

SureBeam Corporation

5 8 8 9 '02 SEP 13

September 20, 2002

HAND DELIVER

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

Re: Docket No. 02N-0209; Request for Comment on First Amendment Issues

Dear Sir or Madam:

The attached comments were submitted by SureBeam Corporation to the Food and Drug Administration electronically on September 13, 2002. Attached please find a hard copy of our comments, together with copies of the articles and reports cited in the comments. Please accept these as an attachment to SureBeam's comments.

Sincerely,

Dennis Olson *ROH*

Dennis G. Olson, Ph.D.
Vice President, Food Technology

Attachments

. 02N-0209

C
54P2



September 13, 2002

BY ELECTRONIC MAIL

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

Re: Docket No. 02N-0209; Request for Comment on First Amendment Issues

Dear Sir or Madam:

SureBeam Corporation (SureBeam) is grateful for this opportunity to submit comments to the Food and Drug Administration (FDA) in response to the agency's Request for Comment on First Amendment Issues. 67 Fed. Reg. 34,942 (May 16, 2002). SureBeam commends the FDA for its willingness to reconsider existing FDA regulations and policies that may infringe First Amendment protections of commercial speech. We believe that FDA's disclosure requirement for irradiated foods is such a regulation.

SureBeam is the nation's leading electron beam processor of foods. For the past two years, SureBeam® technology has been used to treat millions of pounds of ground beef and Hawaiian tropical fruit shipped to the mainland United States.

SureBeam believes that the FDA labeling disclosure requirement for irradiated foods is a clear violation of First Amendment protections of commercial speech. According to a well-established test enunciated by the U.S. Supreme Court, government regulation of commercial speech must be based on a substantial government interest, must directly advance the asserted government interest, and must do so without imposing an unnecessary burden. The FDA disclosure requirement for irradiated foods fails the constitutional test on all three counts. There is no substantial government interest underlying the disclosure requirement for irradiated foods; the disclosure requirement does not directly advance the government interest that has been put forth by the FDA; and, finally, the disclosure requirement is unnecessarily burdensome.

The irradiation disclosure requirement was built on a shaky rationale to begin with. Given the subsequent development of federal case law applying the First Amendment to commercial speech, it cannot survive constitutional scrutiny.

FDA'S DISCLOSURE REQUIREMENT FOR IRRADIATED FOODS

FDA regulations require that the label and labeling of irradiated foods must bear an "irradiation disclosure statement" (i.e., the words "treated with radiation" or "treated by irradiation") and the radura logo (hereinafter referred to collectively as the "irradiation disclosure"). 21 C.F.R. § 179.26(c). This irradiation disclosure must appear on all foods treated

with radiation regardless of the type of food treated, the type of irradiation treatment, the purpose for which the food was treated, or the radiation dose.

In creating this “blanket” disclosure requirement for irradiated foods, the FDA relied on Federal Food, Drug, and Cosmetic Act (FFDCA) §§ 201(n), 403(a), and 409 (21 U.S.C. §§ 321(n), 343(a), and 348) as statutory authority. Under these provisions, labeling is misleading, and the labeled article is misbranded, if such labeling “fails to reveal facts [that are] material in the light of [representations made in labeling or advertising by statement, word, design, device or any combination thereof] or material with respect to consequences which may result from the use of the article...” 21 U.S.C. § 321(n). FDA determined that, although “there is no concern about the safety of such treatment,” a disclosure of the fact of irradiation should be required because “the changes brought about by the safe use of irradiation are material facts in light of representations made, including the failure to reveal material facts, about such foods.” 51 Fed. Reg. 13376, 13388 (April 18, 1986). According to FDA’s analysis, because irradiated foods are “processed” but do not appear to be so, and because such processing may change a food’s organoleptic qualities and shelf life, disclosure is needed to avoid misleading consumers.

