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U.S. Environmental Protection Agency
Information Quality Guidelines Processing Staff MC28220T
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Unacceptable EPA response to March 14, 2003 Request for Reconsideration of Request for Correction IQG# 2293 Submitted by Chemical Products Corporation

Dear Madam or Sir:

In a letter dated December 11, 2003, EPA responded to Chemical Products Corporation's (CPC's) March 14, 2003 Request for Reconsideration of CPC's Request for Correction of EPA's IRIS Barium and Compounds Substance File (Request Number IQG# 2293), filed under the Information Quality Act on October 29, 2002. We respectfully submit that EPA's December 11, 2003 letter does not accurately characterize CPC's Request for Reconsideration and does not adequately respond to it.

This letter is submitted by Chemical Products Corporation (CPC), a Georgia Corporation located at 102 Old Mill Road, SE, Cartersville, GA 30120. The contact at CPC is Jerry A. Cook, Technical Director.

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CPC submitted a Request for Reconsideration of its Request for Correction (Request Number IQG# 2293) on March 14, 2003. EPA responded to this Request for Reconsideration in a letter dated December 11, 2003. We respectfully submit that EPA's response does not meet the requirements of EPA's and OMB's Information Quality Guidelines. We respectfully request that EPA withdraw its December 11, 2003 response and respond to CPC's Request for Reconsideration as prescribed in the Information Quality Guidelines.

In its December 11, 2003 letter to CPC, EPA seeks to incorrectly reclassify CPC's Request for Reconsideration as a Request for Correction, and then to misdirect the reclassified Request for Correction away from a question of compliance with EPA's and OMB's Information Quality Guidelines. EPA seeks to limit CPC's Request for Reconsideration to a question of whether the Oral Reference Dose contained in the EPA's IRIS Barium and Compounds Substance File is within an order of magnitude of the value that would be derived based upon the 1994 NTP study of 2 year (lifetime) exposure of F344 rats to soluble barium administered as Barium Chloride, Dihydrate. A copy of EPA's letter is included with this letter.

CPC strongly objects to EPA's attempt to misdirect CPC's Request for Correction of information that does not meet the requirements of EPA's and OMB's Information Quality Guidelines. EPA seeks to limit consideration to evaluation of the statement, "If one were to solely depend upon data from animal studies demonstrating renal effects as the critical determinants for RID calculation, the employment of customary uncertainty factors would produce a RED similar to that produced through the evaluation of data from human

studies," (this statement was added to the IRIS file in 1999 as an "editorial clarification" without peer review). In its Request for Reconsideration, CPC specifically objected to EPA's attempt to justify its continued use of incorrect information as a "harmless error". EPA is persisting in its reluctance to assess the quality of the information contained in the IRIS Barium and Compounds Substance File based upon the concept that "harmless" errors need not be corrected.

EPA contends that CPC's Request for Reconsideration "provided substantially different information" than the preceding Request for Correction. Any perception on the part of EPA that the Request for Reconsideration contains new and different information can only be attributed to a lack of proper consideration of CPC's Request for Correction. CPC's Request for Reconsideration specifically addresses the incorrect assertions in EPA's letter rejecting CPC's Request for Correction; only information submitted as part of the Request for Correction was used in the Request for Reconsideration to refute the assertions upon which EPA's rejection was based.

EPA's December 11, 2003 letter states on Page 2, "EPA will reassess the IRIS Barium and Compounds Substance File according to its standard IRIS health assessment development and review process" only "If the expanded analysis does not support the statement currently contained in the Toxicological Review for Barium that, 'If one were to solely depend upon data from animal studies demonstrating renal effects as the critical determinants for RfD calculation, the employment of curstomary uncertainty factors would produce a RfD similar to that produced through the evaluation of data from human studies.'" The human studies in question looked for the cardiovascular effects divined by EPA to be the critical effect from chronic soluble barium ingestion, but

found none; thus, the RfD produced through the evaluation of human studies presented in IRIS is based upon no observed effect at the highest levels evaluated.

A Lowest Observed Adverse Effect Level (LOAEL) for cardiovascular effects cannot be determined from the existing human studies because no cardiovascular effect was observed, yet EPA seeks to maintain an RfD for Barium in IRIS based on cardiovascular effects if the Rfd value is "similar" to the RfD value derived from sound scientific studies in animals that identified renal effects as the critical effect for chronic barium ingestion while also looking for cardiovascular effects. This approach by EPA does not satisfy CPC's concern stated on page 14 of its March 14, 2003 Request for Reconsideration which states, "EPA should base its RfD on good science, even if the resulting value is within the range of the existing value.

