

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 00F-0119]

**Food Additives Permitted for Direct Addition to Food for Human Consumption;
Calcium Disodium EDTA and Disodium EDTA**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

DMB

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| Display Date | 8-7-00 |
| Publication Date | 8-8-00 |
| Certifier | W. Reese |

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of calcium disodium EDTA (ethylenediaminetetraacetate) or disodium EDTA to promote color retention for all edible types of cooked, canned legumes. This action is in response to a petition filed by the National Food Processors Association.

DATES: This rule is effective [*insert date of publication in the Federal Register*]. Submit written objections and requests for a hearing by [*insert date 30 days after date of publication in the Federal Register*].

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mary E. LaVecchia, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3042.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of January 20, 2000 (65 FR 3242), FDA announced that a food additive petition (FAP 0A4709) had been filed by the National Food Processors Association, 1350 I St. NW., suite 300, Washington, DC 20005. The petition proposed to amend the food additive regulations in §§ 172.120 *Calcium Disodium EDTA* (21 CFR 172.120) and 172.135 *Disodium EDTA* (21 CFR 172.135) to provide for the safe use of calcium disodium EDTA or disodium EDTA to promote color retention for all edible types of cooked, canned legumes.

A review of the petition establishes that the petition proposes the use of 365 parts per million (ppm) of calcium disodium EDTA or 165 ppm disodium EDTA in all cooked, canned legumes, other than those cooked, canned legumes currently listed in § 172.120 or § 172.135. FDA has determined that consumer exposure to calcium disodium EDTA and disodium EDTA will not increase from the proposed use (Ref. 1). The agency notes that consumption of cooked, canned legumes is substitutional, i.e., the consumer will generally eat one type of cooked, canned legume or another at any given time and not increase the overall consumption of cooked, canned legumes. Additionally, the agency expects that no more of the additive will be used than necessary, up to a maximum of 365 ppm for calcium disodium EDTA and up to a maximum of 165 ppm disodium EDTA, to achieve the intended technical effect of promoting color retention in cooked, canned legumes.

II. Conclusions

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additives is safe, that the additives will achieve their intended technical effect, and therefore, that the regulations in §§ 172.120 and 172.135 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for

inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

III. Environmental Impact

The agency has carefully considered the potential environmental effects of this rule as announced in the notice of filing for FAP 0A4709. No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

IV. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Objections

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by [*insert date 30 days after date of publication in the Federal Register*]. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of

this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VI. Reference

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from M. DiNovi, Division of Product Manufacture and Use, FDA, to M. LaVecchia, Division of Petition Control, FDA, February 8, 2000.

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

2. Section 172.120 is amended in the table in paragraph (b)(1) by removing the entry for ‘Fava beans (cooked canned)’’, and by alphabetically adding an entry for ‘Legumes (all cooked canned, other than dried lima beans, pink beans, and red beans)’’ to read as follows:

§ 172.120 Calcium disodium EDTA.

* * * * *

(b) * * *

(1) * * *

| Food | Limitation (parts per million) | Use |
|---|--------------------------------|--|
| * * Legumes (all cooked canned, other than dried lima beans, pink beans, and red beans). * * | * * 365 * * | * * Promote color retention. * * |

* * * * *

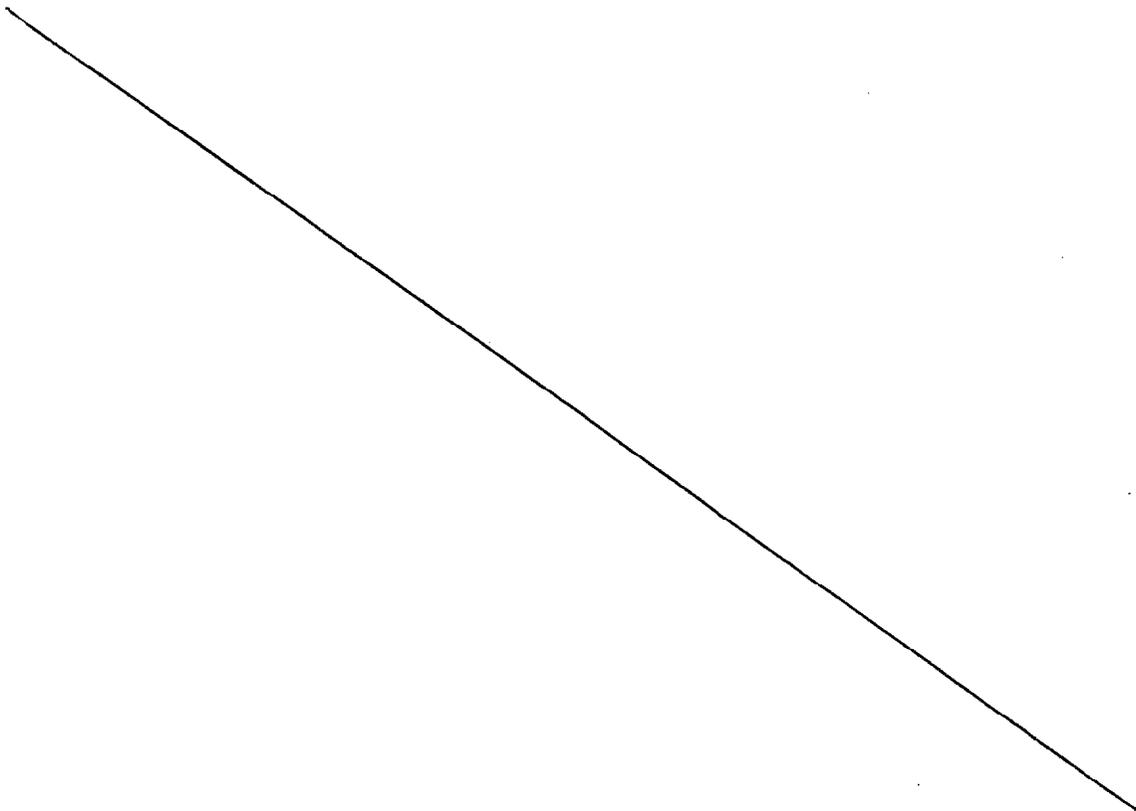
3. Section 172.135 is amended in the table in paragraph (b)(1) by removing the entry for “Canned cooked chickpeas” and by alphabetically adding an entry for “Legumes (all cooked canned, other than black-eyed peas)” to read as follows:

§ 172.135 Disodium EDTA.

* * * * *

(b) * * *

(1) * * *



| Food | Limitation (parts per million) | Use |
|--|--------------------------------|--------------------------|
| Legumes (all cooked canned, other than black-eyed peas). | 165 | Promote color retention. |

* * * * *

Dated: 7/19/00
July 19, 2000

L. Robert Lake

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

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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