



Brussels, **XXX**  
SANTE/10069/2018  
(POOL/E1/2018/10069/10069-EN.doc)  
[...] (2018) **XXX** draft

**COMMISSION REGULATION (EU) .../...**

**of XXX**

**providing derogations from Article 1(3) of Regulation (EC) No 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on food for the use of certain generic descriptors**

(Text with EEA relevance)

## COMMISSION REGULATION (EU) .../...

of **XXX**

### **providing derogations from Article 1(3) of Regulation (EC) No 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on food for the use of certain generic descriptors**

(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 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods<sup>1</sup>, and in particular Article 1(4) thereof,

Whereas:

- (1) Pursuant to Regulation (EC) No 1924/2006, any claim made on food which states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health is to be considered as a health claim and therefore must comply with that Regulation.
- (2) Article 1(4) of Regulation (EC) No 1924/2006 provides for a possible derogation from the rules applicable pursuant to Article 1(3) of that Regulation for generic descriptors (denominations) which have traditionally been used to indicate a particularity of a class of foods or beverages which could imply an effect on human health.
- (3) Applications for a term to be used as generic descriptor may be submitted by food business operators to the national competent authority of a recipient Member State.
- (4) Pursuant to Commission Regulation (EU) No 907/2013 setting the rules for applications concerning the use of generic descriptors (denominations)<sup>2</sup>, a valid application should be transmitted to the Commission and to all Member States; Member States concerned by the application shall provide the Commission with their opinions thereon.
- (5) Following receipt of a valid application and the opinions of Member States concerned the Commission may initiate the procedure of approval of the generic descriptor pursuant to Article 1(4) of Regulation (EC) No 1924/2006.
- (6) On 13 April 2015, the Austrian competent authority provided the Commission with an application from the Austrian Food Industries' Association, submitted pursuant to Article 1(4) of Regulation (EC) No 1924/2006, for the terms 'Hustenbonbon' and 'Hustenstopper' to be used as generic descriptors in Austria.

---

<sup>1</sup> OJ L 404, 30.12.2006, p. 9.

<sup>2</sup> Commission Regulation (EU) No 907/2013 of 20 September 2013 setting up the rules for applications concerning the use of generic descriptors (denominations), (OJ L 251, 21.9.2013, p. 7).

