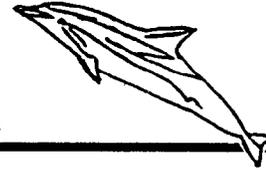


Department of the Planet Earth

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Dr. Lester M. Crawford, DVM, PhD
Commissioner
Food and Drug Administration
Documents Management Branch
5630 Fishers Lane, Room 1061
Rockville, Maryland 20857

September 14, 2005

Citizen Petition

Re: **Petition to Rescind the "Generally Recognized as Safe" or GRAS Status for Aluminum Based Food Additives.**

Dear Dr. Crawford,

This petition requests two actions by the Food and Drug Administration, as listed below. This petition is supported by the accompanying review of evidence paper.

There is an urgent need for FDA to rescind the "generally recognized as safe" or GRAS designation of aluminum food additives, because the evidence does not support it. The adverse human health consequences of FDA's GRAS designation for aluminum based food additives appear substantial. For example:

Rogers and Simon published a study of residents of the Loretto Geriatric Center of Syracuse, New York in 1999. It was found that those who regularly consumed food over five previous years with high aluminum content due to enrichment with food additives had an 8.6 fold increased risk of developing Alzheimer's disease by age 73. Aluminum based baking powder appeared to be a primary problem, producing Alzheimer's in 100 percent of exposed persons. A full copy of this open literature study is attached.

Twenty two drinking water epidemiology studies confirm adverse health effects of dietary aluminum in elevating risk of either Alzheimer's or elderly mental impairment by as much as 50 to 70 percent. (See Charts 2-5 in the review of evidence paper, the drinking water chartbook in Folder 1, and the original epidemiology studies in Folder 3.)

Petition Request 1: FDA should rescind GRAS status for aluminum containing food additives.

We ask that the Food and Drug Administration rescind the generally recognized as safe (GRAS) status for all aluminum based food additives

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destined for human consumption listed in 21 CFR 182, and as summarized in a consolidated form in the Food Additive Status List (Appendix A) – including multi-purpose food substances, anti-caking agents, colorants, and any other direct or indirect aluminum additives to the food supply that can elevate blood, bone, organ and brain aluminum levels in the food consumer.

For perspective, the generally recognized definition of safe would be a substance that does not inflict “damage, danger, or injury” upon a person. Other words included are, “taking no risks or prudent”. It is a derivative of the Latin word *salvus*, “akin to *salus*, health, sound condition”. (Websters New World Dictionary) It is highly unusual for a neurotoxic metal without nutritional value to be considered to be safe.

The extensive evidence reviewed in this petition indicates that dietary aluminum based additives do not meet a standard of safety for the general population or for subsets of it, particularly the very young or the elderly age groups. The United States has one of the most aluminized diets in the world. (See Chart 1 in the review of evidence paper.) The metal is significantly absorbed from the diet.

Petition Request 2: FDA should review safety of other food additives that enhance or decrease aluminum absorption.

We are asking FDA to investigate the interaction of aluminum with food additives like the food flavor maltol, tartrate, citrate, succinate, glutamate and other food products that may more efficiently increase aluminum’s absorption from food, and propose remedies for this situation. For example, maltol, glutamate, citrate and lactate are complexed with aluminum by a number of researchers to efficiently move the metal into the brain of laboratory animals.

Some of food products that affect aluminum absorption are listed as GRAS in Appendix A. The GRAS characterization of these other additives need to be reevaluated for situations where aluminum is present in the food.

Protective Effect of Silicon:

On the other hand, silicon as an additive can reduce aluminum absorption, even in the presence of citrate, and increase excretion. A French study found that consumption of European mineral waters with higher concentrations of silicon was significantly preventative of Alzheimer’s, which is good indication that aluminum is involved in disease causation. We will describe this study in the review of evidence paper, and a copy is found in Folder 3. Silicon is also

presented in solid foods: e.g. in bananas at higher levels. It has been estimated that about 41 percent of ingested silicon from food is excreted in the urine.

However, over-dosage of silicon can erode and damage the kidneys as has been the case in the Balkans where drinking water silicon levels are very high. There is a poorly defined upper public health limit to safe use of silicon in controlling aluminum absorption. The prudent and least expensive program is to eliminate the aluminum based additives from the food supply as the first priority. For example, baking powder can be manufactured with calcium rather than aluminum. Such products are already available at the supermarket at similar prices. Silicon additives may best be saved for cosmetics like deodorants.

