

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Display Date	6/12/01
Publication Date	6/13/01
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[Docket No. 01N-0236]

New Food Chemicals Codex Monographs, Revisions of Certain Food Chemicals Codex Monographs, Revision of a General Test Procedure, and New Test Solutions; Opportunity for Public Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on proposed new Food Chemicals Codex specification monographs, proposed changes to certain Food Chemicals Codex specification monographs, a proposed revision of a general test procedure, and proposed new test solutions. Additions, revisions, and corrections to current specification monographs for certain substances used as food ingredients, as well as new monographs and test solutions, and a revised test procedure, are being prepared by the National Academies, Institute of Medicine (IOM), Committee on Food Chemicals Codex (the committee). This material is expected to be included in the next publication of the Food Chemicals Codex (the third supplement to the fourth edition), scheduled for public release in the summer of 2001.

DATES: Submit written comments by *[insert date 45 days after date of publication in the Federal Register]*. (The committee advises that comments received after this date may not be considered for the third supplement to the fourth edition. Comments received too late for consideration for the third supplement will be considered for the fifth edition of the Food Chemicals Codex.)

ADDRESSES: Submit written comments and supporting data and documentation to the Committee on Food Chemicals Codex/FO-3038, Food and Nutrition Board, Institute of Medicine, 2101 Constitution Ave. NW., Washington, DC 20418. Copies of the proposed new Food Chemicals

Codex specification monographs, proposed new test solutions, proposed changes to certain monographs, and proposed revision to a general test procedure may be obtained upon written request from the IOM (address above) or may be examined at the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests for copies should specify by name the monographs, test procedure, or test solutions desired. For electronic access see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Ricardo A. Molins, Project Director/FO-3038, Committee on Food Chemicals Codex, Food and Nutrition Board, Institute of Medicine, 2101 Constitution Ave. NW., Washington, DC 20418, 202-334-2580; or Paul M. Kuznesof, Division of Product Manufacture and Use (HFS-246), Office of Premarket Approval, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3009.

SUPPLEMENTARY INFORMATION: By contract with IOM, FDA supports the preparation of the Food Chemicals Codex, a compendium of specification monographs for substances used as food ingredients. Before any specifications are included in a Food Chemicals Codex publication, public announcement is made in the **Federal Register**. All interested parties are invited to comment and to make suggestions for consideration. Suggestions should be accompanied by supporting data or other documentation to facilitate and expedite review by the committee.

In the **Federal Register** of August 8, 2000 (65 FR 48521), and of January 22, 2001 (66 FR 6624), as corrected on February 9, 2001 (66 FR 9710), FDA announced that the committee was considering new and revised monographs, new and revised general test procedures, revised test solutions, and revisions to a policy for inclusion in the third supplement to the fourth edition of the Food Chemicals Codex. FDA is now announcing that the committee is soliciting comments and information on additional proposed new Food Chemicals Codex specification monographs, on additional proposed changes to certain monographs, on an additional proposed revised general test procedure, and on proposed new test solutions. These new and revised monographs, revised

test procedure, and new test solutions are also expected to be published in the third supplement to the fourth edition of the Food Chemicals Codex. If comments are received that cannot be addressed by the committee before publication of the third supplement, the new monographs or test solutions, revised monographs, or revised test procedure affected will be considered for the fifth edition of the Food Chemicals Codex. Copies of the proposed items may be obtained upon written request from IOM at the address listed above or through the Internet at <http://www.iom.edu/fcc>.

FDA emphasizes, however, that it will not consider adopting and incorporating any of the committee's new or revised monographs, revised test procedure, or new test solutions into FDA regulations without ample opportunity for public comment. If FDA decides to propose the adoption of new monographs and test solutions and changes that have received final approval of the committee, it will announce its intention and provide an opportunity for public comment in the **Federal Register**.

