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Joan Claybrook, President

August 20, 2004

Food Safety and Inspection Service
Department of Agriculture
Office of Public Health and Science
Aerospace Center, Room 333
1400 Independence Avenue, SW.
Washington, DC 20250-3700

ATTN: Karen Thomas

RE: Docket number 04-028N

Dear Sir or Madam:

On behalf of Public Citizen, a national consumer organization representing over 150,000 members, we welcome this opportunity to comment on the work of the Subcommittee on the Scientific Criteria for Redefining Pasteurization. We have been very interested in the deliberations of this subcommittee as we have attended all of the public sessions it has held since the end of June 2003. The subcommittee should be commended for its hard work as it has had a very difficult issue with which to deal.

One of the main reasons we have taken an interest in this issue comes through our work on food irradiation. It is no secret that the genesis for Section 10808 of the Farm Security and Rural Development Act of 2002 came from some in the food irradiation industry who have made repeated attempts to weaken the current labeling requirements for irradiated foods. In particular, it should be noted that the electronic beam irradiator, the SureBeam Corporation (now defunct),¹ made changing the labeling regulations for irradiated food a major regulatory and legislative priority.² As a consumer group, we have fought against weakening those labeling requirements. Consequently, we believe that it is important that the work of the subcommittee is placed in context of that on-going debate.

¹ Freeman, Mark. "SureBeam Clears Major Block in Bankruptcy Case," San Diego Union-Tribune, April 6, 2004.

² Lee, Elizabeth. "Hi-Tech Meat to Hit Grocery," Atlanta Journal Constitution, January 11, 2003.

As has been mentioned several times during the subcommittee's deliberations, irradiation is a "mature" technology when compared to the others studied. Because of its longer history, it also has a longer track record. We will comment on the redefinition of pasteurization as it relates to irradiation because it is illustrative of some of the problems that both the Food and Drug Administration (FDA) and United States Department of Agriculture (USDA) may face with other technologies and consumer acceptance of broadening the definition of pasteurization.

Legislative History

The current labeling requirements for irradiated foods can be found in 21 CFR 179.26. The current 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 numerous 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.³

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.⁴ Overwhelmingly, respondents opposed changing the current labeling requirements. According to the report prepared by FDA's own consultant on the public's views, 78.7 percent of respondents who addressed the label terminology stated they wanted the current labeling requirements maintained, and 19.5 percent stated they wanted to strengthen the labeling requirements to include foods with irradiated ingredients. (Currently, multi-ingredient foods that contain irradiated meat ingredients must be labeled as such; there is no such requirement, however, for multi-ingredient foods that contain non-meat ingredients that have been irradiated). In total then, 98.2 percent of respondents said they wanted the current labeling requirements

³ H.Rept. 105-399.

⁴ 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.

maintained or strengthened. A de minimis number of commenters - less than 1.1 percent - preferred the word "pasteurized."⁵

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, 2001.⁶

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.⁷

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.

During the summer of 2001, the FDA contracted with ORC Macro,⁸ 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".⁹

⁵ ICF Consulting. "FDA's Proposed Revisions to the Labeling Requirements for Irradiated Foods: Overview of Public Comments – Final Report," March 2001, pp. 19-23.

⁶ H.Rept. 106-948.

⁷ "Response to Congressional Request on Irradiated Labeling Concerns: Report Language – House Committee (H.R. 4461, Report No. 106-619 and Senate Committee (S. 2536, Report No. 106-288)".

⁸ ORC Macro. "Consumers' Understanding of Food Irradiation Labeling: Focus Group Report," submitted to the Food and Drug Administration, Center for Food Safety and Applied Nutrition, April 2002.

⁹ See National Cattlemen's Beef Association. <http://www.beef.org/documents/Irradiation%20fact%20sheet.doc>

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** (emphasis added).¹⁰

Therefore, the original premise for congressional action on modifying the labeling requirements for irradiated foods was proven to be incorrect.

