Commission Regulation (EU) 2018/1497 of 8 October 2018 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards food category 17 and the use of food additives in food supplements (Text with EEA relevance)

COMMISSION REGULATION (EU) 2018/1497

of 8 October 2018

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards food category 17 and the use of food additives in food supplements

(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,

Having regard to 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[(2)], and in particular Article 7(5) 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) Only food additives included in the Union list in Annex II to Regulation (EC) No 1333/2008 may be placed on the market as such and used in foods under the conditions of use specified therein.

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

(4) The Union list includes food additives which are listed on the basis of the categories of food to which they may be added. In Part D of that list, food category 17 covers food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council[(3)] excluding food supplements for infants and young children. Food category 17 includes three subcategories: 17.1 ‘Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms’, 17.2 ‘Food supplements supplied in a liquid form’ and 17.3 ‘Food supplements supplied in a syrup-type or chewable form’. Part E of the Union list sets out the authorised additives for each of these subcategories and their conditions of use.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2018/1497. (See end of Document for details)*

(5) It followed from the discussions with Member States (at the Working Party of Governmental Experts on Additives) that there are difficulties with the implementation of Annex II to Regulation (EC) No 1333/2008 on food additives, in particular for food subcategory 17.3 'Food supplements supplied in a syrup-type or chewable form'. This classification has led to misinterpretation and in order to avoid it, syrup- and chewable-forms should be categorised as liquid and solid forms, respectively.

(6) Therefore, it is appropriate to delete food subcategory 17.3 and to reword the titles of food subcategories 17.1 and 17.2 to 'Food supplements supplied in a solid form, excluding food supplements for infants and young children' and 'Food supplements supplied in a liquid form, excluding food supplements for infants and young children' respectively. This will better reflect which products are covered by/included in each of the food subcategories. As a result of the deletion of food subcategory 17.3 food additives' entries which were included in that food subcategory should be transferred to either food subcategory 17.1 or 17.2 to ensure that there is transparency and legal certainty regarding the use of food additives in those foods. For clarity and enforcement purposes also the title of food category 17 should be amended to 'Food supplements as defined in Directive 2002/46/EC'.

(7) It also followed from the discussions with Member States that it should be clarified whether a maximum (use) level for the food additives in food category 17 applies to the food as marketed or to the food ready for consumption. Therefore, an introduction section should be included referring to certain food additives authorised in that food category. This is in line with the previous entries of those food additives within the Directives of the European Parliament and of the Council 94/35/EC[(4)], 94/36/EC[(5)] and 95/2/EC[(6)].

(8) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission has to seek the opinion of the European Food Safety Authority ('the Authority') in order to update the Union list of food additives set out in Annex II to Regulation (EC) No 1333/2008, except where such update is not liable to have an effect on human health. Since the Union list is amended to provide clarification to the current authorised uses of additives, it constitutes an update of that list which is not liable to have an effect on human health. Therefore, it is not necessary to seek the opinion of the Authority.

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

(10) 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.

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, 8 October 2018.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2018/1497. (See end of Document for details)*

ANNEX

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

(1) in Part D, the entries for food category 17. 'Food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council excluding food supplements for infants and young children' are replaced by the following:

17.	**Food supplements as defined in Directive 2002/46/EC**
17.1	Food supplements supplied in a solid form, excluding food supplements for infants and young children
17.2	Food supplements supplied in a liquid form, excluding food supplements for infants and young children

(2) Part E is amended as follows:

(a) the entry for food category 17. 'Food supplements as defined in Directive 2002/46/EC excluding food supplements for infants and young children' is replaced as follows:

17.	**Food supplements as defined in Directive 2002/46/EC**
	INTRODUCTION PART, APPLIES TO ALL SUBCATEGORIES
	The maximum levels of use indicated for colours, polyols, sweeteners, and E 200-213, E 338-452, E 405, E 416, E 426, E 432-436, E 459, E 468, E 473-475, E 491-495, E 551-553, E 901-904, E 961, E 1201-1204, E 1505 and E 1521 refer to the food supplements ready for consumption prepared following the instructions of use provided by the manufacturer. The dilution factor for those food supplements that have to be diluted or dissolved has to be communicated together with the instructions of use.

(b) the entry for food subcategory 17.1 is amended as follows:

(i) the title is replaced by the following:

17.1	Food supplements supplied in a solid form, excluding food

					supplements for infants and young children

(ii) all the entries therein are replaced by the following entries, inserted in their numerical order:

	Group I	Additives			E 410, E 412, E 415, E 417 and E 425 may not be used to produce dehydrated food supplements intended to rehydrate on ingestion
	Group II	Colours at *quantum satis*	*quantum satis*		Period of application: until 31 July 2014
	Group II	Colours at *quantum satis*	*quantum satis*	(69)	Period of application: from 1 August 2014
	Group III	Colours with combined maximum limit	300		Period of application: until 31 July 2014
	Group III	Colours with combined maximum limit	300	(69)	Period of application: from 1 August 2014
	Group IV	Polyols	*quantum satis*		
	E 104	Quinoline Yellow	35	(61)	Period of application: from 1