Alumina in inorganic membranes can pose a risk to health

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Introduction

Dietary exposure to Aluminium

Toxicological profile for Aluminium

Risk evaluation

Conclusion
Introduction (1)

Aluminium is ubiquitous in our environment:

It is the third most prevalent element and the most abundant metal in the earth's crust after oxygen and silicon, representing approximately 8% of total mineral components.

Aluminium occurs naturally in the environment and is released due to industrial activities such as mining...
A variety of Aluminium compounds are produced and used for different purposes. It is difficult to provide an exhaustive list of the industrial applications and consumer products, but we can however highlight:

- alums (aluminum sulfate) in water-treatment,
- papermaking,
- fire retardant,
- fillers,
- abrasives and ceramics,
- processed food and food additives,
- colors,
- pharmaceuticals (therapeutics, vaccines…)
- antiperspirants, other cosmetics ...

Aluminium metal in the form of alloys has many uses including consumer appliances, building industry, transport, food-processing industry, packaging… food packaging and cookware.
Major routes of exposure to Aluminium

1) Ingestion: foods and beverages, therapeutics...

2) Injection (vaccine), parenteral nutrition...

3) Transdermally absorption:
   Antiperspirants and other cosmetics...
Most unprocessed foods typically contain less than 5 mg Aluminium/kg.

Higher concentrations from 5 to 10 mg/kg are often found in cereal products, vegetables, and beverages and other processed foods.

Under normal and typical conditions the contribution of migration of Aluminium from food contact materials (industrial food-processing or domestic cookery and storage) would represent only a small fraction of the total dietary intake.

However, the EFSA noted that in the presence of acidic foods, the use of Aluminium-based equipment, utensils, and foils increases Aluminium concentrations.
Dietary exposure to Aluminium (1)

Due to the complexity of food manufacture and variety of components it is impossible to identify the sources of Aluminium contamination.

Estimated daily dietary exposure to aluminium in European countries = \(1.6 \text{ to } 13 \text{ mg aluminium per day}

= \(0.2 \text{ to } 1.5 \text{ mg/kg body weight (bw) per week}

in a 60 kg adult.

it is up to \(2.3 \text{ mg/kg bw/week}

in highly exposed consumers.

Children generally have higher food intake than adults when expressed on a body weight basis, and therefore represent the group with the highest potential exposure to Aluminium per kg body weight.
After absorption, Aluminium accumulates in all animal/human tissue and particularly in bone.

Aluminium can enter the brain and reach the placenta and fetus.

If a significant amount exceeds the body's excretory capacity, Aluminium may persist for a very long time in various organs and tissues before it is excreted in the urine.
While Aluminium is not a heavy metal, it has been found to be toxic in high concentrations and is today suspected to also be toxic in much weaker concentrations.

Aluminium has shown neurotoxicity in patients undergoing dialysis and perfusions.

Aluminium is also implicated in the aetiology of Alzheimer’s disease and associated with other neurodegenerative diseases in humans.

Compounds containing aluminium have the potential to produce neurotoxicity (mice, rats) and to affect the male reproductive system (dogs). In addition, after maternal exposure they have shown embryotoxicity (mice) and have affected the developing nervous system in the offspring (mice, rats).

Thus the European Food Safety Authority considered it prudent to take these effects into account when recommending tolerable dietary intake limits.
EFSA’s tolerable intake for all dietary sources:

In view of the cumulative nature of aluminium in the organism after dietary exposure, the EFSA established a tolerable weekly intake (TWI) for aluminium of 1 mg aluminium/kg bw/week.

This TWI is therefore likely to be exceeded in a significant part of the European population.

It should be an obvious precaution not to introduce further Aluminium contamination into human diet.
Although there are a great number of references on the adverse effects of Aluminium...

Aluminium has been exempted from testing for safety by the FDA under a convoluted logic wherein it is classified as GRAS (Generally Regarded As Safe).

Aluminium has never been tested on its safety either by the FDA nor any other Agencies. As such there are no restrictions whatsoever on the amount of Aluminium coming from processing equipment.
Recommendations applicable to Aluminium and compounds for human consumption of food and beverage

European Food Safety Authority (EFSA)
Tolerable weekly intake of 1 mg/kg bw/week

U.S. Environmental Protection Agency (EPA) / EPA 2006f
U.S. Food and Drug Administration (FDA) / FDA 2005 - 21 CFR 165.110
Maximum dietary intake = 0.2 mg/L
TAMI Industries asked IANESCO* for a study to determine the chemical stability of different Al$_2$O$_3$-based membranes from different suppliers (including TiO$_2$-based membranes from TAMI) in aqueous acid solutions in accordance with the Commission directive 2005/31/EC using weak acids: Citric acid and Acetic acid.

