The Special Conditions

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for SA160 Avidyne Entegra Avionics Suite Project airplane modified by Symphony Aircraft Industries, Inc. to add an EFIS.

1. Protection of Electrical and Electronic Systems from High Intensity Radiated Fields (HIRF). Each system that performs critical functions must be designed and installed to ensure that the operations, and operational capabilities of these systems to perform critical functions, are not adversely affected when the airplane is exposed to high intensity radiated electromagnetic fields external to the airplane.

2. For the purpose of these special conditions, the following definition applies:

Critical Functions: Functions whose failure would contribute to, or cause, a failure condition that would prevent the continued safe flight and landing of the airplane.

Issued in Kansas City, Missouri, on July 6, 2007.

David R. Showers,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. E7–14050 Filed 7–18–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. 1994F–0008 (formerly Docket No. 94F–0008)]

Irradiation in the Production, Processing and Handling of Food

AGENCY: Food and Drug Administration, HHS.

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

SUMMARY: The Food and Drug Administration (FDA) is responding to objections and is denying the requests that it has received for a hearing on the final rule that amended the food additive regulations to authorize the use of a machine source of high energy x-rays to inspect cargo containers that may contain food. 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 or modifying the amendment to the regulation.

FOR FURTHER INFORMATION CONTACT: Andrew J. Zajac, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1267.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of February 24, 1994 (59 FR 8995), FDA published a notice announcing the filing of a petition (FAP 4M4407) submitted by Analytical Systems Engineering Corp. (ASEC) (now ACS Defense, Inc.) to amend the food additive regulations in § 179.21 *Sources of radiation used for inspection of food, for inspection of packaged food, and for controlling food processing* (21 CFR 179.21) to provide for the safe use of machine sources of high energy x-rays to inspect cargo containers that may contain food. The rights to the petition were subsequently transferred to R. F. Reiter and Associates. In response to the petition, FDA issued a final rule in the **Federal Register** of April 10, 2001 (66 FR 18537), permitting the use of x-rays produced by machine sources of 10 million electron volts (MeV) or lower to inspect food, providing that no food receives a dose in excess of 0.5 gray (Gy). This rule will be referred to in this document as the ''cargo inspection final rule.'' 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 May 10, 2001).

II. Objections and Requests for a Hearing

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 requesting a public hearing 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. (*Community Nutrition Institute* v. *Young*, 773 F. 2d 1356, 1364 (D.C. Cir. 1985), *cert. denied*, 475 U.S. 1123 (1986)).

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 cargo inspection final rule, FDA received a letter from Public Citizen within the 30-day objection period. Public Citizen sought revocation of the final rule based on three objections and requested a hearing on issues raised by each objection.

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 requlation 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, 214–215 (1980), *reh. denied*, 446 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. *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 Ass'n* 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 (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 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 a fair opportunity.'' *Retail Clerks Union, Local 1401* v. *NLRB*, 463 F.2d 316, 322 (D.C. Cir. 1972). (See *Costle* v. *Pacific Legal Foundation*, supra at 215–220. See also *Pacific Seafarers, Inc.* v. *Pacific Far East Line, Inc.*, 404 F.2d 804 (D.C. Cir. 1968), *cert denied*, 393 U.S. 1093 (1969).)

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 objections to the cargo inspection final rule pertain to FDA's safety determination. 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 for Inspection of Cargo Containers

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 cargo inspection final rule discussed in detail FDA's evaluation of the safety of radiation for inspection of cargo containers that may contain food (66 FR 18537). Under that regulation, machine sources producing x-rays at energies no greater than 10 MeV may be used to inspect containers of food, provided that the absorbed dose not exceed 0.5 Gy.

Among the reports submitted in the petition or that FDA identified in scientific publications, the agency explicitly cited three in its final rule. These reports, which were among the most recent studies or reviews, assessed the potential for induced radioactivity in food by experimental measurement and theoretical calculation, and provided the primary basis for FDA's conclusion regarding safety of the petitioned use of 10 MeV x-rays at a dose not to exceed 0.5 Gy.

