DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket Nos. 86F–0507 and 86F–0509]

Irradiation in the Production, Processing and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; denial of request for stay of effective date and for a hearing; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is denying the requests for a hearing that it has received on the final rule that amended the food additive regulations to authorize the use of sources of ionizing radiation for the control of food-borne pathogens in poultry. After reviewing the objections to the final rule and the requests for a hearing, the agency has concluded that the objections do not raise issues of material fact that justify a hearing or otherwise provide a basis for revoking the amendment to the regulation. FDA is also denying the request for a stay of the effective date of the amendment to the food additive regulations.

DATES: Effective date confirmed: May 2, 1990.

FOR FURTHER INFORMATION CONTACT: Patricia A. Hansen, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3093.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

In the **Federal Register** of May 2, 1990 (55 FR 18538), FDA issued a final rule permitting the use of ionizing radiation for the control of food-borne pathogens in poultry (the ''poultry final rule''). This regulation, codified under 21 CFR 179.26, was issued in response to petitions filed by Radiation Technology, Inc. (RTI) (Docket No. 86F–0507), and the U.S. Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) (Docket No. 86F–0509). In the **Federal Register** of March 3, 1987 (52 FR 6391), FDA published a notice announcing the filing of the petition submitted by RTI (FAP 8M3422), and in the **Federal Register** of February 20, 1987 (52 FR5343), FDA published a notice announcing the filing of the petition submitted by USDA, FSIS, (FAP 7M3974). FDA based its decision on data contained in both petitions and in its files.

II. Objections, Requests for a Hearing, and Request for a Stay

Section 409(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(f)), 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,'' and may request a public hearing based upon such objections. FDA may deny a hearing request if the objections to the regulation do not raise genuine and substantial issues of fact that can be resolved at a hearing.

Under 21 CFR 171.110 of the food additive regulations, 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: (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) on which a hearing is requested must specifically so state; failure to request a hearing on an objection constitutes a waiver of the right to a hearing on that objection; and (5) requesting a hearing must include a detailed description and analysis of the factual information to be presented in support of the objection. 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 poultry final rule, FDA received several identical letters with multiple signatures and two submissions from Food and Water, Inc. (FWI), within the 30-day objection period. The submissions sought revocation of the final rule and requested a hearing. One of FWI's objections also requested that the regulation be stayed pending a public hearing of the scientific issues. The other FWI submission also requested an extension of the ''comment'' [sic] period.

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 the regulation, a hearing will be granted if the material submitted by the requester shows, among other things, that: (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; and (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).

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, 214–215 (1980) *reh. den*., 445 U.S. 947 (1980), citing *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 620–621 (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. E.P.A.*, 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 (*Dyestuffs and Chemicals, Inc.* v. *Flemming*, 271 F.2d 281 (8th Cir. 1959), *cert. denied*, 362 U.S. 911 (1960)). FDA need not grant a hearing in each case where an objector submits additional information or posits a novel interpretation of existing information (see *United States* v. *Consolidated Mines & Smelting Co.*, 455 F.2d 432 (9th Cir. 1971)). In other words, 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 (9th Cir. 1977)). Finally, courts have uniformly recognized that 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 (D.C. 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 can be validly applied to the administrative process. In explaining why these principles ''self-evidently'' ought to apply to an agency proceeding, the D.C. 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 a fair opportunity.

Retail Clerks Union, Local 1401, R.C.I.A. v. *NLRB*, 463 F.2d 316, 322 (D.C. Cir. 1972). (See *Costle* v. *Pacific Legal Foundation, supra* at 1106. See also *Pacific Seafarers, Inc.* v. *Pacific Far East Line, Inc.*, 404 F.2d 804 (D.C. Cir. 1966).)

In sum, 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 objections to the poultry final rule can be categorized into two broad areas—those objecting to FDA's safety determination, and those objecting to FDA's finding of no significant environmental impact (FONSI). FDA addresses each of the objections below, as well as the data 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.

