgency required by the specific matter involved. In the event that no time for comment is feasible, the exemption may be issued as a final determination rather than as a proposal.

(3) The determination identifies the level of contamination allowed by the exemption, and the food to which it applies (e.g., the specific growing area or other identifying information). The exemption shall not apply to any other food produced in any other area or at any other time. Contaminated food not subject to the exemption will remain subject to regulatory action.

(b) Any person responsible for contamination of the food involved, or shipment of any such food in interstate commerce prior to the issuance of an exemption pursuant to this section, shall remain subject to regulatory action pursuant to sections 302 (injunction proceedings) and 303 (penalties) of the act.

(c) In the case of a poisonous or deleterious substance which is a pesticide chemical, the level of contamination allowed by the exemption shall, upon request of the Food and Drug Administration, be specified by the Environmental Protection Agency pursuant to paragraph (a)(1)(i) of this section and promulgated by the Commissioner. No exemption for a pesticide chemical shall be promulgated without the concurrence of the Environmental Protection Agency.

Subpart B—Tolerances for Added Poisonous or Deleterious Substances

§ 122.100 Polychlorinated biphenyls (PCB's).

(a) Polychlorinated biphenyls (PCB's) are toxic, industrial chemicals. Because of their widespread, uncontrolled industrial applications, PCB's have become a persistent and ubiquitous contaminant in the environment. As a result, certain foods and animal feeds, principally those of animal and marine origin, contain PCB's as unavoidable, environmental contaminants. PCB's are transmitted to the food portion (meat, milk, and eggs) of food producing animals ingesting PCB contaminated animal feed. In addition, a significant percentage of paper food-packaging materials contain PCB's which may migrate to the packaged food. The source of PCB's in paper food-packaging materials is primarily of certain types of carbonless copy paper (containing 3 to 5 percent PCB's) in waste paper stocks used for manufacturing recycled paper. Therefore, temporary tolerances for residues of PCB's as unavoidable environmental or industrial contaminants are established for a sufficient period of time following the effective date of this paragraph to permit the elimination of such contaminants at the earliest practicable time. For the purposes of this paragraph, the term "polychlorinated biphenyls (PCB's)" is applicable to mixtures of chlorinated biphenyl compounds, irrespective of which mixture of PCB's is present as the residue. The temporary tolerances for residues of PCB's are as follows:

(1) 2.5 parts per million in milk (fat basis).

(2) 2.5 parts per million in manufactured dairy products (fat basis).

(3) 5 parts per million in poultry (fat basis).

(4) 0.5 parts per million in eggs.

(5) 0.2 parts per million in finished animal feed for food-producing animals (except the following finished animal feeds: feed concentrates, feed supplements, and feed premixes).

(6) 2 parts per million in animal feed components of animal origin, including fishmeal and other by-products of marine origin and in finished animal feed concentrates, supplements, and premixes intended for food producing animals.

(7) 5 parts per million in fish and shellfish (edible portion). The edible portion of fish excludes head, scales, viscera, and inedible bones.

(8) 0.2 parts per million in infant and junior foods.

(9) 10 parts per million in paper food-packaging material intended for or used with human food, finished animal feed and any components intended for animal feeds. The tolerance shall not apply to

paper food-packaging material separated from the food therein by a functional barrier which is impermeable to migration of PCB's.

(b) A compilation entitled "Analytical Methodology for Polychlorinated Biphenyls, February 1973" for determining compliance with the tolerances established in this section is available from the Hearing Clerk, Department of Health, Education, and Welfare, Room 4-65, 5600 Fishers Lane, Rockville, MD 20852.

Interested persons may, on or before March 6, 1975, file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: November 20, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

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