



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

The Honorable John D. Dingell  
Chairman  
Committee on Energy and Commerce  
House of Representatives  
Washington, D.C. 20515-6115

**AUG 06 2007**

Dear Mr. Chairman:

Thank you for providing the Food and Drug Administration (FDA or the Agency) the opportunity to testify at the April 25, 2007, hearing entitled "Perchlorate: Health and Environmental Impacts of Unregulated Exposure." Dr. Robert Brackett, Director, Center for Food Safety and Applied Nutrition, testified on behalf of FDA. We are responding to the letter of July 6, 2007, you sent in follow-up to the hearing.

We have re-stated each question in bold type, followed by FDA's response.

**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?**

FDA recently reviewed the labels of various prenatal vitamin supplements. Product labels indicated that all of the prenatal dietary supplements that were examined contained iodine levels ranging from 150-300 µg.

FDA will continue to monitor additional scientific studies conducted by the Centers for Disease Control and Prevention (CDC) and other organizations with respect to the effect of perchlorate exposure on iodide uptake. As new information is made available, we will consider what additional measures may be necessary and prudent to prevent public health problems in vulnerable populations that may become apparent.

- 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?**

FDA believes it is the Environmental Protection Agency's (EPA) decision to determine if biomonitoring data or exposure modeling data would better serve EPA in determining whether it had sufficient exposure information to move forward with a regulatory determination for perchlorate.

- 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?**

Nitrate occurs in a wide variety of foods naturally, especially in vegetables, or as added, such as in processed meats. Although nitrate is known to inhibit iodide uptake, FDA is not aware of any information demonstrating that the presence of nitrate, either naturally or added, in foods poses such a risk.

- 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 authors of the CDC biomonitoring study recommended further research to affirm the finding of association between perchlorate exposure and reduced thyroid function in women with sub-optimal low urine iodine levels (less than 100 micrograms per liter ( $\mu\text{g/L}$ ) that may indicate iodine deficiency. FDA agrees with this recommendation for further clarifying the potential public health significance of such changes in thyroid function.

#### **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.cfsan.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?**

Yes. FDA's Exploratory Data on Perchlorate in Food, November 2004, found perchlorate in 90 percent of lettuce samples (116 out of 128), and in 101 out of 104 milk samples (3 raw milk samples from a research facility in Maryland and 101 store bought milk samples 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?**

Human exposure to high dosages (e.g., pharmacological levels) of perchlorate can interfere with iodide uptake into the thyroid gland, disrupting the functions of the thyroid and potentially leading to a reduction in the production of thyroid hormone. In fact, perchlorate has been used as a drug to treat hyperthyroidism (excess thyroid hormone production) and to diagnose disorders related to thyroid or iodine metabolism.

The authors of the CDC biomonitoring study recommended further research to affirm the finding of association between perchlorate exposure and reduced thyroid function in women with sub-optimal low urine iodine levels (less than 100 µg/L that may indicate iodine deficiency). FDA agrees with this recommendation for further clarifying the potential public health significance of such changes in thyroid function.

- 3. What levels of contaminant in food, such as perchlorate, warrant the issuance of a "tolerance" or the setting of an "action level?"**

Section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) provides that a food is deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health. In addition, section 402(a)(2)(A) provides that a food is deemed to be adulterated if it bears or contains any added poisonous or deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 406 of the Act.

With respect to perchlorate, insufficient exposure and health effects information for perchlorate in foods exists to support setting action levels above which FDA might take regulatory action based on adulteration under section 402(a)(1) of the Act, or to support setting a tolerance at which a food is deemed to be adulterated under section 402(a)(1) or 402(a)(2)(A) of the Act.

- 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.**

To generate information on the incidence and levels of perchlorate contamination in foods, FDA conducted the following activities during Fiscal Year 2004 and Fiscal Year 2005:

