



October 15, 2002

Dockets Management Branch  
(HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

(Docket No. 02D-0385)

Dear Sir or Madam:

On behalf of Public Citizen, a national consumer organization representing over 150,000 members, and the Center for Food Safety, a non-profit consumer group, we submit this comment on the “Guidance on the Petition to Request Approval of Labeling for Foods That Have Been Treated by Irradiation” that was published on October 7, 2002 in the *Federal Register* (67 FR 62487-62488).

### **Historical Perspective**

The current labeling requirements for irradiated foods can be found in 21 CFR 179.26. The regulations require irradiated foods to display the *radura*, the international symbol for irradiation, and the disclosure “treated with radiation” or “treated by irradiation” on product packaging.

Since 1997, when the Congress enacted the Food and Drug Administration Modernization Act (FDAMA) of 1997 (P.L.105-115), there have been attempts to change the labeling requirements. In the conference committee report that accompanied that legislation, the conferees included the following provision:

*Disclosure of irradiation (Sec. 306)*

The conference agreement ensures that no existing provision of the Federal Food Drug and Cosmetic Act will be considered to require a separate radiation disclosure statement that is more prominent than the declaration of ingredients on the food label. To ensure the intended effect of this provision, the conferees direct the Secretary promptly to publish for public comment proposed amendments to current regulations

relating to the labeling of foods treated with ionizing radiation. The conferees expect final regulations to be issued not more than 12 months after the date of enactment of this measure. The public comment process should be utilized by the Secretary to provide an opportunity to comment on whether the regulations should be amended to revise the prescribed nomenclature for the labeling of irradiated foods and on whether such labeling requirements should expire at a specified date in the future. The conferees intend for any required 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.<sup>1</sup>

The FDA responded by publishing an Advanced Notice of Proposed Rulemaking (ANPR) in 1999 (64 FR 7834-7837) soliciting comments regarding potential changes to the current labeling requirements for irradiated foods. The agency received over 20,000 comments on this issue.<sup>2</sup> Overwhelmingly, respondents opposed changing the current labeling requirements.<sup>3</sup>

In the conference committee report that accompanied the FY 2001 Agriculture, Rural Development, Food and Drug Administration and Related Agencies Appropriations Act, the conferees stated:

The conferees expect FDA to make final the regulations regarding labeling of irradiated foods by March 1, 2002, and report to the House and Senate Committees on Appropriations on the status by November 15, 2000. This agreement changes the dates proposed for final regulations by the House of September 30, 2001, and by the Senate of October 30, 2001.<sup>4</sup>

In its report to the Appropriations Committees, the FDA explained that it had published an ANPR in 1999 on food irradiation labeling as the agency was directed to do under the FDAMA conference committee report. In evaluating the comments that the agency received from the ANPR, FDA stated:

The majority of these comments were letters that urged the agency to retain special labeling for irradiated foods but did not address the specific issues on which FDA requested comment. A preliminary analysis of the comments suggest no consensus about what alternative language for disclosure of irradiation processing would be truthful and not misleading. Because the public comments provided no clear direction for agency rulemaking, FDA believes that 1999 ANPR fulfills the Agency's obligations under the FDAMA Conference Report.<sup>5</sup>

The FDA went on to say in its report to Congress that it intended to impanel consumer focus groups to attempt to obtain further guidance on the labeling issue.

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<sup>1</sup> H. Rept. 105-399.

<sup>2</sup> While the agency acknowledges receipt of 4330 comments, there were some 16,000 postcards received from consumers which were counted as representing one comment by the agency.

<sup>3</sup> ICF Consulting, "FDA's Proposed Revisions to the Labeling Requirements for Irradiated Foods: Overview of Public Comments – Final Report," Fairfax, Virginia, March 2001.

<sup>4</sup> H. Rept. 106-948.

<sup>5</sup> Food and Drug Administration, "Response to Congressional Request on Irradiated Labeling Concerns: Report Language – House Committee (H.R. 4461, Report No. 106-619 and Senate Committee and S. 2536, Report No. 106-288)."

