

114. User assistance is available for eLibrary and the FERC's Web site during normal business hours from FERC Online Support at 202-502-6652 (toll free at 1-866-208-3676) or email at ferconlinesupport@ferc.gov, or the Public Reference Room at (202) 502-8371, TTY (202) 502-8659. Email the Public Reference Room at public.referenceroom@ferc.gov.

VII. Effective Date and Congressional Notification

115. These regulations are effective July 10, 2012. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB, that this rule is not a "major rule" as defined in section 351 of the Small Business Regulatory Enforcement Fairness Act of 1996.

List of Subjects in 18 CFR Part 40

Electric power; Electric utilities; Reporting and record keeping requirements.

By the Commission.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

Appendix Commenters

Abbreviation	Commenter
Dominion	Dominion Resources Services, Inc.
EEL	Edison Electric Institute.
EPISA	Electric Power Supply Association.
FRCC	Florida Reliability Coordinating Council, Inc.
G&T Cooperatives	Associated Electric Cooperative, Inc.; Basin Electric Power Cooperative; and Tri-State Generation and Transmission Association, Inc.
KCP&L	Kansas City Power & Light Company and KCP&L Greater Missouri Operations Company.
MISO	Midwest Independent Transmission System Operator, Inc.
NERC	North American Electric Reliability Corporation.
NYISO	New York Independent System Operator, Inc.
PSEG	Public Service Electric and Gas Company; PSEG Power LLC; PSEG Energy Resources & Trade LLC.
SWPA	Southwestern Power Administration.
TAPS	Transmission Access Policy Study Group.
Wisconsin Electric	Wisconsin Electric Power Company.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. FDA-1999-F-0021; formerly 1999F-2673]

Irradiation in the Production, Processing and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; denial of requests for a hearing and response to objections.

SUMMARY: The Food and Drug Administration (FDA) is denying requests for a hearing on the final rule that amended the food additive regulations to provide for the safe use of ionizing radiation for the control of microbial pathogens in seeds for sprouting. After reviewing objections to the final rule and requests for a hearing, FDA has concluded that the objections do not justify a hearing or otherwise provide a basis for revoking the regulation.

FOR FURTHER INFORMATION CONTACT: Teresa A. Croce, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint

Branch Pkwy., College Park, MD 20740, 240-402-1281.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of August 16, 1999 (64 FR 44530), FDA published a notice announcing the filing of a food additive petition (FAP 9M4673) submitted by Caudill Seed Co., Inc., to amend the regulations in part 179 *Irradiation in the Production, Processing, and Handling of Food* (21 CFR part 179) by providing for the safe use of ionizing radiation to control microbial pathogens in seeds for sprouting. In response to this petition, FDA issued a final rule in the **Federal Register** of October 30, 2000 (65 FR 64605), permitting the irradiation of seeds for sprouting to control microbial pathogens in alfalfa and other sprouting seeds at an absorbed dose not to exceed 8.0 kiloGray (kGy) (hereafter referred to as the "seeds for sprouting rule"). FDA based its decision on data in the petition and in its files. The preamble to the final rule advised that objections to the final rule and requests for a hearing were due within 30 days of the publication date (i.e., by November 29, 2000).

II. Objections and Requests for a Hearing

Section 409(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(f)(1)) provides that, within 30 days after publication of an order relating to

a food additive regulation, any person adversely affected by such order may file objections, "specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor [sic], and requesting a public hearing upon such objections."

Under the food additive regulations at 21 CFR 171.110, objections and requests for a hearing are governed by part 12 (21 CFR part 12) of FDA's regulations. Under § 12.22(a), each objection must meet the following conditions: (1) Must be submitted on or before the 30th day after the date of publication of the final rule; (2) must be separately numbered; (3) must specify with particularity the provision of the regulation or proposed order objected to; (4) must specifically state each objection on which a hearing is requested; failure to request a hearing on an objection constitutes a waiver of the right to a hearing on that objection; and (5) must include a detailed description and analysis of the factual information to be presented in support of the objection if a hearing is requested; failure to include a description and analysis for an objection constitutes a waiver of the right to a hearing on that objection.

