ACCIDENTAL RADIOACTIVE CONTAMINATION OF HUMAN FOOD AND ANIMAL FEEDS: RECOMMENDATIONS FOR STATE AND LOCAL AGENCIES

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Radiation Programs Branch
Division of Mammography Quality and Radiation Programs
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ACCIDENTAL RADIOACTIVE CONTAMINATION OF HUMAN FOOD AND ANIMAL FEEDS: RECOMMENDATIONS FOR STATE AND LOCAL AGENCIES[1]

INTRODUCTION

Recommendations on accidental radioactive contamination of human food and animal feeds were issued in 1982 by the Food and Drug Administration (FDA) (FDA 1982, Shleien et al 1982). Since then, there have been enough significant advancements related to emergency planning to warrant updating the recommendations. New scientific information and radiation protection philosophy are incorporated, experience gained since 1982 is included, and guidance developed by international organizations is taken into account (Schmidt 1988a, 1988b, 1990, Burnett and Rosenstein 1989).

These recommendations provide guidance applicable to accidents at nuclear power plants and many other types of accidents where a significant radiation dose[2] could be received as a result of consumption of contaminated food. These recommendations rescind and replace the 1982 FDA recommendations.

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[2] The term "radiation dose" is used when the intended meaning is general or refers to more than one specific dose quantity.

GENERAL PROVISIONS

(a) Applicability.

The recommendations provide guidance to State and local agencies to aid in emergency response planning and execution of protective actions associated with production, processing, distribution, and use of human food and animal feeds accidentally contaminated with radionuclides. The recommendations do not authorize or apply to deliberate releases of radionuclides which are permitted and limited by general controls and/or terms and conditions stipulated by a regulatory agency.

(b) Scope.

The recommendations advise that health risk to the public be averted by limiting the radiation dose received as a result of consumption of accidentally contaminated food. This will be accomplished by: (1) setting limits, called Derived Intervention Levels (DILs) on the radionuclide activity concentration (concentration) permitted in human food, and (2) taking protective actions to reduce the amount of contamination.

DILs are limits on the concentrations permitted in human food distributed in commerce. They are established to prevent consumption of undesirable amounts of radionuclides and have units of radionuclide activity per kilogram of food, i.e. becquerels per kilogram, Bq/kg (previously used units - picocuries per kilogram, pCi/kg)[3]. Comparable limits were not provided in the 1982 FDA recommendations. DILs apply during the first year after an accident. If there is concern that food will continue to be significantly contaminated beyond the first year, the long-term circumstances need to be evaluated to determine whether the DILS should be continued or if other guidance may be more applicable.

Protective actions would be initiated subject to evaluation of the situation and would continue until, in the absence of the actions, the concentrations remain below the DILs. Protective actions can be taken to:

- avoid or limit, through precautionary measures, the amount of contamination that could become incorporated in human food and animal feeds, or

[3] The International System of Units is used throughout this document. Units that were used in previous FDA guidance are shown in parenthesis in the main text of this document as reference points for the reader.

- delay or limit consumption of human food and animal feeds suspected of being contaminated until the concentration of contamination has been determined, or

- reduce the amount of contamination in human food and animal feeds.

Limits on concentrations permitted in animal feeds are not given in these recommendations. However, protective actions for animal feeds are included as measures to reduce or prevent subsequent contamination of human food.

PROTECTIVE ACTION GUIDES

The 1982 FDA recommendations established two levels of Protective Action Guides (PAGs). PAGs were defined as "projected dose commitment values to individuals in the general population that warrant protective action following a release of radioactive material." The lower level, called the Preventive PAG, was a projected dose commitment of 5 mSv (0.5 rem) to the whole body, active bone marrow, or any other organ except the thyroid, or a projected dose commitment of 15 mSv (1.5 rem) to the thyroid. The Preventive PAG was associated with low-impact protective actions (e.g. placing dairy cows on stored feed). The upper level, called the Emergency PAG, was a projected dose commitment of 50 mSv (5 rem) to the whole body, active bone marrow, or any other organ except the thyroid, or a projected dose commitment of

150 mSv (15 rem) to the thyroid. The Emergency PAG was associated with higher-impact protective actions (e.g., diversion of fresh milk to cheese or milk powder).

