

# Perchlorate

A GUIDE FOR CONSUMERS,  
POLICYMAKERS AND THE MEDIA



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The Association of Food, Beverage  
and Consumer Products Companies

The **Grocery Manufacturers Association (GMA)** represents the world's leading food, beverage and consumer products companies. The association promotes sound public policy, champions initiatives that increase productivity and growth and helps to protect the safety and security of the food supply through scientific excellence. The GMA Board of Directors is comprised of chief executive officers from the Association's member companies. The \$2.1 trillion food, beverage and consumer packaged goods industry employs 14 million workers, and contributes over \$1 trillion in added value to the nation's economy. For more information, visit the GMA web site at [www.gmaonline.org](http://www.gmaonline.org).

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## FOREWORD

**T**his paper addressing perchlorate is one in a series written by the Grocery Manufacturers Association (GMA) to explore some of the most important food-related science policy issues before consumers and policymakers.

The Grocery Manufacturers Association represents the world's leading food, beverage and consumer products companies. The Association promotes sound public policy, champions initiatives that increase productivity and growth, and helps to protect the safety and security of the food supply through scientific excellence. One of the Association's goals is to ensure that the laws and regulations governing food marketing and production are feasible, practical and based on sound information.

Each of our science policy papers includes a review of key scientific peer-reviewed published articles, regulatory considerations, food and beverage applications, and market insights. The Association's goal in publishing these white papers is to provide current, scientifically accurate resources to journalists, health professionals, policy makers, interested consumers and other stakeholders.

For more information, visit the Grocery Manufacturers Association web site at [www.gmaonline.org/science/index.cfm](http://www.gmaonline.org/science/index.cfm). ■

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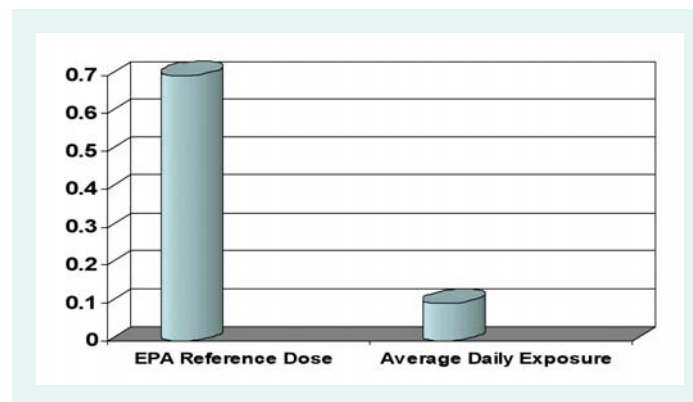
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## EXECUTIVE SUMMARY

Perchlorate is one of the best-studied environmental pollutants, in part due to its prior and current use as a pharmaceutical agent. Many studies in humans and animals have been conducted and published that assess the health effects of perchlorate.

Based on well-established, peer-reviewed science, current levels of perchlorate in the diet do not appear to pose a significant health risk to consumers, including pregnant women and their offspring. Additional studies are in progress to better define the distribution of perchlorate exposure among the U.S. population. FDA does not recommend a change in diet based on current perchlorate data since many of these foods are major dietary sources of iodine and other nutritionally essential substances.

### Comparison of Reference Dose for Perchlorate to the Estimated Average Daily Exposure to Perchlorate for Women of Childbearing Age (micrograms per kilogram body weight per day)



High doses of perchlorate can inhibit the uptake of iodide into the thyroid gland, potentially decreasing the production of thyroid hormones. Thyroid hormones play a critical role in the development of the central nervous system in fetuses and infants. At lower doses of perchlorate, clear evidence of effects on the thyroid has not been observed in humans. ■

## INTRODUCTION

In recent years, the presence of perchlorate in the environment has attracted the attention of scientific organizations, regulatory authorities, environmental activists and the media. Low levels of perchlorate in drinking water and foods are of potential concern because much larger doses of perchlorate have been shown to inhibit iodide uptake, which, if sufficiently severe, can lead to hypothyroidism and abnormal fetal development. Consumers need balanced, scientifically based and practical information about perchlorate. This paper examines peer-reviewed scientific data about the facts and fallacies regarding perchlorate in the diet and its potential impact on health.

