03/09/2018

European Union comments on

Codex Circular Letter CL 2018/26-FA

Request for proposals for change and/or addition to Section 3 of the

Class Name and International Numbering System for Food Additives

(CXG 36-1989)

Mixed Competence
European Union Vote

In accordance with the principles for proposals for changes to section 3 "International Numbering System - INS" the European Union and its Member States (EUMS) kindly request deletion of the following additives from the INS list:

INS 128 Red 2G

INS 201 Sodium sorbate

INS 303 Potassium ascorbate

INS 1411 Distarch glycerol

More details are provided in the Annex.

Annex

1.

Deletion of **INS 128 Red 2G** from CXG 36-1989

The change is requested by the European Union.

Justification for the requested INS change in Section 3: deletion of additive purpose (*Please select only the appropriate option and provide details in the space below)*

x Health risk issues, e.g. JECFA has withdrawn an acceptable daily intake (ADI) based on new toxicological data

x Evidence that the additive is not commercially manufactured or used

□ Evidence that the additive cannot be considered to fall under the definition of a food additive

□ Other justification, what?

Details

The European Food Safety Authority re-evaluated safety of Red 2G (INS 128) in 2007 and concluded that it would be prudent to regard Red 2G as being of safety concern since it is extensively metabolised to aniline which should be considered as a carcinogen for which a genotoxic mechanism cannot be excluded (The EFSA Journal (2007) 515, p. 2 of 28; https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2007.515).

There are no provisions for Red 2G in the GSFA. Safety of Red 2G should have been re-evaluated by JECFA. However, the 50th CCFA agreed to remove Red 2G (INS 128) from the Priority List of Substances for Evaluation by JECFA since no confirmation of data availability had been provided and noted that the specification and the ADI for Red 2G would be withdrawn (REP18/FA, paragraph 130). Based on the lack of the interest to provide the data it can be assumed that the additive is not commercially manufactured or used.

2.

Deletion of **INS 201 Sodium sorbate** from CXG 36-1989

The change is requested by the European Union.

Justification for the requested INS change in Section 3: deletion of additive purpose (*Please select only the appropriate option and provide details in the space below)*

x Health risk issues, e.g. JECFA has withdrawn an acceptable daily intake (ADI) based on new toxicological data

x Evidence that the additive is not commercially manufactured or used

□ Evidence that the additive cannot be considered to fall under the definition of a food additive

□ Other justification, what?

Details

The European Food Safety Authority in 2015 took note of the available positive genotoxicity data on sodium sorbate reported by the Scientific Committee on Food in 1996 (EFSA Journal 2015;13(6):4144; https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2015.4144).

The 50th CCFA agreed to remove Sodium sorbate (INS 201) from the Priority List of Substances for Evaluation by JECFA since no confirmation of data availability had been provided and noted that relevant provisions of Sodium sorbate in both the GSFA and relevant commodity standards would be revoked (REP18/FA, paragraph 132). Based on the lack of the interest to provide the data it can be assumed that the additive is not commercially manufactured or used.

3.

Deletion of **INS 303 Potassium ascorbate** from CXG 36-1989

The change is requested by the European Union.

Justification for the requested INS change in Section 3: deletion of additive purpose (*Please select only the appropriate option and provide details in the space below)*

- □ Health risk issues, e.g. JECFA has withdrawn an acceptable daily intake (ADI) based on new toxicological data
- x Evidence that the additive is not commercially manufactured or used
- □ Evidence that the additive cannot be considered to fall under the definition of a food additive
- □ Other justification, what?

Details

There are no provisions for Potassium ascorbate (INS 303) in the GSFA, no specifications established (see List of Codex Specifications for Food Additives (CAC/MISC 6-2017)), neither Potassium ascorbate is on the JECFA priority list. The EUMS are not aware of any use of this substance as an additive, thus suggest deleting the substance from CXG 36-1989 unless the evidence of its commercial use as an additive is provided.

4.

Deletion of **Distarch glycerol** from CXG 36-1989

The change is requested by the European Union.

Justification for the requested INS change in Section 3: deletion of additive purpose (*Please select only the appropriate option and provide details in the space below)*

- □ Health risk issues, e.g. JECFA has withdrawn an acceptable daily intake (ADI) based on new toxicological data
- x Evidence that the additive is not commercially manufactured or used
- □ Evidence that the additive cannot be considered to fall under the definition of a food additive
- □ Other justification, what?

Details

There are no provisions for Distarch glycerol (INS 1411) in the GSFA, no specifications established (see List of Codex Specifications for Food Additives (CAC/MISC 6-2017)), neither Distarch glycerol is on the JECFA priority list. The EUMS are not aware of any use of this substance as an additive, thus suggest deleting the substance from CXG 36-1989 unless the evidence of its commercial use as an additive is provided.