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| Subject: | COMMISSION REGULATION (EU) No .../..of XXX amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of Extracts of rosemary (E 392) in certain low fat meat and fish products |

Delegations will find attached Commission document D026572/02.

Encl.: D026572/02



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[...](2013) **XXX** draft

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

of **XXX**

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of Extracts of rosemary (E 392) in certain low fat meat and fish products

(Text with EEA relevance)

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

of XXX

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of Extracts of rosemary (E 392) in certain low fat meat and fish products

(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) 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) That list may be amended in accordance with the common 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 flavourings².
- (3) 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.
- (4) An application for the authorisation of use of Extracts of rosemary (E 392) as an antioxidant in meat preparations, low fat non-heat-treated and heat-treated processed meat and low fat processed fish and fishery products including molluscs and crustaceans was submitted on 3 February 2012 and has been made available to the Member States.
- (5) Antioxidants are substances which protect food against deterioration caused by oxidation, such as fat rancidity and colour changes. The current maximum levels of the use of Extracts of rosemary (E 392) authorised in processed meat and processed fish and fishery products including molluscs and crustaceans are set according to the fat content in the respective food categories (except for dried sausages and dehydrated

¹ OJ L 354, 31.12.2008, p. 16.

² OJ L 354, 31.12.2008, p. 1.

meat). The allowed maximum level of use of Extracts of rosemary (E 392) set according to the fat content in the respective food categories does not ensure a sufficient protection of food with low fat content since there is a critical minimum dosage of this antioxidant to achieve the desired effect. Currently, Extracts of rosemary (E 392) could be used at effective dosages in the products with a higher fat content. However, also the low fat products could be subject to severe oxidation due to a high proportion of unsaturated fatty acids. Therefore, it is appropriate to set the maximum level of use of Extracts of rosemary (E 392) at 15 mg/kg for products with a fat content not higher than 10% while maintaining the allowed maximum level of 150 mg/kg expressed on fat basis for the products with a fat content higher than 10%.

- (6) In 2008 the European Food Safety Authority ("the Authority") evaluated the safety of Extracts of rosemary (E 392) when used as a food additive³ and concluded that the proposed uses and use levels would not be of safety concern. In a conservative estimate of dietary exposure it was assumed by the Authority that the Extracts of rosemary would be used at the maximum level of use (i.e. at 150 mg/kg in processed meat, poultry and fish/seafood products) in all the proposed foods in each food category. This assumption covered also non-heat-treated and heat-treated processed meat and processed fish and fishery products including molluscs and crustaceans with a fat content not higher than 10%.
- (7) 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. In view of the aforesaid Authority's opinion of 2008, setting the maximum level of use of Extracts of rosemary (E 392) at 15 mg/kg for non-heat-treated and heat-treated processed meat and processed fish and fishery products including molluscs and crustaceans with a fat content not higher than 10% constitutes an update of that list which is not liable to have an effect on human health, therefore, it is not necessary to seek the opinion of the Authority.
- (8) Following the above, Annex II to Regulation (EC) No 1333/2008 should be amended accordingly.
- (9) 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

Annex II to Regulation (EC) No 1333/2008 is amended in accordance with the Annex to this Regulation.

³ The EFSA Journal (2008) 721, 1-29.

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
José Manuel BARROSO

ANNEX

Part E of Annex II to Regulation (EC) No 1333/2008 is amended as follows:

- (1) In food category 08.2.1 "Non-heat-treated processed meat" the entry concerning the additive E 392 Extracts of rosemary excluding dried sausages is replaced by the following:

"

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|-------|----------------------|-----|-----------|--|
| E 392 | Extracts of rosemary | 15 | (46) | only meat with a fat content not higher than 10%, excluding dried sausages |
| E 392 | Extracts of rosemary | 150 | (41) (46) | only meat with a fat content higher than 10%, excluding dried sausages |

"

- (2) In food category 08.2.2 "Heat-treated processed meat" the entry concerning the additive E 392 Extracts of rosemary excluding dried sausages is replaced by the following:

"

| | | | | |
|-------|----------------------|-----|-----------|--|
| E 392 | Extracts of rosemary | 15 | (46) | only meat with a fat content not higher than 10%, excluding dried sausages |
| E 392 | Extracts of rosemary | 150 | (41) (46) | only meat with a fat content higher than 10%, excluding dried sausages |

"

(3) In food category 09.2 "Processed fish and fishery products including molluscs and crustaceans" the entry concerning the additive E 392 is replaced by the following:

"

| | | | | |
|-------|----------------------|-----|-----------|--|
| E 392 | Extracts of rosemary | 15 | (46) | only fish and fishery products including molluscs and crustaceans with a fat content not higher than 10% |
| E 392 | Extracts of rosemary | 150 | (41) (46) | only fish and fishery products including molluscs and crustaceans with a fat content higher than 10% |

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