

Copied by MCA
for distribution to

FOOD ADDITIVES
CONTACTS

FOOD, DRUG, AND
COSMETIC CHEMICALS
COMMITTEE

April 16, 1973
Distr. "B"
MMHoover

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration
[21 CFR Part 121]

**GENERALLY RECOGNIZED AS SAFE (GRAS)
SUBSTANCES NO LONGER IN USE**

Proposal for Removal From GRAS List

The Food and Drug Administration is conducting a study of the individual substances classified as generally recognized as safe (GRAS) in 21 CFR 121.101. As a part of this study, the National Academy of Sciences, through its Food Protection Committee of the National Research Council, has conducted a comprehensive survey of the production and use of GRAS substances. This survey was made on the basis of a questionnaire provided to all producers, formulators, and users of these substances who could be located through various trade association lists and other sources. Also, notice of the survey was given in the *FEDERAL REGISTER* of October 23, 1971 (36 FR 20546) to insure that all persons interested in participating in the survey were afforded an opportunity to do so. A total of 750 organizations representing individual processors, suppliers, manufacturers, and distributors were surveyed.

The survey questionnaire provided, among other things, for the reporting by each participant of his total production of each GRAS substance manufactured during the year 1970. The results of the survey reveal that a number of the substances listed in 21 CFR 121.101 apparently are no longer in use.

The Commissioner has concluded that it would be a needless and an unwarranted expenditure of resources to evaluate GRAS substances which are no longer in use. Accordingly, he proposes to delete the substances set forth below from 21 CFR 121.101 and the GRAS review except for any of such substances for which adequate evidence of manufacture and/or use may be submitted in response to this proposal within 60 days of its publication in the *FEDERAL REGISTER*.

If the evidence submitted for any such substance is limited to its use in animal feed, the substance will be excluded from the current GRAS review but will be continued in § 121.101 limited to use in animal feed only.

The objective of this action is solely to exclude from the GRAS list review substances that have been discontinued from human food use. Exclusion of these substances is not for the purpose and does not have the effect of classifying

the substances as food additives. Any substance excluded from the GRAS list review may be considered for GRAS affirmation at any future time on the basis of a petition submitted pursuant to § 121.40 (37 FR 25705).

Therefore, pursuant to the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788, as amended; 21 U.S.C. 321(s), 348, 371(a)) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes to amend part 121 by deleting from § 121.101 the following substances:

aluminum calcium silicate	manganese hypo-phosphite
DL-arginine	manganous oxide
DL-aspartic acid	monoisopropyl citrate
bentonite	D-pantothenyl alcohol
butane	potassium bisulfate
calcium ascorbate	potassium glycerophosphate
calcium glycerophosphate	propane
calcium hexameta-phosphate	DL-serine
calcium pyrophosphate	sodium pantothenate
calcium sorbate	sodium pectinate
cholic acid	sodium potassium tartrate
cuprous iodide	sodium sesquicarbonate
desoxycholic acid	sodium sorbate
dextrins	sodium tartrate
dilauryl thiodipropionic acid	sodium taurocholate
ferrous lactate	stearyl citrate
glychocholic acid	taurocholic acid
gum gualac	thiodipropionic acid
helium	DL-threonine
DL-histidine	D-alpha tocopheryl acetate concentrate
linoleic acid	DL-tryptophan
DL-lysine	DL-tyrosine
magnesium phosphate, tribasic	DL-valine
manganese citrate	zinc chloride
manganese gluconate	zinc gluconate
manganese glycerophosphate	zinc stearate

Interested persons may, on or before June 12, 1973, file with the hearing clerk, Food and Drug Administration, Department of Health, Education, and Welfare, room 6-88, 5600 Fishers Lane, Rockville, Md. 20852, written comments (preferably in quintuplicate) regarding this notice. 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 April 5, 1973.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Compliance.

[FR Doc.73-7157 Filed 4-12-73; 8:45 am]