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Subject:	Draft COMMISSION REGULATION amending Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and the Annex to Commission Regulation (EU) No 231/2012 as regards the food additive Potassium diacetate

Delegations will find attached Commission document D022890/02.

Encl.: D022890/02



EUROPEAN
COMMISSION

Brussels, **XXX**
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[...](2012) **XXX** draft

COMMISSION REGULATION (EU) No .../..

of **XXX**

**amending Annexes II and III to Regulation (EC) No 1333/2008 of the European
Parliament and the Annex to Commission Regulation (EU) No 231/2012 as regards the
food additive Potassium diacetate**

(Text with EEA relevance)

COMMISSION REGULATION (EU) No .../..

of **XXX**

amending Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and the Annex to Commission Regulation (EU) No 231/2012 as regards the food additive Potassium diacetate

(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 additives¹, and in particular Article 10(3), Article 14 and Article 30(5) 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 flavourings², 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 foods and their conditions of use.
- (2) Annex III to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in food additives, food enzymes, flavourings, nutrients and their conditions of use.
- (3) Commission Regulation (EU) No 231/2012 lays down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008³.
- (4) Those lists may be amended in accordance with the procedure referred to in 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.
- (5) Pursuant to Article 3(1) of Regulation (EC) No 1331/2008, the Union list of food additives may be updated either on the initiative of the Commission or following an application.

¹ OJ L 354, 31.12.2008, p. 16.

² OJ L 354, 31.12.2008, p. 1.

³ OJ L 83, 22.3.2012, p. 1

- (6) An application for authorisation of the use of Potassium diacetate as a preservative was submitted on 27 September 2010 and was made available to the Member States.
- (7) Potassium diacetate is requested for use as an alternative to the food additive Sodium diacetate E 262 (ii) which is used as a growth inhibitor of microorganisms. The replacement of Sodium diacetate E 262 (ii) by Potassium diacetate can contribute to the reduction of dietary sodium intake.
- (8) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission is to seek the opinion of 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 the update in question is not liable to have an effect on human health. Potassium diacetate is an equimolecular compound of two authorised food additives (Potassium acetate E 261 and Acetic acid E 260). The Scientific Committee for Food evaluated food additives of various technological functions in 1990. For acids, bases and their salts the evaluations were based on the anions and cations listed. Acetic acid (E 260) as well as its salts, ammonium-, sodium-, potassium- and calcium acetates and diacetates, were covered by the evaluation. The Committee established a group Acceptable Daily Intake not specified for all these substances. This implies that their use does not represent a hazard to health in order to achieve the desired technological effect. The authorisation of use of Potassium diacetate in a similar way to Potassium acetate is not liable to have an effect on human health and it is therefore not necessary to seek the opinion of the Authority.
- (9) Potassium diacetate should be authorised to be used in the same way as Potassium acetate. Therefore in the Annexes to Regulation (EC) No 1333/2008 the current name of additive E 261, i.e. "potassium acetate", should be replaced by the expression "potassium acetates" covering both potassium acetate and potassium diacetate.
- (10) Specifications for Potassium diacetate should be included in Regulation (EU) No 231/2012. In the Annex to that Regulation, the number E 261 (ii) should be assigned to Potassium diacetate and the number for Potassium acetate, currently designated as E 261, should be changed to E 261 (i). This renumbering has no consequences on the labelling requirements set out in Articles 22 and 23 of Regulation (EC) No 1333/2008.
- (11) Pursuant to the transitional provisions of Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives, Annex II establishing the Union list of food additives approved for use in foods and conditions of use applies from 1 June 2013. In order to allow the use of potassium diacetate before that date, it is necessary to specify an earlier date of application with regard to that food additive.
- (12) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.
- (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

Annexes II and III to Regulation (EC) No 1333/2008 are amended in accordance with Annex I to this Regulation.

Article 2

The Annex to Regulation (EU) No 231/2012 is amended in accordance with Annex II to this Regulation.

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
José Manuel BARROSO

ANNEX I

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

(1) In Part B, Table 3, the entry for additive E 261 is replaced by the following:

E 261	Potassium acetates	Period of application <i>[the date of the entry into force of this Regulation]</i>
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(2) In Part C, Group I, the entry for additive E 261 is replaced by the following:

E 261	Potassium acetates	<i>quantum satis</i>	Period of application <i>[the date of the entry into force of this Regulation]</i>
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(3) In Part E:

(a) In food category 04.2.3 "Canned or bottled fruit and vegetables", the entry for additive E 261 is replaced by the following:

E 261	Potassium acetates	<i>quantum satis</i>		Period of application <i>[the date of the entry into force of this Regulation]</i>
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(b) In food category 07.1.1 "Bread prepared solely with the following ingredients: wheat flour, water, yeast or leaven, salt", the entry for additive E 261 is replaced by the following:

E 261	Potassium acetates	<i>quantum satis</i>		Period of application <i>[the date of the entry into force of this Regulation]</i>
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					<i>force of this Regulation]</i>
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- (c) In food category 07.1.2 "Pain courant français; Friss búzakenyér, fehér és félbarna kenyerek" the entry for additive E 261 is replaced by the following:

E 261	Potassium acetates	<i>quantum satis</i>	only <i>Friss búzakenyér, fehér és félbarna kenyerek</i>	Period of application <i>[the date of the entry into force of this Regulation]</i>
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- (d) In food category 08.1.2 "Meat preparations as defined by Regulation (EC) No 853/2004" the entry for additive E 261 is replaced by the following:

E 261	Potassium acetates	<i>quantum satis</i>	only prepacked preparations of fresh minced meat	Period of application <i>[the date of the entry into force of this Regulation]</i>
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- (e) In food category 13.1.3 "3 Processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC" the entry for additive E 261 is replaced by the following:

E 261	Potassium acetates	<i>quantum satis</i>	only processed cereal-based foods and baby foods, only for pH adjustment	Period of application <i>[the date of the entry into force of this Regulation]</i>
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- B. Annex III to Regulation (EC) No 1333/2008 is amended as follows:

- (a) In Part 3, the entry for additive E 261 is replaced by the following:

E 261	Potassium acetates	<i>quantum satis</i>	<i>quantum satis</i>	<i>quantum satis</i>	
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(b) In Part 5, Section A, the entry for additive E 261 is replaced by the following:

E 261	Potassium acetates	<i>quantum satis</i>	All nutrients	
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(c) In Part 6, table 1, the entry for additive E 261 is replaced by the following:

E 261	Potassium acetates	
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ANNEX II

The Annex to Regulation (EU) No 231/2012 is amended as follows:

(a) In the entry for additive E 261, the heading is replaced by the following:

E 261 (i) POTASSIUM ACETATE

(b) The following entry is inserted after the entry for additive E 261 (i):

E 261 (ii) POTASSIUM DIACETATE	
Synonyms	
Definition	● Potassium diacetate is a molecular compound of potassium acetate and acetic acid
EINECS	● 224-217-7
Chemical name	● Potassium hydrogen diacetate
Chemical formula	● C ₄ H ₇ KO ₄
Molecular weight	● 158,2
Assay	● Content 36 to 38 % of free acetic acid and 61 to 64% of potassium acetate
Description	● White crystals
Identification	
pH	● 4,5 – 5 (10 % aqueous solution)
Test for acetate	● Passes test
Test for potassium	● Passes test
Purity	
Water content	Not more than 1 % (Karl Fischer method)
Formic acid, formates and other oxidizable substances	Not more than 1 000 mg/kg expressed as formic acid
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg