Responses to Major Comments on Technical Support Document

Public Health Goal
For
Strontium-90
In Drinking Water

Prepared by

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INTRODUCTION

The following are the combined responses to major comments received by the Office of Environmental Health Hazard Assessment (OEHHA) on the public health goal (PHG) technical support document for strontium-90, based on the pre-release review draft. Changes have already been made in response to these comments, and have been incorporated into the final document version posted on the OEHHA website. For the sake of brevity, we have selected the more important or representative comments for responses. Comments appear in quotation marks where they are directly quoted from the submission; paraphrased comments are in italics.

These comments and responses are provided in the spirit of the open dialogue among scientists that is part of the process under Health and Safety Code Section 57003. For further information about the PHG process or to obtain copies of PHG documents, visit the OEHHA Web site at www.oehha.ca.gov. OEHHA may also be contacted at:

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RESPONSES TO MAJOR COMMENTS RECEIVED

Comments from University of California, San Diego

Comment 1: "The document is both detailed and scientifically state of the art. The calculations are done competently. I have some recommendations to improve on the text."

Response 1: Minor editorial changes were recommended, and most were accepted as recommended. However, a recommendation to alter the format of the document was considered, but not applied.

Comments from University of California, Davis

Comment 1: "The information presented on toxicity, toxicokinetics, metabolism mode(s) of action and exposure, and potential for carcinogenicity was accurate and comprehensive."

Response 1: No changes are needed.

Comment 2: *OEHHA chose not to use the carcinogenicity studies conducted in animals for draft PHG determination, but used rather the U.S. EPA (1999) cancer coefficients. The authors should state that this document and its references should be reviewed for a more in-depth understanding of radiation carcinogenic data and mechanisms.*

Response 2: We strive to use the most applicable basis for estimating carcinogenic risks to humans. In this case, the U.S. EPA (1999) cancer coefficients are based on human cancer data and incorporate sophisticated methods to estimate relevant exposures (lifetime for drinking water) and susceptibility. We have added a statement like that suggested.

Comment 3: "It would be helpful to address whether the *de minimis* risk for this radionuclide is consistent with the *de minimis* lifetime cancer risk for chemical carcinogens that have PHGs and MCLs for drinking water. This apparently arbitrarily chosen *de minimis* cancer risk is the one (but extremely important) variable in their equation that needs to be scrutinized thoroughly."

Response 3: OEHHA has used a *de minimis* cancer risk of 1×10^{-6} for development of PHGs for carcinogens since the inception of the drinking water risk assessment program. This is now stated in the Risk Characterization section. The approach was intended as an alternative to the U.S. EPA use of zero as the acceptable level for exposure to carcinogens in development of maximum contaminant level goals (MCLGs), which is the

federal counterpart to the California PHG program. It was felt that there was adequate legal precedent for declaring a one in a million risk to be below the level of regulatory significance. Higher risk levels used in regulatory programs tend to be based on risk/benefit or cost and feasibility considerations, whereas PHGs are by law based only on consideration of public health. For perspective, we also provide the concentration (or pCi/L) values for risk levels of 10^{-4} and 10^{-5} in our PHG documents. We have added a statement about the uniform use of a 10^{-6} risk level for PHGs based on carcinogenicity to the strontium document.

Comment 4: "Note that two statements in the text were somewhat inaccurate by inferring that the method used to determine the PHG followed the U.S. EPA's guidance or practices. … These statements were considered somewhat inaccurate or inappropriate because they infer that their following of the U.S. EPA guidance/practices produced the Cal/EPA proposed PHG. The [U.S. EPA] guidance does not support use of a *de minimis* lifetime cancer risk of 10^{-6} for drinking water."

Response 4: The discussion has been modified along the lines suggested in handwritten comments to make clear that the cancer risk determination was carried out according to U.S. EPA guidelines, whereas the recommended health-protective levels were the result of OEHHA decisions based on health-protective considerations. Following U.S. EPA guidance in developing the health-protective level would result in a PHG of zero, comparable to the MCLG.

Comment 5: "More specific data is needed on the levels of ^{90}Sr already found in California drinking water supplies."

Response 5: The support document notes one instance of a measurable occurrence of ^{90}Sr in California public drinking water supplies, which is based on extensive data available from regular ground-water monitoring carried out by municipal water suppliers.

Comments from U.S. EPA's Radiation and Protection Division

Comment 1: "Provide additional background information on the purpose of the PHGs, and their relationship to the USEPA maximum contaminant level goals (MCLGs)."

