

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

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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 dose² could be received as a result of consumption of contaminated food. These recommendations rescind and replace the 1982 FDA recommendations.

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.

1 This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

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

(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
- 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.

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.

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}.

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.

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 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 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

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.

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

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

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

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.

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
- 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.

Table 1

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

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

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 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 trade⁸ 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 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 + Am-241),
- nuclear weapons (i.e., dispersal of nuclear material without nuclear detonation) (Pu-239)
- 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 radionuclides could be released by an accident at a nuclear

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.

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

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 diet¹⁰ 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.

¹⁰ The “entire diet” includes tap water used for drinking.

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 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.

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

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.

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.

Table 2
Recommended Derived Intervention Level (DIL)
or Criterion for Each Radionuclide Group^{(a),(b)}

Radionuclide Group	All Components of the Diet			
	(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 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. C3 and C6 are the concentrations, at the time of measurement, for Ru-103 and Ru-106, respectively (see discussion in Appendix D).

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,
- 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, (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.

APPENDIX A - GLOSSARY

absorbed dose - the quotient of the mean energy imparted by ionizing radiation, d , to matter of mass dm , unit: Gy (ICRU 1993)

averted dose - the radiation dose saved by implementing a protective action. It may be expressed in any of the relevant dose quantities. (ICRP 1991b)

Becquerel (Bq) - the unit of radionuclide activity or expectation value of the number of spontaneous nuclear transitions per unit of time. $Bq = 1$ transition per second. Unit: 1/s (ICRU 1980) The unit of radionuclide activity used in the previous FDA guidance was the curie (Ci)¹². $1 Bq = 27 \times 10^{-12} Ci = 27$ picocuries (pCi).

committed dose equivalent (H_T) - the dose equivalent accruing in an organ or tissue up to a specified number of years after the intake of a radionuclide into the body. In this document, committed dose equivalent is always computed to age 70 years. Unit: Sv (ICRP 1984a)

committed effective dose equivalent (H_E) - committed dose equivalents to individual organs or tissues, multiplied by weighting factors, then summed. In this document, committed effective dose equivalent is always computed to age 70 years. Unit: Sv (ICRP 1984a)

contamination - radionuclides on or in food or animal feed as a result of an accidental release.

concentration - radionuclide activity concentration. Unit: Bq/kg; $1 Bq/kg = 27 pCi/kg$.

Derived Intervention Level (DIL) - concentration derived from the intervention level of dose at which introduction of protective measures should be considered. Unit: Bq/kg (IAEA 1985)

¹² The International System of Units is used throughout the document. In this Glossary, the units that were used in previous FDA guidance are given as reference points for the reader in the definitions of the units “Becquerel” and “sievert”.

dose coefficient (DC) - the conversion coefficient for committed dose equivalent or committed effective dose equivalent per unit intake of radionuclide activity. Unit: Sv/Bq (ICRP 1989)

dose equivalent¹³ (H_T) - the product of the absorbed dose in an organ or tissue and the quality factor. Unit: Sv (ICRU 1993)

effective dose equivalent (H_E) - sum of weighted dose equivalents for irradiated tissues or organs.

$$H_E = W_T H_T$$

where W_T is a weighting factor representing the proportionate stochastic risk for tissue T, and H_T is the mean dose equivalent received by tissue T. A list of tissues and their weighting factors is given by ICRP (ICRP 1984a). Unit: Sv

gray (Gy) - unit of absorbed dose. 1 Gy = 1 J/kg; 1 milligray (mGy) = 10^{-3} Gy. (ICRU 1993) The unit of absorbed dose in previous FDA publications was the rad. 1 Gy = 100 rad; 1 mGy = 0.1 rad.

intervention level of dose - reference level of dose equivalent to an individual at which introduction of protective actions should be considered. Unit: Sv (ICRP 1977, ICRP 1984b)

Level of Concern (LOC) - concentration in an imported food, set by FDA after the Chernobyl accident, below which unrestricted distribution in U.S. commerce is permitted.

precautionary action - action taken, prior to confirmation of contamination, to avoid or reduce the potential for contamination of food and animal feed.

¹³ In this document, dose equivalent and committed dose equivalent are synonymous, and effective dose equivalent and committed effective dose equivalent are synonymous, because they

always refer to the general public, to radionuclides deposited in the body, and to values computed to age 70 years.

protective action - action taken to limit the radiation dose from ingestion by avoiding or reducing the contamination in or on human food and animal feeds.

Protective Action Guide (PAG) - committed effective dose equivalent or committed dose equivalent to an individual organ or tissue that warrants protective action following a release of radionuclides.

quality factor - modifying factor that weights the absorbed dose for the biological effectiveness of the charged particles producing the absorbed dose. (ICRU 1993)

sievert (Sv) - unit of dose equivalent. $1 \text{ Sv} = 1 \text{ J/kg}$; $1 \text{ millisievert (mSv)} = 10^{-3} \text{ Sv}$. (ICRU 1993)

The unit of dose equivalent used in previous FDA guidance was the rem. $1 \text{ Sv} = 100 \text{ rem}$; $1 \text{ mSv} = 0.1 \text{ rem}$.

APPENDIX B - INTERNATIONAL CONSENSUS ON INTERVENTION LEVELS OF DOSE

In 1984, the International Commission on Radiological Protection (ICRP) recommended basic principles for planning intervention in the event of major radiation accidents and provided general guidance on radiation dose levels for the implementation of countermeasures (ICRP 1984b). The term “intervention level of dose” is used by ICRP for these dose levels. The ICRP guidance indicated that for any countermeasure there is a lower level of radiation dose below which the introduction of the countermeasure is unlikely to be warranted, an upper level of radiation dose above which the countermeasure should almost certainly be implemented, and when between these levels, the specifics of the situation determine which actions (if any) would be taken. For the control of food, ICRP indicated lower and upper levels of 5 mSv¹⁴ and 50 mSv, respectively, for committed effective dose equivalent and 50 mSv and 500 mSv, respectively, for committed dose equivalent to an individual organ or tissue (ICRP 1984b, ICRP 1977).

Since 1984, a number of international organizations have provided guidance dealing with the ingestion of radionuclides that was consistent with the ICRP guidance. These organizations included the Commission of the European Communities (CEC), the Codex Alimentarius Commission (CODEX), the Food and Agricultural Organization of the United Nations (FAO), the International Atomic Energy Agency (IAEA), the Nuclear Energy Agency of the Organization for Economic Cooperation and Development (NEA), and the World Health Organization (WHO). All have adopted 5 mSv committed effective dose equivalent as the radiation dose level above which intervention was recommended (CODEX 1989, FAO 1987, IAEA 1986, Luykx 1989, NEA 1989, Waight 1988, WHO 1988). All except CODEX also adopted 50 mSv committed dose equivalent to an individual tissue or organ when that value is more limiting.

¹⁴ The International System of Units is used throughout this document. See Appendix A, Glossary, for equivalence to units used in previous FDA guidance.

The ICRP has updated its general concepts on intervention in its Publication 60 (ICRP 1991a). Additional advice for intervention for protection of the public was provided in its Publication 63 (ICRP 1991b). The additional advice included an intervention level of averted dose (10 mSv effective dose¹⁵ in a year) for restriction of a single foodstuff. ICRP considered this level appropriate for almost all cases, excepting when alternative food supplies are not available or population groups might suffer serious disruption of their food supply.

