RAS 7092

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

ATOMIC SAFETY AND LICENSING BOARD

Before Administrative Judges:
Michael C. Farrar, Presiding Officer
Charles N. Kelber, Special Assistant

In the Matter of:	)	Docket No.: 30-36239-ML
CFC Logistics, Inc.	)	ASLBP No.: 03-814-01-ML
(Materials License Application)	)	Date: November 21, 2003
	)	License Control No. 132825

RESPONSE OF CFC LOGISTICS, INC. TO INTERVENORS' SECOND MOTION FOR A STAY

CFC Logistics, Inc. (CFC Logistics), by its undersigned counsel of record, hereby submits this Response to Intervenors' Second Motion for a Stay regarding the operation of a Category III cobalt-60 irradiator located at its cold-storage facility in Quakertown, PA. For the reasons described below, CFC Logistics respectfully requests that the Presiding Officer deny Intervenors' motion.

I. BACKGROUND AND PROCEDURAL HISTORY

On August 27, 2003, NRC Staff granted CFC Logistics a materials license in accordance with its February 25, 2003 license application and 10 CFR Part 36 (Part 36) requirements to operate a Category III underwater irradiator using cobalt-60 "sealed sources." That same day, NRC issued an Inspection Report, based on multiple site inspections, which determined that CFC Logistics' irradiator was constructed in accordance with its license application and Part 36 requirements. *See* Letter from John D. Kinneman, NRC to James B. Wood, President, CFC Logistics, Inc., *Inspection*

03036239/2003001, CFC Logistics, Inc., Quakertown, Pennsylvania (August 27, 2003). After receipt and installation of cobalt-60 "sealed sources" by its provider, REVISS Services, Ltd. (REVISS), NRC Staff acknowledged CFC Logistics' successful completion of radiological surveys for its irradiator in compliance with its NRC license. *See* Letter from Sattar Lodhi, NRC to James Wood, CFC Logistics, Inc., *Acceptance of Notification of Satisfactory Completion of Radiological Surveys of the Surveys of the Facility, Control No. 133770*, (October 6, 2003) (Exhibit D).

On August 22, 2003, Intervenors filed their First Motion for a Stay of the effectiveness of CFC Logistics' NRC license alleging prototypical design of the irradiator and various alleged health and safety concerns (e.g., electrical power loss and equipment failure). In an order dated September 23, 2003, the Presiding Officer denied Intervenors' Motion without prejudice and allowed Intervenors to renew their stay motion if "circumstances changed"[1] or if Intervenors' request for a hearing was granted.

In an order dated October 29, 2003, the Presiding Officer granted Intervenors' request for a Subpart L hearing. On November 10, 2003, Intervenors filed their Second Motion for a Stay. For the reasons set forth below, CFC respectfully requests that the Presiding officer deny Intervenors' Motion.

II. STANDARD OF REVIEW

10 CFR § 2.1263 provides that any participant in an ongoing informal adjudication can request that the Presiding Officer stay the effectiveness of a licensing action. *See* 10 CFR § 2.1263. However, the four substantive requirements for imposing

[1] CFC Logistics notes for the record that Intervenors have not demonstrated that any "changed circumstances" with respect to cobalt-60 shipments or licensed operations and, in any event, does not appear to provide any such basis for a second stay motion.

a stay must be satisfied by Intervenors: (1) the movant must make a strong showing that it is likely to prevail upon the merits of its case, (2) the movant must show that, without the requested relief, it will be irreparably injured, (3) whether the issuance of a stay will substantially harm other parties interested in the proceeding, and (4) where the public interest lies? *See* 10 C.F.R. § 2.788(e); *see also Virginia Petroleum Jobbers Ass'n v. FPC,* 259 F.2d 921, 925 (D.C. Cir. 1958).

The party seeking a stay has the burden of persuasion with respect to the four criteria listed above. *See Alabama Power Co.*, CLI-81-27, 14 NRC 795 (1981). Since no one of the four stay criteria is dispositive, the strength or weakness of a movant's showing on a particular factor will determine how strong its showing must be on the other factors. *See Cleveland Electric Illuminating Co.*, ALAB-820, 22 NRC 743, 746, n. 8 (1985). However, if the moving party fails to meet its burden on the first two factors, likelihood of success on the merits and irreparable injury, then it is not necessary to give lengthy consideration to balancing the latter two factors. *See Long Island Lighting Co.*, ALAB-810, 21 N.R.C. 1616, 1620 (1985), *citing Duke Power Co.*, 20 NRC at 1635.

III. ARGUMENT

A. Intervenors Have Failed to Demonstrate a Likelihood of Success on the Merits

Intervenors have failed to raise any new issues which are sufficient to support a finding of a likelihood of success on the merits in this proceeding. As a result, Intervenors' Motion should be denied.

1. Intervenors' Argument Regarding Contract Language Will Not Succeed on the Merits

Intervenors' stay motion is substantially based on alleged "new" information gathered from the Sales Agreement between CFC Logistics and Gray*Star, Inc. (Gray*Star), CFC Logistics' irradiator designer. Specifically, Intervenors allege that various clauses within this Sales Agreement demonstrate that CFC's irradiator is in a "prototype 'developmental' stage." Intervenors' November 10, 2003 Stay Motion. This allegation, while based on a "new" document, is no different from Intervenors' earlier allegation that "[t]he process and facility is new, untested and untried." Intervenors' August 22, 2003 Stay Motion at 4.

Intervenors contract language claims are irrelevant to CFC Logistics' NRC license. The "developmental" aspects of CFC Logistics' irradiator are related to "production efficiency" and not health and safety. Contract terms such as those highlighted by Intervenors are specifically designed to ensure that the irradiator purchaser (CFC Logistics) receives the proper equipment for commercially viable irradiator operations of the type contemplated by CFC Logistics. However, as a general proposition, the CFC Logistics irradiator *would not be licensed by NRC if it did not satisfy NRC regulations* regardless of its potential commercial viability. In other words, "production efficiency" cannot and does not supersede CFC Logistics' NRC license and Part 36 requirements. Indeed, the Sales Agreement explicitly states, "[a]ny and all modifications to the Unit [irradiator] as well as their installation and testing *must be in accordance with CFC LOGISTICS' Byproduct Material License, and approved by CFC LOGISTICS.*" *See* Intervenors' November 10, 2003 Stay Motion at 3. Thus, no irradiator activities are conducted outside the scope of CFC Logistics' NRC license.

2. Intervenors' Argument Regarding CFC's Radiation Safety Officer Will Not Succeed on the Merits

Next, Intervenors argue that "no one will provide an RSO [Radiation Safety Officer] during operation/experimentation." Intervenors' November 10, 2003 Stay Motion at 4. This allegation is incorrect.

Under the CFC Logistics/Gray*Star Sales Agreement, Gray*Star would provide an *interim RSO* in the event that CFC Logistics had not yet hired a full-time RSO for the irradiator facility. *See* Affidavit of James Wood (Exhibit A) at 2. This requirement was necessary to ensure that CFC Logistics had access to a viable, full-time RSO at the site until a full-time, permanent one could be hired. However, in CFC Logistics' February, 2003 license application, prior to the receipt of any licensed "sealed sources," CFC Logistics listed Ms. Marie Turner as the permanent, full-time RSO for the irradiator facility, and she continues to serve in that capacity.[2] *See id.* Thus, Intervenors' allegations on this issue are incorrect.

3. Intervenors' Argument Regarding the Plenum and Its "Check Valve" Will Not Succeed on the Merits

Intervenors allege that the presence of a "check valve" on the plenum holding the "sealed sources" represents a threat to public health and safety, because they claim that REVISS Services, Ltd., CFC Logistics' cobalt-60 "sealed source" provider, stated that the current plenum "may lead to corrosion of the cladding, with consequent escape of radiation" and "insisted" on changes to the facility." Intervenors' November 10, 2003 Stay Motion at 5. This allegation is inaccurate.

[2] Ms. Marie Turner is not employed by Gray*Star contrary to the assertions of Intervenors. *See* Intervenors' November 10, 2003 Stay Motion at 7.

As a general proposition, the "check valve" on the CFC Logistics irradiator's plenum is not related to health and safety, but rather to "production efficiency."[3] As stated in the Affidavit of Russell M. Stein (Exhibit B), the check valve on the plenum is designed to allow the operator to purge water from the plenum and maintain air pressure in the plenum after a source loading and during irradiation operations using a deliberate, systematic process. *See* Exhibit B at 5-6. Should any water be present within the plenum, there would be no health and safety risks because "sealed sources" are specifically designed to be in contact with water, whose purity is mandated by license condition and NRC regulations, while they are stored and/or used in irradiation operations. Thus, any concerns regarding the presence of water in the plenum is nothing more than a "warranty definition" issue for REVISS. *See id.*

Further, Intervenors' allegations with respect to CFC Logistics' "general lack of reliability" as facility operator based on the removal of the "check valve" prior to the receipt of cobalt-60 "sealed sources" is without merit. CFC Logistics experimented with the removal of the "check valve" prior to NRC-licensed "sealed sources" arriving at the site. The "check valve" was removed *prior to* the receipt of "sealed sources" to test the potential for optimizing "production efficiency."[4] Thus, Intervenors' allegation on this point is without merit.

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[3] Intervenors' allegation that "[t]here is now a pending application to change the design to eliminate the [check] valve for safety" is incorrect. Intervenors' November 10, 2003 Stay Motion at 7. CFC Logistics currently is not pursuing any modifications to its irradiator, however, CFC may pursue NRC approval on this or other potential modifications if deemed appropriate by NRC.

[4] For further discussion of this issue, *please see* Exhibit B at 5-6.

4. Intervenors' Argument Regarding Potential Accidental Dispersion of Cobalt-60 Is Incorrect

Finally, Intervenors allege in their Motion and in Dr. Resnikoff's affidavit that potential scenarios resulting in accidental dispersion of cobalt-60 from the CFC Logistics irradiator conclusively demonstrate that Intervenors will succeed on the merits. There is no substance to this allegation.

Intervenors rely primarily on scenarios involving the potential drop of a product bell due to equipment failure and a potential loss of electricity causing overheating of sources. *See* Intervenors' November 10, 2003 Stay Motion at 8-9; *see also* Resnikoff Affidavit at ¶¶ 5, 7, & 8. Both issues were addressed in CFC Logistics' response to Intervenors' First Motion for a Stay. The irradiator's turnbuckles, by which product bells are attached to the hoist/trolley system, have a "ten times safety factor," which is well above typical industry standards for such mechanisms. *See* Exhibit B at 4. These mechanisms provide an ample margin of safety from potential cask/product bell drops.

