



Re-evaluation of food additives permitted in foods for infants below 16 weeks of age: state of play

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Background

The use of food additives is regulated under Regulation (EC) No 1333/2008 on food additives. Only food additives that are included in the Union's lists, in Annexes II and III of this regulation, may be placed on market and the Part E of the Annex II specifies the food categories to which these additives can be used.

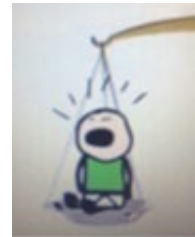
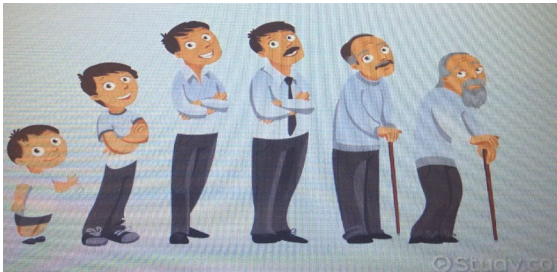


A number of additives are permitted in the food categories 13.1.1 (*Foods for infants and young children*) and 13.1.5.1 (*Dietary foods for infants for special medical purposes and special formulae for infants*) consumed by infants below 4 months of age.

Background

Until the beginning of 2018, the risk assessment approach followed by the former ANS Panel in the re-evaluation of food additives and described in its guidance document on food additive evaluation **did not cover their use in food for infants below 12 weeks of age.**

Therefore the former ANS Panel has **issued scientific opinions** on the safety of these food additives **covering all other uses** and specified in these opinions that the re-evaluation of **uses for this particular age will be performed separately.**



Background

On 31 May 2017, EFSA's SC published a horizontal **guidance document** on the risk assessment of substances present in food intended **for infants below 16 weeks of age enabling the former ANS/FAF Panel to start the assessment of the safe use of food additives in the population group below that age.**

SCIENTIFIC OPINION



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Guidance on the risk assessment of substances present in food intended for infants below 16 weeks of age

EFSA Scientific Committee,
Anthony Hardy, Diane Benford, Thorhallur Halldorsson, Michael John Jeger,
Helle Katrine Knutsen, Simon More, Hanspeter Naegeli, Hubert Noteborn, Colin Ockleford,
Antonia Ricci, Guido Rychen, Josef R Schlatter, Vittorio Silano, Roland Solecki,
Dominique Turck, Jean-Louis Bresson, Birgit Dusemund, Ursula Gundert-Remy,
Mathilde Kersting, Claude Lambré, André Penninks, Angelika Tritscher,
Ine Waalkens-Berendsen, Ruud Woutersen, Davide Arcella, Daniele Court Marques,
Jean-Lou Dorne, George EN Kass and Alicja Mortensen

Background



EFSA & FAF Panel established the **WG on food additives permitted in foods for infants below 16 weeks of age** with the main task to complete the risk assessment of already assessed food additives for uses in infants below 16 weeks of age implementing the above guidance.

List of food additives to be addressed

FA risk assessed so far for all age groups except for infants younger than 16 weeks

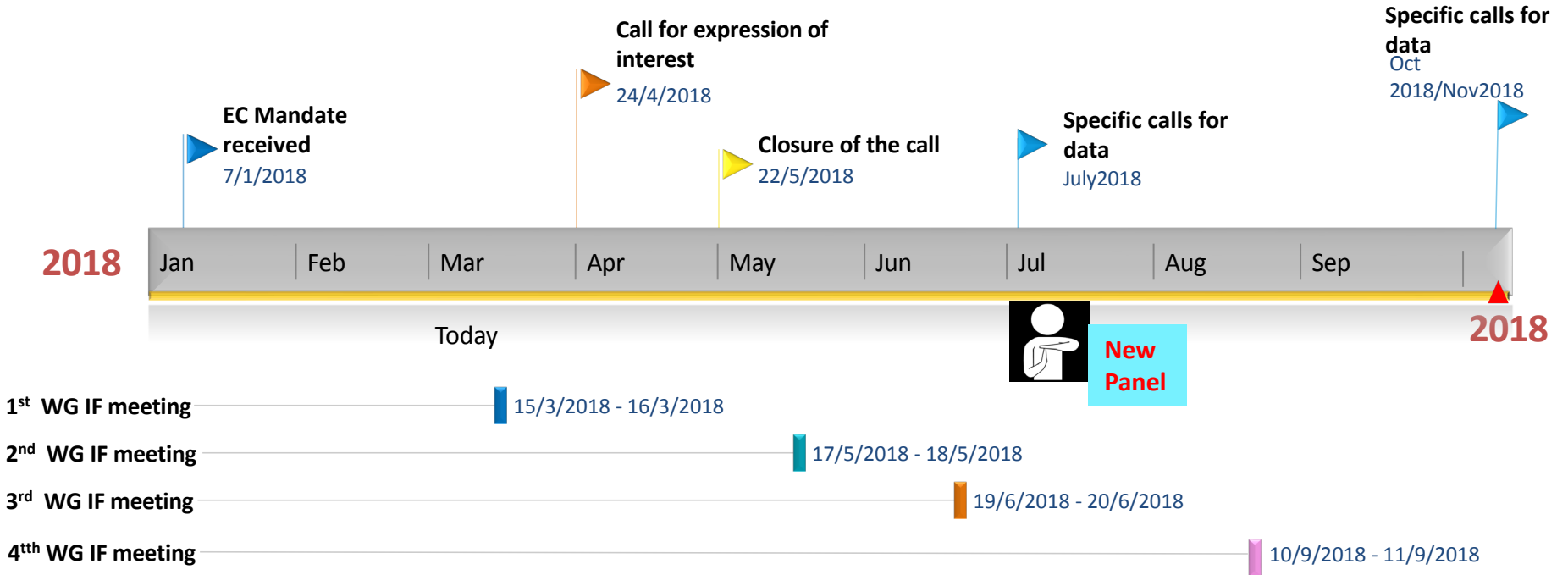
E-number	Name of the food additive
E 170	Calcium carbonate
E 304i	Ascorbyl palmitate
E 306	Tocopherol-rich extract
E 307	α -Tocopherol
E 308	γ -Tocopherol
E 309	δ -Tocopherol
E 322	Lecithins
E 407	Carrageenan
E 410	Locust bean gum
E 412	Guar gum
E 415	Xanthan gum
E 440	Pectins
E 466	Carboxy methyl cellulose
E 471	Mono- and diglycerides of fatty acids
E 472c	Citric acid esters of mono- and diglycerides of fatty acids <i>(to be finalised by the end of 2018)</i>
E 473	Sucrose esters of fatty acids
E 1450	Starch sodium octenyl succinate
Annex III	Silicon dioxide, acacia gum

