

Office of Environmental Health Hazard Assessment



Winston H. Hickox
Agency Secretary

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Gray Davis
Governor

September 12, 2003

CLIENT'S COPY

Mr. Daniel M. Fuchs
Mr. James M. Mattesich
Livingston & Mattesich
1201 K Street, Suite 1100
Sacramento, California 95814

LIVINGSTON & MATTESICH
Addressed to DANIEL M. FUCHS
Received: 9-15-03
by Mail ☒ Fax/E-mail ☐ Courier ☐ Hand
Tackle: _____ Calr: _____
Copy to ☒ Client ☐ Other: _____
9-17-03

Dear Messrs. Fuchs and Mattesich:

This letter is written in response to your request on May 30, 2003, for an interpretive guideline pursuant to Title 22, California Code of Regulations (CCR), Section 12203. More specifically, you requested that the Office of Environmental Health Hazard Assessment (OEHHA) issue an interpretive guideline that "the appropriate 'alternative risk level' for bromate in bottled water under 22 California Code of Regulations section 12703(b) is 1×10^{-4} ."

You also made a related request for OEHHA to issue an interpretive guideline stating that the application of the alternative risk level provision in Section 12703(b) can be applied to the ozonation of bottled water. On July 24, 2003, OEHHA issued a letter granting that request. However, our letter of July 24, 2003, said, "Nor do we mean to imply that we are necessarily in agreement with the notion that OEHHA has the authority to set such an alternative risk level by means of an interpretive guideline pursuant to Title 22, California Code of Regulations, Section 12203." Your current request asks OEHHA to set the alternative risk level for bromate in bottled water as a result of ozonation—by means of an interpretive guideline.

The principal reason OEHHA cannot grant such a request is that the setting of a specific risk level for a listed chemical that would have regulatory status must be accomplished by the adoption of a regulation under the Administrative Procedure Act (Government Code Section 11340 et seq., "APA"). Specifically, Section 11340.5(a) of the APA prohibits the enforceability of certain actions of a State agency unless those actions were taken pursuant to the APA. It provides as follows: "No state agency shall issue, utilize, enforce, or attempt to enforce any *guideline*, criterion, bulletin, manual, instruction, order, standard of general application, or *other rule* which is a regulation as defined in Section 11342.600, unless the guideline, criterion, bulletin, manual, instruction, order, standard of general application, or other rule has been adopted as a regulation and filed with the Secretary of State pursuant to [the APA]." (Emphasis added.) Section 11342.600, in turn, defines a "regulation" as follows: "... every rule, regulation, order, or *standard of general application* or the amendment, supplement, or revision of any rule, regulation, order, or standard adopted by any state agency to *implement, interpret, or make specific the law enforced or administered by it*, or to govern its procedures." (Emphasis added.)

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Examination of the relevant law regarding these principles and application to the case at hand causes us to conclude that adoption of a specific binding regulatory standard for the acceptable risk level posed by bromate in bottled water that does not necessitate a warning under Proposition 65 is a "regulation" as defined by the APA.

In *Grier v. Kizer* (1990, 219 Cal. App. 3d 442), the court upheld a two-part test employed by the Office of Administrative Law for determining whether a challenged rule is a "regulation" for purposes of the APA. Essentially, for our purposes here (1) if the rule or standard is one of general application and (2) it is adopted by the agency to implement, interpret, or make specific the law enforced or administered by the agency, then it is a regulation and must be adopted as such. (Id.) A rule need not apply to all citizens of the state to be regarded as a rule of general application. Rather, it must simply apply to all members of a class, kind, or order (*Roth v. Department of Veteran Affairs* (1980) 110 Cal. App. 3d 622). In the case of your request, the specification of a risk level that would have regulatory consequences would apply to all bottlers, distributors, and retailers of bottled water and would not be specific to an individual entity or fact specific to that entity. The second prong is even more clearly met in this case. That is, the setting of a specific numerical alternative risk level by OEHHA for bromate in bottled water would be done in OEHHA's capacity as lead agency for the implementation of Proposition 65. (See Health and Safety Code Section 25249.12 and Executive Order W-15-91.)

In addition, it should be noted that the setting of an alternative risk level for a given chemical is quite similar to the setting of no significant risk levels (NSRLs) that OEHHA promulgates for various chemicals listed under Proposition 65 as known to the state to cause cancer (Title 22, CCR, Section 12705). In fact, the word "alternative" in the term "alternative risk levels" is in reference to NSRLs that are set at a 1×10^{-5} risk level. All of these NSRLs issued by OEHHA are adopted as regulations for the reasons set forth above. That is, they are rules of general application and are being adopted by OEHHA in its capacity as lead agency for the implementation of Proposition 65. While it may be true that the request here is for a risk level specific to a given medium, the request, or the standard if promulgated, would still be one of "general application." That is, it would still apply to all members of the affected class dealing with bottled water, as described above. Again, this is analogous to NSRLs adopted as regulations by OEHHA that are specific to a certain route of exposure (e.g., arsenic and cadmium), or medium (e.g. formaldehyde).

In the interest of clarity and comprehensiveness, OEHHA has concluded that because it lacks the authority to set an alternative risk level by means of an interpretive guideline, OEHHA has not delved into all of the technical material supporting such a request. By denying this request, OEHHA is not speaking to what the alternative risk level should be if one were to be established; nor is OEHHA indicating that the materials submitted by the requester support the

establishment of a 1×10^{-4} level, or any other level. We simply did not consider these issues because of our determination that we could not grant such a request.

Lastly, we are willing to consider the merits of developing a regulation that specifies an alternative risk level for bromate in bottled water. If you feel a regulation would be desirable and would like to discuss this further, please let me know. However, I must advise you that severe budget constraints currently affecting OEHHA and state government in general could delay the development of a regulation until more resources are available.

If you have any questions or would like to discuss the possibility of the development of an OEHHA regulation, please contact me at (916) 324-2831.

Sincerely,

A handwritten signature in black ink, appearing to read "Val F. Siebal", written in a cursive style.

Val F. Siebal
Chief Deputy Director

cc: Joan E. Denton, Ph.D.
Director