A. Safety of Irradiation to Control Microorganisms in Poultry

1. FDA's Determination of Safety

Under 21 CFR 170.3(i), safety of a food additive means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. FDA's regulations reflect the Congressional judgment that the additive must be properly tested and such tests carefully evaluated, but that the additive need not, indeed cannot, be shown to be safe to an absolute certainty. The House Report on the Food Additives Amendment of 1958 stated: ''Safety requires proof of a reasonable certainty that no harm will result from the proposed use of the additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance'' (H. Rept. 2284, 85th Cong., 2d sess., 1958).

The poultry final rule discussed in detail FDA's evaluation of the safety of ionizing radiation for use to control food-borne pathogens in poultry (55 FR 18538). In concluding that irradiation doses up to 3 kiloGray (kGy) used on poultry had been shown to be safe, FDA reviewed three major animal feeding studies—a multigenerational feeding study in rats, a chronic feeding study in rats, and a 1-year feeding study in dogs. These studies provided the basis for FDA's conclusion regarding toxicological safety of the use of ionizing radiation in poultry. All three studies were conducted at Centraal Instituut Voor Voedingsonderzoek (CIVO); in each study, irradiated chicken constituted 35 percent (by dry weight) of the test diet. FDA concluded that the CIVO studies were of high quality, and that they provided no evidence of any adverse effects attributable to consumption of diets containing chicken irradiated at 3 or 6 kGy.[1]

FDA also reviewed all other data in its files relevant to the safety of irradiated chicken, including several in vitro and in vivo mutagenesis and genetic toxicity studies conducted using irradiated chicken. Such tests are often used to screen for possible association of carcinogenicity with a test substance by looking for positive mutagenic responses (genotoxicity). The agency concluded that several of these tests were well conducted and demonstrated the lack of mutagenic effects from the irradiated chicken. The agency noted deficiencies in other genetic toxicity tests that prevented reliance on such tests as a basis for a safety assessment but none of the tests provided evidence of a mutagenic effect.

In sum, the agency concluded on the basis of all the evidence, including the toxicological information before it, that poultry irradiated at up to 3 kGy was safe (55 FR 18538 at 18543).

2. Objections

a. *Letters*. FDA received several letters with multiple signatures that were substantially identical in content. This group of letters asserted that FDA's safety decision regarding the use of ionizing radiation on poultry was based solely on tests in mice, rats, and dogs, and raised a concern that studies in FDA's files, other than those described previously, used chicken that was irradiated under conditions that are different from those in the regulation issued by FDA. This group of letters states that human epidemiology studies should be conducted to establish the safety of the use of radiation, and that public hearings should be held. None of the letters included any information to support this objection.

Because these submissions provided no information to support their assertion regarding FDA's safety review, they provide no basis for FDA to reconsider its decision to issue the poultry final rule. Moreover, these submissions provide no basis for

[1] FDA also reviewed a carcinogenicity study in mice, conducted by Bio-Research Laboratories Ltd., in which the test diet contained 50 percent irradiated chicken. The agency noted that the mouse study results raised no concern that irradiated chicken is carcinogenic. However, FDA did not rely on this study because there were deficiencies in the data and report.

granting a hearing because a hearing request must include specifically identified reliable evidence that can lead to resolution of a factual issue in dispute. A hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions (§ 12.24(b)(2)). Therefore, FDA is denying the hearing requested by these letters.

b. *Objections by FWI.* In one of its submissions, FWI contends that ''FDA has failed to demonstrate that there is a 'reasonable certainty' that irradiation of poultry at 300 krad [3 kGy] is not harmful, and that therefore the Agency's approval is arbitrary and capricious.'' FWI gives four reasons for its contention.