Response 1: The purpose of the PHGs is discussed in the document's Preface, and some additional perspective has been added to the Introduction, as discussed in response to the comments above. The authorizing legislation for PHGs is similar to that for MCLGs, and the intent of the risk assessments to estimate health-protective levels for chemicals in drinking water is the same, except that U.S. EPA uses the value of zero for MCLGs, rather than a specific *de minimis* risk level for exposure to carcinogens in drinking water.

Comment 2: *Recommended using only one convention for expressing radioactivity units and provide conversion factors separately.*

Response 2: OEHHA feels that providing two conventions for units is more user-friendly, because most readers will not be familiar with radioactivity measurements.

Comment 3. "Ensure that the *general* discussions on radiation exposures, doses, and potential human health effects are identical in all three documents. Use the current ICRP Publication 60 definitions for absorbed dose, equivalent dose, and effective equivalent dose, and consult UNSCEAR 2000 for summary information on radiation-related health effects."

Response 3. Every effort will be made to ensure consistency across the three radionuclide PHG documents (radium, strontium, and tritium) that are being finalized at the same time. We have considered the suggested references, and decided to retain the existing definitions and descriptions to maintain consistency with the U.S. EPA source documents. We thank the commenter for pointing out these important references.

Comments from U.S. EPA's Office of Water

Comment 1: "It would be useful to know how [the Relative Source Contribution factor (RSC) for strontium was] derived. Just giving these numbers, does not convey much information. Also, EPA does not use RSC for calculating health-based numbers for chemicals listed as carcinogens. RSC is only used for non-carcinogenic chemicals."

Response 1: The source and manner in which the RSC is derived is stated in the section titled "Calculation of PHG/Noncarcinogenic Effects. In the PHG program, an RSC is used only for estimating health-protective levels for non-cancer effects of chemicals.

Comment 2: "The noncarcinogenic health-based concentrations are calculated for both a 1-year old child (10 kg) and an adult (70 kg) for chronic exposures for the two radium compounds and tritium; the Sr-90 noncarcinogenic concentration was calculated only for the adult. No rationale was given for not calculating the concentration for a child; would be useful to see why that was not done."

Response 2: Health-based concentrations are calculated for children under particular circumstances, usually when subchronic toxicity values suggest a unique sensitivity for children, which when carried out through a risk calculation results in more conservative or similar risk estimates when compared with chronic (lifetime) risk estimates. In this case, the chronic toxicity was by far the most sensitive indicator of risk to strontium-90. Because the non-cancer health-protective value is based on chronic exposure, it is not necessary or appropriate to compute a specific child risk value.

Comment 3: "In the section on Calculation of PHG, Noncarcinogenic Effects, in the first para you list the doses as 0, 0.02, 0.07, 0.44, 1.33 etc. Then in the same para, in the last sentence you go on to say, The NOAEL of 0.044 μCi/day. You need to check which dose is correct, 0.44 or 0.044?"

Response 3: The dose range is expressed as μCi/day (per dog). Since the dogs weigh on the average of 10 kg, the dose expressed later in the paragraph per kg-day is ten-fold lower. This is clarified by mentioning calculation of dose based on the dogs' weights.

Comment 4: "In the Reference Section, the second U.S. EPA reference should be changed to U.S. EPA (1996). This is when the IRIS evaluated this chemical last."

Response 4: The date provided indicates when the IRIS database was searched and as such indicates the Agency's policy by that date. This was clarified by inserting the statement in the reference "Last Revised -- 12/01/1996."

Comments from the U.S. Department of Energy (William Holman)

Comment 1: *Strontium-90 in the environment is all man-made, and radioactive decay ($t_{1/2}$ 29 years) ensures that exposure will not be constant over a lifetime, so the exposure scenario presented (constant exposure over a 70-year lifetime) is a highly unlikely assumption.*

Response 1: It is true that any individual ingesting strontium from drinking water is unlikely to receive this contaminant at a constant dose rate for their entire life. It is also true for most of the other contaminants for which PHGs have been or will be developed. The assumption of constant dose rate for a lifetime of exposure is a risk assessment convention employed by OEHHA and other risk assessment agencies as a health-protective criterion. No change was made in response to this comment.

Comments from the Committee to Bridge the Gap (Daniel Hirsch, President)

Comment 1: "The draft PHGs do not appear to adequately address these issues of sensitive populations, as required by the California Safe Drinking Water Act. … In particular, however, there is no consideration of increased risks of older adults."

