Update on the re-evaluation of food additives

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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 programme

- Food additives permitted before 20 January 2009 must go through a new risk assessment by EFSA
- Commission Regulation (EU) No 257/2010 sets up a programme for the re-evaluation of approved food additives.
- State of play of the re-evaluation of safety of permitted food additives:
  - 315 food additives approved before 20 January 2009 to be re-evaluated by EFSA
  - 126 scientific opinions published by EFSA on the re-evaluation of the safety of food additives, covering 230 individual food additive
  - 85 food additives still to be re-evaluated by EFSA
  - Re-evaluation not finalized by the deadline (end of 2020)
- Calls for data by EFSA

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Re-evaluation programme

- Calls for data by EFSA: https://www.efsa.europa.eu/en/calls/data
  - Call for data for the re-evaluation of gluconic acid (E 574) and related food additives (E 575-579)
  - Call for data for the re-evaluation of food additives in gaseous form
  - Call for data for the re-evaluation of ribonucleotides (E 626-635) as food additives
  - Call for data on genotoxicity data on sorbitol (E 420 i)
- Assessment by EFSA and publication of the re-evaluation opinion

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Follow-up to the re-evaluation

- Approach for the follow-up of EFSA's scientific opinions by the COM: https://food.ec.europa.eu/system/files/2022-01/fs_food-improvement-agents_reeval_approach.pdf
  - For each additive requiring a follow-up -> **specific call** for data published by DG SANTE
  - 2-step call if call requests toxicity data
  - 1-step call if call requests only technical data (data on specifications and/or use levels)
  - The received data 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.

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Follow-up to the re-evaluation

- Approach for the follow-up of EFSA's scientific opinions by the COM: https://food.ec.europa.eu/system/files/2022-01/fs_food-improvement-agents_reeval_approach.pdf

> **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).

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Follow-up to the re-evaluation

Calls for data by DG SANTE: https://food.ec.europa.eu/safety/food-improvement-agents/additives/re-evaluation_en

- + **Follow-up of EFSA's scientific opinion on the re-evaluation of celluloses E 460(i), E 460(ii), E 461, E 462, E 463, E 464, E 465, E 468 and E 469 as food additives – CALL OPEN**
- + **Follow-up of EFSA's scientific opinion on the re-evaluation of phosphoric acid–phosphates – di-, tri- and polyphosphates (E 338–341, E 343, E 450–452) as food additives – CALL OPEN**
- + **Follow-up of EFSA's scientific opinion on the re-evaluation of sodium aluminium silicate (E 554) as a food additive - CALL OPEN**
- + **Follow-up of EFSA's scientific opinion on the re-evaluation of potassium nitrite (E 249), sodium nitrite (E 250), sodium nitrate (E 251) and potassium nitrate (E 252) as a food additive - CALL CLOSED**
- + **Follow-up of EFSA's scientific opinion on the re-evaluation of citric acid esters of mono- and diglycerides of fatty acids (E 472c) as food additive - CALL CLOSED**

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Sulphur dioxide and sulphites

EFSA Journal 2016;14(4):4438

SCIENTIFIC OPINION

Scientific Opinion on the re-evaluation of 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) as food additives[1]

EFSA Panel on Food additives and Nutrient Sources added to Food (ANS)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

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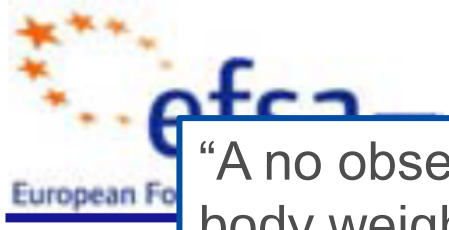
Sulphur dioxide and sulphites



Scient
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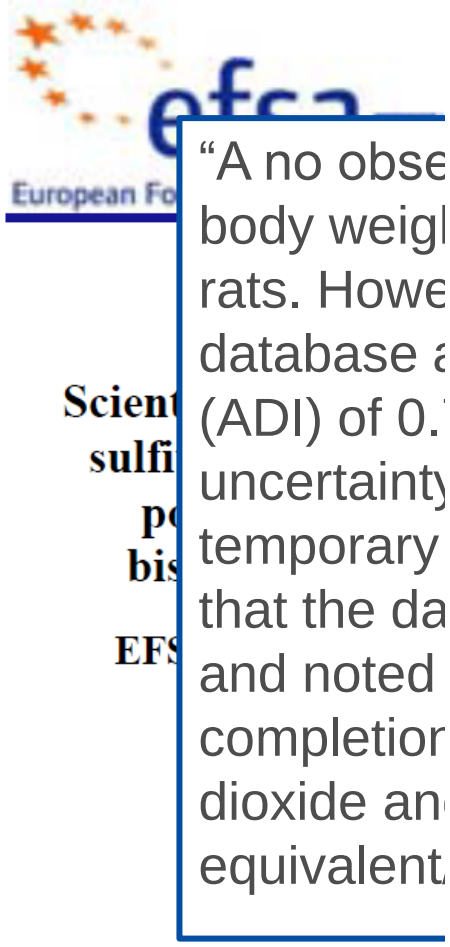
EFS

