

## Document Log Item

### Addressing

**From**

Stuart Walker/DC/USEPA/US

**To**

Charles Openchowski/DC/USEPA/US@EPA

**CC****BCC**

### Description

**Subject**

Most recent PAG comments - focus on water and food

**Date/Time**

01/23/2009 12:08 PM

**# of Attachments**

9

**Total Bytes**

291,188

**NPM****Contributor**

Charles Openchowski

### Processing

**Comments** Clear Category Non-responsive☐ Printed

## Document Body

My last set of comments on the ORIA PAG. These only focus on the water and food stuff since we had been told to not keep making criticisms of the other portions

--- Forwarded by Stuart Walker/DC/USEPA/US on 01/23/2009 11:19 AM ---

From: Stuart Walker/DC/USEPA/US  
To: Sara DeCair/DC/USEPA/US@EPA  
Cc: Doug Ammon/DC/USEPA/US@EPA, Colby Stanton/DC/USEPA/US@EPA, Elizabeth Southerland/DC/USEPA/US@EPA, Juan Reyes/DC/USEPA/US@EPA  
Date: 05/15/2007 06:04 PM  
Subject: Re: ACTION REQ'D: Five-week review of PAG Manual

Hi Sara,

Thanks for providing us an opportunity to review the latest draft of the ORIA PAGs. OSRTI does not have any showstoppers. We request that you let us review a redline/strikeout-version of the next draft after you incorporate comments from the workgroup.

Since, this is the first draft of the ORIA PAG to include concentrations for the drinking water and food interdiction PAGs, we are submitting revised substantive comments on both those PAGs from our comments on the last draft. Our comments on both the drinking water and food interdiction PAGs include a comparison of the PAG concentrations to risk based concentrations, and in the case of the drinking water PAGs, MCLs. These comparisons are similar to the comments I sent Ed Tupin 3-4-2004 on an early draft of the water PAGs.



OSRTI comment on ORIA PAGs April 2007 v1.doc

Below is further explanation of the analysis discussed in the comments on the water and food PAGs.

## Water PAGs

### *Chronic effects*

I put together 3 Lotus 123 Tables comparing ORIA's PAG concentrations to MCLs and concentrations corresponding to a  $1 \times 10^{-4}$  cancer risk. I used MCLs and  $10^{-4}$  since these are measures EPA utilizes when making decisions about providing bottled water during emergencies involving class A carcinogens. I noticed that a number of the ORIA PAG concentrations are thousands of times higher than the MCLs or  $1 \times 10^{-4}$  (a few are over a hundred thousand times higher). This is not evident without looking at the concentrations since the MCL for most radionuclides is 4 mrem/yr and the PAG is 500 mrem/yr. However, I understand that different science may have something to do with it since the MCL is based on ICRP 2 methodology and the PAG is ICRP 60/72 methodology, however the  $1 \times 10^{-4}$  risk based concentrations are also based on ICRP 60/72.

Here is an explanation of the comparison tables I put together on the water PAGs and the 3 tables themselves.



2007ExplainCompareTables.pdf



2007CompareTable\_byRisk.123



2007CompareTable\_byMCL.123



2007CompareTable\_byRad.123

### *Subchronic effects*

It also appears that drinking water at the PAG concentrations for Te-129 and Te-127 may lead to subchronic (acute) effects acute following exposures of a day or a week. In a population, one should see some express of acute effects (not deaths) above 0.25 Gy (25 rad) - that is, vomiting, fever etc. The Te-129 absorbed dose at 1 week was 1.8 Gy (180 rad) for 14 L intake. For these two radionuclides, an acute radiation syndrome (ARS) involving the GI-tract is indicated. Acute dose coefficients for a 30 d period were calculated for the adult using the AcutDose. This analysis focused only on the 16 radionuclides where drinking water at the PAG concentration for 1 week or less would exceed the amount of radioactivity received from drinking a  $1 \times 10^{-4}$  cancer risk level assuming 70 years of exposure.

## Food PAGs

I also put together 3 Lotus 123 Tables comparing ORIA's food PAG concentrations that were adopted from FDA to concentrations corresponding to a  $1 \times 10^{-4}$  cancer risk. I used  $10^{-4}$  since the food interdiction situation is somewhat analogous to the decision of when to provide drinking water. I noticed that some of the ORIA PAG concentrations are hundreds, even thousands of times higher than the MCLs or  $1 \times 10^{-4}$ .

Here is an explanation of the comparison tables I put together on the food PAGs and the 3 tables themselves.



