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The authors of this article say the frenzy surrounding the recent publication of research finding perchlorate in powdered infant formula would suggest the study presents either new information or reveals disconcerting health effects from perchlorate exposure. As it turns out, the authors say, the study does neither. They argue that the perchlorate issue presents a challenge and an opportunity to the Obama administration to demonstrate that it is putting science above unsupported and nebulous scares about a naturally occurring and ubiquitous substance.

Perchlorate Challenges Obama's Pledge to Give Primacy to Science at EPA

BY JEFFREY D. DINTZER AND JESSICA D. GREENSTON

The frenzy surrounding the recent publication of a study[1] detecting perchlorate in powdered infant formula would suggest that the study, at the very least, presents either new information or reveals disconcerting health effects from perchlorate exposure.[2] As it turns out, the study does neither. Instead, through the hysteria it has generated, the study inadvertently poses to the new administration a significant challenge: whether the administration will keep its word to base its decisionmaking concerning perchlorate on science rather than unsupported assumptions.

Study Presents No New Information

The basic finding of the study is that perchlorate is everywhere, including in powdered infant formula.[3] But as the study itself observes in its introduction,

[1] Schier J.G., Wolkin A.F., Valentin-Blasini L., Belson M.G., Kieszak S.M., Rubin C.S., and Blount B.C. Perchlorate exposure from infant formula and comparisons with the perchlorate reference dose. *J of Exposure Sci and Environ Epidemiol* 2009: 1-7 (the ''study'').

[2] *See, e.g.*, Environmental Working Group, CDC Scientists Find Rocket Fuel Chemical In Infant Formula, http://www.ewg.org/report/CDC-Scientists-Find-Rocket-Fuel-Chemical-In-Infant-Formula.

[3] *See* Study, at 6-7.

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''[p]erchlorate exposure is ubiquitous in the United States.''[4] Perchlorate is a naturally occurring salt and is used commercially in rocket propellant, safety flares and fireworks, among other ways. As a consequence of its water solubility and ubiquity, perchlorate has been found in soil and water (including bottled water), vegetables and fruit, and dairy products.[5]

The study found that perchlorate was present in all four of the types of powdered infant formula tested—bovine milk-based with lactose, bovine milk-based lactose-free, soy-based, and elemental (consisting of synthetic amino acids).[6] Unsurprisingly, the study also found that when these powdered infant formulas were reconstituted with water containing perchlorate, the reconstituted formula contained greater amounts of perchlorate.[7] The fact that powdered infant formulas contain perchlorate actually confirmed earlier studies and did not present new information.[8]

Study Fails to Demonstrate Any Health Effects

The study rang alarm bells because it found that in certain cases, reconstitution of powdered infant formula with or without perchlorate-contaminated water could result in perchlorate ingestion by infants in excess of the EPA's reference dose (''RfD'').[9] Putting aside serious limitations in the study's methodology (*e.g.*, the sampling pool of the study was limited to one city; there was no consideration of offsets from supplemental ingestion of iodide), the study does not even attempt to explain whether exceedance of the RfD would result in any health effects. It does not because it cannot.

Perchlorate is of concern because it can block uptake of iodide, an essential dietary nutrient, into the thyroid if present in the blood stream at sufficient concentrations.[10] After a prolonged period of low iodide uptake, decreases in thyroid hormones will occur. A decrease of production of some of these hormones is problematic, particularly during pregnancy, because these hormones are critical for proper fetal brain development.[11]

Importantly, other factors and other iodide inhibitors also cause iodide deficiency and result in decreased thyroid hormone production. The other two well documented iodide inhibitors are thiocyanate and nitrate. Both of these inhibitors are much more prevalent than perchlorate—for example, certain foods are ''particularly rich in thiocyanate'' such as cabbage, broccoli, and tomatoes, among others.[12] And nitrate is commonly found in vegetables, is commonly added to processed meats as a preservative, and is found in drinking water due to agricultural use of nitrate fertilizers.[13]

A recent scientific analysis of perchlorate by the Environmental Protection Agency's Office of Inspector General observes that of the four ''stressors'' on thyroid uptake of iodide (perchlorate, thiocyanate, nitrate, and deficient iodide consumption), the most important is dietary intake of iodide.[14] In fact, the report concluded that the lack of iodide is the ''dominant and principal'' stressor that affects the amount of iodide transmitted to the thyroid.[15]

