

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

SEP 15 2004

OFFICE OF RESEARCH AND DEVELOPMENT

Mr. Michael Girard Chairman The Perchlorate Study Group c/o Aerojet Bldg. 20001 Dept. 0330 PO Box 13222 Sacramento, CA 95813-6000

Re: Request for Correction #13679

Dear Mr. Girard,

The U.S. Environmental Protection Agency (EPA) has reviewed your Request for Correction (RFC) submitted under the EPA and Office of Management and Budget (OMB) Information Quality Guidelines, dated December 3, 2003, regarding certain information associated with the EPA's assessment of Perchlorate Environmental Contamination:

Toxicological Review and Risk Characterization (External Review Draft, January 16, 2002).

The perchlorate risk characterization document (External Review Draft, January 16, 2002) is a draft document. The document clearly states:

"This document is an external review draft. It has not been formally released by EPA and should not at this stage be construed to represent Agency policy. It is being circulated for comment on its technical accuracy and policy implications."

The external review draft document and the associated disposition document are currently under active review with the National Academy of Sciences (NAS). EPA does not consider these materials to be disseminations under the agencies' Information Quality Guidelines.

We intend to treat your request for correction, along with other comments we receive, including those provided by the NAS, as comments received on these documents. They will all be considered in our review and responded to when the perchlorate risk characterization is finalized. This will ensure that our response to your request benefits from the guidance provided by the NAS. This procedure has the advantage of placing our response to Requests for Correction in the context of other comments. We are carefully weighing all of the comments that we received, will carefully consider the report from the National Academy of Sciences, and will also consider the comments that you raised, before we finalize the documents. A more complete response to your comments will be available at that time and we will ensure that a copy is sent directly to you.

We note that you requested certain materials related to the perchlorate assessment, and we would like to inform you where some of these materials can be located:

- Compact disks containing the primary high resolution brain images are available to you, upon request, at Argus Laboratories.
- Methods for the Consultants in Veterinary Pathology (CVP) (2003) contract report are available in the report and appendices. This report can be found at: http://www.epa.gov/ncea/perchlorate/references/documents/cvp-report2003.pdf.
- The EPA analyses in the draft Disposition Document applied and referenced standard statistical methods, and the results can be reproduced using the rat-specific measurement data tabulated in the contractor report (CVP, 2003; appendix). In the Geller (2003) report, results for the linear measurements at each of the posterior corpus callosum plates 30, 31, 32, and 33 are graphed in Figure 1, with the text noting that plate 31 results were included in the profile analysis in Figure 3. These same figures appear in Chapter 4 of the Disposition Document. Univariate analyses for all the brain regions are depicted in Figure 4 of Geller (2003) and described in the Disposition Document. The external review draft of the Disposition Document can be found at: http://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=427420. The Geller (2003) analysis can be found at: http://www.epa.gov/ncea/perchlorate/references/documents/geller.pdf
- EPA is unaware of any missing data in CVP (2003). As explained in the methods section of CVP (2003), the requirement was to measure existing sections of the anterior and posterior corpus callosum and the striatum that had been matched to a standard rat brain atlas plate number. For each specific atlas plate number, it is possible that for one or more individual rats there will be no matching section. Hence, the absence of a tabulated result for that plate number for a given brain region in that individual rat, etc.
- The Marcus (2003c) attachment was uploaded to the internet at the www.epa.gov/ncea perchlorate site on Friday, December 5, 2003. This document can be found at: http://www.epa.gov/ncea/perchlorate/references/documents/greer memo 02.pdf

These citations and other information to assist you in reviewing these documents are available at EPA's perchlorate web site (www.epa.gov/ncea/perchlorate/references/ and www.epa.gov/ncea/perchlorate/references2).

We have also received your August 24, 2004, letter styled as a Request for Reconsideration which sought a response to this RFC. Because we have now responded to your RFC, we will not be treating your August 24 letter as a request for reconsideration.

We hope that you find this information useful and we appreciate your continued interest in Agency activities.

Sincerely yours,

Paul Gilman, Ph.D.

Assistant Administrator