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Food and Drug Administration
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Comments on Irradiation in the Production, Processing and Handling of Food

Pursuant to the notice found at 72 Federal Register 16291 (April 4, 2007), the Center for Food Safety (CFS) provides the following comments to Docket No. 2005N-0272, "Irradiation in the Production, Processing and Handling of Food." CFS is a non-profit, membership organization that works to protect human health and the environment by curbing the proliferation of harmful food production technologies and by promoting organic and other forms of sustainable agriculture.¹ CFS and its True Food Network represent over 50,000 members of the public.

CFS hereby incorporates by reference into this rulemaking docket the materials attached to this comment and all other previous submissions (and the reference material cited therein) concerning food irradiation submitted by the Center for Food Safety, Food and Water Watch and Public Citizen.

More specifically, CFS believes that the Food and Drug Administration (FDA) should withdraw its proposed rulemaking because among other things:

- (1). As required by the Federal Food Drug and Cosmetic Act (FFDCA), the agency did not consider the overwhelming consumer perspective that rescission of mandatory food irradiation labels will render any such food mislabeled and misbranded;
- (2). The agency has excluded any analysis of religious or cultural concerns of consumers from its interpretation of "material fact;"
- (3). Use of the word "pasteurization" as a substitute for the term "irradiated" (or its derivatives) would be misleading; *and*

¹ See generally <http://www.centerforfoodsafety.org>

(4). The results of irradiating foods do not meet the definition of the term “pasteurization” as established in the FFDCA.

I. FDA’s Proposal Allowing the Removal of Many Irradiation Labels Violates Consumers’ Fundamental Right to Know How Their Food is Produced, Processed and Handled.

Members of the Center for Food Safety believe that they have a fundamental right to know how their food is produced. Elimination of most mandatory labeling for foods that have been treated with irradiation abridges this right.

Consumers have a liberty interest in the ability to choose what they will, or will not, ingest into their bodies. The Constitution “places limits on state’s right to interfere with a person’s most basic decisions about . . . bodily integrity.”² Individuals have a protected liberty interest in refusing to receive medically life-sustaining nutrition.³ Hand-in-hand with this right to *refuse* nutrition is the right to *accept* nutrition. “Implicit in accepting nutrition is the notion that we should know what components make up our food so that we can make informed and intelligent decisions regarding our own nourishment and the nourishment of our children.”⁴ States have also recognized that the public has a fundamental “right to know what they are buying.”⁵

Consumers have a fundamental right to receive reliable information about the food and products they purchase in order to make fully informed decisions.⁶ There is a long U.S. history of such labeling and this type of labeling is already mandatory in many respects.⁷ For example, all packaged food must contain a statement of nutritional facts, allowing consumers to make informed nutritional

² Planned Parenthood v. Casey, 505 U.S. 833, 835 (1992); see also Bam Historic District Assistant v. Koch, 723 F.2d 233, 237 (2d Cir. 1983) (“The ‘liberty’ protected by the Fourteenth Amendment extends beyond freedom from bodily restraint and includes the opportunity to make a range of personal decisions concerning one’s life, family, and private pursuits.”).

³ Cruzan v. Missouri Dept. of Health, 497 U.S. 261, 279 (1990).

⁴ Cynthia D. Fisher, The Genie is Out of the Bottle: Consumers Demand Mandatory Labeling on Genetically Engineered Foods, 4 J. LEGAL ADVOC. & PRAC. 88, 118 (2002).

⁵ Paraco, Inc. v. Dep’t of Agric., 188 Cal. App. 348, 353-54 (1953).

⁶ Fredrick H. Degnan, The Food Label and the Right-to-Know, 52 FOOD & DRUG L.J. 49, 50 (1997) (Pursuant to the ‘consumer’s right to know’, “the public has a basic right to know any fact it deems important about food or a commodity before being forced to make a purchasing decision.”).

