



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

CONTENT OF PRESENTATION

- 
- **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
 - (REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety)
- 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

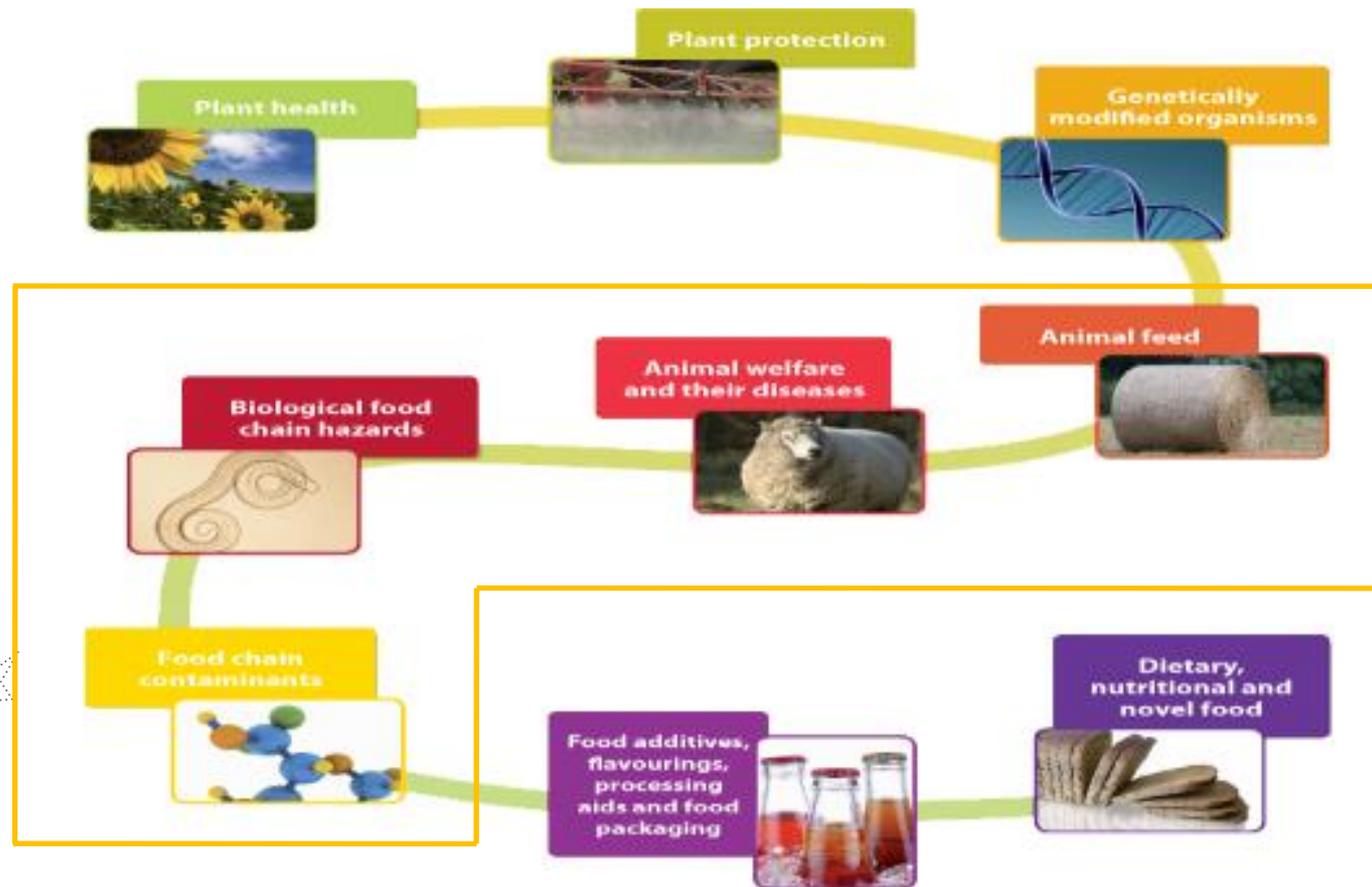


- ❖ Enforce food safety legislation
- ❖ Take charge of food safety/quality controls, labelling or other such issues
- ❖ Substitute for national authorities

HOW DOES EFSA WORK?



AREAS OF ACTIVITIES



10 SCIENTIFIC PANELS AND SCIENTIFIC COMMITTEE



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

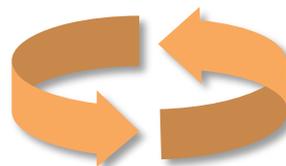


ANS PANEL WORK

The risk assessment scheme:



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



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



Relate **exposure** to **acceptable daily intake (ADI)**



Aluminium and EFSA

A few facts about aluminium: Chemistry

- 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 Al^{3+}



A few facts about aluminium: Human exposure (I)

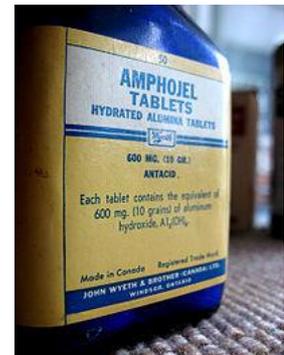
Sources of human exposure to aluminium compounds