i. *Power of the CIVO chronic rat feeding study.* First, FWI raises an issue about the statistical power of the chronic feeding study in rats conducted by CIVO. Specifically, FWI asserts that this feeding study was inadequate for determining safety because the study did not have sufficient statistical power to demonstrate that the cancer risk from consumption of irradiated chicken would be less than one in a million. FWI stated: ''In accordance with procedures applied to food additives generally, testing must be of such sensitivity that even a small incremental risk of cancer cannot escape detection, namely one per million, extrapolated to a typical human consumer.'' FWI provided the results of statistical analyses regarding the power of the test. In a background statement in its submission, FWI also stated that ''(g)iven the evidence that the formation of genotoxic radiolytic products can and does occur, a petitioner seeking approval of irradiation of poultry * * * should bear the burden of establishing the magnitude of expected cancer risk, or that it is below a stated level.'' In support of its objection, FWI submitted only a table entitled ''Identification of Genotoxic Radiolytic Products in Irradiated Organic Media or Food,'' but this table contained no information on genotoxicity data from irradiated poultry. FWI's objection did not dispute FDA's conclusion that the evidence demonstrated that irradiated poultry was not mutagenic (55 FR 18538 at 18540).

Neither FDA's guidelines nor generally accepted scientific procedures suggested for food additive testing recommend that carcinogenicity testing be sufficiently sensitive to detect an increased cancer risk of one in one million.[2] FWI provided no information to support its contention, either by reference to FDA's regulations or to any other requirement. Thus, FDA concludes that this objection raises no issue of fact that can be resolved at a hearing. Instead, the objection simply states FWI's preference for a policy regarding carcinogenicity testing. A hearing will not be granted on issues of policy or law (§ 12.24(b)(1)).

In addition, FDA does not dispute FWI's contention that the statistical power of this test is such that it cannot detect an increased cancer risk of one in one million. However, FWI did not demonstrate why prevailing on this factual issue would be adequate to justify the action requested (§ 12.24(b)(4)).

Additionally, FWI suggested that to increase sensitivity of the testing the radiation dose should have been increased tenfold or that concentrated extracts of all radiolytic products formed by irradiating chicken should have been fed.[3] Once again, FWI submitted no information to establish that the testing it recommended is required to demonstrate safety, or even that such testing would be valid to assess safety. Nor did FWI provide any information concerning how one can conduct such a study or how one can interpret the findings in the context of poultry irradiated at a dose not to exceed 3 kGy. Because FWI provided no evidence to consider in support of its assertion, FDA is denying the request for a hearing on this point because a hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions (§ 12.24(b)(2)).

ii. *Addition of ethoxyquin to irradiated chicken in the CIVO studies.* In the CIVO studies, the researchers removed water from the chicken by drying over hot air, in order to preserve the chicken for the time needed to complete the testing. Prolonged contact with hot air causes lipids (fats) to be oxidized to lipid peroxides, thereby rendering the food rancid and unpalatable. Prolonged storage can also lead to rancidity. Thus, the researchers added ethoxyquin, an antioxidant, to the chicken to prevent rancidity. Preventing rancidity by this means is of importance for a product dried and stored, as in the test.

In its second contention, FWI states that the CIVO studies were seriously compromised because the addition of the antioxidant ethoxyquin to the chicken decreased the levels of lipid peroxides in the irradiated chicken to levels comparable to those in unirradiated chicken. FWI contends that these decreased levels would interfere with the observation of toxicity from the lipid peroxides that were formed in higher amounts during the hot air drying of irradiated chicken than in the unirradiated chicken.

In the poultry final rule, FDA noted that ethoxyquin had been incorporated into both the control diets and the test diets in the CIVO studies. The agency acknowledged (55 FR 18538 at 15839 and 15840) that FDA reviews of the CIVO studies had raised the question of

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[2] In fact, it would not be feasible to conduct such testing in laboratory animals for substances ordinarily consumed at anything other than trivially low levels in the diet. Generally, to increase the power of a test one must increase the amount of test substance fed or increase the number of animals in each group. For example, the standard approach to assess low levels of carcinogenic risk is to feed a substance in large amounts, determine the risk at such a high dose, and extrapolate to lower doses using a linear extrapolation model. Using such a model to detect an increased risk of one in one million from a substance and assuming that the study design could detect a 10 percent cancer incidence at a high dose, one would have to feed an animal 100,000 times the amount it would consume under realistic conditions. This clearly cannot be done with a diet of chicken. Alternatively, testing thousands of animals per group would overwhelm normal laboratory capabilities.

