UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 28 2004

OFFICE OF
RESEARCH AND DEVELOPMENT

Mr. David A. Smith
2210 E. Marconi
Phoenix, AZ 85022

Re: Response to Request for Correction (RFC) of documents that present bromate in all forms as carcinogenic pursuant to United States Environmental Protection Agency (U.S. EPA) and Office of Management and Budget (OMB) Information Quality Guidelines (RFC#12385)

Dear Mr. Smith:

This is in response to your July 21, 2003, Request for Correction (IQG# 12385) concerning ten U.S. EPA web sites you identified that refer to bromate as a likely human carcinogen. In your Request for Correction, you state that documents on certain EPA web sites (e.g., http://www.epa.gov/iris/subst/1002.htm) are misleading or incorrect as to the carcinogenicity of "bromate," and you request that EPA correct these documents because "claims against bromate being a carcinogen are unfounded." EPA issued its IQGs to ensure and maximize the quality, including objectivity, of information disseminated by the Agency. "Objectivity" involves a focus on ensuring accurate, reliable, and unbiased information (U.S. EPA, 2002). You state that the characterization of bromate as carcinogenic in any form other than potassium bromate is not accurate because studies that have used sodium bromate have not found mutagenic activity, nor have they provided evidence that sodium bromate is a carcinogen. EPA has analyzed the available scientific data and has characterized bromate as a likely human carcinogen. There is no evidence to suggest that any of the soluble salt forms of this chemical would behave differently. Therefore, EPA believes that its characterization of bromate as a likely human carcinogen is in conformance with the EPA Information Quality Guidelines.

In 2001, EPA developed a health assessment of bromate for the Integrated Risk Information System (IRIS) which characterizes this chemical as a likely human carcinogen. IRIS is an EPA data base of human health assessments for various chemicals found in the environment (http://www.epa.gov/iris). The bromate assessment was reviewed by three external scientific experts and by representatives from the Agency's various Program and Regional Offices. The bromate assessment represents the Agency's consensus opinion on health effects associated with exposure to this chemical. EPA's assessment of the carcinogenic potential of bromate is supported by the International Programme on Chemical Safety, which determined that bromate causes an increase of tumors in experimental animal models (WHO, 2000), and Health Canada which classified bromate as probably carcinogenic to humans (1999).

In your Request for Correction, you disagree with EPA's designation of bromate as a likely human carcinogen because the studies which most clearly demonstrate the carcinogenic potential of bromate were conducted by administering potassium bromate in drinking water (Kurokawa et al., 1986a, 1986b; DeAngelo et al., 1998). The results from these studies can be generalized to the bromate ion and its soluble salt forms because the water solubility of potassium bromate at room temperature (25°C) is approximately 75000 mg/L (WHO, 1999), and the highest concentration of potassium bromate used in the cancer bioassays was 800 mg/L. Thus, the potassium bromate in these solutions would have completely disassociated into potassium and bromate ions. Moreover, potassium is an essential element and the recommended daily requirement for rodents is substantially greater than what the animals were exposed to in the cancer bioassays (NRC, 1995). Consumption of an essential element within the range of recommended dietary concentrations would not be expected to produce toxic effects.

Considering the solubility of potassium bromate and that potassium is an essential element, the increased incidence of cancer observed in the rodent bioassays is, therefore, presumed to be due to free bromate ions. Furthermore, the mutagenic potential of both potassium and sodium bromate has recently been demonstrated *in vitro*. Harrington-Brock et al. (2003) compared the mutagenic potentials of sodium bromate and potassium bromate using the mouse lymphoma cell assay. The study found no difference in the mutagenic activity of these two bromate salts indicating they are both equally potent clastogenic mutagens. This information was not available when the IRIS assessment was prepared, but further supports the conclusion that bromate and the soluble salt forms of this ion are likely to be carcinogenic to humans.

EPA has determined that your Request for Correction fails to demonstrate that EPA was inaccurate in its characterization of bromate as a likely human carcinogen. If you are dissatisfied with this decision, you may submit a Request for Reconsideration. EPA recommends that this request be submitted within 90 days of the date of this letter. To do so, send a written request to the EPA Information Quality Guidelines Processing Staff via mail (Information Quality Guidelines Staff, Mail Code 28220T, US EPA, 1200 Pennsylvania Ave., N.W, Washington, DC 20460), electronic mail (quality.guidelines@epa.gov) or fax (202 566-0255). The Request for Reconsideration should reference the request number assigned to the original request for correction (identified in the heading of this response). Additional information that should be included in the request is listed on the EPA Information Quality Guidelines web site (http://www.epa.gov/oei/qualityguidelines).

Sincerely yours,

Paul Gilman

Paul Gilman, Ph.D.
Assistant Administrator

Enclosure

Enclosure: References

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Kurokawa, Y; Takayma, S; Konishi, Y; et al. (1986a) Long-term in vivo carcinogenicity test of potassium bromate, sodium hypochlorite, and sodium chlorite conducted in Japan. Environ Health Perspect 69:221-35.

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