The 1982 FDA recommendations were developed from the prevailing scientific understanding of the relative risks associated with radiation as described in the 1960 and 1961 reports of the Federal Radiation Council (FRC 1960, 1961). Since 1982, FDA and the other federal agencies in the United States have adopted the methodology and terminology for expressing radiation doses provided by the International Commission on Radiological Protection (ICRP) in 1977 (ICRP 1977, ICRP 1984a, EPA 1987). The ICRP's dose quantities for radiation protection purposes include effective dose equivalent, committed effective dose equivalent, dose equivalent for a specific tissue, and committed dose equivalent for a specific tissue[4,5].

These current recommendations replace the Preventive and Emergency PAGs with one set of PAGs for the ingestion pathway. The PAGs are 5 mSv (0.5 rem) for committed effective dose equivalent or 50 mSv (5 rem) committed dose equivalent to an individual tissue or organ, whichever is more limiting. These

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[4] See Appendix A (Glossary) for explanation of these dose quantities and their use in this document.

[5] The ICRP adopted new recommendations in 1990, which include revisions in its methodology and terminology for expressing radiation doses and the relative risks associated with irradiation of specific organs (ICRP 1991a). There is not yet consensus among the federal agencies on the use of these changes.

correspond to the "intervention levels of dose" consensus values set by international organizations (see Appendix B). Intervention levels of dose are radiation doses at which introduction of protective actions should be considered (ICRP 1984b). The FDA guidance retains use of the term Protection Action Guide (PAG) for consistency with U.S. federal and state needs.

The current nominal estimate for the general population for lifetime total cancer mortality for low-LET (linear energy transfer) ionizing radiation, delivered at low doses and low dose rates, is 4.5×10^{-3} for a reference dose equivalent in the whole body of 100 mSv (10 rem) (CIRRPC 1992). For 5 mSv (0.5 rem) committed effective dose equivalent (the recommended PAG) the associated lifetime total cancer mortality would be 2.25×10^{-4} or approximately 1 in 4400.[6] For comparison, the estimate of the normal lifetime total cancer mortality in the United States for the general population, not associated with additional radiation dose from ingestion of contaminated food from an accident, is 0.19 or approximately 1 in 5 (CIRRPC 1992). For example, in a general population of 10,000 individuals, each receiving a committed effective dose equivalent of 5 mSv (0.5 rem), the number of cancer deaths over the lifetimes of the individuals

[6] The alternate PAG of 50 mSv (5 rem) committed dose equivalent to a specific tissue or organ is always associated with a lifetime cancer mortality for the specific tissue that is as limiting or in some cases more limiting than the lifetime total cancer mortality associated with the PAG of 5 mSv (0.5 rem) for committed effective dose equivalent.

could increase in theory by about 2 cancer deaths, that is from the normal number of 1900 to 1902.

The numerical estimate of cancer deaths presented above for the recommended PAG of 5 mSv (0.5 rem) was obtained by the practice of linear extrapolation from the nominal risk estimate for lifetime total cancer mortality for the general population at 100 mSv (10 rem) dose equivalent in the whole body. Other methods of extrapolation to the low-dose region could yield higher or lower numerical estimates of cancer deaths. Studies of human populations exposed at low doses are inadequate to demonstrate the actual magnitude of risk. There is scientific uncertainty about cancer risk in the low-dose region below the range of epidemiological observation, and the possibility of no risk cannot be excluded (CIRRPC 1992).

DERIVED INTERVENTION LEVELS

A DIL corresponds to the concentration in food present throughout the relevant period of time that, in the absence of any intervention, could lead to an individual receiving a radiation dose equal to the PAG, or in international terms, the intervention level of dose. The equation given below is the basic formula for computing DILs.[7]

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[7] In the previous system of units DIL would be in units of pCi/kg, intervention level of dose in units of mrem and DCs in units of mrem/pCi.

$$\text{DIL (Bq/kg)} = \frac{\text{PAG (mSv)}}{\text{f x Food Intake (kg) x DC (mSv/Bq)}}$$

Where:

DC = Dose coefficient; the radiation dose received per unit of activity ingested (mSv/Bq).

f = Fraction of the food intake assumed to be contaminated.

