Commission Implementing Regulation (EU) No 1321/2013 of 10 December 2013 establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 1321/2013

of 10 December 2013

establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings

(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 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended to be used in or on foods[(1)], and in particular Article 6 thereof,

Whereas:

(1) Article 10(2) of Regulation (EC) No 2065/2003 provides for the initial establishment of a Union list of authorised smoke flavouring primary products (hereinafter referred to as 'primary products'). That list is to be established on the basis of applications for authorisation submitted by business operators and the opinion issued by the European Food Safety Authority ('the Authority') on the relevant primary product.

(2) In accordance with Article 10 of Regulation (EC) No 2065/2003, the Authority received 14 valid applications for authorisation of primary products before 16 June 2005. Three applications have been withdrawn. Therefore the Authority has evaluated in total 11 primary products. One evaluated application has been withdrawn after completion of the evaluation.

(3) According to Article 4(1) of Regulation (EC) No 2065/2003 the authorisation of smoke flavourings may be subject to specific conditions of use and according to Article 9(3) of that Regulation authorisations should be granted for 10 years, renewable in accordance with Article 12 of that Regulation.

(4) Primary products and derived smoke flavourings are used in or on food to impart a smoke taste or to complement another flavour without imparting smoke flavour. They are also used to smoke meat, fish and dairy products. The refined exposure study carried out by Rijksinstituut voor Volksgezondheid en Milieu (RIVM)[(2)] shows that regardless of the exposure calculation method used, the main contributors to the high intake are predominantly foods that used to be traditionally smoked, such as cooked smoked sausage and bacon. The food groups that are not traditionally smoked, such as crisps, soups and sauces, do not significantly affect exposure. Because primary products are

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produced from smoke which is subjected to fractionation and purification processes, the use of smoke flavourings is generally considered to be of less health concern than the use of smoke that is made by burning wood or by heating saw dust or small wood chips[3].

(5) The safety assessment of the Authority on the primary product Scansmoke PB1110, adopted on 26 March 2009[4], concludes that the data provided by the applicant is sufficient to eliminate the concerns over its genotoxicity. However the uses and use levels as originally proposed by the applicant would provide an insufficient margin of safety. The uses and the use levels have been revised to take into account this opinion. The primary product Scansmoke PB1110 should therefore be authorised subject to specific conditions of use.

(6) The safety assessment of the Authority on the primary product Zesti Smoke Code 10, adopted on 29 January 2009[5] and on 6 July 2011[6], concludes that the data provided by the applicant is sufficient to eliminate the concerns over its genotoxicity. However, the uses and use levels as originally proposed by the applicant provide an insufficient margin of safety. The uses and the use levels have been revised to take into account this opinion. The primary product Zesti Smoke Code 10 should therefore be authorised subject to specific conditions of use.

(7) The safety assessment of the Authority on the primary product Smoke Concentrate 809045, adopted on 29 January 2009[7], concludes that the data provided by the applicant is sufficient to eliminate the concerns over its genotoxicity. The uses and use levels as proposed by the applicant do not give rise to safety concern. The primary product Smoke Concentrate 809045 should therefore be authorised subject to specific conditions of use.

(8) The safety assessment of the Authority on the primary product Scansmoke SEF 7525, adopted on 14 May 2009[8], concludes that the data provided by the applicant is sufficient to eliminate the concerns over its genotoxicity. The uses and use levels as proposed by the applicant do not give rise to safety concern. The primary product Scansmoke SEF 7525 should therefore be authorised subject to specific conditions of use.

(9) The safety assessment of the Authority on the primary product SmokEz C-10, adopted on 14 May 2009[9] and on 4 July 2012[10], concludes that the data provided by the applicant is sufficient to eliminate the concerns over its genotoxicity. However, the uses and use levels as originally proposed by the applicant provide an insufficient margin of safety. The uses and the use levels have been revised to take into account this opinion. The primary product SmokEz C-10 should therefore be authorised subject to specific conditions of use.

(10) The safety assessment of the Authority on the primary product SmokEz Enviro-23, adopted on 14 May 2009[11] and on 4 July 2012[12], concludes that the data provided by the applicant is sufficient to eliminate the concerns over its genotoxicity. However, the uses and use levels as originally proposed by the applicant provide an insufficient margin of safety. The uses and the use levels have been revised to take into account this opinion. The primary product SmokEz Enviro-23 should therefore be authorised subject to specific conditions of use.

