

Testimony

of

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before the

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Summary

Chemical Products Corporation, the last remaining manufacturer of barium carbonate and barium chloride in the U.S., has suffered a continuing decline in the market for its barium products. We believe that this decline is due, in part, to the over-regulation of barium by EPA under RCRA which has posed a continuing hardship on our industrial customers.

EPA's Integrated Risk Information System (IRIS) should function as an up-to-date repository of chemical toxicology assessments to be relied upon as the scientific basis for regulatory decision-making throughout EPA. We found IRIS to be unresponsive to new studies showing that barium was significantly less toxic than previously assumed. It took 11 years, and actions resulting from submission of Requests for Correction and Reconsideration after OMB instituted the "Information Quality Act", to achieve an IRIS barium file assessment that reflected sound science. In July 2005 the IRIS barium file was finally revised to recognize the 1994 National Toxicology Program Technical Report 432 as the principal study defining chronic barium toxicology and identifying a higher No Observed Adverse Level.

The RCRA regulatory level for barium is still the same arbitrary value set in the 1970's when no toxicological studies existed to provide a scientific basis for regulation.

EPA should make every effort to correct the structural deficiencies in IRIS and utilize up-to-date sound science to identify and remove regulatory burdens from U.S. industry which do not benefit human health or the environment.

Testimony

My name is Jerry Allen Cook. I am the Technical Director of Chemical Products Corporation (CPC), a 78 year old Georgia corporation which employs approximately 200 people in Cartersville, Georgia. My company is the last U.S. producer of barium chemicals and I have been dealing with barium toxicology and regulation for more than 28 years. EPA maintains a chemical toxicology database called IRIS – the Integrated Risk Information System. EPA's IRIS database is supposed to determine sound science concerning the toxicology of chemicals to guide EPA's regulatory activities. If IRIS functioned properly, EPA could identify unnecessary regulations offering no benefit to human health and the environment and remove these burdens from U.S. industries. Unfortunately, in the case of the IRIS barium file, I have found IRIS chemical managers, and their superiors, to be much more interested in bureaucratic expediency than in sound science; this has resulted in over-regulation of barium by EPA. An overview of EPA regulation of barium and a history of EPA's IRIS barium file is attached as an appendix.

The barium chemicals manufactured by Chemical Products Corporation are used in the ceramics industry to manufacture bricks and tiles, in the manufacture of luminescent paints for highway signage and airport striping, in heat-treating high-strength steel, and in the manufacture of catalysts. Many of our customers are small and medium-sized U.S. companies which are literally fighting for survival. Our customers tell us that the costs associated with RCRA regulation of barium are a substantial burden on them.

The CEO of Summitville Tiles, Inc., one of our customers, asked me to convey the following message to the members of this committee, "The over-regulation of American industry is making it increasingly more difficult for American manufacturers to compete in today's global economy. Summitville Tiles is a case in point: A 100 year old manufacturer of quarry tile and brick products based in eastern Ohio, in recent years it has had to close two tile manufacturing facilities and sixteen distribution centers, laying off over 450 employees. Summitville Tile is today one of the last American tile companies to remain in business. In fact, it is the only remaining charter member of the tile industry's national trade association, The Tile Council of North America. With foreign imports now comprising approximately 80% of the U.S. domestic tile market, the last thing that the tile industry needs is more regulations. What is needed more than anything else is regulatory relief."

Concern on the part of Chemical Products Corporation's existing and potential customers that the miscellaneous waste they generate in the course of their everyday manufacturing activities could exceed the existing, unnecessarily strict RCRA regulatory limit for soluble barium has led many of these companies to reduce or eliminate the use of CPC's barium products.

Barium is an alkaline earth metal, one of the group which includes magnesium and calcium. It is not carcinogenic and barium is rapidly eliminated from the body. Barium is widely dispersed in the natural environment in the mineral barite (barium sulfate) which is insoluble in water and acids. Because it is insoluble, barium sulfate is not toxic; this

is the chemical administered as an X-ray contrast medium for gastrointestinal X-rays (the infamous “barium meal”).