Following publication of the final rule permitting the irradiation of seeds for sprouting to control food-borne pathogens, FDA received numerous submissions within the 30-day objection

period. FDA received a letter from Public Citizen (letter to Docket No. 4602, November 15, 2000) containing eight numbered objections with a request for a hearing on each objection, and a letter by Jonathan Sprouts, Inc. (letter to Docket No. 5055, December 19, 2000), expressing concern over the labeling of sprouts grown from seeds that have been irradiated. The remaining submissions expressed general opposition to the final rule. Those submissions are brief form letters which state either one or a combination of the following general concerns: That no toxicity studies were performed directly on the consumable sprouts, that nutrition data was submitted for irradiation doses of 6 kGy and not the petitioned maximum of 8 kGy, or that the lack of labeling for sprouts grown from irradiated seeds was a concern. Those concerns were raised with more specificity by the other two submissions and will be addressed as part of the response to those submissions in section IV of this document.

III. Standards for Granting a Hearing

Specific criteria for deciding whether to grant or deny a request for a hearing are set out in § 12.24(b). Under that regulation, a hearing will be granted if the material submitted by the requester shows, among other things, the following: (1) There is a genuine and substantial factual issue for resolution at a hearing; a hearing will not be granted on issues of policy or law; (2) the factual issue can be resolved by available and specifically identified reliable evidence; a hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions; (3) the data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the requestor; a hearing will be denied if the data and information submitted are insufficient to justify the factual determination urged, even if accurate; (4) resolution of the factual issue in the way sought by the person is adequate to justify the action requested; a hearing will not be granted on factual issues that are not determinative with respect to the action requested (e.g., if the action would be the same even if the factual issue were resolved in the way sought); (5) the action requested is not inconsistent with any provision in the act or any FDA regulation; and (6) the requirements in other applicable regulations, e.g., 21 CFR 10.20, 12.21, and 12.22, and in the notice issuing the final regulation or the notice of opportunity for hearing are met.

A party seeking a hearing is required to meet a “threshold burden of tendering evidence suggesting the need for a hearing” (*Costle v. Pacific Legal Foundation*, 445 U.S. 198, 214 (1980), *reh. denied*, 446 U.S. 947 (1980), citing *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 620–21 (1973)). An allegation that a hearing is necessary to “sharpen the issues” or to “fully develop the facts” does not meet this test (*Georgia Pacific Corp. v. U.S. EPA*, 671 F.2d 1235, 1241 (9th Cir. 1982)). If a hearing request fails to identify any factual evidence that would be the subject of a hearing, there is no point in holding one. In judicial proceedings, a court is authorized to issue summary judgment without an evidentiary hearing whenever it finds that there are no genuine issues of material fact in dispute and a party is entitled to judgment as a matter of law (see Rule 56, Federal Rules of Civil Procedure). The same principle applies in administrative proceedings (see § 12.28).

A hearing request must not only contain evidence, but that evidence should raise a material issue of fact concerning which a meaningful hearing might be held (*Pineapple Growers Association v. FDA*, 673 F.2d 1083, 1085 (9th Cir. 1982)). Where the issues raised in the objection are, even if true, legally insufficient to alter the decision, the Agency need not grant a hearing (see *Dyestuffs and Chemicals, Inc. v. Flemming*, 271 F.2d 281, 286 (8th Cir. 1959), *cert. denied*, 362 U.S. 911 (1960)). A hearing is justified only if the objections are made in good faith and if they “draw in question in a material way the underpinnings of the regulation at issue” (*Pactra Industries v. CPSC*, 555 F.2d 677, 684 (9th Cir. 1977)). A hearing need not be held to resolve questions of law or policy (see *Citizens for Allegan County, Inc. v. FPC*, 414 F.2d 1125, 1128 (DC Cir. 1969); *Sun Oil Co. v. FPC*, 256 F.2d 233, 240 (5th Cir.), *cert. denied*, 358 U.S. 872 (1958)).