In 2005, years prior to the issuance of the EPA inspector general's release, EPA set the RfD for perchlorate at 0.0007 mg/kg-day based on the recommendation of a special committee of the National Academy of Sciences.[16] But the RfD for perchlorate was unusually conservative because the value used to derive the RfD was a level of perchlorate ingestion at which ***no observed effects*** were found—adverse or otherwise.[17] Typically, RfDs are derived from a level at which adverse health effects are found. The reason the RfD was not set at the conventional level (*i.e.*, at a level where adverse effects in humans occur) is because no perchlorate study has observed adverse effects in any human population.[18] The RfD selected by the National Academy of Sciences further included a 10-fold uncertainty factor to protect the most sensitive population—fetuses of pregnant women who have hypothyroidism or iodide deficiency.

To recap, the RfD was derived from an extremely conservative figure at which no effects from perchlorate were observed and also includes a 10-fold uncertainty factor to protect sensitive subpopulations. In addition, the RfD was set without regard to what effect supplementing the diet with iodide may have on iodide uptake. The EPA inspector general calculated what a conventional RfD would be—one that is set at a level where no ***adverse*** effects would occur in sensitive subpopulations—and ''confirmed that the NAS-recommended perchlorate RfD is conservative by a factor of 6.6 times.''[19] The study then merely stands for the

[4] Study, at 2.

[5] Study, at 2 (citing Yu L., Cañas J.E., Cobb G.P., Jackson W.A., and Anderson T.A. Uptake of perchlorate in terrestrial plants. *Ecolxicol Environ Saf* 2004: 58: 44-49; Sanchez C.A., Krieger R.I., Khandaker N.R., and Gibbs J.P. Perchlorate and nitrate in leafy vegetables of North American. *Environ Sci Technol* 2005: 39: 9391-9397; Krynitsky A.J., Nierman R.A., and Nortrup D.A. Determination of perchlorate anion in foods by on chromatography-tandem mass specnometry. *Anal Chem* 2004: 76: 5518-5522; Capuco A.V., Rice C.P., Baldwin R.L., Bannerman D.D., Paape M.J., Hare J.L. McConnell L.L., and Van Tassell C.P. Fate of dietary perchlorate in lactating dairy cows: relevance to animal health and levels in the milk supply. *Proc Natl Acad Sci USA* 2005: 102: 16152-16157; Kirk A.B., Martinelango P.K., Tian K., Dutta A., Smith E.E., and Dasgupta P.K. Perchlorate and iodide in dairy and breast milk. *Environ Sci Technol* 2005: 39: 2011-2017).

[6] Study, at 4.

[7] Study, at 6.

[8] Sudy, at 4 (citing Pearce E.N., Leung A.M., Blount B.C., Bazarafshan J.R., He X., Pino S., Valentin-Blasini L., and Braverman L.E. Breast milk iodine and perchlorate concentrations in lactating Boston-area women. *J Clin of Endocrinol Metab* 2007: 92: 673-1677.)

[9] Study, at 6.

[10] EPA, Office of Inspector General Scientific Analysis of Perchlorate, Assignment No. 2008-0010, at 1 (External Reviews Draft released Dec. 30, 2008) (''EPA OIG Release'').

[11] *Id.*

[12] *Id.* at 2.

[13] *Id.*

[14] The EPA OIG Release concluded that ''[i]odide deficiency has a much stronger effect on lower the maternal [thyroid iodide uptake] than can be compensated for by reducing the environmental exposure to perchlorate and/or the other NIS inhibitors.'' EPA, Office of Inspector General Scientific Analysis of Perchlorate, Assignment No. 2008-0010, at 7 (External Review Draft released Dec. 30, 2008).

[15] *Id.* at 8.

[16] *Id.* at 2-3.

[17] *Id.* at 3.

[18] EPA OIG Release, at 4.

[19] *Id.* at 5. The EPA OIG Release also observed, however, that the perchlorate RfD is accurate only for those individuals

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unremarkable proposition that perchlorate is found in powdered infant formula and that reconstitution in some cases may result in an infant ingesting perchlorate at amounts that exceed an unusually conservative reference dose that has not been shown to have any health effects.

