COMMISSION REGULATION (EU) 2022/1923

of 10 October 2022

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of ascorbic acid (E 300), sodium ascorbate (E 301) and calcium ascorbate (E 302) in tuna

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives ([1]), and in particular Article 10(3) thereof,

Whereas:

(1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in food and their conditions of use.

(2) That list may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008 of the European Parliament and of the Council ([2]), either on the initiative of the Commission or following an application.

(3) Pursuant to Annex II to Regulation (EC) No 1333/2008, ascorbic acid (E 300), sodium ascorbate (E 301) and calcium ascorbate (E 302) ('the food additives') are currently authorised as food additives in, among other categories, category 09.1.1 'unprocessed fish' and category 09.2 'Processed fish and fishery products including molluscs and crustaceans', at *quantum satis*. The Scientific Committee on Food considered their use as antioxidants acceptable. The European Food Safety Authority ('the Authority') in its scientific opinion re-evaluating the safety of the food additives ([3]) confirmed that there is no safety concern for their use as food additives at the reported uses and use levels and that there is no need for a numerical acceptable daily intake. Such a conclusion means that the substance is of a very low safety concern, there is reliable information for exposure and toxicity and there is a low probability of adverse health effects in humans at doses that do not induce nutritional imbalance in animals. Currently, no maximum numerical level is laid down for those food additives and they are to be used in accordance with good manufacturing practice, at a level not higher than what is necessary to achieve the intended purpose and provided the consumer is not misled.

(4) In unprocessed fish, antioxidants are used to slow down discoloration of fish flesh and rancidity development. In unprocessed tuna, consumers link freshness to the naturally red colour of fresh tuna flesh.

(5) Thawed tuna loins marketed as 'fresh' tuna are to be obtained from tuna frozen below – 18 °C after fishing ('fresh tuna'), whereas other thawed tuna loins is to be used only for canning ('tuna for canning'), in accordance with Regulation (EC) No 853/2004 of the European Parliament and of the Council ([4]). The use of the food additives in tuna for canning in high amounts to artificially restore the colour of fresh tuna flesh gives an opportunity to deceptively market that tuna for canning as fresh tuna, selling it at a higher price, misleading the consumers about the product and exposing them to the risk of histamine poisoning.

(6) Such use of the food additives, however, does not comply with the general conditions for inclusion and use of food additives in the Union lists and with the *quantum satis* principle.

([1]) OJ L 354, 31.12.2008, p. 16.

([2]) Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1).

([3]) *EFSA Journal* 2015;13(5):4087, 124 pp.

([4]) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

(7) Following food fraud investigations under Regulation (EU) 2017/625 of the European Parliament and of the Council ([5]), competent authorities regularly report cases where tuna loins sold as fresh are found to contain the food additives in amounts higher than those considered by those competent authorities as necessary to achieve the typical antioxidant effect on fresh tuna. On the basis of this, the competent authorities suspect that the food additives are being used on tuna for canning to restore their colour and place them on the market as fresh.

(8) As it is for the national competent authorities to establish that the *quantum satis* principle has not been complied with and this may be difficult, the Member States, and in particular Spain, have requested the Commission to lay down an appropriate maximum level for the use of the food additives as antioxidants in thawed tuna sold as fresh tuna (unprocessed) or marinated tuna (processed).

(9) In the interest of legal certainty, and to ensure a high level of consumer protection and fair practices in food trade, it is therefore appropriate to set a maximum level of use in tuna of the additives in food categories 09.1.1 and 09.2 in Part E of Annex II to Regulation (EC) No 1333/2008.

(10) The maximum level should allow to maintain the current levels of legitimate use following good manufacturing practices. On the basis of the information provided by the industry to the Authority in view of the re-evaluation of the safety of the food additives, a maximum level of 300 mg/kg is considered appropriate. This level is the highest use level reported by the industry, as listed in the Authority's scientific opinion.

(11) The Commission has been made aware of studies carried out by the fish industry and the opinion of one competent authority which concluded that the use of 900 mg/kg of the food additives is necessary to control oxidation in tuna loins maintained below 4 °C for 10 days. However, in light of the information available, and in particular of the fact that official controls carried out by some other competent authorities showed that a shelf-life of 10 days may be achieved for thawed tuna with a treatment at 300 mg/kg without it changing the initial colour, the level of 300 mg/kg appears to be sufficient to achieve the desired antioxidant effect.

(12) Setting a maximum level for the use of ascorbic acid (E 300), sodium ascorbate (E 301) and calcium ascorbate (E 302) as antioxidants in tuna is not liable to have an effect on human health. Therefore, under Article 3(2), second subparagraph, of Regulation (EC) No 1331/2008, it is not necessary to seek the opinion of the Authority.

(13) Annex II to Regulation (EC) No 1333/2008 should therefore be amended accordingly.

(14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 1333/2008 is amended in accordance with the Annex to this Regulation.

([5]) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (OJ L 95, 7.4.2017, p. 1).

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10 October 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Part E of Annex II to Regulation (EC) No 1333/2008 is amended as follows:

(i) in food category 09.1.1 'Unprocessed fish', the following entries are inserted between the entry for E 302 Calcium ascorbate and the entry for E 315 Erythorbic acid:

	'E 300	Ascorbic acid	300 mg/kg	(96)	only tuna
	E 301	Sodium ascorbate	300 mg/kg	(96)	only tuna
	E 302	Calcium ascorbate	300 mg/kg	(96)	only tuna

(96): E 300, E 301 and E 302 are authorised singly or in combination, the maximum limit applies to the sum expressed as ascorbic acid';

(ii) in food category 09.2 'Processed fish and fishery products including molluscs and crustaceans', the following entries are inserted between the entry for E 251–252 Nitrates and E 315 Erythorbic acid:

	'E 300	Ascorbic acid	300 mg/kg	(96)	only tuna
	E 301	Sodium ascorbate	300 mg/kg	(96)	only tuna
	E 302	Calcium ascorbate	300 mg/kg	(96)	only tuna

(96): E 300, E 301 and E 302 are authorised singly or in combination, the maximum limit applies to the sum expressed as ascorbic acid'.