The ICRP approach recommended that in application of this intervention level of averted dose, the net benefit of withdrawing a particular foodstuff be made optimum, based on knowledge of the local situation and other assumptions about the monetary value assigned to the effective dose. The ICRP provided an example of how to evaluate the optimum. Such a procedure requires information that would not be available during the early phases of an accident.

The FDA uses the principles in the general guidance provided by ICRP in 1984 for the immediate response to a major radiation accident, recognizing that at later stages, after the local situation is stabilized and more clearly defined, the longer-term intervention for food can be modified based on more detailed evaluation of local conditions by local authorities. Therefore, the PAGs for the ingestion pathway at the onset of an accident are 5 mSv committed effective dose equivalent or 50 mSv committed dose equivalent to an individual tissue or organ, whichever is more limiting.

¹⁵ Effective dose is the ICRP's revised formulation of effective dose equivalent, as described in its 1990 recommendations (ICRP 1991a)

APPENDIX C - RADIONUCLIDES DETECTED IN FOOD FOLLOWING THE CHERNOBYL NUCLEAR POWER PLANT ACCIDENT OF APRIL 1986

(a) Analyses of Imported Food by the United States and Canada

(1) I-131 and Cs-134 + Cs-137

Shortly after the accident at Chernobyl on April 26, 1986, the FDA and FSIS of the USDA began sampling imported food for analysis to determine radionuclide activity concentrations.

Regulatory actions were based on FDA Levels of Concern (LOCs) and the FSIS Screening Levels which were developed in 1986 and applied to I-131 and Cs-134 + Cs-137.

The regulatory results of FDA and FSIS import monitoring and analyses are summarized in Table C-1¹⁶. The radionuclide activity concentrations (concentrations) exceeded the FDA LOCs (Cunningham et al 1992) in 23 out of 2,600 (0.9%) food samples, and exceeded the FSIS Screening Values (equal to the LOCs) (Engel et al 1989, Randecker 1990) in 107 out of 6,295 (1.7%) meat and poultry samples. In general, Cs-134 and Cs-137 were the principal radionuclides detected by FDA and FSIS in the imported foods analyzed. I-131 was significant for only about two months. Cs-134 and Cs-137 were also the dominant radionuclides in imported foods analyzed by Canada (NHW 1987). The European countries of the Nuclear Energy Agency (NEA) also found that I-131 and Cs-134 + Cs-137 contributed most of the radiation dose from radionuclides ingested with food contaminated by the Chernobyl accident (NEA 1987, NEA 1989).

(2) Radionuclides Other Than I-131 and Cs-134 + Cs-137

In addition to the radionuclides used for regulatory actions (I-131, Cs-134 + Cs-137), a number of other radionuclides were detected in imported food entering the U. S. and Canada. Of these,

¹⁶ The International System of Units is used throughout the document. See Appendix A, Glossary, for equivalence to units used in previous FDA guidance.

the most commonly detected radionuclides were Ru-103, Ru-106, Ba-140, Sr-90, Ce-144 and Zr-95. The results of FDA and Canadian import sampling for the latter radionuclides are summarized in Table C-2. The data supported the prediction that I-131 and Cs-134 + Cs-137 were the most significant radionuclides for screening of imported foods, and that the other radionuclides were of significantly less importance.

During 1986, of about 500 imported samples monitored by FDA, Ru-103 and Ru-106 were above the detection levels for 18 samples and Ba-140 was above the detection levels in 9 samples (Cunningham et al 1992). These radionuclides were not detected after 1986. Only selected samples were analyzed for Sr-90. Two samples, containing relatively high amounts of Cs-134 + Cs-137 were analyzed for Sr-90 in 1986. In the following years, a total of 40 samples (those having Cs-134 + Cs-137 in excess of 110 Bq/kg) were analyzed for Sr-90. The Sr-90 was above the detection levels in all 42 samples.

For Canadian imported foods, Ru-103 was above detection levels in 46 of 840 samples analyzed during 1986 and 1987, and below detection levels in all samples analyzed later. Ru-106 was above detection levels in 130 of 936 samples analyzed from 1986 through 1989 (Marshall 1992). Samples were analyzed for Ce-144 and Zr-95 from 1987 through 1989. Out of 486 samples, Ce-144 was above detection levels in 88 samples and Zr-95 was above detection levels in 3 samples.

Concentrations in FDA and Canadian imported samples were generally below 10% of the respective Derived Intervention Levels (DILs) given in Appendices D and E. The main exceptions were for Ru-106 in Canadian samples which ranged up to 42% of the DIL.

The results of analysis for imported samples collected by the U.S. and Canada are representative of collections distant from the accident site. Therefore, not only was the food variety relatively limited, but time delays between accident and sample collection, processing effects, and selective screening that exporters may have applied could have influenced the findings. Consequently, findings from samples collected at countries close to Chernobyl are most useful for U.S. decision-makers responding to a domestic release because these findings are more representative of a local contamination event.

(b) Analyses of Foods Collected Locally at Central and Eastern European Countries

In 1986, FDA received a variety of foods collected locally by United States Embassy staff in Central and Eastern European countries. A total of 48 samples from Bulgaria, Czechoslovakia, Finland, Hungary, Poland, Romania, Russia, and Yugoslavia, were analyzed. Results for Ru-103, Ru-106, and Ba-140 are summarized in Table C-3. The number of samples above detection levels for each radionuclide is given with the ranges of associated percentages relative to the DILs. I-131 and Cs-134 + Cs-137 (not shown) were also detected in most of the samples. I-131 concentrations exceeded the DIL for 27 samples; while Cs-134 + Cs-137 exceeded the DIL for 2 samples.

Most of the 48 embassy samples were fresh vegetables. The edible portions were leafy for 28 samples and roots, bulbs, shoots, or seedlings for 12 samples. Ru-103 was above detection levels in all vegetables, exceeding its DIL for 6 samples. Ru-106 was above detection levels in all vegetables, exceeding its DIL for 14 samples. Ba-140 was above detection levels in 19, but did not exceed its DIL in any vegetables (maximum, 6.3% of DIL).

Other samples included 3 fresh fruit and 5 processed foods (cheese, yogurt, ice cream, and 2 milk samples). Ru-106 was above detection levels in all fruit (maximum, 14% of DIL) and in 2 processed foods (maximum, 29% of DIL). Ru-103 and Ba-140 were above detection levels but did not exceed 2% of their DILs in the fruit or processed food samples.

In September 1986, 28 samples of spices from Turkey and Greece (not offered for import) were provided by the American Spice Trade Association (ASTA) for testing by FDA. This set of samples represented deposition at a distance comparable to many of the Eastern European embassy samples but were analyzed at a later time after the accident. FDA analyzed spices for gamma-ray emitting radionuclides and Sr-90. Findings are included in Table C-3. Following the advice of CEC (CEC 1989a) and CODEX (CODEX 1989) for minor foods, a dilution factor of ten was applied to the concentrations for herbs, spices and flavorings, because they will be consumed in very small quantities.

Cs-134 + Cs-137 (not shown in Table C-3), Ru-103, Ru-106, and Sr-90 were above detection levels in all samples. I-131 and Ba-140 were below detection levels having undergone ten or more half-lives of radioactive decay.