□ 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 Na_3AlF_6
 - ✓ Naturally occurring Al nanoforms in volcanic ash and clay soils

- ❑ Consumer products
 - ✓ Antiperspirants





Aluminium in food additives



FOOD ADDITIVES IN THE EU: CONDITIONS

- 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

E number	Name
E 173	Aluminium
E 520	Aluminium sulphate
E 521-523	Aluminium Na/K/NH ₄ sulphate
E 541	Sodium aluminium phosphate (SALP) acidic
E 554-556	Na/K/Ca aluminium silicate
E 1452	Starch aluminium octenyl succinate



Currently authorised aluminium-containing food additives

Aluminium lakes of colours

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

First evaluation of aluminium by EFSA

Safety of aluminium from dietary intake¹

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

F. Aguilar, H. Atrup, S. Barlow, L. Castle, R. Crebelli, W. Dekant, K.-H. Engel, N. Gontard, D. Gott, S. Grilli, R. Gürtler, J.-C. Larsen, C. Leclercq, J.-C. Leblanc, F.-X. Malcata, W. Mennes, M.-R. Milana, I. Pratt, I. Rietjens, P. Tobback, F. Toldrá.

Outcome of the 2008 opinion on aluminium (I)

- 
- 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: $\sim 0.3\%$
 - from food and beverages: $\sim 0.1\%$
 - 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)





Outcome of the 2008 opinion on aluminium (III)

- **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

Outcome of the 2008 opinion on aluminium (IV)

- 
- **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**

Outcome of the 2008 opinion on aluminium (V)

■ 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

Consequences of the 2008 opinion on aluminium

L 119/14

EN

Official Journal of the European Union

4.5.2012

COMMISSION REGULATION (EU) No 380/2012

of 3 May 2012

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the conditions of use and the use levels for aluminium-containing food additives

(Text with EEA relevance)

'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 food¹

European Food Safety Authority^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

Aluminium in Food: What has happened since?

- 
- 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%).

Aluminium in Food: What has happened since?

CONCLUSIONS

- Bioavailability values similar to those found in previous studies.
- No need to revise EFSA's safety evaluation of 2008.

Aluminium in Food: What has happened since?

TECHNICAL REPORT

Dietary exposure to aluminium-containing food additives¹

European Food Safety Authority^{2, 3}

European Food Safety Authority (EFSA), Parma, Italy

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.

Aluminium in Food: What has happened since?

- 
- 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



MAXIMUM RESIDUE LEVELS

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

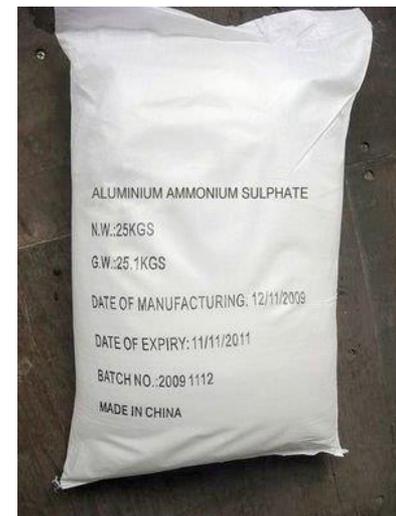
Conclusion on the peer review of the pesticide risk assessment of the active substance aluminium ammonium sulfate¹ (approved as aluminium ammonium sulphate)

European Food Safety Authority²

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.
- Aluminium silicate could be considered a candidate for the inclusion in Annex IV of Commission Regulation (EC) No 396/2005.
- For the inhalation route, a potential for pneumoconiosis has been described for chronic inhalation of aluminium silicate dust in occupational settings.



JECFA Evaluation of Aluminium-containing Food Additives

**WHO FOOD
ADDITIVES
SERIES: 65**

**Safety evaluation of
certain food additives
and contaminants**

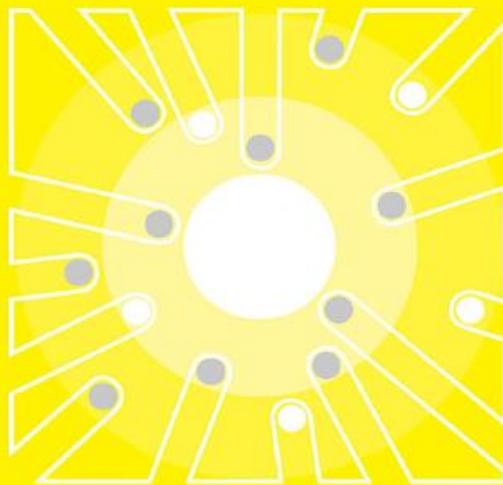
Prepared by the
Seventy-fourth meeting of the Joint FAO/WHO
Expert Committee on Food Additives (JECFA)



Food and Agriculture
Organization of
the United Nations



World Health
Organization



ALUMINIUM-CONTAINING FOOD ADDITIVES (addendum)

First draft prepared by

*D.J. Benford,¹ A. Agudo,² C. Baskaran,¹ M. DiNovi,³ D. Folmer,³
J.-C. Leblanc⁴ and A.G. Renwick⁵*

- 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

26.3.2010

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Official Journal of the European Union

L 80/19

COMMISSION REGULATION (EU) No 257/2010
of 25 March 2010

setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives

(Text with EEA relevance)

- 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