Food Intake = Quantity of food consumed in an appropriate period of time (kg).

The FDA DILs provide a large margin of safety for the public because each DIL is set according to a conservatively safe scenario for the most vulnerable group of individuals (see Appendix D). In addition, protective action would be taken if radionuclide concentrations were to reach or exceed a DIL at any point in time, even though such concentrations would need to be sustained throughout the relevant extended period of time for the radiation dose to actually reach the PAG. In practice, when FDA DILs are used, radiation doses to the vast majority of the affected public would be very small fractions of the PAG. As a result, future adjustments in the absolute values of the PAGs would not necessarily require proportionate modifications in the DILs. Any modification of the DILs would depend on a review of all aspects of the conservatively safe scenario and how the DILs are applied.

Food with concentrations below the DILs is permitted to move in commerce without restriction. Food with concentrations at or above the DILs is not normally permitted into commerce. However, State and local officials have flexibility in whether or not to apply restrictions in special circumstances, such as permitting use of food by a population group with a unique dependency on certain food types.

(a) Use of Derived Intervention Levels for Food Monitoring after the Chernobyl Accident

Developments in the U.S.

Following the Chernobyl accident in 1986, a task group of representatives from FDA and the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture established DILs for application to imported foods under their respective regulatory control. The FDA DILS were called "Levels of Concern" (LOCs)(FDA 1986a, 1986b) and the FSIS DILs were called "Screening Values." Food containing concentrations below the LOCs and Screening Values was allowed to be imported into the U.S.

FDA LOCs were derived from the 1982 Preventive PAGs and used the following assumptions:

- the entire intake of food would be contaminated,

- I-131 could be a major source of radiation dose for only 60 days following the accident, and

- Cs-134 + Cs-137 could be a major source of radiation dose for up to one year.

The LOCs provided such a large margin of safety that derivation of LOCs for other radionuclides, judged to be of less health significance, was considered unnecessary.

The FSIS Screening Value for I-131 was the same as the FDA LOC for I-131 in infant foods. The FSIS Screening Value for Cs-134 + Cs-137 initially differed from the FDA LOC because the FSIS assumed that only meat and poultry (not 100% of the diet) would be contaminated (USDA 1986a). In November 1986, the FSIS changed the Screening Value for Cs-134 + Cs-137 to be the same as the FDA LOC (USDA 1986b, Engel et al 1989). The FDA and FSIS DILs for the Chernobyl accident contamination in imported food after November 1986 are given in Table 1.

The food monitoring results from FDA and others following the Chernobyl accident support the conclusion that I-131, Cs-134 and Cs-137 are the principal radionuclides that contribute to radiation dose by ingestion following a nuclear reactor

Table 1

FDA AND FSIS DERIVED INTERVENTION LEVELS FOR IMPORTED FOOD AFTER THE CHERNOBYL ACCIDENT, Bq/kg (pCi/kg)

	FDA LOC		FSIS Screening Value
Radionuclide	Infant Food	Other Food	Meat and Poultry
I-131	55 (1500)	300 (8000)	55 (1500)
Cs-134 + Cs-137	370 (10,000)	370 (10,000)	370 (10,000)

accident, but that Ru-103 and Ru-106 also should be included (see Appendix C). Also, use of DILs was shown to be a practical way to control the radiation dose from ingestion of food that has been contaminated as a result of a nuclear reactor accident.

International Activities

Efforts by international organizations to develop DILs have been extensive. Derivations have been based on the consensus value for the intervention level of dose, and have been for application within individual countries and in international trade. Each of the various international organizations selected values for the components in the basic formula for

computing DILs, and each introduced additional judgments to arrive at its recommended DILs. As a result, the DILs recommended by the various organizations differed. The DILs adopted by the Commission of European Communities (CEC) for use in future accidents and those adopted by the Codex Alimentarius (CODEX) for use in international trade[8] are presented in Appendix F.

(b) Recommended Derived Intervention Levels

In these recommendations, FDA uses the term Derived Intervention Level (DIL), which is consistent with international usage. DIL is equivalent to, and replaces the previous FDA term Level of Concern (LOC).

