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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 121]

FOOD ADDITIVES

Proposal Regarding Regulation of Prior-Sanctioned Food Ingredients

The Commissioner of Food and Drugs is conducting a study of food ingredients that have been used in food products without approval of a food additive regulation on the ground either that they are generally recognized as safe (GRAS) or that they are subject to a prior sanction. The Commissioner has already published proposed procedures for the affirmation of GRAS status or the determination of food additive status. It is therefore appropriate to establish comparable procedures for the regulation of ingredients subject to prior sanctions.

Section 201(s) of the Federal Food, Drug, and Cosmetic Act excludes from the definition of "food additive":

> (4) Any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act, the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following);

Pursuant to this grandfather clause, a food ingredient subject to a prior sanction may not be regulated under the food additive provisions of the law. Such an ingredient may, however, be regulated under the general adulteration and misbranding provisions of the Act, and in particular may be banned from food if found to be a "poisonous or deleterious substance" in violation of section 402(a)(1) of the Act.

The Food and Drug Administration, between 1938 and 1958, reaffirmed many sanctions or approvals granted under the Federal Food and Drugs Act of 1906, and also granted additional sanctions and approvals. The U.S. Department of Agriculture has similarly granted many sanctions and approvals. Not all of these sanctions and approvals can be ascertained because of the destruction of old records and the retirement of personnel involved in these matters. The Food and Drug Administration has requested information on prior sanctions (35 F.R. 5810) in an effort to make its files on these matters more complete.

Whether or not a food ingredient is used as a result of a determination that it is GRAS, or pursuant to a food additive regulation, or as a result of a prior sanction, the basis for such use should be a matter of public record. The Commissioner has therefore determined to expand Subpart E under Part 121, within which will be established regulations governing all prior-sanctioned direct and indirect food ingredients known to the Commissioner.

New scientific information requires, on occasion, that additional limitations be placed on the use of prior-sanctioned ingredients. Accordingly, the Commissioner has concluded that a procedure should also be established under which a regulation in Subpart E stating the existence of a prior sanction may be established or amended to impose limitations upon the use of the ingredient when scientific data justify such limitations.

As the first action under this proposed new subpart, the Commissioner proposes to issue a regulation for talc, which has a prior sanction for use in coating polished rice. This use was first approved in a food inspection decision issued under the Federal Food and Drugs Act of 1906, and was subsequently recognized in the standard of identity for enriched rice, § 15.525. Talc has also been listed as GRAS in § 121.101(h) for use in paper and paperboard used in dry food packaging, in § 121.101(i) for use in cotton and cotton fabrics used in dry food packaging, in an FDA opinion letter for use in chewing gum base, and in an FDA opinion letter for use as an antisticking agent in forms used in molding various food shapes.

Talc is a naturally occurring hydrous magnesium silicate without well-defined specifications or limitations. A recent publication (Science 173:1141–1142, September 17, 1971) identifies the presence of asbestos-form particles in talc used to coat rice. Independent laboratory investigation by the Food and Drug Administration has confirmed this report. A copy of the FDA report is on file with the Food and Drug Administration Hearing Clerk. Since asbestos, another form of natural magnesium silicate, is carcinogenic when inhaled and asbestos-form particles may therefore be injurious to health when ingested, and since talc can be processed to remove asbestos-form particles, it is prudent to require that talc which is to be used in the manufacture of food or food packaging be free of asbestos-form particles.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055 and 72 Stat. 1784–88, as amended; 21 U.S.C. 321(s), 348, 371(a) and under authority delegated to him (21 CFR 2.120), the Commissioner of Food and Drugs proposes to amend Part 121 as follows:

1. Section 121.101 is amended as follows:

a. Paragraphs (h) and (i) are amended by adding the phrase "free of asbestos-form particles" after the word "talc".

b. Paragraph (d)(8) is amended by adding the following entry in alphabetical sequence:

§ 121.101 Substances that are generally recognized as safe.

Agreement CAB 23184	Resolution	Title
R-1	002	Revalidation Resolution—Sales Agency Rules, Inclusive Tours Initiated by Tour Operators.
R-3	105(PAC)203 205 (PAC)203 505 (PAC)203 JT12 (5PAC)203 JT23 (5PAC)203 JT31 (5PAC)203 JT123 (5PAC)203.	Reduced Fares for Passenger Agents (Except U.S.A.) (Amending).

2. Subpart E of Part 121 is amended as follows:

a. The title of Subpart E is revised to read, "Subpart E—Prior-Sanctioned Food Ingredients".

b. Section 121.2001 is redesignated as § 121.2005 and §§ 121.2000 and 121.2006 are added to read as set forth below:

§ 121.2000 General.

(a) An ingredient whose use in food or food packaging is subject to a prior sanction or approval within the meaning of section 201(s)(4) of the act is exempt from classification as a food additive. The Commissioner will publish in this subpart all known prior sanctions. Any interested person may submit to the Commissioner a request for publication of a prior sanction, supported by evidence to show that it falls within section 201(s)(4) of the act.

(b) Based upon scientific data or information that shows that use of a prior-sanctioned food ingredient may be injurious to health, and thus is in violation of section 402(a)(1) of the act, the Commissioner will establish or amend the applicable prior sanction regulation to impose whatever limitations or conditions are necessary for the safe use of the ingredient, or to prohibit use of the ingredient.

§ 121.2006 Talc.

(a) Talc is a naturally occurring hydrous magnesium silicate for which no food grade specifications exist. Talc is subject to a prior sanction for use in coating polished rice.

(b) Talc containing asbestos-form particles may be injurious to health. Accordingly, any food or food packaging material containing talc that is not free of asbestos-form particles shall be deemed to be adulterated in violation of section 402(a)(1) of the Act.

Interested persons may, within 60 days after publication hereof in the FEDERAL REGISTER, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: August 1, 1972.

SAM D. FINE,
Associate Commissioner for Compliance.

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