

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F-5522]

Food Irradiation Coalition c/o National Food Processors
Association; Filing of Food Additive Petition; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending the filing notice for a food additive petition filed by the National Food Processors Association (NFPA) on behalf of The Food Irradiation Coalition, to provide for the safe use of ionizing radiation for control of food-borne pathogens, and extension of shelf-life, in a variety of human foods up to a maximum irradiation dosage of 4.5 kilograys (kGy) for non-frozen and non-dry products, and 10.0 kGy for frozen or dry products.

FOR FURTHER INFORMATION CONTACT:

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Food and Drug Administration,
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SUPPLEMENTARY INFORMATION: In a notice published in the FEDERAL REGISTER of January 5, 2000 (65 FR 493), FDA announced that a

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Display Date	5/9/01
Publication Date	5/10/01
Certifier	V. [Signature]

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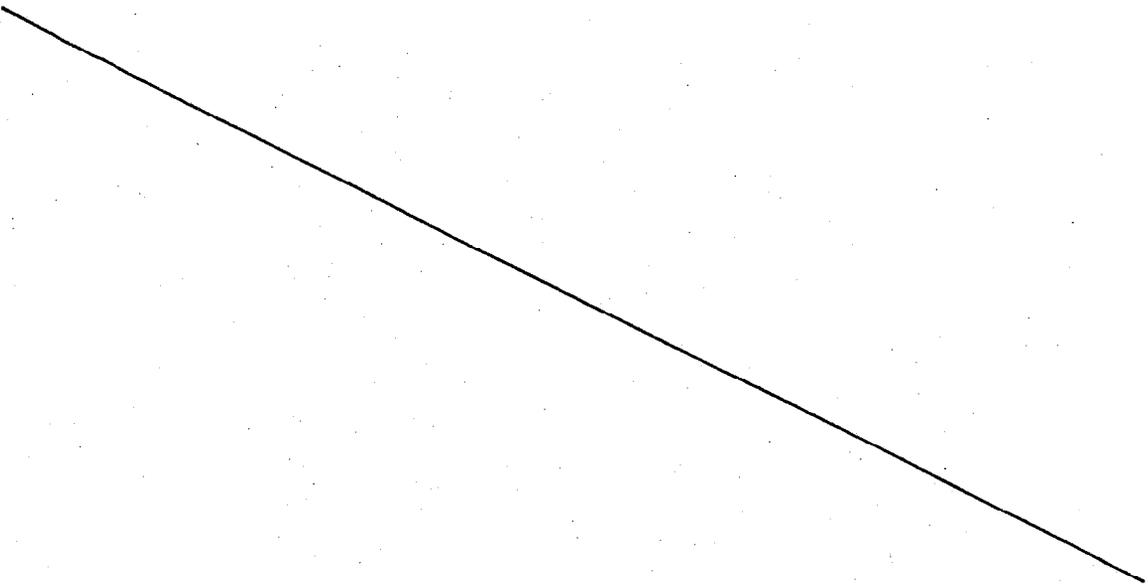
food additive petition (FAP 9M4697) had been filed by the NFPA on behalf of The Food Irradiation Coalition, 1350 I St. NW., suite 300, Washington, DC 20005, proposing that the food additive regulations in part 179 Irradiation in the Production, Processing and Handling of Food (21 CFR part 179) be amended to provide for the safe use of ionizing radiation for control of food-borne pathogens, and extension of shelf-life, in a variety of human foods up to a maximum irradiation dosage of 4.5 kGy for non-frozen and non-dry products, and 10.0 kGy for frozen or dry products, including: (1) Pre-processed meat and poultry; (2) both raw and pre-processed vegetables, fruits, and other agricultural products of plant origin; (3) certain multi-ingredient food products. The notice stated that the petition does not cover products composed in whole or in part of raw meat, poultry, or fish nor does it cover "ready-to-eat" fish products or ingredients made from fish.

Subsequent to the publication of the filing notice, FDA learned from discussions with NFPA that the petitioner intended to include in the scope of the petition certain multi-ingredient products that contain uncooked meat or poultry. In particular, the petitioner noted a clarifying letter, dated October 18, 1999, that it had submitted prior to FDA's filing the petition, that mentioned certain foods, such as country hams and dry and semi-dry sausages, as examples of foods intended to be within the

scope of the petition. In preparing the filing notice, FDA did not recognize that these products are uncooked and, thus, mistakenly excluded such products by virtue of the exclusion for food containing raw meat or poultry. The petitioner recently informed FDA that the January, 2000, filing notice would appear to restrict the scope of the petition and that it was (and is) the petitioner's intent that multi-ingredient meat products (whether containing cooked or uncooked meat or poultry) be included in the scope of the pending petition.

Therefore, FDA is amending the filing notice of January 5, 2000, to indicate that the petitioner has requested that the food additive regulations be amended to permit the irradiation of multi-ingredient foods containing uncooked meat or poultry.

The agency has determined under 21 CFR 25.32(i) that this action is of a type that does not individually or cumulatively have a



significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

Dated: April 20, 2001
April 20, 2001.

Alan M. Rulis

Alan M. Rulis,
Director,
Office of Premarket Approval,
Center for Food Safety and Applied Nutrition.

Monica Oliver