

HENRY A. WAXMAN, CALIFORNIA  
EDWARD J. MARKEY, MASSACHUSETTS  
RICK BOUCHER, VIRGINIA  
EDOLPHUS TOWNS, NEW YORK  
FRANK PALLONE, Jr., NEW JERSEY  
BART GORDON, TENNESSEE  
BOBBY L. RUSH, ILLINOIS  
ANNA G. ESHOO, CALIFORNIA  
BART STUPAK, MICHIGAN  
ELIOT L. ENGEL, NEW YORK  
ALBERT R. WYNN, MARYLAND  
GENE GREEN, TEXAS  
DIANA DEGETTE, COLORADO  
*VICE CHAIRMAN*  
LOIS CAPPS, CALIFORNIA  
MIKE DOYLE, PENNSYLVANIA  
JANE HARMAN, CALIFORNIA  
TOM ALLEN, MAINE  
JAN SCHAKOWSKY, ILLINOIS  
HILDA L. SOLIS, CALIFORNIA  
CHARLES A. GONZALEZ, TEXAS  
JAY INSLEE, WASHINGTON  
TAMMY BALDWIN, WISCONSIN  
MIKE ROSS, ARKANSAS  
DARLENE HOOLEY, OREGON  
ANTHONY D. WEINER, NEW YORK  
JIM MATHESON, UTAH  
G.K. BUTTERFIELD, NORTH CAROLINA  
CHARLIE MELANCON, LOUISIANA  
JOHN BARROW, GEORGIA  
BARON P. HILL, INDIANA

ONE HUNDRED TENTH CONGRESS

**U.S. House of Representatives**  
**Committee on Energy and Commerce**  
**Washington, DC 20515-6115**

JOHN D. DINGELL, MICHIGAN  
CHAIRMAN

July 6, 2007

JOE BARTON, TEXAS  
*RANKING MEMBER*  
RALPH M. HALL, TEXAS  
J. DENNIS HASTERT, ILLINOIS  
FRED UPTON, MICHIGAN  
CLIFF STEARNS, FLORIDA  
NATHAN DEAL, GEORGIA  
ED WHITFIELD, KENTUCKY  
BARBARA CUBIN, WYOMING  
JOHN SHIMKUS, ILLINOIS  
HEATHER WILSON, NEW MEXICO  
JOHN B. SHADEGG, ARIZONA  
CHARLES W. "CHIP" PICKERING, MISSISSIPPI  
VITO FOSSELLA, NEW YORK  
STEVE BUYER, INDIANA  
GEORGE RADANOVICH, CALIFORNIA  
JOSEPH R. PITTS, PENNSYLVANIA  
MARY BONO, CALIFORNIA  
GREG WALDEN, OREGON  
LEE TERRY, NEBRASKA  
MIKE FERGUSON, NEW JERSEY  
MIKE ROGERS, MICHIGAN  
SUE MYRICK, NORTH CAROLINA  
JOHN SULLIVAN, OKLAHOMA  
TIM MURPHY, PENNSYLVANIA  
MICHAEL C. BURGESS, TEXAS  
MARSHA BLACKBURN, TENNESSEE

DENNIS B. FITZGIBBONS, CHIEF OF STAFF  
GREGG A. ROTHSCHILD, CHIEF COUNSEL

Mr. Robert E. Brackett  
Director  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

Dear Mr. Brackett:

Thank you for appearing before the Subcommittee on Environment and Hazardous Materials on Wednesday, April 25, 2007, at the hearing entitled "Perchlorate: Health and Environmental Impacts of Unregulated Exposure." We appreciate the time and effort you gave as a witness before the subcommittee.

Under the Rules of the Committee on Energy and Commerce, the hearing record remains open to permit Members to submit additional questions to the witnesses. Attached are questions directed to you from certain Members of the Committee. In preparing your answers to these questions, please address your response to the Member who has submitted the questions and include the text of the Member's question along with your response.

To facilitate the printing of the hearing record, your responses to these questions should be received no later than the close of business on July 20, 2007. Your written responses should be delivered to 2125 Rayburn House Office Building and faxed to (202) 225-2899 to the attention of Rachel Bleshman. An electronic version of your response should also be sent by e-mail to Ms. Bleshman at [rachel.bleshman@mail.house.gov](mailto:rachel.bleshman@mail.house.gov). Please send your response in a single Word or WordPerfect formatted document.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Rachel Bleshman at (202) 225-2927.