- FDA first developed a rapid, sensitive, and specific ion chromatography-tandem mass spectrometry (IC-MS/MS) method for determining perchlorate levels in foods, such as bottled water, fruits and vegetables, milk, grain products, and seafood.
- During Fiscal Year 2004, FDA conducted an initial exploratory survey in which FDA Field Offices collected samples of domestic origin of seven food products (bottled water, milk, lettuce, tomatoes, carrots, spinach, and cantaloupe). The overall goal of the sampling plan (convenience samples, not necessarily representative of the U.S. food supply) was to gather initial information on occurrence of perchlorate in foods from various locations with a high likelihood of perchlorate contamination.
- During Fiscal Year 2005, FDA conducted a second exploratory survey in which FDA Field Offices collected additional samples of tomatoes, carrots, spinach, cantaloupe, and other high water content foods, including fruits and fruit juices, vegetables, and seafood. In addition, grain products such as wheat flour, cornmeal, and rice were sampled as a follow up to a Texas Tech University study report finding perchlorate in wheat heads. The Fiscal Year 2005 samples collected by FDA consisted of domestic products grown in a broader range of locations, i.e., 14 states within the United States to determine if perchlorate occurs in foods from wider regions of the United States, and not only from regions where water sources are known to be contaminated with perchlorate. In addition, FDA also collected a limited number of imported products commonly entering the U.S. market that were available for sampling during Fiscal Year 2005.
- Food samples collected during Fiscal Year 2004 and Fiscal Year 2005 were sent to FDA Field Laboratories for perchlorate analysis using the FDA's IC-MS/MS analytical method.
- Analytical results were then compiled, showing the incidence (or occurrence) and levels of perchlorate among the food samples collected and analyzed. This information entitled, "2004-2005 Exploratory Survey Data on Perchlorate in Food," is available at <http://www.cfsan.fda.gov/~dms/clo4data.html>.

Based on the 2004-2005 Exploratory Survey Data on Perchlorate in Foods, FDA conducted a preliminary exposure assessment. However, because the preliminary assessment is based on 2004/2005 exploratory survey data for 27 types of foods and beverages that represents only about a third of the total diet for the U.S. population, ages 2 years and older, sources of uncertainty for this preliminary exposure estimate exist. Therefore, sampling of additional food types to increase representation of the total U.S. diet, collection of more samples within a food type, and collection of food types from wider regions of the country would better characterize perchlorate distribution in the U.S. food supply. Additional sampling such as the data expected from FDA's forthcoming Total Diet Study (TDS) will provide a more precise assessment of the scope of perchlorate exposure and the public health implications for food with more reasonable certainty to determine if action is warranted under the FD&C Act to protect the public health.

- 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.**

There is an allowable level of lead in bottled water of 5 ppb (Title 21, *Code of Federal Regulations*, 165.110(b)(4)(iii)(A)). Lead is also present in drinking water regulated by EPA. In November 2006, FDA issued a guidance level for lead in candy of 0.1 part per million (see <http://www.cfsan.fda.gov/~dms/pbguid3.html>). FDA stated that the new guidance level is achievable with the use of good manufacturing practices in the production of candy and candy ingredients and is not harmful to human health. In assessing lead levels in candy products, FDA had found certain chili and high-salt containing Mexican candy products to contain excessive levels of lead that could be avoided by washing the chili peppers prior to grinding and by controlling the sourcing of salt to avoid salt types that have high levels of naturally occurring lead. FDA will continue to monitor lead levels in imported candy.

- 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.**

In the summer of 2005, FDA participated in a series of teleconferences with EPA and the United States Department of Agriculture (USDA) to discuss possible approaches EPA can use to estimate perchlorate exposure based on available information in the literature on perchlorate levels in foods, including FDA's Exploratory Data on Perchlorate in Food, November 2004, to better inform EPA for determining the relative source contribution.

In 2006, FDA participated in a series of teleconferences with EPA and USDA to discuss the possibility of sampling and analyzing additional food samples for perchlorate to better inform EPA for determining the relative source contribution. In January 2007, FDA entered into an Interagency Agreement with EPA to analyze approximately 820 food samples collected by USDA for perchlorate during Fiscal Year 2007. FDA plans to use the additional perchlorate data to update its preliminary exposure assessment.

In the summer of 2006, FDA's draft preliminary exposure assessment, based on 2004-2005 exploratory survey data, was peer reviewed by USDA. The peer review charge, peer reviewers' comments, and FDA's response to peer reviewers' comments are contained in a peer review report available at <http://www.cfsan.fda.gov/~dms/clo4ee2.html>.

In early 2007, a revised draft preliminary exposure assessment, based on USDA peer reviewers' comments, was reviewed by the Interagency Working Group (IWG) on Perchlorate, which includes EPA and USDA. Based on comments by the IWG on Perchlorate, FDA finalized the preliminary exposure assessment and posted it on its website at <http://www.cfsan.fda.gov/~dms/clo4ee.html> in May 2007.