In mandating a disclosure on all irradiated foods, the FDA was cognizant of widespread consumer concerns about food irradiation at that time. According to FDA, “the large number of consumer comments requesting retail labeling attest to the significance placed on such information by consumers.” 51 Fed. Reg. at 13388. In its comprehensive rulemaking on food irradiation, FDA originally proposed not to require any special labeling of irradiated foods, stating that “information about radiation processing is not material.... and therefore need not be provided on the label of retail foods.” 49 Fed. Reg. 5714, 5718 (Feb. 14, 1984). Following publication of this proposed rule, FDA was the target of a massive consumer letter-writing campaign orchestrated by the consumer advocacy group Public Citizen. Its final rule requiring disclosure of irradiation refers repeatedly to consumer desire for mandatory labeling of irradiated foods. The final rule included a “sunset provision” that would have phased out the irradiation disclosure statement (i.e., “treated with radiation” or “treated by irradiation”) two years after publication of the final rule, but the phaseout of this requirement was later extended and then abandoned. 53 Fed. Reg. 12756 (April 18, 1988); 55 Fed. Reg. 14413 (April 18, 1990).

Irradiation is the only food processing technology required to be disclosed as a “material fact” under FFDCA § 201(n). One legal commentator has characterized the irradiation disclosure requirement as a departure from FDA’s traditional exercise of its authority under FFDCA § 201(n):

Although FDA’s application of section 201 has been consistent over the years, arguably there is one case in which the agency has invoked section 201(n) to impose labeling requirements for which it is difficult to muster the degree of support that accompanies other applications of the section. The case involved irradiated foods.... Irradiation is the only instance in which a processing technique has been required to be disclosed under section 201(n). The requirement was not based on safety concerns about irradiation, but rather on the fact that irradiation could cause changes in flavor or shelf-life of finished foods, and that these changes could be

significant and material in light of the consumer's perception of such foods as unprocessed. Arguments can be mustered that FDA may have focused on processing as material information in an effort to accommodate consumer concerns over the safety of irradiation. In so doing, FDA may have stretched its traditional exercise of authority under section 201(n).

F. Degnan, "Biotechnology and the Food Label: A Legal Perspective," 55 Food and Drug Law Journal 301, 306.

THE CENTRAL HUDSON TEST

The U.S. Supreme Court has enunciated a four-part test for determining whether government regulation of commercial speech is constitutionally permissible:

- (1) Is the commercial speech protected by the First Amendment? To enjoy any First Amendment protection, commercial speech must concern lawful activity and not be misleading.
- (2) If the commercial speech is protected, is the asserted government interest in regulation of such speech substantial?
- (3) If the asserted government interest is substantial, does the government regulation directly advance the government interest asserted?
- (4) If the regulation of speech directly advances the government interest asserted, is the regulation not more extensive than is necessary to serve that interest?

To withstand constitutional scrutiny, a government regulation must be able to answer the three latter questions above in the affirmative. Central Hudson Gas & Electric Corp. v. Public Service Com'n of New York, 447 U.S. 557, 566 (1980); Thompson v. Western States Medical Center, 122 S. Ct. 1497 (2002).

Government regulations that compel commercial speech, as well as those that restrict or prohibit such speech, must pass muster under the Central Hudson test. "The right not to speak inheres in political and commercial speech alike.... and extends to statements of fact as well as statements of opinion." International Dairy Foods Association v. Amestoy, 92 F.3d 67, 71 (2nd Cir. 1996) (citing Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626 (1985)).

THE COMMERCIAL SPEECH IN QUESTION, THE LABELING OF IRRADIATED FOODS, INVOLVES LAWFUL ACTIVITY AND IS NOT MISLEADING

The labeling of a food product that has been treated with radiation in accordance with an FDA regulation clearly meets the first prong of the Central Hudson test. The FDA has approved a number of uses of irradiation in food, and these approved uses are set forth in 21 C.F.R. § 179.26(b). Labeling of such products that complies with FDA's food labeling regulations is lawful and not misleading. Therefore, such labeling is entitled to First Amendment protection.

THERE IS NO SUBSTANTIAL GOVERNMENT INTEREST IN THE IRRADIATION DISCLOSURE

In order for FDA's irradiation disclosure requirement to withstand First Amendment scrutiny under the second prong of the Central Hudson test, it must advance a substantial government interest. The FDA must be able to point to a real harm that the disclosure requirement is designed to address. "[A] government body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." Edenfield v. Fane, 507 U.S. 761, 770-771 (1993). Thus, FDA must be able to show that consumers would be misled, and thereby harmed, without such a disclosure.

