

U.S. RECOMMENDATIONS FOR CONTROL OF ACCIDENTAL RADIOACTIVE CONTAMINATION OF HUMAN FOOD AND ANIMAL FEEDS

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ABSTRACT

Recommendations for control of accidental radioactive contamination of human food and animal feeds issued in 1982 by the Food and Drug Administration (FDA)⁽¹⁾ are being revised to incorporate current scientific information and radiation protection philosophy, to include experience gained since 1982, and to take into account international guidance. The revised guidance will update the 1982 FDA recommendations regarding protective actions and will provide additional recommendations for limits on radioactive contamination permitted in foods distributed in commerce.

INTRODUCTION

The 1982 FDA recommendations for the control of accidental radioactive contamination of human food and animal feeds are under revision. The revised guidance will be designed to avert risk to the public, in the event of an accidental release of radioactive materials, through: (1) limits on the radioactive contamination permitted in foods distributed in commerce, and (2) preventive actions to mitigate the amount of radioactive contamination reaching the diet. The objective of the revision is to produce a consistent set of guides, applicable to accidental contamination of human food and animal feeds, for use by Federal, state and local agencies in the exercise of their respective authorities.

GENERAL PROVISIONS

The guidance will be for use in radiological emergency response planning and in the conduct of radiation protection activities associated with the production, processing, distribution, and use of human food and animal feeds accidentally contaminated with radioactivity.

An intervention level for radiation dose is included in the guidance and is called the Protective Action Guide (PAG). The recommended PAG in the current draft is 5 mSv (0.5 rem) committed effective dose equivalent with an overriding PAG of 50 mSv (5 rem) committed dose equivalent to an individual organ.

The recommended PAGs are consistent with the approach to the establishment of intervention levels recommended by the International Commission on Radiological Protection (ICRP) in ICRP Publication 40⁽²⁾. ICRP Publication 40 provides general

guidance on the selection of dose levels for the implementation of countermeasures, and indicates that the introduction of countermeasures for the control of foodstuffs would be appropriate within a range of 5 mSv to 50 mSv committed effective dose equivalent and an associated range for committed dose equivalent to individual organs of 50 mSv to 500 mSv . The recommended PAGs are also consistent with the intervention levels of dose selected as the basis for derived intervention levels for foodstuffs established independently by both the Commission of the European Communities and the Joint Food Standards Program of the Food and Agriculture Organization of the United Nations and the World Health Organization. The ICRP included updated concepts concerning intervention in Publication 60⁽³⁾. The application of the concepts in ICRP Publication 60 are currently under development by ICRP.

The revised FDA guidance will provide recommendations on limiting the radiation dose through: (1) limits on the concentration (in Bq/kg) of radionuclides permitted in foods distributed in commerce, called levels of concern, and (2) implementation of various types of protective actions.

The guidance will provide clear advice in advance of an accident, which can be immediately implemented at the onset of an accident. The guidance also will permit the flexibility necessary to respond to unanticipated or unique situations.

LEVELS OF CONCERN

The key feature of the guidance will be the establishment of levels of concern, the limits on the concentrations of radionuclides permitted in food after accidental contamination. The purpose of the levels of concern is to limit consumption of food confirmed as containing undesirable levels of radioactive contamination. Levels of concern are derived concentrations of radionuclides in food, which, if not exceeded, should assure that the PAGs would not be exceeded. In practice, when the levels of concern are not exceeded, the radiation doses to members of the public would be expected to be a small fraction of the PAGs. The levels of concern are being developed for application immediately following an accident; their application would not require early identification of all radionuclides present.

Food with concentrations of radionuclides below the levels of concern would be permitted to move in commerce without restriction. Food with concentrations of radionuclides at or above the levels of concern would normally not be permitted into commerce; however, flexibility would be permitted for special circumstances.

Levels of concern are based on typical quantities of food intake, the fraction of food intake that is assumed likely to be contaminated, and the relationship between radioactivity concentrations in food and radiation dose delivered to the individual per unit of radioactivity intake (i.e. the dose conversion factor).

The relationship between the levels of concern and the PAGs is given by:

$$\text{Level of Concern (Bq/kg)} = \frac{\text{PAG (mSv)}}{f \times \text{Food Intake (kg)} \times \text{DCF(mSv/Bq)}}$$

Where: DCF = the dose conversion factor; the radiation dose per unit of radioactivity ingested (mSv/Bq).

f = the fraction of the food intake that is assumed to be contaminated.