If a large amount of soluble barium is ingested or inhaled, it is toxic because it temporarily interferes with the body's cellular potassium transport. EPA's IRIS database deals with chronic toxicity – smaller amounts of a chemical consumed daily for many years. There is no known instance of any chronic toxic effect in a human due to barium and no animal studies were available when EPA began regulating barium in the mid-1970's, so EPA arbitrarily set a drinking water standard and a RCRA hazardous waste regulatory limit.

When EPA's IRIS database first put its barium file on-line in 1987, EPA had funded limited chronic barium toxicity studies. The IRIS chemical manager for barium appeared to be placing inordinate weight only the single study that tended to justify the arbitrary regulatory levels set by EPA in the mid-1970's instead of seeking a sound scientific basis which could have eased EPA's regulation of barium – a study conducted through EPA's own Health Effects Research Laboratory found barium to be much less toxic than the study emphasized in the IRIS assessment. IRIS adopted a very low level of barium intake as its recognized safe exposure level.

In 1994 the National Toxicology Program published a study of soluble barium toxicity – NTP Technical Report 432. This 2-year study is still the definitive scientific study for assessment of barium chronic toxicity.

The IRIS toxicological evaluation of barium should have been a

straightforward exercise after the publication of the NTP technical report. Instead, EPA's IRIS staff failed to adopt sound science when the IRIS barium file was revised in 1998. I examined the peer review record of this 1998 revision – available only in a Reading Room in Cincinnati - and found that the peer review had not been conducted according to EPA required procedures. Ineffective accountability and oversight mechanisms had resulted in EPA's IRIS database failing to fulfill its purpose.

Finally, after 11 years had elapsed, and only as a result of OMB implementation of the “Information Quality Act”, the IRIS barium file was revised in July 2005 to recognize the 1994 NTP study as the principal study from which to derive a critical effect for barium.

For most of the period that Chemical Products Corporation was struggling to achieve revision of the IRIS barium file to reflect sound science, the IRIS assessment program was completely under the control of EPA. Then, for several years, interagency reviews of draft IRIS file revisions were required and managed by OMB. Since 2009, the IRIS assessments and revisions are, once again, entirely managed by EPA. Unless EPA is able to establish and maintain much better oversight mechanisms than it previously employed, this change is unlikely to correct the deficiencies we encountered when seeking to correct the 1998 IRIS barium file revision.

Unfortunately, EPA has not adjusted the RCRA regulatory level for barium upward to relieve some of the burden on U.S. industry even though an upward revision is appropriate based on the information now available in the IRIS database.

APPENDIX

Overview of Barium Regulation and history of the IRIS barium file

EPA established a drinking water Maximum Contaminant Level (MCL) for barium in 1975. In "Statement of Basis and Purpose for the National Interim Primary Drinking Water Regulations", December 1975, under "barium", EPA stated, "No study appears to have been made of the amounts of barium that may be tolerated in drinking water or of effects from prolonged feeding of barium salts from which an acceptable water guideline may be set." Arbitrarily, a Maximum Contaminant Level (MCL) of 1 ppm of barium was promulgated at that time in the absence of scientific data. The RCRA regulatory limit for barium was set at 100 times this drinking water standard; this RCRA regulatory level remains in effect. CPC believes that this regulatory level for barium in solid waste is far below a level which would be protective of human health and the environment. Our efforts to make the Oral Reference Dose for soluble barium in IRIS reflect sound science are motivated by our desire to eventually achieve an increase in the RCRA regulatory limit for soluble barium.

