INTERNATIONAL
Food Additives Council

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May 29, 2002

Dockets Management Branch
HFA -305 Room 1061
5630 Fishers Lane
Rockville, Maryland 20852

To: The Hearing Clerk Re: 02P 0013

The International Food Additives Council (IFAC) a trade association representing producers of high priority materials used as direct food additives, files the following comments in response to the above identified petition.

1. A number of IFAC producers market aluminum containing food additives. We therefore have familiarity with the medical, scientific and technical literature on food additives containing aluminum.

2. In addition to its long history of use, there is a considerable amount of data, which forms the basis for the safe use in food of aluminum containing food additives. Such is not made clear in the above-mentioned petition.

3. A number of years ago, claims were raised suggesting that use of aluminum containing foods, food additives, cosmetics and drinking water could represent a health hazard, especially exacerbation of neurodegenerative conditions such as Alzheimer's disease and like illnesses.

4. Numerous scientists and physicians familiar with neurodegenerative disease have now evaluated the literature on this aspect of neuroscience and concluded that detection of aluminum in pathological samples reflected a consequence, not a cause of the pathology observed.

5. A recent review of the topic is contained in the comments filed with the Hearing Clerk on April 11, 2002 by Dr. T.I. Lidsky of the Center for Trace Element Studies and Environmental Neurotoxicology, an institution well experienced in the clinical and experimental aspects of neuropathological disease.

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6. IFAC agrees with the conclusions listed by Dr. Lidsky that there is little support of the notion that research on aluminum as a cause of neurodegenerative disease reveals evidence that it can be identified as a causative agent. Such a concept appears to those knowledgeable in the field as an idea whose time has come ----and gone.

7. Of great practical significance, is that the fund of knowledge indicating that aluminum is not an etiologic agent in brain disease, is the view that there is no scientific evidence to support the idea that persons suffering from neurodegenerative disease could reasonably expect relief from their syndrome should they go to the considerable effort of avoiding aluminum containing materials they use in their daily lives.

8. The database also indicates that had these persons avoided aluminum containing materials in the past, there is no reason to believe they could have avoided the disease symptoms they now, unfortunately, experience.

9. IFAC scientists have experience in the toxicologic evaluation of food additives, including those containing aluminum. We are also familiar with the numerous regulatory reviews completed by government agencies that have evaluated the safety of aluminum exposure from use in water, food and cosmetics.

   A. In the United States, aluminum in various chemical forms is used in foods, drugs, colors and cosmetics. Aluminum Sulfate (21 CFR 582.1125) Aluminum Ammonium Sulfate (582.1127), Aluminum Potassium Sulfate (582.1129) and Aluminum Sodium Sulfate (582.1131) and Aluminum Calcium Silicate (582.2122) are Generally Recognized as Safe by FDA as indicated in the CFR citations mentioned.

   B. FDA regulations also describe the numerous permitted uses of aluminum containing pharmaceutical products.

10. On an International basis, the Joint Expert Committee on Food Additives (JECFA) evaluated aluminum at its 33rd session and a monograph was prepared.

    A. Numerous aluminum containing materials were reviewed. Regulatory recommendations ranged from establishing no ADI for aluminum potassium sulfate and aluminum sodium sulfate to an ADI of "not specified" for aluminum salts of fatty acids or silicates.

B. JECFA commented that estimates of aluminum intake ranged from 206 mg/day in children to 6-14 mg/ day for adults. Low total body burdens and high urinary excretion (except those with chronic renal disease) led JECFA to conclude that even at high levels of consumption, only a small amount of aluminum would be absorbed. Pathologic examination of tissues where aluminum was located, e.g., heart, spleen and bone, revealed no histopathology.

C. JECFA established and currently maintains a PTWI (provisional tolerable weekly intake) of 0-7 mg/kg body weight for aluminum from all sources. The JECFA monograph goes on to point out that there is no need to set a separate ADI for the popular aluminum containing food additives Sodium Aluminum Phosphate, acidic or basic. Although somewhat dated, the JECFA monograph (IPCS, Food Additive Series: 24) provides considerable valuable background information on aluminum and its safety in use in foods.

The overall fund of information provides sufficient evidence to deny the above-identified petition.

IFAC appreciates this opportunity to comment.

Sincerely yours,

Andrew G. Ebert

Andrew G. Ebert, Ph.D.
President

AGE/jcr

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