The committee invites comments and suggestions by all interested parties on specifications to be included in the 33 proposed new monographs, 22 proposed revisions of current monographs, proposed revised general test procedure, and 2 proposed new test solutions listed below:

I. Proposed New Monographs

Acidified sodium chlorite solutions

Aspartame-acesulfame salt

Curdlan

Flavor Chemicals

2,6-Dimethoxyphenol

3,4-Dimethyl-1,2-cyclopentandione

5-Ethyl-3-hydroxy-4-methyl-2(5H)-furanone

3-Ethyl pyridine

Furfuryl mercaptan

Geranyl isovalerate

2,3-Heptandione

Hexyl butyrate

Hexyl hexanoate

Isoamyl isobutyrate

Isobutyl formate

Isobutyl hexanoate

Linalool oxide

Methyl hexanoate

Methyl isovalerate

Methyl thiobutyrate

Methyl valerate

5-Methyl furfural

beta-Naphthylethyl ether

Phenylethyl cinnamate

Phenylethyl propionate

Propyl mercaptan

Propyl formate

delta-Tetradecalactone

2-Tridecanone

gamma-Cyclodextrin

Polyglycerol polyricinoleic acid

Pork collagen

Solin oil

Sucrose acetate isobutyrate

II. Current Monographs to which the Committee Proposes to Make Revisions

Calcium sulfate (Formula weight and CAS number revised to show the dihydrate; Heavy Metals determination deleted)

Canola oil (Description and Functional Use in Foods modified; Heavy Metals determination deleted)

Cellulose gum (Specifications for Degree of Substitution and Sodium modified; Heavy Metals determination deleted)

Citric acid (Description revised; Heavy Metals and Ultraviolet Absorbance specifications deleted; Tridodecylamine specification revised; Readily Carbonizable Substances test replaced; Residue on Ignition test reworded)

Cocoa butter substitute (Description corrected; Heavy Metals determination deleted)

Ethoxyquin (Description, Assay Limit, and Assay Test modified; Heavy Metals specification deleted; Lead, *p*-Phenetidine, and *p*-Phenetidine-Related Impurities specifications added)

Flavor Chemicals

Acetoin (structures revised)

2-Acetylpyrrole (physical form and melting range revised; water deleted)

Anisole (assay revised)

Ethylene brassylate (assay revised)

Ethyl phenylglycidate (assay revised)

Geranyl benzoate (assay revised)

alpha-Ionone (assay revised)

*d*l-Menthyl acetate (solubility in alcohol added)

4-Methyl-2-pentanone (refractive index revised)

delta-Nonalactone (refractive index and specific gravity revised)

(E)-2-Nonen-1-ol (refractive index revised)

delta-Octalactone (specific gravity revised)

(E)-2-Undecenol (solubility in alcohol added)

Maltitol (Description corrected; Assay limit of D-Maltitol revised; entire Identification, Assay, and Reducing Sugars tests provided; Other Hydrogenated Saccharides specifications added)

Rapeseed oil, fully hydrogenated (Description and Functional Use in Foods modified; Heavy Metals determination deleted)

Rapeseed oil, superglycerinated (Description and Functional Use in Foods modified; Heavy Metals determination deleted)

III. Proposed Revised General Test Procedure

Peroxide Value (A second Peroxide Value test has been added to Appendix VII: Fats and Related Substances)