## BACKGROUND

Perchlorate is both a naturally-occurring and man-made chemical. Perchlorate is used as an oxidizing agent in solid rocket propellant and is found in other products (e.g., explosives, fireworks, road flares, automobile airbags). Naturally-occurring perchlorate is found throughout the world, in arid areas of the U.S., as well as in the potash found in the U.S. and Canada and in Chilean nitrate fertilizer, which has been used in the U.S. Perchlorate can also form naturally in the atmosphere, leading to trace levels of perchlorate in rainfall.<sup>1</sup> The presence of trace levels of perchlorate in the environment results from a combination of human activities and natural sources.

## PERCHLORATE AND HEALTH

### *Toxicity and health effects of perchlorate*

Perchlorate is one of the best-studied environmental pollutants, in part due to its prior and current use as a pharmaceutical agent. The National Academy of Sciences (NAS)<sup>2</sup> and Environmental Protection Agency (EPA)<sup>3</sup> have published detailed reviews of the toxicity and health effects of perchlorate. In addition, the Department of Health and Human Services' Agency for Toxic Substances and Disease Registry (ATSDR) released its draft "Toxicological Profile for Perchlorates" in September 2005; this document has yet to be finalized.<sup>4</sup> And, the FDA's Center for Food Safety and Applied Nutrition (CFSAN)<sup>5</sup> published its "Perchlorate. Questions and Answers," updated in May 2007, which includes a summary of the health effects of perchlorate.

Perchlorate has been studied extensively in human studies, including occupational studies, epidemiology studies in neonates and school age children, and clinical studies in adults. Animal toxicity studies of perchlorate include rat developmental neurotoxicity, 90-day systemic toxicity, developmental toxicity, and two-generation reproductive toxicity studies.

At high doses, the actions of perchlorate on the body are well understood. Historically, physicians used high doses of perchlorate as a pharmaceutical agent to treat patients with hyperthyroidism (excess thyroid hormone production). High doses of perchlorate can inhibit the uptake of iodide into the thyroid gland, potentially interfering with function of the thyroid gland and decreasing the production of thyroid hormones. Iodide and thyroid hormones play a critical role in the development of the central nervous system in fetuses and infants. Pregnant women and their fetuses and newborns represent the most susceptible population to the potential adverse effects of iodide deficiency from perchlorate exposure.<sup>6</sup>

Importantly, effects on the thyroid have not been observed in humans exposed to lower doses of perchlorate. According to the FDA, "Perchlorate-induced changes to thyroid function have not been demonstrated in any human population exposed to perchlorate, even at doses as high as 0.5 milligrams [500 micrograms] per kilogram body weight per day."<sup>7</sup> There is suggestive evidence from a single study, published in 2006, that lower levels of perchlorate in the urine may correlate with changes in serum thyroid hormones in women with sub-optimal iodine levels.<sup>8</sup> The authors of this study reported a statistically significant association at a point in time between urinary perchlorate and altered levels of two thyroid hormones in the serum of women with urine iodine levels less than 100 micrograms per liter (an indication of iodine deficiency). The study did not use the measure of thyroid hormone used to medically assess thyroid health ("free T4"). These results do not establish a causal relationship, and the study authors concluded that their results need to be confirmed in another study of women with low iodine levels as a sensitive subpopulation. These results have yet to be confirmed. It is unclear what any such association means for public health since: (1) iodine deficiency in the U.S. is rare; (2) the thyroid gland has the ability to regulate itself; and (3) many other iodine uptake-inhibiting chemicals occur naturally in the diet.

Fortunately, iodine deficiency is now rare in the U.S. as a result of widespread distribution of foods from iodine sufficient areas. Infants, children, women and men generally appear to receive adequate dietary intakes of iodine, based on recent testing by the FDA.<sup>9</sup> The estimated average iodine intakes for the various age/sex groups ranged from 138 to 353 micrograms per day. These averages are all well above the Estimated Average Requirement (EAR) recommended by the NAS. Significantly, many of the

foods with detectable levels of perchlorate are also major dietary sources of iodine, as well as other essential nutrients.<sup>10</sup>

The issue of whether perchlorate causes cancer has been carefully evaluated. The NAS recently concluded that perchlorate was unlikely to cause cancer in humans.<sup>11</sup> EPA drew a similar conclusion: “The overall confidence is high that perchlorate is not likely to be carcinogenic to humans, at least at doses below those necessary to alter thyroid hormone homeostasis.”<sup>12</sup>

