Roadmap for the follow-up of EFSA scientific opinions on the re-evaluation of the safety of permitted food additives

Plenary meeting of the Advisory Group on the Food Chain and Animal and Plant Health
29 April 2016

Re-evaluation programme

- Established by Commission Regulation (EU) No 257/2010, in accordance with Regulation (EC) No 1333/2008
- All additives authorised before 20 January 2009
  - **Colours to be re-evaluated by 31.12.2015**
    Artificial colours with higher priority
  - **Sweeteners to be re-evaluated by 31.12.2020**
    Aspartame by 30.11.2013
  - **All other additives to be re-evaluated by 31.12.2018**
    Preservatives and antioxidants by 31.12.2015
    Emulsifiers, stabilisers, gelling agents, Silicon dioxide, Glutamates by 31.12.2016

Re-evaluation procedure

When re-evaluating an approved food additive, EFSA shall:

a) examine the original opinion and the working documents of the Scientific Committee on Food ('SCF') or EFSA;

b) examine, where available, the original dossier;

c) examine the data submitted by the interested business operator(s) and/or any other interested party;

d) examine any data made available by the Commission and Member States;

e) identify any relevant literature published

Call for data

EFSA shall make open call(s) for available data which may comprise among others:

(a) study reports from the original dossiers,

(b) information of safety data not previously reviewed,

(c) information on the specifications,

(d) information on the manufacturing process,

(e) information on analytical methods available for determination in food,

(f) information on the human exposure to the food additives from food (e.g. consumption pattern and uses, actual use levels and maximum use levels, frequency of consumption and other factors influencing exposure),

(g) reaction and fate in food.

Submission of data

- Within the period set by EFSA in its call for data;
- If additional information is needed, EFSA shall request from the interested business operators, and set a deadline having considered, where relevant, the interested business operator's and/or other interested parties' view of the time required.
- Where the requested information has not been submitted to EFSA within the set deadlines, the food additive may be removed.

State of play re-evaluation by EFSA

- **316 food additives** approved before 20 January 2009 to be re-evaluated by EFSA
- So far EFSA has issued **71 scientific opinions** on the safety re-evaluation of food additives, covering **102 individual food additives**
- **214 food additives** still need to be re-evaluated by EFSA before 31 December 2020
- EFSA intends to complete the re-evaluation of **79 food additives in 2016** (re-evaluation of 11 of these additives already delivered)

State of play re-evaluation by EFSA

(status as of 21 April 2016)

Type of food additive	N° of additives to be re-evaluated	N° of additives already re-evaluated	N° of additives still to be re-evaluated
Colours	41	38	3
Sweeteners	16	1	15
Additives other than colours and sweeteners	259	63	196
Total	316	102	214

Type of issues identified by EFSA in the re-evaluation 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 many 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 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 and/or Acceptable Daily Intake (ADI) derived due to the lack of relevant toxicological data (a so-called "inconclusive opinion")
- EFSA lowered the ADI due to the limited availability of toxicological data.
- The exposure assessment carried out by EFSA suggests a potential exceedance of the ADI for 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 the safety re-evaluation by EFSA

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

Approach for follow-up of EFSA re-evaluation opinions

- Additives whose safety 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 specification issues.

- Once the new data has been assessed by EFSA (if appropriate) or the Commission, the current authorisation of the FA 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.

Approach for follow-up of EFSA re-evaluation opinions

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

- The calls for data issued by EFSA for the re-evaluation of the safety of food additives concern existing/available data.
- Only after the analysis of the available data EFSA can identify if there are data gaps, which are described in the re-evaluation scientific opinions.
- In general, new toxicological studies are needed to generate those data.

Approach for follow-up of EFSA 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.
- Requests for extension of use of additives under re-evaluation 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 follow-up of EFSA re-evaluation opinions: other general remarks

Prioritisation criteria for follow-up of EFSA re-evaluation opinions:

- EFSA was not able to evaluate the safety of the additive and to derive an Acceptable Daily Intake (ADI) due to the lack of data.
- EFSA did not identify concerns with respect to carcinogenicity or genotoxicity, but EFSA could not derive an ADI, or lowered the ADI due to lack of/limited data.
- The exposure assessment carried out by EFSA suggests a potential exceedance of the ADI for one or more population groups (sometimes linked to the lowering of the ADI by EFSA).
- EFSA identified problems in the specifications of an additive.

Approach for communication to, and consultation of, business operators

- Communication to business operators via a dedicated web site on the new data needed to complete the risk assessment of an additive and to address issues
- Business operators are requested to communicate to the Commission within 6 weeks whether they are interested that the additive remains permitted and therefore whether they are interested in providing the new data.
- The Commission receives and publishes in the web site the list of business operators interested in submitting data in order to facilitate interactions among them and possibly coordination in the data submission.
- An appropriate deadline is given to business operators to send a confirmation that new data will be submitted (this deadline should allow BOs to make plans for the studies, and, if needed/possible, to form consortia for sharing the costs of studies).

Approach for communication to, and consultation of, business operators

- Business operators also have to propose a timeline for data submission as well as milestones.
- Confirmation of the deadline and milestones.
- 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 and its uses/use levels, specifications) will be taken on the basis of the outcome of analysis of the new data submitted
- When the new data requested can be more easily gathered (such as additional data on specifications or uses/use levels), it can be envisaged that a deadline for data submission is fixed already in the initial Commission notification

Food additives whose re-evaluation follow-up will start first

1. Sorbic acid (E 200), potassium sorbate (E 202), calcium sorbate (E 203)
2. Chlorophyllins (E 140(ii)), Cu-chlorophylls (E 141(i)) and Cu-chlorophyllins (E 141(ii))
3. Iron oxides and hydroxides (E 172)
4. Sulfur dioxide (E 220), sodium sulfite (E 221), sodium bisulfite (E 222), sodium metabisulfite (E 223), potassium metabisulfite (E 224), calcium sulfite (E 226), calcium bisulfite (E 227) and potassium bisulfite (E 228)
5. Octyl gallate (E 311) and Dodecyl gallate (E 312)
6. Benzoic acid (E 210), sodium benzoate (E 211), potassium benzoate (E 212) and calcium benzoate (E 213)
7. Sodium stearoyl-2-lactylate (E 481) and calcium stearoyl-2-lactylate (E 482)

Next steps

- The web page dedicated to the follow-up of the re-evaluation programme is expected to go online by the end of May 2016
- It will be linked to the current DG SANTE's Additives (Food Improvement Agents) section: http://ec.europa.eu/food/safety/food_improvement_agents/additives/index_en.htm
- Visit that page regularly to remain updated about the follow-up of EFSA's safety revaluation of individual food additives

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