Background

In addition, the **published opinions highlighted data gaps** preventing final conclusions or suggesting more studies in the recommendations which would have been also relevant for the evaluation of uses for young infants.

Additional mandate from the EC analysed at the next presentation.

Timetable and Milestones 2018



Timetable and Milestones 2018

Two last specific calls published in November:

- mono- and di-glycerides of fatty acids (E 471)
- sucrose esters of fatty acids (E 473)

Data to be requested for all food additives in the list

- **Technical data** (analytical data on heavy metals, protein levels, solvent residuals) for all uses;
- Information on **usage levels**, reaction products and fate in infant formulae;
- **Post-marketing surveillance** reports on undesired and adverse reactions in infants;
- Published and unpublished **case reports** (e.g. available nutriviigilance data) on undesired and adverse effects in infants
- Literature searches

Data to be requested for all food additives in the list

- **Literature searches**

Literature searches for relevant information including **chemistry, animal and human data** (clinical and epidemiological studies) on the use of FA in infant formula and foods for young children including FSMPs using appropriate strings e.g. the name of the additive together with complete relevant names for infant formulae and foods for special medical purposes. The literature research should cover all aspects of information requested above and be documented. The search should be performed in bibliographic database platforms but has to include Chemical Abstract, Pubmed and Web of Science and at least one other relevant toxicity database (e.g. Toxnet). The outcome of the search should include a document compiling abstracts according to each topic (chemistry, animal data and human data) and the pdfs of the retrieved articles/reports.

Specific data requested

E-number	Name of the food additive	Specific data
E 170	Calcium carbonate	Particle size and particle size distribution
E 304i	Ascorbyl palmitate	Residual solvents
E 322	Lecithins	Residual proteins Origin of lecithins Phosphatidyl choline content in lecithins as FA used in IF Neurotoxicity study (applicable also to RA for infants below 16 weeks of age)
E 410	Locust bean gum	Residual proteins Use of clarified LBG in IF Impurities Postnatal study in piglets, unless justification for another species is provided Clinical data

Specific data to be requested

E-number	Name of the food additive	Specific data
E 412	Guar gum	Residual proteins Use of clarified Guar gum in IF Impurities Postnatal study in piglets, unless justification for another species is provided Clinical data
E 466	Carboxy methyl cellulose	Impurities Postnatal study in piglets, unless justification for another species is provided Clinical data
E 440	Pectins	Clinical data in infants and raw data for postnatal study in piglets
E 1450	Starch sodium octenyl succinate	Raw data for postnatal study in piglets and clinical data in infants

FA in the remit of the WG and specific data to be requested

E-number	Name of the food additive	Specific data
E 415	Xanthan gum	Protein levels, residues.
E 407	Carrageenan	Specific data to address the uncertainties identified in the opinion.
E 471	Mono-and diglycerides of fatty acids	Solvent residuals
E 473	Sucrose esters of fatty acids	Clinical studies
E 472c	Citric acid esters of mono- and diglycerides of fatty acids	Opinion on uses other than in IF below 16 weeks of age not yet finalised
E 306	Tocopherol-rich extract	Data on composition
E 307	α-Tocopherol	EOGRTS
E 308	γ-Tocopherol	
E 309	δ-Tocopherol	
E 551	Silicon dioxide	EOGRTS
E 414	Acacia gum	No specific data

Food additives not yet re-evaluated

E number	Name of FA	
E 507	Hydrochloric acid	Fist Panel evaluations for all food uses including for IF below 16w
E 338	Phosphoric acid	
E 340	Potassium phosphates	
E 341	Calcium phosphates	
E 339	Sodium phosphates	
E 333	Calcium citrates	Calls to be launched for all uses including for IF below 16w in 2019
E 270	Lactic acid	
E 330	Citric acid	
E 331	Sodium citrates	
E 332	Potassium citrates	
E 500	Sodium carbonates	
E 501	Potassium carbonates	
E 526	Calcium hydroxide	
E 524	Sodium hydroxide	
E 525	Potassium hydroxide	
Annex III: E 421	Mannitol --→ to be assessed first in the frame of sweeteners	

Provisional workplan for the publication of 16 opinions

Calls	Opinions foreseen	Number of opinions
15 calls launched 1 pending	By the end of 2019	5
	By the end of 2020-mid 2021	11

Thank you