Under FDA guidelines, testing of a food additive is generally conducted at levels no higher than 5 percent of the diet for nonnutritive substances. This level can be higher for a nutritive substance, however, provided it does not cause a significant nutritional deficit (Ref. 1). As noted previously and discussed in detail in the poultry final rule, the CIVO studies fed chicken irradiated at the maximum dose allowed by the regulation, as well as at twice that dose, in amounts equivalent to 35 percent of the diet (by dry weight). Moreover, based on its review of the mutagenicity data, FDA concluded that there was no basis to suspect that irradiated chicken would be carcinogenic.

[3] Irradiation doses typically can be raised only marginally higher than would be used in practice before they produce effects that would change food significantly, often producing an unpalatable product that animals will not eat. Special processing conditions can be used to minimize such effects, however, such as irradiating food in the frozen state in the absence of air. In the poultry final rule, FDA cited tests conducted at a dose approximately 10 times higher than the CIVO studies, which studies showed no adverse effects related to irradiation (55 FR 18539 at 18540). FDA relied primarily on the CIVO studies, however, because FDA would not expect irradiation of poultry at a dose below 3 kGy to be conducted using the processing conditions required for the higher dose.

Extracts of irradiated foods have not been relied on primarily for testing because radiolytic products of food do not differ in any particular chemical or physical properties from other components of food that would allow them to be specifically extracted from food. Additionally, radiolytic products are typically identical to substances that occur naturally in foods. Therefore, FDA is not aware of how one could prepare an extract that would ensure the presence of all radiolytic products while excluding the presence of other similar components of food that did not result from irradiation. The only way to ensure that all radiolytic products are present is to feed the irradiated food itself.

whether the addition of ethoxyquin could compromise the study and that this issue needed to be resolved before FDA could reach a safety decision. After careful consideration, FDA concluded that the addition of ethoxyquin to prevent rancidity of the chicken fat did not confound the results of the study.

The effect of ethoxyquin is to retard, during storage, the normal oxidation to peroxides of the fatty content of the diet. Importantly, ethoxyquin cannot reverse oxidation that has already taken place. In the CIVO studies, ethoxyquin was added after irradiation of the meat. Therefore, its presence would not alter the effects of radiation on the food (including any potential effects on the formation of lipid peroxides), as might occur if ethoxyquin had been added beforehand and were present during irradiation.[4]

FWI did not dispute FDA's explanation in the final rule as to why addition of ethoxyquin did not compromise the CIVO studies, and provided no information to contradict the agency's conclusion. Further, FWI did not show that FDA failed to consider important information that would have altered the agency's conclusion on this issue. Therefore, FDA is denying this objection and request for a hearing because a hearing will not be held if there is no factual issue that can be resolved by available and specifically identified reliable evidence (§ 12.24(b)(2)).

iii. *Adequacy of all CIVO studies—other issues.* In its objection, FWI also refers to ''* * * additional concerns regarding all the CIVO studies (storage of the irradiated chicken for periods far in excess of those anticipated for human consumers; possibly excessive supplementation of diets with vitamins A and E) and for the chronic feeding study in particular as noted in memoranda provided by the FDA * * *.'' FWI submitted no information to substantiate these concerns. FWI stated, however, that the short amount of time available to file objections following issuance of the poultry final rule precluded a detailed examination of the issues raised by these studies.[5]

FDA is denying FWI's request for a hearing to the extent that it is based on these particular contentions because FWI's request identified no particular factual issue in dispute and also because FWI provided no specific evidence that could be considered at such a hearing. As noted, a hearing will not be granted on the basis of mere allegations or descriptions of positions or contentions (see § 12.24(b)(1) and (b)(2)).

iv. *Compliance with the Bureau of Foods Irradiated Food Committee (BFIFC) report of 1980.* Finally, FWI asserts that the irradiated poultry final rule did not comply with all the recommendations of the BFIFC report issued in 1980. FWI also expressed disagreement with recommendations in that report.