Potential accidental dispersion scenarios related to overheating of the "sealed sources" are also without merit because, as stated previously, heat calculations were provided to NRC during its review, and there is no plausible scenario where the sources could be heated above their pre-certification "test temperature" of 600 degrees centigrade (1,112 degrees Fahrenheit). *See* Exhibit B at 4. Further, potential electrical power failures at the CFC Logistics facility have been addressed previously, and NRC Staff has found CFC Logistics' procedures adequate to protect public health and safety.[5] *See*

[5] As in his first affidavit, Dr. Resnikoff claims that "the licensee has no emergency procedures for accidents involving a break in the compressed air line." Resnikoff November 6, 2003 Affidavit at ¶ 9. Such emergency procedures were provided to NRC Staff and local response teams and were found to be adequately protective of public health and safety. *See* Letter from John D. Kinneman,

Letter from John D. Kinneman, NRC to James B. Wood, President, CFC Logistics, Inc., *Inspection 03036239/2003001, CFC Logistics, Inc., Quakertown, Pennsylvania* (August 27, 2003).

Intervenors' conclusory allegations regarding potential accidental dispersion of cobalt-60 due to the presence of the "check valve" are also without merit. As stated above, the check valve on the plenum does not address issues of health and safety, but rather issues of "production efficiency" and "warranty definition." Exhibit B at 5-6. The presence of water in the plenum does not pose a significant risk of accidental dispersion of cobalt-60 material, because, as noted previously, cobalt-60 "sealed sources" are designed to be exposed to water during licensed operations. Dr. Resnikoff has failed to demonstrate that a plausible scenario exists where water present in the plenum could result in degradation of the cobalt-60 "sealed sources" thereby leading to the accidental dispersion of cobalt-60 material outside the confines of the CFC Logistics irradiator.

B. Petitioners Have Failed to Demonstrate Irreparable Harm

A party must *reasonably demonstrate, and not merely allege*, irreparable harm. *Philadelphia Electric Co.*, 22 N.R.C. at 196, *citing Duke Power Co.*, ALAB-794, 20 NRC at 1633-35. Intervenors have failed to *reasonably demonstrate* irreparable harm.

As stated in CFC Logistics' response to Intervenors' First Motion for a Stay, the Commission concluded in its Part 36 rulemaking that, after an environmental assessment pursuant to the National Environmental Policy Act of 1969 (NEPA), irradiators operating within the scope of Part 36 regulations adequately to protect public health and safety. Thus, as stated above, Intervenors must *reasonably demonstrate* and not *merely allege*

NRC to James Wood, President, CFC Logistics, Inc., *Inspection 03036239/2003001, CFC Logistics, Inc., Quakertown, Pennsylvania* (August 27, 2003).

that there is some aspect of the CFC Category III irradiator that is outside the scope of such regulations and that poses a significant threat to public health and safety. *Compare Philadelphia Electric Co.*, 22 N.R.C. at 196, *citing Duke Power Co.*, ALAB-794, 20 NRC 1630, 1633-35 (1984).

Intervenors have offered no evidence, "new" or otherwise, that CFC Logistics is operating its irradiator in a manner which does not comply with Part 36 regulations or its NRC license. The only "new" information offered by Intervenors is the aforementioned Sales Agreement which explicitly requires that all irradiator activities be conducted in compliance with CFC Logistics' NRC license. This failure to even allege that CFC Logistics' Category III irradiator operates in any significantly different way for *health and safety purposes* than other such irradiators makes it impossible for Intervenors to show irreparable harm/injury because "[i]n order to substantiate a claim that irreparable injury is likely to occur, a movant must provide some evidence that the harm has occurred in the past and is likely to occur again." *See Wisconsin Electric Co. v. FERC et al.*, 758 F.2d 669, 674 (D.C. Cir 1985). Since no evidence of past harm has been presented and no evidence of a likelihood of such harm occurring as a result of the operation of the CFC Logistics irradiator has been offered, Intervenors have failed to demonstrate that they will suffer irreparable harm.

C. CFC Logistics Will Suffer Serious Harm If a Stay Is Granted

Intervenors have not even addressed the potential harm to CFC Logistics as a result of the issuance of a stay. If a stay is imposed, CFC Logistics potentially could be forced to remove all cobalt-60 "sealed sources" from its irradiator and cease licensed operations. As shown in Exhibit A, CFC Logistics would incur substantial financial

losses, the loss of industry credibility, and the potential loss of skilled employees who would be without a job, if a stay were issued. *See* Exhibit A at 2-3. Such losses *can be considered* by a Licensing Board even though economic factors are not traditionally the subject for review. *Philadelphia Electric Co.*, 21 N.R.C. at 1602-3. Therefore, CFC Logistics *will* suffer significant harm if a stay is imposed.

D. The Public Interest Lies With the Denial of a Stay

Finally, Petitioners have only made general conclusory statements to demonstrate that the public interest will be served if a stay is imposed—that CFC Logistics has not complied with its NRC license and that CFC Logistics is incapable of monitoring its irradiator. Therefore, Intervenors have failed to demonstrate that a public interest exists justifying the issuance of a stay of CFC Logistics' NRC license.

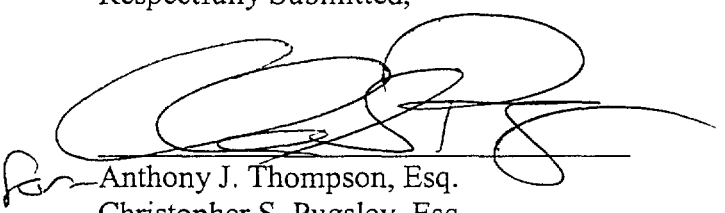
Further, the public interest *will be served* if Petitioners' motion is denied because members of the public will be protected from diseases and illnesses due to the use of the CFC Logistics irradiator to irradiate food and other products. For example, "[t]he Centers for Disease Control and Prevention, along with the World Health Organization and many other health organizations, welcomes the use of food irradiation as an important technology that can protect against foodborne diseases...The potential benefit of irradiating meat and poultry alone is substantial." Robert V. Tauxe, *Foodborne Safety and Irradiation: Protecting the Public from Foodborne Infections*, www.cdc.gov/ncidod/eid/volno3_supp/tauxe.htm, at 10 (2000). Thus, *there is a public*

interest in denying Intervenors' stay motion because food irradiation provides a recognized valuable service to the public.[6]

IV. CONCLUSION

CFC respectfully requests that the Presiding Officer deny Petitioners' motion because they have not satisfied the requirements for the grant of a stay.

Respectfully Submitted,



Anthony J. Thompson, Esq.
Christopher S. Pugsley, Esq.

COUNSEL FOR CFC LOGISTICS, INC.

[6] Additional periodicals regarding the public's interest in food irradiation have been attached to this Response as Exhibit C for the Presiding Officer's reference.

EXHIBIT "A"

AFFIDAVIT

I, James B. Wood, being duly sworn, depose and state as follows:

(1) I am the President of CFC Logistics, Inc. (CFC Logistics) located at 4000 AM Drive, Quakertown, Pennsylvania. In that capacity, I negotiated the Sales Agreement between CFC Logistics and Gray*Star, Inc. (Gray*Star) for the Genesis irradiator.

(2) The Sales Agreement with Gray*Star is a commercial agreement which ensures that CFC Logistics specifically gets what it pays for in terms of capacity, productivity and return on investment in purchasing the equipment. All language referring to "prototype" and "performance specifications" does not refer to health and safety and security aspects of the equipment's performance, but rather to the productivity and capacity that it could achieve given the irradiator design which impacts the economics of CFC Logistics' irradiation business.

(3) Knowing that the Nuclear Regulatory Commission (NRC) would be the authority to oversee and ensure the integrity of the design and installation of the equipment, my chief concern from a business standpoint was the productivity and economic feasibility of the equipment. CFC Logistics had developed a pro-forma business plan based on capacity and productivity numbers that were suggested by Gray*Star to be attainable with the Genesis unit. In other words, Gray*Star claimed (based on mathematical models and experience with similar licensed underwater irradiators) that with 1,000,000 curies, ground beef would have a cycle time of "x" and therefore you could put through "y" lbs. per week at a maximum, and at a price of "z" dollars, you could generate "XXX" dollars annually at maximum capacity. Obviously, these assumptions were critical to the success of the business plan and return on investment. In putting a sales agreement together, CFC Logistics wanted assurances that the equipment's performance will be within the range of these assumptions, otherwise our business plan would be faulty and, in that case, CFC Logistics would not pay for the equipment. The Sales Agreement basically states that if the economics are not met to CFC Logistics' satisfaction, Gray*Star will continue to work on fine-tuning the system (in areas such as precise placement of cobalt-60 pencils and positioning of the product bells next to the plenum in order to maximize product exposure), and, thus, improve the productivity of the unit. As it turns out, their capacity predictions were extremely close to the reality of the Genesis unit's capability.

(4) If Gray*Star observed any opportunities to improve or enhance any features of the equipment following start-up operations, we agreed it would be in everyone's best interest to make it known to us and to pursue those improvements if possible and, if approved by NRC. Examples of potential improvements would be in areas of improved maintenance, efficiency, or ease of operation.

(5) Despite the fact that the Sales Agreement discusses issues of "production efficiency," the Sales Agreement also states that all modifications are subject to our NRC license, so that no changes would be made without notification to and approval by NRC authorities.

(6) In regard to the "interim RSO (Radiation Safety Officer)" discussed in the Sales Agreement (Russell Stein), this was intended to provide us with Gray*Star's experience and expertise acting as a consultant RSO until CFC Logistics identified and hired its own full-time, permanent RSO. CFC Logistics thought this was necessary and prudent as we were undertaking the NRC license application process and, subsequently, the installation of the equipment. In its February, 2003 license application, Ms. Marie Turner was listed as CFC Logistics full-time, permanent RSO and, in June, 2003, prior to the issuance of CFC Logistics' NRC license and the subsequent receipt of licensed cobalt-60 "sealed sources," Ms. Turner was CFC Logistics full-time, permanent RSO. Ms. Turner is a "full-time" RSO and will not be located at an off-site location.

(7) With respect to the issue of potential harm to CFC Logistics if a stay were to be granted, since CFC Logistics has been investing in the project for almost one (1) year, there will be significant financial harm. If the stay motion is granted and the cobalt-60 sources must be removed, but then we later succeed on the merits in this proceeding and the cobalt-60 sources are returned, there would be financial hardship due to removal and reloading business interruption and delay. The operational expenses for the facility currently are running at approximately $85,000 per month. The costs to transport the cobalt-60 sources back to REVISS Services, Ltd. and then re-purchase and return such sources at a later date to CFC Logistics would be an additional $50,000. Lost customer revenues for this period of time would also be approximately $50,000 per month. Assuming a twelve month period to secure additional cobalt-60 sources and then reinstate a customer base, I would anticipate financial losses to be on the order of $1,670,000.

(8) Should the stay motion be granted, all workers currently employed by CFC Logistics to operate the irradiator, including our RSO, will lose their jobs for whatever period of time it takes for the licensing proceeding to be completed and for continued irradiator operations to be resumed, and there will be no guarantee they will be available in the future if CFC Logistics seeks to restart operations.