According to the FDA, the government interest advanced by the irradiation disclosure requirement is notice to consumers of certain "material facts" about irradiated foods. FDA has determined that the irradiation disclosure is necessary to reveal to consumers the following "material facts" about irradiated foods: organoleptic changes in food caused by irradiation treatment, changes in shelf life caused by irradiation treatment, and the fact that irradiated food is "processed" but does not appear to be so. 51 Fed. Reg. at 13388-90. According to FDA's analysis, there is a substantial government interest in requiring disclosure of irradiation treatment in order to prevent consumers from being misled about the nature (processed versus unprocessed), organoleptic traits, and shelf life of irradiated foods.

When carefully examined, however, this analysis falls apart. FDA's assertion that consumers will suffer real harm if they are not informed that irradiated foods are "processed" is unpersuasive, because other food processing technologies that are also not readily apparent to the consumer and that have effects on food similar to those of radiation are not required to be disclosed. Moreover, FDA's position that consumers will be harmed if they are not told that irradiated foods have been processed is undercut by the fact that FDA does not treat irradiated foods as processed foods in other contexts. FDA's assertion that consumers will be harmed if not alerted by the irradiation disclosure to irradiated foods' altered organoleptic properties and shelf life is also unconvincing, because most irradiated foods undergo no, or only minimal, changes in organoleptic traits and shelf life. The minor changes that do occur in some irradiated foods are generally beneficial, resulting in improved organoleptic properties and extended shelf life.¹ Where irradiation treatment of a particular food results in significant organoleptic change, there is arguably a substantial government interest in requiring a disclosure in that case. However, there is no substantial government interest sufficient to justify a blanket disclosure requirement for all irradiated foods.

- **There is no substantial government interest in disclosure that irradiated foods are "processed"**

FDA has stated that the irradiation disclosure is needed, because irradiated foods are "processed" but (unlike, for example, frozen foods or canned foods) do not appear to be so. 51 Fed. Reg. at 13388. Yet, FDA's basic position (i.e., that irradiated foods are "processed" foods) is inconsistent with FDA's own regulations. FDA allows foods irradiated at doses up to 1 kiloGray (kGy) to be labeled as "fresh," a designation generally prohibited on labels of processed foods. 21 C.F.R. § 101.95(c)(1)(iv). In addition, FDA does not treat irradiated foods as processed foods for other purposes. For example, irradiated fruits and vegetables are treated by FDA as "raw agricultural commodities," not as "processed foods," for purposes of nutrition labeling. See 21 U.S.C. §§ 321(r), (gg); 343(q)(4); 21 C.F.R. §§ 101.42, 101.45. If the fact that

¹ Food irradiation technology has made significant advances since 1986 when the FDA offered its most detailed justification for the irradiation disclosure requirement.

irradiated foods are “processed” is so important that its disclosure to consumers constitutes a substantial government interest, why does FDA not treat irradiated foods as processed in these other contexts?

Even if foods treated with radiation are in some sense processed, FDA has never explained why this fact is so important that its disclosure is a substantial government interest. Other food technologies, including some that are not readily apparent to consumers and that have effects on food similar to those of irradiation, do not require disclosure. For example, foods treated with ultrasound are not required to bear an ultrasound disclosure statement; foods treated with ultraviolet (UV) light are not required to bear a UV light disclosure; and foods fumigated with insecticides and fungicides are not required to bear any disclosure.² Foods developed using modern biotechnology, or processed using genetically engineered processing aids, are not required to bear a biotechnology disclosure unless they differ significantly in safety, nutritional value, or functional properties from their conventional counterparts. Disclosure that a food has been irradiated, absent some significant change in the food induced by the treatment, is simply not a substantial government interest.

- **There is no substantial government interest in disclosure of organoleptic change in irradiated foods**

² According to one of the leading authorities on food irradiation, sonication, or treatment of food with ultrasound, results in formation of “sonolysis products, which are largely identical with the products of radiolysis.” J.F. Diehl, *Safety of Irradiated Foods*, second edition, Marcel Dekker, New York, 1995, p. 176. Ultrasound is used in food processing to detect leaks in containers, to homogenize milk, and to produce stable emulsions of other fat-water combinations. *Id.*

For many irradiated foods, irradiation treatment does not result in any significant organoleptic change. As food irradiation technology has improved, organoleptic changes caused by irradiation have largely disappeared. Most irradiated foods are indistinguishable from non-irradiated foods in taste, texture, color, smell, and other sensory qualities.³ Therefore, organoleptic change cannot justify a blanket disclosure requirement for all irradiated foods.