Even if the objections raise material issues of fact, FDA need not grant a hearing if those same issues were adequately raised and considered in an earlier proceeding. Once an issue has been so raised and considered, a party is estopped from raising that same issue in a later proceeding without new evidence. The various judicial doctrines dealing with finality, such as collateral estoppel, can be validly applied to the administrative process (see *Pac. Seafarers, Inc. v. Pac. Far East Line, Inc.*, 404 F.2d 804, 809 (DC Cir. 1968), *cert. denied*, 393 U.S. 1093 (1969)). In explaining why these principles ought to apply to an agency proceeding, the

U.S. Court of Appeals for the District of Columbia Circuit wrote: “The underlying concept is as simple as this: Justice requires that a party have a fair chance to present his position. But overall interests of administration do not require or generally contemplate that he will be given more than one fair opportunity.” *Retail Clerks Union, Local 1401 v. NLRB*, 463 F.2d 316, 322 (DC Cir. 1972; see also *Costle v. Pacific Legal Foundation*, 445 U.S. at 215–217).

In summary, a hearing request must present sufficient credible evidence to raise a material issue of fact and the evidence must be adequate to resolve the issue as requested and to justify the action requested.

IV. Analysis of Objections and Response to Hearing Requests

The letter from Public Citizen contains eight numbered objections and requests a hearing on each of them. Where Public Citizen’s objections overlap, FDA has combined its response. The letter from Jonathan Sprouts, Inc., raised one objection and requested a hearing on its objection. FDA addresses each of the objections below, as well as the evidence and information filed in support of each, comparing each objection and the information submitted in support of it to the standards for granting a hearing in § 12.24(b).

A. Application of 100-Fold Safety Factor

The first objection raised by Public Citizen in response to the seeds for sprouting rule contends that the Agency failed to apply a 100-fold safety factor, as required by § 170.22 (21 CFR 170.22),¹ for the irradiation of seeds for sprouting. While FDA agrees that § 170.22 states that FDA will use a 100-fold safety factor when applying animal data to man, FDA notes that § 170.22 provides for use of a different safety factor “where evidence is submitted which justifies use of a different safety factor.”

The Agency has determined that use of a different safety factor is appropriate based on the considerable body of data available from studies involving irradiated foods fed to laboratory animals and reviewed by FDA. FDA’s Bureau of Foods Irradiated Foods

¹ Section 170.22 states: “In accordance with section 409(c)(5)(C) of the Act, the following safety factors will be applied in determining whether the proposed use of a food additive will be safe: Except where evidence is submitted which justifies use of a different safety factor, a safety factor in applying animal experimentation data to man of 100 to 1, will be used; that is, a food additive for use by man will not be granted a tolerance that will exceed 1/100th of the maximum amount demonstrated to be without harm to experimental animals.”

Committee (BFIFC) determined that the studies involving irradiated foods that they evaluated did not appear to show adverse effects (Ref. 1). These studies, taken as a whole, serve as an independent method to assess toxicological safety. The studies included in that evaluation are those which have been relied on by the Agency in previous evaluations of the safety of other irradiated foods, such as lettuce, spinach, molluscan shellfish, shell eggs, meat, and poultry (see 73 FR 49593, August 22, 2008; 70 FR 48057, August 16, 2005; 65 FR 45280, July 21, 2000; 62 FR 64107, December 3, 1997; 55 FR 18538, May 2, 1990; and 51 FR 13376, April 18, 1986), and additional data and information from FDA files or other published reports regarding studies in which animals were fed a wide variety of foods irradiated at different doses.

The Agency's analysis incorporates the principle that toxicological data collected from studies on a given food may be applied to the toxicological evaluation of foods of a similar generic class and that data from foods irradiated at high doses can be applied to the toxicological evaluation of foods of similar generic class receiving lower doses (Ref. 2). The Agency's analysis also draws upon the integrated toxicological database derived from the extensive body of work reviewed by the Agency (see 51 FR 13376 at 13378) and by WHO² in previous evaluations of the safety of irradiated foods (Refs. 3 and 4).

In light of the substantial data and the toxicological assessments that have been reviewed by FDA, the Agency concludes that under § 170.22 the Agency is not required to apply the 100-fold safety factor to the use of ionizing radiation for seeds for sprouting. This collective information is sufficient to justify the use of a different safety factor. Further, the applicability of § 170.22 is a legal issue, and a hearing will not be granted on issues of law (§ 12.24(b)(1)).