During the summer of 2001, the FDA contracted with ORC Macro, a public opinion research firm, to organize six consumer focus groups. Two of these focus groups were held in Calverton, Maryland (suburban Washington, DC), two were held in Minneapolis, Minnesota and two were held in Sacramento, California.

In all of the focus groups, the moderator attempted to make a strong association between pasteurization and irradiation. This was significant since there have been some food irradiation proponents who have argued that a more appropriate term to describe irradiation on product labeling is either “cold pasteurization” or “electronic pasteurization.”<sup>6</sup>

In a report to Congress, the FDA summarized the results of those focus groups:

Most of the participants viewed alternate terms such as “cold pasteurization” and “electronic pasteurization” as misleading, because they appeared to conceal rather than disclose information about irradiated food products. Participants did not see the current disclosure labeling as a warning...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.<sup>7</sup>

Furthermore, in testimony before the House Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies Appropriations, Dr. Lester Crawford, Deputy Commissioner of the FDA stated:

(W)hen we did focus groups at FDA on cold pasteurization, the general feeling of the average citizen was that this was kind of a ruse or a means to conceal the fact that the food had been irradiated. And so we are kind of back to square one. We don't have a good synonym for irradiation and we would like to have one. We don't want to mislead the public.<sup>8</sup>

Also, consumer focus groups impaneled in early 2002 by the Food Safety and Inspection Service of the United States Department of Agriculture in Philadelphia, Pennsylvania; Raleigh, North Carolina; and St. Louis, Missouri mirrored those conducted by the FDA in 2001. The research showed:

Participants consider irradiation and pasteurization to be two different processes; hence, they consider it misleading to label irradiated meat and poultry products as ‘pasteurized.’<sup>9</sup>

FDA's implementation of section 10809 (Irradiation labeling) of the Farm Security and Rural Investment Act 2002 by the Congress must take into account the consumer research on this issue. **If FDA does so faithfully, there is no way the agency can allow the use of the word “pasteurized” as a euphemism for “irradiated” because all the evidence shows it is flat-out misleading.**

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<sup>6</sup> See National Cattlemen's Beef Association. <http://www.beef.org/documents/Irradiation%20fact%20sheet.doc>

<sup>7</sup> Food and Drug Administration, “Congressional Report on Food Labeling – House Report 107-116; HR 2330 and Conference Action P.L. 107-76,” June 2002, p.3.

<sup>8</sup> Testimony of Dr. Lester Crawford, Deputy Commissioner of the Food and Drug Administration, before the House Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies Appropriations, March 21, 2002.

<sup>9</sup> RTI International, “Consumer Research on Food Safety Labeling Features for the Development of Responsive Labeling Policy,” March 22, 2002.

## Other Relevant Consumer Research

Independent of what the agency has already done on this issue, there has been additional consumer research that supports what the FDA has found:

- In a 1999 nationwide poll of 1000 consumers conducted for the Center for Science in the Public Interest (CSPI) and the Association for the Advancement of Retired People (AARP) by OmniTel, less than a quarter of those surveyed preferred changing the current labeling requirements to either cold pasteurization or electronic pasteurization;<sup>10</sup>
- In a January 2002 nationwide poll of 1000 consumers conducted for Public Citizen by Lake, Snell, Perry and Associates, only about a quarter of those surveyed preferred changing the current labeling requirements to either “cold pasteurization” or “electronic pasteurization” – corroborating the results of the 1999 CSPI/AARP poll.<sup>11</sup>

## Research Submitted to FDA in Support of Citizen’s Petitions Under Section 10809 of Farm Bill

While we applaud the agency’s requirement that consumer research needs to be submitted in support of any Citizen’s Petitions received for alternative irradiated food labeling, in light of the research already conducted, any research received by the agency that differs dramatically from the studies cited above must receive rigorous scrutiny. We would urge that the FDA validate the results of such research, especially if a petitioner is attempting to use a familiar term in place of the word “irradiation.” We call attention to recent material that the agency was instrumental in drafting for the Codex Committee on Food Labeling:

{Consumer} confusion often occurs because a promotional communication uses a word, phrase, symbol, or image that is similar to a more familiar word, phrase, symbol, or image, but that does not have a similar meaning.<sup>12</sup>

Consequently, any attempt by a petitioner to use the term “pasteurization” or any other euphemism to describe irradiation in product labeling needs to be met with skepticism.