FDA Should Evaluate Any Possible Adverse Effect of Aluminum Food Additives on the Effectiveness of FDA's Folic Acid Supplementation Program:

Folic acid is an aluminum chelator in laboratory animals - i.e. reducing aluminum in the bone, kidney and especially the brain, though without affecting blood levels. (See Chart 16 in the enclosed review of evidence paper.) This interaction suggests that aluminum based food additives could reduce the effectiveness of folic acid by bonding with the vitamin, preventing absorption or interfering with biology. FDA might investigate this interaction in light of FDA's recommended folic acid supplementation programs for pregnancy. Teenagers have a higher dietary aluminum intake than adults. (See Chart 1 in review of evidence paper.)

- Aluminum Food Additives, Elderly Cognitive Impairment – “Beyond Any Doubt” Conflicts With The GRAS Designation.

This petition focuses particularly on the evidence linking dietary aluminum to elderly cognitive impairment and Alzheimer's, which are extraordinarily expensive to the medical system. Gupta reaches the following conclusion in the enclosed 2005 review of the literature entitled, Aluminum in Alzheimer's disease: are we still at a crossroad? (See Folder 2.)

“Finally, it is concluded based on extensive literature that the neurotoxic effect effects of aluminum are beyond any doubt, and aluminum as a factor in AD cannot be discarded. However, whether aluminum is a sole factor in AD and whether it is a factor in all AD cases still needs to be understood.”

A neurotoxic metal, “beyond any doubt”, added to the food supply cannot be considered “GRAS”. There exists a strong conflict between aluminum's neurotoxicity and the GRAS designation. Epidemiology and human contamination studies indicate that this toxicity takes place at existing dietary exposure levels.

It is clear that there are multiple causation factors in Alzheimer's, as will be pointed out in the review of evidence paper. The following may put aluminum's role in Alzheimer's into perspective:

1. In 1993, based on extensive research at their laboratory and elsewhere, and a successful human clinical trial based on aluminum chelation, D.R.C. McLachlan, then director of the Tanz Center for Research in Neurodegenerative Diseases of the University of Toronto, concluded that aluminum was a "necessary but not sufficient risk factor for Alzheimer's". An extensive subsequent literature supports this viewpoint.
2. In 2005, Lukiw published a study probing human brain cell gene expression after exposure of human neural cells to 100 nanomolar aluminum sulfate. Of the most altered gene expression levels, 71 percent of aluminum-affected genes and 87 percent of aluminum-induced genes exhibit expression patterns similar to those observed in Alzheimers.

This finding of a 71 to 87 percent interaction of aluminum with Alzheimer's genes should spark an emergency action by FDA to reduce aluminum contamination of the food supply. This petition asks FDA to respond to the extensive published literature concerning adverse health effects linked to dietary and drinking water aluminum, and rescind the generally recognized as safe (GRAS) designation for aluminum based food additives. This would be a first small step towards consideration of the issue.

Previous Petition to FDA: Dr. Colin Meyers submitted a petition, dated 12/03/2001, asking FDA to rescind the "Generally Recognized as Safe" (GRAS) status for food additives that contain aluminum. The Docket number of that petition was 02P-0013/CP1 (Food Additive Petition No. 2A4742). It should be noted that Dr. Meyer's petition is not related to this present petition, and he has not participated in the writing or review of this petition.

On January 27, 2003, the Food and Drug Administration discontinued the review of that petition because the petitioner had not provided full copies of all references cited in the petition, and also an adequate explanation of how said information is relevant. A letter signed by Consumer Safety Officer, Dr. Mical Honigfort concluded, "We have discontinued our review of the petition because of the above deficiency. If you wish to have the review continued, you must provide complete copies of the missing references."

The Department of the Planet Earth is a non-profit citizen group formed in 1991, based in Washington, DC. We focus on environmental, health, and toxic issues,

and have had a special focus on US-Canadian cooperative efforts. Dr. William Forbes, now deceased and last with Statistics Canada, was an early mentor of our effort to put aluminum into a more comprehensive package with regard to the metal's effect on elderly mental impairment and Alzheimer's.

An environmental impact statement does not seem to be needed for the actions requested by this citizen petition.

Official Certification Statement: The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.”

With best regards,

A handwritten signature in black ink that reads "Erik Jansson". The signature is written in a cursive style with a long, sweeping tail on the "n".

Erik Jansson, Exec. Dir.
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