²During the early 1980s, a joint Food and Agriculture Organization/International Atomic Energy Agency, World Health Organization (FAO/IAEA/WHO) Expert Committee evaluated the toxicological and microbiological safety and nutritional adequacy of irradiated foods. The Expert Committee concluded that irradiation of any food commodity at an average dose of up to 10 kGy presents no toxicological hazard (Ref. 3). In the 1990s, WHO reanalyzed the safety data including additional studies (see 51 FR 13376 at 13378) and concluded that the integrated toxicological database is sufficiently sensitive to evaluate safety and that no adverse toxicological effects due to irradiation were observed in the dose ranges tested (Ref. 4).

B. Application of the National Academy of Sciences-National Research Council Principles and Procedures

Public Citizen's second objection asserts that FDA did not follow the "principles and procedures for establishing the safety of food additives stated in current publication of the National Academy of Sciences-National Research Council," as required by § 170.20.

The Agency has consistently taken the position that many scientifically valid types of data may properly support a finding that the proposed use of a food additive is safe. The Agency pointed out in the molluscan shellfish final rule (70 FR 48057 at 48068) that the National Academy of Sciences-National Research Council testing standards and guidelines have been stated in relatively general terms and that in practice, FDA has applied exposure and toxicological criteria that were both current for the time and appropriate for assessing the safety of a particular food additive.

In its objection, Public Citizen asserts that FDA failed to properly interpret its own regulation, but has provided no new information that would refute the Agency's reasoning. The objection implies that the Agency is obligated to explicitly discuss its consideration of National Academy of Sciences-National Research Council guidelines in its rules, but there is nothing in § 170.20 that imposes such an obligation on the Agency. Further, the applicability of § 170.20 is a legal issue, and a hearing will not be granted on issues of law (§ 12.24(b)(1)). Public Citizen has not provided a basis for a hearing and FDA is denying their request for a hearing based on this objection.

C. Toxicology Issues

Public Citizen objects to the seeds for sprouting final rule because the petitioner, Caudill Seed Co. Inc., submitted, "[n]o conventional animal toxicity studies on sprouts from irradiated seeds." Additionally, Public Citizen asserts that the references contained within FAP 9M4673 "do not address the potential toxicity of irradiated sprouts."

The Agency agrees that the petition did not include toxicological studies conducted using irradiated sprouts. As noted in the seeds for sprouting final rule (65 FR 64605), the Agency has reviewed both the data included in its database, as well as the published references, submitted by the petitioner, of toxicology studies related to irradiated foods. FDA has consistently taken the position that various scientifically validated types of data

may properly support a safety determination for a proposed use of a food additive (see § 170.20). In the case of food irradiation, the Agency has taken advantage of the extensive research and large body of knowledge, such as the information compiled by BFIFC and other studies in FDA's files, concerning the principles of radiation chemistry and the chemical composition of foods.

Public Citizen also contends that FDA's statement that the "petitioner submitted published articles and other study reports containing data and information related to seeds for sprouting * * * in the areas of radiation chemistry [and] toxicity" in the final rule is incorrect. Public Citizen's claim is without merit. The petitioner provided articles on the toxicity of irradiated foods along with their submission, which are listed and summarized in the toxicology memorandum (Ref. 5). As previously stated, in reviewing the petitioner's application, FDA considered the articles submitted by the petitioner in addition to relevant international reports and relevant scientific articles in FDA's files (see e.g. Refs. 2, 6, and 7). However, FDA does agree that there were no toxicological studies conducted using irradiated seeds for sprouting. FDA has consistently taken the position that it is unnecessary for a safety analysis to be performed involving the specific food to be irradiated. As noted in the meat final rule (62 FR 64107 at 64112), the Agency relies on scientific studies evaluating the extent to which safety data on an irradiated food type can be extrapolated to other food types and the extent to which individual studies of irradiated foods can be evaluated as a whole (Ref. 4). Thus, data and information derived from studies of irradiated foods in general are sufficient to support a determination of safety for irradiated seeds for sprouting. Public Citizen's suggestion that such information is not sufficient to support a determination of safety is unsupported by specific data or other factual information.

Public Citizen failed to include any new information or data that would refute the Agency's findings about the toxicity of irradiated seeds for sprouting. The request for a hearing merely alleges that there is a potential for harm, without providing any evidence that the Agency has not considered previously. A hearing will not be granted on the basis of mere allegations or general descriptions of positions and contentions (§ 12.24(b)(2)). The objectors must, at a minimum, raise a material issue

concerning which a meaningful hearing might be held.

