



DEC 18 2001

0458 '03 JAN 29 10:22

Colin G. Meyer, D.V.M, Ph.D.
Director, Food Analysis and Diagnostic Laboratory
2472 Schofield Road, Building 2632
Fort Sam Houston, TX 78234-6232

Re: Docket No. 02P-0013/CP 1

Dear Dr. Meyer:

This refers to your citizen petition dated December 18, 2001, and filed on January 11, 2002, under docket number 02P-0013/CP 1, requesting that the Food and Drug Administration rescind the generally recognized as safe (GRAS) status for aluminum containing food additives, specifically sodium aluminum sulfates, sodium aluminum phosphates, and aluminum sulfates.

The purpose of this response is to advise you, in accordance with 21 CFR 10.30(e)(2), that we have not reached a decision on your petition within the first 180 days of its receipt because of a number of competing priorities. However, be advised that your petition is currently under active evaluation by our staff and we anticipate completion of our review in the near future.

We will contact you again when our review has been completed, at which time we will inform you of the actions, if any, the Agency decides are appropriate in response to your petition. In the interim, you and other interested parties may continue to submit additional supplemental materials for Agency consideration to the docket number referenced above.

Sincerely yours,

Alan M. Rulis, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

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Authors

Gauthier E. Fortier I. Courchesne F. Pepin P. Mortimer J. Gauvreau D.

Institution

Departement de Geographie, Universite de Montreal, Montreal, Quebec, Canada.

Title

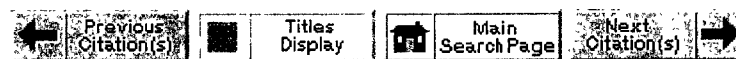
Aluminum forms in drinking water and risk of Alzheimer's disease.

Source

Environmental Research. 84(3):234-46, 2000 Nov.

Abstract

The objective of this study was to assess the relation between long-term exposure to different **aluminum** (Al) forms in drinking water and Alzheimer's disease (AD). The study participants were selected from a random sample of the elderly population (> or = 70 years of age) of the Saguenay-Lac-Saint-Jean region (Quebec). Sixty-eight cases of Alzheimer's disease diagnosed according to recognized criteria were paired for age (+/-2 years) and sex with nondemented controls. **Aluminum** speciation was assessed using established standard analytical protocols along with quality control procedures. Exposure to Al forms (total Al, total dissolved Al, monomeric organic Al, monomeric inorganic Al, polymeric Al, Al(3+), AlOH, AlF, AlH(3)SiO (2+)(4), AlSO(4)) in drinking water was estimated by juxtaposing the subject's residential history with the physicochemical data of the municipalities. The markers of long-term exposures (1945 to onset) to Al forms in drinking water were not significantly associated with AD. On the other hand, after adjustment for education level, presence of family cases, and ApoE varepsilon4 allele, exposure to organic monomeric **aluminum** estimated at the onset of the disease was associated with AD (odds ratio 2.67; 95% CI 1.04-6.90). On average, the exposure estimated at the onset had been stable for 44 years. Our results confirm prime the importance of estimation of Al speciation and consideration of genetic characteristics in the assessment of the association between **aluminum** exposure and Alzheimer's disease. Copyright 2000 Academic Press.



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Medline Identifier

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Authors

Newman PE.

Institution

Paris, France.

Title

Alzheimer's disease revisited.

Source

Medical Hypotheses. 54(5):774-6, 2000 May.

Abstract

In a previous paper, it was suggested that a relative deficiency of essential fatty acids might play a role in the etiology of sporadic or non-familial Alzheimer's disease. A recent article regarding dementia in the Rotterdam Study reinforces this suggestion. It is also hypothesized that this relative deficiency could facilitate passage of **aluminum** into the brain, **aluminum** being increasingly suggested as one of the possible pathogenic factors in AD. It is further suggested that hypomethylation caused by a deficiency of S-adenosylmethionine might also play a role in the etiology of this disease and perhaps even of Parkinson's disease. Copyright 2000 Harcourt Publishers Ltd.



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