- (7) On 13 April 2015, the Austrian competent authority provided the Commission with an application from Drapal GmbH, submitted pursuant to Article 1(4) of Regulation (EC) No 1924/2006, for the term 'Hustenzuckerl' to be used as generic descriptor in Austria.
- (8) On 19 May 2015, the German competent authority provided the Commission with an application from the Association of the German Confectionery Industry, submitted pursuant to Article 1(4) of Regulation (EC) No 1924/2006, for the term 'Brust-Caramellen' to be used as generic descriptors in Germany and in Austria.
- (9) On 29 May 2015, the German competent authority provided the Commission with an application from SOLDAN Holding + Bonbonspezialitäten GmbH and from the Association of the German Confectionery Industry, submitted pursuant to Article 1(4) of Regulation (EC) No 1924/2006, for the term 'Hustenmischung' to be used as generic descriptor in Germany.
- (10) On 8 June 2015, the German competent authority provided the Commission with an application from SOLDAN Holding + Bonbonspezialitäten GmbH, submitted pursuant to Article 1(4) of Regulation (EC) No 1924/2006, for the term 'Hustenperle' to be used as generic descriptor in Germany.
- (11) On 18 June 2015, the German competent authority provided the Commission with two applications from SOLDAN Holding + Bonbonspezialitäten GmbH and the Association of the German Confectionery Industry, submitted pursuant to Article 1(4) of Regulation (EC) No 1924/2006, for the terms 'Halsbonbon' and 'Keelpastille' to be used as generic descriptors in Germany ('Halsbonbon') and in the Netherlands ('Keelpastille').
- (12) On 18 November 2015, the German competent authority provided the Commission with three applications from SOLDAN Holding + Bonbonspezialitäten GmbH, Josef Mack GmbH & Co. KG and the Association of the German Confectionery Industry, submitted pursuant to Article 1(4) of Regulation (EC) No 1924/2006, for the terms 'Hustenbonbon', 'Hoestbonbon', 'rebucados para a tosse', and 'cough drops', to be used as generic descriptors in Germany and in Austria ('Hustenbonbon'), in the Netherlands ('Hoestbonbon'), in Portugal ('Rebucados para a tosse') and in the United Kingdom ('Cough drops').
- (13) The Austrian and German competent authorities provided all other Member States with the applications. The competent authorities of Member States concerned provided the Commission with their opinions on the applications.
- (14) The terms 'Hustenbonbon', 'Hustenstopper', 'Hustenzuckerl', 'Brust-Caramellen', 'Hustenmischung', 'Hustenperle', 'Halsbonbon', 'Keelpastille', 'Hoestbonbon', 'rebucados para a tosse', and 'cough drops' fall into the scope of Regulation (EC) No 1924/2006, because they can imply a relationship between the foods bearing these terms and health.
- (15) However, evidence has been provided that these terms have been traditionally used in Germany and in Austria ('Hustenbonbon', 'Brust-Caramellen'), in Germany ('Halsbonbon', 'Hustenmischung' and 'Hustenperle'), in Austria ('Hustenstopper' and 'Hustenzuckerl'), in the Netherlands ('Keelpastille', and 'Hoestbonbon'), in Portugal ('rebucados para a tosse') and in the United Kingdom ('cough drops') in the meaning of Article 1(4) of this Regulation, as generic descriptors to describe a class of sweets based on sugars as well as sugar-free and calorie-reduced variants based on sweeteners (polyols and/or intense sweeteners) containing extracts of herbs, fruit or other plant substances, such as menthol, honey or malt.

- (16) In particular, the terms 'Hustenbonbon', 'Brust-Caramellen', 'Halsbonbon', 'Hustenmischung', 'Hustenperle', 'Hustenstopper', 'Hustenzuckerl', 'Keelpastille', 'Hoestbonbon', 'rebucados para a tosse' and 'cough drops' have neither been used in Germany, in Austria, in the Netherlands, in Portugal and in the United Kingdom respectively, with the aim to indicate a health effect of this class of food nor are understood by an average consumer as claiming a health effect of this class of food.
- (17) Derogation from Regulation (EC) No 1924/2006 should therefore be granted for the use of the generic descriptors 'Hustenbonbon' and 'Brust-Caramellen' in Germany and in Austria, 'Halsbonbon', 'Hustenmischung' and 'Hustenperle' in Germany, 'Hustenstopper' and 'Hustenzuckerl' in Austria, 'Keelpastille' and 'Hoestbonbon' in the Netherlands, 'rebucados para a tosse' in Portugal and 'cough drops' in the United Kingdom when used in the respective Member State on sweets based on sugars as well as sugar-free and calorie-reduced variants based on sweeteners (polyols and/or intense sweeteners) containing extracts of herbs, fruit or other plant substances, honey or malt.
- (18) On 12 January 2017, the Finnish competent authority provided the Commission with an application from the Finnish Food Industries' Association, submitted pursuant to Article 1(4) of Regulation (EC) No 1924/2006, for the term 'Kurkkupastilli/ Halspastill' to be used as generic descriptor in Finland.
- (19) The Finnish competent authority provided all other Member States with the application; it also provided the Commission with its opinion on the application.
- (20) The term 'Kurkkupastilli/ Halspastill' falls into the scope of Regulation (EC) No 1924/2006, because it can imply a relationship between foods bearing this term and health. However, evidence has been provided that this term has been used traditionally in Finland, in the meaning of Article 1(4) of this Regulation, as generic descriptor to describe a class of sweets based on sugars as well as sugar-free and calorie-reduced variants based on sweeteners (polyols and/or intense sweeteners).
- (21) In particular, the term 'Kurkkupastilli/ Halspastill' has neither been used in Finland with the aim to indicate a health effect of this class of food nor is understood by an average consumer as claiming a health effect of this class of food.
- (22) Derogation from Regulation (EC) No 1924/2006 should therefore be granted for the use of the generic descriptor 'Kurkkupastilli/ Halspastill' when used in Finland on hard sweets based on sugars as well as sugar-free and calorie-reduced variants based on sweeteners (polyols and/or intense sweeteners).
- (23) On 13 April 2015, the Austrian competent authority provided the Commission with an application from Drapal GmbH, submitted pursuant to Article 1(4) of Regulation (EC) No 1924/2006, for the term 'Hustensirup' to be used as generic descriptor in Austria.
- (24) The Austrian competent authority provided all other Member States with the application; it also provided the Commission with its opinion on the application.
- (25) The term 'Hustensirup' falls into the scope of Regulation (EC) No 1924/2006, because it can imply a relationship between foods bearing this term and health. However, evidence has been provided that this term has been used traditionally in Austria, in the meaning of Article 1(4) of this Regulation, as generic descriptor to describe a class of confectionery products made of solutions of sugar, starch syrup, inverted sugar and/or honey with the addition of herbal ingredients, 'Hustensirup' referring to a class of products in the form of a syrup.

