



Follow-up of the food additive re-evaluation programme by the European Commission

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The views expressed are purely those of the speaker and may not in any circumstances be regarded as stating an official position of the European Commission



Re-evaluation of approved food additives

Regulation (EC) No 1333/2008, Article 32:

"Food additives which were permitted before 20 January 2009 shall be subject to a new risk assessment carried out by the Authority" (EFSA)

General conditions inclusion and use of food additives in Union lists (Article 6.1(a)):

(the food additive) "does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer at the level of use proposed"



Other situations which trigger a new risk assessment for approved food additives

Changes in the production process or starting materials of a food additive already included in a Union list (Article 12):

When "there is a significant change, the food additive prepared by those new methods or materials shall be considered as a different additive and a new entry in the Union lists or a change in the specifications shall be required before it can be placed on the market".

Information obligation (Article 26.1):

"A producer or user of a food additive shall inform the Commission immediately of any new scientific or technical information which might affect the assessment of the safety of the food additive".



Re-evaluation programme

Commission Regulation (EU) No 257/2010 sets up a programme for the re-evaluation of approved food additives by EFSA, in accordance with Regulation (EC) No 1333/2008

- Priorities for the re-evaluation/general and more specific deadlines (programme ends in 31 December 2020 with the re-evaluation of sweeteners)
- Re-evaluation procedure/open calls for data
- Obligation for submission of data by interested business operators/interested parties

"Where the requested information has not been submitted to EFSA within the set deadlines, the food additive may be removed from the Union list in accordance with the procedure laid down in Article 10.3 of Regulation (EC) No 1333/2008" (Article 6.5)



Re-evaluation programme

- The re-evaluation programme by EFSA concerns food additives which were permitted before 20 January 2009
- Approved food additives, for which the re-evaluation by EFSA is already completed at the time of the adoption of Commission Regulation (EU) No 257/2010 (25 March 2010), shall not be re-evaluated again (Article 1.2)

316 food additives approved before 20 January 2009 to be re-evaluated by EFSA



Type of issues identified by EFSA in the re-evaluation scientific opinions

- So far EFSA has not identified a major safety concern (such as a proven carcinogenic or genotoxic activity) for any of the re-evaluated food additives
- In most cases EFSA re-confirms the safety of the food additive at its currently reported use and use level





Type of issues identified by EFSA in the re-evaluation scientific opinions

However, for some additives EFSA has identified issues that require a follow-up, such as:

- The safety of an additive could not be re-evaluated/an Acceptable Daily Intake (ADI) could not be established due to the lack of relevant toxicological data (a so-called "inconclusive opinion")
- EFSA established a temporary ADI due to the limited availability of toxicological data.
- The exposure assessment carried out by EFSA indicates that the ADI is exceeded in one or more population groups.
- EFSA raised issues concerning the specifications of some additives laid down in Commission Regulation (EU) No 231/2012





Modification of the authorisation of some food additives as a consequence of EFSA's safety re-evaluation

- Regulation (EU) No 232/2012: restriction of the use food colours Quinoline yellow (E 104), Sunset Yellow (E 110) and Ponceau 4R (E 124).
- Regulation (EU) No 380/2012: removal (calcium aluminium silicate, bentonite and aluminium silicate) and restriction of the use of aluminium containing additives.
- Regulation (EU) No 505/2014: introduction of maximum levels for the use of ammonia caramel (E 150c) in beer
- Regulation (EU) No 957/2014: removal of montan acid esters





Approach for follow-up of EFSA's re-evaluation scientific opinions

- Additives whose re-evaluation by EFSA was hindered by limited data availability, but which are not expected to pose an immediate food safety concern, are not going to be right away banned or their uses and use levels revised.
- Business operators will be requested to provide, by a certain deadline, the new data needed to complete the risk assessment, revise ADI, address exposure issues and/or specifications issues (Calls for data).
- Once the new data has been assessed by EFSA (if appropriate) or the Commission, the current authorisation of the additive may be revised, if needed.
- If the business operators indicate no further interest for an additive under re-evaluation and therefore provide no new data, a withdrawal of the current authorisation can be envisaged.

No additional calls for data will be organised





Approach for follow-up of EFSA's re-evaluation scientific opinions

The approach for the follow-up of EFSA's re-evaluation opinions does not represent a "second chance" for provision of data

Business Operators should continue providing to EFSA all available data which is requested in EFSA's calls for data





Approach for follow-up of EFSA's re-evaluation opinions: other general remarks

- Most issues raised by EFSA in the re-evaluation are additive-specific and therefore the follow-up should be additive per additive (or per group of related additives).
- Requests for extension of use of re-evaluated additives will not be processed until the issues raised by EFSA are satisfactorily addressed.
- The number of additives requiring a follow-up and the different nature of the issues raised by EFSA in the re-evaluation scientific opinions make it necessary to organise the follow-up on the basis of a risk-based prioritisation approach





Approach for communication to, and consultation of, business operators

- Communication to business operators via a dedicated web page

LINK:

http://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation/index_en.htm

Business operators are encouraged to visit that page regularly to remain updated about the follow-up of EFSA's safety re-evaluation of food additives.





FOOD

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Re-evaluation

Food additives permitted **before 20 January 2009 must go through a new risk assessment** by the [European Food Safety Authority \(EFSA\)](#).

Commission Regulation (EU) No 257/2010 set up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008.