The BFIFC report is an internal document prepared by FDA scientists that provides recommendations for evaluating the safety of irradiated foods based on the known effects of radiation on foods and on the capabilities of toxicological testing. The report was made available to the public for comment in the **Federal Register** of March 27, 1981 (46 FR 18992). While the report and the comments received on it have aided FDA's thinking regarding the safety testing of irradiated foods, the report established no requirements. FDA cited the BFIFC report in a footnote in the poultry final rule (55 FR 18538 at 18541) to illustrate how the toxicological data the agency considered (much of which was submitted before issuance of the BFIFC report) compared to the recommendations in the report.

Consistent with section 409 of the act, FDA's decision on the safety of irradiation of poultry was based on the entire record of that proceeding. Further, as discussed in the poultry final rule, in reaching its conclusion that irradiation of poultry under conditions specified in the regulation does not present a toxicological hazard (55 FR 18538 at 18541), FDA evaluated both studies submitted in the petitions as well as other studies of irradiated chicken available in agency files. Although FWI alleged that some of the studies that FDA evaluated did not comply with recommendations in the BFIFC report, FWI did not present any evidence that these alleged inconsistencies, even if true, would have led to a different conclusion concerning the safety of irradiation of poultry. Therefore, FDA is denying this objection and request for a hearing because it raises no factual issue that, even if resolved in the way sought by the objection, would justify the action requested (§ 12.24(b)(4)).

B. Environmental Issues

1. FDA's Finding of No Significant Impact

In reaching its decision to permit the irradiation of poultry at up to 3 kGy, the agency carefully considered the environmental effects of this action, as required under the National Environmental Policy Act (NEPA). After carefully reviewing the environmental assessment (EA) submitted by FSIS for FAP 7M3974 and environmental information submitted by RTI for FAP 8M3422, FDA concluded that this particular action would not have a significant impact on the human environment, and that an environmental impact statement was not required. The agency's FONSI and the evidence supporting it, including material from both the FSIS' EA and the submissions from RTI, were placed on display at FDA's Dockets Management Branch.

A key element in the EA and in FDA's FONSI is the regulatory controls exerted by various regulatory bodies, such as the Nuclear Regulatory Commission (NRC), the Occupational Safety and Health Administration, the Department of Transportation, the Environmental Protection Agency, FDA itself, and various State and local authorities. These controls are designed to ensure that any substances that may be lawfully emitted into the environment will not pose a significant environmental impact. These controls and regulations were cited in the materials considered by FDA, which material formed the basis of its FONSI.

2. Objections by FWI

In its second objection, FWI contends that FDA's FONSI is ''inadequate.'' FWI requested the preparation of an Environmental Impact Statement (EIS) and an open public hearing on the existing and potential dangers of the irradiation industry. Specifically, FWI maintained that the agency's FONSI is inadequate because it:

* * * relies strictly on information submitted by those who stand to gain from the approval of poultry irradiation; * * * extensively cites materials submitted by Martin Welt, a convicted felon with a criminal record of deceiving federal regulatory agencies; * * * completely disregards the fact that there have already been numerous irradiation accidents and, thus, must be deemed inadequate.

The objection also states that:

In documents released by FSIS within the past year, initially there is no mention of

[4] Moreover, ethoxyquin would not be needed for poultry irradiated and stored under typical commercial conditions. Commercial needs would require processing and storage practices that would prevent development of rancidity in order to provide a marketable product. Thus, the agency does not expect that high levels of lipid peroxides will be present in foods that are sold for human consumption.