The recommended DILs are for radionuclides expected to deliver the major portion of the radiation dose from ingestion during the first year following an accident. The DILs are for accidental releases of radionuclides from large nuclear reactors and for other radiological emergencies where there is a possibility of accidental radioactive contamination of human food. The approach provides the flexibility necessary to respond to special circumstances that may be unique to a

[8] An application of the CODEX DILs can be found in the International Atomic Energy Agency's (IAEA) interim edition of its basic safety standards for protection against ionizing radiation (IAEA 1994). IAEA based its "generic action levels for foodstuffs," found in Schedule V of IAEA 1994, on CODEX DILs.

particular accident. A summary of the considerations in selecting DILs is given in this section, with a more detailed explanation available in Appendix D.

The types of accidents and the principal radionuclides for which the DILs were developed are:

- nuclear reactors (I-131; Cs-134 + Cs-137; Ru-103 + Ru-106),

- nuclear fuel reprocessing plants (Sr-90; Cs-137; Pu-239 + Am-241),

- nuclear waste storage facilities (Sr-90; Cs-137; Pu-239 +

- nuclear weapons (i.e., dispersal of nuclear material without nuclear detonation) (Pu-239), and

- radioisotope thermoelectric generators (RTGs) and radioisotope heater units (RHUs) used in space vehicles (Pu-238).

The radionuclides listed are expected to be the predominant contributors to radiation dose through ingestion.[9] Several

[9] A discussion of the principal radionuclides for an accident at a nuclear reactor is given in Appendix C.

radionuclides could be released by an accident at a nuclear reactor, a nuclear fuel processing plant or a nuclear waste storage facility, while only the specific radionuclide used in a nuclear weapon or a space vehicle would be released in that type of accident. When more than one radionuclide is released, the relative contribution that a radionuclide makes to radiation dose from ingestion of subsequently contaminated food depends on the specifics of the accident and the mode of release (NRC 1975, DOE 1989, EPA 1977).

In unique circumstances, such as transportation accidents, other radionuclides may contribute radiation doses through the food ingestion pathway. These situations are not specifically treated in these recommendations. An evaluation of the radiation dose from ingestion of these other radionuclides should be performed, however, to determine if the PAGs would be exceeded. FDA should be notified during such an evaluation.

DILs were calculated for the nine radionuclides noted above. For each radionuclide, DILs were calculated for six age groups using Protective Action Guides, dose coefficients, and dietary intakes relevant to each radionuclide and age group. The age groups included 3 months, 1 year, 5 years, 10 years, 15 years and adult (>17 years). The dose coefficients used were from ICRP Publication 56 (ICRP 1989).

The DILs were based on the entire diet[10] for each age group, not for individual foods or food groups. The calculation presumed that contamination would occur in thirty percent of the dietary intake. The value of thirty percent was based on the expectation that normally less than ten percent of the annual dietary intake of most members of the population would consist of contaminated food. An additional factor of three was applied to account for limited sub-populations that might be more dependent on local food supplies. An exception was made for I-131 in the diets of the 3-month and 1-year age groups, where the entire intake over a sixty-day period was assumed to be contaminated.

The nine radionuclides comprised five radionuclide groups, each having common characteristics. The five groups are: Sr-90; I-131; Cs-134 + Cs-137; Ru-103 + Ru-106; and Pu-238 + Pu-239 + Am-241. An accident could involve more than one of the five groups.

Protection of the more vulnerable segments of the population and the practicality of implementation were major considerations in the selection of the recommendations. These considerations lead to the single DIL or the single criterion for each radionuclide group that is presented in Table 2, based on the most limiting Protective Action Guide (PAG) and

[10] The "entire diet" includes tap water used for drinking.

age group for the radionuclide group.[11]

The recommended DILs may be applied immediately following an accident. Early identification of other radionuclides that may be present in food is not required. However, the recommended DILs should be evaluated as soon as possible after an accident to ensure that they are appropriate for the situation. Appendix E presents a discussion on DILs for a number of other radionuclides that could be released from the reactor core of a nuclear power plant.