D. Radiolysis Products

Public Citizen alleges that there are unsubstantiated statements contained in the review memorandum and final rule regarding radiolytic byproducts. There are two parts to this objection; the Agency will address each part as follows.

The first statement to which Public Citizen objects is found in the Chemistry Memorandum from K. Morehouse to J. Ziyad dated February 23, 2000 (Ref. 8), asserting that “radiolysis products which may have been formed by irradiation of the seeds will be ‘diluted’ in the final product * * *. Also, it is likely that the water-soluble products will be removed by the growth medium.” Public Citizen claims that this statement is unfounded because no data was cited regarding the dilution potential of radiolytic byproducts.

The Agency disagrees that the statement was unsubstantiated. The full statement is as follows: “As the seeds mature and form sprouts, radiolysis products which may have been formed by irradiation of the seeds will be ‘diluted’ in the final product. For example, alfalfa seeds contain only 7.4 percent water whereas alfalfa sprouts contain 88.3 percent water (see Table I of Ref. 8). Also, it is likely that water-soluble products will be removed by the growth medium.”

“Table I,” referred to in the previous quotation, contains the nutrient composition for alfalfa seeds and raw alfalfa sprouts. This data was obtained from a published study which determined the nutrient content of various seeds and sprouts (Ref. 9). It is apparent from the data supplied that as the seeds sprout to the final product, they absorb water, in the case of alfalfa sprouts the water content increases from 7.4 percent to 88.3 percent. It follows that any byproducts would be diluted by the absorption of water, which is the growth medium for sprouts. The same study asserts that it is possible for sugars to leach into the growth medium during the sprouting procedure; therefore, it is likely that other water-soluble products could also be removed by the growth medium. Furthermore, Public Citizen did not provide any information related to the safety of irradiated seeds for sprouting that the Agency had not considered, and the objection contains no information that would cause the Agency to change its safety determination. An objector must make an adequate proffer of evidence to support its allegations and to show that

they provide a basis on which to call into question the Agencies conclusions (§ 12.24(b)(2)). Public Citizen has not provided a basis for a hearing, and FDA is denying Public Citizen’s request for a hearing based on this objection.

Public Citizen also objects to the Agency’s conclusion that because the concentrations and types of radiolysis products formed by the irradiation of seeds for sprouting will be comparable to those products produced by the irradiation of foods of similar composition the chemical compositions of sprouts grown from irradiated seeds will not differ in any significant manner from sprouts grown from seeds that have not been irradiated. Public Citizen feels that these statements are unsupported and is requesting a hearing based on this matter.

FDA disagrees with the allegation that the statements made in the final seed for sprouting rule (65 FR 64605) are unsupported. Through information compiled by FDA and the materials submitted with each food additive petition involving irradiation (see e.g., section IV.A of this document), FDA has established that the effect ionizing radiation has on the characteristics of foods are a direct result of the chemical reactions induced by the absorbed radiation. This large body of data includes studies regarding the effects of ionizing radiation on different foods under various conditions of irradiation allowing FDA to extrapolate data obtained from one food to other foods (for more information see 73 FR 49593 at 49594 and 70 FR 48057 at 48059). Research has established that the types and amounts of products generated depend on the chemical constituents of the food and the conditions of radiation (Refs. 6, 7, and 10). See the final rule permitting the irradiation of meat (62 FR 64107) for a more in depth discussion of radiation chemistry, nutrition, toxicology, and microbiology related to irradiation of foods under various conditions of use. Additionally, the review memorandum and the evidence reviewed and discussed therein, support the statement that radiolytic byproducts would be formed in low amounts in seeds for sprouting (Ref. 8). The Agency also notes that ionizing radiation causes fewer chemical changes in dry material (i.e. the seeds for sprouting) than in fresh fruits and vegetables due to the increased water content of the fresh items (Ref. 6).

Public Citizen’s assertion provides no basis to challenge FDA’s assessment of the safety of irradiated seeds for sprouting. A hearing will not be granted on the basis of mere allegations or general descriptions of positions and

contentions (§ 12.24(b)(2)). The objector must, at a minimum, raise a material issue concerning which a meaningful hearing might be held. Public Citizen has not provided a basis for a hearing; therefore, FDA is denying their request for a hearing based on this objection.

