



# **Food additives re-evaluation work programme**

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Stakeholder Workshop, Brussels, 28<sup>th</sup> April 2014

# Food additives re-evaluation programme

## ✓ The re-evaluation programme (16 April 2014)



EFSA with its Food Ingredients and Packaging (FIP) Unit have 3 main activities in relation to food additives:

- ✓ Evaluating the safety of new food additives or proposed new uses of existing food additives
- ✓ Re-evaluating all food additives already permitted for use in EU before 20 January 2009
- ✓ Responding to ad-hoc requests from the EC to review certain food additives in the light of new scientific information and/or changing condition of use

Additional activities comprise the evaluation of safety for nutrient sources added to food (e.g. minerals) and other substances deliberately added (e.g. botanical extracts).

- ✓ **Regulation (EU) No 257/2010 (re-evaluation programme)**
  - Re-evaluation of all food additives that were permitted before 20.01.2009

26.3.2010

EN

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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)

THE EUROPEAN COMMISSION,

requested or became otherwise available. As a consequence, those additives do not need to be re-evaluated again.

## ✓ Re-evaluation finalised by 2020

- Food colours 2015
- FA other than food colours & sweeteners 2015, 2016 & 2018
- Sweeteners 2020
- Exception: aspartame 2013

## ✓ Priority criteria

Time since last evaluation, availability of new scientific evidence, increased human exposure (extent of use), EU Commission request, emerging concerns

- ✓ For efficiency and practical purposes food additives are grouped according to the main functional class to which they belong
- ✓ In the 2014-2016 timeframe a total of approximately **65** opinions should be adopted

## ✓ Opinions/statements finalized in 2013:

- food additives re-evaluation  
(e.g. anthocyanins E163i-iii, riboflavins E101i-ii),
- new food additives  
(e.g. advantame)
- nutrient sources and botanicals  
(e.g. ephedra)
- other Panel statements  
(e.g.  $\beta$ -apo-8'-carotenal E160e)
- EFSA statements  
(e.g. amaranth E123 exposure assessment)

**total of 24 scientific outputs adopted**

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**Please  
remember  
that a  
re-evaluation  
was  
ASPARTAME !**

**total of 24 scientific outputs adopted**



## Facts:

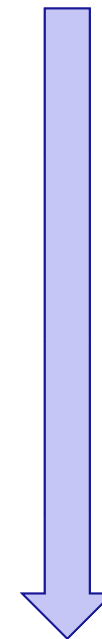
- ✓ The re-evaluation is time-consuming
- ✓ In the past sometimes requests/calls for data with 'suboptimal' timing
- ✓ The approach is not "set in stone"

The re-evaluation process requires:



- Preparation of pre-evaluation document
- Public call for data
- Revision within working group
- Additional call for data (if needed)
- Preparation of draft opinion
- Revision of opinion at ANS Panel
- Adoption of the opinion (and publication)

1.5-2 years



Challenges faced by EFSA and ANS Panel in the programme for the re-evaluation of food additives:

- ✓ No dossiers
- ✓ Scientific information and data available highly variable in terms of quality and quantity.
- ✓ Highly variable response to EFSA's public call for data

**Consequence: potential data gaps for many food additives**

Cooperation with Member States (e.g. analytical data from foodstuff, National food consumption data, Information Exchange Platform)

Cooperation with Interested Business Operators

- meetings of EFSA stakeholder consultative platform
- 1<sup>st</sup> meeting of Discussion Group on Chemical Occurrence Data under EFSA stakeholder platform (Brussels, Nov 2013)
- *ad hoc* workshops and meetings with Associations

# Food additives re-evaluation programme

## Call for data



“EFSA asks national food authorities, research institutions, academia, food business operators and other interested parties to submit the following data for the above mentioned food additives:

**Metabolism and toxicokinetics** (absorption, distribution, metabolism, excretion)

- metabolism and pharmacokinetic studies

**Toxicological data**

- genotoxicity
- acute oral toxicity, short-term and subchronic toxicity, chronic toxicity and carcinogenicity
- reproductive and developmental toxicity
- special studies aimed at investigating immunotoxicity, hypersensitivity, neurotoxicity, endocrine activity, allergy and intolerance
- any other information relevant to the safety assessment“

# Food additives re-evaluation programme

## Call for data

- Deadline 1 July 2014 (batch A):	
E140ii	chlorophyllins
E141i	copper complex of chlorophylls
E141ii	copper complex of chlorophyllins
E160b	annatto, bixin, norbixin
E210	benzoic acid
E211	sodium benzoate
E212	potassium benzoate
E213	calcium benzoate
E311	octyl gallate
E312	dodecyl gallate
E315	erythorbic acid
E316	sodium erythorbate
E444	sucrose acetate isobutyrate
E483	stearyl tartrate

