

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

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 fact, in most cases EFSA confirms the safety of those food additives at their currently reported uses and use levels.

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

- EFSA was not able to re-evaluate, and therefore to reconfirm, the safety of an additive and/or derive an Acceptable Daily Intake (ADI) due to the lack of relevant scientific data.
- EFSA lowered the ADI of an additive 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 as laid down in Commission Regulation (EU) No 231/2012.

For each additive (or groups of additives that can be addressed simultaneously) requiring a follow-up a specific **call for data** will be published on DG SANTE's [website](#) on food additives¹. Those calls will summarise the conclusions of EFSA's scientific opinions on the re-evaluation of the safety of permitted food additives, the specific issues identified by EFSA that require a follow-up and the new data (generally new toxicological studies) necessary to address them.

The Commission will undertake that the time assigned for addressing the issues identified by EFSA in those scientific opinions is as short as possible and dependent on the time needed to generate and assess the required new data.

Requests for extension of use or amendment of the specifications of additives subject to a follow-up in the context of the re-evaluation will not be dealt with until the issues raised by EFSA are satisfactorily clarified.

The 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 immediately removed from the Union list of permitted additives, or their uses and/or use levels revised. Instead, business operators will be requested to indicate to the Commission, within a certain deadline (in general 6 weeks), whether they are interested in the continuity of approval of the additive(s) under re-evaluation and in providing the data needed by EFSA to complete the risk assessment (**step 1**).

At the end of step 1 the Commission will publish on that [website](#) the list of business operators interested in submitting data. This aims at facilitating interactions among the business operators and a possible coordination in the generation and submission of data.

As a next step (**step 2**) interested business operators will have to confirm by a predefined deadline (in general 12 weeks; 24 weeks if new toxicological studies are needed to generate the data) that they will submit the new data required, providing also the timeline for that submission and its justification. If appropriate, business operators will be asked to additionally provide a list of intermediate milestones of the data generation and when they

¹ http://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation/index_en.htm

will be achieved. Business operators will be requested to keep the Commission informed of the timely achievement of these milestones.

Overall, the timeline for data submission and milestones should be in line with the EFSA's scientific report on "Indicative timelines for submitting additional or supplementary information to EFSA during the risk assessment process of regulated products"².

The Commission will acknowledge receipt of this confirmation of data submission and will confirm the proposed timetable for data submission, the defined milestones and their time scheduling. After completion of this step (step 2), the data to be submitted and both deadlines and milestones will be published on the DG SANTE's [website](#).

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** on whether an additive and its uses/use levels remain permitted, and/or on the content of its specifications will be taken based on the outcome of EFSA's final scientific opinion.

If business operators do not provide the requested data (by the predefined deadline), the risk management decision will be taken based on EFSA's current scientific opinion and the additives may be removed from the Union list of permitted additives. The same applies if the **new data submitted is not sufficient for EFSA to conclude the risk assessment** (there will be no successive requests for additional data).

Food additives for which EFSA has identified **concerns in terms of exposure or specifications** will be subject to the same follow-up approach, but EFSA's assessment of the new data may not always be needed.

² http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/3553.pdf