(9) In addition to the "sunk costs" and operating expenses described in Paragraphs 7 & 8, CFC Logistics also would be severely impacted by the loss of economic goodwill with our prospective customers. Once the Intervenors' initial stay motion was denied in October, CFC Logistics initiated a significant investment program focused on publicity and marketing campaigns. The irradiation industry, like any other, is a competitive industry that requires a great deal of time and energy to market services and to develop customer relationships in order to build

credibility prior to signing a paying customer. CFC Logistics currently is engaged in active discussions with over 30 potential customers. CFC Logistics also has launched a significant public relations campaign including major stories being written in national trade magazines regarding CFC Logistics' company profile which will be printed in January, 2004. If this stay motion is granted and CFC Logistics is unable to operate, we will lose all credibility in the food and irradiation industries in general and with all currently identified potential customers. After spending 15 years as a consultant to entrepreneurial and small businesses on growth strategies, and the last 4 years working in the food industry, in my opinion, it will take years to recover from this loss of credibility and, in the near-term, set CFC Logistics back at least two (2) years on its business plan amounting to approximately $2,000,000 in lost revenues.

I, James B. Wood, being duly sworn, deposes and says:

That he has read the foregoing affadavit and the matters stated herein are true and correct to the best of his knowledge, information and belief.

Executed at Hatfield Township, Pennsylvania, this 18th day of November, 2003

James B. Wood, President

Subscribed and sworn before me this 20 day of NOVEMBER, 2003

Notary Public, State of Pennsylvania

Notarial Seal
Philip E. Keeler, Notary Public
Hatfield Twp., Montgomery County
My Commission Expires Aug. 10, 2004
Member, Pennsylvania Association of Notaries

My commission expires _____

EXHIBIT "B"

Affidavit

I, Russell N. Stein, being duly sworn, depose and state as follows:

(1) I am the Vice President and Chief Operating Officer of GRAY*STAR, Inc. ("GRAY*STAR") at 200 Valley Rd., Ste. 103, Mt. Arlington, New Jersey.

(2) I have been in the irradiator industry for over 23 years and am considered a leading irradiator designer. I have specific experience designing several irradiators, two of which have been built. Not only have I designed irradiators, but I have also operated irradiators as an Irradiator Operator, Radiation Safety Officer and Manager. I have never been cited with an item of non-compliance by the NRC.

(3) I am currently a member of the American Nuclear Society, the American Society for Materials and the American Society for Testing and Materials. I have presented many technical papers to various forums on irradiators and irradiator design, including a training session to NRC and Agreement State inspectors from across the country.

(4) I am the chief designer of the Genesis Irradiator(tm) and am responsible for all of its design, engineering, manufacturing and operating procedures.

(5) I am not and have not been in the direct employment of CFC Logistics, Inc. (CFC Logistics). I do provide consulting services to CFC Logistics on the Genesis Irradiator(tm) as part of the terms and conditions of a contractual agreement between GRAY*STAR, Inc. and CFC Logistics. I am not, and have not been the active Radiation Safety Officer (RSO) for CFC Logistics. I would have functioned as interim RSO, if necessary, until CFC Logistics could hire a qualified full-time, permanent RSO. CFC hired Ms. Marie Turner as RSO prior to the issuance of its NRC license and the receipt of licensed "sealed sources," so I never had to fulfill this task.

(6) The first Genesis Irradiator(tm) is installed at CFC Logistics in Quakertown, PA is a "Prototype" unit. "Prototype" defined by Webster's New World Dictionary, Third College Edition as: *"1) the first thing or being of its kind; original; model; pattern; archetype."* The Genesis Irradiator(tm) is designed as a piece of equipment. It is the intention of GRAY*STAR, Inc. to sell Genesis Irradiators of the same design to other entities in the future. Therefore, since the unit installed in Quakertown is the first of its model, it is defined as a "prototype".

(7) The Genesis Irradiator is a "Category III - Self-contained, wet source storage, irradiator" as defined by the American National Standard (ANSI) N 433.3: *"An irradiator in which the sealed source(s) is contained in a storage pool (usually containing water), the sealed source(s) is shielded at all times, and human access to the sealed source(s) and the volume(s) undergoing irradiation is physically restricted in its designed configuration and proper mode of use."*

(8) *None* of the *safety* systems as outlined in 10 CFR 36 and licensed, implemented and approved on the Genesis Irradiator are novel in scope, except there are some elements of the Genesis that may be termed "defence in depth" such as the multi-layered shielding pool which contains an extra protective layer to prevent a release of pool water.

(9) GRAY*STAR, Inc. chose to design and market an irradiator (the Genesis) as a Category III irradiator. This decision was made because a Category III irradiator utilizes a *passive* safety system. There are about 65 other commercial irradiators in the United States that irradiate the same type of products that might be irradiated in CFC Logistics' Genesis Irradiator. All of these other irradiators are defined by American National Standard N433.4 as: Category IV - Panoramic, wet storage irradiator, "*A controlled human access irradiator in which the sealed source(s) is contained in a storage pool (usually containing water), and the sealed source(s) is fully shielded when in use; the sealed source(s) is exposed within a radiation volume(s) that is maintained inaccessible during use by an entry control system.*" In other words, the "sealed source" array is raised out of the shielding pool to irradiate product within a radiation room. To "control human access...by an entry control system" requires the safety systems to be *active* instead of *passive*. *Active* safety systems inherently require more oversight, training and management by their nature. Both types of irradiators are regulated under 10 CFR 36 with relevant differences in their oversight, training and management requirements.

(10) There are many Category III irradiators licensed and used in the United States for either research or the irradiation of "wood-plastic" composite materials. To my knowledge, the Genesis is the first commercial irradiator designed to irradiate packaged materials to compete with Category IV irradiators.

(11) Category III irradiators prior to the Genesis have low processing efficiencies, therefore, they are not economically competitive with Category IV irradiators. The Genesis has developed new design concepts to increase the efficiency to be able to compete with Category IV irradiators. These new design concepts are "developmental," however, they are related to *production efficiency* and not *safety.*

(12) To date, all of the concerns of the Intervenors have related to safety issues which are *not* "developmental" and are well within the scope of 10 CFR 36. One could argue that every issue raised by the Intervenors could be raised with respect to *all* pool type irradiators of both Categories III and IV and the issues are *not* unique to the Genesis Irradiator.

(13) GRAY*STAR's intent to bring the Genesis to market is to provide a commercial "package" irradiator with the *inherent safety* of a Category III irradiator *passive* safety system. We view this as a very positive safety advancement.

(14) I have reviewed Dr. Marvin Resnikoff's 2nd Declaration In Support of Petitioners'

Motion for a Stay. My review of his Affidavit follows utilizing his paragraph numbering.

1. I do not accept or deny his statements in paragraph #1. However, Item #1 does not exhibit any experience of Dr. Resnikoff with irradiator design, safety, nor regulatory aspects of irradiators. Dr. Resnikoff has not indicated if he has ever designed, operated or even seen a commercial irradiator.

2. I do not accept or deny his statements in paragraph #2.

3. Items in paragraph #3 are inaccurate. GRAY*STAR is the designer, manufacturer and marketer of the Genesis Irradiator(tm). Presently, GRAY*STAR contracts the engineering and manufacture of the unit to a third party. Also, GRAY*STAR contracts with various entities for sales support. GRAY*STAR is a third party from CFC Logistics, Inc. and REVISS Services, Ltd. (REVISS). REVISS is a provider of Cobalt-60 "sealed sources." REVISS is a third party from GRAY*STAR and CFC Logistics. REVISS also provides related services such as transportation and installation of Cobalt-60 to CFC Logistics. CFC Logistics purchased a Genesis Irradiator from GRAY*STAR. As part of the purchase agreement ("Sales Agreement"), GRAY*STAR will provide consulting services to CFC Logistics at no additional cost for a period of two years. REVISS was contracted to supply, transport and install the initial load of Cobalt-60 into CFC Logistics' Genesis Irradiator. CFC Logistics has provided no financing to either GRAY*STAR or REVISS. CFC Logistics is the sole operator of their Genesis Irradiator. As an NRC licensee, they are responsible for all aspects of safety and operation. Depending on the nature of any "repairs", it is their obligation to assure the repairs are performed properly and in accordance with their Materials License from NRC. At least initially, these repairs would be covered under warranty of the unit by GRAY*STAR or warranty of the Cobalt-60 by REVISS. If any incident were to occur at the facility, the RSO, with the advice of the Radiation Safety Committee, would determine if they could make the repairs themselves or would require outside services for the specific repair. In either event, they would make the determination if the NRC need to be notified (note: many specific events require mandatory notification to the NRC).

4. Items in paragraph #4 are inaccurate. The potential modifications discussed in paragraph #4 were experimentally considered before the license was issued and before licensed cobalt-60 was received at the CFC facility. The potential modifications were removed *prior to* the receipt of cobalt-60. CFC Logistics made a request to NRC that the potential modifications be approved prior to the receipt of cobalt-60, but when it was determined that the NRC could not perform their review in time for the receipt of the cobalt-60, the request for modification was retracted.

5. Regardless of what the Sales Agreement shows, CFC Logistics employs a full time RSO who is approved by the NRC. Further, she has previous experience in acting as a full-time RSO on a *commercial Category III* irradiator making her ideally suited for the task. In my opinion, she is a well qualified professional and capable of performing her responsibilities as an RSO on the Genesis Irradiator located in Quakertown, Pennsylvania. *No* irradiation facility has, or is qualified to have on site expertise to conduct *any and all* repairs. Indeed, NUREG - 1556, Vol. 6. states: "*Repair and Preventive Maintenance - Outlines of maintenance, service, and repair procedures are not required. However, these should be done according to the manufacturer's written instructions, where applicable, by qualified personnel using their knowledge, experience, judgement, and skills to respond to each particular situation.*"

6. There is no reason given to explain why a turnbuckle would fail, and if one did fail, why the second turnbuckle might also fail. The potential for a failure of a turnbuckle has been addressed by NRC in their August Inspection Report where they concluded that "...a load drop is considered an unlikely event." There is a ten (10) times safety factor of the turnbuckles on the Genesis which is far above and beyond required safety factors for lifting devices. However, using that as an example, the RSO at CFC Logistics would be notified immediately should a turnbuckle fail. Depending on the nature of the incident, the RSO would take action based on the circumstance. Most likely this would involve an immediate meeting of the Radiation Safety Committee to determine the course of action. This type of event would be reported to the NRC. As described, this event *would not present any imminent threat to the health, safety or property of any of the Petitioners*. Most likely, CFC Logistics would contact GRAY*STAR to assess the damage and contract with them (if not covered by the warranty) to facilitate repairs.

7. I disagree with Dr. Resnikoff statements in paragraph #6 of his affidavit. To help clarify the prototype nature of the Genesis Irradiator, please refer to the earlier sections of this Affidavit. As for how repairs are implemented please refer to the previous two sections.