Ru-103, having decayed for over four half-lives, ranged to a maximum of only 4.5% of its DIL while Sr-90, though having decayed very little, reached 10% of the DIL in only 8 samples (maximum, 30% of DIL). Ru-106 exceeded its DIL in 2 samples, was 50% to 100% in 5, and 10% to 50% in another 17.

(c) Conclusions

The results support the expectation that concentrations of I-131 and Cs-134 + Cs-137 would serve as the main indicators of the need for protective actions for imported and local food. However, concentrations of Ru-106 were consistently in excess or at a significant fraction of the DIL, which suggests that Ru-106 should also serve as an indicator, i.e. be included as a principal radionuclide for nuclear reactor incidents.

Also, for local samples of fresh vegetables harvested during the first week of the incident, half of the samples had Ru-103 concentrations a significant fraction of the DIL and another quarter of the samples had Ru-103 concentrations in excess of the DIL. Consequently, it would be prudent to consider Ru-103 as a principal radionuclide for local deposition, particularly in the early phase of a nuclear reactor incident.

Sr-90 did not exceed 11% of the DIL in imported food (Table C-2). For the series of 28 local (ASTA) spice samples (Table C-3), Sr-90 was less than 30% of its DIL (generally a lower percent of the DIL than found for Ru-106 or Cs-134 + Cs-137). Also, the analytical method for determination of Sr-90 in food is lengthy compared to analysis for the gamma-ray emitting radionuclides, such that protective actions based on the concentration of Sr-90 could not be taken in a timely manner. Therefore, Sr-90 would not be an effective indicator of the need for protective actions in the early phase of a nuclear reactor incident.

During the first year after an accident, concentrations in local or imported food other than for I-131, Cs-134, Cs-137, Ru-103 and Ru-106 are expected to be significant only when one or more of these principal radionuclides has exceeded its DIL. Therefore, the food would already have been subject to protective action.

Table C-1
SUMMARY OF U.S. REGULATORY FINDINGS FOR IMPORTED FOOD
FOLLOWING THE CHERNOBYL ACCIDENT

Agency	Number of Samples Analyzed	Sampling Period	Number of Samples Contaminated Above Regulatory Limits ^(c)	
			I-131	Cs-134 + Cs-137
FDA ^(a)	2600	5/86-9/92	2	21
FSIS ^(b)	6295	5/86-10/88	-	107
Regulatory Limits ^(c)			300 Bq/kg	370 Bq/kg

(a) Food and Drug Administration

(b) Food Safety and Inspection Service of the U.S. Department of Agriculture

(c) FDA: Levels of Concern FSIS: Screening Levels

Table C-2

Ru-103, Ru-106, Ba-140, Sr-90, Ce-144, and Zr-95
IN IMPORTED FOOD SAMPLES^(a) (UNITED STATES AND CANADA)

Year, Number, and Type of Samples Analyzed ^(b)				Number of Samples with Measurable Concentration (Maximum Percent of Derived Intervention Level)					
				Ru-103 ^(c)	Ru-106 ^(c)	Ba-140	Sr-90	Ce-144	Zr-95
<u>U.S. (FDA)</u>	1986	500 ^(d)	Herbs	2 (0.02)	2 (9)				
			Others	16 (1.3)	16 (6)	9 (1.9)	2 ^(e) (8)		
	1987	37 ^(f)	Herbs				24 (3)		
			Others				13 (11)		
	1989	3 ^(f)	Herbs				3 (2)		
	<u>Canada</u>	1986	450 ^(d)	Herbs	26 (0.5)	13 (42)			58 (9)
Others				10 (0.5)	1 (3)				
1987		390 ^(d)	Herbs	10 (0.05)	75 (22)				
			Others		2 (19)				
1988		76	Herbs		30 (10)			26 (4)	
1989		20	Herbs		9 (4)			4 (2)	

(a) For herbs (which include herbs, spices, and flavorings), a dilution factor of ten was applied to the concentrations. No dilution factor was applied for other foods.

(b) Number of samples analyzed for the featured radionuclides. Not equal to number of samples analyzed for principal radionuclides.

(c) The reported Ru-106 concentrations in FDA reports were usually the sum of Ru-103 + Ru-106. Values in this table are the individual Ru-103 and Ru-106 concentrations.

(d) Approximate number.

(e) Number of samples tested for Sr-90, one of which exceeded the 1986 LOC for Cs-134 + Cs-137.

(f) Only samples with Cs-134 + Cs-137 in excess of 0.3 of 1986 LOC were analyzed for Sr-90.

Table C-3

Ru-103, Ru-106, Ba-140, and Sr-90
 IN SAMPLES FROM U.S. EMBASSIES IN CENTRAL AND EASTERN EUROPE
 AND FROM THE AMERICAN SPICE TRADE ASSOCIATION (ASTA)

Type and Number of Samples Analyzed	Number of Samples with Measurable Concentrations in 1986 (Range, as Percent of Derived Intervention Level)				
	Ru-103 ^(a)	Ru-106	Ba-140	Sr-90	
EMBASSY SAMPLES	Leafy Vegetables 28	28 (0.1-507)	28 (1-3500)	14 (0.1-6.3)	NA
	Non-leafy Vegetables 12	12 (1-222)	12 (9-1570)	5 (0.2-5.4)	NA
	Fruit 3	3 (0.3-1.4)	3 (4-14)	ND	NA
	Processed Food 5	2 (0.6-2)	2 (4-29)	3 (0.2-1.4)	NA
<u>ASTA SAMPLES</u>	<u>Spices 28</u>	<u>28 (0.2-4.5)</u>	<u>28 (6-1640)</u>	<u>ND</u>	<u>28 (0.9-30)</u>

(a) Embassy samples were received primarily in May and June 1986 and the ASTA samples in September 1986. Due to radioactive decay, the relative concentration of Ru-103 compared to Ru-106 is considerably lower for the ASTA samples than for the embassy samples.

NA Not analyzed.

ND Not detected.

APPENDIX D - DERIVATION OF RECOMMENDED DERIVED INTERVENTION LEVELS

The Derived Intervention Level (DIL) for a specific radionuclide is calculated as follows:

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

Where: DIL = Derived Intervention Level
PAG = Protective Action Guide
DC = Dose coefficient
Food Intake = Quantity of food consumed in an appropriate period of time
f = Fraction of food intake assumed to be contaminated

The recommended Protective Action Guides (PAGs) are 5 mSv¹⁷ committed effective dose equivalent, or 50 mSv committed dose equivalent to individual tissues and organs, whichever is more limiting. These PAGs are consistent with the consensus of international organizations on the levels of radiation dose below which ingestion pathway interventions are generally not appropriate (see Appendix B).

Dose coefficients (DCs) are given in Table D-1 and food intakes are given in Tables D-2 and D-3. The fraction of food intake assumed to be contaminated (f) equals 0.3, except for I-131 in infant diets where f equals 1.0.