⁷ See e.g., Douglas Kysar, Preferences for Processes: The Process/Product Distinction and the Regulation of Consumer Choice, 118 HARV. L. REV. 525 (2004).

choices and avoid unhealthy foods. Further, all food packages must contain a list of ingredients in order for consumers to avoid those ingredients they deem unsavory or unappealing. Much in the same vein, mandatory labeling of food characteristics such as the presence of genetically modified organisms, treatment by irradiation, or presence of synthetic growth hormones or antibiotics should be subject to mandatory labeling.⁸

Many decisions regarding labeling and consumer notification center on risk analysis and management. Risk management is a “decision-making process that entails consideration of political, social, economic, and engineering information with risk-related information to develop, analyze and compare regulatory options and to select the appropriate regulatory response to a potential health hazard.”⁹ Depending on the level of identified risk, a given product may be subject to informational labeling, restricted access or prohibition. Determining the level of risk a product poses, however, is an imperfect pursuit, requiring a regulator to balance conflicting interests and make numerous assumptions. “Risk decisions are, ultimately, public policy choices.”¹⁰

There are many situations in which regulatory bodies have recognized that administrative determinations of “acceptable risk” may not suffice, and thus provide additional information to individual consumers in order to facilitate informed decision making regarding the personal level of risk deemed acceptable. Even after the FDA determines that a particular drug is safe enough to be available without a prescription, that product is still labeled with all relevant possible side effects, lest it be deemed “misbranded” for failure to contain “adequate directions for use.”¹¹ This provision allows consumers to weigh the potential benefits and risks of a particular product when making purchasing decisions.

Similarly, consumers have a right to make personalized risk assessments regarding the food they consume. Consumers should have access to full information about the production methods of their food where those methods have been associated with *potential* short- or long-term health impacts or where that information has been deemed by the consuming public to be determinative in making consumer choices, whether it be possible increased risk of allergic reactions or the consumption of irradiated foods.

⁸ This type of labeling would not violate the protection of commercial free speech, as some courts have suggested. The purpose of the first amendment is to “favor the flow of accurate, relevant information” rather than stifle or suppress communication of information relevant to consumers. Int’l Dairy Foods Ass’n v. Amestoy, 92 F.3d 67, 74 (1st Cir. 1996) (Leval, J. dissenting).

⁹ Commission on Life Sciences, Risk Assessment in the Federal Government: Managing the Process (1983), at 19.

¹⁰ Commission on Behavioral and Social Sciences and Education, Understanding Risk: Informing Decisions in a Democratic Society (1993), at 26.

¹¹ 21 U.S.C. §352(f)(2).

Indeed, a number of studies associate irradiation with significant human impacts. At least 27 *in vivo*, or live animal, feeding studies published in scientific journals examine the potential mutagenicity of irradiated diets in mice, rats, monkeys, and humans. Also, at least 13 published journal articles report *in vitro* studies on mammal or human cells grown on, or exposed to, irradiated substances in a laboratory setting.¹² Many of these published studies state in frighteningly clear terms the potential hazards posed by these foods (emphasis added):

- Male mice fed a diet of freshly irradiated food had *offspring with an increased incidence of early deaths* week 7 and to a lesser extent in week 4.¹³
- Cytogenetic (i.e., related to cell DNA) examinations of the developing spermatogonia in 30 mice of each group revealed that *cytogenetic abnormalities were significantly more frequent in the group fed irradiated flour* than in the control group.¹⁴
- Male and female mice fed a in which 50% of solid cakes had been irradiated with 5 Mrads of radiation for two months before mating exhibited *a significant increase of pre-implantation embryonal deaths.*¹⁵
- *Human children receiving freshly-irradiated wheat developed polyploid cells and certain abnormal cells* in increasing numbers as the duration of feeding increased and showed a gradual reversal to basal level of nil after withdrawal of the irradiated wheat. In marked contrast, *none of the children fed unirradiated diet developed any abnormal cells.*¹⁶

¹² Full referencing of these studies can be found in our past comments to the FDA opposing food irradiation. See generally www.centerforfoodsafety.org.

¹³ Anderson, D., *et al.*, Irradiated laboratory animal diets - Dominant lethal studies in the mouse. MUTATION RESEARCH (1981) 80:333-345.

¹⁴ Bugyaki, L., *et al.* Do irradiated foodstuffs have a radiomimetic effect? II. Trials with mice fed wheat meal irradiated at 5 MRAD. ATOMPRACTICE (1968)14:112-118.

¹⁵ Moutschen-Dahmen, M., *et al.* Pre-implantation death of mouse eggs caused by irradiated food. INTERNATIONAL JOURNAL OF RADIATION BIOLOGY (1970) 18:201-216.

¹⁶ Bhaskaram, C., and G. Sadasivan. Effects of feeding irradiated wheat to malnourished children. AMERICAN J. OF CLINICAL NUTRITION (1975)28:130-135.

