

Purina Mills, Inc.

ENVIRONMENTAL ASSESSMENT
21 CFR 25.31a

FAP 2225

- 1. **Date:** March 9, 1992
- 2. **Name of applicant/petitioner:** Purina Mills Inc.
- 3. **Address:** P.O Box 66812
St.Louis, MO 63166

4. Description of the proposed action:

The proposed action would provide for the use of gamma irradiation from Cobalt 60, Cesium 137 or Electron Beam for microbial disinfection of laboratory animal diets (rabbit, guinea pig, rats, mice and hamsters) with a maximum absorbed dose of 4.5 Mrads. 21 CFR 579 presently provides for the same irradiation sources for rat, mice and hamster diets with a maximum absorbed dosage of 2.5 Mrads. Therefore this assessment is to consider the environmental effects of increasing the permitted dosage from 2.5 to 4.5 Mrads, and adding rabbit and guinea pig complete feeds to the list of approved species feeds.

The need for our proposed action is adequately demonstrated in our petition dated March 9, 1992. Such irradiation will only be conducted at facilities licensed by the United States Nuclear Regulatory Commission (NRC). All provisions for environmental safety are contained in 10 CFR Part 51. The agency has reviewed the same procedures for other foods approved pursuant to part 579 & 179 of this chapter and found no significant impact.

Laboratory animal diets are presently manufactured by many animal feed producers. Laboratory animal diets will be sent only to NRC licensed facilities for irradiation in accordance with 21 CFR 579. Irradiated animal diets are used by the scientific community for feeding to test or breeding laboratory animals. Irradiated diet is used through animal feeding and little feed is disposed of. Animal feed not consumed however, would be disposed of primarily through a sanitary land fill in accordance with local, state and federal disposal requirements.

Purina Mills Inc estimates that 350 tons of laboratory feeds were irradiated in 1991. Purina estimates the growth rate of irradiated laboratory diets with the addition of increased permitted dose levels and inclusion of rabbit and guinea pig diets could increase the total amount of feed irradiated annually to 5,000 tons.

5. Identification of chemical substances that are the subject of the proposed action:

The cesium-137 is manufactured or encapsulated under the jurisdiction of the Department of Energy.

The Nuclear Regulatory Commission (NRC) has regulatory jurisdiction over the current manufacturing and encapsulation of other radioisotopes in the United States (such as cobalt-60).

Manufacture of machine-generated radiation sources (such as electron beams) are subject to the Radiation Control for Health and Safety Act of 1968 and must comply with appropriate reporting requirements (21 CFR 1002) established by the Center for Devices and Radiological Health of FDA. These sources must be shielded to prevent extraneous radiation in the food processing plants.

There are no chemical substances created in the irradiated laboratory diets (see section E of this food additive petition). Therefore other than the control of the irradiation source which is operated in accordance with 10 CFR 51, no other chemical substances are produced or created.

6. 21 CFR 25.31a(b)(2)(i)

Purina Mills Inc., as may other animal feed sponsors, may use several contractors to irradiate animal feeds, with the location of the irradiation facility depending in part on where the feed will be shipped for sale or use. Purina Mills does not expect to provide a major part of any contractor's business, nor will the total demand for the radiation by all feed manufacturers of all laboratory diets irradiated in accordance with this approval.

Purina Mills Inc., will obtain a certification of the following items from each irradiation facility used for irradiation of laboratory animal diets.

1. The laboratory diet have been irradiated in a facility licensed by NRC.
2. The facility operates in accordance with provisions of 10 CFR 51.
3. The facility operates in accordance with all applicable Federal, state, and local emission requirements, including occupational exposure requirements;
4. No known pollutants are expected to be emitted during the use of the radiation sources in the irradiation of laboratory animal diets.