2007ExplainCompareFOODTables.pdf



2007CompareFoodTable\_convertPRG.123



2007CompareFoodTable.123



2007CompareFoodTable\_byRad.123

Sara DeCair/DC/USEPA/US

Sara DeCair/DC/USEPA/US

04/10/2007 10:26 AM

To Andrew.Wallo@eh.doe.gov, cymw6@cdc.gov,  
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pxs@cdrh.fda.gov, stanton.colby@epa.gov, Sara



## COMMENT FORM

Point of Contact (name/phone number/email): Stuart Walker/USEPA - OSRT/703-603-8748/walker.stuart@epa.gov

Page #	Line #	Comment Type	Comment
GEN			We have no Critical comments on the April 2007 draft. We are making several substantive comments, either new comments or revisions of previous comments due to our ability to evaluate the concentration tables in version of the draft PAGs. We would also suggest you send around a final redline/strikeout version to see if there are any objections to any of the revised language.
4-1 to 4-8		Substantive	<p>We realize that this issue was decided for the DHS RDD/IND PAG Federal Register notice, however we are making this comment because this ORIA document covers a wider scope of response actions and this draft of the ORIA document includes radionuclide concentrations corresponding to the PAG.</p> <p>The 500 mrem/yr Drinking Water PAG should be deleted or replaced with EPA CERCLA Removal Action Level (RAL) concentrations. OSWER Directive 9360.1-02 "Final Guidance on Numeric Removal Action Levels for Contaminated Drinking Water Sites" recommends providing alternative drinking water supplies during CERCLA removal actions when water is contaminated above a concentration corresponding to the MCL or <math>1 \times 10^{-4}</math> cancer risk using EPA's Office of Water methodology (e.g., 70 period of exposure and cancer morbidity), whichever allows the greater concentration. In general, a 500 mrem/yr drinking water PAG would correspond to a risk of <math>2.01 \times 10^{-2}</math> cancer mortality risk using 70 period of exposure, suggesting the PAG would allow the public to drink water at concentrations 200 times greater than EPA's guidance for emergency removals. However, for most of the radionuclides the PAG would be much more than 200 times the RAL, and up to 765,000 times greater for one radionuclide. The PAGs are up to 7.65 million times greater than the MLC. Providing alternative drinking water in the intermediate phase should not be that difficult, the government has been doing it at sites and disaster areas for years. Please see attached analysis comparing ORIA drinking water PAGs to RAL (<math>1 \times 10^{-4}</math> and MCL) concentrations.</p> <p>Also, for two of the ORIA Drinking Water PAG concentrations it appears that ingestion of the water may result in greater than 25 Rad absorbed dose, resulting in subchronic effects such as vomiting and fever.</p>

Page #	Line #	Comment Type	Comment
5-1 to 5-17		Substantive	<p>We realize that this issue was decided for the DHS RDD/IND PAG Federal Register notice, however we are making this comment because this ORIA document covers a wider scope of response actions and this draft of the ORIA document includes radionuclide concentrations corresponding to the PAG.</p> <p>The 500 mrem/yr Food Interdiction PAG based on FDA DILs should be deleted or replaced with a protective value similar to EPA RALs such as <math>1 \times 10^{-4}</math> concentrations over 70 years. In general, a 500 mrem/yr Food Interdiction PAG would correspond to a risk of <math>4.23 \times 10^{-4}</math> cancer morbidity risk for each year of exposure for members of public who would have this contaminated food shipped out to them, a risk of <math>2.01 \times 10^{-2}</math> cancer mortality risk using 70 period of exposure. This could greatly expand the population dose as a result of the WMD incident if the public accepted the food, and potentially damage the uncontaminated agricultural industry in that region if the public becomes alarmed that radioactive food is being shipped around the country. Considering the food surplus in this country, the document should not use such a high dose number as a starting point. In addition, FDA DILs only apply during first year of an accident, starting with the early phase (see pg. 8 of "Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies, August 13, 1998). In general, a 500 mrem/yr food PAG would correspond to a risk of <math>2.01 \times 10^{-2}</math> cancer mortality risk using 70 period of exposure, suggesting the PAG would allow the public to ingest food at concentrations 200 times greater than EPA's guidance for drinking water during emergency removals. OSRTI's analysis of FDA DILs with concentrations corresponding to <math>1 \times 10^{-4}</math> indicate that the DILs are generally tens or hundreds of times higher than the <math>10^{-4}</math> concentrations, and in a few instances thousands of times higher. In a few other instances, they are actually lower. Please see attached analysis comparing FDA food PAGs to RAL-like (<math>1 \times 10^{-4}</math>) concentrations.</p>

### PROCEDURES FOR COMPLETING THE COMMENT FORM

1. In the Page #, and Line # columns, insert the relevant page and line number(s) pertaining to the comment.  
**Note:** For general comments that do not correspond to a specific page number, place the word 'GEN' under the page # column.
2. In the Comment Type column, indicate whether the comment is Critical, Substantive, or Administrative in nature. If Critical comments are not incorporated, you will be informed as to the reason for the decision.

3. In the Comment column, place only one comment per row, and provide comment, recommendation (specific language) and rationale. Because of the short timeframe for incorporation of comments, only specific language suggestions (deletions, additions, or changes) will be considered.