July 3, 2007

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

RE: Comments on Proposed Rule Regarding Irradiation in the Production, Processing, and Handling of Food (Food and Drug Administration Docket No. 2005N-0272)

The Center for Science in the Public Interest (CSPI) appreciates this opportunity to comment on the Food and Drug Administration (FDA) proposed rule regarding the labeling of irradiated food products. CSPI is a non-profit consumer advocacy and education organization that focuses largely on food safety and nutrition issues. It is supported principally by the 900,000 subscribers to its Nutrition Action Healthletter and by foundation grants.

I. Background

FDA’s current regulation for irradiated food states that irradiated food must bear both the radura logo and the phrase “Treated with radiation” or “Treated by irradiation.”¹ FDA history shows a clear and unambiguous commitment to proper labeling, beginning with the Food, Drug, and Cosmetic Act of 1938 (FDCA).² In section 403(a) of that Act, Congress clarified that the prohibition against false and misleading representations was meant to be comprehensive: “the labels of food … are not considered … to be the proper media for making any representations … which are not in accord with the facts.”³ Notably, the Act went even further when crafting

---

¹ 21 CFR 179.26
labeling requirements, mandating the inclusion of the ingredients used to fabricate the food; the prominent, clear declaration of the net weight of the contents of the food; the name and address of the manufacturer or responsible party of the food; and a precise statement of the identity — the name — of the food.\(^4\)

In addition to these narrow but fundamental requirements, Congress enacted section 201(n), which amplifies the general prohibition against false and misleading labeling found in section 403(a). Section 201(n) provides as follows:

> 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 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 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.\(^5\)

This language gives FDA the authority to require additional key information to appear on the food label if such a requirement is necessary to prevent consumers from being misled. The clear import of section 201(n), therefore, is that labeling may be misleading not only because of what it says but because of what it fails to say.

Since the adoption of the Act, FDA has relied on sections 403(a) and 201(n) to require the disclosure on the food label of irradiated products, the only processing technique as yet mandated to be labeled.\(^6\) Interestingly, the comments FDA received regarding its initiative rarely expressed concern about the safety of irradiation.\(^7\) Instead, the agency concluded that irradiation could cause changes in the flavor or shelf-life of the finished foods and that these

---

\(^4\) See 21 U.S.C. §§ 301, 343(e), (g), (i) (FDCA §§ 1, 403 (e), (g), (i)).
\(^5\) Id. § 321(n) (FDCA § 201(n))(italics added).
\(^6\) 51 Fed. Reg. 13,376 (Apr. 18, 1986); 21 C.F.R. § 179.26(c).
\(^7\) 51 Fed. Reg. at 13,376.
changes alone could be significant and material in light of the consumer’s perception of the foods. The agency stated, “in the absence of a statement that a food has been irradiated, the implied representation to consumers is that the food has not been processed.” Further, since irradiated food has been labeled as such for over 20 years, consumers have developed a reasonable expectation that in the absence of irradiation labeling, no irradiation has occurred. Dramatic modifications to the labeling requirements will only serve to frustrate those expectations.

As FDA revisits the labeling requirements for irradiated foods, CSPI supports a continued commitment to consumer information, and urges FDA to maintain its current robust standards for irradiated food labeling.

II. Adoption of a “Material Change” Standard is Cumbersome and Misleading

FDA is proposing to require that only those irradiated foods in which irradiation causes a material change in a food’s characteristics (e.g., organoleptic, nutritional, or functional properties) under the conditions of use prescribed in the label and labeling or under customary or usual conditions of use bear the radura logo and the term “irradiated” or any derivative thereof. Under the proposal, the fact that a food has been irradiated will not by itself require disclosure on the label.

CSPI strongly supports the continued use of irradiation labeling based on the use or non-use of irradiation processing, not on the level or extent of that processing. Prescribing a material change standard for irradiation at this juncture in its development would require the adoption of standards based on incomplete data and on industry’s desire to minimize labeling, rather than on adequate analysis.

---

8 Id. at 13,389-90.
9 Id. at 13,390.
Irradiation has potentially positive public-health utility, but is by no means a panacea ensuring food safety. Irradiation has been shown to kill bacteria and parasites, for example, but it does not destroy viruses, chemicals including pre-formed toxins, or prions. According to CSPI’s outbreak database, which comprises more than 5000 foodborne illness outbreaks over the last 15 years, bacteria and parasites caused 63% of all foodborne illness outbreaks from 1990-2004, while viruses, chemicals, and toxins together caused 37%.

Irradiation has much greater utility for foods such as meat and poultry—USDA-regulated foods—than for seafood and other products that carry other types of hazards. Notably, consumers appear to be more supportive of irradiation of meat and poultry products than of irradiation of other foods. However, evidence suggests that irradiating certain foods may alter or destroy basic and essential qualities of the food—such as taste and nutrition—thereby rendering the process impractical. For example, irradiation of eggs can kill the pathogen *Salmonella*—which causes 500 deaths each year in the United States—but irradiation of eggs “causes the egg whites to become milky and more liquid, which means it looks like an older egg and may not serve as well in some recipes,” according to the Centers for Disease Control and Prevention. Similarly, irradiation can kill deadly *Vibrio vulnificus* bacteria, but its shelf life and quality is lessened because the oyster itself is also damaged or killed during the process.

