How does FDA approach the issue of radionuclide contamination of food?
Outline

assets
process (risk analysis)
guidance
a misconception
update
greatest technical assets - people

**Regional**
- George Allen
- Rachael Evans
- Scotty Hargrave
- Terri Jones
- Jeff Sincek
- Karen Smallwood

**Headquarters**
- Mike Noska
- Pat Hansen
- Bill Cunningham
- Dave Anderson
- Paul South

**Analytical**
- Michael Casey
- Kelly Garnick
- Deborah Gillis-Landrum
- Joseph Hagan
- Shayne Harrel
- Stephanie Healey
- Zhichao Lin
- Eileen Maher
- Anne Raymond
- Stephen Schayer
- Thomas Scott
- Zhongyu Wu
- Cong Wei
- Pam Mackill
Regional
day-to-day operations typically conducted through these people
FDA's Emergency Operations Center (EOC)

( Emergency 1-866-300-4374 )

"When activated, the FDA's EOC serves as the Agency-wide focal point for emergency operations, coordination and communications ... "

technical questions to headquarters
typically fielded by Mike Noska, Bill Cunningham
Winchester Engineering and Analytical Center (WEAC)

US Food & Drug Administration
109 Holton Street Winchester, MA 01890
Phone Number: 781-756-9700

analytical questions fielded by Cong Wei, Pam Mackill
Outline

assets

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 a misconception

 update
in the international food safety community

DECISION MAKING is to be:

risk-based
science-based
transparent
consistent
in the international food safety community

DECISION MAKING is to be:

- risk-based
- science-based
- transparent
- consistent

(to rely on data, facts, scientific principles)
(to address fundamental issue (health risk))

(so people can understand & know what to expect)
in the international food safety community

DECISION MAKING is to be:

- risk-based
- science-based
- transparent
- consistent

(to address fundamental issue (health risk))

(to so people can understand & know what to expect)

(to rely on data, facts, scientific principles)

but also accounts for:

- social / cultural aspects
- local-national-international factors
FDA Center for Food Safety and Applied Nutrition (CFSAN) Approach – Consistent with CODEX Framework
RISK ANALYSIS

- Risk Management
  - monitor, evaluate, decide, act

- Risk Communication
  - motivate & involve all ‘stakeholders’

- Risk Assessment
  - collect & study data & information
RISK ASSESSMENT

a process (not a conclusion)

tells us what we know and how well we know it

answers 4 key questions:

what can go wrong?
how likely is it to occur?
what are the consequences?
what factors can influence it?
Components of Risk Assessment

Hazard

Exposure

Risk
What radionuclide(s)?

Consumption data

Contaminant level

How likely an adverse effect?

Probability of occurrence?

Options?
Outline

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FDA Guidance for Radionuclides in Food


for food, universally accepted as the basis for radiological risk analysis
Extremely conservative

(but)

Decision makers have great flexibility

(but)

Unlikely that deviation from conservative will be warranted
1982 (FDA)
Projected dose commitment values to individuals in the general population that warrant protective action.

1992 (EPA)
The projected dose to reference man, or other defined individual, . . . at which a specific protective action . . . is recommended.
Radioactivity 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.
The risk analysis process is considered "flexible"

What does this mean for radionuclides in food?
CFSAN’s Risk Management Framework

Triggers & Inputs

Prioritization -> Process -> Decision -> Implementation

Monitor/ Evaluate/ Modify

Outcome
the projected dose . . . at which a specific protective action to reduce or avoid that dose is recommended

The PAGs are not legally binding regulations or standards and do not supersede any environmental laws; they are not intended to define “safe” or “unsafe” levels of exposure or contamination. Rather, they define the projected radiation doses at which specific actions may be warranted in order to reduce or avoid that dose. The PAG Manual provides flexibility to be more or less restrictive as deemed appropriate by decision makers based on the unique characteristics of the incident and the local situation.
Excerpts from FDA Guidance (1998)

"This document is intended to provide guidance. It represents the Agency’s current thinking . . . 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. . .