Food Intake = the total quantity of food intake in the time period of concern (kg).

Levels of concern were calculated for twenty three radionuclides and for six age groups using PAGs, DCFs and dietary intakes appropriate to each radionuclide and age group. Calculations were performed for the following age groups: 3 months, 1 year, 5 years, 10 years, 15 years and adult (>17 years). The DCFs used were from ICRP Publication 56⁽⁴⁾. The levels of concern were calculated based on the total annual dietary intake for each age group, not for individual foods or food groups. The calculation also included the assumption that contamination would occur in thirty percent of the total annual dietary intake or sixty day intake for I-131. The value of thirty percent is based on the expectation that less than ten percent of the total dietary intake would consist of contaminated food, and then applying an arbitrary additional safety factor of three. An exception was made for the case of I-131 in the infant diet where the entire sixty day intake was assumed to be contaminated.

The resulting levels of concern were evaluated to identify the radionuclides most likely to be the predominant contributors to dose through ingestion during the first year following an accident. Four radionuclide groups were identified as most likely to be the major contributors: Sr-90, I-131, Cs-134 + Cs-137, and Pu-238 + Pu-239 + Pu-240 + Am-241.

The final structure of the levels of concern to be recommended is still under review. The ease of implementation is a major consideration in the selection of the structure for the levels of concern. For example, one practical approach would be to group the six age groups to represent two population groups: infants (age groups 3 months and 1 year) and all others (age groups 5 years, 10 years, 15 years and adult). Recommended levels of concern for each radionuclide group would consist of two values, one to be applied to foods consumed by infants and the other to be applied to foods consumed by all other members of the population. Another practical approach would present a single level of concern for each radionuclide group which would be applicable to all foods and all members of the population. In either of these approaches, the most limiting level of concern for any of the age groups included in a population group would be selected (i.e. for each radionuclide group).

The guidance will recommend that the levels of concern be evaluated as soon as possible after an accident to insure that they are appropriate for the actual situation. In unique accidents, radionuclides for which levels of concern are not specified may contribute significant radiation doses. There may be other exceptions

or special conditions which could require additional or revised levels of concern. In these situations an evaluation would need to be performed to determine if the PAGs would be exceeded. The guidance will recommend that, when needed, the FDA be consulted for the development of additional or special purpose levels of concern.

The recommended levels of concern apply to the distribution and use in the U.S. of food grown, produced or manufactured in the U.S. Imported foods are currently controlled by existing guidance set out in FDA Compliance Policy. Foods exported from the U.S. are controlled by standards, regulations and guidance adopted by the importing country.

PROTECTIVE ACTIONS

The guidance will present recommendations for mitigating radionuclide contamination through protective actions taken to prevent or reduce the contamination of food and animal feeds or to delay the use of food and animal feeds suspected of being contaminated until the level of contamination can be determined. Many of the protective actions will be similar to those recommended in the 1982 FDA guidance, such as: sheltering livestock and placing them on stored feed, holding food to allow for decay of short half-life radionuclides, and removal of surface contamination. The draft will recommend that protective actions be selected as appropriate to the situation and once initiated, the action or actions continue until such time that, in the absence of the action, the affected food can be expected to meet the levels of concern.

STATUS OF REVISION

A draft of the revised guidance, including proposed values for the levels of concern and specific proposals on the application of protective actions has been circulated to the principal Federal agencies and the Conference of Radiation Control Program Directors for preliminary review and comment.

REFERENCES

1. Food and Drug Administration (1982). Accidental Radioactive Contamination of Human Food and Animal Feeds; Recommendations for State and Local Agencies. Federal Register (47FR47073), October 2, 1982
2. International Commission on Radiological Protection (1984). Protection of the Public in the Event of Major Radiation Accidents: Principles for Planning. ICRP Publication 40, Pergamon Press, Oxford
3. International Commission on Radiological Protection (1991). 1990 Recommendations of the International Commission on Radiological Protection. ICRP Publication 60, Pergamon Press, Oxford
4. International Commission on Radiological Protection (1989). Age-dependent Doses to Members of the Public from Intake of Radionuclides: Part 1. ICRP Publication 56, Pergamon Press, Oxford