(a) Radionuclides

Based upon data on radionuclides in human food following the Chernobyl accident, DILs for I-131, Cs-134, Cs-137, Ru-103 and Ru-106 would facilitate application of food monitoring programs following accidents involving nuclear reactors. For accidents at nuclear fuel

¹⁷ The International System of Units is used throughout the document. See Appendix A, Glossary, for equivalence to units used in previous FDA guidance.

reprocessing facilities and nuclear waste storage facilities, DILs for Sr-90, Cs-137, Pu-239, and Am-241 would be used. For nuclear weapons accidents and accidents involving radioisotope thermal generators (RTGs) and radioisotope heater units (RHUs) used in space vehicles, DILs for Pu-239 and Pu-238, respectively, would be used. The selection of these radionuclides as the major contributors to radiation dose through ingestion is consistent with recommendations on DILs published by NEA, WHO, CODEX, and CEC (NEA 1989, WHO 1988, CODEX 1989, CEC 1989b, IAEA 1994).

(b) Age Groups and Dose Coefficients (DCs)

The general population was divided into six age groups ranging from infants to adults and corresponding to the age groups in ICRP Publication 56 (ICRP 1989) for which ICRP has published DCs. The age groups are 3 months, 1 year, 5 years, 10 years, 15 years, and adult. The radionuclides, age groups and dose coefficients used in the calculations are presented in Table D-1.

(C) Food Intake

Food intake included all dietary components including tap water used for drinking, and is the overall quantity consumed in one year, with exceptions in the period of time for I-131 ($T_{1/2} = 8.04$ days) and Ru-103 ($T_{1/2} = 39.3$ days). For these, the quantities consumed were for a 60-day period and a 280-day period, respectively, due to the more rapid decay of these radionuclides. The intake periods for I-131 and Ru-103 are the nearest whole number of days for decay of these radionuclides to less than 1% of the initial activities.

Dietary intakes were derived from a 1984 EPA report which presented average daily food intake by age and gender (EPA 1984a, EPA 1984b). The EPA intakes were based on data from the 1977-1978 Nationwide Food Consumption Survey published by the U. S. Department of Agriculture (USDA 1982, USDA 1983). The age groups and annual dietary intakes for various food classes and the total, calculated from data in the EPA report, are given in Table D-2.

The dietary intakes derived for the ICRP age groups for which DCs are available, using the results in Table D-2, are presented in Table D-3.

(d) Fractions of Food Intake Assumed to be Contaminated (f)

For food consumed by most members of the general public, ten percent of the dietary intakes was assumed to be contaminated. This assumption recognizes the ready availability of uncontaminated food from unaffected areas of the United States or through importation from other countries, and also that many factors could reduce or eliminate contamination of local food by the time it reaches the market¹⁸.

Use of ten percent of the dietary intake as the portion contaminated was consistent with recommendations made by a Group of Experts to the Commission of the European Communities (CEC 1986a) and by the Nuclear Energy Agency (NEA) of the Organization for Economic Cooperation and Development (NEA 1989). The NEA noted that modification of this value would be appropriate if justified by detailed local findings.

FDA applied an additional factor of three to account for the fact that sub-populations might be more dependent on local food supplies. Therefore, during the immediate period after a nuclear accident, a value of 0.3 (i.e., thirty percent) is the fraction of food intake that FDA recommends should be presumed to be contaminated. If, subsequently, there is convincing local information that the actual fraction of food intake that is contaminated (f) is considerably higher or lower, there will be adequate time for State and local officials to determine whether to adjust the value of f (and therefore adjust the values of the DILs) for the affected area.

For infants, (i.e., the 3-month and 1-year age groups) the diet consists of a high percentage of milk and the entire milk intake of some infants over a short period of time might come from supplies directly impacted by an accident. Therefore, f was set equal to 1.0 (100%) for the infant diet.

¹⁸ In most situations, one would expect less than ten percent of the dietary intakes to be contaminated.

(e) Selection of Recommended Derived Intervention Levels

DILs are presented in Table D-4 for Sr-90, I-131, Cs-134, Cs-137, Ru-103, Ru-106, Pu-238, Pu-239, and Am-241 for six population age groups and applicable PAGs. To facilitate the execution of food monitoring programs, two criteria were used in selecting FDA's recommended DILs. First, the most limiting DIL for either of the applicable PAGs was selected for each of the nine radionuclides. These DILs are presented in Table D-5 for each of the six age groups. In addition, the average DIL is presented for the radionuclide group Pu + Am, composed of Pu-238, Pu-239, and Am-241, and the radionuclide group Cs, composed of Cs-134 + Cs-137. The three radionuclides in the Pu + Am group deposit on the bone surface and are alpha-particle emitters. The radionuclides in the Cs group are deposited throughout the body and are beta-particle and gamma-ray emitters. The average values are recommended for these groups because the calculated DILs for radionuclides in each group are similar.

The radionuclides Ru-103 and Ru-106 are chemically identical, are deposited throughout the body, and are beta-particle and gamma-ray emitters. However, their widely differing half lives (i.e., 39.3 days and 373 days, respectively) result in markedly differing individual DILs which do not permit simple averaging. Instead, the concentrations of Ru-103 (C_3) and Ru-106 (C_6) are divided by their respective DILs and are then summed¹⁹. The sum must be less than one.

Therefore,
$$\frac{C_3}{DIL_3} + \frac{C_6}{DIL_6} < 1.0 \quad \text{(equation D-1)}$$

This assures that the sum of the separate radiation dose contributions from the Ru-103 and Ru-106 concentrations will be less than that required by the Protective Action Guide during the first year after an accident.

¹⁹ Laboratories that are not equipped to resolve separately the concentrations for Ru-103 and Ru-106 should contact FDA for alternate procedures.

Second, there are dietary components which are common to all six age groups. A principal example is fresh milk, for which the consumer of particular supplies cannot be identified in advance. Therefore, the most limiting DIL for all age groups in Table D-5, for each radionuclide or radionuclide group, was selected and is applicable to all components of the diet.

These DILs are presented in Table D-6 and were rounded to two significant figures (one significant figure for the Pu + Am group). These are the FDA's recommended DILs.

The DILs in Table D-6 apply independently to each radionuclide or radionuclide group, because they apply to different types of accidents, or in the case of a nuclear reactor accident, to different limiting age groups. However, the DILs for Ru-103 and Ru-106 are used in equation D-1 to evaluate that criterion for the radionuclide group Ru-103 + Ru-106.

The FDA recommended DILs in Table D-6 are given in Table 2 in the main text, along with clarifying notes on application of the DILs.

Table D-1

DOSE COEFFICIENTS (mSv/Bq)^(a)

Radionuclide	Age Group					
	3 month	1 year	5 years	10 years	15 years	Adult
Sr-90 bone srfc	1.0E-03	7.4E-04	3.9E-04	5.5E-04	1.2E-03	3.8E-04
Sr-90	1.3E-04	9.1E-05	4.1E-05	4.3E-05	6.7E-05	3.5E-05
I-131 thyroid	3.7E-03	3.6E-03	2.1E-03	1.1E-03	6.9E-04	4.4E-04
I-131	1.1E-04	1.1E-04	6.3E-05	3.2E-05	2.1E-05	1.3E-05
Cs-134	2.5E-05	1.5E-05	1.3E-05	1.4E-05	2.0E-05	1.9E-05
Cs-137	2.0E-05	1.1E-05	9.0E-06	9.8E-06	1.4E-05	1.3E-05
Ru-103	7.7E-06	5.1E-06	2.7E-06	1.7E-06	1.0E-06	8.1E-07
Ru-106	8.9E-05	5.3E-05	2.7E-05	1.6E-05	9.2E-06	7.5E-06
Pu-238 bone srfc	1.6E-01	1.6E-02	1.5E-02	1.5E-02	1.6E-02	1.7E-02
Pu-238	1.3E-02	1.2E-03	1.0E-03	8.8E-04	8.7E-04	8.8E-04
Pu-239 bone srfc	1.8E-01	1.8E-02	1.8E-02	1.7E-02	1.9E-02	1.8E-02
Pu-239	1.4E-02	1.4E-03	1.1E-03	1.0E-03	9.8E-04	9.7E-04
Am-241 bone srfc	2.0E-01	1.9E-02	1.9E-02	1.9E-02	2.1E-02	2.0E-02
Au-241	1.2E-02	1.2E-03	1.0E-03	9.0E-04	9.1E-04	8.9E-04

(a) Dose coefficients are from ICRP Publication 56 (ICRP 1989). The committed effective dose equivalents or committed dose equivalents are computed to age 70 years.