Sincerely,



JOHN D. DINGELL  
CHAIRMAN

Attachment

cc: The Honorable Joe Barton, Ranking Member  
Committee on Energy and Commerce

The Honorable Albert Wynn, Chairman  
Subcommittee on Environment and Hazardous Materials

The Honorable John Shimkus, Ranking Member  
Subcommittee on Environment and Hazardous Materials

The Honorable Joe Barton and the Honorable John Shimkus

1. Do you think that an appropriate way to protect the sensitive subpopulation of concern (pregnant and nursing mothers and their babies) would be to ensure that their prescription prenatal vitamins contain adequate iodine (150 µg/day), as recommended by the American Thyroid Association and as mentioned in the NAS report? What further actions do you think are reasonable for FDA to take in this regard?
2. In its recently released proposal for regulatory determinations under the second Contaminant Candidate List (CCL2), EPA stated that it had insufficient exposure information, particularly from food, in order to move forward with a regulatory determination for perchlorate. EPA also identified the option of relying on urinary biomonitoring data such as the type released by CDC and relied upon by Dr. Blount in his fall 2006 population study. Do you believe that this type of data, which provides results on total exposure in humans, would better serve EPA rather than relying on exposure modeling data, which is subject to information gaps and therefore increases the level of uncertainty?
3. I understand that other compounds in food besides perchlorate, like nitrates, also inhibit iodine uptake. Is this true? If so, since milk, meats and lots of foods we eat everyday contain nitrates, do you think these compounds pose a risk in the diet?
4. I understand the Blount study also looked for an effect from other compounds that inhibit iodine uptake. The study either found that these other compounds didn't show the effect they should, or that one of them actually worked opposite of the way all other science says it should. Based on these inconsistent outcomes, do you think the Blount study should be used for policy decisions?

The Honorable Albert Wynn

1. In both written and oral testimony, FDA neglected to report what the specific findings were of its Exploratory Data Studies. (Referring to *FDA's Exploratory Data on Perchlorate in Food*, November 2004 at <http://www.cfscan.fda.gov/~dms/clo4data.html>). Is it correct that FDA tested 500 samples of food, including lettuce, milk and bottled water from areas where water was thought to have perchlorate contamination and perchlorate was found in 90 percent of lettuce samples and 101 out of 104 of store bought milk from 14 states?
2. Referring to *FDA's Collection and Analysis of Food for Perchlorate Memorandum, February 23, 2005* which states that "Perchlorate at high doses can interfere with iodide uptake into the thyroid gland, disrupting its functions." Please explain what FDA considers to be "high doses" of perchlorate and the basis for this assertion. Additionally, is the FDA going to revise this statement in view of CDC biomonitoring data finding that levels of perchlorate common in the population were associated with small to medium changes in thyroid hormone levels? If not, why not?
3. What levels of contaminant in food, such as perchlorate, warrant the issuance of a "tolerance" or the setting of an "action level"?
4. *FDA's Collection and Analysis of Food for Perchlorate Memorandum, February 23, 2005* states that objective of collecting and analyzing food for perchlorate is "to generate information on the incidence and levels of perchlorate contamination in selected food items. The data will be used to determine the need for future monitoring and/or enforcement strategies." Please explain in detail how the "incidence" and the "level" of perchlorate contamination is derived and noted. Also, please explain in detail and with examples, how such data is used to determine: 1) the need for monitoring, and 2) enforcement strategies in terms of the levels and incidences that are needed for implementing particular enforcement activity under the Food and Drug Cosmetic Act.
5. Has the FDA ever mandated the monitoring and/or taken an enforcement action on a contaminant that is present in both the drinking water and food supply, if so, please provide specific information as to the contaminant of concern, the levels and incidence of the contaminant and the type of FDA action taken. Please include citations to guidance and/or regulations where appropriate.
6. Please explain in detail the interaction between the FDA, USDA and EPA regarding the assessment of exposure risks presented by perchlorate. This answer should include, but not be limited to, whether EPA discussed how FDA food sampling data will be used by EPA in its decision to whether to regulate perchlorate under the Safe Drinking Water Act.
7. Does the sampling of perchlorate in baby food and infant formula indicate the presence of perchlorate and if so, at what levels? Will the processing of milk into infant formula concentrate the levels of perchlorate contamination if perchlorate-

The Honorable Albert Wynn (continued)

containing water is used to reconstitute the formula?

