

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1685]

NMB

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**New Food Chemicals Codex Monographs, Revisions of Certain Food Chemicals Codex Monographs, a New General Test Procedure, and Revisions to a Policy; Opportunity for Public Comment**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**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 new general test procedure, and proposed changes to a policy in the fourth edition. Additions, revisions, and corrections to current specification monographs for certain substances used as food ingredients and to a policy, as well as new monographs and a new general 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 later supplements or for a new edition of the Food Chemicals Codex.)

**ADDRESSES:** Submit written comments and supporting data and documentation to the Committee on Food Chemicals Codex/FO-3042, 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 changes to certain monographs, the proposed new general test procedure, and the proposed changes to a policy 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, general test procedure, or policy desired. For electronic access see the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:**

Ricardo Molins, Project Director/FO-3042, 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 the 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), FDA announced that the committee was considering revised monographs, new and revised general test procedures, and revised test solutions 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 proposed new Food Chemicals Codex specification monographs, additional proposed changes to certain monographs, a proposed new general test procedure, and proposed changes to a policy. These

new and revised monographs, new general test procedure, and revised policy are also expected to be published in the third supplement to the fourth 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/fnb/fcc>.

FDA emphasizes, however, that it will not consider adopting and incorporating any of the committee's new and revised monographs, new general test procedure, or revised policy into FDA regulations without ample opportunity for public comment. If FDA decides to propose the adoption of new monographs 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 14 proposed new monographs, proposed revisions of 24 current monographs, proposed new general test procedure, and proposed revisions to a policy listed below:

## **I. Proposed New Monographs**

### Flavor Chemicals

Acetaldehyde Diethyl Acetal

2-Acetyl Thiazole

Allyl Phenoxy Acetate

Allyl Propionate

Borneol

Butyl 2-Methyl Butyrate

2-sec-Butyl Cyclohexanone

Diphenyl Ether

*d*-Fenchone

Fenchyl Alcohol

Furfuryl Alcohol

2-Furyl Methyl Ketone

Salatrim

Soy Protein Concentrate

## II. Current Monographs to Which the Committee Proposes to Make Revisions

Ammonium Phosphate, Monobasic (fluoride test corrected)

Carmine (description and assay test revised)

Enzyme Preparations (classifications and reactions added for  $\alpha$ -Acetolactatedecarboxylase;  
Aminopeptidase, Leucine; and Lysozyme)

Flavor Chemicals

Cinnamic Acid (solubility in alcohol revised)

*d*-Dihydrocarvone (solubility in alcohol revised)

2-Heptanone (specific gravity revised)

Hexyl Isovalerate (solubility in alcohol revised)

Isoamyl Benzoate (solubility in alcohol revised)

Nerolidol (assay revised)

(*Z*)-6-Nonen-1-ol (refractive index revised)

alpha-Pinene (angular rotation revised)

2-Undecenol (specific gravity revised)

Potassium Phosphate, Monobasic (fluoride test corrected)

Potassium Phosphate, Tribasic (fluoride test corrected)

Potassium Pyrophosphate (fluoride test corrected)

Potassium Tripolyphosphate (fluoride test corrected)

Sodium Acid Pyrophosphate (fluoride test corrected)

Sodium Metaphosphate, Insoluble (fluoride test corrected)

Sodium Phosphate, Dibasic (fluoride test corrected)

Sodium Phosphate, Monobasic (fluoride test corrected)

Sodium Polyphosphate, Glassy (fluoride test corrected)

Sodium Potassium Tripolyphosphate (fluoride test corrected)

Sodium Trimetaphosphate (fluoride test corrected)

Sodium Tripolyphosphate (fluoride test corrected)

### **III. Proposed New General Test Procedure**

Lipase (Microbial) Activity for Medium- and Long-Chain Fatty Acids (new enzyme assay)

### **IV. Proposed Revised Policy**

Heavy Metals Limits Policy (reference to heavy metals as lead removed, additional revisions)

### **V. Comments and Electronic Access**

Interested persons may, on or before [*insert date 45 days after date of publication in the Federal Register*], submit to the Committee on Food Chemicals Codex written comments regarding the monographs, general test procedure, and proposed revision of the policy identified in this notice. Timely submission will ensure that comments are 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 subsequent supplements or for a new 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, general test procedure, or policy 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 may also be obtained through the Internet at <http://www.iom.edu/fnb/fcc>.

Dated: 1/10/01

January 10, 2001

L. Robert Lake

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

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Supette N. Reese