Clearly, maintaining mandatory labeling for all irradiated foods is necessary so that consumers' may exercise their fundamental right to make an informed decision concerning how much risk each consumer deems personally acceptable.

II. Failure to Label Foods That Have Been Irradiated Violates the FFDCA.

(A). The Agency Must Look At More Than Material Fact.

Under the FFDCA, a food shall be deemed to be misbranded if “its labeling is false or misleading in any particular.”¹⁷ This statutory language requires that the FDA broadly analyze the nature of a labeling requirement from numerous points of view not just that of “materiality.” The structure of the statute is unambiguously clear in this requirement. The word “any” “has an expansive meaning, that is, one or some indiscriminately of whatever kind.”¹⁸ Similarly, the term “particular” has a broad meaning and is commonly defined as an “individual fact, point, circumstance, or detail” or “a specific item or detail of information.”¹⁹ Read together, the statute requires the agency to consider all manners in which a proposal to limit or eliminate mandatory irradiation labeling will be misleading to consumers.

In its notice, however, the FDA incorrectly truncates the scope of 21 U.S.C. §343(a)(1) by failing to consider whether there is “any particular” in altering the current irradiation labeling that would make it misleading. In doing so, the agency attempts to avoid an important “particular”: consumer focus groups show that the absence of mandatory irradiation labeling and/or calling “irradiated” “pasteurized” would be misleading to average, reasonable consumers.²⁰

Instead of analyzing such “particulars,” the agency points only to 21 U.S.C. §321(n) on misbranding to assert that “material change” is the only factor it will consider when making or amending labeling requirements. This agency action impermissibly narrows the factors FDA must use to determine whether labeling or lack of labeling is misleading. Indeed, §321(n) itself speaks to the broad factors FDA must consider when determining whether a label is required. Section 321(n) states:

If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or

¹⁷ 21 U.S.C. §343(a)(1).

¹⁸ See Massachusetts v. EPA, 127 S.Ct. 1438, 1460 n. 25 (2007).

¹⁹ Merriam Webster's Collegiate Dictionary, 11th ed. 2004 at 903; see also FDIC v. Meyer, 510 U.S. 471, 476 (1994) (in absence of a statutory definition “we construe a statutory term in accordance with its ordinary or natural meaning”).

²⁰ 67 Fed. Reg. 78002, 78003 (Dec. 20, 2002) (in assessing whether food labeling is misleading and, therefore, misbranded, FDA uses the “reasonable consumer” standard).

suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to the consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

FDA has attempted to limit its review of irradiation labeling only to those facts deemed “material.” This narrowing of scope is contrary to the text of the FFDCFA.²¹ While FDA must consider material facts when proposing a new labeling scheme or amendment, the statute also clearly indicates that the agency cannot base its entire decision on whether to get rid of mandatory irradiation labeling on materiality.²² The agency shall take “into account” “other things.” In its proposal, FDA has neither identified “other things” it is taking into account nor provided any analysis of “other things” it has taken into account when proposing to amend the irradiation labeling requirements. This failure means that the agency’s reasons for its proposed action has not conformed to the authorizing statute and the agency has not complied with a clear statutory command.²³

Among the “particulars” the agency must address is overwhelming, near unanimous, consumer sentiment that doing away with mandatory labeling for irradiated foods is misleading and denies consumers their fundamental right to have labeling that informs them how their food is processed.

(1). FDA’s Has Not Justified Its Deviation From the 1986 Regulation Requiring Mandatory Labeling of All Irradiated Foods.

As the agency notes, in the past it has received significant public comment showing consumers will be misled without mandatory labeling of all irradiated foods. These studies are evidence that a change in irradiation labeling standards will mislead the reasonable consumer. In its new proposal the agency seeks to overturn a 1986 determination that found a failure to require mandatory labeling of

²¹ In Stauber v. Shalala, 895 F.Supp. 1178, 1193 (W.D. Wis. 1995) the plaintiffs challenged that consumer preference was part fo the “materiality” analysis and a district court suggested that the agency must find a material change in order to have the authority to require mandatory labeling. This dicta ignores the plain text of the statute indicating the agency only must “take into account” any material change and that the agency can look at “any particular.”