Table D-2

ANNUAL DIETARY INTAKES (kg/y) ^(a)

Food Class	AGE GROUP(years)									
	< 1	1-4	5-9	10-14	15-19	20-24	25-29	30-39	40-59	60 & up
Dairy (fresh milk) ^(b)	208 (99.3)	153 (123)	180 (163)	186 (167)	167 (148)	112 (96.5)	98.2 (79.4)	86.4 (66.8)	80.8 (61.7)	90.6 (70.2)
Egg	1.8	7.2	6.2	7.0	9.1	10.3	10.2	11.0	11.4	10.5
Meat	16.5	33.7	46.9	58.4	69.2	71.2	72.6	73.4	70.7	56.3
Fish	0.3	2.5	4.0	4.9	6.1	6.8	7.6	7.1	8.0	6.3
Produce	56.6	59.9	82.3	96.0	97.1	91.4	99.1	102	115	121
Grain	20.4	57.6	79.0	90.6	89.4	77.3	78.4	73.7	70.2	67.1
Beverage (tap water) ^(b)	112 (62.3)	271 (159)	314 (190)	374 (226)	453 (243)	542 (240)	559 (226)	599 (232)	632 (268)	565 (278)
Misc	2.0	9.3	13.3	14.8	13.9	10.9	11.9	12.5	13.3	13.0
TOTAL	418	594	726	832	905	922	937	965	1001	930

(a) Computed from daily intake values in grams per day provided in (EPA 1984b). The total annual intakes are rounded to nearest 1 kg/y.

(b) Fresh milk is included in the dairy entry, and tap water used for drinking is included in the beverage entry. The total annual intakes (kg/y) for fresh milk and tap water are also each given separately in parentheses.

Table D-3

DIETARY INTAKES
FOR ICRP AGE GROUPS

ICRP age group	Intake (kg)		
	annual ^(a)	280-day Ru-103	60- day I-131
3 months	418	320	69
1 year	506	387	83
5 years	660	506	109
10 years	779	597	128
15 years	869	666	143
Adult	943	723	155

(a) The annual dietary intakes for the ICRP age groups were obtained by assigning or averaging the appropriate annual dietary intakes given in Table D-2 for the EPA age groups, as follows:

3 months: <1
 1 year: average <1 and 1-4
 5 years: average 1-4 and 5-9
 10 years: average 5-9 and 10-14
 15 years: average 10-14 and 15-19
 Adult: average 15-19, 20-24, 25-29, 30-39, 40-59, 60 and up

Table D-4

PAGs AND DERIVED INTERVENTION LEVELS^(a)

(individual radionuclides, by age groups)

Radionuclide	PAG (mSv)	Derived Intervention Levels(Bq/kg)					
		3 months	1 year	5 years	10 years	15 years	Adult
Sr-90 bone srfc.	50	400	445	648	389	160	465
Sr-90	5	308	362	616	497	286	505
I-131 thyroid	50	196	167	722	1200	1690	2420
I-131	5	659	548	2410	4110	5540	8180
Cs-134	5	1600	2190	1940	1530	958	930
Cs-137	5	2000	2990	2810	2180	1370	1360
Ru-103	5	6770	8410	12200	16400	25000	28400
Ru-106	5	449	621	935	1340	2080	2360
Pu-238 bone srfc.	50	2.5	21	17	14	12	10
Pu-238	5	3.1	27	25	24	22	20
Pu-239 bone srfc.	50	2.2	18	14	13	10	9.8
Pu-239	5	2.9	24	23	21	20	18
Am-241 bone srfc.	50	2.0	17	13	11	9.1	8.8
Am-241	5	3.3	27	25	24	21	20

(a) Derived Intervention Levels were computed using dose coefficients from Table D-1, dietary intakes from Table D-3, and "f" as given below:

0.3 (except for I-131 in infant diets, i.e., the 3-month and 1-year age groups)

1.0 (I-131 in infant diets)

(b) The observed trend in Derived Intervention Levels for Sr-90 as a function of age, i.e. minimum values at 15 years, results primarily from the mass of exchangeable strontium in bone as a function of age (Leggett et al 1982).

Table D-5

DERIVED INTERVENTION LEVELS (Bq/kg)
 (individual radionuclides, by age group, most limiting of either PAG)

Radionuclide	3 months	1 year	5 years	10 years	15 years	Adult
Sr-90	308	362	616	389	160	465
I-131	196	167	722	1200	1690	2420
Cs-134	1600	2190	1940	1530	958	930
Cs-137	2000	2990	2810	2180	1370	1360
Cs group ^(a)	1800	2590	2380	1880	1160	1150
Ru-103	6770	8410	12200	16400	25000	28400
Ru-106	449	621	935	1340	2080	2360
Pu-238	2.5	21	17	14	12	10
Pu-239	2.2	18	14	13	10	9.8
Am-241	2.0	17	13	11	9.1	8.8
Pu+Am group ^(b)	2.2	19	15	13	9.6	9.3

(a) Computed as: (DIL for Cs-134 + DIL for Cs-137)/2

(b) Computed as: (DIL for Pu-238 + DIL for Pu-239 + DIL for Am-241) /3

Table D-6

DERIVED INTERVENTION LEVELS (Bq/kg)
 (radionuclide groups, most limiting of all diets)

<u>Radionuclide Group</u>	<u>Derived Intervention Levels</u>
Sr-90	160 (15 years)
I-131	170 (1 year)
Cs group	1200 (adult)
Ru-103 ^(a)	6800 (3 months)
Ru-106 ^(a)	450 (3 months)
<u>Pu + Am group</u>	<u>2 (3 months)</u>

(a) Due to the large differences 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.

APPENDIX E - DERIVED INTERVENTION LEVELS FOR OTHER RADIONUCLIDES IN THE INVENTORY OF THE CORE OF AN OPERATING NUCLEAR REACTOR

After a reactor accident, radionuclides other than the principal radionuclides may also be detected in the food supply, usually at much lower concentrations (See Appendix C). However, in the event other radionuclides are present in significant concentrations, this Appendix presents Derived Intervention Levels (DILs) for a number of other radionuclides commonly found in a reactor core inventory.

The DILs for fifteen other radionuclides were determined by the same procedure used in Appendix D. The Protective Action Guides were also the same, i.e. 5 mSv²⁰ committed effective dose equivalent, or 50 mSv committed dose equivalent to individual tissues and organs.