- Deadline 1 September 2014 (batch B):	
<b>E120</b>	cochineal, carminic acid, carmines
<b>E160c</b>	paprika extract, capsanthin, capsorubin
<b>E174</b>	silver
<b>E175</b>	gold
<b>E220</b>	sulphur dioxide
<b>E221</b>	sodium sulphite
<b>E222</b>	sodium hydrogen sulphite
<b>E223</b>	sodium metabisulphite
<b>E224</b>	potassium metabisulphite
<b>E226</b>	calcium sulphite
<b>E227</b>	calcium bisulphite
<b>E228</b>	potassium bisulphite
<b>E304ii</b>	ascorbyl stearate
<b>E445</b>	glycerol ester of wood rosin
<b>E475</b>	polyglycerol esters of fatty acids
<b>E491</b>	sorbitan monostearate
<b>E492</b>	sorbitan tristearate
<b>E493</b>	sorbitan monolaurate
<b>E494</b>	sorbitan monooleate
<b>E495</b>	sorbitan monopalmitate

# Food additives re-evaluation programme

## Call for data



Call for scientific data on selected food additives permitted in the EU:

- ✓ Call for data (metabolism, toxicokinetic and toxicology)
- ✓ Response to the call of interest (1 month)
- ✓ Public list of interested business operators
- ✓ Submission of data (3-5 months)

*ans@efsa.europa.eu*

## The tentative work programme 2014-2015

<http://www.efsa.europa.eu/en/topics/topic/additives.htm>



# Food additives with discussion and possible adoption in 2014

<i>Food additive</i>	<i>E No.</i>	<i>Legal deadline</i>	<i>Call for data<sup>2</sup> use levels toxicological</i>		<i>ANS Panel<sup>3</sup></i>
Polyoxyethylene sorbitans	E432-436	2016*	--	--	1Q2014
Propyl gallate	E310	2015*	Batch 1	--	1Q2014 <b>A</b>
Sunset yellow (c)	E110	Sept 2014 <sup>1</sup>	Batch 2	--	1Q2014
Acacia gum	E414	2016*	Batch 3	--	1Q2014
Hexamethylene tetramine	E239	2015*	Batch 2	--	2Q2014
Sorbic acid, sorbates	E200-203	2015*	--	--	2Q2014
Ascorbic and ascorbates	E300-302	2015	Batch 2	--	2Q2014
4-hexylresorcinol	E586	2015	Batch 2	--	2Q2014 <b>A</b>
Indigotine, indigo carmine (c)	E132	July 2015 <sup>1</sup>	Batch 1	--	2Q2014

(c) colour, \* with priority as set in (EC) 257/2010, -- not included

<sup>1</sup> negotiated deadline; <sup>2</sup> calls for data – *ref.*; <sup>3</sup> ANS Panel Scientific Panel on Food Additives and Nutrient Sources (ANS); the Q (quarter) refers to the tentative first discussion in a plenary meeting, not necessarily to a possible “adoption”

# Food additives with discussion and possible adoption in 2014

<b>Food additive</b>	<b>E No.</b>	<b>Legal Deadline</b>	<b>Call for data <sup>2</sup> use levels toxicological</b>		<b>ANS Panel <sup>3</sup></b>
<b>Tocopherols</b>	E306-309	2015*	Batch 2	--	3Q2014
<b>Propionates</b>	E280-283	2015*	--	--	3Q2014
<b>Dimethyl dicarbonate</b>	E242	2015*	--	--	3Q2014
<b>Titanium dioxide (c)</b>	E171	2015	Batch 1	--	3Q2014
<b>Chlorophylls (c)</b>	E140i	2015	Batch 1	--	3Q2014
<b>Iron oxides (c)</b>	E172	2015	Batch 1	--	3Q2014
<b>Beetroot red (c)</b>	E162	2015	--	--	3Q2014
<b>Oxidized polyethylene wax</b>	E914	2018	--	--	3Q2014
<b>Glycerol</b>	E422	2016*	Batch 2	--	4Q2014
<b>Locust bean gum</b>	E410	2016*	Batch 3	--	4Q2014
<b>Benzoic acid, benzoates</b>	E210-213	2015*	--	Batch A	4Q2014
<b>Annatto (c)</b>	E160b	2015	Batch 2	Batch A	4Q2014
<b>Octyl, dodecyl gallate</b>	E311-312	2015	Batch 1	Batch A	4Q2014