"A no observed adverse effect level (NOAEL) of 70 mg SO2 equivalent/kg body weight (bw) per day was identified from a long-term toxicity study in rats. However, the Panel noted several uncertainties and limitations in the database and concluded that the current group acceptable daily intake (ADI) of 0.7 mg SO2 equivalent/kg bw per day (derived using a default uncertainty factor) would remain adequate but should be considered temporary while the database was improved. The Panel recommended that the database and the temporary group ADI should be re-evaluated and noted that the recommended studies could require 5 years for completion. The Panel further concluded that exposure estimates to sulfur dioxide and sulfites were higher than the group ADI of 0.7 mg SO2 equivalent/kg bw per day for all population groups."

Sulphur dioxide and sulphites



— **Follow-up of EFSA's scientific opinion on the re-evaluation of E 220, E 221, E 222, E 223, E 224, E 226, E 227 and E 228 as food additive - CALL CLOSED**

Call for scientific and technical data on the permitted food additives 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)

- **Published:** 10/10/2016
- **Registration of the contact details of business operators interested in submitting data (step 1)**
  - **Deadline:** 10/11/2016 (CLOSED)
  - List of interested business operators
- **Confirmation of data submission, deadlines and milestones (step 2)**
  - **Deadline:** 10/4/2017 (CLOSED)
  - Outcome of step 2 of the call for data and overview of data that will be submitted, deadlines and milestones.

Sulphur dioxide and sulphites

SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 28 September 2022

doi: 10.2903/j.efsa.2022.7594

Follow-up of the re-evaluation of 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)

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Sulphur dioxide and sulphites

"No new biological or toxicological data addressing the data gaps described in the re-evaluation were submitted by IBOs. Taking into account data identified from the literature search, the Panel concluded that there was **no substantial reduction in the uncertainties** previously identified in the re-evaluation. Therefore, the Panel considered that **the available toxicity database was inadequate to derive an ADI** and withdrew the current temporary group ADI. A **margin of exposure (MOE)** approach was considered appropriate to assess the risk for these food additives. …… **The Panel concluded that this raises a safety concern** for both dietary exposure scenarios. The Panel also performed a risk assessment for toxic elements present in sulfur dioxide–sulfites (E 220–228), based on data submitted by IBOs, and concluded that the maximum limits in the **EU specifications** for arsenic, lead and mercury should be lowered and a maximum limit for cadmium should be introduced."

Sulphur dioxide and sulphites: risk management follow-up

Working Party of Governmental Experts on Additives (WGA), a working group of the Standing Committee on Plants, Animals, Food, and Feed.

- EFSA recommendation to explore the technological need to maintain the authorizations for **calcium sulphite** and **calcium bisulphite** on the positive list of authorized food additives. In addition, no technical data were submitted on the presence of toxic elements by business operators for these two food additives and **potassium bisulphite**.
- It has also been noted that for many authorised uses, **no use levels were submitted** by interested business operators during the call for data.

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Sulphur dioxide and sulphites: risk management follow-up

- DG SANTE performed a targeted stakeholder consultation to collect feedback:
  - whether there is interest that the use of calcium sulphite, calcium bisulphite and potassium bisulphite remains authorised within the EU;
  - on the intention to withdraw the authorization for uses for which no actual use levels have been submitted.
- Serves as input for the discussion on the revision of the list of authorised food additives and use levels within Regulation (EC) No 1333/2008 as well as a revision of the specifications for these food additives in Regulation (EU) 231/2012.

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Sulphur dioxide and sulphites: risk management follow-up

- Next steps:
  - WGA 23 05: 14 and 15 November 2023
  - WGA 24 01
  - WGA 24 02
  - ….
  - Meeting of the Novel Food and Toxicological Safety Section of the Standing Committee on Plants, Animals, Food and Feed (PAFF) https://food.ec.europa.eu/horizontal-topics/committees/paff-committees/novel-food-and-toxicological-safety_en

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