E. Nutritional Considerations

In its request for a hearing, Public Citizen questions the nutritional adequacy of the irradiated seeds for sprouting and cites an FDA toxicology review memorandum (Ref. 5) in which the reviewer describes the data submitted by the petitioner as “crude” and notes a discrepancy between laboratory assessments in the vitamin A content of sprouts grown from irradiated seeds. Moreover, Public Citizen objects to the final rule on the grounds that nutritional assessments were conducted on sprouts grown from seeds that were irradiated at 6 kGy, rather than the petitioned maximum of 8 kGy.

As noted in the final rule, there were no relevant losses in the vitamin A content when comparing the sprouts grown from irradiated seeds to the control sprouts, which were grown from non-irradiated seeds. Rather, the vitamin A content was higher in all instances comparing the sprouts grown from irradiated seeds to the control seeds (65 FR 64605). The final rule also indicated that any vitamin loss that occurs in sprouts grown from irradiated seeds is expected to be inconsequential when compared to the total dietary nutrient consumption (Ref. 5).

In response to Public Citizen’s objection based on the studies conducted at 6 kGy as opposed to 8 kGy, the Agency notes that there were no nutritional losses associated with sprouts grown from seeds irradiated at 6 kGy. Changes in the level of vitamins associated with irradiation are gradual with each increasing dose; scientific evidence does not support a threshold effect above which significant losses would occur (Ref. 6). Therefore, it is reasonable to anticipate that sprouts grown from seeds irradiated at 8 kGy would not lead to nutritionally relevant losses either. Furthermore, the Codex Alimentarius Commission (Codex) published its standard for irradiated foods in 1983 for adoption by Codex member countries (Ref. 11). This standard was based on the conclusion that the irradiation of any food commodity at an overall average dose of up to 10 kGy presents no concerns (Ref. 3). The Codex standard was revised in

2003,³ at which time Codex integrated the joint FAO/IAEA/WHO study group conclusion that food irradiated to any dose appropriate to achieve the intended technological effect is both safe to consume and nutritionally adequate (i.e. at doses up to and above 10 kGy) (Ref. 12).

Overall, Public Citizen's request for a hearing suggests that there is potential for harm from possible nutritional losses from the irradiation of seeds for sprouting, without providing any evidence to support this suggestion. An objector must make an adequate proffer of evidence to support its allegations and to show that they provide a basis on which to call into question the Agency's conclusions. A hearing will be denied if the Commissioner of Food and Drugs concludes that the data and information submitted are insufficient to justify the factual determination urged, even if accurate (§ 12.24(b)(3)). Public Citizen does not submit or otherwise identify any factual data that would cause the Agency to alter its conclusions about the nutritional changes in irradiated seeds. Therefore, FDA is denying the request for a hearing based on this objection.

F. Labeling Concerns

The final objection to the seeds for sprouting rule was submitted by Jonathan Sprouts, Inc., objecting to the lack of a requirement that sprouts grown from seeds that have been irradiated be labeled as treated by irradiation. Some of the general objections FDA received to the seeds for sprouting final rule also raised this point. Most of these objections were brief and expressed general dissatisfaction regarding FDA's decision on labeling, but did not provide any substantive data or information. Jonathan Sprouts, Inc., claimed that there are morphological differences between sprouts grown from irradiated versus non-irradiated seeds, which, they claim, support the need for labeling sprouts grown from seeds that have been irradiated; however, they failed to provide any additional data or information to substantiate their claim.

The Agency specifically discussed in the seeds for sprouting rule the labeling of irradiated seeds for sprouting and sprouts grown from such seeds (65 FR 64605 at 64606). The FDA evaluated the need for special labeling against the labeling provisions for food treated by ionizing radiation in § 179.26(c) (21 CFR 179.26(c)). Specifically, § 179.26(c) states that "the label and labeling of retail packages of *foods* irradiated * * *

shall bear the * * * logo along with either the statement 'Treated with radiation' or * * * 'Treated by irradiation.'" (emphasis added). Thus, the requirement applies only to the food that has been irradiated. It was noted in the seeds for sprouting rule that the irradiated article, the unsprouted seed, is not what is generally consumed and that the nutritional and flavor characteristics of the sprouts is based upon the fact that the irradiated seeds were grown into sprouts; therefore, sprouts grown from irradiated seeds do not require labeling as they are not the food that is being irradiated.