In addition, any attempt to use the term pasteurization in labeling for irradiated foods should be supported by research that proves that the food has been, in fact, pasteurized in accordance with current regulations.

When the Food Safety and Inspection Service (FSIS) approved irradiation for red meat, it commented on requests by industry for a relaxation of labeling requirements for irradiated foods. In the final rule, FSIS stated:

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<sup>10</sup>OmniTel, Food Irradiation poll conducted by for the Center for Science in the Public Interest, April 16-19, 1999.

<sup>11</sup> Lake, Snelling and Associates, “Public Citizen: Questions on Irradiated Food and Inspection of Meat-Processing Plants; Banners from an Omnibus Survey of 1000 Nationwide Registered Voters,” January 13-15, 2002.

<sup>12</sup> United States Delegates to CODEX Committee on Food Labeling, “Discussion Paper on Misleading Food Labels,” presented at the 29<sup>th</sup> Session of the Committee held in Ottawa, Canada, April 30 – May 4, 2001, p. 6.

FSIS will review, on a case-by-case basis, labels with alternative or euphemistic statements regarding irradiation. FSIS is requiring, however, that labels of meat food or poultry products that have been irradiated in their entirety be labeled with statements such as "Treated with irradiation" or "Treated by irradiation," or, that the word "Irradiated" be part of the product name. FSIS will allow the terms "cold," "electronic," and "ionizing" to be used in conjunction with term "irradiation," if truthful. At this time, however, labeling statements or claims for irradiated product that include the term "pasteurization" probably would be misleading. "Pasteurization" implies the destruction of all vegetative microorganisms in the product as a result of irradiation. At the maximum dosages allowed by FDA and FSIS, it would be highly unlikely that all of the vegetative microorganisms in irradiated product would be destroyed.<sup>13</sup>

This point was reiterated in a letter from Philip Derfler, Deputy Administrator for the Office of Policy, Program Development and Evaluation of the Food Safety and Inspection Service in response to a claim made by the SureBeam Corporation that its irradiation equipment could pasteurize meat and poultry products:

The Food Safety and Inspection Service (FSIS) has no information as to whether the SureBeam Corporation irradiation equipment is capable of pasteurizing meat and poultry products.

Furthermore, FSIS has not approved any labeling submitted by the SureBeam Corporation or any other firm that includes claims or statements indicating that meat and poultry products treated by ionizing radiation using the Surebeam (sic) equipment are pasteurized.<sup>14</sup>

Furthermore, FSIS's website document entitled, "Irradiation Q's & A's", states the following:

15. Would FSIS consider the term "pasteurized" as an acceptable term to describe the irradiation process?

At this time, labeling statements or claims for irradiated products that include the term "pasteurization" are misleading. FSIS will continue to examine this term in light of developments in irradiation technology and FDA policy. In the future, use of the term "pasteurization" will be considered on a case-by-case basis and would require significant documentation and validation as to process controls that demonstrate that vegetative cells of pathogens have been reduced to safe levels and produces a ready-to-eat product.<sup>15</sup>

Therefore, we urge the FDA to require all petitions that propose to use the term pasteurization in labeling for irradiated food to take into account the concerns that the USDA has already expressed on this issue.

## **The Pasteurization Standard**

At a recent meeting of the National Advisory Committee on Microbiological Criteria for Foods, a presentation was made by Dr. Robert Brackett, Director of Food Safety for the FDA entitled, "Redefining Pasteurization' 2002 Farm Bill Provision."<sup>16</sup> The purpose of the presentation was

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<sup>13</sup> 64 FR 72158.

<sup>14</sup> Letter from Philip Derfler to Public Citizen, September 29, 2001.

<sup>15</sup> See [http://www.fsis.usda.gov/oppde/larc/Irradiation\\_Q\\_&A.htm#LABELING%20ISSUES](http://www.fsis.usda.gov/oppde/larc/Irradiation_Q_&A.htm#LABELING%20ISSUES).