The study made no demonstration that exceedance of the perchlorate RfD results in adverse health effects in humans, much less the subpopulation of infants. The closest the study came was citing to a prior study which concluded that perchlorate exposure was associated with changes in thyroid function in U.S. women with low iodine intake.[20] But a different study of pregnant women who were exposed to drinking water with perchlorate levels of 114 ppb, several times the EPA drinking water equivalent level of 24.5 ppb based on the RfD, found no statistically significant changes in neonatal thyroid function or birth weight.[21]

More disconcerting in all this is that the study's focus on the presence of perchlorate obscures the true culprit in the health risk associated with deficient iodide update by the thyroid—dietary consumption of iodide.[22] Luckily, it appears that the problem of iodide deficiency has a fairly straightforward and cheap remedy. Iodide can easily be added to the diet in the form of vitamins and food supplements, as it often is in table salt. In fact, the study states that ''in situations with higher iodine intakes, no infants would be expected to be iodine deficient.''[23] Although managing iodide consumption is the ''most effective action'' according to the EPA inspector general, it is not within EPA's legislative mandate. Rather, other federal agencies such as the Food and Drug Administration and the National Institutes of Health are tasked with addressing these issues.[24]

In light of the potential and immediate health benefits to be realized by managing iodide consumption, the focus of this issue should be on increasing iodide consumption, not on expending countless public and private sums to remove infinitesimal amounts of perchlorate from drinking water to an unknown effect. Indeed, a recent Supreme Court decision, *Entergy Corp. v. Riverkeeper, Inc.*, permits EPA to set regulatory standards through the use of cost-benefit analysis so long as not legislatively prohibited.[25]

Task Before the New Administration

The Environmental Working Group is hailing the study as ''perhaps the strongest evidence to date supporting the need for a legally enforceable safe drinking water level that protects pregnant women, infants and others who are most vulnerable to the effects of this harmful chemical.''[26] But as described above, the study cannot possibly provide a reasoned basis to make any regulatory decision on a drinking water standard for perchlorate and will not necessarily remedy the public health threat caused by iodide deficiency.

Days before taking her post as administrator of EPA, Lisa Jackson issued a memo to all EPA employees.[27] In that memo, Administrator Jackson identified that ''President Obama has articulated three values that he expects EPA to uphold''—scientific integrity, the rule of law, and transparency. Administrator Jackson went on to underscore that ''[s]cience must be the backbone for EPA programs'' and that ''rigorous adherence to the best available science'' would be the benchmark of the Obama administration. In prescient observation, the memo warns that ''scientific judgments'' can be ''misrepresented or distorted by political agendas.'' But Administrator Jackson pledged to ''not compromise the integrity of EPA's experts in order to advance a preference for a particular regulatory outcome.''

The perchlorate issue, as the powdered infant formula study highlights, presents a challenge and an opportunity to the administration to demonstrate that it is indeed vaulting science above unsupported and nebulous scares about a naturally occurring and ubiquitous substance.

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who have a typical background exposure to the other three iodide inhibitor stressors and thus should change depending on the exposure level to the other stressors. *Id.*

[20] Study, at 2 (citing Blount B.C., Pirkle J.L., Osterloh J., Valentin-Blasini L., and Caldwell K.L. Urinary perchlorate and thyroid hormone levels in adolescent and adult men and women living in the United States. *Environ Health Perspect* 2006: 114: 1865-1871).

[21] *See* Tellez R.T., Chacon P.M., Abarca C.R., Blount B.C., Van Landingham C.B., Crump K.S., and Gibbs J.P. Long-term environmental exposure to perchlorate through drinking water and thyroid function during pregnancy and the neonatal period. *Thyroid* 2005: 15: 963-975.

[22] EPA OIG Release, at 8.

[23] Study, at 6.

[24] EPA OIG Release, at 8.

[25] *Entergy Corp. v. Riverkeeper, Inc.* Nos. 07-588, 07-589, 07-597, 68 ERC 1001 (U.S. 2009). EPA guidance concerning the Safe Drinking Water Act identifies that it is able, indeed it must, consider costs when setting regulatory standards under the act. *See* EPA, Understanding the Safe Drinking Water Act, http://www.epa.gov/OGWDW/sdwa/30th/factsheets/pdfs/fs_30ann_sdwa_web.pdf.

[26] Environmental Working Group, CDC Scientists Find Rocket Fuel Chemical In Infant Formula, http://www.ewg.org/report/CDC-Scientists-Find-Rocket-Fuel-Chemical-In-Infant-Formula.

[27] Administrator Lisa Jackson, Memo to EPA Employees, dated Jan. 23, 2009, http://www.epa.gov/administrator/memotoemployees.html.