8. I disagree with Dr. Resnikoff's statements in paragraph #7 of his affidavit. Heat calculations *were* provided to the NRC. Assuming that the "sealed sources" satisfy the NRC's Part 32 regulatory criteria, which they must in order to be registered with NRC as licensed "sealed sources," and that the shielding pool water satisfies the relevant Part 36 criteria, the number of hours until there is any heat degradation to the "cladding" is virtually infinite. George Pangburn of the NRC affirmed this at the second meeting with residents of Milford Township at the Quakertown High School. There is no plausible scenario that would heat the source above their *tested* heat rating of 600 degrees centigrade (1,112 degrees Fahrenheit).

9. The NRC has already determined that CFC Logistics is in compliance with 10 CFR 36.53(b)(6). *See* NRC letter to James Wood dated August 27, 2003, "Inspection 03036239/2003001, CFC Logistics, Inc., Quakertown, Pennsylvania". The NRC has determined that CFC Logistics is in compliance with all of 10 CFR 36. This is not an appropriate forum for challenging the Commission's regulations. 10 CFR 2.1239. Further, this issue was already addressed in the previous Stay proceedings. See "MEMORANDUM AND ORDER (Ruling on Petitioners' Motion to Stay License Effectiveness), LBP-03-16."

10. Similar to paragraph #8 above, this is a challenge to the procedures. However, if for any reason the ion exchange resin is ineffective, CFC Logistics has procedures in place and the in-house ability and capability to replace the resin. Further, this issue was already addressed in the previous Stay proceedings. See "MEMORANDUM AND ORDER (Ruling on Petitioners' Motion to Stay License Effectiveness), LBP-03-16."

11. Shielding pool water entering the plenum *is not* a "serious matter" in relation to public health and safety. *See* Paragraph 14(7) above. It would however effect production. In any event, "Accidental Dispersion" has already been addressed in the previous Stay proceedings. Resnikoff has not made it clear "on how the solid (essentially water-insoluble), nickel-plated, doubly-encapsulated cobalt metal source...lends itself to ready dispersion in accident situations". See "MEMORANDUM AND ORDER (Ruling on Petitioners' Motion to Stay License Effectiveness), LBP-03-16."

To help clarify this issue, REVISS indicated to GRAY*STAR that they did not know how to classify the irradiator for *warranty purposes*. They are familiar with supplying cobalt to typical Category II irradiators where no water storage of any kind is used and, thus, the sources never come in contact with water. They are familiar with supplying cobalt-60 to typical Category III irradiators where the sources are always in contact with water. They are familiar with supplying sources to Category IV irradiators where the sources are constantly cycling between water and dry conditions. They have an aggressive warranty program including retrieval and destructive testing of representative sources from all of the above types of irradiators. The Genesis is a Category III irradiator which deviates in one respect from a typical Category III irradiator. The sources are stored dry. Therefore, from a warranty point of view, REVISS was not sure whether to warranty the sources as "dry storage" or "wet storage" without positive assurance that the plenum was or was not always dry. They indicated to GRAY*STAR that they would like some indication that the sources will indeed be maintained in a dry state in the Genesis. They suggested that they would prefer the system to be modified so that there would be some positive indicator of the presence of any shielding pool water in the plenum. During the negotiations of the

REVISS/CFC Logistics cobalt-60 contract, the only test for plenum water was to monitor relative humidity in the plenum. Shortly afterwards, the engineers working on the system came up with a positive way of determining whether or not there was water in the plenum and, the method for keeping water out of the plenum was designed to include running the plenum at a slightly positive pressure. Therefore, this positive pressure not only prevents water from entering the plenum but, if there should be a leak, allows detectable air bubbles to escape. Thus, the sources will indeed be dry at all times, and if there is a leak, it will be detected allowing for maintenance of the plenum. The placement of the check valve limits the positive pressure in the plenum. If the pressure is too high, the air will escape from the check valve. If the pressure is too low, a positive pressure will not be maintained. With the check valve in place, it requires more time and oversight to balance out the pressures. Further, the check valve greatly restricts the rate at which the plenum can be purged after a source loading. If the check valve were removed, it would make the removal of water from the plenum more efficient and simplify the procedure. In conclusion, if the check valve were to be removed, it would facilitate the method used to assure that the plenum is always dry and, thus, clarify REVISS' classification of the unit as a dry storage irradiator. However, the Genesis with the check valve in place provides more than adequate protection of public health and safety and is within the confines of Part 36 regulations and CFC Logistics' NRC license.

12. CFC Logistics does not intend on removing the valve without authorization from the NRC per License Condition #18. At present, there is no license amendment application pending.

13. Detailed manufacturing drawings of the Genesis Irradiator are the property of GRAY*STAR, Inc. CFC Logistics has no inherent rights to these drawings. GRAY*STAR, Inc. has supplied CFC Logistics with specific drawings which are germane to its license application and NRC review according to relevant regulations and guidance. The NRC has reviewed the information supplied by CFC Logistics and deemed the material complete and sufficient for review. CFC Logistics cannot supply materials that it does not have rights to.

14. I do not believe that Dr. Resnikoff has illustrated that the "petitioners could suffer irreparable harm" under the benchmarks outlined in the "MEMORANDUM AND ORDER (Ruling on Petitioners' Motion to Stay License Effectiveness), LBP-03-16."

15. It is not clearly illustrated how any of the information provided above "...increase[s] risk of significant dispersion" of "the solid (essentially water-insoluble), doubly-encapsulated cobalt metal source". See "MEMORANDUM AND ORDER (Ruling on Petitioners' Motion to Stay License Effectiveness), LBP-03-16."

16. I cannot confirm or deny that Dr. Resnikoff will avail himself to testify on this issue.

I Russell N. Stein, being duly sworn, deposes and says:

That he has read the foregoing affidavit and the matters stated therein are true and correct to the best of his knowledge, information and belief.

Executed at Morris Township, New Jersey, this 20th. day of November, 2003.

Russell N. Stein
Vice President
GRAY*STAR, Inc.

Subscribed and sworn before me this 20th day of November, 2003

Megan E. Bianchetti
Notary Public, State of New Jersey

My Commission Expires 01.19.2005

EXHIBIT "C"

Past Issue

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Presentation from the 2000 Emerging Infectious Diseases Conference in Atlanta, Georgia

On April 21, 2003, the following correction was made to this article: In Table 1, third column, the 5-log reduction dose in kGrays for *Salmonella* was changed to 3.50.

Food Safety and Irradiation: Protecting the Public from Foodborne Infections (1)

Robert V. Tauxe
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Early in the 20th century, when food safety was a major concern to the public, two technologies, milk pasteurization and retort canning, were developed, promoted, and, virtually canonized as prevention measures against foodborne diseases. Fear of contracting typhoid fever from watered milk and outbreaks of botulism from commercially canned products are now part of the distant past, controlled by these food industry processes in many countries. Nonetheless, at the beginning of the 21st century, foodborne disease remains a major threat to public health, as new pathogens and products have emerged (1). Many of these threats can be controlled by applying new technologies, when we as a society are willing to use them.

In the United States, foodborne infections cause an estimated 76 million cases of illness and 323,000 hospitalizations annually--more than one in 1 in 1000 (2). The economic burden is substantial, estimated at up to $6.7 billion annually in patient-related costs for treatment of bacterial infections alone (3). Five pathogens account for much of the most severe illness: *Salmonella*, *E. coli* O157 and other Shiga toxin-producing *E. coli*, *Campylobacter*, *Listeria*, and *Toxoplasma* cause an estimated 3.5 million infections, 33,000 hospitalizations, and 1600 deaths each year (2).

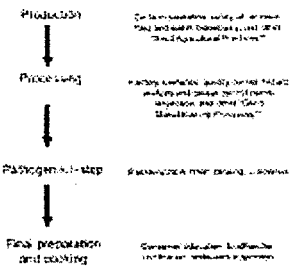
In the early 1990s, large and devastating foodborne outbreaks of *E. coli* O157:H7 infections heightened public concern about foodborne diseases (4). Efforts to improve food safety were intensified in industry and regulatory agencies, and supported by the National Food Safety Initiative (5). As a result of these efforts, the process control strategy of the Hazard Analysis-Critical Control Point is becoming the norm to use for producing many foods. In slaughter inspection it is replacing manual and visual carcass-by-carcass inspections. An expanded focus on regulating sanitation and hygiene with

good manufacturing and agricultural practices means that food would be produced under cleaner conditions. In restaurants and home kitchens, new attempts have been made to educate food preparers in the basic principles of food safety, though paid sick leave for foodhandlers is still the exception, and handwashing is intermittent. These developments may collectively help explain a decline in the reported incidence of *Salmonella* and *Campylobacter* infections that were observed in active surveillance by FoodNet between 1996 and 2000 (6). However, we are still far from the public health goals established for 2010. These goals include reducing the national incidence of infections with *Salmonella*, *E. coli* O157, *Campylobacter*, and *Listeria* to 50% of their 1997 incidence (7). Reaching those goals means preventing 50% of foodborne diseases now occurring. This will require new approaches for prevention.

Traditional Methods: Sanitation and Pasteurization

In general, effective vaccines are not available to protect against pathogens that cause foodborne diseases, either for immunizing humans or for animals that serve as hosts and may be eaten by humans. Educating consumers, foodhandlers, and food producers in basic food safety is important but is not sufficient by itself. Protecting consumers from the most severe diseases has been achieved by increasing the safety of food along the chain of production, from farm to table (Figure). For many foodborne infections, control has been most successful when mechanisms of transmission are understood well enough to prevent contamination from occurring before consumers purchase food. This has meant rethinking food production processes and sometimes introducing new safety steps to reduce levels of microbial contamination. The degree of safety built into the process varies, depending on the risk and the technologies available to address the risk.

Figure



Click to view enlarged image

Figure. The chain of food production and foodborne disease prevention from farm to table.

For all foods, using basic principles of sanitation and food hygiene preserves wholesomeness and shelf life. For foods susceptible to contamination with particularly deadly pathogens, we as a society have demanded additional protective measures be taken to eliminate those pathogens from the food altogether. A definitive food safety measure is necessary when contaminated food products put the general population at risk for severe illness and when typical food production practices do not eliminate the risk reliably, especially those pathogens that cause severe illness to humans exposed to even small amounts; it is not sufficient to rely on routine food handling practices in the kitchen to prevent illness if the pathogen is already present in the food. In the past, it has often been a catastrophe resulting from a large foodborne outbreak that spurs the demand for new measures to completely eliminate the pathogen from food.

Implementation of definitive new measures for food safety has historically

been slow. For example, canning was widely practiced as a means of preserving food in the 19th century, but methods were not standardized. The principal risk associated with eating improperly canned foods is botulism, a devastating paralytic illness that follows ingestion of food containing botulinum toxin. Botulinum is an extremely potent toxin produced by the bacterium *Clostridium botulinum* under certain anaerobic conditions, such as those that may be found inside a hermetically sealed can. This bacterium can live inside a can because it forms a hardy spore that can survive the temperature at which water boils at ordinary air pressure. It takes higher than 100 degree Celsius temperatures to kill spores in canned food.