<sup>16</sup> Meeting of the National Committee on Microbiological Criteria for Foods, Jurys Washington Hotel, Washington, DC, August 28, 2002.

to introduce the committee to Section 10808 of the Farm Security and Rural Investment Act of 2002 for further study.<sup>17</sup> The committee will select a subcommittee to begin meeting on this issue during the fall of 2002.

In his presentation, Dr. Brackett listed the current regulations that define pasteurization. These regulations cover the pasteurization of milk<sup>18</sup>, juice<sup>19</sup>, eggs<sup>20</sup>, and seafood.<sup>21</sup> In all of these instances, products can be pasteurized using heat. There is no definition of pasteurization that includes irradiation. Consequently, there is currently no recognized governmental definition making the two processes synonymous.

## **Irradiation and Palatability of Food**

There is research that shows that the irradiation of foods at high levels can make the food acquire taste, texture and smell that might be unpalatable.<sup>22</sup> In order to achieve the same level of pathogen reduction as traditional pasteurization methods, irradiation could leave the food unfit for consumption. There has been some experience with this problem with the irradiation of mail that contained food products.<sup>23</sup>

Consequently, the agency should require all petitioners to furnish research that irradiation can pasteurize under traditional definitions without affecting the taste, smell, and texture of foods.

## **Process Transparency**

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<sup>17</sup> Section 10808. Pasteurization

(b) Pasteurization of Food as Pasteurized. Section 403 (h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(h)) is amended –

- (1) by striking “or” at the end of paragraph (1);
- (2) by striking the period at the end of paragraph (2) and inserting “;or”; and
- (3) by adding the following:

“(3) a food is pasteurized unless –

“(A) such food has been subjected to a safe process or treatment that is prescribed as pasteurization for such food in a regulation that promulgated under this Act; or

“(B) (i) such food has been subjected to a safe process or treatment that –

“(I) is reasonably certain to achieve destruction or elimination in the food of the most resistant microorganisms of public health significance that are likely to occur in the food;

“(II) is at least as protective of the public health as a process or treatment described in subparagraph (A);

“(III) is effective for a period that is at least as long as the shelf life of the food when stored under normal and moderate abuse conditions; and

“(IV) is the subject of a notification to the Secretary, including effectiveness data regarding the process or treatment; et seq.”

<sup>18</sup> 21 CFR 131.

<sup>19</sup> 21 CFR 146.140.

<sup>20</sup> 21 CFR 160.115; 21 CFR 160.140; 21 CFR 160.180.

<sup>21</sup> Food and Drug Administration, *Fish and Fisheries Products Hazards and Controls Guidance*, Center for Food Safety and Applied Nutrition, , Third edition, June 2001.

<sup>22</sup> Ahn, Dong, “Causes and Remedies for Off-Odor Production and Color Changes in Irradiated Meat”, presented at Food Irradiation 2002, Westin Park Central, Dallas, Texas, March 25-27, 2002.

<sup>23</sup> Lazar, Kay, “Post Office Gives Up on Germ-zapping Machines,” *Boston Herald*, September 24, 2002.

Notwithstanding the 180-day turnaround requirement, we believe that all Citizen's Petitions received under Section 10809 of the Farm Bill need to be published in the *Federal Register* and should be open to public comment. Further, the petitions and related documents should be promptly posted on the agency's website and an announcement made indicating that this will occur. It is within FDA's discretion to create formal ways by which other Federal and State agencies, outside food safety experts, involved stakeholders, and the public may be informed of the raw existence, contents, and outcomes of these petitions. FDA's keeping these documents and actions invisible plainly would go against the public interest. (Experience shows that normal FDA Freedom of Information Act (FOIA) response times would not provide documents within the number of days allowed under the new laws for deciding on the proposals, even if the FOIA requestor had notice of a notification or petition being filed.) Food safety and consumer labeling decisions must be held to a high standard of scrutiny. The failure of FDA to engage in a public process would lead to unnecessary controversy and potentially to litigation, as well as undermine public confidence in the accuracy of food labels.

We appreciate this opportunity to comment on this guidance document. Should you have any questions regarding our comments, please feel free to contact us.

Sincerely,

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