AGWAY

AGWAY INC., COUNTRY FOODS DIVISION, PO BOX 4933, SYRACUSE, NEW YORK 13221-4933

Environmental Assessment
per 21 CFR 25.31 a(a)

1. February 3, 1992

2. Agway Country Foods, Inc.

3. P.O. Box 4933
   Syracuse, New York 13221-4933

4. <u>Description of proposed action</u>

This is a request to obtain approval to expose laboratory animal feeds to cobalt-60 gamma energy to an absorbed energy level not to exceed 5.0 Mrads. Cesium 137 and electron beams as sources of irradiation are excluded from this application. The proposed action is necessary to sterilize the subject feeds in order to help maintain a sterile environment for test animals. Feed will be manufactured at several locations including Agway.

Upon completion of manufacture, feeds will be sent to Isomedix, Inc. for cobalt-60 processing. Isomedix is a service irradiation company which currently operates 8 facilities in the US, with a 9th unit under construction. Locations are:

Northboro, MA	Morton Grove, IL
Whippany, NJ	Libertyville, IL
Spartanburg, SC	Sandy, UT
Columbus, OH	El Paso, TX

All facilities are duly licensed by the US Nuclear Regulatory Commission (NRC) or the appropriate Agreement State and registered with FDA for drug and/or device processing. (An Agreement State is one which has been delegated the authority and responsibility by the NRC to conduct and monitor its own radioisotope utilization programs).

The facility under construction, to be operational by the end of 1992, will be located in Chester, New York.

Agway might use any or all Isomedix facilities.

Upon completion of processing by Isomedix, product will be distributed in one of two manners. The majority of the product will be shipped directly from Isomedix processing units to the end consumers. The actual transportation for this product will be completed by licensed common carriers.

The second method of distribution will be utilized for customers requiring the small quantities of product, i.e., one and two case orders. This product will be transported from the Isomedix processing facility to the Agway manufacturing facility located in Waverly, New York. Here the product will be kept in a clean room until orders are received for this product. Organizations that would make up a customer base for sterilized laboratory animal diets would be hospitals, laboratories, universities, and laboratory animal breeders. These organizations are all licensed under USDA Animal Welfare standards, 9CFR Part II. Appendix I. With respect to feed storage and animal care and environment, the above mentioned organizations are regulated under the USDA Animal Welfare standards 9CFR Part III. Appendix II. The law specifically states that supplies of food shall be stored in facilities which adequately protect such supplies against infestation or contamination by vermin. Food supplies shall be stored in containers with tightly fitting lids or covers or in the original containers as received from the commercial sources of supply.

Because of the sterilized nature of irradiated diets, consumers will be storing this product in its original container.

The sterilized laboratory animal diets will be the sole source of nutrition for these animals, thus, the diet will be consumed in its entirety by the animals.

5. <u>Identification of chemical substances that are subject of the proposed action</u>

There are no chemical substances involved in the proposed action. Cobalt-60 is a radioactive form of metallic cobalt, which decays via the emission of gamma rays, which are classified as non-radioactive electromagnetic energy. The radiation treatment leaves no radioactive residuals in processed product, regardless of total dose.

Typical sources are supplied by Nordion Intl (Canada) and are designated as model C-188, Types 1, 2, 3 or 4, and have been approved by the US Nuclear Regulatory Commission for general industrial processing. The cobalt-60 metal is in the form of cylinders, each approximately 1/4" in diameter and one (1) inch long. Eight such units are laid end to end and placed into a zirconium encapsulation. Two of the eight inch sections are laid end to end and placed into a sealed stainless steel cylinder, resulting in a source pencil approximately 5/16" diameter by 18" long. Such a pencil can contain up to 14,000 curies.

In their several facilities, Isomedix utilizes over 20 million curies of cobalt-60, utilizing several thousand source pencils. As the cobalt-60 decays (approx. 12% per year) additional pencils are added to maintain or increase source strength, usually on an annual basis. Spent sources are returned to the supplier for final disposition, as will be described later.

The number of curies to be utilized for the processing of laboratory animal feeds will be dependent upon customer demand and cannot be exactly determined at this time. In any case, we estimate that usage will most likely be less than 1% of Isomedix current capacity to process.