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(11) The safety assessment of the Authority on the primary product Tradismoke™ A MAX, adopted on 26 November 2009[13], concludes that the data provided by the applicant is sufficient to eliminate the concerns over its genotoxicity. However, the uses and use levels as originally proposed by the applicant provide an insufficient margin of safety. The uses and the use levels have been revised to take into account this opinion. The primary product Tradismoke™ A MAX should therefore be authorised subject to specific conditions of use.

(12) The safety assessment of the Authority on the primary product Scansmoke R909, adopted on 26 November 2009[14], concludes that the data provided by the applicant is sufficient to eliminate the concerns over its genotoxicity. However, the uses and use levels as originally proposed by the applicant provide an insufficient margin of safety. The uses and the use levels have been revised to take into account this opinion. The applicant notified to the Commission on 26 November 2012 that the name of the primary product had been changed to proFagus-Smoke R709. The primary product proFagus-Smoke R709 should therefore be authorised subject to specific conditions of use.

(13) The safety assessment of the Authority on the primary product Fumokomp, adopted on 24 September 2009[15] and on 6 July 2011[16], concludes that the data provided by the applicant is sufficient to eliminate the concerns over its genotoxicity. The uses and use levels as proposed by the applicant do not give rise to safety concern. The primary product Fumokomp should therefore be authorised subject to specific conditions of use.

(14) The safety assessment of the Authority on the primary product AM 01, adopted on 26 November 2009[17] and on 2 February 2012[18], concludes that the data provided by the applicant is sufficient to eliminate the concerns over its genotoxicity. However, the uses and use levels as originally proposed by the applicant provide an insufficient margin of safety. The uses and the use levels have been revised to take into account this opinion. The primary product AM 01 should therefore be authorised subject to specific conditions of use.

(15) In respect of each authorised primary product, the Union list should provide a unique product code, the name of the product, the name and address of the authorisation holder, a description and characterisation of the product, the conditions of its use in or on specific foods or food categories, the date from which the product is authorised and the date until which the product is authorised. 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[19], should be referred to.

(16) Conditions for the production of primary products are laid down in Annex I of the Regulation (EC) No 2065/2003 including maximum content of polycyclic aromatic hydrocarbons.

(17) When authorised smoke flavourings are used in or on food, their use must be in accordance with the conditions of use, including maximum levels, set in the Annex to this Regulation. When authorised smoke flavourings are used in combination, the individual levels should be reduced proportionally.

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(18) Smoking by regenerated smoke is a process of treating food by exposing it to smoke which is regenerated by atomizing smoke flavourings in a smoking chamber under the time and temperature conditions similar to those for hot or cold smoking. In that case it is difficult to estimate how much of the smoke flavourings will be present in the final food as marketed due to loss of smoke flavouring during smoking. Therefore, the use should be in accordance with good manufacturing practices.

(19) Unless subject to further restrictions, an authorised smoke flavouring may be present in food, other than by direct addition, as a result of carry-over from an ingredient in which the smoke flavouring was permitted, provided that the level of the smoke flavouring in the final food is no greater than would be introduced by the use of the ingredient under proper technological conditions and good manufacturing practice.

(20) The Union list of smoke flavourings should apply without prejudice to other provisions laid down in sector specific legislation.

(21) Since smoke flavourings 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 in Article 20 of Regulation (EC) No 2065/2003.

(22) Pursuant to Article 12 of Regulation (EC) No 2065/2003, authorisations are renewable for 10-year periods on application to the Commission by the authorisation holder. The application must be accompanied by the documents listed in Article 12(2) of that Regulation. Those documents must include any available information concerning toxicological data following the advice of Authority given in its guidance document of 7 October 2004 or its latest update.

(23) 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

The list of the smoke flavouring primary products authorised to the exclusion of all others in the Union for use in or on foods and/or for the production of derived smoke flavourings, as referred to in Article 6 of Regulation (EC) No 2065/2003, is laid down in 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*.

The list of the authorised smoke flavourings is established with the effect from 1 January 2014.

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

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Done at Brussels, 10 December 2013.

For the Commission

The President

José Manuel BARROSO