Age groups and their related food intakes for one year were given previously in Table D-3, Appendix D. Dietary intakes for seven of the fifteen other radionuclides that have half-lives much less than one year were computed for the periods of time (i.e. in nearest whole number of days) required for the radionuclides to decay to less than 1% of the initial activities. Table E-1 and Table E-2 give the relevant data for these seven radionuclides.

Dose coefficients for seven of the fifteen other radionuclides included in this Appendix are provided in ICRP Publication 56 (ICRP 1989) for all six age groups. For the remaining eight radionuclides, DCs are available in NRPB Publication GS7 (NRPB 1987), but for only three age groups, i.e. 1-year, 10-year and adult. The more limited data in NRPB publication GS7 are supplemented as indicated in the next section.

Fractions of food intake assumed to be contaminated (f) are:

- 0.3 for all radionuclides except Te-132, I-133 and Np-239 in infant diets (i.e., the 3-month and 1-year age groups);
- 1.0 for Te-132, I-133 and Np-239 in infant diets.

²⁰ The International System of Units is used throughout the document. See Appendix A, Glossary, for equivalence to units used in previous FDA guidance.

SELECTION OF DERIVED INTERVENTION LEVELS

The dose coefficients in ICRP Publication 56 and NRPB Publication GS7 are for individual tissues and the effective dose equivalent, as formulated in ICRP Publication 26. ICRP has also developed dose coefficients for individual tissues and the effective dose, as formulated in ICRP publication 60. These latter dose coefficients were published in ICRP Publication 67 (ICRP 1993) and ICRP 72 Publication (ICRP 1996) for all six age groups. Review of all these DCs demonstrated that the trend for relative values of DCs with age for any given radionuclide or for radionuclides with common biokinetic characteristics and half lives is similar. Therefore, DCs for the missing 3-month, 5-year, and 15-year age groups were derived for the eight radionuclides in NRPB Publication GS7, based on the trends observed in the three sets of ICRP tables. Table E-3 presents the derived DCs for these three age groups and the data from ICRP Publication 67 or 72 used in the derivations. Table E-4 gives the DCs used in computing the DILs for all fifteen radionuclides presented in Table E-5. DILs have been rounded to two significant figures (except one significant figure for Np-237 and Cm-244).

In the same manner as for the principal radionuclides in Appendix D, the most limiting Derived Intervention Level for a radionuclide for either PAG is given in Table E-6 for each age group. Then, the most limiting DIL for a radionuclide for each age group is presented in Table E-7.

During the immediate period after a nuclear reactor accident, decisions on protective actions for food may be required and may need to be based on the general status of the facility or the overall prognosis for worsening conditions. Once food monitoring data is available, the recommended DILs or criterion for the principal radionuclides I-131, Cs-134 + Cs-137, and Ru-103 + Ru-106 recommended in Table 2 of the main text should be used.

The more complex radiochemical or gamma-ray spectrometric analyses for the fifteen other radionuclides listed in this Appendix would not be generally available. If other radionuclides are subsequently detected in food, there will be adequate time to review the data on the concentrations of the other radionuclides to evaluate whether their contributions to radiation dose

via ingestion are unexpectedly high, and to determine whether additional radionuclides should be controlled by their respective DILs in Table E-7. The evaluation takes place with knowledge of the radiation dose represented by the concentrations of the principal radionuclides, which may already exceed one or more of their DILs.

Table E-1

NEAREST WHOLE NUMBER OF DAYS FOR SHORT-LIVED RADIONUCLIDES
TO HAVE DECAYED TO LESS THAN 1% OF INITIAL ACTIVITY (A_0)

Radionuclide	Half-life	Number of Days for Decay to Less Than 1% of A_0
I-133	20.8 h	6
Np-239	2.36 d	16
Te-132	3.26 d	22
Ba-140	12.7 d	85
Ce-141	32.5 d	217
Nb-95 ^(a)	35.2 d	236
Sr-89	50.5 d	336

- (a) Applies to Nb-95 existing in core inventory of an operating reactor at the time of release. Nb-95 produced as a result of decay of released parent Zr-95 is accounted for in the treatment of Zr-95.

TABLE E-2
DIETARY INTAKES

ICRP Age Group (annual intake, kg) ^(a)	Radionuclide and days ^(b) for decay to 1%						
	Sr-89 336	Nb-95 236	Ce-141 217	Ba-140 85	Te-132 22	Np-239 16	I-133 6
	Intake (kg)						
3 months (418)	385	270	249	97	25	18	6.9
1 year (506)	466	327	301	118	31	22	8.3
5 years (660)	608	427	392	154	40	29	11
10 years (779)	717	503	463	181	47	34	13
15 years (869)	799	562	517	202	52	38	14
Adult (943)	868	610	561	220	57	41	16

- (a) The annual intakes (from Table D-3) are for radionuclides which do not decay to less than 1% of initial activity within a year.
 (b) Time periods for intakes are for specified radionuclides (from Table E-1) which decay to less than 1% of the initial activity within a year.

Table E-3

DOSE COEFFICIENTS (mSv/Bq) DERIVED FOR THE 3-MONTH, 5-YEAR AND 15-YEAR AGE GROUPS^(a)
 NOT AVAILABLE IN NRPB PUBLICATION GS7, USING DATA IN ICRP PUBLICATIONS^(b)

Radionuclide ^(c)		References Used	Dose Coefficients by Age Group					
			3 months	1 year	5 years	10 years	15 years	Adult
Sr-89	HE	NRPB GS7	3.0E-05	1.5E-05	7.7E-06	5.2E-06	3.5E-06	2.2E-06
Sr-89	E	ICRP 72	3.6E-05	1.8E-05	8.9E-06	5.8E-06	4.0E-06	2.6E-06
Y-91	LLI	NRPB GS7	3.3E-04	2.1E-04	1.1E-04	7.1E-05	3.8E-05	3.0E-05
Y-91	E	ICRP 72	2.8E-05	1.8E-05	8.8E-06	5.2E-06	2.9E-06	2.4E-06
Te-132	THY	NRPB GS7	4.6E-04	2.2E-04	1.3E-04	6.0E-05	3.5E-05	1.9E-05
Te-132	THY	ICRP 67	6.2E-04	3.0E-04	1.6E-04	7.1E-05	4.6E-05	2.9E-05
I-133	THY	NRPB GS7	9.6E-04	8.6E-04	5.0E-04	2.3E-04	1.5E-04	8.3E-05
I-133	E	ICRP 72	4.9E-05	4.4E-05	2.3E-05	1.0E-05	6.8E-06	4.3E-06
Ba-140	LLI	NRPB GS7	2.1E-04	1.8E-04	9.7E-05	6.0E-05	3.1E-05	2.6E-05
Ba-140	LLI	ICRP 67	2.2E-04	1.9E-04	9.9E-05	5.7E-05	3.1E-05	2.9E-05
Ce-141	LLI	NRPB GS7	9.3E-05	6.0E-05	3.3E-05	2.0E-05	1.2E-05	8.7E-06
Ce-141	LLI	ICRP 67	9.8E-05	6.3E-05	3.2E-05	1.9E-05	1.1E-05	8.7E-06
Cm-242	BS	NRPB GS7	2.1E-02	2.6E-03	1.4E-03	8.9E-04	5.6E-04	4.5E-04
Cm-242	E	ICRP 72	5.9E-04	7.5E-05	3.9E-05	2.4E-05	1.5E-05	1.2E-05
Cm-244	ES	NRPB GS7	2.5E-01	2.5E-02	1.6E-02	1.2E-02	9.9E-03	9.8E-03
Cm-244	E	ICRP 72	2.9E-03	2.9E-04	1.9E-04	1.4E-04	1.2E-04	1.2E-04

(a) The dose coefficients (DCs) derived for age groups not available in NRPB Publication GS7 are indicated in bold font.

