*This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.*

16 June 2023

**WORKING DOCUMENT**

**Follow-up to EFSA’s updated scientific opinion on the safety of the permitted food additives sulfur dioxide-sulfites (E 220-228)**

**Background**

Sulfur dioxide–sulfites (E 220–228) were re-evaluated in 2016[[1]](#footnote-1), resulting in the setting of a temporary ADI of 0.7 mg SO2 equivalents/kg bw per day. In its opinion, EFSA listed several recommendations. In line with the approach[[2]](#footnote-2) agreed for the follow-up of such inconclusive scientific opinions, SANTE E2 organised a call for data[[3]](#footnote-3) (published 10 October 2016) requesting business operators to submit the scientific and technical data needed to address the issues identified by EFSA. The call for data specified “*If business operators do not provide the requested data (by the predefined deadline) the present authorisation will be revised based on EFSA’s current scientific opinion and the additive(s) 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, since there will be no successive requests for additional data*.”

Following the closure of the call for data, EFSA was requested to provide an updated scientific opinion as regards the safety of the permitted food additives 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).

On 28 September 2022, the EFSA Panel on Food Additives and Flavourings (FAF) adopted a scientific opinion addressing the follow-up to the re-evaluation. 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 temporary group acceptable daily intake (ADI). A margin of exposure (MOE) approach was considered appropriate to assess the risk for these food additives. A lower confidence limit of the benchmark dose of 38 mg SO2 equivalents/kg bw per day, which is lower than the previous reference point of 70 mg SO2 equivalents/kg bw per day, was estimated based on prolonged visual evoked potential latency. An assessment factor of 80 was applied for the assessment of the MoE. At the estimated dietary exposures, when using a refined exposure scenario (Data set D), MOEs at the maximum of 95th percentile ranges were below 80 for all population groups except for adolescents. The dietary exposures estimated using the maximum permitted levels would result in MOEs below 80 in all population groups at the maximum of the ranges of the mean, and for most of the population groups at both minimum and maximum of the ranges at the 95th percentile. The Panel concluded that this raises a safety concern for both dietary exposure scenarios.

**Risk management follow-up to the re-evaluation**

The Working Party of Governmental Experts on Additives (WGA), i.e. a working group of the Standing Committee on Plants, Animals, Food and Feed, section Novel Food and Toxicological Safety of the Food Chain, has initiated the discussion on the follow-up to the re-evaluation of sulfur dioxide-sulfites (E 220-228). In the context of this ongoing work, the WGA would like to consult interested business operators with respect to the authorisation of E 226-228 and the uses of E 220-228 in accordance with Annex II, Part E and Annex III of Regulation (EC) No 1333/2008.

**Inclusion of calcium sulfite (E 226), calcium bisulfite (E 227) and potassium bisulfite (E 228) in the Union list of authorised food additives as laid down in Regulation (EC) No 1333/2008**

EFSA recommended in the 2022 opinion to explore the technological need to maintain calcium sulfite (E 226) and calcium bisulfite (E 227) on the EU positive list of authorised food additives. Moreover, it was noted that the opinion reports that an interested business operator stated that he is not aware of any member producing E 226, E 227 or E 228 and that the production of calcium bisulfite (E 227) was stopped by the lead registrant in 2012. In addition, no technical data on toxic elements were submitted by business operators for E 226, E 227 or E 228.

Therefore, it is concluded that there is no interest that calcium sulfite (E 226), calcium bisulfite (E 227) and potassium bisulfite (E 228) remain permitted in the EU and the current authorisation for the use of these food additives should be terminated (these substances should be removed from the list of authorised food additives).

**Uses in accordance with Annex II and III to Regulation (EC) No 1333/2008**

In accordance with Annex II, Part E, sulfur dioxide-sulfites (E 220-228) are authorised in 40 food categories. In accordance with Annex III, Part 2 and 3, sulfur dioxide-sulfites (E 220-228) may be added to food additive preparations and to food enzymes.

For the 2022 risk assessment, EFSA considered the use levels collected at the time of the 2016 re-evaluation and the EC call for data published in 2016. However, for many food categories for which direct addition of sulfur dioxide-sulfites (E 220-228) is authorised no use levels were provided. The EFSA opinion did not report use levels in accordance with Annex III.

In-line with the approach outlined in the call for data, it is considered that there is no interest that the use of sulfur dioxide-sulfites (E 220-228) as food additives remains authorised for the uses for which no actual use levels have been submitted. Consequently, the authorisation for the use of sulfur dioxide-sulfites (E 220-228) as food additives in these food categories/restrictions, food additive preparations and/or food enzymes will be withdrawn.