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<b>Nitrates</b>	E251-252	2015*	Batch 2	--	1-2Q2015
<b>Nitrites</b>	E249-250	2015*	Batch 2	--	1-2Q2015
<b>Chlorophyllins (c)</b>	E140ii	2015	Batch 2	Batch A	1-2Q2015
<b>Chlorophyll copper complex (c)</b>	E141i	2015	Batch 2	Batch A	1-2Q2015
<b>Chlorophyllins copper complex (c)</b>	E141ii	2015	Batch 2	Batch A	1-2Q2015
<b>Paprika extract (c)</b>	E160c	2015	--	Batch B	1-2Q2015
<b>Erythorbates</b>	E315-316	2015	Batch 3	Batch A	1-2Q2015
<b>B-cyclodextrin</b>	E459	2016	Batch 3	--	1-2Q2015
<b>Tragacanth</b>	E413	2016	Batch 3	--	1-2Q2015
<b>Xanthan gum</b>	E415	2016	Batch 3	--	1-2Q2015
<b>Cochineal, carminc acid, carmines (c)</b>	E120	2015	Batch 1	Batch B	1-2Q2015
<b>Ascorbyl palmitate and stearate</b>	E304i-ii	2015*	Batch 2	Batch B	1-2Q2015
<b>Silver (c)</b>	E174	2015	Batch 3	Batch B	1-2Q2015
<b>Gold (c)</b>	E175	2015	Batch 3	Batch B	1-2Q2015

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<b>Sulphur dioxide and sulphites</b>	E220-228	2015*	Batch 2	Batch B	3-4Q2015
<b>Quillaia extract</b>	E999	2015 <sup>1</sup>	--	--	3-4Q2015
<b>Sorbitans</b>	E491-495	2016*	Batch 2	Batch B	3-4Q2015
<b>Sucrose acetate isobutyrate</b>	E444	2016*	Batch 2	Batch A	3-4Q2015
<b>Lecithins</b>	E322	2016	Batch 3	--	3-4Q2015
<b>Agar</b>	E406	2016	Batch 3	--	3-4Q2015
<b>Carrageenan</b>	E407	2016	Batch 3	--	3-4Q2015
<b>Stearyl tartrate</b>	E483	2016*	--	--	3-4Q2015
<b>Processed eucheuma seaweed</b>	E407a	2016	Batch 3	--	3-4Q2015
<b>Tara gum</b>	E417	2016*	Batch 3	--	3-4Q2015
<b>Guar gum</b>	E412	2016	Batch 3	--	3-4Q2015
<b>Karaya gum</b>	E416	2016	Batch 3	--	3-4Q2015
<b>Gellan gum</b>	E418	2016	Batch 3	--	3-4Q2015
<b>Konjac gum and glucomannane</b>	E425i-ii	2016	Batch 3	Batch B	3-4Q2015

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## The tentative work programme 2016

# Food additives with discussion and possible adoption in 2016

<b>Additive</b>	<b>E No.</b>	<b>Deadline</b>	<b>Call for data</b>		
			<b>use levels</b>	<b>toxicological</b>	<b>ANS Panel</b>
<b>Polyglycerol esters of fatty acids</b>	E475	2016*	tbd	tbd	2016
<b>Soybean hemicellulose</b>	E426	2016	tbd	tbd	2016
<b>Pectins</b>	E440i-ii	2016	tbd	tbd	2016
<b>Ammonium phosphatides</b>	E442	2016	tbd	tbd	2016
<b>Glutamic acid and glutamates</b>	E620-625	2016	tbd	tbd	2016
<b>Cellulose</b>	E460	2016	tbd	tbd	2016
<b>Other celluloses</b>	E461-469	2016	tbd	tbd	2016
<b>Glycerol esters of wood rosins</b>	E445	2016	tbd	tbd	2016
<b>Cassia gum</b>	E427	2016	tbd	tbd	2016
<b>Alginic acid and alginates</b>	E400-405	2016	tbd	tbd	2016
<b>Salts of fatty acids</b>	E470a-b	2016	tbd	tbd	2016
<b>Mono and diglycerides of fatty acids and their esters</b>	E471-472a-f	2016	tbd	tbd	2016
<b>Polyglycerol polyricinoleate</b>	E476	2016	tbd	tbd	2016
<b>Propane esters of fatty acids</b>	E477	2016	tbd	tbd	2016
<b>Oxidized soya bean with mono- and diglyc- fatty acids</b>	E479b	2016	tbd	tbd	2016
<b>Silicon dioxide</b>	E551	2016	tbd	tbd	2016
<b>Polyvinyl alcohol</b>	E1203	2016	tbd	tbd	2016
<b>Starches</b>	E1404,1410, ..., 1452	2016	tbd	tbd	2016

\* with priority as set in (EC) 257/2010

# Final remarks

- ✓ European regulations are available for new additives and re-evaluation of those already in the market
- ✓ Re-evaluation programme up to 2020 is set up for re-assessment on authorized food additives based on scientific information and variable data ((EU) 257/2010)
- ✓ Tentative work programme with identified food additives is available for the period 2014-2016
  - ✓ The process should be further streamlined
  - ✓ Significant contribution is needed from interested business operators

# Food additives re-evaluation programme

...thank you for your attention!

