Activities of EFSA in the area of aluminium

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The content of this presentation does not necessarily represent the position of the European Food Safety Authority

15th BfR Consumer Protection Forum “Aluminium in Everyday Life”
Berlin, 26-27 November 2014
• EFSA’s mission and way of working
• Aluminium: A brief introduction
• Past safety assessments of aluminium-containing compounds by EFSA
  - Aluminium in food additives
  - Aluminium in pesticides
• Future activities
• Conclusions
EFSA’S ORIGINS

• Formally set up in January 2002 as an independent source of scientific advice and communication on risks associated with the food chain


• Created as part of a comprehensive programme to:

  • improve EU food safety
  • help ensure a high level of consumer protection
  • restore and maintain confidence in the EU food supply.
WHAT EFSA DOES

- Provides independent scientific advice and support for EU law/policies on food and feed safety
- Provides independent risk communication
- Promotes scientific cooperation
  ✓ Networking
  ✓ Monitoring
WHAT EFSA CANNOT DO

- Enforce food safety legislation
- Take charge of food safety/quality controls, labelling or other such issues
- Substitute for national authorities
HOW DOES EFSA WORK?

European Commission
European Parliament
Member States
EFSA (“self mandate”)
AREAS OF ACTIVITIES
1. Animal health and welfare
2. Food additives and nutrient sources
3. Biological hazards
4. Food contact materials, enzymes, flavourings
5. Contaminants in the food chain
6. Feed additives
7. Genetically modified organisms
8. Nutrition
9. Plant health
10. Plant protection products

The Scientific Committee
MEMBERS OF THE ANS PANEL 2014 - 2017

- Chair: Dr. Alicja Mortensen (DK)
- Vice-chairs: Dr. Claude Lambré (FR)  
  Prof. Ruud Woutersen (NL)
- 21 Panel members

The risk assessment scheme:

EXPOSURE ASSESSMENT

Levels in food, dietary exposure, food consumption relevant food groups, time trends

HAZARD IDENTIFICATION

ADME, acute/sub-chronic/chronic toxicity, human data, genotox, reprotox, etc. Derivation of a health based guidance value (e.g. ADI, TDI, MOS)

HAZARD CHARACTERIZATION

RISK CHARACTERIZATION

Relate exposure to acceptable daily intake (ADI)
Aluminium and EFSA
Aluminium is the third most abundant element (after oxygen and silicon), and the most abundant metal in the Earth's crust

- As alumino-silicates, hydroxydes, phosphates, sulphates and cryolite
- Redistributed throughout environment due to natural erosion and anthropogenic activities

- Exists mainly in the oxidation state $\text{Al}^{3+}$
A few facts about aluminium: Human exposure (I)

Sources of human exposure to aluminium compounds

- **Dietary exposure**
  - Natural occurrence in foodstuffs (e.g., vegetables, shellfish, cereals, teas, fruit juices)
  - Aluminium-containing food additives
  - Food-contact materials (e.g., ceramics, Al foil)
  - Pesticides
  - Treated water

- **Medical**
  - Gastric antacids
  - Immunisation (IM injections)
  - Parenteral nutrition products
  - (Dialysis)
A few facts about aluminium: Human exposure (II)

- Exposure to ambient and occupational airborne particulates
  - Al oxides and $\text{Na}_3\text{AlF}_6$
  - Naturally occurring Al nanoforms in volcanic ash and clay soils

- Consumer products
  - Antiperspirants
Aluminium in food additives
Regulation (EC) No 1333/2008

- There must be a technological need for their use
- Their use must not mislead the consumer
- They must be of benefit to the consumer
- **Food additives must be safe when used**
### Currently authorised aluminium-containing food additives

<table>
<thead>
<tr>
<th>E number</th>
<th>Name</th>
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<tbody>
<tr>
<td>E 173</td>
<td>Aluminium</td>
</tr>
<tr>
<td>E 520</td>
<td>Aluminium sulphate</td>
</tr>
<tr>
<td>E 521-523</td>
<td>Aluminium Na/K/NH$_4$ sulphate</td>
</tr>
<tr>
<td>E 541</td>
<td>Sodium aluminium phosphate (SALP) acidic</td>
</tr>
<tr>
<td>E 554-556</td>
<td>Na/K/Ca aluminium silicate</td>
</tr>
<tr>
<td>E 1452</td>
<td>Starch aluminium octenyl succinate</td>
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</table>
Currently authorised aluminium-containing food additives

Aluminium lakes of colours

<table>
<thead>
<tr>
<th>E number</th>
<th>Authorised aluminium lakes</th>
</tr>
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<tbody>
<tr>
<td>E 100</td>
<td>Curcumin</td>
</tr>
<tr>
<td>E 102</td>
<td>Tartrazin</td>
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<tr>
<td>E 104</td>
<td>Quinoline yellow</td>
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<tr>
<td>E 110</td>
<td>Sunset yellow FCF</td>
</tr>
<tr>
<td>E 120</td>
<td>Cochineal, carminic acid, carmines</td>
</tr>
<tr>
<td>E 122</td>
<td>Azorubine, carmoisine</td>
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<tr>
<td>E 124</td>
<td>Ponceau 4R, cochineal red A</td>
</tr>
<tr>
<td>E 127</td>
<td>Erythrosine</td>
</tr>
<tr>
<td>E 129</td>
<td>Allura red AC</td>
</tr>
<tr>
<td>E 131</td>
<td>Patent Blue V</td>
</tr>
<tr>
<td>E 132</td>
<td>Indigotine, indigo carmine</td>
</tr>
<tr>
<td></td>
<td>+ 8 other colours</td>
</tr>
</tbody>
</table>
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

PANEL MEMBERS
The major route of exposure to aluminium for the general population is through food.

