

**European Union comments on
Codex Circular Letter CL 2021/61-FA:
"Priority list of substances proposed for evaluation by JECFA"**

*Mixed Competence
Member States Vote*

The European Union and its Member States (EUMS) would like to provide the following comments:

3. Azodicarbonamide (INS 927a)

Azodicarbonamide (INS 927a) is not authorised as a food additive in the EU. The EUMS take note of the discussion in the Working Group on Alignment, which noted safety concerns in countries that have removed the permission for the use of INS 927a and of the fact that the JECFA assessment dates back to 1965. Therefore, the EUMS are of the view that **the safety of this substance needs to be re-evaluated** should it stay included in the Codex standards. The EUMS consider that if this substance is not supported and there is no commitment to provide the data, it shall be removed from the GSFA and the Codex commodity standards.

4. Carob bean gum (INS 410)

The EUMS would like to inform about the recent findings of ethylene oxide in INS 410. The EUMS would like to draw the attention of the Committee and JECFA to this matter, as it may be a more global issue and as, to the EUMS knowledge, there is no limit for ethylene oxide in the JECFA specifications. Please be informed that ethylene oxide may not be used for sterilising purposes in food additives in the EU.

10. Dioctyl sodium sulfosuccinate (INS 480)

The EUMS **support** the request.

20. Pentasodium triphosphate (INS 451 (i)) and 22. Pentasodium triphosphate (INS 451)

The EUMS observe that in CL 2021/61-FA there is a duplication of the request submitted by CEFIC and captured in CX/FA 21/52/12.

The EUMS **support** this request.

21. Ortho-Phenylphenol (INS 231) and sodium ortho- phenylphenol (INS 232)

The EUMS notice that JECFA seeks advice from CCFA on the current usage of ortho-phenylphenols as food additives (CX/FA 21/52/3, para. 11). In this regard, the EUMS would like to inform that INS 231 and INS 232 are not considered as food additives in the EU but as 'plant protection products'. Due to their major use as a post-harvest treatment of fruits and vegetables, as noted by JECFA (CX/FA 21/52/3, para. 11), the EUMS are of the view that the Committee shall consider whether the entries for INS 231 and INS 232 need to be kept in the GSFA. The EUMS would support their removal, when classified as food additives, from the Codex texts.

Should the Committee decide to keep the provisions for INS 231 and 232 as food additives, the EUMS consider that their safety needs to be re-evaluated as suggested in CL 2021/61-FA.

24. Polyglycerol Esters of Interesterified Ricinoleic Acid (INS 476)

The EUMS **support** the request.

25. Polyoxyethylene (20) sorbitan monolaurate (INS 432), Polyoxyethylene (20) sorbitan monooleate (INS 433), Polyoxyethylene (20) sorbitan monopalmitate (INS 434), Polyoxyethylene (20) sorbitan monostearate (INS 435), Polyoxyethylene (20) sorbitan tristearate (INS 436) and 31. Sorbitan monostearate (INS 49), Sorbitan tristearate (INS 492), Sorbitan monolaurate (INS 493), Sorbitan monooleate (INS 494), Sorbitan monopalmitate (INS 495)

The EUMS **support** the re-evaluation proposed by JECFA as the JECFA assessments are very old.

29. Rosemary extract (INS 392)

The EUMS support keeping Rosemary extract (INS 392) on the JECFA priority list in order to complete its safety assessment.

34. Sucroglycerides (INS 474), 37. Sucrose esters of fatty acids (INS 473) and 38. Sucrose oligoesters, type I and typeII (INS 473a)

The EUMS **support** that JECFA performs the exposure estimates due to a concern that the ADI could be exceeded.

40. Thaumatin II

In case this request is supported, the EUMS consider that the safety of the new source materials and the production process need to be taken into account in the safety assessment.

The EUMS are of the view **that the request cannot be considered as a re-evaluation of thaumatin and its existing specifications** as there is a significant change in the production method and the starting materials used. Therefore, the product (food additive) needs to be clearly distinguished from thaumatin produced by aqueous extraction of the arils of the fruit of strains of *Thaumatococcus daniellii* (Benth).

41. Titanium dioxide (INS 171/ E 171)

The EUMS **support** the JECFA request to re-evaluate safety of titanium dioxide (INS 171).

As noted by JECFA, titanium dioxide used as a food additive has been recently re-evaluated by EFSA¹, which concluded that E 171 can no longer be considered as safe when used as a food additive. This conclusion has been reached on the basis of all currently available evidence along with all the uncertainties, in particular the fact that a genotoxicity concern could not be ruled out.

On the basis of the EFSA opinion, the use of titanium dioxide as a food additive in foods (E 171) will be banned in the EU. The EU will soon inform its trading partners on the measure to be taken (SPS notification).

TABLE 2 LIST OF SUBSTANCES USED AS PROCESSING AIDS PROPOSED FOR EVALUATION BY JECFA

The EUMS keep supporting its previous submissions indicated in Table 2. The EUMS also **support** their new submission related to chymosin from *Camelus dromedarius* expressed in *Aspergillus niger*.

¹ <https://www.efsa.europa.eu/en/efsajournal/pub/6585>

Alpha-amylase from *Bacillus licheniformis* expressing a modified alpha-amylase gene from *Geobacillus stearothermophilus*

The EUMS keep supporting submissions related to alpha-amylase from a genetically modified strain of *Bacillus licheniformis* submitted in 2015 and 2016 by 2 different data providers. Alpha-amylase from *Bacillus licheniformis* expressing a modified alpha-amylase gene from *Geobacillus stearothermophilus* should be kept in Table 2 for the forthcoming JECFA meeting.

Glutaminase from *Aspergillus niger*

The EUMS take note of the request for the assessment of glutaminase from *Aspergillus niger* listed in Table 2 among substances used as processing aid.

The information provided shows that glutaminase is intended to be used to catalyse hydrolysis of L-glutamine to L-glutamate in the manufacture of glutamic acid-rich yeast extracts and glutamic acid-rich protein hydrolysates to be added to other foods to increase L-glutamate content in order to impart or enhance the flavour profile. The use is intended as an alternative to MSG (monosodium L-glutamate, INS 621)/ glutamates (INS 620-625).

The EUMS observe that glutamates are food additives recognised by Codex Alimentarius for their functional class “flavour enhancer”. The EUMS have some concern that using glutaminase to produce high amounts of L-glutamate (in yeast extracts and protein hydrolysates), which is consequently added to other foods for its “flavour enhancing effect”, may be bypassing the regulatory rules applicable to food additives. The EUMS have therefore some doubts about the regulatory status of this request including about its listing in the Table, which refers to processing aids.