Deadlines for re-evaluation:

Most food colours	by the end of 2011 (closed)
Aspartame	by November 2013 (closed) - <i>NB: this re-evaluation was advanced due to the publication of new scientific data</i>
Remaining colours	by the end of 2015 (closed)
Preservatives, antioxidants, glutamates, silicon dioxide	by the end of 2015-2016
Other sweeteners	by the end of 2020
All other additives	by the end of 2018

State of play of the re-evaluation of safety of permitted food additives by EFSA as of 10 October 2017:

- **316 food additives** approved before 20 January 2009 to be re-evaluated by EFSA
- **93 scientific opinions** published by EFSA on the re-evaluation of the safety of food additives, covering **150 individual food additives**
- **166 food additives** still to be re-evaluated by EFSA before 31 December 2020



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State of play of the re-evaluation of safety of permitted food additives by EFSA as of 10 October 2017:

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[Summary table](#) of permitted food additives and status of their re-evaluation by EFSA (status as of 10 October 2017).

[Approach](#)  for the follow-up of EFSA's scientific opinions on the re-evaluation of the safety of permitted food additives for which some concerns have been identified.

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Follow-up of EFSA's scientific opinion on the re-evaluation of sorbic acid (E 200), potassium sorbate (E 202) and calcium sorbate (E 203) as food additives **CALL CLOSED**

Follow-up of EFSA's scientific opinion on the re-evaluation of sulphur dioxide (E 220), sodium sulphite (E 221), sodium bisulphite (E 222), sodium metabisulphite (E 223), potassium metabisulphite (E 224), calcium sulphite (E 226), calcium bisulphite (E 227) and potassium bisulphite (E 228) as food additive - **CALL CLOSED**

Follow-up of EFSA's scientific opinion on the re-evaluation on the re-evaluation of iron oxides and hydroxides (E 172) as food additives - **CALL CLOSED**

Follow-up of EFSA's scientific opinion on the re-evaluation of titanium dioxide (E 171) as a food additive - **CALL CLOSED**

Follow-up of EFSA's scientific opinions on the re-evaluation of E 140(i) chlorophylls, E 140(ii) chlorophyllins, E 141(i) copper complexes of chlorophylls and E 141(ii) copper complexes of chlorophyllins as food additives - **CALL CLOSED**

Follow-up of EFSA's scientific opinions on the re-evaluation of propyl gallate (E 310), octyl gallate (E 311) and dodecyl gallate (E 312) as food additives **CALL OPEN**



Calls for scientific and technical data from individual food additives

- Background
- Main conclusions of EFSA's scientific opinion
- Overall purpose of this call for data
- Scientific and technical data required
- Procedure of the call for data
 - ✓ Step 1: Registration of the contact details of business operators interested in submitting data
 - ✓ Step 2: Confirmation of data submission, deadlines and milestones
- Procedure for submission of the required data
- Confidential data
- Possibility for EFSA to use the data for the safety assessment of the same substance under other legal or regulatory frameworks





Calls for scientific and technical data from individual food additives

- List of data that will be submitted, deadlines and milestones will be published in the web site after completion of step 2
- Once the new data are received, they are submitted to EFSA for evaluation and preparation of a scientific opinion, if appropriate.
- A risk management decision (whether an additive remains permitted or not, and its uses/use levels, specifications) will be taken on the basis of the outcome of analysis of the new data submitted.

No additional calls for data will be organised





Calls for scientific and technical data

- Sorbic acid (E 200), potassium sorbate (E 202) and calcium sorbate (E 203) (call closed)
- Sulphur dioxide (E 220), sodium sulphite (E 221), sodium bisulphite (E 222), sodium metabisulphite (E 223), potassium metabisulphite (E 224), calcium sulphite (E 226), calcium bisulphite (E 227) and potassium bisulphite (E 228) (call closed)
- Iron oxides and hydroxides (E 172) (call closed)
- Titanium dioxide (E 171) (call closed)
- Chlorophylls E 140(i), chlorophyllins E 140(ii), copper complexes of chlorophylls E 141(i) and copper complexes of chlorophyllins E 141(ii) (call closed)
- Propyl gallate (E 310), octyl gallate (E 311) and dodecyl gallate (E 312) (call closes on 31/11/17)





Outcome of the calls for scientific and technical data

In general, good response to the calls (business operators committed to providing the requested data within a reasonable timeframe)

One exception (so far): no commitment was received for the provision of the requested data on genotoxicity of calcium sorbate (E 203)

Calcium sorbate (E 203) will be deleted from the Union list of authorised food additives since due to the absence of appropriate genotoxicity data its inclusion in the list can no longer be justified.





Future calls for data

- Glutamic acid (E 620), sodium glutamate (E 621), potassium glutamate (E 622), calcium glutamate (E 623), ammonium glutamate (E 624) and magnesium glutamate (E 625)
- Sulphur dioxide (E 220), sodium sulphite (E 221), sodium bisulfite (E 222), sodium metabisulphite (E 223), potassium metabisulphite (E 224), calcium sulphite (E 226), calcium bisulphite (E 227) and potassium bisulphite (E 228)
- Gold (E 175)
- Silver (E 174)
- Sodium stearyl-2-lactylate (E 481) and calcium stearyl-2-lactylate (E 482)
- Benzoic acid (E 210), sodium benzoate (E 211), potassium benzoate (E 212) and calcium benzoate (E 213)
- Glycerol (E 422), polyglycerol polyricinoleate (E 476) and other glycerol-based food additives

http://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation/index_en.htm





More information

European Commission, Directorate General for Health and Food Safety, Website Food Improvement Agents:

http://ec.europa.eu/food/safety/food_improvement_agents/index_en.htm