For some irradiated foods, irradiation treatment has been shown to result in improved organoleptic properties.⁴ As previously noted, to regulate commercial speech, the government must show a real harm that its regulation will alleviate. It is not clear how a beneficial characteristic, such as improved taste, can be the kind of harm that justifies regulation of speech.

- **There is not substantial government interest in disclosure of the extended shelf life of irradiated foods**

³ See, e.g., Crawford, LM and EH Ruff, A review of the safety of cold pasteurization through irradiation, *Food Control*; 7 (2): 87-97 (1996) ("Following good manufacturing practices, irradiated food is virtually indistinguishable from its non-irradiated counterparts."); Vickers, ZM and J Wang, Liking of ground beef patties is not affected by irradiation, *J. of Food Science*; 67 (1): 380-383 (2002). If irradiated foods were organoleptically inferior to non-irradiated foods, they would not be marketable. M.L. Mattison, A.A. Kraft, D.G. Olson, H.W. Walker, R.E. Rust and D.B. James, Effect of Low Dose Irradiation of Pork Loins on the Microflora, Sensory Characteristics and Fat Stability, *J. of Food Science*; 51 (2): 284-287 (1986). Effect of irradiation on sensory characteristics of pork loin was minimal with no detectable differences between irradiated and nonirradiated pork after 14 days of storage. S.E. Luchsinger, D.H. Kropf, E. Chambers IV, C.M. Garcia Zepeda, M.C. Hunt, S.L. Stroda, M.E. Hollingsworth, J.L. Marsden and C.L. Kastner, Sensory Analysis of Irradiated Ground Beef Patties and Whole Muscle Beef, *J. of Sensory Studies* 12 (1997): 105-126, Irradiation had minimal effects on flavor, texture, and aroma of frozen, raw and precooked, ground beef patties; frozen boneless beef steaks; and vacuum-packaged, chilled boneless beef steaks. S.E. Luchsinger, D.H. Kropf, C.M. Garcia Zepeda, E. Chambers IV, M.E. Hollingsworth, M.C. Hunt, J.L. Marsden, C.L. Kastner, and W.G. Kuecker, Sensory Analysis and Consumer Acceptance of Irradiated Boneless Pork Chops, *J. of Food Science*, 61 (6): 1261-1266 (1996), Consumers reported no difference ($P>0.05$) between irradiated (2.5 kGy cobalt⁶⁰ irradiated, chilled, vacuum-packaged, boneless, port chops) and control samples for overall acceptance, meatiness, freshness, tenderness and juiciness. I.B. Hashim, A.V.A. Resurreccion and K.H. McWatters, *J. of Food Science*, 60 (4): 664-666 (1995), Cooked irradiated frozen dark meat had more chicken flavor, and cooked irradiated refrigerated dark meat was more tender than controls. No other sensory attributes of cooked chicken were affected.

⁴ See, e.g., Vickers and Wang, *supra* (study participants found irradiated beef patties juicier than non-irradiated patties). A. Prakash, P. Inthajak, H. Huibregtse, F. Caporaso and D.M. Foley, Effects of Low-dose Gamma Irradiation and Conventional Treatments on Shelf Life and Quality Characteristics of Diced Celery, *J. of Food Science*, 65 (6): 1070-1075 (2000), While the acidified and blanched samples had significantly different sensory profiles compared to other treatments, the irradiated samples maintained their color, texture, and aroma longer and were preferred in the sensory tests. Christian Chervin and Patrick Boisseau, Quality Maintenance of "Ready-to-eat" Shredded Carrots by Gamma Irradiation, *J. of Food Science*, 59 (2): 359-361 (1994), Sensory analysis demonstrated preferences for irradiated vegetables. Irradiation, avoiding three potential denaturing steps preserved "ready-to-eat" shredded carrots with better quality than those prepared by conventional industrial processes. M. Damayanti, G.J. Sharma, and S.C. Kundu, Gamma Radiation Influences Postharvest Disease Incidence of Pineapple Fruits, *HortScience*, 27(7): 807-808 (1992), Fruits irradiated with up to 105 Gy and then stored at 25 to 28C maintained their texture better than did the controls. Y.P. Chen, L.S. Andrews and R.M. Grodner, Sensory and Microbial Quality of Irradiated Crab Meat Products, *J. of Food Science*, 61(6): 1239-1242 (1996), Overall acceptability scores for irradiated crab samples were higher than for control samples throughout 14-days ice storage.