6. <u>Introduction of substances into the environment</u>

Regarding the cobalt-60 treatment, gamma rays cause the ionization of small amounts of oxygen into ozone. At a maximum loading of any Isomedix facility to a level of 5.0 million curies of cobalt-60, approximately 8 ounces of ozone are produced in a 24-hour period. This amount is below regulatory concern. It should be noted that the currently operating Isomedix facilities have been duly licensed by State or Federal agencies wherein the generation of ozone was a matter for initial license review and approval. Approval of the proposed action will not have an effect on these maximum levels because the appropriate licenses establish a maximum cobalt-60 loading, which Isomedix cannot exceed.

Specific licenses applicable to Isomedix facilities follow:

Northboro, MA	#2-19769-02
Whippany, NJ	#29-19769-03
Spartanburg, SC *	#267
Columbus, OH	#34-19769-04
Morton Grove, IL *	IL 01123-01
Libertyville, IL *	#29-19769-05
Sandy, UT *	UT 1800074
El Paso, TX *	L04268
Chester, NY *	Pending

* Indicates Agreement States

No other substances other than ozone are expected to enter the environment.

7. <u>Fate of emitted substances in the environment</u>

A. Air: Ozone production (8 oz./day maximum) is below regulatory concern. Ozone quickly breaks down into oxygen, usually within a distance of several feet from the point of emission from the irradiator exhaust stack.

B. Freshwater: None

C. Terrestial ecosystems: None. Each Isomedix contract for cobalt-60 purchases includes a provision that the cobalt-60, when spent, will be returned to the seller. Although others may eventually be sellers, virtually all Isomedix cobalt-60 has been purchased from the Canadian government, or the successor to the government agency which has been privatized (Nordion, Intl.). The spent cobalt-60, when returned to Nordion can be reused, stored or buried in an approved Canadian low level waste burial site, at Nordion's choosing.

8. Environmental effects of released substances

There are negligible environmental effects of ozone, the only released substance. As a matter of fact, industrial cobalt-60 irradiators of the type employed by Isomedix are categorically excluded from the requirements to generate an Environmental Impact Statement (EIS) per 10 CFR51.22(c)(14)(vii). We assume that this exclusion resulted from past EIS's performed by the NRC and has been based on a finding of insignificance.

9. Use of resources and energy

Cobalt metal is in adequate supply and is used primarily as an alloy in making steel. The total amount of cobalt converted to cobalt-60, from the early 1960's to present, is estimated to be on the order of 8,000 - 10,000 pounds.

Activation from cobalt-59 (natural) to cobalt-60 occurs when cobalt-59 is placed into a nuclear reactor and absorbs a neutron, thus becoming cobalt-60. Some 90% of the world supply is generated in Canada in Canadian reactors.

As noted in item 7, spent cobalt-60 is returned to the supplier in Canada.

There is no effects upon endangered or threatened species or upon property listed in or eligible for listing in the National Register of Historic Places.

10. Mitigation measures

Industrial irradiators operated by Isomedix must conform to safety (employee and public) measures as outlined in 10 CFR Parts 20 and 30, and to American National Standard N 43.10, "Safe Design and Use of Panoramic, Wet Source Storage Gamma Irradiators (Category IV)". Cobalt-60 sources must conform to requirements of American National Standard N 43.6, "Sealed Radioactive Sources, Classification," and be approved for use by the NRC. The issuance of operating licenses for irradiators are partially contingent upon adequate plans to avoid or mitigate potential adverse environmental impacts associated with facility operation.

All such licenses are available to the public through the appropriate public document rooms.

11. Alternatives to the proposed action

Cobalt-60 is a terminal sterilization step to a final packaged product, and there is no economically or technically feasible alternative which can yield the same result. The largest use of cobalt-60 is in the sterilization of single use disposal medical devices, and there are approximately 40 units in the US devoted primarily to this use. The technology is well known and there are no reasonable potential adverse environment impacts to identify.

Isomedix services approximately 700 customers in various radiation processing applications, including radiation research projects on foods for FDA.

12. **List of preparers**

From Isomedix: George R. Dietz, V.P.
Jon Young, Director of Corporate Safety
(Resumes attached)

Agency consulted: Nordion International

From Agway: Ronald P. Hazenstab
Dr. Merle Stillions

13. **Certification**

The undersigned officials certify that the information presented is true, accurate and complete to the best of the knowledge of the firm responsible for preparation of this environmental assessment.

For Agway	For Isomedix
Bruce E. Chapman	2-10-92
Date	Date
Feb 3, 1992	George R. Dietz
Bruce E. Chapman	George R. Dietz
Vice President	Vice President
Title	Title
Agway Country Foods, Inc.	

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