²² Alliance for Bio-Integrity v. Shalala, 116 F.Supp.2d 166, 178 (D.D.C. 2000) challenged the agency’s interpretation of “materiality,” but neither analyzed the need of the FDA to assess other factors when determining whether a food is misbranded nor the ability of the agency to mandate labels whether or not a material change has been found in the food.

²³ See Massachusetts v. EPA, 127 S.Ct. 1438, 1462 (2007).

irradiated foods would be misleading because there would be an implied representation that the food had not been so processed.²⁴ Throughout the proposal FDA provides no justification as to why the 1986 agency findings are not still true today. In fact, the only justification provided by the agency is that FDA policy has shifted to assessing the materiality of processing effects and away from disclosure of the processing itself.²⁵ This is an unsupported and arbitrary shift in a long standing agency interpretation.²⁶ First, as noted supra, the FDA's sole focus on materiality is unsupported by statute. Even if the agency policy has shifted in the weight it gives materiality, the agency still must look at other particulars that can cause misleadingly labeled food. As a result, the FDA cannot simply disavow the determination it made in 1986. Second, FDA's "policy" change is not supported by any evidence that consumers in 2007 will be less misled by not knowing a food was processed using irradiation than they were when the 1986 regulation was implemented. In sum, the agency's new position on irradiation is a departure from a past interpretation and the agency has failed to explain why the change is reasonable.²⁷ To support its changed position the agency must demonstrate that consumers will not be misled, a burden it cannot satisfy.

(B). Congress Recognized the Continued Labeling Requirements in FDAMA.

The FDA refers to the statutory changes made under the Food and Drug Administration Modernization Act (FDAMA) in discussing its proposed changes.²⁸ The amendments do not provide grounds for removing irradiation labeling. The amendments state only that the label cannot be more prominent than the declaration of ingredients required by the FFDCA.²⁹ In fact, the text's qualification of existing labeling requirements indicates that Congress clearly contemplated the continued use of radiation disclosure statements (i.e. labels).

²⁴ 72 Fed Reg 16292.

²⁵ 72 Fed Reg 16295.

²⁶ Compare 51 Fed Reg. 13376, 13390 (April 18, 1986) (finding that information can be material and stating that the agency "must decide whether the changes in the organoleptic properties of irradiated foods constitute a material fact or whether the information that a food has been irradiated constitutes information that is material to a consumer even if organoleptic changes were not significant") (emphasis added).

²⁷ See e.g., Western States Petroleum Assoc. v. EPA, 87 F.3d 280, 284-85 (9th Cir. 1996) (holding that when agency departs from an existing interpretation it must set forth a reasoned explanation for its departure from previous norms).

²⁸ 72 Fed Reg 16292.

²⁹ 21 U.S.C. §343-3.

Further, the House Report discussed by FDA sought consideration of nomenclature changes of irradiation labeling and whether, if such nomenclature changes were made, such changes (not the entirety of mandatory labeling) should expire at a certain time.³⁰ In no manner did the House Report indicate that the labeling of irradiated food product as a whole should expire.

(C). FDA Is Fully Aware That Elimination of Any Mandatory Irradiation Labeling or Substitution of the Term “Pasteurized” Would be Misleading.

FDA makes cursory references to consumer view points but never discusses how its proposal is informed by these consumer viewpoints. The agency indicates that during a 1999 Advanced Notice of Proposed Rulemaking (ANPRM) it received a majority of comments stating that consumers wanted the labeling requirements retained.³¹ The agency also mentions consumer focus groups it held in 2001. FDA fails to evaluate the clear import of these studies: that consumers believe revocation of mandatory food irradiation labeling would be misleading.

The 2001 Focus Group Report clearly supports the continued mandatory nature of irradiation labeling. At numerous points the Report concludes that participants were in unanimous agreement that the labeling of irradiated food should be mandatory and regulated.³² The Report finds further:

Participants considered the key labeling requirement to be honest disclosure. By this they mean that products treated with irradiation should be acknowledged as such on the label. They indicated that the current FDA-required statement seems to fulfill the need for a straightforward way of labeling irradiated food products.³³

As a result, removing any of the now mandated labeling would create food products that consumers will feel omit pertinent information and are misleading.

Additionally, the Report also clearly indicates that use of the term “pasteurization” as a substitute for the exist labeling statements will be misleading. As the Report notes:

Participants actively objected to labeling options they saw as intending to conceal the fact that a product was irradiated. Wording that failed to mention irradiation

³⁰ H. Rep.105-399 at 98.

