PUBLIC NOTICE

Initiation of Process to Develop/Update Public Health Goals in Drinking Water and Request for Relevant Information: 1,4-Dioxane and n-Nitrosodimethylamine

Office of Environmental Health Hazard Assessment
California Environmental Protection Agency

March 27, 2020

Public Health Goals (PHGs) are concentrations of contaminants in drinking water that pose no significant acute or chronic health risks. The Office of Environmental Health Hazard Assessment (OEHHA) establishes PHGs, which are used as the health basis for the development of California's primary drinking water standards (Maximum Contaminant Levels or MCLs). OEHHA also reviews and updates existing PHGs. This public notice announces the initiation of PHG development for 1,4-dioxane and of an update of the PHG for n-nitrosodimethylamine (NDMA).

Development of PHGs for these chemicals is being initiated at the request of the State Water Resources Control Board (SWRCB). 1,4-Dioxane currently has a notification level[1] (NL) of 1 µg/L or 1 part per billion (ppb) based on cancer risk.[2] A PHG of 0.003 ppb for NDMA was established in 2006, also based on cancer risk. The PHG analyses will incorporate relevant new data and methodologies. OEHHA is requesting information on these contaminants that could assist in conducting the risk assessments and in calculating the PHGs.

All information submitted to OEHHA in response to this request is considered public. Please do not submit proprietary information. In order to be considered during the PHG development or update process, **OEHHA must receive information by Monday, April 27, 2020. Electronic submission of information via OEHHA's website (https://oehha.ca.gov/comments) is encouraged.** Information submitted in paper form may be mailed or delivered in person to the address below:

Pesticide and Environmental Toxicology Branch
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency
P.O. Box 4010, MS-12B
Sacramento, California 95812-4010

Attention: PHG Program

[1] A notification level is a non-regulatory, health-based advisory level that SWRCB establishes as a precautionary measure for a contaminant for which a regulatory standard has not been set. Certain requirements are triggered when a chemical is detected at levels that exceed its respective notification level.
[2] https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/14-Dioxane.html

If you have any questions, please contact Hermelinda Jimenez at (916) 324-7572 or email PHG.Program@oehha.ca.gov.

All relevant information will be considered in developing/updating the PHGs for these chemicals. SWRCB will use the final risk assessments in the development/review of California regulatory MCLs for these chemicals. For more information on this process, go to the SWRCB website.

Background on the PHG Program

The Calderon-Sher California Safe Drinking Water Act of 1996 (Health and Safety Code section 116365), hereafter referred to as the Act, requires OEHHA to post a notice on its website when it initiates work to develop or update PHGs. PHGs are concentrations of chemicals in drinking water that are not anticipated to produce adverse health effects. OEHHA is required to consider potential adverse effects on members of sensitive subgroups of the population, including infants, children, pregnant women, the elderly, and individuals with a history of serious illness.

PHGs are non-regulatory in nature but are used as the health basis for SWRCB to establish or update the state's primary drinking water standards or MCLs. The Act requires OEHHA to develop PHGs for the approximately 100 chemicals that have either state or federal MCLs. The Act states that OEHHA shall review these PHGs every five years and update them as appropriate unless there has not been a detection of the corresponding contaminant in the preceding five years. SWRCB may also ask OEHHA to develop a PHG for a contaminant that it wishes to regulate through the adoption of a California MCL.

At the initial posting of a draft document, OEHHA provides a 45-day public comment period. OEHHA also conducts a public workshop to receive public comments and engage in dialogue with interested parties on the draft document. An external scientific peer review is then conducted as required by Health and Safety Code section 57004(b). OEHHA considers all relevant comments in the preparation of the second draft, which is posted for a 30-day public comment period. After consideration of any additional comments, the PHG is finalized and posted on the OEHHA website for public reference and for use by SWRCB in developing or reviewing California MCLs.

All PHGs and their supporting documents are available on OEHHA's website.

Program priorities for 2020

In addition to initiating PHGs for 1,4-dioxane and NDMA, OEHHA’s drinking water priorities for 2020 include:

- Haloacetic acids PHGs: A public review draft was released in January 2020, initiating a public comment period currently scheduled to close May 1. A public

workshop had been scheduled for March 26 but is being rescheduled due to the COVID-19 virus emergency.

- PFOA and PFOS PHGs: OEHHA announced the initiation of PHG assessments for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS) in October 2019. OEHHA is working on a public review draft of the PHG assessments.

- PFAS notification levels: In February 2020, SWRCB asked OEHHA to develop recommended notification levels for seven per- and polyfluoroalkyl substances (PFAS)[3] that have been detected in California drinking water supplies. OEHHA is beginning work on these notification level recommendations.

PHGs recently completed

PHGs for trihalomethanes (bromoform, chloroform, bromodichloromethane,and dibromochloromethane) were finalized on February 7, 2020. Updated PHGs for cis-and trans-1,2-dichloroethylene were finalized on July 20, 2018 and for nitrate and nitrite on May 11, 2018.

