

Application of FDA Food Contamination Protective Action Guidelines for MSL

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FDA Provides Guidance for Addressing Contaminated Food

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

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The food of concern for MSL is primarily produce, including leafy vegetables such as spinach and lettuce



FDA Derived Intervention Levels (DILs)

- ***A DIL is the concentration of a radionuclide in food at which point protective actions should be considered***
 - ***For MSL, ^{238}Pu is the driving radionuclide***
 - ***FDA Guidance specifically addresses ^{238}Pu food contamination due to an accident involving an RTG***
- **DILs are based on the assumption that contaminated food is eaten during the first year after an accident**
 - **Addressing food contamination is a lower priority during the Emergency Phase (~ first 4 days)**
- **DILs are based on the most limiting population and dose to the most sensitive organ/organ system**
 - **For ^{238}Pu , the most sensitive population is three-month old infants**
 - **Dose to surface bone is the most limiting organ**
- **DILs assume no intervention**



FDA Ingestion Protective Action Guides (PAGs)

	Dose Construct	Qualifier
5 mSv (0.5 rem)	70-year CEDE	Whichever is more limiting
50 mSv (5 rem)	70-year CDE to individual organ	

CEDE = Committed Effective Dose Equivalent

CDE = Committed Dose Equivalent



Basic formula for computing a DIL

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

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).

For ^{238}Pu , $f = 0.3$



Dose Coefficients from FDA 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.



Annual Dietary Intake from FDA 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	208	153	180	186	167	112	98.2	86.4	80.8	90.6
(fresh milk) ^(b)	(99.3)	(123)	(153)	(167)	(148)	(96.5)	(79.4)	(66.8)	(61.7)	(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	112	271	314	374	453	542	559	599	632	565
(tap water) ^(b)	(62.3)	(159)	(190)	(226)	(243)	(240)	(226)	(232)	(268)	
	(278)									
Misc	2.0	9.3	13.3	14.8	13.9	10.9	11.9	12.5	13.3	13.0
TOTAL ANNUAL INTAKE, (kg/y)	418	594	726	832	905	922	937	965	1001	930

Note: To calculate a DIL, FDA uses the TOTAL diet, not just the applicable food class



The FDA DIL for ^{238}Pu is 2.5 Bq/kg

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

$$\begin{aligned} \text{DIL (Bq/kg)} &= \frac{50 \text{ (mSv)}}{0.3 \times 418 \text{ (kg)} \times 0.16 \text{ (mSv/Bq)}} \\ &= 2.5 \text{ Bq/kg (6.8 E-05 uCi/kg)} \end{aligned}$$



The DIL for ^{238}Pu will increase by a factor of 2.4 when the revised EPA PAG manual is approved

Current EPA Dose Conversion Factor:

$$\begin{aligned} \text{DIL (Bq/kg)} &= \frac{50 \text{ (mSv)}}{0.3 \times 418 \text{ (kg)} \times 0.16 \text{ (mSv/Bq)}} \\ &= 2.5 \text{ Bq/kg (6.8 E-05 uCi/kg)} \end{aligned}$$

Proposed EPA Dose Conversion Factor **(Using the new ICRP 60 DCFs)**

$$\begin{aligned} \text{DIL (Bq/kg)} &= \frac{50 \text{ (mSv)}}{0.3 \times 418 \text{ (kg)} \times 0.068 \text{ (mSv/Bq)}} \\ &= 5.9 \text{ Bq/kg (1.6 E-04 uCi/kg)} \end{aligned}$$

It will be advantageous to MSL to seek FDA's pre-approval to use the revised FDA DCFs



FRMAC uses a Derived Response Level (DRL) to determine the deposition contour value associated with the FDA DIL

$$\text{DRL} = \frac{\text{DIL} * Y}{R} \text{ , Bq/m}^2$$

where:

DRL = Derived Response Level for Ingestion (Bq/m²)

DIL_i = Derived Intervention Level (Bq/kg)

Y = Crop yield (kg/m²)

R = Crop retention factor = the fraction of deposited material that is retained by the edible portion of the crop



The FRMAC DRL for ^{238}Pu

$$\text{DRL} = \frac{\text{DIL} * Y}{R} \text{ , } \underline{\text{Bq/m}^2}$$

$$\text{DRL} = \frac{(2.5 \underline{\text{Bq/kg}}) (2 \text{ kg/m}^2)}{0.2}$$

$$= 2.5 \text{ E } +01 \underline{\text{Bq/m}^2}$$

$$= 6.8\text{E-}04 \text{ } \underline{\mu\text{Ci/m}^2}$$

**Based on the new EPA PAG Manual,
the DRL would increase to $1.6 \text{ E-}03 \text{ } \mu\text{Ci/m}^2$**



Conclusions

- FDA DILs are used to address potential ingestion dose during the first year after the incident
- Addressing food contamination is a lower priority during the Emergency Phase (~ first 4 days)

- **Summary of FRMAC DRLs:**

$$\text{DRL}_{\text{Current}} = 0.00068 \text{ } \mu\text{Ci}/\text{m}^2$$

$$\text{DRL}_{\text{Proposed}} = 0.0016 \text{ } \mu\text{Ci}/\text{m}^2$$

- **Measurement Limit of Sensitivity (LOS):**

$$\text{LOS}_{\text{FIDLER}} = 0.05 \text{ } \mu\text{Ci}/\text{m}^2$$

$$\text{LOS}_{\text{ECAM}} = 0.00008 \text{ } \mu\text{Ci}/\text{m}^2 \text{ (calculated*)}$$

FIDLER = Field Instrument for the Detection of Low Energy Radiation

ECAM = Environmental Continuous Air Monitor

$$\begin{aligned} * \text{LOS}_{\text{ECAM}} &= 0.002 \text{ rem} = (0.002 \text{ rem} \times 0.003 \text{ m/s}) / (4.17 \text{ E-}04 \text{ m}^3/\text{s} \times 1.71 \text{ E+}08 \text{ rem/Ci}) \\ &= 8.4 \text{ E-}11 \text{ Ci}/\text{m}^2 = 0.00008 \text{ uCi}/\text{m}^2 \end{aligned}$$