(c) Imported or Exported Food

The LOCs that applied to radioactive contamination from the Chernobyl accident in imported foods subject to FDA authority were given in an FDA Compliance Policy Guide (FDA 1986b). This guidance remains in effect and would be reviewed and modified as necessary to respond to any future accident resulting in radioactive contamination of imported food.

[11] The PAG of 5 mSv (0.5 rem) for committed effective dose equivalent was most limiting for Cs-134 + Cs-137 and Ru-103 + Ru-106; the PAG of 50 mSv (5 rem) for committed dose equivalent to a single specific tissue or organ was most limiting for Sr-90, I-131 and Pu-238 + Pu 239 + Am-241.

Table 2

Recommended Derived Intervention Level (DIL)

or Criterion for Each Radionuclide Group[a],[b]

All Components of the Diet

Radionuclide Group	(Bq/kg)	(pCi/kg)
Sr-90	160	4300
I-131	170	4600
Cs-134 + Cs-137	1200	32,000
Pu-238 + Pu-239 + Am-241	2	54
Ru-103 + Ru-106[c]	$\frac{C_3}{6800} + \frac{C_6}{450} < 1$	$\frac{C_3}{180,000} + \frac{C_6}{12,000} < 1$

Notes:

(a) The DIL for each radionuclide group (except for Ru-103 + Ru-106) is applied independently (see discussion in Appendix D). Each DIL applies to the sum of the concentrations of the radionuclides in the group at the time of measurement.

(b) Applicable to foods as prepared for consumption. For dried or concentrated products such as powdered milk or concentrated juices, adjust by a factor appropriate to reconstitution, and assume the reconstitution water is not contaminated. For spices, which are consumed in very small quantities, use a dilution factor of 10.

(c) Due to the large difference in DILs for Ru-103 and Ru-106, the individual concentrations of Ru-103 and Ru-106 are divided by their respective DILs and then summed. The sum must be less than one. C_3 and C_6 are the concentrations, at the time of measurement, for Ru-103 and Ru-106, respectively (see discussion in Appendix D).

Food exported from the United States is controlled by standards, regulations and guidance in the importing countries. Two examples of guidance applicable to accidentally contaminated foods exported from the United States are the guidelines issued by the CODEX Alimentarius Commission of the Joint FAO/WHO Food Standards Program and the regulations adopted by the Commission of the European Communities (CEC). The DILs adopted by these two organizations (presented in Appendix F) differ from each other and from the FDA LOCs.

PROTECTIVE ACTIONS

Protective actions are steps taken to limit the radiation dose from ingestion by avoiding or reducing the contamination that could occur on the surface of, or be incorporated into, human food and animal feeds. Such actions can be taken prior to and/or after confirmation of contamination. The protective actions for a specific accident are determined by the particulars of the situation and once initiated they continue at least until the concentrations are expected to remain below the DILs.

For contamination events not effectively managed using DILs, protective actions appropriate to the situation would still be established and applied by the responsible officials. For example, in 1988 FDA developed guidance for use in responding to a contamination event that could have occurred from an

uncontrolled reentry of the Russian satellite Cosmos 1900. FDA issued an advisory which specified protective actions against contamination in the form of widely but sparsely distributed discrete radioactive particulates and large pieces of radioactive debris (FDA 1988). The uncontrolled reentry of Cosmos 1900 did not occur.

(a) Protective Actions Prior to Confirmation of Contamination

Protective actions which can be taken within the area likely to be affected and prior to confirmation of contamination consist of:

- simple precautionary actions to avoid or reduce the potential for contamination of food and animal feeds, and

- temporary embargoes to prevent the introduction into commerce of food which is likely to be contaminated.

Protective actions can be taken before the release or arrival of contamination if there is advance knowledge that radionuclides may accidentally contaminate the environment.

For some types of accidents, determination of when and what protective actions would be taken may be facilitated by

associating them with the accident classifications designated by the Nuclear Regulatory Commission (NRC) or the Department of Energy (DOE). For accidents involving commercial nuclear power reactors, the NRC has established four emergency classes: Notification of Unusual Event, Alert, Site Area Emergency, and General Emergency. Criteria for declaring these classes were published by the NRC (NRC 1980, 1991).

