Commission Implementing Regulation (EU) No 793/2012 of 5 September 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 793/2012

of 5 September 2012

adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC

(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 2232/96 of the European Parliament and of the Council of 28 October 1996 laying down a Community procedure for flavouring substances used or intended for use in or on foodstuffs[(1)] and in particular Articles 3(2), 4(1) and 5 thereof,

Having regard to Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC[(2)] and in particular Article 25(1) thereof,

Whereas:

(1) Regulation (EC) No 2232/96 provides for a Community procedure for evaluation and authorisation of flavouring substances. The Member States notified to the Commission the list of flavouring substances which may be used in or on foods marketed on their territory.

(2) Regulation (EC) No 2232/96 provides for a list of flavouring substances that are authorised to the exclusion of all others. That list is to be established on the basis of a register containing the flavouring substances notified by the Member States and on the basis of a specific evaluation programme.

(3) The notified substances were entered in a register laid down by Commission Decision 1999/217/EC of 23 February 1999 adopting a register of flavouring substances used in or on foodstuffs drawn up in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council of 28 October 1996[(3)].

(4) Commission Regulation (EC) No 1565/2000[4] has laid down the measures necessary for the adoption of an evaluation programme in application of Regulation (EC) No 2232/96. Pursuant to Article 5(2) of Regulation (EC) No 2232/96, flavouring substances not included in the register have also been included in the evaluation programme.

(5) The European Food Safety Authority (hereinafter referred to as 'the Authority') evaluated a number of flavouring substances[5] through a stepwise approach that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. Those flavouring substances which do not give rise to safety concerns at their levels of dietary intakes should be included in the list referred to in Regulation (EC) No 2232/96.

(6) Pursuant to Article 2(1) of Regulation (EC) No 1565/2000 substances that are contained in the register and have already been classified by the Scientific Committee on Food (hereinafter referred to as 'the SCF') in Category 1[6] or by the Council of Europe in Category A[7] or by Joint FAO/WHO Expert Committee on Food Additives (hereinafter referred to as 'JECFA'), so as to present no safety concern, as laid down in the reports of its 46th, 49th, 51st and 53rd meeting[8] need not be re-evaluated within the evaluation programme. These substances should be included in the list referred to in Regulation (EC) No 2232/96.

(7) Pursuant to Article 2(2) of Regulation (EC) No 1565/2000, substances contained in the register and classified by JECFA, since 2000, so as to present no safety concern on the basis of the default approach for estimation of intake, have to be considered by the Authority. Those substances, for which the Authority agreed with the JECFA conclusion, should be included in the list referred to in Regulation (EC) No 2232/96.

(8) Flavouring substances may be used in or on foods in accordance with the good manufacturing practices or, if necessary, with specific conditions. The list referred to in Regulation (EC) No 2232/96 should contain information on the unique identification number of the substance (FL No), the name of the substance (Chemical name), the Chemical Abstracts Service registry number, the JECFA number, the Council of Europe number, the purity, the specific conditions of use and reference to the scientific body that has carried or is carrying out the evaluation.

(9) For the purpose of this Regulation, the food categories as laid down in Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives[9], should be referred to. When necessary, interpretation decisions can be adopted in accordance with Article 13(c) of Regulation (EC) No 1334/2008 in order to clarify whether or not a particular food belongs to a certain category of food.

(10) Flavouring substances which did not receive a favourable assessment on their safety have been listed in Part A of Annex III to Regulation (EC) No 1334/2008 concerning substances which shall not be added as such to food or have been deleted from the register by Commission Decisions 2005/389/EC[10], 2006/252/EC[11] and 2008/478/EC[12].

(11) Flavouring substances for which the requested information has not been provided and which, therefore, have not been evaluated by the Authority in accordance with Article 3(5) of Regulation (EC) No 1565/2000, should not be included in the list referred to in Regulation (EC) No 2232/96.

(12) Flavouring substances for which the persons responsible for placing them on the market have withdrawn the application should not be included in the list referred to in Regulation (EC) No 2232/96.

(13) For a number of substances, the Authority has not completed the evaluation or it has requested additional scientific data to be provided for completion of the evaluation. In accordance with the objectives of Regulation (EC) No 2232/96 and Regulation (EC) No 1334/2008 and in order to enhance legal certainty it is appropriate to include those substances in the list referred to in Regulation (EC) No 2232/96 to allow those substances which are currently placed on the market, to continue to be used in or on foods until risk assessment and authorisation procedures have been concluded.

(14) To manage the submissions of additional scientific data requested by the Authority, time limits should be set for the persons responsible for placing flavouring substances on the market so as to comply with the Authority's requests as expressed in the published opinions. Therefore, footnotes 2 to 4 have been assigned for those substances for which the Authority has requested additional scientific data in the list referred to in Regulation (EC) No 2232/96. A time limit should be set for the Authority to evaluate the submitted data. Where the necessary information is not provided by the time requested the flavouring substance in question may not be evaluated in accordance with Article 3(5) of Regulation (EC) No 1565/2000 and therefore will be withdrawn from the Union list in accordance with the procedure laid down in Article 7 of Regulation (EC) No 1331/2008 of the European Parliament and of the Council[(13)].

(15) Flavouring substances for which the Authority has not yet completed the evaluation and no request for additional information is pending, should be identified as such by footnote 1 in the list referred to in Regulation (EC) No 2232/96.

(16) If the authorised flavouring substance is a racemate (an equal mixture of optical isomers), both the R- and S- form should also be authorised for use. If only the R-form is authorised then the S-form should not be covered by that authorisation and vice versa.