## Safe levels of perchlorate established by regulatory agencies

In 2005, EPA adopted a Reference Dose of 0.7 micrograms per kilogram body weight per day.<sup>13</sup> The Reference Dose is an estimate of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects over a lifetime. The National Academy of Sciences conducted an extensive review of the scientific literature on perchlorate and, in 2005, advised EPA that a Reference Dose of 0.7 micrograms per kilogram body weight per day would protect the most sensitive population — the fetuses of pregnant women who might have hypothyroidism or iodide deficiency. The Reference Dose is based on a No-Observed-Effect-Level (NOEL) from a study in human subjects by Greer *et al.* (2002) and an uncertainty factor of 10. In other words, the Reference Dose is one-tenth of the lowest dose that is without effect in humans.

Furthermore, the Reference Dose for perchlorate is especially conservative (*i.e.*, health protective) because the NOEL in the Greer *et al.* study is based on a precursor to an adverse effect (*i.e.*, inhibition of iodine uptake), and not an adverse effect (*i.e.*, changes in thyroid hormone levels).<sup>14</sup> Humans regulate thyroid hormones through compensatory mechanisms. According to the National Academy of Sciences, iodine uptake would have to be reduced by at least 75 percent for months or longer in order to produce declines in thyroid hormone production that would have adverse health effects.<sup>15</sup> In fact, a human study showed no change in thyroid hormone levels in men or women when iodine uptake was inhibited 70 percent.<sup>16</sup> The use of a study measuring inhibition of iodine uptake as the primary basis for establishing a Reference Dose was criticized as overly conservative and “problematic” in a 2004 published scientific article by Toxicology Excellence for Risk Assessment (TERA), a non-profit scientific organization.<sup>17</sup> TERA proposed a Reference Dose for perchlorate of 2 micrograms per kilogram body weight per day based on changes in thyroid hormone levels in pregnant women as the critical effect. However, EPA chose to adopt the more conservative Reference Dose

recommended by the NAS (0.7 micrograms per kilogram body weight per day).

EPA stated that its overall confidence in its Reference Dose is “high because it is based on a no-effect level for a well-characterized biochemical precursor effect (iodide uptake inhibition), accompanied by a tenfold uncertainty factor for susceptible populations.”<sup>18</sup> According to EPA, its Reference Dose “should protect the health of even the most sensitive populations, because a dose that does not inhibit thyroid iodide uptake will not affect thyroid function, even in subjects with an abnormal thyroid gland or a very low iodide intake.”<sup>19</sup>

## EXPOSURE TO PERCHLORATE

### Sources of exposure to perchlorate

The two major sources of exposure to perchlorate for the U.S. general public are drinking water and food. For the vast majority of people, food is a larger source of exposure than drinking water. However, there are certain areas of the country that have high concentrations of perchlorate in drinking water; in these regions, drinking water is the predominant source of exposure. Perchlorate was found in the Colorado River, an important source of water for Arizona and southern California, due to contamination from manufacturing facilities in Nevada.<sup>20</sup> California established a drinking water Maximum Contaminant Level (MCL) for perchlorate of 6 micrograms per liter in October 2007.<sup>21</sup>

Perchlorate has been detected in a wide variety of foods.<sup>22</sup> It is currently unclear exactly how perchlorate gets into foods. Food growers and processors do not intentionally add perchlorate to foods. Possible sources include: naturally-occurring perchlorate in irrigation water or soil, perchlorate contaminated irrigation water, and fertilizer containing perchlorate. The relative contribution of man-made and natural perchlorate is unknown,<sup>23</sup> but one analysis estimated that, averaged over the past sixty years, contamination from perchlorate use in propellants has been the dominant source.<sup>24</sup>

In early 2008, FDA published the results of its testing for perchlorate in 1,065 samples of foods; this testing was performed as part of FDA’s Total Diet Study (TDS). Food samples were collected across all regions of the United States between 2003–2006 and analyzed for perchlorate. Perchlorate was detected in 59 percent (625/1065) of the total samples analyzed. Further, perchlorate was found in at least one sample of 74 percent of the 285 different types of foods analyzed. In other words, perchlorate was not

detected in any sample for only 26 percent of the 285 different types of foods analyzed.