³¹ 72 Fed Reg 16292.

³² ORC Macro, Consumers’ Understanding of Food Irradiation Labeling: Focus Group Report (2002) at 2, 16, 28.

³³ ORC Macro at 2.

such as “treated by electronic pasteurization,” “Treated by ion pasteurization,” or “treated by cold pasteurization” was denounced as “deceptive” or “intended to conceal.” No participant in any group defended such labeling options as acceptable in the face of such criticism.³⁴

Therefore, even if irradiation meets the new criteria defining pasteurization (which it does not, see *infra*), use of the term “pasteurization” would still be a violation of 21 U.S.C. §343(a)(1).

Furthermore, the FDA has even reported to Congress on the outcome of the 2001 focus groups stating in a report that “[m]ost participants viewed alternate terms such as “cold pasteurization” and “electronic pastuerization” as misleading, because they appeared to conceal rather than disclose information about irradiated food products.”³⁵ The report also stated that the “current FDA required statement is a straightforward way for labeling irradiated foods.”³⁶

III. 2002 Farm Bill Does Not Authorize Removal of Irradiation Labeling.

The agency also cites to the Farm Security and Rural Investment Act of 2002 (2002 Farm Bill) as support for its proposal.³⁷ The law does not provide any authority for the removal of mandatory labeling. Section 10809 guides the agency to “revise” the current labeling system. The word “revise” does not entail “elimination” of some mandatory labeling as is proposed by the agency.

IV. Irradiated Foods Are All Materially Changed.

The Center for Food Safety supports and incorporates by reference the comments submitted to this docket by Food and Water Watch in which that organization details the material changes that take place in all irradiated foods. The information incorporated by reference, various attachments submitted with this comment, and the Food and Water Watch comment present extensive and broad examples of irradiation causing nutritional, organoleptic, and functional changes in food.

CFS also notes that the agency has failed to consider consumers’ desire to avoid certain foods for religious or cultural reasons as an issue of materiality. In addressing labeling issues involving protein hydrolysates used as food flavors or flavor enhancers the FDA has stated:

³⁴ ORC Marco at 24.

³⁵ FDA, Congressional Report on Irradiation Food Labeling (June 2002) at 3 (emphasis added).

³⁶ Id.

³⁷ 72 Fed. Reg. 16293.

The agency tentatively finds that a food source of a protein hydrolysate is information of material importance for a person who desires to avoid certain foods for religious or cultural reasons. This information is necessary for such an individual to determine whether food is acceptable or non-acceptable for inclusion in their diet. If such information is not included in the declaration of a protein hydrolysate, a consumer would have no way of knowing that he/she was consuming a food prohibited by his/her personal convictions.³⁸

The FDA's interpretation of materiality in the current proposal eliminates any consideration of cultural concerns without providing any reasoned basis for this statutory interpretative change. The change eliminates any analysis of religious or cultural groups that have concern over irradiated foods and seek to avoid them. Many consumers have cultural concerns about the use of irradiation and the desire to avoid products that have been treated with irradiation. Indeed, in the past over 275,000 members of the public commented to USDA stating their cultural desire to avoid irradiated foods.³⁹

V. Use of the Term “Pasteurization” Is Inconsistent With The FFDCFA.

FDA suggests that irradiation nomenclature could be substituted with the term “pasteurization” using a notification process.⁴⁰ FDA's proposal should be removed because the scope of use for the term “pasteurization” is limited and irradiation cannot meet the definition contained at 21 U.S.C. § 343(h)(3).

(A). Section 343(h)(3) applies only to containers.

First, section 343(h)(3) applies to “representations as to the standards of quality and fill of container.”⁴¹ The statute's language clearly indicates that only certain foods may be represented as pasteurized, namely something that fills a container such as milk and juice. At a minimum, the provisions does not allow the word “pasteurized” to be used on labels of any food that is not filling a container -- i.e., whole foods.

(B). Irradiation is not a “safe process or treatment” nor is it “reasonably certain to achieve destruction or elimination” of microorganisms.

³⁸ 56 Fed. Reg. 28592, 28600 (June 21, 1991).

³⁹ See 62 Fed Reg 65850 (Dec. 16, 1997) (docket of first proposed rule for the National Organic Program).