Additionally, neither Jonathan Sprouts, Inc., nor any of the other objectors that raised this point, provided any evidence that sprouts grown from irradiated seeds differ from sprouts grown from seeds that were not irradiated. An objector must make an adequate proffer of evidence to support its allegations and to show that they provide a basis on which to call into question the Agency's conclusions (§ 12.24(b)(2)). Therefore, the Agency is denying Jonathan Sprouts' objection.

V. Summary and Conclusion

Section 409 of the Federal Food, Drug and Cosmetic Act requires that a food additive be shown to be safe prior to marketing. Under § 170.3(i), a food additive is "safe" if "there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use." In the Agency's October 30, 2000, seeds for sprouting rule, FDA concluded that the studies conducted, based on its evaluation of the data submitted in the petition and other relevant material, that this use of irradiation is safe for its intended use in seeds for sprouting.

The petitioner has the burden to demonstrate the safety of the additive to gain FDA approval. However, once FDA makes a finding of safety in an approval document, the burden shifts to an objector, who must come forward with evidence that calls into question FDA's conclusion (see section 409(f)(1) of the Federal Food, Drug, and Cosmetic Act).

Despite their allegations, neither Public Citizen nor Jonathan Sprouts, Inc., has established that FDA overlooked significant information contained within the record in reaching its conclusion that the use of irradiation for microbial control of pathogens in seeds for sprouting is safe. In such circumstances, FDA has determined that the objections do not raise any genuine and substantial issue of fact that can be resolved by an evidentiary hearing

(§ 12.24(b)). Accordingly, FDA is denying the requests for a hearing.

VI. References

The following references are on display in the Division of Dockets Management (HFA-303) Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857, under Docket No. FDA-1999-F-0021 (formerly 1999F-2673) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum to file, FAP 4M4428, from David G. Hattan, Acting Director, Division of Health Effects Evaluation, dated November 20, 1997.
2. Taub, I.A. et al., "Factors Affecting Radiolytic Effects In Food," *Radiation Physics and Chemistry*, 14:639-653, 1979.
3. WHO, "Wholesomeness of Irradiated Food: Report of a Joint FAO/IAEA/WHO Expert Committee," World Health Organization Technical Report Series, No. 659, World Health Organization, Geneva, 1981.
4. WHO, "Safety and Nutritional Adequacy of Irradiated Food," World Health Organization, Geneva, 1994.
5. Memorandum to the file, FAP 9M4673, from I. Chen, FDA, to J. Ziyad, FDA, dated February 28, 2000.
6. Diehl, J.F., "Safety of Irradiated Foods," 2nd Edition, Marcel Dekker, New York, 1995.
7. Merritt, C., Jr., "Qualitative and Quantitative Aspects of Trace Volatile Components in Irradiated Foods and Food Substances," *Radiation Research Reviews*, 3:353-368, 1972.
8. Memorandum to the file, FAP 9M4673, from K. Morehouse, FDA, to J. Ziyad, FDA, dated February 23, 2000.
9. Kylen, A.M. and R.M. McCready, "Nutrients in Seeds and Sprouts of Alfalfa, Lentils, Mung Beans and Soybeans," *Journal of Food Science*, 40:1008-1009, 1975.
10. Diehl, J.F., "Radiolytic Effects in Foods," pp. 279-357, in *Preservation of Food by Ionizing Radiation*, vol. I, E.S. Josephson and M.S. Peterson, eds., CRC Press, Boca Raton, FL, 1982.
11. Codex 1983, "Codex General Standard for Irradiated Foods (CODEX STAN 106-1983)" Codex Alimentarius Commission, Food and Agriculture Organization and World Health Organization, Rome, 1983.
12. WHO, "High-Dose Irradiation: Wholesomeness of Food Irradiated With Doses Above 10 kGy," World Health Organization Technical Report Series, No. 890, World Health Organization, Geneva, 1999.

Dated: May 1, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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BILLING CODE 4160-01-P

³ It should be noted that the revisions of the Codex standards in 2003 do not impact this rulemaking.