FDA assigned all foods in the TDS to one of 12 major food groups: baby food, beverage, dairy, egg, fat/oil, fruit, grain, legume, mixture (primarily entrée items with no predominant ingredient), meat/poultry/fish, sweets and vegetables. Only three major food groups (*i.e.*, egg, fat/oil, legumes) did not contribute at all to the estimated daily intake of perchlorate.<sup>25</sup>

FDA estimated the percentage contribution of each major food group to the estimated daily intake of perchlorate, and the results varied by age group.<sup>26</sup> For example, for infants (6–11 months), the majority (81 percent) of total estimated daily intake of perchlorate intake comes from baby foods (49 percent) and dairy foods (32 percent), including infant formula. For children, dairy foods contribute about half the total estimated daily intake of perchlorate. For teenagers and adults, vegetables and dairy foods combined account for 46–59 percent of the total estimated daily intake of perchlorate in the diet.

## Are the levels of perchlorate in foods increasing?

There is evidence that uncontrolled releases of perchlorate from past contamination have gone down over the past fifteen years.<sup>27</sup> There is not yet enough information to conclude that levels of perchlorate in foods are increasing or decreasing. Until recently, foods were not analyzed for the presence of perchlorate because an appropriate method to analyze foods for low levels of perchlorate was not available. Around 2004, FDA developed a suitable analytical method for perchlorate in foods. At the same time, FDA conducted an initial exploratory survey to identify perchlorate concentrations in a limited number of foods. Therefore, most of the testing of food products has taken place in the past few years, which is not enough time to determine whether the levels are increasing or decreasing. FDA has a program in place to monitor perchlorate in foods, and if the levels are changing over time, FDA's program will be able to detect the change.

## Estimated exposure to perchlorate from the diet

FDA recently estimated average perchlorate intakes from the diet in 2005–2006 for various age groups in the U.S.<sup>28</sup> The results are presented in *Table 1*. The results are presented two ways: (1) micrograms per day, and (2) micrograms per kilogram body weight per day. A microgram is one of the smallest measurements

of weight; a microgram is 1/1,000,000 of a gram or 1/28,000,000 of an ounce. According to the FDA, the estimated average exposure to perchlorate ranged from 2.4–2.7 micrograms per day for infants to 7.4–9.4 micrograms per day for men 40–45 years of age (*Table 1*).

When the results are expressed in terms body weight (*Table 1*, last column), dietary exposures to perchlorate are higher in infants and children than adults because infants and children eat proportionately more food relative to their body weight than do adults. Of particular interest is the estimated average dietary intake of perchlorate for women of childbearing age, since pregnant women represent the most sensitive population to the potential effects of perchlorate. The estimates for teenage girls, women 25–30 years and women 4–45 years provide insight into the range of average exposure for women of childbearing age. In all three cases, FDA estimated the average total dietary intake of perchlorate to be 0.09–0.11 micrograms per kilogram per day, which is about one-seventh of the EPA Reference Dose.

**TABLE 1. FDA estimates of average dietary intake of perchlorate for 2005–2006**

Group	Total Dietary Intake of Perchlorate <sup>a</sup>	
	Micrograms per day	Micrograms per kilogram body weight per day
Infants (6–11 months)	2.4–2.7	0.26–0.29
Children (2 years)	4.9–5.5	0.35–0.39
Children (6 years)	5.4–6.1	0.25–0.28
Children (10 years)	6.1–6.9	0.17–0.20
Teenage girls (14–16 years)	5.1–6.1	0.09–0.11
Teenage boys (14–16 years)	7.7–9.1	0.12–0.14
Women (25–30 years)	5.4–6.8	0.09–0.11
Men (25–30 years)	6.7–8.6	0.08–0.11
Women (40–45 years)	5.9–7.3	0.09–0.11
Men (40–45 years)	7.4–9.4	0.09–0.11
Women (60–65 years)	5.9–7.1	0.09–0.10
Men (60–65 years)	7.2–8.8	0.09–0.11
Women (70+ years)	5.8–6.9	0.09–0.11
Men (70+ years)	7.1–8.3	0.11–0.12

<sup>a</sup> Each value is the range of estimated lower and upper bound average perchlorate intakes

A limitation of the exposure estimates in *Table 1* is that they represent *average* intakes, albeit the lower and upper bound average values. Some individuals will be exposed to more or less than the lower and upper bound average values. But, the FDA Total Diet Study does not include the data needed to estimate the range of exposure values for individuals. To fill this data gap, FDA will use more detailed food consumption data from another database (*e.g.*, CSFII, NHANES).