(b) The derived DCs were obtained by multiplying the DC for the NRPB age group contiguous to the missing NRPB age group by the following: the ratio of the DC for the desired age group to the DC of the contiguous age group, from the supporting ICRP data. When there were two contiguous age groups (i.e. for the 5-year and 15-year age groups), the two resulting DCs for the missing NRPB age groups were averaged.

(c) The dose quantity used is noted for each radionuclide. LLI is lower large intestine, THY is thyroid, BS is bone surface, H_E is effective dose equivalent, and E is effective dose.

Table E-4 DOSE COEFFICIENTS (mSv/Bq)^(a)

Radionuclides	AGE GROUP					
	3 months	1 year	5 years	10 years	15 years	Adult
Sr-89 lower large intestine	2.8E-05	1.4E-04	7.1E-05	4.8E-05	2.3E-05	2.1E-05
Sr-89	3.0E-05	1.5E-05	7.7E-06	5.2E-06	3.5E-06	2.2E-06
Y-91 lower large intestine	3.3E-04	2.1E-04	1.1E-04	7.1E-05	3.8E-05	3.0E-05
Y-91	2.8E-05	1.7E-05	8.8E-06	5.7E-06	3.1E-06	2.4E-06
Zr-95	1.0E-05	6.6E-06	3.6E-06	2.2E-06	1.4E-06	1.1E-06
Nb-95	5.2E-06	3.7E-06	2.1E-06	1.3E-06	8.6E-07	6.8E-07
Te-132 thyroid	4.6E-04	2.2E-04	1.3E-04	6.0E-05	3.5E-05	1.9E-05
Te-132	3.0E-05	1.9E-05	1.1E-05	6.4E-06	3.4E-06	2.0E-06
I-129 thyroid	3.7E-03	4.3E-03	3.5E-03	3.8E-03	2.8E-03	2.1E-03
I-129	1.1E-04	1.3E-04	1.0E-04	1.1E-04	8.4E-05	6.4E-05
I-133 thyroid	9.6E-04	8.6E-04	5.0E-04	2.3E-04	1.5E-04	8.3E-05
I-133	2.9E-05	2.6E-05	1.8E-05	7.0E-06	4.3E-06	2.5E-06
Ba-140 lower large intestine	2.1E-04	1.8E-04	9.7E-05	6.0E-05	3.1E-05	2.6E-05
Ba-140	2.5E-05	1.4E-05	7.6E-06	5.1E-06	3.7E-06	2.3E-06
Ce-141 lower large intestine	9.3E-05	6.0E-05	3.3E-05	2.0E-05	1.1E-05	8.7E-06
Ce-141	7.8E-06	4.9E-06	2.5E-06	1.6E-06	9.0E-07	7.0E-07
Ce-144 lower large intestine	7.6E-04	4.9E-04	2.4E-04	1.5E-04	8.2E-05	6.6E-05
Ce-144	8.0E-05	4.3E-05	2.1E-05	1.3E-05	7.2E-06	5.8E-06
Np-237 bone surface	1.0E-01	8.9E-03	9.3E-03	9.9E-03	1.2E-02	1.2E-02
Np-237	5.5E-03	4.9E-04	4.3E-04	4.0E-04	4.7E-04	4.5E-04
Np-239 lower large intestine	9.8E-05	6.4E-05	3.2E-05	1.9E-05	1.1E-05	8.8E-06
Np-239	9.6E-06	6.3E-06	3.2E-06	1.9E-06	1.1E-06	8.7E-07
Pu-241 bone surface	3.3E-03	3.4E-04	3.5E-04	3.9E-04	3.9E-04	3.7E-04
Pu-241	2.2E-04	2.2E-05	2.1E-05	2.0E-05	2.0E-05	1.9E-05
Cm-242 bone surface	2.1E-02	2.6E-03	1.4E-03	8.9E-04	5.6E-04	4.5E-04
Cm-242	1.4E-03	1.8E-04	9.8E-05	6.4E-05	3.8E-05	3.0E-05
Cm-244 bone surface	2.5E-01	2.5E-02	1.6E-02	1.2E-02	9.9E-03	9.8E-03
Cm-244	1.4E-02	1.4E-03	9.2E-04	6.7E-04	5.9E-04	5.4E-04

(a) When dose coefficients were available from ICRP Publication 56 (ICRP 1989), they were given for all six age groups. When dose coefficients were available only from NRPB GS7 (NRPB 1987), they were given for only three age groups (i.e. 1 year, 10 years, and adult), and derived for the other three age groups (see Table E-3). The committed effective dose equivalents or committed dose equivalents are computed to age 70 years.

TABLE E-5 PAG AND DERIVED INTERVENTION LEVELS^(a)

Radionuclide	PAG (mSv)	Derived Intervention Levels (Bq/kg)					
		3 months	1 year	5 years	10 years	15 years	Adult
Sr-89 lower large intestine	50	1600	2600	3900	4800	9100	9100
Sr-89	5	1400	2400	3600	4500	5800	8700
Y-91 lower large intestine	50	1200	1600	2300	3000	5300	5900
Y-91	5	1500	1900	2900	3800	6200	7400
Zr-95	5	4000	5000	7000	9700	14000	16000
Nb-95	5	12000	14000	19000	26000	35000	40000
Te-132 thyroid	50	4400	7300	35000	59000	89000	150000
Te-132	5	6700	8500	38000	55000	94000	150000
I-129 thyroid	50	110	76	72	56	69	84
I-129	5	360	250	250	200	230	280
I-133 thyroid	50	7600	7000	30000	56000	79000	130000
I-133	5	25000	23000	84000	180000	280000	420000
Ba-140 lower large intestine	50	8200	7900	11000	15000	27000	29000
Ba-140	5	6900	10000	14000	18000	22000	33000
Ce-141 lower large intestine	50	7200	9200	13000	18000	27000	34000
Ce-141	5	8600	11000	17000	23000	36000	43000
Ce-144 lower large intestine	50	530	670	1100	1400	2300	2700
Ce-144	5	500	770	1200	1700	2700	3100
Np-237 bone surface	50	4	37	27	22	16	15
Np-237	5	7	67	59	54	41	39
Np-239 lower large intestine	50	28000	36000	180000	260000	400000	460000
Np-239	5	29000	36000	180000	260000	400000	470000
Pu-241 bone surface	50	120	970	720	550	490	480
Pu-241	5	180	1500	1200	1100	960	930
Cm-242 bone surface	50	19	130	180	240	340	390
Cm-242	5	29	180	260	330	510	590
Cm-244 bone surface	50	2	13	16	18	19	18
Cm-244	5	3	24	27	32	33	33

(a) Derived Intervention Levels derived using dose coefficients from Table E-4, dietary intakes from Table E-2 and “F” as given below:
 0.3 (except for I-133, Te-132 and Np-239 in infant diets, i.e., the 3-month and 1-year age groups)
 1.0 for I-133, Te-132 and Np-239 in infant diets.