Descriptions of 1,4-Dioxane and n-Nitrosodimethylamine

1,4-DIOXANE

1,4-Dioxane (Chemical Abstracts Service (CAS) Registry Number 123-91-1) is a volatile compound, typically used as a stabilizer for chlorinated solvents. It is used as a solvent for a number of products such as paints, resins, varnishes, fumigants and dyes. It can also be found as a contaminant in some cleaning and personal care products.

1,4-dioxane was listed by California's Proposition 65 program as a carcinogen in 1988. A NL of 3 ppb was established for 1,4-dioxane in 1998 based on a one-in-one-million cancer risk. The value was derived from the cancer potency for combined hepatocellular adenomas and carcinomas in female B3C6F1 mice (NCI, 1978), in concordance with US EPA's risk assessment (US EPA, 1990). In 2010, US EPA revised its assessment such that a one-in-one-million cancer risk would correspond to 0.35 ppb and as a result, the NL was revised to 1 ppb.

Although public water systems are not required to monitor 1,4-dioxane, systems that have done so voluntarily have reported numerous detections above the NL in the last five years,[4] with the highest measurement at 32 ppb. OEHHA will conduct a risk assessment for 1,4-dioxane and establish a PHG in response to the request by

[3] perfluorohexane sulfonic acid (PFHxS), perfluorobutane sulfonic acid (PFBS), perfluorohexanoic acid (PFHxA), perfluoroheptanoic acid (PFHpA), perfluorononanoic acid (PFNA), perfluorodecanoic acid (PFDA), and 4,8-dioxia-3H-perfluorononanoic acid (ADONA).
[4] Drinking water analyses reported directly from laboratories, data from January 1, 2015 through February 17, 2020. https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/EDTlibrary.html

SWRCB. OEHHA will evaluate toxicological literature since the publication of the NL and apply updated risk assessment methodologies.

Selected References

Gi M, Fujioka M, Kakehashi A, Okuno T, Masumura K, Nohmi T, Matsumoto M, Omori M, Wanibuchi H, Fukushima S (2018). In vivo positive mutagenicity of 1,4-dioxane and quantitative analysis of its mutagenicity and carcinogenicity in rats. Arch Toxicol 92: 3207-3221.

Kano H, Umeda Y, Kasai T, Sasaki T, Matsumoto M, Yamazaki K, Nagano K, Arito H, Fukushima S (2009). Carcinogenicity studies of 1,4-dioxane administered in drinking-water to rats and mice for 2 years. Food Chem Toxicol 47: 2776-2784. http://dx.doi.org/10.1016/j.fct.2009.08.012.

Kano H, Umeda Y, Saito M, Senoh H, Ohbayashi H, Aiso S, Yamazaki K, Nagano K, Fukushima S (2008). Thirteen-week oral toxicity of 1,4- dioxane in rats and mice. J Toxicol Sci 33: 141-153. http://dx.doi.org/10.2131/jts.33.141.

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U.S. EPA (1990). 1,4-Dioxane. In: Integrated Risk Information System (IRIS). Last revision dates for carcinogenicity assessment: September 1, 1990. Washington, D.C.: IRIS, United States Environmental Protection Agency.

N-NITROSODIMETHYLAMINE

n-Nitrosodimethylamine (NDMA; CAS No. 62-75-9), also known as dimethylnitrosamine, is a chemical formed in both industrial and natural processes. It is a byproduct of water treatment and is also created from nitrates and nitrites in the human gastrointestinal tract. Studies in experimental animals showed that NDMA is an animal carcinogen. It is also considered a likely human carcinogen (NTP, 2016; WHO, 2008) and was listed by California's Proposition 65 program as a carcinogen in 1987.

OEHHA published a PHG of 0.003 ppb for NDMA in 2006 (OEHHA, 2006) based on bile duct tumors induced in female rats by oral administration of NDMA (Peto et al, 1991a and 1991b). SWRCB established 0.01 ppb[5] as the NDMA NL, which is a health-based advisory level for chemicals in drinking water that lack maximum contaminant levels (MCLs).

[5] https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/NDMA.html

NDMA is not currently produced or commercially used in the United States. Within the last five years, there have been numerous detections of NDMA in California public drinking water supply wells above the NL of 0.01 ppb.[6] The update of the risk assessment for NDMA will consider the toxicology literature since the publication of the PHG in 2006 and will incorporate the application of updated risk assessment methodologies.

Selected References

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Larsson SC, Bergkvist L, Wolk A (2006). Processed meat consumption, dietary nitrosamines and stomach cancer risk in a cohort of Swedish women. Int J Cancer 119:915-919.

NTP (2016). Report on Carcinogens, Fourteenth Edition. National Toxicology Program, US Department of Health and Human Services, Public Health Service, Research Triangle Park, NC. Accessed at: https://ntp.niehs.nih.gov/whatwestudy/assessments/cancer/roc/index.html?utm_source=direct&utm_medium=prod&utm_campaign=ntpgolinks&utm_term=roc

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[6] Drinking water analyses reported directly from laboratories, data from January 1, 2015 through February 17, 2020. https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/EDTlibrary.html

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