[5] With respect to the limited time available for objections, FDA notes that the notice of filing for FAP 8M3422, which petition contained these studies, was published more than 3 years prior to FDA's decision. Thus, all safety information in the petition, including the CIVO studies, was available to FWI under the Freedom of Information Act for a significant period of time (21 CFR 171.1(h)(1)).

irradiation as a potential research area; and then, later, the FSIS declares that alternatives to the irradiation solution need not be discussed when considering the environmental impact of the technology. This contradiction alone warrants a hearing and should prove the need for a full Environmental Impact Statement.

Finally, the objection also requested an extension of the comment period, asserting that:

FDA; * * * received the original petition (FAP 7M3974) seeking approval for poultry irradiation in February, 1977 [sic] and, thus, it has taken your agency more than 13 years to come to your final decision. You are now granting the public a mere 30 days to comment on a ruling that took your agency more than 13 years to decide upon.

FDA notes that FWI misinterprets the statutory 30-day objection period, which is specified in section 409(f) of the act, as an opportunity for comment. The poultry final rule issued in the **Federal Register** of May 2, 1990, was a final rule and the opportunity for comment ended at that time. As noted in section I of this document, the agency had announced in the **Federal Register** of February 20, 1987, the filing of FAP 7M3974 and the filing of FAP 8M3422 in the **Federal Register** of March 3, 1987. Thus, FWI had notice of the filing of the petitions and had ample time to comment. The time to submit objections is established by statute (section 409(f) of the act), and thus, is not a deadline established by FDA. However, because the submission from FWI was submitted within the objection period, FDA is considering it as an objection.

In the following discussion, FDA addresses each of FWI's points outlined previously, as well as the data and information filed in support of each, comparing each to the standards for a hearing in § 12.24.

a. *Information submitted by interested parties.* The mere fact that information has been submitted by a party with an interest in an issue under agency consideration is not sufficient reason to reject that information.[6] In fact, each petitioner is required by FDA regulations to submit an EA as part of its food additive petition unless the action sought by the petitioner qualifies for a categorical exclusion. In assessing the potential environmental impact that could result from the approval of use of a food additive, including the use of sources of radiation in food processing, FDA critically evaluates the information submitted in the petitioner's EA, consistent with the applicable agency regulations (part 25 (21 CFR part 25)).

FWI has failed to submit any evidence that would call into question the validity of any of the specific information submitted by the petitioners and relied upon by FDA. FWI is merely asserting its opinion that an EA submitted by a petitioner is inherently inadequate. Accordingly, the agency is denying FWI's request for a hearing because a hearing will not be granted on issues of policy or law (§ 12.24(b)(4)), nor will one be granted on the basis of mere allegations or denials or general descriptions of positions or contentions (§ 12.24(b)(1)).

b. *Petitioner convicted of crimes.* In its objection, FWI also contends that the agency's FONSI is inadequate because ''* * * it extensively cites materials submitted by Martin Welt, a convicted felon with a criminal record of deceiving federal regulatory agencies.'' FWI did not provide any specific information to question the reliability or accuracy of the environmental information contained in FAP 8M3422[7] or FAP 7M3974. To support its objection, FWI submitted a copy of the government's sentencing memorandum in *United States* v. *Welt*, Criminal #88–87, U.S. District Court, District of New Jersey, 1988, (dated August 30, 1988, from Samuel A. Alito, Jr., United States Attorney, to the Honorable Maryanne Trump Barry, United States District Court, District of New Jersey, with attachments).