Between 1980 and 1985 EPA funded three sub-chronic exposure studies of barium; two of these found no hypertensive effect, but one study (Perry), administering substantially lower doses than the other two studies, reported a small but significant increase in blood pressure in rats exposed to 100 ppm barium for only 4 weeks. In 1985 a study by McCauley in EPA's Health Effects Research Laboratory concluded, "There were no significant trends toward hypertension in any of the rats given as much as 1000 ppm Ba for 16 weeks." This refers to the highest dose tested by McCauley; it is 10 times higher than

the dose reported by Perry to cause hypertension in rats after only 4 weeks exposure.

When the IRIS barium file was brought on-line in 1987, the safe oral intake level for barium that was established roughly corresponded to the drinking water Maximum Contaminant Level established by EPA in 1975 and the critical effect from chronic barium ingestion was stated to be hypertension. Perry's reported blood pressure increase in rats exposed to relatively low levels of barium was cited as the basis for this IRIS determination – other studies which did not find hypertensive effects in rats exposed to much higher levels of soluble barium for longer periods of time were essentially ignored.

In 1989 EPA proposed raising the drinking water standard (Maximum Contaminant Level Goal or MCLG) for barium to 5 ppm from 1 ppm (54 Federal Register, page 22062, May 22, 1989); the drinking water standard was eventually raised only to 2 ppm barium in 1991.

In 1994 NTP issued “Technical Report on the Toxicology and Carcinogenesis Studies of Barium Chloride Dihydrate (CAS no. 10326279) in F344/N rats and B6C3F1 mice (drinking water studies)” (NTP TR 432, NIH pub. no. 943163. NTIS pub PB94214178, 1994). It reported finding no blood pressure increase in rats after administration of up to 4000 ppm barium chloride dihydrate for 13 weeks in the drinking water; this is 40 times the dose reported by Perry to cause hypertension in rats after only 4 weeks exposure. None of the physiological effects of hypertension were found after 2 years exposure to elevated levels of soluble barium in the drinking water. This NTP

report states at page 52, "... an association between barium and cardiovascular effects in the present studies does not seem to be likely....".

CPC submitted information letters to the IRIS Information Submission Desk dated July 11, 1994; October 13, 1994; June 16, 1995; and January 3, 1996 bringing 6 recently published papers concerning barium toxicology, in addition to NTP Technical Report 432, to the attention of IRIS. We repeatedly urged IRIS to place a high priority on basing its oral reference dose for barium on credible science - stated in the February 25, 1993 Federal Register at page 11491 to be EPA's goal for IRIS.

On June 28, 1996, CPC submitted a petition to EPA seeking to have the barium compounds category deleted from EPCRA Section 313 Toxic Release Inventory reporting requirements. In that petition CPC, citing the 1994 NTP technical report on barium chloride which had not been considered in IRIS, asked that the effects of chronic barium ingestion be evaluated as part of the consideration of CPC's petition. EPA's Office of Pollution Prevention and Toxics (OPPT) performed a toxicological assessment and the conclusions of OPPT's toxicological assessment were published in the Federal Register on January 3, 1997 (62 FR 366-372). This OPPT toxicological assessment identified kidney effects as the critical effect for chronic ingestion of soluble barium and identified a No Observed Adverse Effect Level (NOAEL) and a Lowest Observed Adverse Effect Level (LOAEL) based on NTP Technical Report 432 (making it the principal study for OPPT's assessment).

EPA published a revised IRIS toxicological assessment for barium in

1998 through its newly-implemented IRIS Pilot Program. This 1998 IRIS assessment continued to identify cardiovascular effects (hypertension) as the critical effect for chronic barium ingestion as had earlier IRIS assessments. It contained no mention of the toxicological evaluation conducted by OPPT reported in 62 FR 366-372 (January 3, 1997). There was no explanation of how a radically different interpretation of the same data could be justified. The No Observed Adverse Effect Level (NOAEL) adopted in the IRIS barium file was 0.21 mg/kg/day, whereas OPPT had adopted the NOAEL values from the NTP Technical Report 432 - 70 mg/kg/day in rats and 165 mg/kg/day in mice (cardiovascular effects were not detected in the NTP studies at dose rates far above those reputed to cause hypertension in IRIS).