- (26) In particular, the term 'Hustensiup' has neither been used with the aim to indicate a health effect of this class of food nor is understood by an average consumer as claiming a health effect of this class of food in Austria.
- (27) Derogation from Regulation (EC) No 1924/2006 should therefore be granted for the use of the generic descriptor 'Hustensirup' when used in Austria on confectionery products made of solutions of sugar, starch syrup, inverted sugar and/or honey with the addition of herbal ingredients in the form of syrup.
- (28) Definitions for sugars intended for human consumption have been laid down in point A of the Annex to Council Directive 2001/111/EEC of 20 December 2001 relating to certain sugars intended for human consumption<sup>3</sup>. In order to ensure legal certainty, those definitions should also apply for the purpose of this Regulation.
- (29) On 2 April 2015, the UK competent authority provided the Commission with an application from the British Soft Drinks Association, submitted pursuant to Article 1(4) of Regulation (EC) No 1924/2006, for the term 'tonic' (in English) used as part of the descriptive name of a beverage in the form of 'tonic water', 'Indian tonic water' or 'quinine tonic water' and also substituting the word 'tonic' (in English) with 'tonique' (in French), 'tónico' or 'tonica' (in Italian, Spanish, and Portuguese), 'τονωτικό' or 'tonotikó' (in Greek), 'tonik' (in Croatian, Czech, Hungarian, Polish, Slovak and Slovenian), 'тоник' (in Bulgarian), to be used as generic descriptor in all Member States except in Romania.
- (30) On 30 September 2015, the Romanian competent authority provided the Commission with an application from the Romanian Soft Drinks Association, submitted pursuant Article 1(4) of Regulation (EC) No 1924/2006, for the term 'tonic' (in English) used as part of the descriptive name of a food in the form of 'tonic water', 'Indian tonic water' or 'quinine tonic water' and also substituting the word 'tonic' (in English) with 'tónico', 'tonică' or 'tonica' (in Romanian), to be used as generic descriptor in Romania.
- (31) The UK competent authority and the Romanian competent authority provided all other Member States with the applications; Member States have provided the Commission with their opinions on these applications.
- (32) The Greek competent authority consider that the term 'τονωτικό' is considered as a health claim within the meaning of Regulation (EC) No 1924/2006.
- (33) The German competent authority and the Austrian competent authority consider that the term 'tonic' used as part of 'tonic water', 'Indian tonic water' or 'quinine tonic water' is part of a customary name of the food and as such out of the scope of Regulation (EC) No 1924/2006.
- (34) Certain competent authorities consider that when the term 'tonic' (in English) is substituted by 'tonotikó' (in Greek) it is not an exact translation, and when the term 'tonic' is substituted by 'tonik' in Croatian, Hungarian, Polish and Slovenian, it is not considered as a health claim in those respective Member States within the meaning of Regulation (EC) No 1924/2006; therefore in their views these terms are out of the scope of the Regulation.
- (35) The term 'tonic' and the equivalent linguistic forms, namely, 'tonique', 'tonik', 'tónico', 'tónica' and 'tonică', when they are used as part of the descriptive name of a beverage, fall into the scope of Regulation (EC) No 1924/2006, because they can imply a relationship between a food bearing this term and health. However, evidence has been