One of the reports is from the World Health Organization (WHO). This WHO report concluded that no detectable radioactivity will be induced in foodstuffs by x-rays with a maximum energy level of 10 MeV when a radiation dose of 0.5 Gy is not exceeded.

The second report (Wakeford and Blackburn, 1991) discussed a study investigating the radioactivity induced in codfish, rice, and a macerated meat product irradiated with high energy bremsstrahlung[1] x-rays produced by an electron linear accelerator that generated electrons at energies up to 12 MeV and predominantly at 8 MeV. The authors reported that the bremsstrahlung x-rays used to irradiate the food had a maximum energy in the region of 10 MeV. These foods received radiation doses ranging from 8.8 to 14 kilogray (kGy), which is 17,600 to 28,000 times higher than the 0.5 Gy maximum dose permitted by the final rule. Induced activities in the foods from the bremsstrahlung x-rays were reported to be extremely small and of the same order as natural background levels, and any induced activities dropped quickly.

The third report (Findlay et al., 1992) summarized a study that investigated the induced radioactivity in chicken, prawns, cheeses, and spices irradiated with electron beams at two energies, 10 MeV and 20 MeV and at different doses up to 10 kGy. The authors noted that any induced radioactivity was due to photonuclear reactions resulting from bremsstrahlung x-rays and electronuclear reactions induced by the electron beams. The authors found that even when the food was irradiated with

[1]Bremsstrahlung refers to the type of x-rays that are emitted when high-speed electrons are suddenly decelerated due to interactions with atomic nuclei. X-rays also can be produced when accelerated electrons have sufficient energy to eject electrons from the inner shells of atoms. As outer-shell electrons move in to fill the vacancies in the lower energy level, x-rays are emitted, called characteristic x-rays.

electrons at 20 MeV and doses at 10 kGy, the highest energy and dose tested, any induced activity was negligible after 1 day.[2] The authors reported that the measured values agreed well with calculated values. Based on the totality of the data and other relevant material evaluated by FDA, the agency concluded that no detectable radioactivity will be induced in food when an x-ray energy of 10 MeV and a dose of 0.5 Gy are not exceeded, and that the use of x-rays, produced by a machine source at energies of 10 MeV or lower, to inspect food, is safe.

B. Objections

Public Citizen contends that FDA has failed to demonstrate that the use of the subject additive is safe and gives three reasons for objecting to the final rule. Public Citizen requests a public hearing on their objections.

First, Public Citizen contends that FDA's use of the conclusion in the WHO report that ''no detectable radioactivity will be induced in foodstuffs when an x-ray energy level of 10 MeV and a dose of 0.5 Gy are not exceeded'' is flawed because the conclusion is based on an extrapolation of theoretical and experimental studies that the report does not reference.

The WHO report states that ''* * * relevant experimental data are available from studies designed to evaluate the use of activation analysis and the application of x-rays and electrons in food irradiation and medical uses at energy levels up to 24 MeV and at doses up to 50 kGy. Such studies, both theoretical and experimental, can be used to extrapolate downwards to a lower dose such as the 0.5 Gy considered for surveillance systems and that these studies show no evidence that detectable levels of radioactivity would be induced at these lower doses.'' Although not specifically cited, it is clear that the experimental data referred to in the report are the data from studies that were discussed in several working papers that were presented to the WHO consultation group and several relevant published papers referenced in the WHO report. These working papers were included in the petition along with the WHO report. For example, one paper that discussed experimental and theoretical work concerning the possible induction of radionuclides in food by high energy x-ray systems used for cargo surveillance referenced several relevant studies, including one by Glass and Smith.[3] This particular study, which was submitted with the petition, examined isomer radioactivities in elements and food using a variety of radiation sources, including 4–24 MeV x-ray sources at doses up to 50 kGy. FDA is denying the request for a hearing on this point because a hearing will not be granted if there is no genuine and substantial factual issue to be resolved (§ 12.24(b)(1)).