To present our concerns regarding deficiencies in the 1998 revision of the IRIS barium file, a colleague and I met with Dr. William H. Farland, Director of the National Center for Environmental Assessment, on July 7, 1998. Dr. Farland indicated that minor editorial revisions could be made. During our meeting we expressed our belief that even with significant editorial changes, the March 30, 1998 IRIS barium file revision would be seriously flawed because it incorrectly evaluated and weighted the scientific evidence to arrive at an incorrect and untenable Oral Reference Dose for barium.

I visited the IRIS reading room in Cincinnati in early 1999 to review the barium file revision dossier. I found that the peer review of this revision had not been conducted according to required EPA procedures. We informed Assistant Administrator Norine Noonan and Deputy Administrator Peter D.

Robertson, as well as GAO, by letter of the serious deficiencies in the peer review conducted on this work product. In a May 25, 1999 letter to Mr. Peter F. Guerrero, Director of Environmental Protection Issues at GAO, I described the serious deficiencies I found in the Peer Review Record for the IRIS barium file revision and further stated, “CPC is submitting the above information to you to demonstrate the veracity of the statement in your 1996 report, GAO/RCED-96-236 Peer Review at EPA, on page 6, 'Although we agree that the issues EPA and others have raised may warrant further consideration, we believe that EPA's uneven implementation is primarily due to (1) confusion among agency staff and management about what peer review is, what and when and how it should be conducted and (2) ineffective accountability and oversight mechanisms to ensure that all products are properly peer reviewed by program and regional offices.' Ineffective accountability and oversight mechanisms may extend to the highest levels within EPA. We ask that the information contained in this letter and its attachments be included in GAO's continuing evaluation of EPA's peer review practices; we consider this information to be particularly worrying in view of the fact that the Office of Research and Development, of which IRIS is a part, is entrusted with the responsibility of determining whether peer reviews throughout EPA are conducted according to EPA policies.”

Uncorrected deficiencies in the IRIS barium file prompted CPC to submit a Request for Correction under the “Information Quality Act” on October 29, 2002 seeking revisions in the IRIS barium file to make it consistent with the OPPT toxicological evaluation published in the January 3, 1997 Federal

Register – the principal study should be NTP Technical Report 432 and the critical effect should be kidney effects. CPC's Request for Correction was denied in a letter from EPA dated January 30, 2003 on the grounds that our 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.”

A Request for Reconsideration under the “Information Quality Act” was submitted on March 14, 2003 based on the premise that our request was a matter of scientific objectivity, not simply “an alternative assessment.” I met with EPA Assistant Administrator Paul Gilman later in 2003. Based partly on EPA's characterization of a 1995 University of Michigan study which CPC had submitted to IRIS as “new information” a review of the IRIS barium file was initiated. The University of Michigan study, which was available to IRIS staff long before the 1998 barium file revision, found that barium acted to prevent sodium-induced hypertension [Schnermann, J (1995) Effects of barium ions on tubuloglomerular feedback. *Am. J. Physiol.* 268 (Renal Fluid Electrolyte Physiol. 37): F960-F966].

Finally, on July 11, 2005, a revised IRIS barium file reflecting the conclusions presented in the 1997 OPPT toxicological assessment – NTP Technical Report 432 is recognized as the principal study and nephropathy (kidney effects) are recognized as the critical effect – was put on-line. From 1997 until 2005 there were two divergent toxicological assessments of barium within EPA. In 2005 the straightforward assessment of a very small number of

scientific studies completed by OPPT in only a few months was finally recognized in IRIS after an untold number of man-hours of effort over a period of 8 1/2 years.

The RCRA regulatory level for barium has not been revised to reflect the higher Oral Reference Dose now contained in the IRIS barium file.