Responses to Major Comments on Technical Support Document

Public Health Goal
For
Tritium
In Drinking Water

Prepared by

Pesticide and Environmental Toxicology Branch
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency

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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 tritium, based on the pre-release review draft. Changes have already been made in response to these comments, and have been incorporated into the final 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 used for chemical carcinogens that have PHGs or 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: Choice of the *de minimis* risk level of one in one million for carcinogenic risk determinations reflects the policy instituted by OEHHA from the very beginning of the program for development of PHGs for chemicals in drinking water. We acknowledge in the support document that this was a health-protective policy decision, and we agree that other programs have used different *de minimis* levels. For example, the federal program for establishment of MCLs based on maximum contaminant level goals (MCLGs) for carcinogens uses a concentration of zero (and thus zero risk) by U.S. EPA

policy. The federal MCL legislation is very similar to California's Safe Drinking Water Act, in that both statutes require MCLs to be set as close as feasible to the values determined in the risk assessment (zero for the MCLG, a 10^{-6} risk level for the PHG). Therefore, while we agree that setting the PHGs at a 10^{-6} risk level was a policy decision, it is not an unusually restrictive one. 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 tritium 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 Federal Guidance Report 13. … These statements were considered somewhat inaccurate or inappropriate because they infer that their following of this U.S. EPA guidance report's "practices" produced the Cal/EPA proposed PHG. The [U.S. EPA] guidance report 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 an OEHHA policy decision. Following U.S. EPA guidance in developing the health-protective level would result in a PHG of zero, comparable to the MCLG.

Comment from the University of California, Los Angeles

Comment 1: "In general the information on toxicity, carcinogenesis teratogenicity and other health effects is comprehensively and accurately reviewed. The major problem with this document is, however, that none of this information is used to set the PHG."

Response 1: This document does examine and use the experimental (animal) data when appropriate, i.e., in development of a non-cancer health-protective level. However, for addressing the carcinogenic endpoint, the available animal data do not demonstrate conclusively the carcinogenic potential of tritium even at high doses. Thus cancer potency modeling cannot be carried out using the available tritium data.

Comment 2: "In fact, just for our own information, we used the data for the mouse carcinogenicity experiment (Balonov 1993) and obtained a figure (see below) which is roughly half the current MCL (see below)." *A calculation is provided based on one of the tumor types in the Balonov report, which applies a linear extrapolation to a dose associated with 10^{-6} risk in rats, corrects to human body weight and drinking water consumption, and divides by 100 for variability between rats and humans.*

Response 2: The approach taken by the commenter to determine a cancer risk-based protective concentration is not based on standard practice, nor is it consistent with our cancer risk assessment methods. Balonov *et al.* (1993) simply does not provide adequate information to develop a cancer potency factor. To calculate a cancer potency factor,

tumor rates in dosed animals must be compared with control animals. Furthermore, human carcinogenic potency-based health protective concentrations are not determined by applying a 100-fold uncertainty factor to an animal potency estimate based on a one in a million risk.

Comments from U.S. Environmental Protection Agency, 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 background for the PHG program is discussed in the document's Preface. While some additional perspective has been added to the Introduction, as discussed in response to the comments above, a more extensive discussion of the U.S. EPA's program seems outside the scope of the document. Basically, the authorizing legislation is similar for both programs, 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 also provide conversions.*

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 this 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.

Comment 4: *Incorporate editorial changes.*

Response 4: Most of these editorial comments have been incorporated except for rewriting of the first sentence on page 18, *Carcinogenic Effects* to " For tritium, the direct evidence for carcinogenicity in humans is limited." This section refers to weight of evidence for carcinogenicity from experimental studies only, not to direct evidence, which does not exist for humans.

Comments from U.S. Environmental Protection Agency, Office of Water

Comment 1: "It would be useful to know how these RSCs were 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 RSC was only used to calculate our public-health protective concentration for the non-carcinogen effects. The RSC was based on assumed distribution of tritium into the ecosystem after a large environmental release; actual releases vary, and the relative sources contribution is highly uncertain. An explanation is provided in the text to reflect how the RSC was derived, but it should be noted that this is based on professional judgment, not a precise calculation.

Comment 2: "Please explain what 'HTO' stands for?"

Response 2: HTO (monotritiated water) is defined on page 4, *Physical and Chemical Properties*, first paragraph, and again at the start of the Toxicology section on page 11.

Comment 3: "The second line after table 8 is 'k' before 'g' to read 'kg'

Response 3: The correct designation is "g."

Comment 4: *Page 23, second paragraph, replace*, "No additional assumptions are needed with respect to the use of RSC for tritium." *with* "Relative Source Contribution is not calculated for carcinogenic effects."

Response 4: Although it is true that Relative Source Contribution is not applied to carcinogenic potencies to derive water-specific risk guidance values, nevertheless, the follow up sentence states, "The U.S. EPA's risk value is specific for ingestion of tritium in the form of water." Thus the cancer potency already takes into account drinking water only exposures. We have modified this concluding sentence for additional clarity to the following: "The U.S. EPA's risk value is specific for the intake of tritium from drinking water only."

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

Comment 1: "The proposed drinking water PHG of 400 pCi/L for tritium presumes a constant dose rate for 70 years. You neglect tritium's relatively short half-life of 12.33 years; over 70 years, tritium's radioactivity will decline 50-fold to only 2% of its original value. This is salient because virtually all significant tritium contamination in California is from past or batch releases to the environment, so it decays away without

replenishment." *Since it is unlikely that emissions of tritium released into the environment would be periodic or consistent, the 70-year exposure assumption seems an unlikely assumption.*

Response 1: It is true that any individual ingesting tritium 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.