For many irradiated foods, irradiation treatment does not result in any significant change in shelf life. Approved food applications of irradiation often have no, or only a minimal, effect on shelf life. Moreover, where irradiation does affect a food's shelf life, it invariably prolongs shelf life.⁵ As with improved taste, prolonged shelf life is a benefit that cannot be the basis for regulation of speech.

- **A consumer “desire to know” is not a substantial government interest**

“[M]ere consumer concern is not, in itself, a substantial interest.” IDFA v. Amestoy, 92 F.3d at 73, n. 1. In IDFA v. Amestoy, the Second Circuit rejected a State's argument that consumer concerns about recombinant bovine somatotropin (rBST) in milk justified a State law requiring label disclosure of milk from cows treated with rBST. The court considered at length whether a consumer desire to know can justify compelled commercial speech and concluded that it cannot:

Were consumer interest alone sufficient, there is no end to the information that states could require manufacturers to disclose about their production methods... Absent, however, some indication that this information bears on a reasonable concern for human health or safety or some other sufficiently substantial governmental concern, the manufacturers cannot be compelled to disclose it... We hold that consumer curiosity is not a strong enough state interest to sustain the compulsion of even an accurate, factual statement.

IDFA v. Amestoy, 92 F.3d at 74.

The FDA itself has traditionally refused to require label disclosure of information based on a consumer “desire to know” or “right to know” without more.

The agency has exercised that authority [the authority to require disclosure of “material facts” under FFDCFA § 201(n)] sparingly, largely reserving its use for the disclosure of truly important, noncollateral and nonlabel-cluttering ‘material’ information. The food label would be an entirely different entity from what it is today if FDA had acted otherwise: for example, imagine the possible array of different types of

⁵ According to the General Accounting Office, “... Irradiation can prolong the shelf life of many fruits and vegetables... As a result, products can be harvested when fully ripened and can be transported and displayed for longer periods while maintaining desirable sensory qualities longer than nonirradiated products.” U.S. General Accounting Office, *Food Irradiation: Available Research Indicates that Benefits Outweigh Risks* (GAO/RCED-00-217) (Aug. 2000). See also, Council for Agricultural Science and Technology, *Radiation Pasteurization of Food* (April 1995), p. 4; Diehl, *Safety of Irradiated Foods*, pp. 299-301; Follett, PA and SS Sanxter, Comparison of Rambutan quality after hot forced-air and irradiation quarantine treatments, *Hort. Science* 35 (7): 1315-1318 (2000). SureBeam's SureBeam® technology can double the shelf life of many foods. Peter S. Murano, Elsa A. Murano and Dennis G. Olson, Irradiated Ground Beef: Sensory and Quality Changes During Storage Under Various Packaging Conditions, *J. of Food Science*, 63 (3): 548-551 (1998) Shelf life of ground beef patties was extended 55 days at 4°C. J.G. Niemand, H.J. Vanderlinde and W.H. Holzapfel, Radurization of Prime Beef Cuts, *J. of Food Protection*, 44: 677-681 (1981) A doubling in the shelf-life of samples irradiated to 2 kGy was attained when compared to non-irradiated (control) samples. P.O. Lamuka, G.R. Sunki, C.B. Chawan, D.R. Rao, and L.A. Shackelford, Bacteriological Quality of Fresh Processed Broiler Chickens as Affected by Carcass Pretreatment and Gamma Irradiation, *J. of Food Science*, 57 (2): 330-332 (1992) As evidenced by the bacterial counts in the shelf-life was found to be 15 days for irradiated carcasses compared to about 6 days for unirradiated samples.

information that could be 'required' if FDA deemed 'public desire' for information an indicator of materiality....