Working independently of the FDA, the Labeling and Additives Policy Division of the Food Safety and Inspection Service at USDA also commissioned a consumer focus group study in late 2001 on this issue, and it arrived at the same conclusions:

Participants consider irradiation and pasteurization to be two different processes; hence, they consider it misleading to label irradiated meat and poultry products as “pasteurized”. This finding is consistent with FSIS’ current belief that the labeling of irradiated meat and poultry products as “pasteurized” has the potential for creating consumer confusion.¹¹

Furthermore, on March 21, 2002, 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.¹²

Independent of what the FDA and USDA had already done on this issue, there has been additional consumer research that supports what these government agencies have found:

- In a 1999 nationwide poll of 1000 consumers conducted for the Center for Science in the Public Interest (CSPI) and the American Association of Retired Persons (AARP) by OmniTel, a very small minority of those surveyed preferred changing the current labeling requirements to either cold pasteurization or electronic pasteurization;¹³

¹⁰ “Congressional Report on Food Irradiation Labeling – House Report 107-116; HR 2330 and Conference Action P.L. 107-76, June 2002, p. 3.

¹¹ RTI International . “Consumer Research on Food Safety Labeling Features for the Development of Responsive Labeling Policy”, prepared for Robert C. Post, U.S. Department of Agriculture, Food Safety and Inspection Service, Labeling and Additives Policy Division, March 22, 2002, pp. ES-5-6.

¹² 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.

¹³ Food Irradiation poll, conducted by OmniTel for the Center for Science in the Public Interest and the American Association of Retired Persons, April 16-19, 1999.

- In a January 2002 nationwide poll of 1000 consumers conducted for Public Citizen by Lake, Snell, Perry and Associates, again, only a small minority 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.¹⁴

The 2002 Farm Bill

As the United States Senate was considering its version of the 2002 Farm Bill (S. 1731 --the Agriculture, Conservation, and Rural Enhancement Act of 2001), a 396-page amendment was offered on the Senate floor on February 13, 2002.¹⁵ Very few Senators knew the full content of the amendment prior to its being offered. Buried in that amendment was the following language:

“SECTION 1079E

PASTEURIZATION.

For the purposes of any provision of Federal law under which a food or food product is required to undergo a treatment of pasteurization, the term ‘pasteurization’ means any safe treatment that--

(1) is a treatment prescribed as pasteurization applicable to the food or food product under any Federal law (including a regulation); or

(2) has been demonstrated to the satisfaction of the Secretary of Health and Human Services to achieve a level of reduction in the food or food product of the microorganisms of public health concern that--

(A) is at least as protective of the public health as a treatment described in paragraph (1); and

(B) is effective for a period that is at least as long as the shelf life of the food or food product when stored under normal, moderate, and severe abuse conditions.”

This language – along with most of the other provisions of the amendment – had not been subjected to congressional hearings or even debate on the Senate floor. Nevertheless, the 396-page amendment with the section on redefining pasteurization was passed by the Senate.

The United States House of Representatives had passed its own version of the Farm Bill on October 5, 2001 (H.R. 2646 – the Farm Security Act of 2001),¹⁶ and it was silent on the issue of redefining pasteurization. Consequently, a conference committee was appointed in the late winter of 2002 to work out the differences between the House and Senate versions.

The conference committee held several public sessions, but the issue of redefining pasteurization was never discussed in open session. However, there were private discussions in which concerns emerged over the broadness of the Senate language redefining pasteurization. As a consequence of those concerns, the language that was eventually adopted in the final version of the Farm Bill

¹⁴ “Public Citizen: Questions on Irradiated Food and Inspection of Meat-Processing Plants; Banners from an Omnibus Survey of 1000 Nationwide Registered Voters”, Lake, Snell, Perry and Associates, January 13-15, 2002.

¹⁵ Congressional Record, February 13, 2002, pp. S680-S683.

¹⁶ Congressional Record, October 5, 2001, pp. H6510-H6511.

was dramatically different.¹⁷ The 2002 Farm Bill – with the revised section on the redefinition of pasteurization – was signed into law by President Bush on May 13, 2002.

Positions Taken by FSIS on Irradiation as a Pasteurization Method and Labeling

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:

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.¹⁸

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.¹⁹

¹⁷ 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 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.”

¹⁸ 64 FR 72158.