List of food categories and their restrictions for which no actual use levels were reported by business operators under the re-evaluation and follow-up to the re-evaluation:

| **Food category number** | **Food category description** | **Restrictions/exceptions** |
| --- | --- | --- |
| 04.1.1 | Entire fresh fruit and vegetables | Only table grapes, fresh lychees (measured on edible parts) and blueberries (*Vaccinium corymbosum*) |
| Only vacuum packed sweetcorn |
| 04.1.2 | Peeled, cut and shredded fruit and vegetables | Only peeled potatoes |
| Only onion, garlic and shallot pulp |
| Only horseradish pulp |
| 04.1.3 | Frozen fruit and vegetables | Only white vegetables including mushrooms and white pulses |
| Only frozen and deep-frozen potatoes |
| 04.2.1 |  Dried fruit and vegetables | Only dried coconut |
| Only white vegetables, processed, including pulses |
| Only dried mushrooms |
| Only dried ginger |
| Only dried tomatoes |
| Only white vegetables, dried |
| Only dried fruit and nuts in shell, excluding dried apples, pears, bananas, apricots, peaches, grapes, prunes and figs |
| Only dried bananas |
| 04.2.2 | Fruit and vegetables in vinegar, oil or brine | Only golden peppers in brine |
| 04.2.3 | Canned or bottled fruit and vegetables | Only white vegetables, including pulses and processed mushrooms |
| Only bottled whiteheart cherries; vacuum packed sweetcorn |
| 04.2.4.1 | Fruit and vegetable preparations excluding compote | Only processed white vegetables and mushrooms |
| Only rehydrated dried fruit and lychees, mostarda di frutta |
| Only onion, garlic and shallot pulp |
| Only Jellying fruit extract, liquid pectin for sale to the final consumer |
| 04.2.5.1 | Extra jam and extra jelly as defined by Directive 2001/113/EC | Only jams, jellies and *mermeladas* made with sulfited fruit |
| 04.2.5.2 | Jam, jellies and marmalades, and sweetened chestnut puree as defined by Directive 2001/113/EC |  |
| Only jams, jellies and marmalades made with sulfited fruit |
| 04.2.5.3 | Other similar fruit or vegetable spreads |  |
| 04.2.6 | Processed potato products |  |
| 05.2 | Other confectionery including breath refreshening microsweets | Only candied, crystallised or glacé fruit, vegetables, angelica and citrus peel |
| 05.4 | Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4 | Only toppings (syrups for pancakes, flavoured syrups for milkshakes and ice cream; similar products) |
| Only glucose syrup-based confectionery (carry over from the glucose syrup only) |
| Only fruit fillings for pastries |
| 06.1 | Whole, broken or flaked grain | Only sago and pearl barley |
| 09.1.2 | Unprocessed molluscs and crustaceans | Only fresh, frozen and deep-frozen crustaceans and cephalopods; crustaceans of the Penaeidae, Solenoceridae and Aristaeidae family up to 80 units |
| Only crustaceans of the Penaeidae, Solenoceridae and Aristaeidae family between 80 and 120 units |
| Only crustaceans of the Penaeidae, Solenoceridae and Aristaeidae family over 120 units |
| 09.2 | Processed fish and fishery products, including molluscs and crustaceans | Only cooked crustaceans and cephalopods |
| Only cooked crustaceans of the Penaeidae, Solenoceridae and Aristaeidae family up to 80 units |
| Only cooked crustaceans of the Penaeidae, Solenoceridae and Aristaeidae family between 80 and 120 units |
| Only dried salted fish of the 'Gadidae' species |
| Only cooked crustaceans of the Penaeidae, Solenoceridae and Aristaeidae family over 120 units |
| 11.1 | Sugars and syrups as defined by Directive 2001/111/EC | Only sugars, except glucose syrup |
| 11.2 | Other sugars and syrups |  |
| Only treacle and molasses |
| 12.2.1 |  Herbs and spices | Only cinnamon (Cinnamomum ceylanicum) |
| 12.2.2 | Seasonings and condiments | Only citrus juice-based seasonings |
| 12.9 | Protein products, excluding products covered in category 1.8 | Only analogues of meat, fish, crustaceans and cephalopods |
| 14.1.2 | Fruit juices as defined by Directive 2001/112/EC and vegetable juices | Only orange, grapefruit, apple and pineapple juice for bulk dispensing in catering establishments |
| Only grape juice, unfermented, for sacramental use |
| Only concentrated grape juice for home wine making |
| 14.1.4 | Flavoured drinks | Only carry-over from concentrates in non-alcoholic flavoured drinks containing fruit juice |
| Only non-alcoholic flavoured drinks containing at least 235 g/L glucose syrup |
| 14.2.4 | Fruit wine and made wine | Only made wine |
| 14.2.5 | Mead |  |
| 14.2.6 | Spirit drinks as defined in Regulation (EC) No 110/2008  | Only distilled alcoholic beverages containing whole pear |
| 14.2.7.2 | Aromatised wine-based drinks |  |
| 14.2.7.3 | Aromatised wine-product cocktails |  |
| 14.2.8 | Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15% of alcohol | Only in fermented grape must-based drink |
| Only nalewka na winie owocowym, aromatyzowana nalewka na winie owocowym, nalewka na winie z soku winogronowego, aromatyzowana nalewka na winie z soku winogronowego, napój winny owocowy lub miodowy, aromatyzowany napój winny owocowy lub miodowy, wino owocowe niskoalkoholowe and aromatyzowane wino owocowe niskoalkoholow |
| 15.1 | Potato-, cereal-, flour- or starch-based snacks | Only cereal-and potato-based snack |
| 15.2 | Processed nuts | Only marinated nut |

1. <http://www.efsa.europa.eu/en/efsajournal/pub/4438> [↑](#footnote-ref-1)
2. <https://ec.europa.eu/food/system/files/2022-01/fs_food-improvement-agents_reeval_approach.pdf> [↑](#footnote-ref-2)
3. <https://food.ec.europa.eu/system/files/2019-01/fs_food-improvement-agents_reeval_call_20161010_e220-e228_data.pdf> [↑](#footnote-ref-3)