Hi Sara,

Thanks for providing us an opportunity to review the latest draft of the ORIA PAGs. CRSTI 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 PAGsApril2007v1.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 x 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 x 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 x 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.

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 day 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 x 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 x 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 x 10^{-4}.

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

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04/10/2007 10:26 AM

To Andrew.Wallo@eh.doe.gov, ormw6@cdc.gov, cym3@cdc.gov, Kenneth.Wierman@eha.gov, man@cdrh.fda.gov, psm@nrc.gov, paul.nelson@ctra.mil, pxs@cdrh.fda.gov, stanton.colby@epa.gov, Sara
PROCEDURES FOR COMPLETING THE COMMENT FORM

<table>
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<th>Comment</th>
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| [Incorporated, you will be informed as to the reason for the decision. In the Comment Type column, indicate whether the comment is Critical, Substantive, or Administrative in nature. If Critical comments are not noted, for General comments that do not correspond to a specific page number, place the word "GEN" under the page # column. In the Type # and Line # columns, insert the relevant page and line number(s) pertaining to the comment.]

1. (X) "10" (Commentary) Industry, they are actually lower. Please see attached exhibit(s) comparing PDA from PAG 10 PAG 10.
   - However, higher than the FPA of 10,000 calories, and in few instances, the PDA of hundreds of times.
   - The effect of the PDA to be considered are generally for PDA and PDA, the effect of the PDA to be considered are generally for PDA and PDA.

2. [Note: For General comments that do not correspond to a specific page number, place the word "GEN" under the page # column.]
   - In the Page # and Line # columns, insert the relevant page and line number(s) pertaining to the comment.

3. [5-17] 10

4. [5-17] 10

5. [5-17] 10