Irradiation has similar effects on alfalfa sprouts, as the viability of the seeds themselves may be

---

11 Center for Science in the Public Interest, Outbreak Alert! Database (2006).
14 Id.
destroyed in an effort to kill *Salmonella*. It cannot be used on lettuce and other leafy vegetables because they are “too fragile to withstand the irradiation.”

There are other limitations to the usefulness of irradiation. One undesirable side effect of irradiation may be the destruction of some vitamins in foods. Early experiments testing vitamin survival in water or some solution (rather than in foods) suggested that the loss of certain vitamins during irradiation might be significant. Another undesirable effect of irradiation is the formation of lipid oxides by the reaction of membrane lipids and other lipids in foods with oxygen radicals, produced by gamma rays. These oxides may impart off-odors and tastes to foods and may contribute to lipid-related diseases. Irradiation of cooked pork sausages, for example, resulted in sausages smelling like “wet wool” or “wet animal hair.”

Further, since post-irradiation contamination can be minimized by irradiating foods in their final packaging, the effects of irradiation on packaging materials and the migration of components such as plasticizers into foods must be considered. Experiments have shown that:

Food-grade PVC (polyvinyl chloride) film exposed to high doses of electron beam irradiation (20–50 kGy) demonstrated that increased amounts of diocyl adipate, a plasticizer, migrated into olive oil after the higher dose of irradiation. These radiation doses are in excess of those usually recommended for foods. … [T]his experiment points out a potential problem for irradiation of foods in plastic containers. Any such plastics must be tested for effects of irradiation on the migration of components of the plastic into the types of foods which would be stored in these containers. Irradiation can also affect the structure and stability of some plastics, thereby rendering them unsuitable for exposure to irradiation. Whether the accumulated dose from these different exposures can be harmful to humans is as yet uncertain but should be considered.

---

20 Food Research Institute Briefings, University of Wisconsin, http://www.wisc.edu/fri/briefs/foodirrd.htm
Many quality and safety issues are still under discussion, and consumers have a desire to know if irradiation has been used. The term “material change” cannot yet be adequately defined to encompass consumer interests, and therefore FDA should not create an arbitrary distinction which would allow manufacturers to omit proper labeling of irradiated foods.

III. Consumers Want to be Clearly Informed About Whether Their Food Has Been Irradiated

Disclosure to consumers that food has been irradiated satisfies a generally accepted principle termed the consumer’s “right to know.” That right is recognized by the General Assembly of the United Nations in its Guidelines for Consumer Protection, which are intended in part to provide “[a]ccess of consumers to adequate information to enable them to make informed choices according to individual wishes and needs.”\(^{21}\) The U.N. guidelines were inspired by President John F. Kennedy's pronouncement, in his landmark message to Congress in March 1962, that consumers have a right “to be given the facts [they] need to make an informed choice,” as well as a right “to be protected against fraudulent, deceitful, or grossly misleading information, advertising, labeling, and other practices.”\(^{22}\)

Consumers want irradiated foods to be clearly and conspicuously labeled. That strong preference, as well as other consumer preferences about how irradiated products should be labeled, is reflected in a nationally representative poll of over 1000 adults commissioned by CSPI and the American Association of Retired Persons (AARP).\(^{23}\) The poll found:

- Overwhelming support for labeling of irradiated foods to indicate that they have been irradiated (88.6 percent in favor); and

---


\(^{22}\) President John F. Kennedy, Message Relating to Consumers’ Protection and Interest Program (March 15, 1962), p. 2.

\(^{23}\) Bruskin/Goldring Research, Irradiation Telephone Survey for the Center for Science in the Public Interest and AARP, (April 16-18, 1999).
• Strong support for placement of the irradiation label on the front of the food package (59.1 percent in favor) as opposed to the back of the package (9.8 percent in favor).

In addition, research conducted by the Axiom Research Company on behalf of the International Food Information Council (IFIC) on six focus groups in three major U.S. cities found that “consumers agreed that irradiated food should be labeled with the following information: an explanation of the process, a measure of the energy used, the name of a U.S. government agency approving the process, any possible side effects, and an expiration date. 24

CSPI feels strongly that the threshold issue of irradiation labeling should not be whether, but rather how products are labeled. FDA has asked for comment both on the utility of expanded labeling (i.e., labeling that explains the purpose of the irradiation) and on the use of alternative terms for irradiation, such as “pasteurized” and other euphemisms. CSPI conditionally supports voluntary expanded labeling, but strongly opposes euphemistic terminology.

The Addition of Descriptive or Purposive Phrases to Irradiated Food Labels Should be Voluntary and Strictly Delineated by FDA.