(17) Several D- and D,L-amino acids have been evaluated as safe by the Authority for use as flavouring substances, provided that the substances are in an unchanged form when they are consumed. Therefore, the amino acids should be included in the list referred to in Regulation (EC) No 2232/96 concerning their use as flavouring substances only.

(18) The list referred to in Regulation (EC) No 2232/96 is intended only to regulate the use of flavouring substances which are added to food in order to impart or modify odour and/or taste. Certain substances on the list may be also added to food for other purposes than flavouring and such uses remain subject to other rules. For some substances it is necessary to lay down a use level which refers to their use as a flavouring substance. These substances are caffeine (FL 16.016), theobromine (FL 16.032), neohesperidin dihydrocalcone (FL 16.061) and rebaudioside A (FL 16.113). For ammonium chloride

(FL 16.048) national provisions are already in place. Therefore, for ensuring the functioning of the internal market the use levels should be harmonised.

(19) The Authority has recommended in its opinion adopted on 22 May 2008[(14)], that for d-camphor (FL 07.215), a maximum use level should be set to ensure that exposure to d-camphor does not exceed 2 mg/kg body weight on a single day in any age group. Therefore, specific conditions of use should be set for d-camphor.

(20) The SCF concluded in its opinion adopted on 19 February 1988[(15)], that it saw no objection from a toxicological point of view to the continued use at present levels (up to max 100 mg/l) of quinine in bitter drinks. The Authority does not contest this evaluation but recommends that the toxicological database on quinine should be reconsidered[(16)]. Pending the re-evaluation of quinine, the use of three quinine salts (FL 14.011, FL 14.152 and FL 14.155) should be restricted to non-alcoholic and alcoholic drinks.

(21) The Authority considered glycyrrhizic acid and its ammoniated form in the opinion adopted 22 May 2008[(17)]. The Authority agreed with the evaluation by the SCF[(18)], which considered that the intake up to 100 mg/person/day would not give rise to safety concerns. Therefore, specific conditions of use should be set for glycyrrhizic acid (FL 16.012) and its ammoniated form (FL 16.060) as flavouring substances.

(22) Regulation (EC) No 1334/2008 repeals Regulation (EC) No 2232/96 from the date of application of the list referred to in Article 2(2) of that Regulation. It is therefore appropriate, for reasons of legal certainty, to fix the date of application of that list. The principle of mutual recognition laid down in Regulation (EC) No 2232/96 should however continue to apply to flavouring substances included in the Annex to this Regulation for which footnotes 1 to 4 have been assigned. Regulation (EC) No 2232/96 will cease to apply and will become obsolete once the risk assessment and authorisation procedures for those flavouring substances have been concluded.

(23) The evaluation programme provided for by Regulation (EC) No 1565/2000 was intended for the establishment of the list referred to in Article 2(2) of Regulation (EC) No 2232/96. With the establishment of that list Regulation (EC) No 1565/2000 becomes obsolete and should be repealed. It should however continue to apply to flavouring substances included in the Annex to this Regulation for which footnotes 1 to 4 have been assigned. Regulation (EC) No 1565/2000 will cease to apply and will become obsolete once the risk assessment and authorisation procedures for those flavouring substances have been concluded.

(24) The register of flavouring substances used in or on foods adopted by Decision 1999/217/EC has become obsolete with the establishment of the list referred to in Article 2(2) of Regulation (EC) No 2232/96 and should be repealed.

(25) Regulation (EC) No 1334/2008 provides that the Union list of flavourings and source materials shall be established by introducing the list of flavouring substances referred to in Article 2(2) of Regulation (EC) No 2232/96 into Annex I to Regulation (EC) No 1334/2008 at the time of its adoption. The list of flavouring substances referred to in Article 2(2) of Regulation (EC) No 2232/96 should be introduced into Annex I to Regulation (EC) No 1334/2008 accordingly.

(26) The Union list of flavourings and source materials is to apply without prejudice to other provisions laid down in sector specific legislation.

(27) The use of flavourings and source materials in infant formulae, follow-on formulae, processed cereal-based foods and baby foods and dietary foods for special medical purposes intended for infants and young children as referred to in Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses[19] will be harmonised in the future in the framework of specific rules to be adopted on the composition of foodstuffs intended for infants and young children. Meanwhile, the Member States should be able to apply national provisions in this matter stricter than the ones provided for in the list of flavouring substances referred to in Article 2(2) of Regulation (EC) No 2232/96.

(28) Pursuant to Regulation (EC) No 1334/2008 flavouring substances not included in the Union list may be placed on the market as such and used in or on food until 18 months after the date of application of the Union list. Since flavouring substances are already on the market in the Member States, provisions have been made to ensure that the transition to a Union authorisation procedure is smooth. To this effect transitional periods have been laid down for food containing those flavouring substances in Commission Regulation (EU) No 794/2012[20].

(29) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Definitions

For the purposes of this Regulation the following definitions shall apply:

(a) 'Union list' means the list of flavourings and source materials set out in Annex I to Regulation (EC) No 1334/2008.

(b) 'Evaluated flavouring substances' means substances for which the evaluation and approval have been completed at Union level. Those substances are assigned no footnotes in Part A of the Union list of flavourings and source materials.

(c) 'Flavouring substances under evaluation' means substances for which the risk assessment at Union level has not been completed at the time of entry into force of this Regulation. Those substances are assigned footnotes 1 to 4 in Part A of the Union list of flavourings and source materials.

Article 2

Adoption of the list of flavouring substances referred to in Regulation (EC) No 2232/96

The list of flavouring substances referred to in Article 2(2) of Regulation (EC) No 2232/96 is hereby adopted as set out in Part A of the Annex to this Regulation.