**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 containing water is used to reconstitute the formula?**

In Fiscal Year 2005 and Fiscal Year 2006, FDA tested for perchlorate levels in samples of baby foods, infant formulas and adult foods, respectively, collected under FDA's TDS survey. FDA is preparing an exposure assessment based on FDA's Fiscal Year 2005/2006 TDS data for perchlorate which is expected to be released in the fall of 2007. TDS is FDA's ongoing market basket survey in which more than 280 core foods (TDS foods) in the U.S. food supply are collected and analyzed to determine levels of various contaminants and nutrients in those foods. For more information on TDS, see <http://www.cfsan.fda.gov/~comm/tds-toc.html>.

FDA is not aware of any studies to determine whether perchlorate, if present in milk, is concentrated or reduced (e.g., by volatilization) due to processing of that milk into infant formula. If infant formula powder is reconstituted with perchlorate-containing water, the net perchlorate level in the resulting solution would be higher than the perchlorate level that may be present in the infant formula powder.

**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.**

In the spring of 2005, FDA provided EPA with information on FDA's Fiscal Year 2004 exploratory survey for perchlorate in foods, i.e., the type and number of food samples collected and analyzed, and the results obtained from the survey. FDA also provided EPA with information on FDA's Fiscal Year 2005 exploratory survey for perchlorate in foods, i.e., the type and number of food samples that are being collected and analyzed, and FDA's plan for collecting and analyzing FDA's TDS food samples for perchlorate in Fiscal Year 2006.

**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.**

FDA conducted the preliminary exposure assessment to obtain initial information on exposure based on information available at the time and because of significant public interest in the issue of perchlorate exposure from food. However, this is a "preliminary" assessment based on exploratory survey data for 27 types of foods and beverages that represents only about a third of the total diet for the U.S. population, ages 2 years and older. Sampling of additional food types to increase representation of the total U.S. diet, collection of more samples within a food type, and collection of food types from wider regions of the country would better characterize perchlorate distribution in the U.S. food supply. Additional sampling such as the data expected from FDA's forthcoming TDS will provide a more precise assessment of the scope of perchlorate exposure and the public health implications for food with more reasonable certainty to determine if action is warranted to protect the public health.

- 10. Various studies have shown that nursing and bottle fed infants could receive doses of perchlorate from breast milk above EPA's RfD of 24 µg/L. Recent studies have determined the existence of perchlorate doses that were above EPA's RfD of 24 µg/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 µg/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.**

In Fiscal Year 2005 and Fiscal Year 2006, FDA tested for perchlorate levels in samples of baby (including infant formula) and adult foods, respectively, collected under FDA's TDS survey. FDA is preparing an exposure assessment based on FDA's Fiscal Year 2005/2006 TDS data for perchlorate, which is expected to be released in the fall of 2007, for assessing perchlorate exposure of bottle-fed infants with infant formulas. For breast milk, FDA intends to utilize referenced studies in the literature on assessing perchlorate exposure of nursing infants with breast milk.

- 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 µg/kg bw/day is similar to geometric mean perchlorate dose of 0.066 µg/kg bw/day found in the CDC Blount et al, 2006 study of *Perchlorate Exposure of US Population*?**

Yes. FDA found the presence of perchlorate at varying levels in 27 types of foods and beverages and the total mean population exposure from 27 foods and beverages of 0.053 micrograms per kilogram body weight per day (µg/kg bw/day) is similar to geometric mean perchlorate dose of 0.066 µg/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 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?**

If the Reference Dose (RfD) is revised downward, FDA will use the revised RfD to assess the potential risk of perchlorate exposure from foods in its exposure assessments based on perchlorate data obtained from its surveys, such as the preliminary exposure assessment based on 2004 and 2005 exploratory survey data and any updates of the preliminary exposure assessment.

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

If the RfD is lowered, FDA will use the lower RfD to assess the potential risk of perchlorate exposure from foods in its exposure assessments based on perchlorate data obtained from its surveys, such as the preliminary exposure assessment based on 2004 and 2005 exploratory survey data.

However, because the preliminary exposure assessment is based on 2004/2005 exploratory survey data for 27 types of foods and beverages that represents only about a third of the total diet for the U.S. population, ages 2 years and older, sources of uncertainty for this preliminary exposure estimate exist. Therefore, sampling of additional food types to increase representation of the total U.S. diet, collection of more samples within a food type, and collection of food types from wider regions of the country would better characterize perchlorate distribution in the U.S. food supply. Additional sampling such as the data expected from FDA's forthcoming TDS will provide a more precise assessment of the scope of perchlorate exposure and the public health implications for food with more reasonable certainty to determine if action is warranted under the FD&C Act to protect the public health.

