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Delegations will find attached document D050364/02.

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Encl.: D050364/02



EUROPEAN  
COMMISSION

Brussels, **XXX**  
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[...](2017) **XXX** draft

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

of **XXX**

**amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of use of silicon dioxide (E 551) in potassium nitrate (E252)**

(Text with EEA relevance)

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

of **XXX**

**amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of use of silicon dioxide (E 551) in potassium nitrate (E252)**

(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 Article 10(3) thereof,

Whereas:

- (1) Annex III to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in food additives, food enzymes, food flavourings, nutrients and their conditions of use.
- (2) The Union list of food additives may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008 of the European Parliament and of the Council<sup>2</sup> either on the initiative of the Commission or following an application.
- (3) An application for authorisation of the use of silicon dioxide (E 551) as an anti-caking agent added to potassium nitrate (E 252) was submitted on 7 July 2016 and was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (4) When stored, potassium nitrate (E 252) shows a strong caking tendency which hinders its use in food processing. Therefore, an anti-caking agent is needed to ensure the flow and correct dosing of this additive. The applicant has demonstrated that the authorised anti-caking agents for potassium nitrate (E 252) are not efficient or may lead to undesired changes in the pH, disturbing food processing. Meanwhile silicon dioxide (E 551) is proven to be efficient and does not react with the food nor influence the further processing of the food.

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

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

- (5) The Scientific Committee for Food established a group ADI (Acceptable Daily Intake) level of 'not specified' for silicon dioxide (E 551) and certain silicates (i.e. sodium, potassium, calcium, and magnesium silicates) when used as anticaking agents<sup>3</sup>. That implies that silicon dioxide (E 551) does not represent a hazard to health when used at the levels necessary to achieve the desired technological effect. The additional exposure of the consumer to silicon dioxide (E 551) when used as an anticaking agent in potassium nitrate (E 252) would remain limited.
- (6) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission is to seek the opinion of the European Food Safety Authority ('the Authority') in order to update the Union list of food additives set out in Annex III to Regulation (EC) No 1333/2008, except where the update in question is not liable to have an effect on human health.
- (7) Since the authorisation of the use of silicon dioxide (E 551) in potassium nitrate (E 252) constitutes an update of that list which is not liable to have an effect on human health, it is not necessary to seek the opinion of the Authority.
- (8) It is therefore appropriate to authorise the use of silicon dioxide (E 551) as an anti-caking agent in potassium nitrate (E 252).
- (9) Annex III to Regulation (EC) No 1333/2008 should therefore be amended accordingly.
- (10) 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 III to Regulation (EC) No 1333/2008 is amended in accordance with 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*.

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*

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<sup>3</sup> Report from the Scientific Committee for food, 25th series, 1990.