⁴⁰ 72 Fed. Reg. 16296 (April 4, 2007).

⁴¹ 21 U.S.C. § 343(h)(3).

Second, to be represented as pasteurized the food filling container must be “subjected to a safe process or treatment” that 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 food.”⁴² In assessing this standard, the USDA’s National Advisory Committee on Microbiological Criteria for Foods (NACMCF) has found that there needs to be a procedure for determining the requisite equivalence of alternative methods of pasteurization prior to conclusion being drawn about equivalency.⁴³ The FDA has not yet suggested how its notification process will determine equivalency.

As CFS has noted several times in this comment, it incorporates by reference the numerous and voluminous submissions it has previously made to the FDA concerning all aspects of food irradiation. These submissions provided numerous references showing that irradiation is not a “safe” process.

In addition, while pasteurization does not mean commercial sterility, it still appears that irradiation cannot reasonably meet the definition provided in § 343-3(h). FDA has set a standard of a 5-log (99.999 percent) reduction for *E. coli*, *Listeria* and *Salmonella* for most foods. This is the reduction normally achieved by HTST (high temperature/short time) pasteurization, which is used for most dairy products.

Research has shown that irradiation has not been able to achieve a 5-log reduction of these bacteria on a consistent, predictable basis. This is troubling, as *E. coli*, *Listeria* and *Salmonella* account for approximately 1,100 of the estimated 1,250 food-related deaths attributed to bacteria each year.

In pork, achieving a 5-log reduction of *Listeria* required a radiation dose of 3.0 kGy, according to a recent published study.⁴⁴ Another recent study on pork showed 4 kGy was needed to achieve 2.4-log and 5.5-log reductions for *Listeria* and *E. coli* O157:H7, respectively.⁴⁵ Because the FDA-approved maximum dose for pork is 1 kGy, current regulations would not permit irradiation to be used to achieve the equivalent of pasteurization for these foods.

⁴² 21 U.S.C. § 343(h)(3)(B)(i)(I) (emphasis added).

⁴³ National Advisory Cmte. On Microbiological Criteria for Foods; (2006). Requisite Scientific Parameters for Establishing the Equivalence of Alternative Methods of Pasteurization, JOURNAL OF FOOD PROTECTION, 69:1190-1216.

⁴⁴Bari, M.L., *et al.* Irradiation inactivation of *Listeria monocytogenes* in low-fat ground pork at freezing and refrigeration temperatures. JOURNAL OF FOOD PROTECTION, 69(12):2955-2960(6), December 2006.

⁴⁵Samelis, J. *et al.* Use of ionizing radiation doses of 2 and 4 kGy to control *Listeria* spp. and *Escherichia coli* O157:H7 on frozen meat trimmings used for dry fermented sausage production. MEAT SCIENCE, 70(1):189-195, May 2005.

In chicken, Salmonella was reduced by only 4 logs when irradiated at 3 kGy, the FDA-approved maximum dose for poultry, according to a recent published study.⁴⁶ In another study on chicken, a 3-4-log reduction of E. coli (which is below the FDA's 5-log standard) was achieved with a 5 kGy dose (which is above the FDA-approved maximum dose).⁴⁷ In August 2003, Consumer Reports published results of tests on more than 500 samples of irradiated beef and chicken available commercially in the U.S. The tests included detection of Listeria and generic E. coli. The samples included meat irradiated by Food Technology Service (FTS) in Mulberry, FL. Discussing the results in a letter to the University of Minnesota's Center for Infectious Disease Research & Policy, Consumer Reports Vice President Julia Kagan wrote:

In our tests, we did not get results that approached a five-log difference between the irradiated and nonirradiated samples we acquired at retail or at the FTS plant. We found differences of about two logs or less for all enumerated test organisms, and suggest that claims for higher levels of bacterial inactivation may be misleading to consumers.⁴⁸

Irradiation has not been shown to be able to achieve the same results as pasteurization, namely a 5-log reduction in E. coli, Listeria and Salmonella.