The results of the FDA estimates of perchlorate exposure are similar to an estimate made by the Centers for Disease Control and Prevention (CDC).<sup>29</sup> By measuring the levels of perchlorate in the urine, CDC was able to estimate a total daily perchlorate intake for adults 20 years of age and older. CDC estimated the median estimate of total daily perchlorate intake of 0.064 micrograms per kilogram body weight per day, which is about two-thirds of the estimates for adults in *Table 1*. In addition, CDC estimated the 95<sup>th</sup> percentile total daily perchlorate intake to be 0.234 micrograms per kilogram body weight per day.

## RISK ASSESSMENT OF PERCHLORATE IN FOODS

### *The levels of perchlorate in foods do not pose a significant health risk*

The results of testing to date do not indicate that perchlorate in foods poses a health risk. As noted earlier, EPA has established a Reference Dose of 0.7 micrograms per kilogram body weight per day. Based on the FDA study of exposure, the average daily exposure for women of childbearing age appears to be about 0.1 micrograms per kilogram per day, or about seven times less than the EPA Reference Dose (*Figure 1*). All of the FDA estimates of the average daily exposure to perchlorate exposure from the smallest lower bound to the highest upper bound for the 14 age/sex groups were all below the EPA Reference Dose.

Critics have expressed concern that a small percentage of children may be exposed to perchlorate in foods at levels above the EPA Reference Dose (even though exposures for most children are well below the EPA Reference Dose).<sup>30</sup> Assuming this may be true, it is important to recognize that exposures above the Reference Dose, while undesirable, are not necessarily unsafe. The Reference Dose is not the threshold for adverse health effects; in the case of perchlorate, the Reference Dose represents a dose which is ten times less than the human dose that does not affect a precursor to an adverse effect. In other words, the Reference Dose for perchlorate has a large margin of safety.

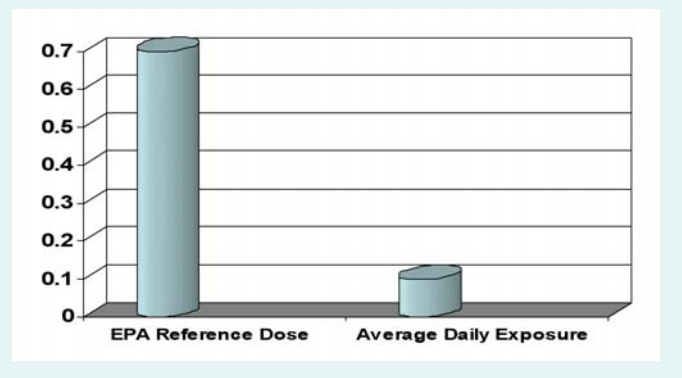
Other chemicals naturally present in foods also have the potential to inhibit iodine uptake, and these foods are considered safe. These include nitrate and thiocyanate, which are present in high concentrations in certain foods, such as vegetables. Nitrate and thiocyanate inhibit iodine uptake by exactly the same mechanism as perchlorate.

While nitrate and thiocyanate are less potent inhibitors of iodine than is perchlorate, they occur at much higher concentrations in foods than perchlorate and therefore pose a potential to inhibit iodine uptake similar to perchlorate in foods.

### *What is FDA recommending to consumers?*

“FDA recommends a healthy eating plan, consistent with the *Dietary Guidelines for Americans*, that emphasizes fruits, vegetables, whole grains and fat-free or low-fat milk and milk products, including lean meats, poultry, fish, beans, eggs and nuts; and is low in saturated fats, trans fats, cholesterol, salt (sodium) and added sugars. Additionally, adequate intake of iodine has previously been recognized as important for healthy thyroid function. *FDA does not recommend at this time that consumers alter their infants’ and children’s diets and eating habits based on current perchlorate data.*”<sup>31</sup>

**Figure 1. Comparison of Reference Dose for Perchlorate to the Estimated Average Daily Exposure to Perchlorate for Women of Childbearing Age (micrograms per kilogram body weight per day)**



## SUMMARY

Based on well-established, peer-reviewed science, current levels of perchlorate in the diet do not appear to pose a significant health risk to consumers, including pregnant women and their offspring. Additional studies are in progress to better define the distribution of perchlorate

exposure among the U.S. population. Avoiding major food groups containing low levels of perchlorate would not be recommended because many of these foods are major dietary sources of iodine and other nutritionally essential substances.

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