Response 1: The PHG document presents the information regarding the toxicity of strontium reported in the scientific literature. No particular sensitivity to older individuals has been noted for this chemical, although some suggestion of increased sensitivity to other types of radiation has been noted in other studies. The health-based cancer coefficient values developed by the U.S. EPA represent the state of the art in estimating cancer risk and take into account the unique sensitivity of various human populations including the elderly.

Comment 2: "The TSDs [technical support documents] at times treat the various assumptions leading, step by step, to their risk estimates as those these were absolute values rather than somewhat controversial estimates with substantial uncertainties associated with them. To get to a risk estimate, numerous steps are required, and the

uncertainties about each increase when taken together. … It is not clear that the resulting PHGs are appropriately conservative, given these large uncertainties."

Response 2: We acknowledge the presence of large uncertainties in our assumptions and calculations. However, our position has been to use health-protective estimates, which in acknowledging the uncertainty are highly unlikely to underestimate the risks - for which we have been criticized by other reviewers. It should be noted that all available information is considered in our risk characterizations. A substantial body of information exists on the carcinogenic effects of radionuclides on human subjects. In addition, several agencies have developed and are refining models to estimate the effects of human body exposures to radionuclides, which have added to the certainty of these estimations. OEHHA considers the U.S. EPA cancer potency estimates for radioactive compounds to be the most appropriate health-protective values presently available on which to base the proposed PHG values.

Comment 3: "Failure to consider biological and epidemiological factors that might result in higher risks than presumed."

Response 3: OEHHA has selected the current U.S. EPA potency estimates as presented in Federal Guidance Report 13 as the most relevant and comprehensive approach available and is based on accumulated and validated knowledge regarding radiation to date. We acknowledge that there is a wide disparity of opinions on the extant of radiation risks.

Comment 4: "The TSDs end with a listing of radiation standards from different agencies. However, the choice of the standards included is weighted toward the more lax standards in existence... Other standards that are more protective have been left out. … Furthermore, if one is to include such a table, one should discuss the contradiction between the risk levels associated with many radiation standards and those considered acceptable for all other carcinogens – many radiation standards carry with them associated risk levels far outside the acceptable risk range for chemical carcinogens."

Response 4: A range of standards is shown; no attempt was made to present only "lax" standards in the table of regulatory standards and criteria. The numbers are there for information and perspective, and should not be considered as a complete compilation of radiation exposure criteria values. OEHHA feels that the large disparity between the PHG values based on a 10^{-6} risk level and the federal and state MCLs is an adequate reminder of the theoretical risk involved, if drinking water were to contain the radionuclides at the MCL levels.

Comment 5: "The TSDs simply use EPA Federal Radiation Guidance document with no consideration whether other risk estimates are more appropriate and no consideration of the numerous studies showing it understates true risks. A series of relatively recent studies all demonstrate radiation risks about an order of magnitude greater than that assumed in the TSDs. These include the Hanford, Oak Ridge, and SSFL studies

mentioned above, and the Canadian Radiation Workers study, among others. The draft PHGs may thus be too lax by an order of magnitude or more."

Response 5: In the development of our public-health protective concentrations, an extensive literature search was done, pertinent articles were reviewed, and all arguments judged to be relevant were considered. The decision to utilize the U.S. EPA radiation guidance was not taken lightly, and we acknowledge the strong opinions on both sides of the issues (too lax versus too strict). However, we feel that the risk coefficients and assumptions used in Federal Guidance Report No. 13 (U.S. EPA, 1999) are adequately health-protective and the most defensible at this time. OEHHA therefore considers the public-health protective concentration to be appropriate.

Comment 6: "The overall cancer mortality and morbidity risks from a rad appear questionable, in that they assume morbidity rates only 50% higher than mortality rates, when generally there is 1 fatal cancer for every non fatal one."

Response 6: The Federal Guidance Report No. 13 (U.S. EPA, 1999) provides morbidity and mortality rates for specific cancers and an overall rate. The ratios of morbidity to mortality vary widely, based on the observed survivability for each type of cancer.

REFERENCES

U.S. EPA (1999). Cancer Risk Coefficients for Environmental Exposures to Radionuclides. Federal Guidance Report No. 13, EPA 402-R-99-001. U.S. Environmental Protection Agency, Washington, DC. September 1999. http://www.epa.gov/radiation/federal/docs/fgr13.pdf.