EPA's [January 30, 2003] rejection letter [of CPC's October 29, 2002 Request for Correction] effectively adopts the 'harmless error' defense, stating on page 3 that *'The result of applying this uncertainty factor to the chronic NOAEL from the NTP (1994) study would have been an RfD within an order of magnitude (and therefore within the definition) of the current RfD.'* This statement may possibly be true. However, it cannot overcome the fact that EPA's own guidelines require it to use good science. As shown above, the IRIS file for Barium and Compounds misidentifies the critical effect for chronic barium ingestion and bases its Oral RfD on an inappropriate study. No matter what the resulting Oral RfD is determined to be, EPA should revise its IRIS file to rely on objective and reproducible science."

EPA rejected CPC's Request for Correction (IQG# 2293) on the grounds that the request "offers an alternative assessment of the relevant science but fails to demonstrate that EPA's assessment is not consistent with EPA guidelines regarding objectivity and reproducibility." We respectfully disagreed and submitted a Request for Reconsideration of our original Request for Correction on March 14, 2003. EPA's December 11, 2003 letter, its first written response to CPC's March 14, 2003 Request for Reconsideration, seeks to circumvent EPA's own guidelines regarding objectivity and reproducibility by limiting its response to evaluation of how the employment of objective and reproducible science might change the value of the RfD contained in the IRIS Barium and Compounds Substance File, rather than directly addressing the objectivity and reproducibility of the derivation of the RfD value contained in IRIS. CPC, once again, respectfully disagrees with this approach by EPA and submits that it does not constitute a satisfactory response from EPA under EPA's and OMB's Information Quality Guidelines.

EPA's December 11, 2003 states that EPA intends to treat CPC's March 14, 2003 Request for Reconsideration as a Request for Correction "...due to the fact that your request provided substantially different information." Our Request for Reconsideration did not provide substantially different information, or any new information; all of the information provided in our March 14, 2003 Request for Reconsideration was provided with our original Request for Correction. Because EPA asserted in its rejection of CPC's Request for Correction that *"the Dallas and Williams (2000) assessment does not cite any significant new data or provide compelling insight into the existing data."*, CPC was compelled to describe in detail the new data and compelling insights into existing data contained in the Dallas and Williams (2000) toxicological assessment in its

Request for Reconsideration. The Dallas and Williams (2000) assessment was submitted to EPA as an attachment to CPC's Request for Correction and referred to extensively in that Request for Correction. CPC can only assume that the Dallas and Williams (2000) assessment was considered in detail by EPA before EPA rejected CPC's Request for Correction; this being the case, the Request for Reconsideration does not contain substantially different information, or any new information. There is no basis consistent with the OMB Information Quality Guidelines upon which EPA can reclassify this Request for Reconsideration.

Quoting from CPC's March 14, 2003 Request for Reconsideration, "In rejecting CPC's Request for Correction, EPA asserted that *'the Dallas and Williams (2000) assessment does not cite any significant new data or provide compelling insight into the existing data.'* In fact, the Dallas and Williams assessment contains new and highly significant studies, including the Schnermann (1995), Rao (1996), and Rao et al. (1996) studies. Furthermore, the Dallas and Williams analysis provides compelling insights into the existing data in the IRIS assessment which demonstrate that EPA's hazard assessment and dose-response determination for the IRIS barium RfD are not objective, transparent, or reproducible." There is no information in CPC's Request for Reconsideration that is not contained in the Dallas and Williams (2000) assessment submitted as an attachment to CPC's Request for Correction (IQG# 2293).

In EPA's December 11, 2003 letter, Dr. Paul Gilman states, "In addressing your March 14 Request for Correction, I am directing that the Toxicological Review and IRIS Summary of Barium be revised to include a more explicit and

transparent analysis of data from animal studies." This directive falls short of addressing the Information Quality deficiencies in the IRIS Barium and Compounds Substance File. The methodology employed in IRIS to identify the critical effect for chronic barium ingestion lacks a scientific foundation. A directive addressing the use of sound, reproducible science in identifying the critical effect for chronic barium ingestion is required.

If I can answer any questions concerning this letter or provide any further information, please telephone me at 770-382-2144.

Sincerely,

Jerry A. Cook
Technical Director

Enclosure: December 11, 2003 EPA letter to CPC

CC: Assistant Administrator Paul Gilman, Environmental Protection Agency
Dr. John D. Graham, OIRA, Office of Management and Budget