Before the invention of artificial ventilation and intensive care, half of those who contracted botulism died, and even now, botulism means many weeks in intensive care. Large outbreaks during and following World War I drew attention to the public health hazard of poorly canned foods. A 1919 multistate outbreak that resulted in 15 deaths was traced to canned ripe olives from California (8,9). This outbreak led to the development in 1923 of an industry standard method for cooking food at high enough temperatures to kill the botulinum toxin, the so-called botulism retort cook. This method would reliably reduce the clostridial spore counts by 12 decimal logs, the highest conceivable level of contamination (10). In 1930, a federal standard for quality of canned foods was developed, because of concern that vegetables that were canned might be of inferior quality (11). However, it was not until 1973, following an outbreak of botulism traced to defectively canned commercial vichysoisse soup (12), that the current federal regulation of canned foods was passed.

Pasteurization of milk, another fundamental technology used to prevent foodborne disease, was also adopted slowly over many years. At the turn of the last century, cows' milk was recognized as the source of a large number of different infections, including typhoid fever, bovine tuberculosis, diphtheria, and severe streptococcal infections (13). A commercial pasteurizer was patented in Germany in 1893, and, by 1900, a standard set of pasteurization conditions were defined, based on the time and temperature required to inactivate *Mycobacterium tuberculosis*, which was thought to be the most heat-resistant pathogen. However, pasteurization was opposed because it was believed that it might be used to market dirtier milk and also because of fears that it might affect the nutritional value of milk (14); therefore, the technology was implemented slowly. For some, the best way to prevent infections spread through milk was to pay scrupulous attention to the health of animals and to create sanitary conditions for the milk production process. This "certification movement" led to substantial improvements in dairy conditions. However, recurrent outbreaks of illness traced to some certified dairies clearly indicated a need for pasteurization. Initially, different jurisdictions adopted either improved sanitation or pasteurization. The requirements of the Public Health Service Standard Milk Ordinance in 1927 combined the two strategies: first, milk was to be graded based on a variety of sanitation measures; second, only Grade A milk could be pasteurized (15). By the end of the 1940s pasteurization was heavily promoted throughout the industry and became the norm. Now, 99% of fresh milk consumed in the United States is pasteurized, Grade A (16).

The use of both retort canning and milk pasteurization took decades to gain universal acceptance. Many were concerned that the use of these technologies would lead to slippage of standards for quality and sanitation. These concerns were ultimately addressed by using formal grading processes to assure the public that only clean milk would be pasteurized, and only vegetables of clearly defined quality would be canned. Concerns that loss of nutrients would be an important issue were found to be unwarranted. Although a wide variety of times and temperatures were initially used, clear microbial target endpoints were ultimately defined for both canning and pasteurization so that milk pasteurization and botulism retort cook have standard meanings everywhere in the United States. Quality grading standards and pathogen elimination processes were first developed by the industry and then formally adopted via federal regulation. Both processes are generally applied to foods that are either packaged or that will be immediately packaged. This method minimizes the opportunity for posttreatment recontamination.

Use of these processes has eliminated outbreaks of botulism in commercial canned food and has made outbreaks of illness from milk extremely rare. Foodborne botulism is now a rare illness, with approximately 25 cases a year that are almost always associated with home-canning or home-preserving (16). Bovine tuberculosis, typhoid fever, and septic sore throat resulting from milk tainted with bacteria have disappeared. Outbreaks of infections due to unpasteurized milk still occur (16). The rare outbreaks that are traced to pasteurized milk are usually the result of breaks in postpasteurization hygiene (16,18).

Today's Technology: Food Irradiation

The use of high energy irradiation to kill microbes in food was evaluated in this country as early as 1921, when scientists at the United States Department of Agriculture reported that it would effectively kill trichinae in pork (19). Irradiation has become a standard process used to sterilize many consumer and medical products, from adhesive strips to surgical implants. Three different technologies that can be used to treat food have been developed by the sterilization industry.

Gamma Irradiation

Gamma irradiation technology uses high energy gamma rays that are emitted by radioactive Cobalt 60 or Cesium 137. These radioactive sources are produced in commercial nuclear reactors and have a long half-life that makes them useful for commercial installation. Food or other products are brought into a heavily-shielded chamber and exposed to gamma rays for a defined length of time. When the source is not in use, it is stored in a pool of water that absorbs all irradiation, effectively turning it off. These high energy rays can penetrate deeply, making it possible to treat bulk foods on shipping pallets.

Electron Beam Irradiation

Electron beam technology uses a stream of high energy electrons, also known

as beta rays, that are emitted from an electron gun. The technology is analogous to an electron beam in a television tube, though far more powerful. Electrons can only penetrate several centimeters of food, and for this reason, foods are treated in relatively thin layers. Modest metal shielding of the treatment cell is sufficient to prevent the escape of stray electrons. When not in use, the electron source is turned off by switching off the electric current. No radioactivity is involved.

X-Irradiation

The most recently developed technology, X-irradiation, mixes properties of both of the above. High energy X-rays can be produced if an electron beam hits a thin metal foil target. Like gamma rays, a beam of X-rays can penetrate foods to a much greater depth than electron beams and requires heavier shielding. However, like electron beams, X-ray sources can be switched on and off and do not use a radioactive source.

Effect of Irradiation on Microbes

The high energy rays of irradiation directly damage the DNA of living organisms, inducing cross-linkages and other changes that make an organism unable to grow or reproduce. When these rays interact with water molecules in an organism, they generate transient free radicals that can cause additional indirect damage to DNA. An absorbed dose of irradiation energy is now measured in units called Grays, rather than an older measure called a rad. One Gray equals 100 rads, and 10 kiloGray equal 1 megarad. Complex life forms with large DNA molecules are affected by relatively low doses. Simpler organisms with smaller DNA can take progressively higher doses. Thus, a low dose of under 0.1 kiloGray kills insects and parasites and inhibits plants from sprouting. A medium dose, between 1.5 and 4.5 kiloGray, kills most bacterial pathogens other than spores, and a higher dose of 10-45 kiloGray will inactivate bacterial spores and some viruses. Prions, which do not contain nucleic acid, are difficult to inactivate by irradiation. For humans, the lethal dose is 4 Gray.

The actual dose required to treat food varies with the specific pathogen and the specific circumstances of the food. It generally takes a higher dose to kill the same number of organisms in frozen food than it does to kill them in refrigerated food. A D-dose is the amount of irradiation that it takes to destroy 90% of the organisms or one decimal log. Thus, a one log kill would reduce a million bacteria to 100,000. Getting rid of more bacteria takes more irradiation as they are small targets and it is not easy to hit each of them. To eliminate 99.999% of the bacteria (a so-called 5 logarithm kill) takes 5 times the irradiation dose needed for a 1 log kill and would reduce a million bacteria to ten. For example, it takes 0.2 kiloGray to reduce *Campylobacter* in meat by one decimal log or 1 kiloGray to reduce it by 5 decimal logs (Table 1).

Table 1. Doses required to decrease selected pathogens at refrigerator temperatures by one decimal log/90% (D-dose)

Pathogens	D-dose in kGray*	5-log reduction dose in kGrays
Campylobacter	0.20	1.00
Toxoplasma cysts	0.25	1.25
E. coli O157	0.30	1.50
Listeria	0.45	2.25
Salmonella	0.70	3.50
Cl. botulinum spores	3.60	18.00

*1 Gray = 100 rads; 10 kGray = 1 Megarad

Irradiation has been approved for use on a broad range of foods for different purposes (Table 2). The use of irradiation on food was formally approved as though it were something added to food, rather than a process to which the food is subjected. This means that for meats and poultry, approval is required from both the FDA and USDA. The effect of irradiation on food itself is usually minimal at doses up to 7.5 kGray. Treated food does not become radioactive, and, in general, shelf life is prolonged because organisms that cause spoilage are reduced along with pathogens. Irradiation has been used effectively in meats, poultry, grains, and produce. However, not all foods can be irradiated without changing their quality. Meats with a high fat content may develop off-odors; the whites of eggs may go milky and liquid; and grapefruit gets mushy. Alfalfa seeds do not seem to sprout as well if they are irradiated, and raw oysters may die, which shortens their shelf life substantially.

Table 2. Irradiation approved for foods in the United States

Year	Food	Dose (kGy)	Purpose
1963	Wheat flour	0.20-0.50	Control mold
1964	White potatoes	0.05-0.15	Inhibit sprouting
1986	Pork	0.30-1.00	Reduce cases of Trichinosis
1986	Fruits & vegetables	1.00	Increase shelf life and control insects
1986	Herbs and spices	30.00	Sterilize
1990 (FDA)	Poultry	3.00	Reduce bacterial pathogens
1992 (USDA)	Poultry	1.50-4.50	Reduce bacterial pathogens
1997 (FDA)	Fresh meat	4.50	Reduce bacterial pathogens
2000 (USDA)	Fresh meat	4.50	Reduce bacterial pathogens

Nutritional and other chemical changes induced in food by irradiation have been studied extensively. In general, these changes are limited to modest declines in the quality and amount of a few vitamins, particularly thiamine (vitamin B1), that are not likely to change the overall adequacy of dietary intake, and to production of transient free radical oxidants, which react almost immediately in the food and do not persist. Similar oxidants are also produced by cooking, and, in any event, would be hydrolyzed immediately in the stomach if any are present. Other radiolytic products are difficult to detect and are present in only trace amounts. It is important to remember that the processes of cooking, such as grilling or frying, themselves induce profound chemical

changes in foods, which we depend on to make them edible and tasty. The safety of consuming irradiated foods has been evaluated in large scale trials in animals, some of which lived for several generations (19). No ill effects were observed, and, in particular, no teratogenic effects were seen in mice, hamsters, rats or rabbits. Formal feeding trials were also conducted with human volunteers without ill effects, and NASA routinely uses irradiated meats in the diet of astronauts.

Acceptance of Irradiated Foods

Will the public accept irradiated foods? Surveys conducted recently by the Food Marketing Institute and one conducted at FoodNet sites on the general population have had results similar to those obtained in the studies mentioned above (20,21). About 50% of the population is ready to buy irradiated foods, if asked. Acceptance will be greater if irradiated food is not much more expensive than nonirradiated food. The rate of acceptance can increase from 50% up to 80% to 90% if customers understand that irradiation reduces harmful bacteria in food. Similar results have been observed when test marketing irradiated products. Since 2000, irradiated ground beef has been for sale in many markets, and the medical and public health communities can respond to this with enthusiasm.

Candidates for Food Irradiation

E. coli O157 and other Shiga toxin-producing *E. coli* cause more than 100,000 cases of illness per year (2). This infection is untreatable and can lead to severe complications, including hemolytic uremic syndrome, chronic renal failure, and death (22). Ground beef is the most commonly identified source of infection. Pooling the meat of many thousands of animals into ground beef may increase the rate of contamination. Just a few organisms are sufficient to cause severe illness, and efforts to decrease the contamination of ground beef have probably reduced but not eliminated the risk. Irradiating ground beef would effectively destroy *E. coli*.