Public Citizen has failed to submit any evidence that would call into question the scientific validity of extrapolation of results obtained at higher energy levels and radiation doses to draw conclusions regarding effects that might be produced at lower energy levels and doses. Public Citizen is merely alleging that this approach is scientifically unsound. 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 or contentions (§ 12.24(b)(2)).

In its second objection, Public Citizen contends that the Wakeford report is cited in the final rule to support the statement that electrons with energies of 8–10 MeV induced an extremely small level of radioactivity in various types of food, but that this statement is irrelevant to this petition because the petition concerns the use of x-rays. The objection further asserts that the statement in the final rule ''FDA would not expect any detectable radioactivity above background in food resulting from the petitioned use,'' is based on no data or evidence.

Contrary to Public Citizen's contention, the Wakeford report did concern the use of x-rays. As referenced in the final rule, the report by Wakeford, Blackburn, and Swallow (FDA inadvertently omitted the name of the third co-author, A.J. Swallow), titled ''Induction and Detection of Radioactivity in Foodstuffs Irradiated with 10 MeV Electrons and X-rays,'' studied food irradiated with electron beams as well as with high energy bremsstrahlung x-rays. The authors state that the food was irradiated directly by 0–10 MeV x-rays to a maximum dose of 15–20 kGy (the results table shows an average dose ranging from 8.8 to 14 kGy, which is 17,600 to 28,000 times higher than the maximum permitted dose level under the final rule of 0.5 Gy). The authors concluded that the induced activity from the 0–10 MeV bremsstrahlung x-rays was extremely small. Public Citizen provided no information to support its contention that the radiation reported as x-rays in the Wakeford report is irrelevant to the safety review of the subject additive. FDA is denying the request for a hearing on this point because a hearing will not be held on the basis of mere allegations or denials or general descriptions of positions or contentions (§ 12.24(b)(2)).

Similarly, the objection does not identify any evidence to support its assertion that FDA's conclusion is based on no data or evidence. The data and evidence relied upon by FDA is set out in the final rule. The Wakeford report, the WHO report and Findlay report are all part of the data relied upon by FDA in making its determination. FDA is denying the request for a hearing on this point because a hearing will not be held on the basis of mere allegations or denials or general descriptions of positions or contentions (§ 12.24(b)(2)).

Public Citizen also states in its second objection that, according to the Wakeford report, x-rays of energy greater than 3 MeV could induce radioactivity, and four isotopes can be activated at x-ray energies below 5 MeV and cause neutron induced activity in food. Among the four isotopes, Public Citizen specifically mentions carbon-13, oxygen-17, and deuterium. The objection does not show that FDA failed to consider important information that would have altered the agency's conclusion that the x-rays at energies up to 10 MeV at the maximum proposed dose of 0.5 Gy will result in negligible amounts of induced radioactivity in food. Indeed, the WHO report cited in the final rule concluded that thresholds for inducing radioactivity in some isotopes is less than 10 MeV, but that the probability of radioactivity being induced under these conditions is so low that it would not be detected by methods that can determine activity that is only 1 percent of what occurs naturally in food. The language from the Wakeford report cited in the objection is consistent with the conclusions in the WHO report. Public Citizen identifies no information to support a conclusion contrary to that reached by FDA. Therefore, FDA is denying the request for a hearing on this point 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)).

In its third objection, Public Citizen states that the Findlay report is not relevant to the petition because induction of radioactivity in food was studied using electron beams whereas the petition concerns the use of x-rays.

[2] The authors reported a specific activity after 1 day of 0.01 becquerel/gram.

[3] R.A. Glass and H.D. Smith, ''Radioactive Isomer Production in Foods by Gamma Rays and X-rays,'' Stanford Research Institute Report S–594, No. 3 (DA 19–129–1QM–1511), 1960.

In support of its assertion, Public Citizen references a report from the International Consultative Group on Food Irradiation titled ''The Development of X-Ray Machines for Food Irradiation (Proceedings of a Consultants' Meeting),'' dated October 1995 (ICGFI report), for its statement that ''neutron activity produced by 5 MeV x-rays is in the order of 60 times greater than that produced by 10 MeV electrons.''