---

<sup>3</sup> OJ L 10, 12.1.2002, p. 53.

provided that these terms have been used traditionally, in the meaning of Article 1(4) of this Regulation, as generic descriptors to describe a class of beverages, namely, a non-alcoholic carbonated beverage containing the bittering agent quinine in the form of the flavourings FL 14.011, FL 14.152 or 14.155 as referred to in the Union list of flavourings laid down in Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods<sup>4</sup>.

- (36) In particular, the terms 'tonic' and the equivalent linguistic forms, namely, 'tonique', 'tonik', 'tónico', 'tónica' and 'tonică', when they are used as part of the descriptive name of a beverage, have neither been used with the aim to indicate a health effect of this class of beverages nor are understood by an average consumer as claiming a health effect of this class of beverages.
- (37) Derogation from Regulation (EC) No 1924/2006 should therefore be granted for the use of the generic descriptor 'tonic' (in English), when used as part of the descriptive name of a non-alcoholic carbonated beverage containing the bittering agent quinine in the form of the flavourings FL 14.011, FL 14.152 or 14.155 as referred to in the Union list of flavourings as laid down in Regulation (EC) No 1334/2008. The term 'tonic' (in English) may be replaced by 'тоник' (in Bulgarian), 'tonik' (in Czech and in Slovak), 'tonique' (in French), 'tónica' (in Spanish) 'tonica' (in Italian and in Portuguese), or 'tonică' (in Romanian).
- (38) On 23 April 2015, the Italian competent authority provided the Commission with an application from Monviso S.P.A., submitted pursuant to Article 1(4) of Regulation (EC) No 1924/2006, for the term 'biscotto salute' to be used as generic descriptor in Italy and in Malta.
- (39) The Italian competent authority provided all other Member States with the application; the Member States concerned have provided the Commission with their opinions on the application.
- (40) The term 'biscotto salute' falls into the scope of Regulation (EC) No 1924/2006, because it can imply a relationship between a food bearing this term and health. However, evidence has been provided that this term has been used traditionally in Italy, in the meaning of Article 1(4) of this Regulation, as a generic descriptor to describe a class of rusk-type bakery products.
- (41) In particular, the term 'biscotto salute' has neither been used with the aim to indicate a health effect of this class of foods nor is understood by an average consumer as claiming the health effect of this class of food in Italy.
- (42) Malta indicated that the term 'biscotto salute' was not used to describe rusk-type bakery products on the Maltese market.
- (43) Derogation from Regulation (EC) No 1924/2006 should therefore be granted for the use of the generic descriptor 'biscotto salute' when used in Italy on rusk-type bakery products.
- (44) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

---

<sup>4</sup> 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 (OJ L 354, 31.12.2008, p. 34).

HAS ADOPTED THIS REGULATION:

*Article 1*

The generic descriptors listed in the Annex to this Regulation are exempted from the application of Article 1(3) of Regulation (EC) No 1924/2006 under the conditions laid down in that Annex.

*Article 2*

For the purposes of this Regulation, the definitions for sugars intended for human consumption laid down in point A of the Annex to Council Directive 2001/111/EEC shall apply.

*Article 3*

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,

*For the Commission*  
*The President*  
*Jean-Claude JUNCKER*