**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?**

EPA, which is responsible for establishing national drinking water standards, conducted a draft risk assessment for perchlorate in 2002. In 2003, EPA, the Department of Defense (DOD), the Department of Energy (DOE), and the National Aeronautics and Space Administration (NASA) asked the National Academy of Sciences (NAS) to review several important questions relating to whether perchlorate is a public health concern. In January 2005, the NAS Committee to Assess the Health Implications of Perchlorate Ingestion released its study report that recommended an RfD of 0.7  $\mu\text{g}/\text{kg}$  bw/day. Therefore, FDA did not consider it necessary to duplicate EPA and NAS health assessments by conducting its own health assessment.

FDA is using the NAS recommended RfD that was adopted by EPA to assess potential risk of perchlorate exposure from foods, such as FDA's preliminary exposure assessment based on 2004 and 2005 exploratory survey data on perchlorate levels in 27 types of foods and beverages.

**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?**

Yes, carrot samples that FDA collected from growers in Arvin, California and Moorpark, California were found to contain 87.6 ppb and 81.3 ppb perchlorate, respectively. The collected samples were destroyed during sample preparation for perchlorate analysis and therefore were not marketed. FDA did not take any action to prevent carrots from these growers from entering the nation's food supply because insufficient scientific information exists for FDA to consider carrots containing perchlorate at these levels to present a public health risk. Therefore, it is possible carrots from these growers 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 80 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?**

Yes, spinach samples that FDA collected from growers in Brawley, California and Riverside, California were found to contain 927 ppb and 680 ppb perchlorate, respectively. The collected samples were destroyed during sample preparation for perchlorate analysis and therefore were not marketed. FDA did not take any action to prevent spinach from these growers from entering the nation's food supply because insufficient scientific information exists for FDA to consider spinach containing perchlorate at these levels to present a public health risk. Therefore, it is possible spinach from these growers 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?**

Yes, cantaloupe samples that FDA collected from growers in Goodyear, Arizona were found to contain 57.8 ppb, 63.3 ppb, and 66.6 ppb perchlorate. The collected samples were destroyed during sample preparation for perchlorate analysis and therefore were not marketed. FDA did not take any action to prevent cantaloupes from these growers from entering the nation's food supply because insufficient scientific information exists for FDA to consider cantaloupes containing perchlorate at these levels to present a public health risk. Therefore, it is possible cantaloupes from these growers 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?**

Yes, the broccoli sample that FDA collected from a grower in Greensburg, Pennsylvania was found to contain 40.2 ppb perchlorate. The collected sample was destroyed during sample preparation for perchlorate analysis and therefore was not marketed. FDA did not take any action to prevent broccoli from this grower from entering the nation's food supply because insufficient scientific information exists for FDA to consider broccoli containing perchlorate at this level to present a public health risk. Therefore, it is possible broccoli from this grower would have been made available for public purchase and consumption.

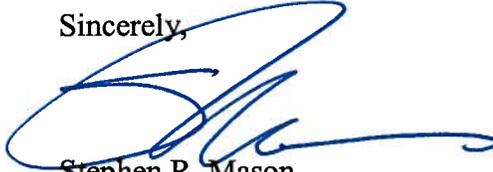
**19. Is it correct that FDA sampled collard greens of growers in Mount Olive, North Carolina; Newton Grove, North Carolina; Raleigh, North Carolina; and Peleion, South Carolina, and that these samples were found to contain 238 ppb., 47.8 ppb., 39.7 ppb., and 69.1 ppb. of perchlorate respectively? Based 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?**

Yes, FDA collard greens samples collected from growers in Mount Olive, North Carolina; Newton Grove, North Carolina; Raleigh, North Carolina; and Peleion, South Carolina were found to contain 238 ppb, 47.8 ppb, 39.7 ppb, and 69.1 ppb perchlorate, respectively. The collected samples were destroyed during sample preparation for perchlorate analysis and therefore were not marketed. FDA did not take any action to prevent collard greens from these growers from entering the nation's food supply because insufficient scientific information exists for FDA to consider collard greens containing perchlorate at these levels to present a public health risk. Therefore, it is possible collard greens from these growers would have been made available for public purchase and consumption.

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Thank you for your continued interest in these important public health matters. If you have any further questions or concerns, please let us know.

Sincerely,



Stephen R. Mason  
Acting Assistant Commissioner  
for Legislation

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

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

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