Campylobacter jejuni, the most common of all bacterial foodborne infections, causes an estimated 2,000,000 cases of illness per year (2), and has been associated with Guillain-Barre′ syndrome (GBS), an acute neurologic disorder (23). Treatment of a *Campylobacter* infection does not prevent its progression to GBS. Poultry is the most commonly identified source of infection. Cross-contamination during slaughter may lead to nearly universal contamination of poultry meat. It takes only a small number of organisms to cause infection. Current efforts to reduce cross-contamination may be responsible for a decrease in *Campylobacter* infections, but these efforts are not likely to eliminate the risk altogether. Irradiating poultry meat would effectively eliminate *Campylobacter* from that food.

Salmonella, whose many serotypes are harbored by mammals, birds, and reptiles, causes an estimated 1,400,000 cases of illness and 16,400 hospitalizations per year (2). Up to 2% of humans develop reactive arthropathy after being infected. Foods of animal origin have been the most commonly

identified sources, including meat, poultry, eggs, and raw milk (24). Improvements in the safety of egg production and handling have been associated with a recent substantial reduction in the incidence of one common egg-associated serotype, *Salmonella* Enteritidis. Further progress is possible with increased use of eggs pasteurized in their shells, which reached the market in 2000. Improvements in meat and poultry slaughter practices under HACCP may have also had an impact, but they have not eliminated the risk of salmonellosis from raw meat. Irradiating meat and poultry would eliminate Salmonella from those foods.

Listeria monocytogenes is an opportunistic pathogen that causes an estimated 2600 cases per year of severe invasive illness (2). This infection affects those who have compromised or undeveloped immune systems, particularly the elderly, the immunocompromised, and pregnant women (25). Approximately 25% of infections lead to death of the compromised patient or loss of the fetus. The number of organisms sufficient to cause infection has not been clearly established. In a healthy host, exposure to extremely high numbers of Listeria can result in nothing more than febrile gastroenteritis; in a high-risk individual, a low amount may be sufficient to cause severe infection. The most frequently identified sources are ready-to-eat processed meats and soft cheeses made from unpasteurized milk. Ready-to-eat meats, such as hot dogs, have already been subjected to a pathogen killing step when the meat is cooked at the factory, so contamination is typically the result of in-plant contamination after that step. Improved sanitation in many plants has reduced the incidence of infection by half since 1986, but the risk persists, as illustrated by a large hot dog-associated outbreak that occurred in 1999 (26). Additional heat treatment or irradiation of meat after it is packaged would eliminate Listeria that might be present at that point.

Toxoplasma gondii is the most common of all parasitic foodborne infections. As with Listeria monocytogenes, the consequences of infection with *T. gondii* are most evident in an immunocompromised person or a pregnant woman (27). Toxoplasmosis causes an estimated 400-4,000 cases of congenital disease each year, including hydrocephalus, mental retardation, blindness, and sometimes even death, as well as more than 200,000 noncongenital illnesses, leading to approximately 750 deaths per year, 375 of which may be the consequence of foodborne infections. Consumption of or contact with undercooked meat, especially pork, is an important source of infection, as is contact with feces of an infected cat. Up to 3% of market pigs show serologic evidence of infections or have Toxoplasma cysts. Irradiation would inactivate parasites in meat.

Potential Health Benefits of Irradiating Meat and Poultry

We can roughly estimate the potential benefit of irradiating meat and poultry with a simple calculation. Let us assume that 50% of poultry, ground beef, pork, and processed meats are irradiated. Let us also assume that these foods are the source of 50% of foodborne *E. coli* O157, *Campylobacter*, *Salmonella*, *Listeria* and *Toxoplasma* infections. The potential benefit of the irradiation would be a 25% reduction in the morbidity and mortality rate caused by these infections (Table 3). This estimated net benefit is substantial, as the measure could prevent nearly 900,000 cases of infection, 8,500 hospitalizations, over 6,000

catastrophic illnesses, and 350 deaths each year. With this estimate we assume that heavily contaminated meat is just as likely to be treated with irradiation as meat which is less contaminated. This estimate does not include the impact on other known pathogens contained in these foods, such as *Yersinia enterocolitica*, or those yet to be identified. This estimate also does not account for the benefits of using irradiation to treat other foods, such as fresh produce that can also be a source of infection.

Table 3. Potential number of health problems prevented annually if 50% of meat and poultry are irradiated

Pathogen	Cases	Hospitalizations	Major complications	Deaths
E. coli O157:H7 and other STEC	23,000	700	At least 250 cases of hemolytic uremic syndrome	20
Campylobacter	500,000	2,600	250 cases of GBS	25
Salmonella	330,000	4,000	6,000 cases of reactive arthropathy	140
Listeria	625	575	60 miscarriages	125
Toxoplasma	28,000	625	100-1,000 cases of congenital toxoplasmosis	94
Total	881,625	8,500	6,660 catastrophic illnesses	352

Potential Public Concerns About Irradiation

Just as in the early days of milk pasteurization and retort canning, several concerns about this technology have been expressed. Some may ask whether irradiated food is safe to eat. The safety of irradiated food has been studied for four decades, making it the most intensively assessed of any food safety process. Extensive nutritional assessments, toxicity studies, and feeding trials have not indicated a risk, and the process has been approved by many regulatory agencies around the world (28). The nutritional changes produced by irradiation are fewer than those produced by canning or pasteurization.

Others may question the safety of the technology. Irradiation is also used to sterilize products such as surgical implants and instruments; this is a well-established procedure that has been practiced for many years. With regulatory oversight by the Nuclear Regulatory Commission and the Department of Transportation, these procedures are models for how to safely use radioactive sources. Electron beam facilities, which do not have radioactive sources, at this point require less regulatory oversight. Others may wonder if "radiophobia" will prevent the acceptance of irradiation. Actually, most of the American public is prepared to accept irradiation when the benefit of pathogen elimination is clear. For example, it makes sense to use irradiation to sterilize surgical supplies. The population has shown that it is also generally willing to accept X-rays and microwaves as essential to medical diagnosis and convenient cooking respectively. In the future, a logo indicating that a food product has been

irradiated will make it easy for consumers to identify food that has been treated.

Some people may be concerned that gamma ray sources Cobalt 60 and Cesium 137 are produced in nuclear power reactors. However, this is true of many other radionuclides used routinely in industry, science, and medicine as tracers and treatment agents. Even if nuclear energy is no longer used for commercial power generation in the future, these radionuclides will still be produced in smaller scale reactors. Electron beams and X-rays, of course, do not use radioactive sources and have no link to nuclear energy.

Finally, some people may object to the use of irradiation because it might allow standards to slip in the food industry, substituting irradiation for other efforts to sanitize the food supply. Actually, combining irradiation with increased sanitation is advantageous because less contamination means lower doses of irradiation would be needed, decreasing the chance of changes in taste or smell of a product. This concern may not be fully resolved until the food industry demonstrates that irradiation is only used in concert with other methods that maintain food sanitation.

Many concerns about irradiation harken back to earlier objections to pasteurization and retort canning. Progressive development in processes and regulations of both technologies ultimately brought about a high measure of safety. The debate between those advocating improved sanitation and those advocating a definitive pathogen reduction technology was finally resolved when both strategies were combined. Instituting pretreatment standards and meat grading would ensure that meat would be clean enough to irradiate. Both milk pasteurization and retort canning became codified with a defined log kill against specific organisms, so that treatment in one place was comparable to treatment in another. Similarly, as the food irradiation industry becomes organized, the process should be defined so that the word "irradiated" will have a standard meaning, thereby ensuring uniform applications. Finally, both pasteurization and retort canning are used to treat food just before or in the final packaging step, at a point when the opportunity for recontamination of the food is minimal. Irradiating food in the same way will increase confidence that the it is not contaminated.

The Centers for Disease Control and Prevention, along with the World Health Organization and many other health organizations, welcomes the use of food irradiation as an important technology that can protect the public against foodborne diseases (28-30). Like pasteurization and retort canning, irradiation is a safe and effective food processing step. Preventing foodborne diseases requires a "farm-to-table" strategy with multiple control steps along the way. For some foods, this includes a measure that eliminates pathogens definitively. Defined standards and norms for the process of irradiation could enhance general acceptance of this technology, and it would benefit the food industry to begin developing them. Irradiation procedures can be monitored and regulated as are procedures for pasteurization and medical sterilization. The potential benefit of irradiating meat and poultry alone is substantial; it could prevent hundreds of thousands of foodborne illnesses, thousands of hospitalizations, and hundreds of deaths each year. Using these promising technologies is critical to meeting national goals for foodborne disease prevention by 2010.

Robert V. Tauxe is a medical epidemiologist and chief of the Foodborne and Diarrheal Diseases Branch at the Centers for Disease Control where he has worked for 17 years. He graduated from Yale College in 1975, was awarded an M.D. degree from Vanderbilt University and an M.P.H. degree from Yale in 1980, and is board certified in Internal Medicine.

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References

1. Tauxe RV. Emerging foodborne diseases: an evolving public health challenge. Emerg Infect Dis 1997;3:425-34.
2. Mead PS, Slutsker L, Dietz V, McCaig LF, Bresee JS, Shapiro C, et al. Food-related illness and death in the United States. Emerg Infect Dis 1999;5:607-25.
3. Buzby JC, Roberts T, Lin C-TJ, MacDonald JM, Bacterial foodborne disease: medical costs and productivity losses. Agricultural Economic Report No. 741. Washington: Economic Research Service, U.S. Department of Agriculture, 1996.
4. Committee to Ensure Safe Food from Production to Consumption. Ensuring safe food: from production to consumption. Washington: National Academy Press, 1998.
5. Food safety from farm to table: a national food-safety initiative. Report to the president. Washington: EPA/HHS/USDA, May 1997.
6. Centers for Disease Control and Prevention. Preliminary FoodNet data on the incidence of foodborne illnesses--selected sites, United States, 2000. MMWR Morb Mortal Wkly Rep 2001;50:241-46.
7. Healthy people 2010 objectives: draft for public comment. Office of Public Health and Science. Washington: U.S. Department of Health and Human Services, September 15, 1998.
8. Armstrong C. Botulism from eating canned ripe olives. Public Health Rep 34. 1919;2877-905.
9. Anonymous. Botulism. Protective measures and cautions from the U.S. Bureau of Chemistry, Department of Agriculture. Public Health Rep 1920;35:327-30.
10. Esty JR, Meyer KF. The heat resistance of spores of *B. botulinus* and allied anaerobes, XI. J Infect Dis 1992;31:650-63.
11. McNary-Mapes amendment to the U.S. Food and Drugs Act, fifth paragraph, Section 8, enacted July 8, 1930. Cited in Shrader JH. Food control: its public health aspects. New York: Wiley 1939. p. 443.
12. Thermally-processed low acid foods packaged in hermetically sealed containers. Fed Reg 2398, January 24, 1973, part 113.
13. Rosenau MJ. Diseases spread by milk. In: Preventive medicine and hygiene. 5th ed. New York: Appleton, 1928. p. 718-26.
14. Potter ME, Kaufmann AF, Blake PA, Feldman RA. Unpasteurized milk: the hazards of a health fetish. JAMA 1984;252:2048-54.
15. U.S. Public Health Service. Milk investigations: preparation of a standard milk-control code. Annual report of the Surgeon General of the Public Health Service of the United States, for the fiscal year 1928. Washington:

U.S. Government Printing Office, 1928, p. 53.
16. Headrick ML, Korangy S, Bean NH, Angulo FJ, Altekruse SF, Potter ME, et al. The epidemiology of raw milk-associated foodborne disease outbreaks reported in the United States, 1973 through 1992. Am J Public Health 1998;88:1219-21.
17. Centers for Disease Control and Prevention. Botulism in the United States, 1899-1996. Handbook for epidemiologists, clinicians and laboratory workers, Atlanta: Centers for Disease Control and Prevention, 1998.
18. Ackers, M-L, Schoenfeld S, Markman J, DeWitt W, Cameron DN, Griffin PM, Slutsker L. An outbreak of Yersinia enterocolitica O:8 infections associated with pasteurized milk. J Infect Dis 2000;181:1834-7.
19. Josephson ES. An historical review of food irradiation. J Food Safety 1983;5:161.
20. Food Marketing Institute. Consumers' views on food irradiation. Washington: Food Marketing Institute and Grocery Manufacturers of America; 1998.
21. Frenzen P, Buzby J, Majchrowicz A, DeBess E, Hechemy K, Kassenborg H, et al. Consumer acceptance of irradiated meat and poultry in the United States. Program and Abstracts Book, International Conference on Emerging Infectious Diseases 2000, Atlanta, Georgia July 16-19, 2000, Abstract, p. 147-8.
22. Griffin PM. Epidemiology of Shiga toxin-producing *Escherichia coli* infections in humans in the United States. Kaper JB, O'Brien A, editors. In: *Escherichia coli* O157H7 and other Shiga toxin-producing *E. coli* strains. Washington: American Society for Microbiology; 1998. p. 15-22.
23. Friedman CR, Neimann J, Wegener HC, Tauxe RV. Epidemiology of *Campylobacter jejuni* infections in the United States and other industrialized nations. In Campylobacter, 2nd edition. Nachamkin I, Blaser MJ, eds. Washington: American Society for Microbiology; 2000. p. 121-38.
24. Tauxe RV, Pavia AT. Salmonellosis: nontyphoidal. In: Bacterial infections of humans, epidemiology and control. 3rd ed. Evans AS, Brachman PS, editors. New York: Plenum Medical Book Co.; 1998. p 223-42.
25. Slutsker L, Schuchat A. Listeriosis in humans. In: Listeria, listeriosis and food safety. 2nd ed. Ryser ET, Marth EH, editors. New York: Marcel Dekker; 1999. p. 75-95.
26. Centers for Disease Control and Prevention. Multistate outbreak of listeriosis--United States, 1998. MMWR Morb Mortal Wkly Rep 1998;47:1085-6.
27. Lopez A, Dietz VJ, Wilson M, Navin TR, Jones JL. Preventing congenital toxoplasmosis. MMWR Morb Mortal Wkly Rep 2000;49:RR-02,57-75.
28. Steele JH. Food irradiation: a public health opportunity. Int J Infect Dis 2000;4:62-6.
29. Osterholm MT, Potter ME. Irradiation pasteurization of solid foods: taking food safety to the next level. Emerg Infect Dis 1997;3:575-7.
30. World Health Organization. Safety and nutritional adequacy of irradiated food. Geneva: The Organization; 1984.

1. Adapted from a talk given on July 19, 2000 at the 2nd International Conference on Emerging Infectious Diseases, Atlanta, GA.

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Release No. 0172.03

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USDA RELEASES SPECIFICATIONS FOR THE PURCHASE OF IRRADIATED GROUND BEEF IN THE NATIONAL SCHOOL LUNCH PROGRAM

Provides Education Recommendations for Local School Districts

WASHINGTON, May 29, 2003 - The U.S. Department of Agriculture today released specifications for the purchase of irradiated ground beef for donation through the National School Lunch Program. The product will be available for schools to order in January 2004.

The 2002 Farm Bill directs USDA to not prohibit the use of approved food safety technologies on foods purchased for the National School Lunch Program. The law's report language also indicates that USDA should consider "the acceptability by recipients of products purchased" by USDA for commodity distribution. Therefore, before irradiated beef is made available for order by schools in January 2004, USDA will provide balanced consumer education materials to all school districts to use in educating parents, students and the community in their decision to order the product. The decision to order and serve irradiated ground beef will be made by local school districts.

"Each school district will have the option to choose between irradiated and non-irradiated ground beef products and will decide how to notify parents and students if they choose to offer them," said Under Secretary for Food, Nutrition and Consumer Services Eric Bost. "While USDA does not have the authority to require that schools inform parents and students about whether or not the district will be ordering irradiated beef, USDA is strongly encouraging schools to provide information to students, teachers, food service personnel, school administrators, parents and caregivers as part of the decision-making process."

USDA's Food and Nutrition Service will provide all school districts with an informational package to prepare them to decide whether to order irradiated beef products. The package will be mailed in June 2003 and will include a letter from Under Secretary Bost strongly encouraging schools to notify parents, students and the community if they are planning to order irradiated beef. In addition, the package will include a brochure with answers to commonly asked questions about irradiation. This letter will also include web-site addresses for the brochure as well as the site for the Food and Drug Administration irradiation consumer information. The letter will give information regarding the community educational materials currently under development by the State of Minnesota that will be available to schools in Fall 2003.

On May 1, 2003, USDA announced specification for all ground beef items purchased for the National School Lunch Program that added new process and testing requirements throughout the manufacturing process. "USDA's Agricultural Marketing Service will utilize test results to measure the performance of processing systems producing raw and finished ground beef products for purchase by USDA," said Under Secretary for Marketing and Regulatory Programs Bill Hawks. "Both irradiated and non-irradiated ground beef products will be subject to these new requirements."

"Protecting the public from foodborne illnesses is a priority for USDA," said Under Secretary for Food Safety Elsa Murano. "Irradiation technology is another tool to enhance food safety. It is important to remember, however, that this technology is not a substitute for proper hygiene, good sanitation and safe handling and preparation practices in the processing plant and school cafeterias."

In 1997, the Food and Drug Administration approved irradiation of raw meat and poultry products after a thorough scientific review of a substantial number of studies conducted worldwide on the effects of irradiation on a wide variety of products. The studies included examination of the chemical effects of irradiation on food, impact on nutrient content of irradiated products, potential toxicity concerns and effects on microorganisms in or on irradiated products. FDA concluded that irradiation is safe in reducing disease-causing microbes and that it does not compromise the nutritional quality of treated products. USDA's Food Safety and Inspection Service (FSIS) approved its use in raw meat and poultry in 1999. Food irradiation has been approved in 37 countries for more than 40 food products. The United Nation's World Health Organization, Codex Alimentarius Commission, American Medical Association and many others have endorsed the process.

FSIS inspects all meat and poultry products, including those that are irradiated. Additionally, FSIS conducts microbial testing to be sure plants are producing wholesome products. Only FSIS federally-inspected establishments and state-inspected facilities that meet the same requirements specified in the federal regulations are able to irradiate meat.

Meat and poultry establishments that use irradiation must meet sanitation and Hazard Analysis and Critical Control Point (HACCP) regulations. Additionally, FSIS conducts microbial testing to be sure plants are producing wholesome products.

For information on the National School Lunch Program, visit www.fns.usda.gov/cnd/ More details on irradiation can be found at www.fsis.usda.gov/OA/topics/irrmenu.htm and the new ground beef specifications with irradiation included is available at www.ams.usda.gov/lsg/cp/beef/beef_whatsnew.htm.

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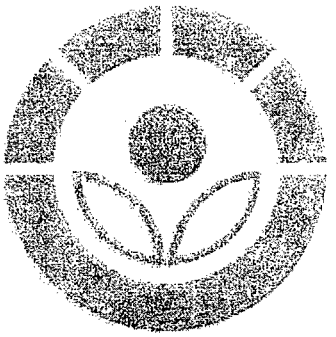
U.S. Food and Drug Administration January 2000	This brochure is based on an article that appeared in the May-June 1998 FDA Consumer magazine. **The brochure is no longer being updated.** For current information on this topic, visit FDA's Center for Food Safety and Applied Nutrition.

Food Irradiation: A Safe Measure



Food safety is a subject of growing importance to consumers. One reason is the emergence of new types of harmful bacteria or evolving forms of older ones that can cause serious illness. A relatively new strain of *E. coli*, for example, has caused severe, and in some cases life-threatening, outbreaks of food-borne illness through contaminated products such as ground beef and unpasteurized fruit juices.

Scientists, regulators and lawmakers, working to determine how best to combat food-borne illness, are encouraging the use of technologies that can enhance the safety of the nation's food supply.

Many health experts agree that using a process called irradiation can be an effective way to help reduce food-borne hazards and ensure that harmful organisms are not in the foods we buy. During irradiation, foods are exposed briefly to a radiant energy source such as gamma rays or electron beams within a shielded facility. Irradiation is not a substitute for proper food manufacturing and handling procedures. But the process, especially when used to treat meat and poultry products, can kill harmful bacteria, greatly reducing potential hazards.

The Food and Drug Administration has approved irradiation of meat and poultry and allows its use for a variety of other foods, including fresh fruits and vegetables, and spices. The agency determined that the process is safe and effective in decreasing or eliminating harmful bacteria. Irradiation also reduces spoilage bacteria, insects and parasites, and in certain fruits and vegetables it inhibits sprouting and delays ripening. For example, irradiated strawberries stay unspoiled up to three weeks, versus three to five days for untreated berries.

Food irradiation is allowed in nearly 40 countries and is endorsed by the World Health Organization, the American Medical Association and many other organizations.

Irradiation does not make foods radioactive, just as an airport luggage scanner does not make luggage radioactive. Nor does it cause harmful chemical changes. The process may cause a small loss of nutrients but no more so than with other processing methods such as cooking, canning, or heat pasteurization. Federal rules require irradiated foods to be labeled as such to distinguish them from non-irradiated foods.

Studies show that consumers are becoming more interested in irradiated foods. For example, the University of Georgia created a mock supermarket setting that explained irradiation and found that 84 percent of participating consumers said irradiation is "somewhat necessary" or "very necessary." And consumer research conducted by a variety of groups, including the American Meat Institute, the International Food Information Council, the Food Marketing Institute, the Grocery Manufacturers of America, and the National Food Processors Associationhas found that a large majority of consumers polled would buy irradiated foods.

Some special interest groups oppose irradiation or say that more attention should be placed on food safety in the early stages of food processing such as

in meat plants. Many food processors and retailers reply that irradiation can be an important tool for curbing illness and death from food-borne illness. But

it is *not* a substitute for comprehensive food safety programs throughout the food distribution system. Nor is irradiation a substitute for good food-handling practices in the home.

Questions and Answers About Irradiation

What is food irradiation?