Current labeling regulations do not explicitly address the inclusion of additional information to explain the use of irradiation as a processing tool. FDA’s proposed rule would not only allow the inclusion of such explanatory phrases, but would require it. While expanded labeling in this instance may serve to educate consumers on the purpose of irradiation, it also carries a risk of confusion and obfuscation. A product bearing the label, “Irradiated to guarantee freshness,” for example, would be wholly inappropriate and misleading. A label stating, “Irradiated to inhibit sprouting,” by contrast, is sufficiently forthright. Thus, expanded labeling must be employed sparingly and judiciously, with an eye toward transparency for consumers.

CSPI feels strongly that any rule allowing for expanded labeling must specify a list of pre-approved phrases eligible for inclusion. Those phrases may themselves be an appropriate topic for public comment. A general allowance for expanded labeling of the manufacturer’s design is inappropriate without government approval. Further, CSPI believes that expanded labeling should be voluntary, and that any updated rule should allow manufacturers to maintain the current standard of labeling under Section 179.26.

**Euphemistic Labeling is Potentially Misleading to Consumers and Should Not be Allowed.**

Consumers’ support for clear, informative labeling of irradiated foods is incontrovertible. While expanded labeling may provide additional—potentially useful—information for consumers, the use of euphemistic terminology such as “pasteurized” does the opposite. Research on consumer attitudes has shown that while industry may favor these euphemisms, consumers do not. For example, a 2000 poll conducted for Public Citizen found that only about a quarter of the 1000 people surveyed favored changing the current “irradiation” label to “cold pasteurization” or “electronic pasteurization.”

In addition, focus group discussions sponsored by FDA in 2001 indicated that consumers don’t like the “cold pasteurized” label, even if it is qualified with the word “irradiated” in parentheses. Consumers said that describing irradiation as “pasteurization” was misleading and deceitful.

---


26 According to excerpts from these discussions, consumers in Minnesota said the label “pasteurized by irradiation” was confusing and that the label “treated by cold pasteurization (irradiation)” “didn’t help.” Furthermore, participants of the focus group in Maryland said that describing irradiation as “pasteurization” is “deceitful,” “sneaky,” and “misleading.” Consumers in California said using the term “pasteurization” would be “a twist of words” used because “they’re trying to fool you,” “cheating,” “pulling the wool over your eyes” and “trying to fake you out.” Letter from Andrew Kimbrell, Executive Director, Center for Food Safety and Wenonah Hauter, Director, Public Citizen Critical Mass Energy and Environment Program to six FDA officials, Dec. 17, 2001.
FDA should be judicious in the use of the term “pasteurization,” in particular, since that term has a common consumer definition that is not the same as irradiation. In fact, FDA’s own discussion paper on food labeling (written in conjunction with USDA in 2001) 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.27

Proper labeling of irradiated foods will not only enable consumers who are wary of irradiated foods to avoid them, but would also allow consumers who want to buy irradiated food to choose to do so. Industry studies have generally found that if consumers are educated about irradiation, they are more willing to buy the products.28 According to a survey conducted by Food Practice Consulting Group and CMF&Z in 1999, of the 54% of consumers surveyed who were aware of food irradiation, 68% were likely to purchase irradiated meat, 67% were likely to purchase irradiated poultry, and 68% were likely to purchase irradiated dairy.29

CSPI feels strongly that, given the potential food safety benefits of irradiation, industry can and should undertake a campaign to educate consumers on the processing technique. FDA’s regulation should in no way circumvent the need for such a campaign. Further, the current regulation allows manufacturers to include additional factual information along with the required label, describing the benefits of irradiation. Such inclusion should be sufficient—in addition to a public education campaign—to educate consumers about the actual benefits and risks of irradiated food.

27 “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.
29 1999 Food Safety Survey Results, Food Practice Consulting Group and CMF&Z, “Consumer Awareness of Food Irradiation” and “Of Those Consumers Who Were Aware, Percentage Likely to Purchase Irradiated Foods.”
Consumers vary in their susceptibility to foodborne disease, and they have different opinions about irradiated food. Therefore, all irradiated foods (including processed foods with irradiated ingredients and foods on restaurant menus) should be clearly labeled with the word irradiated and without confusing terminology such as “pasteurized.”

IV. Conclusion
Labeling of irradiated food is an important, non-alarmist tool for educating consumers about the way their food has been processed. Current FDA regulations provide the information necessary for consumers to make informed decisions about food purchasing. CSPI urges FDA to continue its commitment to consumer information by promulgating a rule that mandates the continued labeling of all irradiated food products, not only those which undergo a material change. Further, CSPI supports the voluntary use of pre-approved additional descriptive phrasing, which may inform consumers of the benefits of irradiated processing. Finally, CSPI is strongly opposed to the use of euphemistic terminology, which only serves to confuse and mislead consumers about irradiated food.

Respectively submitted,

Sarah Klein, JD, MA
Food Safety Staff Attorney