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From:	European Commission
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To:	General Secretariat of the Council
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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of the Iron tartrate as an anti-caking agent in salt and its substitutes

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Delegations will find attached document D040073/03.

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Encl.: D040073/03



Brussels, **XXX**  
SANTE/10652/2015  
(POOL/E7/2015/10652/10652-EN.doc)  
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[...](2015) **XXX** draft

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

**of **XXX****

**amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of the Iron tartrate as an anti-caking agent in salt and its substitutes**

(Text with EEA relevance)

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

of **XXX**

**amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of the Iron tartrate as an anti-caking agent in salt and its substitutes**

(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<sup>1</sup>, and in particular Articles 10(3) and 14 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 flavourings<sup>2</sup>, 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 food and their conditions of use.
- (2) Commission Regulation (EU) No 231/2012<sup>3</sup> lays down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (3) That list may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application.
- (4) On 18 January 2012, an application was submitted for the authorisation of the use of iron tartrate as an anti-caking agent in salt and its substitutes. The application was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (5) The European Food Safety Authority evaluated the safety of iron tartrate, which is a complexation product of sodium tartrate and iron (III) chloride, as a food additive and

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<sup>1</sup> OJ L 354, 31.12.2008, p. 16.

<sup>2</sup> OJ L 354, 31.12.2008, p. 1.

<sup>3</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

in its opinion<sup>4</sup> of 9 December 2014 concluded that, taking into account toxicological data and the conservative assumptions included in the exposure assessment, there is no safety concern for its use as an anti-caking agent in salt and its substitutes at the level of use proposed.

- (6) Addition of an anti-caking agent to salt and its substitutes is considered necessary in order to improve flow properties and to avoid the formation of hardened agglomerates when exposed to moisture and during storage. The use of iron tartrate can serve as an alternative to other currently authorised additives, such as ferrocyanides (E 535 – 538) and silicon dioxide silicates (E 551 – 553). It is therefore appropriate to authorise the use of iron tartrate as an anti-caking agent in salt and its substitutes and to assign E 534 as E-number to that additive.
- (7) The specifications for iron tartrate (E 534) should be included in Regulation (EU) No 231/2012 when it is included in the Union list of food additives laid down in Annex II to Regulation (EC) No 1333/2008 for the first time.
- (8) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

Annex II to Regulation (EC) No 1333/2008 is 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.

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<sup>4</sup> EFSA Journal 2015;13(1):3980

Done at Brussels,

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