8. Did FDA consult with EPA about the nature and extent of sampling of food for the presence of perchlorate with EPA? If so, please describe in detail what those consultations entailed.
9. Please explain the purpose for conducting the Preliminary Exposure Assessment and how this assessment will be used by FDA and/or the EPA in making any regulatory decisions regarding perchlorate.
10. Various studies have shown that nursing and bottled fed infants could receive doses of perchlorate from breast milk above EPA's RfD of 24 ug/L. Recent studies have determined the existence of perchlorate doses that were above EPA's RfD of 24 ug/L for infants drinking reconstituted formula made with water containing perchlorate (Baier-Anderson et al. 2006)(Kirk et al. 2005) and have also estimated that nursing infants could receive doses above the RfD even without considering the added exposure associated with EPA's preliminary remedial goal of 24 ug/L (Pearce et al. 2007 and Kirk et al. 2007). Please describe whether the Agency is considering the impact of perchlorate on nursing and bottle-fed infants and/or whether the Agency intends to utilize the above referenced studies or conduct its own studies on the impact of perchlorate on nursing and bottle-fed infants.
11. Referring to FDA's *Estimation of Perchlorate Dietary Exposure*, May 2007, in which FDA issued a preliminary estimate of the exposure to perchlorate in foods, is it correct that FDA found the presence of perchlorate at varying levels in 27 types of foods and beverages? Is it also correct that FDA's estimate of the total mean population exposure from 27 foods and beverages of 0.053 ug/kg bw/dy is similar to geometric mean perchlorate dose of 0.066 ug/kg bw/day found in the CDC Blount et al, 2006 study of *Perchlorate Exposure of US Population*?
12. Despite the fact that levels of perchlorate were found in at varying levels in 27 types of foods tested by the FDA, the Agency concluded that "this exposure assessment suggests that the overall dietary exposure to perchlorate is likely to be below the RfD recommended by the National Academy of Sciences and adopted by the Environmental Protection Agency." Given that 2005 National Academy Report "acknowledges that the RfD may need to be adjusted upward or downward on the basis of future research" and that the CDC studies have found that that levels of perchlorate common in the population, which are significantly less than EPA's RfD of 24.5 ppb., were associated with small to medium changes in thyroid hormone levels, if the RfD were revised downward would that change FDA's assessment regarding overall dietary exposure to perchlorate?
13. If the results of the health effects on the United States population documented by the CDC studies were applied, rather than ignored, resulting in a lower RfD, would the levels of perchlorate found in the 2004 and 2005 Exploratory Surveys conducted by

The Honorable Albert Wynn (continued)

FDA, result in the Agency utilizing any of its response or enforcement authorities under the Food and Drug Cosmetic Act?

14. Please explain why the FDA has chosen not to conduct its own health assessment for perchlorate, an exercise typically conducted by FDA in determining whether a contaminant may be deleterious to the Nation's food supply, and instead has abdicated its authority, by adopting the 2005 National Academy Report, *Health Implications of Perchlorate Ingestion*? How can the FDA continue to support the proposed National Academy RfD in light of the additional health data that has been published by the CDC and documented existence of perchlorate in food as documented by the Agency's own studies?
15. Is it correct that FDA sampled carrots of growers in Arvin, California and Moorpark, California and that these samples were found to contain 87.6 ppb. and 81.3 ppb. Of perchlorate respectively? Based upon these sampling results, did FDA take any action to prevent these perchlorate contaminated carrots from entering the nation's food supply? If the answer to the prior question is "no," is it possible that these perchlorate containing carrots would have been made available for public purchase and consumption?
16. Is it correct that FDA sampled spinach of growers in Brawley, California and Riverside, California, and that these samples were found to contain 927 ppb. and 680 ppb. of perchlorate respectively? Based upon these sampling results, did FDA take any action to prevent this perchlorate contaminated spinach from entering the nation's food supply? If the answer to the prior question is no, is it possible that this perchlorate containing spinach would have been made available for public purchase and consumption?
17. Is it correct that FDA sampled cantaloupes of growers in Goodyear, Arizona and that these samples were found to contain 57.8 ppb., 63.3 ppb., and 66.6 ppb. of perchlorate? Based upon these sampling results, did FDA take any action to prevent these perchlorate contaminated cantaloupes from entering the nation's food supply? If the answer to the prior question is "no," does this mean that it is possible that these perchlorate containing cantaloupes would have been made available for public purchase and consumption?
18. Is it correct that FDA sampled broccoli of a grower in Greensburg, Pennsylvania and that this broccoli sample was found to contain 40.2 ppb. of perchlorate? Based upon this sampling result, did FDA take any action to prevent this bunch of perchlorate contaminated broccoli from entering the nation's food supply? If the answer to the prior question is "no," is it possible that these perchlorate containing carrots would have been made available for public purchase and consumption?
19. Is it correct that FDA sampled collard greens of growers in Mount Olive, North Carolina; Newton Grove, North Carolina; Raleigh, North Carolina; and

The Honorable Albert Wynn (continued)

Peleion, South Carolina, and that these samples were found to contain 238 ppb., 47.8 ppb., 39.7 ppb., and 69.1 ppb. of perchlorate respectively? Based upon these sampling results, did FDA take any action to prevent these perchlorate contaminated collard greens from entering the nation's food supply? If the answer to the prior question is "no," is it possible that these perchlorate containing collard greens would have been made available for public purchase and consumption?