There are also numerous studies showing that irradiation of food sources may initially reduce food pathogens but it does not reasonably achieve destruction or elimination of those pathogens. For example:

- Gursel, B., *et al.* (1997) found that an irradiation dose of 2.5 kGy retards the subsequent development of *L. monocytogenes* during storage at 4 C but did not eliminate it completely from raw chicken or beef when the initial load of the organism was higher than 10³ cells per gram.⁴⁹

⁴⁶Sarjeant, K.C. *et al.* The effect of electron beam irradiation on the survival of Salmonella enterica serovar Typhimurium and psychrotrophic bacteria on raw chicken breasts stored at four degrees celsius for fourteen days. POULTRY SCIENCE, 84(6):955-958, 2005.

⁴⁷European Commission, Report of the Scientific Committee on Veterinary Measures Relating to Public Health (SCVPH) on Benefits and Limitations of Antimicrobial Treatments for Poultry Carcasses (1998).

⁴⁸Roos, Robert, Irradiation proponents object to Consumer Reports article. CIDRAP News, Center for Infectious Disease Research & Policy, University of Minnesota, Aug. 22, 2003.

⁴⁹ Gursel, B. *et al.* (1997). Effects of gamma irradiation on the survival of *Listeria monocytogenes* and in its growth at refrigeration temperature in poultry and red meat. POULTRY SCIENCE, 76:1661-1664.

- Varabioff, *et al.* (1992) found that *L. monocytogenes* was detected in vacuum packaged chickens treated with 2.5 kGy irradiation and stored at 4 C for 15 days.⁵⁰
- Mead, *et al.* (1990) found that 22% of irradiated poultry carcasses were positive for the pathogen after 21 days of storage.⁵¹
- Patterson, *et al.* (1993) found that the pathogen was detected in raw poultry treated with 2.5 kGy irradiation and stored for 15 days at 6 C.⁵²
- Zhu, *et al.* (2005) found irradiation was very effective in reducing *L. monocytogenes* in RTE (ready-to-eat) turkey hams, but that surviving *L. monocytogenes* could proliferate during subsequent storage.⁵³
- Foong, *et al.* (2004) *L. monocytogenes* was detected in ready-to-eat meats treated with 2 kGy irradiation and stored at 10 C after 2 week and ready-to-eat meats treated with 4 kGy irradiation and stored at 4 C after 5 weeks.⁵⁴
- Sarjeant, K. C., *et al.* (2005) finding that irradiation was an effective tool for reducing *S. Typhimurium* and spoilage organisms, but it did not completely eliminate *S. Typhimurium* or spoilage organisms.⁵⁵

⁵⁰ Varabioff, Y.; Mitchell, G. E.; Nottingham, S.M.; (1992). Effects on bacterial load and *Listeria monocytogenes* in raw chicken. JOURNAL OF FOOD PROTECTION, 55:389-391.

⁵¹ Mead, G.C.; Hudson, W.R.; Arrifin, R. (1990). Survival and growth of *Listeria monocytogenes* on irradiated poultry carcasses. LANCET, 28:1036.

⁵² Patterson, M.F.; Damoglu, A.P.; Buick, R.K. (1993). Effects of irradiation dose and storage temperature on the growth of *Listeria monocytogenes*. FOOD MICROBIOLOGY, 10:197-203.

⁵³ Zhu, M.J.; Mendonca, A.; Ismail, H.A.; Du, M.; Lee, E.J.; Ahn, D.U. (2005). Impact of antimicrobial ingredients and irradiation on the survival of *Listeria monocytogenes* and the quality of ready-to-eat turkey ham. POULTRY SCIENCE, 84: 613-620.

⁵⁴ Foong, S.C.; Gonzalez, G.L.; Dickson, J.S. (2004). Reduction and survival of *Listeria monocytogenes* in ready-to-eat meats after irradiation. JOURNAL OF FOOD PROTECTION, 67:77-82.

⁵⁵ Sarjeant, K.C.; Williams, S.K.; Hinton Jr., A. (2005). The effect of electron beam irradiation on the survival of *Salmonella enterica*, Serovar *Typhimurium* and Psychrotrophic bacteria on raw chicken breast stored at four degrees Celsius for fourteen days. POULTRY SCIENCE, 84:955-958.

In sum, the scientific data show that irradiation cannot meet the definition of pasteurization provided for under the FFDCA. Accordingly, FDA's proposal to allow a notification procedure for pasteurization labeling should be withdrawn.

VI. Conclusion

For the reasons contained herein, the CFS requests that the agency **withdraw** its proposed rule found at 72 Federal Register 16291 (April 4, 2007).

Respectfully submitted,

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Legal Director

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Attachments