A food additive regulation is a conclusion that use of the additive in compliance with the conditions of use specified in such regulation is safe; a food additive regulation is not a license for an individual petitioner. Similarly, the FONSI is a conclusion that use of the additive under the proposed conditions of use, which includes compliance with applicable Federal, State, and local regulations, will not result in a significant impact on the human environment. The fact that Martin Welt (once the president of one of the petitioners) is a convicted felon is not in dispute. However, Dr. Welt's status is wholly irrelevant to the agency's evaluation of the potential environmental impact of the poultry final rule. FDA evaluated the environmental information supplied by RTI and the EA submitted by FSIS in an independent, scientific and critical fashion. It is the quality of the data and conclusions drawn from the information provided that are important. FWI raised no allegation as to the accuracy or credibility of the submitted information, nor did it identify any information FDA ignored or misinterpreted in issuing its FONSI. Accordingly, FDA is denying FWI's request for a hearing on this issue because a hearing will not be granted on factual issues that are not determinative to the action requested (see § 12.24(b)(4)).

c. *Accidents at irradiation facilities.* FWI also objected to the agency's FONSI on the grounds that the EA prepared by USDA ''fails to mention the numerous irradiation accidents which have already occurred in the U.S.—many of which have resulted in environmental, worker and product contamination.'' FWI contends that should the poultry industry widely adopt the use of irradiation, the need for irradiation facilities will be greatly expanded and that there are additional risks inherent in such an expanded irradiation industry. In support of its objection, FWI submitted the following:

1. A document entitled ''Fact Sheet—Radiation Sterilizers, Inc. (RSI) Incident, prepared by James L. Setser.''

2. A document entitled ''Summary—First Interim Report of the RSI Incident Evaluation Task Force,'' June 1989.

3. A document entitled ''Statement Before the Incident Evaluation Task Force for the Governor of Georgia,'' prepared by Judith H. Johnsrud, Research Director, Food and Water, Inc., October 17, 1988.

4. A list of ''Irradiation incidents at large scale gamma irradiation facilities, 1974 to 1988,'' compiled by Brion Sprinsock, National Coalition to Stop Food Irradiation.

5. A transcript of the morning session of the U.S. Nuclear Regulatory Commission Irradiator Workshop held on May 24, 1988.

FDA's action in issuing a food additive regulation permitting the irradiation of poultry at up to 3 kGy allows licensed irradiation processors to include poultry among the products treated at their facilities. Such irradiation of poultry is subject, however, to all applicable regulations, including local, State, and Federal safety regulations. FDA's FONSI is a statement that irradiation of poultry, in compliance with all applicable regulations, will not have a significant impact on the environment. It is entirely reasonable for FDA to evaluate the environmental effects of this food additive approval on the basis that facilities will operate in compliance with applicable safety rules. To assume that facilities will not operate in such

[6] Moreover, the agency notes that, the USDA, one of the petitioners, does not stand to gain from the approval of poultry irradiation, contrary to FWI's contention that the environmental information was submitted by those who do.

[7] Dr. Martin Welt was the president of RTI when it submitted FAP 8M3422. As the responsible company official, he signed the environmental information submitted in that petition. At the time FDA issued its final rule, Dr. Welt was no longer part of RTI management.

compliance would be highly speculative and essentially be a requirement that FDA perform a worst-case analysis when evaluating the potential environmental impact of an agency action. This is simply not what NEPA requires (see *Robertson* v. *Methow Valley Citizens Council*, 490 U.S. 332, 355 (1989)).

Importantly, the poultry final rule, in and of itself, does not permit any additional building or operation of irradiation facilities, and thus, does not directly result in any increased risk of accidents at such facilities. Before an irradiation facility is built, other regulatory agencies with oversight regarding its site design, location, licensing, and radiation control procedures (such as the NRC) must issue permits. The evaluation of the environmental impact of the construction and operation of these facilities is, under NEPA, the responsibility of the licensing agency or agencies. FDA's environmental evaluation in this case, and thereby FDA's FONSI, was not intended to reassess the environmental impact issues that are the responsibility of other regulatory agencies. In fact, under NEPA, an agency is not required to assess the environmental impact of a portion of a project where a second agency has jurisdiction over such portion (see *State of N.C.* v. *City of Virginia Beach*, 951 F.2d 596 (4th Cir. 1991)).