Degnan, *supra* at 306. Most recently, the FDA has refused to mandate a disclosure requirement for bioengineered foods despite a reportedly widespread consumer "desire to know" whether food is genetically engineered. 57 Fed. Reg. 22984, 22991 (May 29, 1992). *See also*, FDA, "Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering."

THE IRRADIATION DISCLOSURE REQUIREMENT DOES NOT *DIRECTLY* ADVANCE A SUBSTANTIAL GOVERNMENT INTEREST

The third prong of the Central Hudson test requires that the government regulation directly advance the substantial government interest asserted. Even if the government interest asserted by the FDA (i.e., informing consumers of the "material facts" that an irradiated food is "processed" and may have altered organoleptic traits and shelf life) were accepted as a substantial government interest, FDA's irradiation disclosure does not directly advance that asserted interest. The mandated disclosure does not inform consumers of these "material facts." It only tells consumers that the food has undergone irradiation treatment. It does not inform consumers of the product's changed organoleptic properties, and most consumers are not aware that this is FDA's rationale for requiring disclosure of irradiation treatment.

Not only does the irradiation disclosure requirement not inform consumers of the "material facts" it is intended to convey, it conveys other information that is misleading. It is well known that consumers perceive the irradiation disclosure as a warning that irradiated food may pose a chemical or radiological hazard.⁶ As the Second Circuit said of the rBST disclosure requirement struck down in IDFA v. Amestoy, the irradiation disclosure is "the functional equivalent of a warning." IDFA v. Amestoy, 92 F.3d at 73. Consumer misperceptions about irradiated food have proven to be persistent, despite government and industry efforts to educate the public. The existence of the disclosure requirement itself encourages such misperceptions, since most consumers are not aware that FDA's rationale for requiring disclosure is organoleptic and shelf life change. Most consumers assume that the government requires disclosure, because irradiated foods pose some kind of hazard. Since FDA has determined that foods irradiated in accordance with FDA regulations are safe, the irradiation disclosure, rather than preventing consumers from being misled, is itself misleading.

At the same time that many consumers perceive the irradiation disclosure as a warning about radiological or chemical hazards in irradiated foods, many consumers may also perceive

⁶ See, e.g., Resurreccion et al., Consumer attitudes toward irradiated food: results of a new study, *J. of Food Protection*; 58 (2): 193-196 (1994) ("Over 30% of consumers had the perception that irradiated foods are radioactive..."); Hashim et al., Consumer attitudes toward irradiated poultry, *Food Technology*, March 1996, pp. 77-80 (most study participants expressed concern that eating irradiated poultry may cause cancer). This misperception is actively encouraged by several consumer groups. For example, the consumer group Public Citizen, which publishes a bimonthly *Food Irradiation Alert!*, claims that food irradiation "results in the formation of potentially carcinogenic and/or mutagenic chemical compounds." Testimony of Wenonah Hauter, Director, Critical Mass Energy and Environment Program, Public Citizen, before the House Subcommittee on Agriculture, Rural Development, FDA and Related Agencies Appropriations, April 10, 2001.

the irradiation disclosure as a claim about improved microbiological safety.⁷ In this way, the irradiation disclosure is doubly misleading. Since irradiation has been approved for a number of purposes other than food safety (e.g., extending shelf life, disinfestation of insects), and since non-food safety uses of irradiation may not “pasteurize” the treated food, the irradiation disclosure may mislead consumers into believing that an irradiated food has a better microbiological profile than is the case. Consumers who are aware that foods may be irradiated to kill pathogens may think that all irradiated foods have been treated for food safety when this is not the case.⁸

THE IRRADIATION DISCLOSURE REQUIREMENT DOES NOT DIRECTLY ADVANCE A SUBSTANTIAL GOVERNMENT INTEREST *WITHOUT IMPOSING AN UNNECESSARY BURDEN*

Under the fourth prong of the Central Hudson test, government regulation of commercial speech must be no more extensive than is necessary to serve the government interest. There must be a reasonable fit between the regulation and the substantial government interest served by such regulation. Government regulation of commercial speech may not impose unnecessary burdens.

