Congressional Report on Irradiation Food Labeling

House Report 107-116; H.R. 2330 and
Conference Action P. L. 107-76

Food and Drug Administration
June 2002

Date 7/3/02

Lester M. Crawford, D.V.M, Ph.D.
Deputy Commissioner

Congressional Report on Irradiated Food Labeling

Report Language – House Report 107-116; H.R. 2330 and Conference Action. P.L. 107-76

> ***The Conferees direct the FDA to report to the Committees on Appropriations by February 1, 2002, on the outcome of recent focus groups regarding the labeling of irradiated food products and to report on how the results will be integrated into future rulemaking decisions.***

CONTENTS OF REPORT

Executive Summary..... 1

Background..... 2

Focus Group Summary..... 3

Current Status..... 4

Executive Summary

Irradiation of food has potential as a means of controlling pathogenic microorganisms in or on food. Under the Federal Food, Drug and Cosmetic Act (the Act), a source of radiation for use on food is subject to premarket approval. Current Food and Drug Administration (FDA) regulations require the label of an irradiated food to contain the words "Treated with radiation" or "Treated by irradiation", along with the radura (), a symbol used throughout the world to represent food irradiation.

The label requirement does not apply to foods that contain an irradiated ingredient, such as irradiated spices, but are not themselves irradiated. Under current regulations, the label may contain additional wording to explain why the food was irradiated; such additional statements must be truthful and not misleading. The Joint Explanatory Statement included in the conference report for the Food and Drug Administration Modernization Act of 1997 (FDAMA) directed FDA to solicit public comment to determine whether the labeling requirement should be changed to ensure that consumers would not perceive the label statement to be a warning.

Consistent with the FDAMA conference report, on February 17, 1999, FDA published an advance notice of proposed rulemaking (ANPR) to solicit comment on the labeling of irradiated foods. By the close of the comment period for the ANPR, FDA had received more than 5,500 comments. The majority of these comments were letters that urged the Agency to retain current labeling for irradiated foods, but did not address the specific issues on which FDA requested comment. Further, these comments did not provide alternative language for the disclosure statements. Although some comments suggested alternate wording, such as "cold pasteurization" or "electronic pasteurization," other comments contended that these terms serve only to obscure information and confuse consumers. A few comments stated that additional labeling, such as "irradiated to kill harmful bacteria," was helpful.

To help the Agency better understand how the current label is perceived by consumers and what message would be perceived as properly informative but not as a warning, FDA conducted focus group research in Maryland, Minnesota, and California, during June and July of 2001. The focus group data indicates that the participants did not necessarily view the required statements as a warning statement and that they saw the statements as useful information when making an informed choice about the product.

On May 13, 2002, the President signed into law the Farm Bill that includes two provisions that relate to irradiation labeling. One of these provisions, section 10808 includes new criteria for use of the term "pasteurization" in labeling. The other provision, section 10809, directs FDA to publish a proposed rule and, with due consideration to public comment, a final rule to revise, as appropriate, the current regulation governing the labeling of foods that have been treated by irradiation. FDA is now beginning the process of implementing these provisions.

Background

FDA published a final rule in the Federal Register of April 18, 1986 (51 FR 13376), requiring that the labeling of retail packages and displays of irradiated food bear both the radura logo and a radiation disclosure statement ("Treated with radiation" or "Treated by irradiation"). We stated in the preamble of that final rule that in addition to the mandatory language, the manufacturer also may state on the wholesale or retail label the purpose of the treatment process or expand upon the kind of treatment used.

For example, the manufacturer may include in the labeling any phrase, such as "treated with radiation to control spoilage," or "treated with radiation to extend shelf life," or "treated with radiation to inhibit maturation," as long as the phrase truthfully describes the primary purpose of the treatment.

Section 306 of FDAMA amended the FD&C Act to provide that no existing provision of the Act would be considered to require a separate radiation disclosure statement that is more prominent than the declaration of ingredients on the food label. The Joint Explanatory Statement included with the FDAMA Conference Report directed the Agency to publish promptly proposed amendments to current regulations to ensure the intended effect of this provision.

In addition, the FDAMA Joint Explanatory Statement suggested that the Agency use the public comment process to provide an opportunity for comment on whether the Agency's regulations should be amended to revise the current prescribed wording for the labeling of foods that have been irradiated and on whether such labeling requirements should sunset. The FDAMA Joint Explanatory Statement also indicated "The conferees intend for any required irradiation disclosure to be of a type and character such that it would not be perceived to be a warning or give rise to inappropriate consumer anxiety."

In response to this direction, FDA issued a direct final rule on August 17, 1998 (63 FR 43875) that clarified that the agency's regulations are to be interpreted in conformance with the provisions of the Act (Sec. 403C (a) and (b)) added by FDAMA.

In addition, on February 17, 1999, FDA issued an ANPR (64 FR 7834) seeking public comment on the meaning of the agency's current irradiation labeling regulations and soliciting suggestions for possible revisions to the label.

This notice described the intent of the Joint Explanatory Statement, cited several documents related to irradiation labeling, and asked for comment on 15 issues regarding how the current label is perceived by consumers and whether other labeling would more accurately convey the type of processing (irradiated or not irradiated) without implying a warning or causing inappropriate consumer anxiety. By the close of the comment period for the ANPR, FDA had received more than 5,500 comments. FDA also conducted focus group research to help the Agency better understand how the current label is perceived by consumers and what messages would be perceived as properly informative but not as a "warning," with the goal of using the results of the focus group studies in developing future rulemaking decisions.

Focus Group Summary

Consistent with FDA's usual protocol for focus group research, in June and July 2001, FDA contracted with ORC Macro to conduct six focus groups. The focus groups were used to help FDA's Center for Food Safety and Applied Nutrition determine consumers' understanding of irradiation and identify consumers' preferences for different labeling options for irradiated food products. Each group consisted of 7 to 10 people recruited at random by telephone from large lists of the general population. Participants were recruited according to specified criteria to ensure a mix of age, sex and education characteristics in each group. One group at each site consisted of people who said they knew little or nothing about food irradiation while the other group consisted of people who said they considered themselves somewhat or very well informed about food irradiation. An ORC Macro moderator facilitated the groups, using a discussion guide prepared by FDA in consultation with a Project Advisory Group (PAG). The PAG consisted of public and private sector individuals representing varied points of view on irradiation labeling. The Macro moderator gave the background of the topic and then engaged the participants in a discussion of irradiated foods and labeling of irradiated foods. All groups were audio and videotaped, and written transcripts of the sessions were prepared.

The majority of participants were uncertain about the safety, effectiveness and appropriateness of irradiated food products and greatly desired more information. Most of the participants viewed alternate terms such as "cold pasteurization" and "electronic pasteurization" as misleading, because they appeared to conceal rather than to disclose information about irradiated food products. Participants did not see the current disclosure labeling as a warning, per se, because some knowledgeable participants spoke in positive terms about the purpose of irradiation. Less knowledgeable participants, who associated irradiation with things such as x-rays or radiation, still wanted more information about the appropriateness of food irradiation. Everyone agreed that irradiated foods should be labeled honestly. They indicated that the current FDA required statement is a straightforward way for labeling irradiated foods.

Current Status

On May 13, 2002, the President signed into law the Farm Bill that includes two provisions that relate to irradiation labeling. One of these provisions, section 10808 includes new criteria for use of the term "pasteurization" in labeling. The other provision, section 10809 directs FDA to publish a proposed rule and, with due consideration to public comment, a final rule to revise, as appropriate, the current regulation governing the labeling of foods that have been treated by irradiation. FDA is now beginning the process of implementing these provisions.