Comment 2: "Because tritium is chemically inseparable from water, the only practical "treatment" for tritium contamination is to isolate it from potential consumers. Thus an MCL based upon a PHG set too low simply denies Californians a portion of their water supply. These are serious consequences, yet the admittedly conventional dose-response function you've used is essentially arbitrary, for there is no compelling evidence either for or against health effects at such low activities. Your proposed PHG corresponds to an incremental lifetime dose of 0.01 mSv. I've attached a study that detected cytogenetic changes, but no health effects, in residents exposed to far greater incremental doses averaging 18 mSv/year for up to ten years; statistically, it was inconclusive with respect to cancers."

Response 2: We thank the commenter for submitting this article for our review. However, we believe it is more appropriate to retain the approach in Federal Guidance Report No. 13 for tritium. The energy level of tritium decay is incorporated into the potency model used by U.S. EPA, and it is based on a wide variety of human data. The regulatory concentration for tritium derived by the California DHS, using, in part, the OEHHA risk assessment, will consider technical and economic feasibility, whereas the PHG can be based only on public health considerations.

Comments from Lawrence Berkeley National Laboratory (Linnea Wahl)

Comment 1: "The document's logic is inconsistent and fundamentally flawed. The document's authors reviewed the literature and 'found no epidemiological studies of tritium ingestion causing cancer in humans' (p 16). They state that 'it appears unlikely that tritium in the environment from present sources would produce detectable effects' (p. 16); nonetheless, the authors have based their recommendations on the risk of cancer, which is not supported by the scientific evidence. The public health goals should not be based on the risk of cancer; they should be based instead on noncarcinogenic effects of tritium exposure, which have been established by scientific studies."

Response 1: As the commenter states, OEHHA has noted that there are no scientific studies for tritium that associate an increase of cancer incidence with exposure. However, prevailing scientific opinion, including that of U.S. EPA and other entities concerned with health risks of radioactive exposure, hold to the view that all forms of ionizing radiation have the potential to cause cancer. Thus, we need to assume tritium

increases the risk of cancer, and use cancer potencies to determine a health-protective water-borne tritium concentration.

Comment 2: *Monitoring data cited from a report on emissions from the Lawrence Berkeley Tritium Labeling Facility were incorrectly presented, do not reflect the current situation at the lab environs, and may be misinterpreted.*

Response 2: OEHHA presented data out of a report to illustrate that tritium occurrences in the environment are associated with production or use facilities. No intention was made to isolate the Berkeley facility as a more notable case over other such facilities. The commenter does not establish that OEHHA has actually misstated any of the data presented. OEHHA has added a statement that tritium-labeling activities have ceased at the Berkeley facility.

Comment 3: "The report states that tritium can accumulate in biota (p. 4); however, this is not supported by research."

Response 3: We did not wish to suggest that tritium is biomagnified in the food chain. The wording was changed to say 'bioconcentration,' which suggests an enhancement of tritium levels in water-retaining plants when compared to other forms of biota.

Comment 4: "The statement on page 7 that 'Okada and Momoshima (1993) estimated the amount of tritium intake through food to be about 4.2 Bq/day' is misleading. This estimate is for a family of 5 or 6 people, not for a single person."

Response 4: The document has been revised to make that clear.

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

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. There is a brief mention that the US EPA Federal Radiation Guidance document takes into account in some unspecified fashion effects at younger ages, but there is no examination of whether the factors employed are appropriate. In particular, however, there is no consideration of increased risks of older adults."

Response 1: The PHG document summarizes what is known regarding the toxicity of tritium as reported in the scientific literature. 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, insofar as possible. With regard to tritium effects on older individuals including animals, no particular sensitivity to older individuals has been noted in any studies examined.

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 conservative estimates, that 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 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 recommendations as presented in Federal Guidance Report 13 as the most relevant and comprehensive approach available. 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 PHGs 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 draft TSD presumes a very short biological half-life for tritium in the human body, based on the assumption that it behaves as water and is flushed out of the

system quickly. However, some of the tritium exchanges with regular hydrogen in the body and is bonded and remains in the body for long periods of time."

Comment 5: The PHG support document clearly states that there are three pools for tritium, one being a longer lasting pool reflecting incorporation of tritium into biological molecules.

Comment 6: "The draft TSD also appears to assume that the only mechanism of carcinogenesis from tritium is from exposure of tissue to the relatively weak beta emission from decaying tritium. However, there is an additional mechanism that should be considered. When tritium is incorporated into DNA, replacing a regular hydrogen atom, the decay of the tritium atom to helium can result in the breaking of the DNA bond. This is not factored into the tritium risk assessment."

Response 6: Cancer associated with radiation exposure has long been assumed to be due to disruption of DNA integrity. Radiation can probably affect other cellular mechanisms to cause cancer as well. All these processes are taken into account by using the cancer potency factors that were derived on the basis of exposure and observed/presumed outcomes.

Comment 7: "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 non-fatal cancer for every fatal one."

Response 7: In Federal Guidance Report No. 13 (U.S. EPA, 1999), U.S. EPA 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

Balonov MI, Muksinova KN, Mushkacheva GS (1993). Tritium radiological effects in mammals: review of experience of the last decade in Russia. Health Physics 65(6):713-726.

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.