However, contrary to Public Citizen's objection, the ICGFI report shows that the difference in expected neutron activation in irradiated food from electron beams and x-rays has been calculated, thereby permitting use of electron beam studies to estimate neutron activation expected from irradiation with x-rays. Public Citizen has offered no evidence to support its assertion that electron beam studies are inappropriate to support conclusions about x-ray irradiation. FDA is denying the request for a hearing on this point because the evidence submitted by Public Citizen in support of their argument, even if established at a hearing, would not be adequate to justify resolution of the factual issue in the way sought by the objector (§ 12.24(b)(3)).

Moreover, it bears noting that the ICGFI report directly supports FDA's conclusion of safety in the final rule, when it cites 10 MeV x-rays at doses less than 0.5 Gy (the maximum energy and dosage in the final rule) as an example of ''extremely low'' dosage that ''would not produce any significant radioactivity.'' Public Citizen's reference to the conclusion in the ICGFI report that ''increasing the energy of x-rays above 7.5 MeV would result in * * * possible induction of radioactivity in the irradiated food'' is unavailing because that conclusion refers to the uses permitted by the Codex Alimentarius Commission for treating food at dosages up to 10 kGy, which is 20,000 times higher than the 0.5 Gy maximum dosage permitted by the final rule for inspecting food.

Although Public Citizen alleged that the studies that FDA evaluated do not support the safety of x-rays of 10 MeV or lower used for inspection of cargo containers that may contain food, Public Citizen did not present any evidence that would have led to a different conclusion concerning the safety of the subject additive. Because Public Citizen's first and second objections provided no information to support their assertions regarding FDA's safety review, they provide no basis for FDA to reconsider its decision to issue the cargo inspection final rule. As noted previously, a hearing will not be granted on the basis of general descriptions of positions and contentions (see § 12.24(b)(1) and (b)(2)). Public Citizen's third objection relied on information that, even if established at a hearing, would not be adequate to justify resolution of the factual issue in the way sought by the objector. A hearing will be denied if the information submitted are insufficient to justify the factual determination urged, even if accurate (§ 12.24(b)(3)). The issues posed by Public Citizen in support of the objections do not justify the granting of a hearing.

V. Summary and Conclusions

The safety of x-rays produced by a machine source at energies of 10 MeV or lower, to inspect food irradiated at doses up to 0.5 Gy 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 food for human consumption irradiated at doses up to 0.5 Gy as a result of being subjected to x-rays produced by a machine source at energies of 10 MeV or lower. 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 F. 2d 1307, 1314–1315 (D.C. Cir. 1979)). For the reasons set out previously, the objections do not raise genuine and substantial issues of fact supported by specifically identified reliable evidence that, if established at a hearing would be adequate to justify resolution in the way sought by Public Citizen. Therefore, Public Citizen's objections are not sufficient to justify a hearing under the requirements of § 12.24(b). Accordingly, FDA is overruling the objections and is denying the requests for a hearing.

Dated: July 11, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–13947 Filed 7–18–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. 1998F–0196] (Formerly 98F–0196)

Food Additives Permitted in Feed and Drinking Water of Animals; Selenium Yeast

AGENCY: Food and Drug Administration, HHS

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for food additives permitted (FAP) in feed to provide for the safe use of selenium yeast as a source of supplemental selenium in feed supplements for limit feeding for beef cattle and in salt mineral mixes for free-choice feeding for beef cattle. This action is in response to an amendment of a food additive petition filed by Alltech, Inc.

DATES: This rule is effective July 19, 2007. Submit written or electronic objections and requests for a hearing by August 20, 2007. See section V of this document for information on the filing of objections.

ADDRESSES: You may submit written or electronic objections and requests for a hearing identified by Docket No. 1998F–0196, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written objections in the following ways:

- Fax: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of objections, FDA is no longer accepting objections submitted to the agency by e-mail. FDA encourages you to continue to submit electronic objections by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.