IV. Proposed New Test Solutions

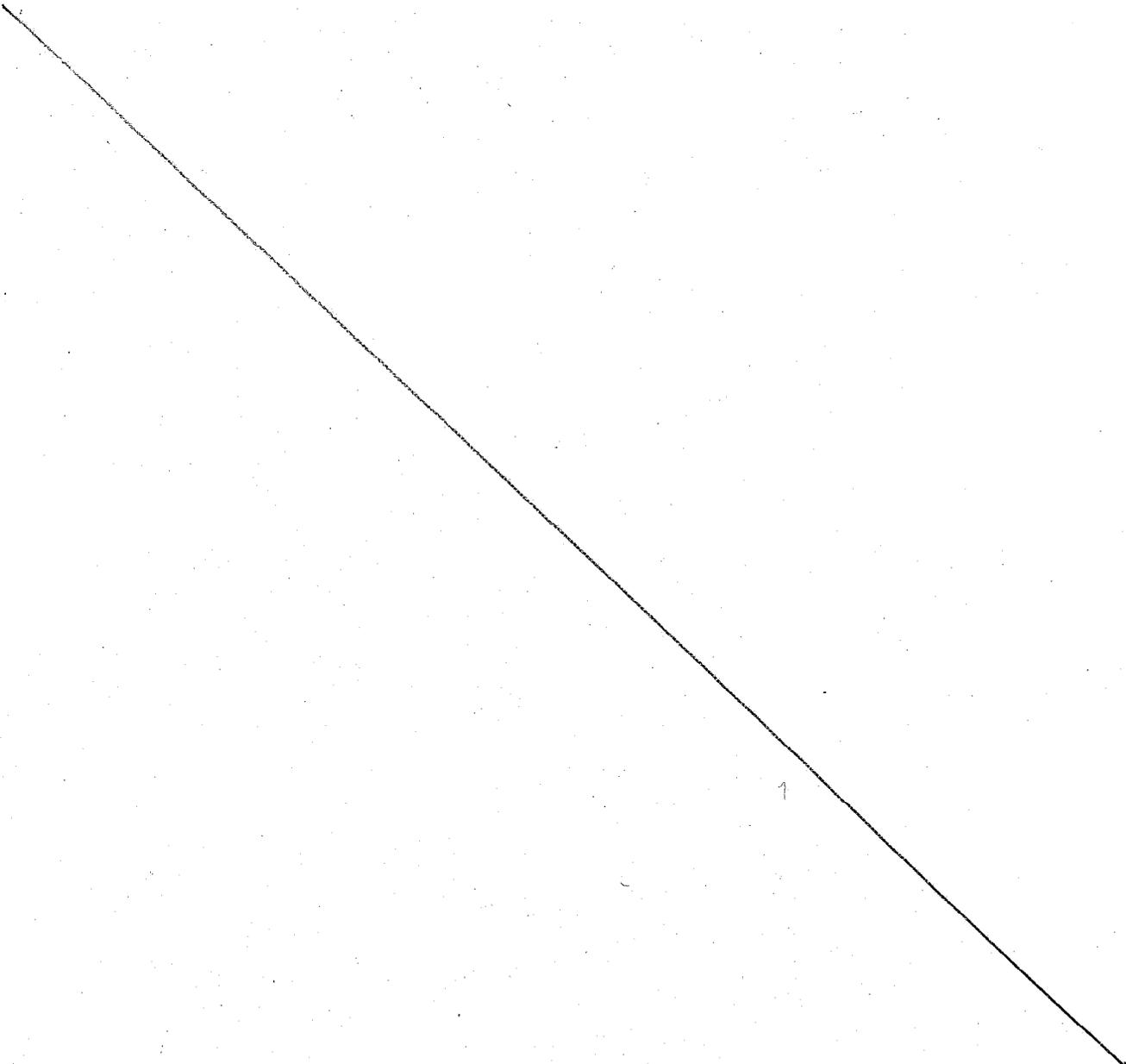
Nickel Standard Solution TS (10 milligrams per kilogram)

Acetic Acid TS, Strong (5 Normal)

V. Comments and Electronic Access

Interested persons may submit to the Committee on Food Chemicals Codex written comments regarding the monographs, general test procedure, and test solutions identified in this notice by *[insert date 45 days after date of publication in the Federal Register]*. Timely submission will allow comments to be considered for the third supplement to the fourth edition of the Food Chemicals Codex. Comments received after this date may not be considered for the third supplement, but will be considered for the fifth edition of the Food Chemicals Codex. Those wishing to make comments are encouraged to submit supporting data and documentation with their comments. Two copies of any comments regarding the monographs, the general test procedure, or the test solutions listed in this notice are to be submitted to the Committee on Food Chemicals Codex (address above). Comments and supporting data or documentation are to be identified with the docket number found in brackets in the heading of this document and each submission should

include the statement that it is in response to this **Federal Register** notice. The committee staff will forward a copy of each comment to the Dockets Management Branch (address above). Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. Copies of the proposed changes may also be obtained through the Internet at <http://www.iom.edu/fcc>.



Dated: 6/4/01
June 4, 2001.

L. Robert Lake

L. Robert Lake,
Director of Regulations and Policy,
Center for Food Safety and Applied Nutrition.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

Honori Oliver

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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