- Mainly from aluminium present in unprocessed food and food additives
- Drinking water and food contact materials are a minor source

The bioavailability of oral aluminium

- from water: ~ 0.3%
- from food and beverages: ~ 0.1%

The presence or absence in the intestines of dietary ligands may either increase (e.g. citrate) or decrease the absorption (e.g. phosphate).
Outcome of the 2008 opinion on aluminium (II)

- Aluminium in blood is transported by transferrin and distributes to all tissues.
  - Accumulation in bones
- Elimination in the urine
- Persistence for a very long time (years)
Genotoxicity: Aluminium not found to be of genotoxic concern to humans

Carcinogenicity: Aluminium unlikely to be of carcinogenic concern to humans

Neurotoxicity: Observed in patients with high parenteral exposure but oral exposure not considered to constitute risk (Alzheimer’s disease)

Animal studies
- Limited database of studies on aluminium-containing food additives
- The AFC Panel considered the entire database of studies on dietary administration of aluminium compounds
Animal studies (contd)

- Used the Lowest-Observed Adverse Effect Levels (LOAELs) and the No-Observed Adverse Effect Levels (NOAELs) of the studies.
- Endpoints were neurotoxicity, testes, embryotoxicity and neurodevelopmental toxicity
  - Lowest LOAEL: 50 mg aluminium/kg bw/day (range 50-100)
  - Lowest NOAEL: 10 mg aluminium/kg bw/day (range 10-100)

Health-based guidance value
- **TWI of 1 mg aluminium/kg bw/week**
Exposure assessment

- Adults: Large variation from 0.2 to 1.5 mg aluminium/kg bw/week
- Children: 0.7 to 2.3 mg aluminium/kg bw/week

Conclusions:
The TWI of 1 mg aluminium/kg bw/week is likely to be exceeded in a significant part of the European population
'It is therefore appropriate to amend the current conditions of use and reduce the use levels for aluminium-containing food additives, including aluminium lakes, to ensure that the revised TWI is not exceeded.'

'The aluminium containing carrier bentonite, E 558 (...) and (t)he aluminium containing food additives calcium aluminium silicate E 556 and aluminium silicate (kaolin) E 559 should be deleted from the list of all additives in Part B of Annex II to Regulation (EC) No 1333/2008 (...).'}
Aluminium in Food: What has happened since?

STATEMENT OF EFSA

On the Evaluation of a new study related to the bioavailability of aluminium in food

European Food Safety Authority

European Food Safety Authority (EFSA), Parma, Italy
Evaluation of a new study on the bioavailability of aluminium from 12 different aluminium compounds in the rat.

$^{26}$Al-labelled compounds and accelerator mass spectrometry ($^{26}$Al:$^{27}$Al ratios)

Outcome (fraction absorbed):

- soluble aluminium citrate, chloride, nitrate and sulphate salts: 0.045 to 0.21% of the dose.
- insoluble aluminium hydroxide, aluminium oxide, Allura Red AC aluminium lake and sodium aluminium silicate: 0.018 to 0.12% of the dose.
- SALP acidic and SALP basic, and aluminium metal were below the limit of detection (<0.024%).
CONCLUSIONS

- Bioavailability values similar to those found in previous studies.
- No need to revise EFSA’s safety evaluation of 2008.
EFSA support document for EU’s positions for provisions for aluminium-containing food additives of the General Standard for Food Additives (GSFA) under discussion at the 45th session of the Codex Committee on Food Additives (CCFA) held in Beijing, China, on 18 to 22 March 2013.
Dietary exposure assessment based on the maximum levels recommended by the CCFA for:

- E 523: aluminium ammonium sulphate
- E 541 (i, ii): sodium aluminium phosphates (acidic and basic)
- E 554: sodium aluminosilicate
- E 556: calcium aluminium silicate
- E 559: aluminium silicate

Mean and 95th percentile dietary exposure estimates to the five aluminium-containing food additives largely exceed the TWI established by EFSA.
Aluminium in pesticides
MRL assessment

✓ Dossier compliant with data requirements was submitted (GAPs, field trials, ...)  

✓ MRL proposals are based on **good agricultural practice and the lowest consumer exposure** necessary to protect vulnerable consumers
CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance aluminium ammonium sulfate\(^1\) (approved as aluminium ammonium sulphate)

European Food Safety Authority\(^2\)

European Food Safety Authority (EFSA), Parma, Italy
Pesticide risk assessment of aluminium ammonium sulphate

- Representative uses: as a repellent in agriculture, horticulture, amenity areas and for amateur use.
- ADI and ARfD of 0.14 mg/kg bw and an Acceptable Operator Exposure Level (AOEL) of 0.002 mg/kg bw/d based on the TWI for aluminium of 1 mg/kg bw/week.
- Consumer exposure to aluminium ion residues resulting from the use of aluminium ammonium sulphate on crops to be determined in order to conduct a consumer risk assessment.
- Further data on the use of aluminium ammonium sulphate required
Pesticide risk assessment of aluminium silicate

- Representative uses: as an insect repellent on pear trees and vines.
- There is no need to set the acceptable daily intake (ADI) and acute reference dose (ARfD) because consumer exposure is very unlikely.
- For the inhalation route, a potential for pneumoconiosis has been described for chronic inhalation of aluminium silicate dust in occupational settings.
New developmental and chronic neurotoxicity study (2010) on aluminium citrate in the rat conducted according to GLP with a design based on OECD Test Guideline 426.

Provided a NOAEL of 30 mg/kg bw per day.

JECFA established a PTWI of 2 mg/kg bw.
Aluminium in Food: Future activities at EFSA

- Re-evaluation of all food additives that were permitted before 20.01.2009
- Deadline for aluminium-containing food additives: 2018
Thank you very much for your attention