Food irradiation is a process in which food products are exposed to a controlled amount of radiant energy to kill harmful bacteria such as *E. coli* O157:H7, *Campylo-bacter*, and *Salmonella*. The process also can control insects and parasites, reduce spoilage, and inhibit ripening and sprouting.

Is irradiated food safe?

Yes. The Food and Drug Administration has evaluated the safety of this technology over the last 40 years and has found irradiation to be safe under a variety of conditions and has approved its use for many foods. Scientific studies have shown that irradiation does not significantly reduce nutritional quality or significantly change food taste, texture or appearance. Irradiated foods do not be-come radioactive. Irradiation can produce changes in food, similar to changes caused by cooking, but in smaller amounts.

How does irradiation work?

Food is packed in containers and moved by conveyer belt into a shielded room. There the food is exposed briefly to a radiant-energy source the amount of energy depends on the food. Energy waves passing through the food break molecular bonds in the DNA of bacteria, other pathogens, and insects. These organisms die or, unable to reproduce, their numbers are held down. Food is left virtually unchanged, but the number of harmful bacteria, parasites and fungi is reduced and may be eliminated.

How do I know if food has been irradiated?

FDA currently requires that irradiated foods include labeling with either the statement "treated with radiation" or "treated by irradiation" and the international symbol for irradiation, the radura (pictured at the top of this document).

Are irradiated foods available now?

Not widely yet. Some stores have sold irradiated fruits and vegetables since the early 1990s. Irradiated poultry is available in some grocery storesmostly small, independent marketsand on menus of a few restaurants.

On the other hand, some spices sold wholesale in this country are irradiated, which eliminates the need

for chemical fumigation to control pests. American astronauts have eaten irradiated foods in space since the early 1970s. Patients with weakened immune systems are sometimes fed irradiated foods to reduce the chance of a life-threatening infection.

Are food irradiation facilities safe for workers and surrounding communities?

Yes. The transport and handling of radioactive material is strictly regulated, and irradiation facilities are made to withstand natural disasters such as earthquakes. The radioactive cobalt commonly used is made specially to serve as a safe radiation source for hospitals and irradiation facilities. Workers in irradiation plants are protected by thick walls surrounding the radiation source. If workers need to enter the irradiating room, the energy source is lowered into a pool of water that absorbs the radiation and protects the workers from any exposure. In electron beam facilities, the energy source is turned off. There are about 30 licensed irradiation facilities in the United States, used mainly to sterilize medical equipment, many consumer products, and, in some cases, food.

Will irradiated foods cost more?

Irradiated products sold to date have cost slightly more than their conventional counterparts. Some industry experts estimate the increase at two to three cents per pound for fruits and vegetables and three to five cents a pound for meat and poultry products. But these costs may be offset by advantages such as keeping a product fresh longer and enhancing its safety. Food trade groups say that as irradiated foods become more widespread, their cost is likely to drop.

Proper Food Handling Still Needed

Experts emphasize that though food irradiation can reduce food-borne illness risk, the process *complements*, but doesn't replace, proper food handling practices by producers, processors and consumers. For example, a few bacteria may survive the irradiation process in meats and poultry and could multiply if the meat is left unrefrigerated. Also, bacteria from other foods can be carried to irradiated foods if care isn't taken to avoid cross-contamination. So consumers should continue to follow these food safety precautions:

- Clean--Wash hands in hot, soapy water before preparing food and after using the bathroom, changing diapers and handling pets. Wash cutting boards, knives, utensils and countertops in hot, soapy water after preparing each food item and before going on to the next one.
- Separate--Avoid cross-contamination by keeping raw meat, poultry and seafood separate from other foods in the grocery cart and in the refrigerator. If possible, use one cutting board for raw meat products and another for salads and other foods that are ready to be eaten. Don't place cooked food on a plate that has held raw meat, poultry, seafood, or uncooked marinades.
- Cook--Use a meat thermometer to measure the internal temperature of cooked meat and poultry to ensure thorough cooking. Ground poultry should be cooked to at least 165 degrees F; ground meat, 160 degrees F; roasts and steaks, 145 degrees F; and poultry (whole bird), 180 degrees F. Cook eggs until the yolk and white are firm, and cook fish until it is opaque and flakes easily. Boil sauces, soups and gravy when reheating, and heat other leftovers to 165 degrees F.
- Chill--Refrigerate or freeze perishables, prepared foods, and leftovers within two hours. Never defrost or marinate foods on the counter. Use the refrigerator, cold running water, or a microwave oven. Divide large amounts of leftovers into small, shallow containers for quick cooling in the refrigerator. Remove stuffing from poultry and other stuffed meats after cooking and refrigerate in

a separate container. Don't pack the refrigerator full. Cool air must circulate to keep food safe.

Call 1-888-SAFEFOOD for more information on food safety.

The organizations listed below have contributed to the content and printing of this brochure:
American Meat Institute
Department of Health and Human Services (U.S. Food and Drug Administration)
Food Marketing Institute
Grocery Manufacturers of America
National Cattlemen's Beef Association
National Food Processors Association
The American Dietetic Association

January 2000
Publication No. (FDA) 00-2329

USDA Approves Irradiation of Meat to Help Improve Food Safety

Release No. 0486.99

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USDA APPROVES IRRADIATION OF MEAT TO HELP IMPROVE FOOD SAFETY

WASHINGTON, Dec. 14, 1999 Industry will soon be able to irradiate raw meat and meat products such as ground beef, steaks, and pork chops to reduce significantly or eliminate E. coli O157:H7 and other hazardous microorganisms, Agriculture Secretary Dan Glickman announced today.

"While there is no single silver bullet to cure all food safety problems, irradiation has been shown to be both safe and effective, "said Glickman. "USDA is committed to approving new technologies that offer industry additional tools to help produce even safer food."

Food irradiation is the process of exposing food to high levels of radiant energy to reduce or eliminate potentially dangerous microorganisms on meat and poultry. The Food and Drug Administration (FDA), which approves food additives such as irradiation, determined in December 1997 that irradiation of raw meat is safe.

Irradiation is currently the only known method to eliminate deadly E. coli O157:H7 bacteria in raw meat. The technology also significantly reduces levels of Listeria, Salmonella, and Campylobacter on raw product. However, consumers need to continue to handle and prepare irradiated meat and poultry as they would other raw products because some bacteria, especially spoilage organisms, are not destroyed by irradiation, and bacteria from other foods can cross-contaminate irradiated foods.

Under USDA's plan, which will be published in the Federal Register in the next week, and will take effect 60 days after publication, radiation will be permitted to treat refrigerated or frozen raw meat and meat products. As with other antimicrobial interventions USDA has approved for meat and poultry, irradiated products must still meet all other food safety requirements, including sanitation and pathogen reduction standards.

Ensuring consumer choice, USDA is requiring that irradiated meat and meat products bear the radura international symbol for irradiation, which appears below, and a statement that the product was treated by irradiation. Irradiated meat used in other products such as sausages and bologna also must be labeled. For unpackaged meat products that do not have labels, the statement and logo must be displayed at the point of sale to consumers. These labeling requirements do not apply to products purchased through foodservice operations, such as restaurants.

In a related action, USDA is streamlining the approval process for

food additives by ending the requirement that food additives be approved separately by both FDA and USDA. Currently, once FDA approves a food additive, USDA must conduct separate rulemaking in order for it to be approved for use in meat or poultry. This regulatory reform effort will pave the way for the use of irradiation on ready-to-eat products such as luncheon meat. On August 23, 1999, a consortium of industry organizations petitioned FDA to approve irradiation for processed meat and poultry products.

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EXHIBIT "D"

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

October 6, 2003

Docket No. 03036239 License No. 37-30804-02
Control No. 133770

James Wood
President
CFC Logistics, Inc.
4000 AM Drive
Quakertown, PA 18951

SUBJECT: CFC LOGISTICS, INC., ACCEPTANCE OF NOTIFICATION OF SATISFACTORY COMPLETION OF RADIOLOGICAL SURVEYS OF THE FACILITY, CONTROL NO. 133770

Dear Mr. Wood:

This refers to the letter dated October 6, 2003, from Ms. Marie Turner of your staff, notifying this office of the satisfactory completion of the assurance tests and radiological surveys as required by Conditions 13.A., and 14. of the above listed NRC License. The letter is accepted as the notification required by Condition 13.C. of the license.

In accordance with 10 CFR 2.790, a copy of this letter will be placed in the NRC Public Document Room and will be accessible from the NRC Web site at http://www.nrc.gov/reading-rm.html.

A response to this letter is not required. Your cooperation with us is appreciated.

Sincerely,

Original signed by Sattar Lodhi, Ph.D.

Sattar Lodhi, Ph.D.
Health Physicist
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety

cc:
Marie Turner, Radiation Safety Officer

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

ATOMIC SAFETY AND LICENSING BOARD

Before Administrative Judges:

Michael C. Farrar, Presiding Officer
Charles N. Kelber, Special Assistant

In the Matter of: CFC Logistics, Inc. (Materials License Application)	Docket No.: 30-36239-ML ASLBP No.: 03-814-01-ML License No. 132825 Date: November 21, 2003

CERTIFICATE OF SERVICE

THIS IS TO CERTIFY that a copy of the foregoing Response of CFC Logistics, Inc. to Intervenors' Second Motion for a Stay in the above-captioned matter has been served upon the following via electronic mail, facsimile and U.S. First Class Mail on this 21st day of November, 2003.

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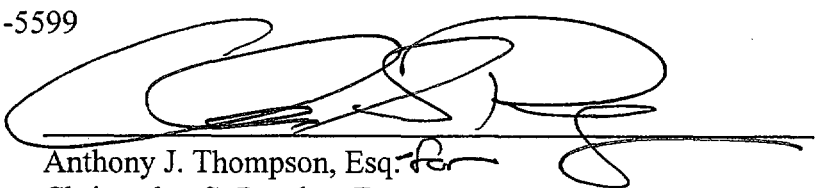

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November 21, 2003

BY ELECTRONIC MAIL, FACSIMILE AND U.S. FIRST CLASS MAIL

U.S. Nuclear Regulatory Commission
Office of the Secretary
Attn: Rulemaking and Adjudications Staff
One White Flint North
11555 Rockville Pike
Rockville, MD 20852

Re: In the Matter of: CFC Logistics, Inc.
Docket No: 3036239-ML
ASLBP No. 03-814-01-ML
License No. 132825

Dear Sir or Madam:

Please find attached for filing Response of CFC Logistics, Inc. to Intervenors' Second Motion for a Stay in the above-captioned matter. Copies of the enclosed have been served on the parties indicated on the enclosed certificate of service. Additionally, please return a file-stamped copy in the self-addressed, postage prepaid envelope attached herewith.

If you have any questions, please feel free to contact me at (202) 496-0780. Thank you for your time and consideration in this matter.

Sincerely,

for Anthony J. Thompson, Esq.
Christopher S. Pugsley, Esq.
Law Offices of Anthony J. Thompson, P.C.
Counsel of Record to IUSA

Enclosures

(CFCCOVERLETTTER1.DOC)