For accidents at DOE facilities, the DOE has established three emergency classes: Alert, Site Area Emergency, and General Emergency. These classes are comparable to those established by NRC. Incidents considered as Unusual Events by NRC licensees are covered as Unusual Occurrences by DOE (DOE 1992).

Simple precautionary actions include modest adjustment of normal operations prior to arrival of contamination. These will not guarantee contamination in food will be below the DILs but the severity of the forthcoming problem would be significantly reduced. Typical precautionary actions include covering exposed products, moving animals to shelter, corralling livestock and providing protected feed and water.

Precautionary actions should be implemented so as to avoid placing in jeopardy persons implementing the action. For

example, in the case of an accident involving a commercial nuclear power plant, if the predictions of the magnitude of future off-site contamination are persuasive, precautionary actions that could be taken and completed before a declaration of Site Area Emergency or General Emergency could be considered. However, precautionary actions that would involve persons either not seeking shelter or leaving the immediate vicinity of shelter should not be taken after declaration of a Site Area Emergency or General Emergency. A temporary embargo on food and agricultural products (including animal feeds) prevents the consumption of food that is likely to be contaminated. Distribution and use of possibly contaminated food and animal feeds is halted until the situation can be evaluated and monitoring and control actions instituted. Temporary embargoes are applied when the concentrations are not yet known. Because there is potential for negative impact on the community, justification for this action must be significant. The embargo should remain in effect at least until results are obtained. For nuclear power plants, a temporary embargo should be issued only upon declaration of a General Emergency and if predictions of the extent and magnitude of the off-site contamination are persuasive. The geographical area under control by the embargo would depend on the accident sequence, the meteorological conditions, and the food affected.

(b) Protective Actions for Foods Confirmed to be Contaminated

Protective actions which should be implemented when the contamination in food equals or exceeds the DILs consist of:

- temporary embargoes to prevent the contaminated food from being introduced into commerce, and

- normal food production and processing actions that reduce the amount of contamination in or on food to below the DILs.

A temporary embargo to prevent the introduction into commerce of food from a contaminated area should be considered when the amount of contamination equals or exceeds the DILs or when the presence of contamination is confirmed, but the concentrations are not yet known. The temporary embargo would continue until measurements confirm that concentrations are below the DILs.

Normal food production and processing procedures that could reduce the amount of radioactive contamination in or on the food could be simple, (e.g., such as holding to allow for radioactive decay, or removal of surface contamination by brushing, washing, or peeling) or could be complex (Grauby and Luykx 1990, FDA 1982, USDA 1989). The blending of

contaminated food with uncontaminated food is not permitted because this is a violation of the Federal Food, Drug and Cosmetic Act (FDA 1991).

Protective actions focus on the specific foods having the greatest sources of radiation dose to the population. Factors that determine which foods are most significant include the agricultural practices in the area of contamination and the stage of the growing or harvest season at the time of the accident. In general, foods consumed fresh, such as milk, leafy vegetables, and fruit, are initially most important. Grains, root crops, other produce, and animal-derived food products are significant later as they come to market.

Specific protective actions to be implemented following an accident are not provided in these recommendations because there is such a wide variety of actions that could be taken. The protective actions would be determined by state and local officials with assistance from the growers, producers, and manufacturers.

(c) Protective Actions for Animal Feeds Confirmed as Contaminated

Protective actions to reduce the impact of contamination in or on animal feeds, including pasture and water, should also be taken on a case-by-case basis. Accurately forecasting

the transfer of radioactive contamination through the agricultural pathway, from animal feed to human food, is problematic. The forecast is influenced by many factors, such as: the type of feed (e.g., fresh pasture, grain), other intakes (e.g., other feeds, supplements), the chemical form of the radionuclide, medications being administered, the animal species, and the type of resulting human food (e.g., milk, meat, eggs).

Protective actions that could be taken when animal feeds are contaminated include the substitution of uncontaminated water for contaminated water and the removal of lactating dairy animals and meat animals from contaminated feeds and pasture with substitution of uncontaminated feed. Corralling livestock in an uncontaminated area could also be effective. The protective actions would be determined by State and local officials, with assistance from growers, producers, and manufacturers.

To Part 2 of Document