TABLE E-6

DERIVED INTERVENTION LEVELS (Bq/kg)

Most limiting of Derived Intervention Levels for 5 mSv H_E or 50 mSv H_T
(individual radionuclides, by age group)

Radionuclide	3 months	1 year	5 years	10 years	15 years	Adult
Sr-89	1400	2400	3600	4500	5800	8700
Y-91	1200	1600	2300	3000	5300	5900
Zr-95	4000	5000	7000	9700	14000	16000
Nb-95	12000	14000	19000	26000	35000	40000
Te-132	4400	7300	35000	55000	89000	150000
I-129	110	76	72	56	68	84
I-133	7600	7000	30000	56000	79000	130000
Ba-140	6900	7900	11000	15000	27000	29000
Ce-141	7200	9200	12000	18000	29000	34000
Ce-144	500	670	1100	1400	2300	2700
Np-237	4	37	27	22	16	15
Np-239	28000	36000	180000	260000	400000	460000
Pu-241	120	970	720	550	490	480
Cm-242	19	130	180	240	340	390
Cm-244	2	13	16	18	19	18

TABLE E-7

DERIVED INTERVENTION LEVELS (Bq/kg)

(radionuclide groups, most limiting of all diets)

Radionuclide Group	Derived Intervention Level	
Sr-89	1400	(3 months)
Y-91	1200	(3 months)
Zr-95	4000	(3 months)
Nb-95	12000	(3 months)
Te-132	4400	(3 months)
I-129	56	(10 years)
I-133	7000	(1 year)
Ba-140	6900	(3 months)
Ce-141	7200	(3 months)
Ce-144	500	(3 months)
Np-237	4	(3 months)
Np-239	28000	(3 months)
Pu-241	120	(3 months)
Cm-242	19	(3 months)
Cm-244	2	(3 months)

APPENDIX F - DERIVED INTERVENTION LEVELS ADOPTED BY THE COMMISSION OF THE EUROPEAN COMMUNITIES AND THE CODEX ALIMENTARIUS COMMISSION FOR INTERNATIONAL TRADE

Foods exported from the U.S. are subject to the criteria used by the importing country, such as the recommendations of the CODEX Alimentarius Commission (CODEX) or the regulations of the Commission of the European Communities (CEC). CODEX is operated by the Joint Food Standards Programme of the Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO). CODEX develops and recommends standards and other guidance which are widely used in international trade. CEC regulations govern trade within the European Economic Community (EEC) and between the EEC and other countries. U.S. food exporters need to be familiar with the guidance from these organizations.

A discussion of CEC and CODEX Derived Intervention Levels (DILs)²¹ is given below to provide insight into their differences.

(a) Commission of The European Communities: DILs for Future Accidents

The CEC adopted regulations in 1987 and 1989, establishing DILs for human food and animal feeds following a nuclear accident or any other case of radiological emergency (CEC 1987, 1989a, 1989b). These were established for use following any future accident and do not apply to residual contamination from the accident at Chernobyl. DILs addressing radioactive contamination from the Chernobyl accident were adopted by the CEC in 1986 (CEC 1986b).

The DILs for foods contaminated by future accidents are presented in Table F-1. DILs were given for four radionuclide groups and four food categories. The radionuclide groups include: isotopes of strontium, notably Sr-90; isotopes of iodine, notably I-131; alpha-emitting isotopes of

²¹ The International System of Units is used throughout the document. See Appendix A, Glossary, for equivalence to units used in previous FDA guidance.

plutonium and transplutonium elements, notably Pu-239 and Am-241; and all other radionuclides of half-life greater than 10 days, notably Cs-134 and Cs-137. For each group, CEC specified DILs for four food categories: baby foods, dairy produce, other food except minor food, and liquid foods.

Baby foods were defined as “foodstuffs intended for the feeding of infants during the first four to six months of life, ... and are put up for sale in packages which are clearly identified and labeled food preparation for infants”. Dairy produce, liquid food, and minor foods were defined by reference to specific CEC regulations and nomenclature. Liquid foods included tap water and the CEC stated the “same values should be applied to drinking water supplies at the discretion of competent authorities of member states”. Dried products referred to the products as prepared for consumption. Dilution factors were not specified and the CEC permitted member states to specify the dilution conditions.

DILs for minor foods such as spices were established, in a separate regulation, at ten times the DILs specified for “other foods” (CEC 1989a). Each DIL is to be applied independently. However, for each radionuclide group, the concentrations within the group are to be added when more than one radionuclide is present. The DILs are to be reviewed within three months following an accident to determine if they should be continued.

(b) CODEX Alimentarius Commission: DILs for Use in International Trade

CODEX adopted guidance in 1989 establishing DILs for food contaminated with radionuclides. The CODEX DILs were issued as guideline levels following an accidental nuclear contamination event (CODEX 1989). The guidance was developed from earlier publications of FAO (FAO 1987, Lupien and Randall 1988) and WHO (Waight 1988, WHO 1988). The DILs are presented in Table F-2. They were given for several radionuclide groups categorized by the magnitude of their dose coefficients and two food groups.

The food groups are milk and infant foods and foods destined for general consumption. CODEX defined infant food as a food prepared specifically for consumption by infants in the first year of

life and stated that such foods are packaged and identified as being for this purpose (CODEX 1989). The radionuclides were grouped according to the magnitude of their dose coefficients (DCs). The specific groupings differed for the two food groups. CODEX listed representative radionuclides for each DC group. CODEX guidelines were not restricted to these radionuclides; any radionuclide can be placed into the appropriate DC group.

CODEX DILs apply for one year following a nuclear accident. They are intended to be applied to food prepared for consumption. Each DIL is to be applied independently. However, for each, the concentrations within the group are to be added. No guidance is provided for foods which are consumed in small quantities, although CODEX stated that application of the DILs to products of this type may be unnecessarily restrictive (CODEX 1989).

Table F-1
DILs ADOPTED BY CEC FOR FUTURE ACCIDENTS^(a) (CEC 1989b)

Radionuclide Group	Derived Intervention Levels(Bq/kg)			
	Baby Foods	Dairy Produce	Other except minor foods	Liquids
Isotopes of strontium, notably Sr-90	75	125	750	125
Isotopes of iodine, notably I-131	150	500	2000	500
Alpha-emitting isotopes of Pu and transplutonium elements, notably Pu-239, Am-241	1	20	80	20
All other radionuclides of half-life greater than 10 days, notably Cs-134, Cs-137	400	1000	1250	1000

(a) Do not apply to residual contamination from the accident at Chernobyl.

Table F-2
DIL VALUES RECOMMENDED BY CODEX (CODEX 1989)

FOODS DESTINED FOR GENERAL CONSUMPTION		
Approximate Dose Coefficient (Sv/Bq)	Representative Radionuclides	DIL (Bq/kg)
10^{-6}	Am-241, Pu-239	10
10^{-7}	Sr-90	100
10^{-8}	I-131, Cs-134, Cs-137	1000

MILK AND INFANT FOODS		
Approximate Dose Coefficient (Sv/Bq)	Representative Radionuclides	DIL (Bq/kg)
10^{-5}	Am-241, Pu-239	1
10^{-7}	I-131, Sr-90	100
10^{-8}	Cs-134, Cs-137	1000

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