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

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EFSA's stakeholder workshop on "Data requirements for the re-evaluation of food additives used in foods for infants below 16 weeks of age", Parma, 30 November 2018

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"

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 permitted 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

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 business operators indicate no further interest for an additive under re-evaluation and therefore do not provide the data requested in the call, 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.

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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) - *NB: this re-evaluation was advanced due to the publication of new scientific data*
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 20 July 2018:

- **316 food additives** approved before 20 January 2009 to be re-evaluated by EFSA
- **104 scientific opinions** published by EFSA on the re-evaluation of the safety of food additives, covering **175 individual food additives**
- **141 food additives** still to be re-evaluated by EFSA before 31 December 2020

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Summary table of permitted food additives and status of their re-evaluation by EFSA (status as of 20 July 2018).

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 glycerol (E 422) as a food additive - CALL OPEN

Follow-up of EFSA's scientific opinion on the re-evaluation of glycerol esters of wood rosin (E 445) as a food additive - CALL OPEN

Follow-up of EFSA's scientific opinion on the re-evaluation of polyglycerol esters of fatty acids (E 475) as a food additive - CALL OPEN

Follow-up of EFSA's scientific opinion on the re-evaluation of polyglycerol polyricinoleate (E 476) as a food additive - CALL OPEN

Follow-up of EFSA's scientific opinion on the re-evaluation of calcium silicate (E 552), magnesium silicate (E 553a(i)), magnesium trisilicate (E 553a(ii)) and talc (E 553b) as food additives - CALL OPEN

Follow-up of EFSA's scientific opinion on the re-evaluation of processed Eucheuma seaweed (E 407a) as a food additive - CALL OPEN

Follow-up of EFSA's scientific opinion on the re-evaluation of tocopherol-rich extract (E 306), α-tocopherol (E 307), γ-tocopherol (E 308) and δ- tocopherol (E 309) as food additives - CALL OPEN

Follow-up of EFSA's scientific opinion on the re-evaluation of carrageenan (E 407) as a food additive - CALL OPEN

Follow-up of EFSA's scientific opinion on the re-evaluation of calcium carbonate (E 170) as a food additive - CALL OPEN

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 closed)
- Gold (E 175) (call closed)
- Silver (E 174) (call closed)
- Indigotine, indigo carmine (E 132) (call closed)

Outcome of the calls for scientific and technical data

In general, business operators committed to providing the requested data within a reasonable timeframe

Exceptions (so far): no commitment was received for the provision of the requested data on

- calcium sorbate (E 203)
- octyl gallate (E 311)
- dodecyl gallate (E 312)

Calcium sorbate (E 203), octyl gallate (E 311) and dodecyl gallate (E 312) have been deleted from the Union list of authorised food additives since due to the absence of appropriate toxicological data it cannot be concluded on their safety (their inclusion in the list can no longer be justified).

Mandate to EFSA to address data gaps specified in the already delivered re-evaluation of food additives permitted in food for infants below 12 weeks of age

On 7 December 2017 the Commission requested EFSA:

> "In accordance with Article 29(1)(a) of Regulation (EC) No 178/2002, and as part of EFSA's work in completing its risk assessments concerning the use of food additives in food for infants below 12 weeks of age, covered by the re-evaluation programme and its terms of reference, the European Commission requests the European Food Safety Authority to address all the data gaps specified in the recommendations made in its scientific opinions on the re-evaluation of the safety of food additives permitted in food category 13.1 (food for infants and young children) of Annex II to Regulation (EC) No 1333/2008."

Mandate to EFSA to address data gaps specified in the delivered re-evaluation of food additives permitted in food for infants below 12 weeks of age

Therefore, calls for data for the additives in question will be issued by EFSA and not by the European Commission

However, the same principles as for calls for data issued by the Commission apply:

If business operators indicate no further interest for an additive under re-evaluation and therefore do not provide the data requested in the call, a withdrawal of the current authorisation can be envisaged.

No additional calls for data will be organised

Complementary calls for data issued by the European Commission

related to the mandate to EFSA to address data gaps specified in the already delivered re-evaluation of food additives permitted in food for infants below 12 weeks of age
:

- Processed Eucheuma seaweed (E 407a)
- Calcium silicate (E 552), magnesium silicate (E 553a(i)), magnesium trisilicate (E 553a(ii)) and talc (E 553b)
- Glycerol (E 422)
- Glycerol esters of wood rosin (E 445)
- Polyglycerol esters of fatty acids (E 475)
- Polyglycerol polyricinoleate (E 476)

(all these calls are currently open; see *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