*IANESCO is a laboratory accredited and certified by the French Government and by other public organizations to realize chemical analysis / food safety and environment.

The majority of ceramic membranes present on the market contains ALUMINA.

All membranes tested have a cut-off of 0.2µm.

**Experimental:**
Amount of Aluminium released measured by means of atomic emission spectroscopy (ICP/AES)

**Result unit:** mg of Aluminium / dm$^2$ of membrane
Risk evaluation (2) : Ianesco results

Milligram of Aluminium released by square decimeter of membrane

The membranes tested are of the world's major manufacturers

<table>
<thead>
<tr>
<th>Company</th>
<th>Acetic Acid 4% - 24 hrs - 22°C</th>
<th>Citric Acid 0.5% - 24 hrs - 40°C</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOVASEP/CTI</td>
<td>4 mg/dm²</td>
<td>0.5 mg/dm²</td>
</tr>
<tr>
<td>ATECH</td>
<td>12 mg/dm²</td>
<td>12 mg/dm²</td>
</tr>
<tr>
<td>PALL SCHUMASIV</td>
<td>4 mg/dm²</td>
<td>12 mg/dm²</td>
</tr>
<tr>
<td>TAMI</td>
<td>2 mg/dm²</td>
<td>0.5 mg/dm²</td>
</tr>
<tr>
<td>Food Product</td>
<td>pH Value</td>
<td></td>
</tr>
<tr>
<td>--------------------------</td>
<td>----------</td>
<td></td>
</tr>
<tr>
<td>Citric Acid 0.5% dilution</td>
<td>pH ≈ 2.1</td>
<td></td>
</tr>
<tr>
<td>Lemon juice</td>
<td>pH ≈ 2.3</td>
<td></td>
</tr>
<tr>
<td>Cranberry juice</td>
<td>pH ≈ 2.4</td>
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</tr>
<tr>
<td>Vinegar</td>
<td>pH ≈ 2.7</td>
<td></td>
</tr>
<tr>
<td>Pomelo juice</td>
<td>pH ≈ 3</td>
<td></td>
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<tr>
<td>Wine</td>
<td>pH ≈ 3</td>
<td></td>
</tr>
<tr>
<td>Cider</td>
<td>pH ≈ 3.1</td>
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<td>Appel juice</td>
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<td>Orange juice</td>
<td>pH ≈ 3.9</td>
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<td>Grape juice</td>
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<td>Tomato juice</td>
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<td>Beer</td>
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<td></td>
</tr>
<tr>
<td>Curd cheese</td>
<td>pH ≈ 4.5</td>
<td></td>
</tr>
<tr>
<td>Acid whey</td>
<td>pH ≈ 4.5</td>
<td></td>
</tr>
</tbody>
</table>
Risk evaluation (4) : Scale up example

Milligram of Aluminium released / liter of permeat assuming pH=2.1 in a filtration unit of 74 m² - 100 l/h.m²

![Bar chart showing mg/liter of Aluminium released per company: NOVASEP/CTI, ATECH, PALL SCHUMASIV, TAMI]
There is no doubt about Aluminium toxicity,

Testing has proved that Aluminium contamination occurs when using alumina-based ceramic membranes in the presence of an acidic media,

Numerous studies in industrial situations would be necessary to measure and to confirm the risk,

It’s a sensitive subject which could become a real problem of public health,

like the artificial sweetener aspartame which has been the subject of several controversies since its initial approval by the US Food and Drug Administration (FDA) in 1974.
Conclusion (2)

The choice of the ceramic support composition is an important strategic choice.

In 2005 TAMI Industries banished alumina.

TAMI Industries always privileges the use of the highest chemical resistant ceramics for its membranes: TiO$_2$

When governments will decide to take a number of steps to protect humans from excessive Aluminium exposure... the inorganic alumina free TiO$_2$ membranes will be the best choice.
Conclusion (3)

Alumina based ceramic membranes contribute to increase the quantity of Aluminium in a certain number of processed foods and beverages.
Alumina based ceramic membranes contribute to increase dietary exposure to aluminium ...!

What is the risk ...?
Thank you for your attention
Main References

- U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
  "TOXICOLOGICAL PROFILE FOR ALUMINUM"
  Public Health Service - Agency for Toxic Substances and Disease Registry
  September 2008

- EFSA Journal (2008) 754 1-34 opinion
  “Safety of aluminium from dietary intake” Scientific Opinion of the Panel
  on Food Additives, Flavourings, Processing Aids and Food Contact Materials
  (AFC) - (Question Nos EFSA-Q-2006-168 and EFSA-Q-2008-254) -
  Adopted on 22 May 2008

- Aluminium-Containing food Additives (other than Colours and Sweeteners)
  authorised for use in the European Union, Directive 95/2/EC.