

Section H - Environmental assessment

Summary

With this petition we request a categorical exclusion of the requirement to do an environmental assessment

Previous environmental assessment decisions -

In the Federal Register of April 18, 1986, the rule that originally allowed the use of irradiation in the production, processing and handling of food, the Agency stated "existing safeguards in regulations issued by the Occupational Safety and Health Administration (OSHA), the Nuclear Regulatory Commission (NRC), the Department of Transportation (DOT) and FDA are adequate to ensure there will be no adverse environmental effect". (pg. 13395).

The petition resulting in approval of irradiation for poultry feed (21 CFR Part 179) included an environmental assessment (Nordion International Inc. petition of June 26, 1992). From the viewpoint of potential environmental impact, the poultry feed petition is very similar to the one we will be submitting.

In November 1995, FDA determined that, "for radiation sources to be used as components of food-contact sources of permanent or semi-permanent equipment, certain parts of the standard EA format may be abbreviated as described in 21 CFR 25.31a(b)(2) (FDA, November 1995)

In considering the potential environmental impact of the irradiation of first poultry and then red meats, FDA determined the action would not have a significant impact on the human environment and did not require an environmental impact statement (Federal Register, May 2, 1990; Federal Register, Dec. 3, 1997).

Most importantly, in its Final Rule of July 29, 1997, FDA determined that "approval of a food additive petition, GRAS affirmation petition, or the granting of request for exemption from regulation as a food additive under §170.39 of this chapter, when the substance is to be used as a component of a food contact surface or permanent or semi-permanent equipment or of another food contact article intended for repeated use" was categorically excluded of the need to prepare an EA or EIS (Federal Register, National Environmental Policy Act. 21 CFR Part 10, et al, 1997, §25.32(j). page 40595).

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General structure of the radiation processing industry -

The radiation processing industry is currently characterized by four types of commercial irradiator owners.

1. Contract irradiation companies own and operate irradiation facilities (both gamma and electron beam accelerators), processing medical products only or a wide variety of goods (including foods and medical products). Of the 25 contract irradiation facilities in the United States, there are two major contract irradiation companies (owning several facilities each) and also other small irradiation contract companies. Since contract irradiation companies currently process lab animal feeds, it is expected they will also process other feeds once the approval is obtained.
2. Medical products companies also own in-house irradiators usually solely for the sterilization of their own medical products. These products include syringes, gauze, wound coverings, personal care goods, etc. It is not expected that these facilities would be used for feed processing since these companies generally make a point of not processing any non-medical products.
3. Just as medical products manufacturers have purchased and operate industrial irradiators to process their own products, it is possible that feed manufacturers might own and operate irradiation facilities to process their own products. Currently, we are not aware of any feed company that owns an irradiator.
4. Additionally, there are many commercial electron beam accelerators of varying power levels used for a variety of industrial purposes, such as in the printing industry, tape manufacture, wire coating and other plastics industry etc. It is not expected these facilities would be used for feed processing.

Besides commercial irradiation facilities, there are a wide variety of research irradiator owners, including universities, government facilities, and private ownership. Some research equipment owners also provide commercial irradiation services. These facilities are sufficient only for research, or small scale irradiation services and are not likely to be involved in commercial scale feed irradiation.

Regulatory responsibility for irradiation equipment and sources -

Gamma irradiators are regulated under 10 CFR Part 36 (NUREG 1556, see also Appendix G for training issues and Attachment 5 for radioactive materials, sealed sources and devices) (Federal Register, 1993). The regulatory authority is held by the United States Nuclear Regulatory Commission (US NRC) or by state governments under agreements with the US NRC. Gamma irradiator operators have to be licensed to own a radioactive source and the irradiator is also licensed.

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Electron beam accelerators and X-Ray equipment are regulated by state governments (usually the state Department of Radiological Health, or a similar department). Licensing is required for operation.

In addition to regulation, there are several guidelines for the safe use of irradiators, published by the American National Standards Institute (with the US NRC), by the American Society of Testing Materials and, internationally, by the IAEA.

Transport and disposal of irradiation sources -

Transport of cobalt 60 is conducted in containers approved by the US NRC, the International Atomic Energy Agencies and other international nuclear regulatory agencies. Installing cobalt 60 in the irradiator is done by the petitioner, or by the supplying company's staff. Staff installing radioactive materials must meet the qualifications established by the US NRC, and/or by state nuclear regulating authorities (depending on different state agreements.) This work is conducted under the supervision of a qualified radiation safety officer. Since the industry started, over 300 million curies of cobalt 60 have been shipped to radiation processing and medical industry customers; the public has never been exposed to a radiation hazard over this time.

Agreements for disposal of cobalt 60 are usually included in sales arrangements; generally, the selling company in Canada or the United Kingdom agrees to take back spent sources. The selling company could then reprocess the slugs in the cobalt 60 pencils or provide long term storage. The American cobalt 60 supplier (Nutron Products) reprocesses low energy pencils. Cobalt 60 pencils remain in service in irradiation facilities for 25-30 years (approximately 5 half lives), although as their energy level decreases, they may be moved to a facility where lower dose applications are more common. After 200 years, cobalt 60 does not present a radiation hazard.

Several years ago when cesium 137 was allowed to be used in commercial irradiation facilities, it was owned by the US Department of Energy and was only leased to irradiation facility owners. Thus, disposal was the responsibility of the US government. There is now no cesium 137 in commercial irradiators in the US, although there is a company who has requested approval for a new irradiator design that uses cesium 137 as it radiation source.

Request an exclusion regarding a need for further environmental assessment -

Based on the information provided above, and on the basis of previous regulatory decisions concerning the environmental safety of irradiation equipment, SteriGenics International Inc. requests an exclusion for the need to do further environmental assessment for this petition. Based on FDA's experience with earlier petitions, and since irradiation is a process effected by regulated multi-use equipment, FDA should be able to grant an exclusion.

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Section H. References

21 CFR Parts 25.31, 179

Federal Register. April 18, 1986. Irradiation in the production, processing and handling of food. Final Rule. pp. 13376-13399.

10 CFR Part 36, as amended. Federal Register. Feb. 9, 1993. Licenses and radiation safety requirements for irradiators. Final Rule. pp. 7715-

Federal Register. May 2, 1990. Irradiation in the production, processing and handling of food. Final Rule. pp. 18538-18544.

Federal Register. July 29, 1997. National Environmental Policy Act; Revision of Policies and Procedures; Final Rule. pp.40570-40595.

Federal Register. December 3, 1997. Irradiation in the production, processing and handling of food. Final Rule. pp. 64107-64121.

Food and Drug Administration. 1997. National Environmental Policy Act, Revision of policies and procedures. Federal Register. Vol 62. pp 40570-40600.