Commission Regulation (EU) No 1130/2011 of 11 November 2011 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients (Text with EEA relevance)

COMMISSION REGULATION (EU) No 1130/2011

of 11 November 2011

amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients

(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 Articles 10 and 30(2), (3) and (5) thereof,

Whereas:

(1) Annex III to Regulation (EC) No 1333/2008 provides for the establishment of Union lists of approved food additives and their conditions of use in food additives (Parts 1 and 2), in food enzymes (Part 3), in food flavourings (Part 4) and in nutrients or categories thereof (Part 5), to which the food additives may be added according to Article 4(4) of that Regulation. The aim of the use of those food additives is to have a technological function in food additives or enzymes or flavourings or nutrients.

(2) Food additives included in Annex III to Regulation (EC) No 1333/2008 may be assigned one of the functional classes laid down in Annex I on the basis of the principal technological function of the food additive. However, according to Article 9 of that Regulation, allocating a food additive to a functional class should not preclude it from being used for several functions.

(3) Food additives authorised having a function as carriers for use in food additives in European Parliament and Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners[(2)] and their conditions of use should be included in Part 1 of Annex III to Regulation (EC) No 1333/2008 as their compliance with general conditions for inclusion and use of food additives in Union lists and particularly with Article 6(1)(a) of that Regulation has been reviewed.

(4) Food additives listed as permitted carriers and carrier solvents in Directive 95/2/EC and having a function as a food additive other than carrier, should be included in Part 2 of

Annex III to Regulation (EC) No 1333/2008 with the same conditions of use. Other food additives having a function other than carriers should also be included in this list.

(5) Food additives and carriers authorised for use in food enzymes as referred to in Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on enzymes[3] and their conditions of use should be included in Part 3 of Annex III to Regulation (EC) No 1333/2008.

(6) Food additives authorised for use in food flavourings in Directive 95/2/EC and their conditions of use should be included in Part 4 of Annex III to Regulation (EC) No 1333/2008, as their compliance with Article 6 of that Regulation has been reviewed.

(7) Food additives and carriers authorised for use in nutrients defined by Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods[4] as well as by Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements[5], Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses[6], and Commission Regulation (EC) No 953/2009 of 13 October 2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses[7], and their conditions of use should be included in Part 5 Section A of Annex III to Regulation (EC) No 1333/2008. Other food additives having a function other than carriers should also be included in that list, because of a technological need, which was not foreseen at the time of the adoption of Regulation (EC) No 1333/2008.

(8) Food additives listed as food additives permitted in foods for infants and young children by Directive 95/2/EC and having a function as a food additive in nutrients should be included with the same conditions of use in the list set out in Part 5 Section B of Annex III to Regulation (EC) No 1333/2008. That list should be completed by taking into account the opinion of Scientific Committee on Food on additives in nutrient preparations for use in infant formulae, follow-on formulae and weaning food of 13 June 1997[8].

(9) For the reasons of transparency and consistency specific rules for conditions of use of food additives in food additive/enzyme/nutrient preparation should be laid down.

(10) Substances like sulphites, benzoates, polysorbates, sorbitan esters and sucrose esters should be listed in Annex III to Regulation (EC) No 1333/2008; those substances are subject to tier 3 screening according to Commission Report of 2001 on Dietary Food Additive Intake in the European Union[9] and are raising concerns with respect to the ADI value. The conditions of use of those substances may be revised as a follow-up of the expected opinion of the European Food Safety Authority in the framework of the re-evaluation programme as established by Commission Regulation (EU) No 257/2010[10] setting up a programme for the re-evaluation of approved additives, which includes among others an intake assessment.

(11) The specifications of food additives listed in Annex III to Regulation (EC) No 1333/2008 relating to origin, purity criteria and any other necessary information

are set out in Commission Directives 2008/128/EC of 22 December 2008 laying down specific purity criteria concerning colours for use in foodstuffs[(11)], 2008/60/EC of 17 June 2008 laying down specific purity criteria concerning sweeteners for use in foodstuffs[(12)] and 2008/84/EC of 27 August 2008 laying down specific purity criteria on food additives other than colours and sweeteners[(13)].

(12) Due to the fact that some of preparations have been used since decades, a transitional period of 24 months following the entry into force of this Regulation should be provided to enable the food business operators to adapt to the requirements laid down in Parts 2, 3 and 5 Section A of Annex III to Regulation (EC) No 1333/2008 as amended by this Regulation. A transitional period of 18 months following the entry into force of this Regulation should be provided to enable the food business operators to adapt to the requirements laid down in Parts 1 and 4 of the Annex III as amended by this Regulation.

(13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

Amendment to Regulation (EC) No 1333/2008

Annex III to Regulation (EC) No 1333/2008 is replaced by the text of the Annex to this Regulation.

Article 2

Transitional measures

Preparations not complying with Parts 2, 3 and/or Section A of Part 5 of Annex III to Regulation (EC) No 1333/2008, as amended by this Regulation, may continue to be placed on the market in accordance with national provisions during a period of 24 months from the date of entry into force of this Regulation. Foods containing such preparations that have been lawfully placed on the market within that period may be marketed until stocks are exhausted.

Preparations not complying with Parts 1 and 4 of Annex III to Regulation (EC) No 1333/2008, as amended by this Regulation, may continue to be placed on the market in accordance with the provisions of Annexes I to VI to Directive 95/2/EC until 31 May 2013. Foods containing such preparations that have been lawfully placed on the market within that period may be marketed until stocks are exhausted.

Article 3

Entry into force

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 1130/2011. (See end of Document for details)

It shall apply from 2 December 2011.

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

Done at Brussels, 11 November 2011.

For the Commission

The President

José Manuel BARROSO

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) No 1130/2011. (See end of Document for details)*

ANNEX

ANNEX III

Union list of food additives including carriers approved for use in food additives, food enzymes, food flavourings, nutrients and their conditions of use

Definitions

1. "nutrients" for the purposes of this Annex means vitamins, minerals and other substances added for nutritional purposes, as well as substances added for physiological purposes as covered by Regulation (EC) No 1925/2006, Directive 2002/46/EC, Directive 2009/39/EC and Regulation (EC) No 953/2009.

2. "preparation" for the purposes of this Annex means a formulation consisting of one or more food additives, food enzymes and/or nutrients in which substances such as food additives and/or other food ingredients are incorporated to facilitate their storage, sale, standardisation, dilution or dissolution.

PART 1

CARRIERS IN FOOD ADDITIVES

E number of the carrier	**Name of the carrier**	**Maximum level**	**Food additives to which the carrier may be added**
E 1520	Propane-1, 2-diol (propylene glycol)	1 000 mg/kg in final food (as carry-over)[a]	Colours, emulsifiers and antioxidants
E 422	Glycerol	*quantum satis*	All food additives
E 420	Sorbitol		
E 421	Mannitol		
E 953	Isomalt		
E 965	Maltitol		
E 966	Lactitol		
E 967	Xylitol		
E 968	Erythritol		
E 400 – E 404	Alginic acid – alginates (Table 7 of Part 6)		
E 405	Propane-1, 2-diol alginate		
E 406	Agar		

a Maximum level from all sources in foodstuffs 3 000 mg/kg (individually or in combination with E 1505, E 1517 and E 1518). In the case of beverages, with the exception of cream liqueurs, the maximum level of E 1520 shall be 1 000 mg/l from all sources.