(food) 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"
(The DILs) are not binding on FDA, the regulated industry, or the courts. In any given case, FDA may decide to initiate an enforcement action against food with concentrations below the DILs or decide not to initiate an enforcement action against food with concentrations that meet or exceed the DILs.”
Why MUST we be "flexible"?

many variables (all interrelated)

involves highly-technical details

many don't understand the technical lingo

logistics, opinions, perception,

overlapping jurisdictions, etc.
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)
strict adherence to procedure used in FDA Guidance

FDA DILs

OGT Guidelines\(^1\)

FRMAC Assessment Products \(\big\{\)

only difference - newer dosimetry

inclusion of environmental factors and chemistry

DOE DIL for Tritium\(^2\)

accounted for environmental half-life

tritium mix (oxide and organically-bound)

conversion between the two forms

\(^1\) Preliminary Report on Operational Guidelines Developed for Use in Emergency Preparedness and Response to a Radiological Dispersal Device Incident (2009)

\(^2\) Guidance on Deriving Intervention Levels for Tritium Contaminated Crops and Animal Feed for DOE Emergency planning and Response Activities, for exercises at Savannah River Site (2006)
FDA's approach for dealing with radiological food safety issues is therefore:

a conservative (but broad-scope and flexible) process for applying Federal radiological Guidance
Outline

assets
process (risk analysis)
guidance

- a misconception
update
- A core RISK COMMUNICATION issue -

misunderstanding radionuclides in food
## CONTRASTING TYPES of "PROBLEMS"

<table>
<thead>
<tr>
<th></th>
<th>acute &amp; life-threatening</th>
<th>chronic with uncertain outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>exposure</strong></td>
<td>an event</td>
<td>years of exposure</td>
</tr>
<tr>
<td><strong>onset</strong></td>
<td>symptoms quickly</td>
<td>may get cancer in distant future</td>
</tr>
<tr>
<td><strong>need</strong></td>
<td>immediate</td>
<td>on-going</td>
</tr>
<tr>
<td><strong>examples</strong></td>
<td>salmonella, poisoning</td>
<td>UV-a/b exposure, cholesterol</td>
</tr>
</tbody>
</table>
Several ways to represent a DIL value

- unacceptable
- questionable
- no concern

benchmark
generic value
default level
screening value
level of concern
DIL

early phase
- an immediate option
- as information comes in
- adjust later, if needed
considered a late phase option

protective but without added conservatism

typically considered appropriate for extreme cases with food shortage
Regulatory Options

- Technical arguments favor protection with as few restrictions as possible ("more realistic")

- Emotional arguments favor added conservatism ("reality")

unacceptable

acceptable
FDA Guidance

Extremely conservative

(but)

Decision makers have great flexibility

(but)

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update - sample analysis

- guidance
recent attention — options worth considering to augment sample throughput

use appropriate LOD/LOQ

screening via analysis of pooled-samples
use appropriate LOD/LOQ

shift analysis protocol from research to compliance

10% uncertainty at DIL is more than adequate

shorten count time, reduce analysis mass
for example

**Cs-137**

LOD ~ 0.1 Bq/kg  
DIL 1,200 Bq/kg  
count time typically 1+ hour → 10-min count sufficient

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**Sr-90**

LOD ~ 0.1 Bq/kg  
DIL 160 Bq/kg  
typically 100 grams analyzed → 4 grams sufficient
screening via pooled samples

combine equal portions from n samples

"screening level" equal to DIL / n

if result < screening level, all samples < DIL

further, all levels known to be ≤ result times n

( exact levels for individual samples unknown )
Example - Equal portions from 5 samples combined for a single pooled analysis. If analysis result is below 1/5 of the DIL, then all samples must be below the DIL.
Example, Sr-90

typical

100 grams
LOD ~ 0.1 Bq/kg
DIL 160 Bq/kg

pooled analysis, n=10

10g/each combined from 10 samples
screening level 160/10 = 16 Bq/kg

e.g.

2 Bq/kg result means all <20 Bq/kg
- or -
<LOD result means all <1 Bq/kg
Status Update

revision of existing guidance
- and/or -
development of new guidance