The irradiation disclosure requirement fails this prong of the Central Hudson test as well. If the government interest is to inform consumers of material changes in irradiated foods, a blanket disclosure requirement that applies to all irradiated foods, regardless of the effect of treatment on the food, is overly broad. Just as blanching, a heat treatment, is not required to be disclosed in labeling because it does not materially change food, so irradiation should not be required to be disclosed where it does not result in material changes in the treated product.

Moreover, the irradiation disclosure requirement, as FDA has acknowledged, carries a particularly heavy burden. As previously discussed, the irradiation disclosure is perceived by many consumers as a warning. In creating the disclosure requirement, FDA recognized this fact and stated that the industry will need to design and conduct consumer education programs to counter this impression:

One comment stated that a retail label requirement would imply that there is a hazard involved in radiation processing and that such a statement would mislead the public about the safety of the process and have a negative impact on the development of this technology.... Although FDA recognizes the potential for consumer confusion, any confusion created by the presence of a retail label requirement can be corrected by proper consumer education programs.... any confusion created by the terms ‘radiation’ or ‘irradiation’ required to appear as part of retail labeling can be corrected by appropriate consumer education programs.

51 Fed. Reg. at 13389.

⁷ See, e.g., Hashim et al., *supra* at 81 (Study participants felt that “some consumers might assume irradiated poultry did not need refrigeration”).

⁸ The U.S. Department of Agriculture’s Animal and Plant Health Inspection Service (APHIS) is currently in the midst of a rulemaking that would permit irradiation of imported fruits and vegetables at low doses as a phytosanitary treatment to kill insect pests. If imported produce were irradiated, its labeling would be required to bear the irradiation disclosure. Some consumers might be misled by the irradiation disclosure into believing that the produce had been irradiated for food safety and might forego appropriate safe handling practices, such as washing the produce.

SureBeam submits that a disclosure requirement that necessarily entails a major public education campaign does not satisfy the requirement that government regulation of commercial speech not impose unreasonable burdens.

ANY DISCLOSURE REQUIREMENT FOR IRRADIATED FOODS SHOULD ENSURE THAT CONSUMERS ARE ACCURATELY ADVISED OF MATERIAL FACTS, WITHOUT IMPOSING UNCONSTITUTIONAL REQUIREMENTS

For the reasons discussed above, SureBeam believes that the existing blanket disclosure requirement for irradiated foods should be rescinded. In its place, FDA should publish a guidance document setting standards for mandatory, and voluntary, disclosures in labeling of irradiated foods. Such a guidance document could set out FDA's policies regarding irradiation disclosure, similar to FDA's draft guidance for voluntary labeling of bioengineered foods.

In this guidance document, FDA should explain the material facts that will trigger mandatory disclosure. If significant organoleptic change is designated as a material fact that would trigger mandatory disclosure, FDA may wish to define "significant." Where irradiation of food results in a true material fact, such as significant organoleptic change, FDA should require disclosure of the material fact, not the irradiation treatment. Since the radura symbol is misleading and does not disclose a material fact, it should not be required.

CONCLUSION

As the foregoing discussion makes clear, FDA's irradiation disclosure requirement fails the second, third, and fourth prongs of the Central Hudson test. First, there is no substantial government interest served by a blanket disclosure requirement applicable to all irradiated foods. Second, the existing irradiation disclosure does not directly advance the government interest that has been asserted by FDA. Finally, the irradiation disclosure requirement is more extensive than is necessary to advance the asserted government interest.

We envision that a narrowly tailored disclosure requirement, one that applies only to irradiated foods that have significantly altered organoleptic characteristics and that discloses this fact rather than the processing technology, would be constitutional.

We urge FDA to rescind its regulation requiring the irradiation disclosure, and we recommend that FDA issue in its place a guidance for industry setting standards for both mandatory and voluntary disclosure.

Sincerely,



Dennis G. Olson, Ph.D.

Vice President Food Technology

SureBeam Corporation

9300 Underwood Ave., Suite 150

Omaha, NE 68114

dgolson@surebeam.com

**COPYRIGHTED MATERIAL CAN BE
VIEWED IN THE
DOCKETS MANAGEMENT PUBLIC
READING ROOM
5630 FISHERS LANE, ROOM 1061
ROCKVILLE, MD**