



Safety provisions of food and drug law indicate need for more research on sterilization with radioisotopes

USE OF RADIOISOTOPES to sterilize foods and drugs is one civilian application of atomic energy which may offer important commercial advantages. Like some other potentially useful products, however, fission products have their potential dangers. It is for this reason that the Food and Drug Administration is being very cautious in its approach to this relatively new field.

In a recent talk at the Oak Ridge Institute of Nuclear Studies, W. B. Rankin, assistant director of FDA's Division of Field Operations, outlined the major issue involved in using radioisotopes under the federal food and drug laws.

One basic consideration from a legal viewpoint, he said, is the fact that radiation is a poison. Radioisotopes are poisons not only because many of them are heavy metals but also because their radiations are toxic. Radioactivity is harmful to living material, and even small amounts of radiation are injurious to plant and animal cells.

The fact that radioisotopes are poisons does not, per se, result in their being banned from use in food and drug manufacturing. Mr. Rankin emphasized that other poisons are used by biological industries to the benefit of agriculture, industry, and the consumer.

The question then resolves itself to determining what safeguards must be placed around the use of radioisotopes to protect the consuming public.

The criterion for use of common poisons is that they be used only where necessary and when such use does not endanger the consumer. Typical examples are insecticides containing lead, arsenic, fluorides, organic chlorides, and the newer organic phosphates. Although these materials are used extensively in

agriculture, their commercial use was preceded by careful research which led to a determination of the conditions under which each could be used safely.

The same sort of fundamental study and research will have to be carried out by the biological industries before radioisotopes or radiation can be used commercially.

The Food and Drug Administration, Mr. Rankin added, is concerned with the use of radioisotopes as drugs and devices, in cosmetics and foods, and for sterilization of foods and drugs.

Potential Uses in Drugs, Devices, and Cosmetics

A radioisotope intended for use as a drug is a "new drug" by law. Before a "new drug" can be distributed in interstate commerce for general therapeutic use, its safety must be established by careful and adequate testing by qualified experts. The results are then submitted to the Department of Health, Education and Welfare as a "new drug application." Only when it is approved by the Department (of which FDA is a part), can the manufacturer ship the new drug in interstate commerce. Substantial quantities of iodine 131, for example, are shipped for use in study and treatment of certain thyroid disorders.

There are exceptions to this rule, Mr. Rankin said, to allow the interstate shipment of new drugs for investigations to establish their safety. Specific regulations have been devised to provide for such studies.

The use of radioisotopes in therapeutic devices is permitted in many cases. FDA stipulates, however, that adequate directions for their use and precautions against misuse be supplied and further that they be used under competent medi-

cal supervision. FDA is concerned with efforts of some persons to exploit the public through sale of useless or dangerous devices.

Because of the danger associated with their uses, radioisotopes have no place in cosmetics, Mr. Rankin said.

Uses in Foods

The Federal Food, Drug and Cosmetic Act poses a substantial legal barrier to the use of radioisotopes in foods. The law says that a food is adulterated if it contains any added poisonous substance except where such material is required in production and cannot be avoided by good manufacturing practice. Mr. Rankin noted that the added poison does not even have to be present in sufficient quantity to cause definite injury to be ruled out by law.

In most cases, for example, the law would appear to rule out the addition of an isotope to an ingredient which is used in small amounts in a large mix of food, as a quick check on the thoroughness of the mix.

Mr. Rankin emphasized that FDA does not wish to bar progress in the use of radioisotopes and will consider industry proposals for their use in solving manufacturing problems which can be solved in no other way so long as no hazard to the consumer results.

The Atomic Energy Commission, with large amounts of "waste" fission materials produced in its operations, has sought to develop possible uses for such materials. AEC has done so by sponsoring research projects at various universities and research centers. One of the major potential uses resulting is in the cold sterilization of foods and drugs.

Considerable research is under way to determine the sterilization effects of beta and gamma rays or mixed radiation from fission products. Such a process might be useful commercially. Before such processes can be used, much information is needed. It is known that radiation disrupts bonds in complex molecules yielding small amounts of entirely different chemicals. At present, Mr. Rankin observed, it is impossible to predict what new chemicals may be formed by intensive irradiation of such complex organic materials as are found in foods and most drugs.

Data are needed on the molecular changes which occur during food and drug sterilization, the effects on nutritional properties of food or the therapeutic efficiency of a drug, and the possibility of the irradiated products being toxic (for example, capable of producing cancer over a long period of time).

FDA recognizes that many studies have been and are being carried out on individual foods and drugs. Commercial adoption of cold sterilization, however, will depend on the establishment of absolute safety of the process.