¹⁹ Letter from Philip Derfler to Tony Corbo, Public Citizen, September 29, 2001 (see http://www.citizen.org/documents/derfler_letter.pdf).

Furthermore, FSIS's 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.²⁰

Consequently, FSIS has consistently expressed certain reservations regarding defining irradiation as a synonym for pasteurization.

Some Additional Concerns

Some subcommittee members have expressed concern about using the term pasteurization on product labeling to describe raw meat and poultry that has been treated with the technologies being considered. We share those concerns. Consumers know that they can safely drink pasteurized milk from a properly stored bottle or package; can consumers safely eat properly stored raw hamburger meat even after it has been treated with a technology, such as irradiation, that has deemed to be a form of pasteurization? At the present time, USDA does not seem to think so.

In a May 2003 brochure prepared by USDA's Food and Nutrition Service entitled, "Irradiation of Raw Meat and Poultry: Questions and Answers," the following statement is made:

Q. Do you still need to cook irradiated meat?

A. Yes. Irradiation does not cook the meat or make it safe to eat raw. Eating raw meat (like "steak tartare") or poultry is not safe.²¹

In a June 2003 press release issued by FSIS entitled, "For an Enjoyable Fourth, Consumers Should Practice Food Safety," the following statement is made by Dr. Elsa Murano, USDA's Under Secretary for Food Safety, about irradiated meat and poultry products:

"While irradiation is an added step in making meat and poultry safer, irradiation does not make the product sterile and should not replace safe food handling. Consumers will still need to remember and follow the four basic steps in handling food safely."²²

²⁰ <http://www.fsis.usda.gov/oppde/larc/policies/irradiation%20qa.pdf>

²¹ <http://www.fns.usda.gov/cnd/Lunch/Downloadable/irrad.pdf>

²² <http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OA/news/2003/july4.htm>

The four basic steps enumerated in the press release include:

- Wash hands and surfaces often.
- Separate raw meat and poultry from cooked/ready-to-eat food to prevent cross-contamination.
- Cook food to a safe internal temperature. Check temperature with a food thermometer. Cook hamburger patties to 160 °F and ground poultry to 165 °F.
- Refrigerate or freeze promptly. Store food in a cooler with a cold source such as a frozen gel pack. Unpack the cooler just before cooking or serving the food. Meat and poultry should be returned to the cooler or stored in the refrigerator or freezer within two hours after being cooked and only one hour when the temperature is above 90 °F.

Based on FSIS' own recommendations to consumers, it does not seem that irradiated raw meat or poultry can be considered to be pasteurized as consumers commonly understand the concept. In fact, the same can be said about all of the other technologies being considered by the subcommittee.

We also have a concern that the subcommittee may have deviated from the statutory language when it developed its own working definition of pasteurization. We realize that the Congress may have not presented the subcommittee with a suitable definition from which to work. But we would caution against using a broad definition upon which regulatory decisions will be made which does not comport with the statutory language.

Recommendations

We urge both FDA and USDA to be judicious in their use of the term pasteurization to describe processes and treatments that do use traditional time and temperature requirements to achieve food safety objectives. Before even considering petitions from industry, we believe that both FDA and USDA need to conduct additional consumer research on the understanding of pasteurization and whether non-traditional technologies that have the potential to achieve food safety objectives will be accepted by consumers as pasteurization techniques.

In addition, since redefining pasteurization will have far-reaching ramifications, we believe that a full rule-making process needs to be undertaken to solicit input from all stakeholders on this issue before petitions are accepted for review by the FDA.

We were struck by a statement contained in a paper entitled, "Discussion Paper on Misleading Food Labels," that was jointly prepared by representatives of FDA and USDA and presented to the Codex Committee on Food Labelling in 2001. That document stated:

{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.²³

²³ "Discussion Paper on Misleading Food Labels," United States Delegates to CODEX Committee on Food Labelling, presented at the 29th Session of the Committee held in Ottawa, Canada, April 30 – May 4, 2001, p. 6.

When it comes to the concept of pasteurization, we should move very cautiously to ensure that changing its traditional meaning does not have the effect of destroying it as an accepted food safety measure in the minds of consumers.

Sincerely,

Wenonah Hauter, Director
Public Citizen's Food Program