Accordingly, even if there have been accidents at irradiation facilities, or even if there would be an increased risk of such accidents as a result of the poultry final rule, these facts have no bearing on FDA's EA of its action. Thus, FDA is denying a hearing on this issue because a hearing will not be granted on factual issues that are not determinative with respect to the action requested (§ 12.24(b)(4)).

d. *Alleged contradiction*. FWI also objects to FDA's FONSI on the grounds of an alleged contradiction between information in FSIS's EA and other FSIS documents and cites an article from *The Food and Drug Letter* (April 28, 1989) in support of its objection. According to FWI, FSIS declared in its EA that alternatives to irradiation need not be discussed when considering the environmental impact of the technology and yet, in the article in *The Food and Drug Letter*, did not mention irradiation as one of the research areas for potentially solving the bacterial problem.

The material cited by FWI does not support its contention. In preparing an EA, petitioners are required, under § 25.31a(a)(11), to consider alternatives to the proposed action if potential adverse environmental impacts have been identified for the proposed action (§ 25.31a(a)(11)). After evaluating the FSIS' EA, the agency found that irradiation of poultry in compliance with existing laws and regulations will not lead to a significant impact on the environment. Because no adverse impacts are expected, the agency did not require, and FSIS did not address, alternatives to the proposed action under format item 11 of the EA. It should also be noted that, contrary to FWI's contention, FSIS did not claim in its EA that irradiation is the only solution to food-borne pathogens.

The article referred to by FWI from *The Food and Drug Letter* discusses areas identified by FSIS for future research for potential solutions to the problem of microbial contamination in poultry; at that time, irradiation had already been a subject of research as a potential solution to this problem. Thus, there is no contradiction between the statements made by FSIS in its EA and in the article in *The Food and Drug Letter*.

In order to justify a hearing on this issue, FWI would need to provide credible evidence that challenges FDA's conclusion that the irradiation of poultry in compliance with existing regulations will not lead to a significant impact on the environment (see § 12.24(b)(2)). FWI has not done so and, thus, has failed to meet a threshold burden of tendering evidence that suggests a need for a hearing (*Costle* v. *Pacific Legal Foundation*, *supra*, 445 U.S. at 214).

V. Summary and Conclusions

The safety of poultry irradiated at up to 3 kGy has been thoroughly tested and the data have been reviewed by the agency. As discussed previously, FDA concluded that the available studies establish the safety of poultry irradiated at doses up to 3 kGy for human consumption.

The petitioner has the burden to demonstrate safety before FDA can approve the use of a food additive. Nevertheless, once the agency 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 (*American Cyanamid Co.* v. *FDA*, 606 F2d. 1307, 1314–1315 (D.C. Cir. 1979)).

None of those objecting to the final rule has identified any information in the record that was misconstrued by FDA to support the objector's claim that the agency incorrectly concluded that consumption of poultry irradiated at up to 3 kGy is safe. Nor has any objector established that the agency overlooked significant information in reaching its conclusion. Indeed, none of the objections presented any relevant evidence that has not already been carefully reviewed and weighed by the agency. The agency has determined that the objections do not raise any genuine and substantial issue of fact that would justify an evidentiary hearing on any of the objections raised (§ 12.24(b)). Accordingly, FDA is overruling the objections and is denying the requests for a hearing. In addition, FWI's request for a stay of the effectiveness of the May 2, 1990, regulation until a hearing is held is moot because FDA is denying all hearing requests.

FDA is confirming May 2, 1990, as the effective date of the regulation.

VI. Reference

The following reference has been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA, Bureau of Foods, ''Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food,'' Appendix III, p. 18, 1982.

Dated: November 26, 1997.

Michael A. Friedman

Lead Deputy Commissiner for the Food and Drug Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. 94F–0289]

Irradiation in the Production, Processing and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of a source of radiation to treat refrigerated or frozen uncooked meat, meat byproducts, and certain meat food products to control foodborne pathogens and extend product shelf-life. This action is in response to a petition filed by Isomedix, Inc.