Licenses include provisions covering worker notification of hazards in the workplace (10 CFR 19), worker exposure to radiation (10 CFR 20), disposal of radioactive wastes (10 CFR 20), loss of radioactive materials (10 CFR 20), permissible quantities of radioactive materials on the premises, leakage of radioactive materials, and radioactive emissions (copies of references attached).

Attached is a certification from one irradiation facility of the various regulations that must be complied with in the irradiation of these laboratory diets. This certification would be typical of all irradiators.

FDA has established GMP's under 21 CFR 179.25 (copy attached) which is adopted by reference to be applicable to irradiated animal feeds under 21 CFR 579.12 (copy attached).

Dosimeters, such as ferrous sulfate/cupric sulfate solutions or radiochromic dyed nylon, are used with cesium 137, cobalt 60, and electron beams and represent the only chemical emissions that may follow the irradiation process. After use the solutions are usually neutralized and then evaporated and the nylon is disposed of as solid waste. Purina expects approval of this petition to result in only small increases in radiation processes by any one contractor and thus only small increases in dosimeter use. Therefore, Purina expects any increases in waste dosimetry materials to be extremely small and environmental impacts are not expected to occur from these releases.

There are no radiolytic products of significance associated with irradiation of animal diets at 4.5 Mrads, indeed, the energy taken up by the irradiated food is much less than that taken up by heated foods (see page 13 of the Report of a Joint FAO/IAEA/WHO Expert Committee, World Health Organization, Geneva 1981 "Wholesomeness of irradiated food" (reference attached).

Mutations are an inevitable consequence of irradiating food, yet the creation of new organisms and/or organisms with increased pathogenicity is not a probable event for the following three reasons;

1. Most mutations will be deleterious and will make the mutated organism less fit to survive in the environment;
2. There is no selection for mutated organisms over nonmutated organisms;
3. Changes in DNA will induce DNA repair mechanisms so that many mutations will only be temporary (Ingram and Farkas, 1977).

In a review of the scientific literature concerning food irradiation, Mossel (1983) could not find any reports of increased pathogenicity of microbes due to single doses of irradiation, loss of determinative traits above the species level, or changes in the microbial communities which allowed pathogens to proliferate beyond what would occur with other processes used to treat food.

7. 21 CFR 25.31a (b)(2)(ii) Format items 7 through 11 and 15 is not ordinarily required.

12. Preparers;

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Mark Roos Ph.D. - Animal Science...Manager Technical Services

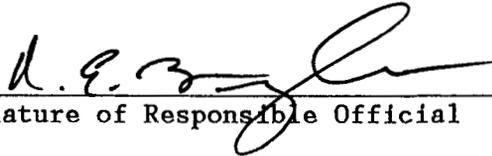
Roselina Angel Ph.D. - Animal Science...Nutritionist

R.E. Broyles - 25 years experience Regulatory Affairs Director Regulatory, Quality & Safety

13. Certification

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Purina Mills Inc.

Date: March 9, 1992



Signature of Responsible Official

Director Regulatory, Quality & Safety
Purina Mills Inc.

14. References:

References included:

- 21 CFR 179.25
- 21 CFR 579.12
- 10 CFR Parts 19, 20 & 51
- Report of a Joint FAO/IAEA WHO Expert Committee, World Health Organization, Geneva 1981; "Wholesomeness of irradiated food".
- Certification from SteriGenics, irradiation facility
- FDA finding of "No Significant Impact" Food-Borne pathogens in poultry

References not included:

- FDA's "Finding of no significant impact" for Food Additive Petition 2198: 1985
- Ingram, M. and J. Farkas. 1977. Microbiology of Food Pasteurized by Ionizing Radiation. *Acta Alimentaria* 6 (2): 123-185.
- Mossel, D.A.A. 1983. the Microbiological Safety of Irradiated Food. Annex C: Health Hazards of Microbiological Nature Inherent to Foods Irradiated at a Level of Below 10 KGY. Codex Alimentarius Commission. FAO/WHO/CX/FH 83/9.