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To:	General Secretariat of the Council
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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 benzoic acid – benzoates (E 210 – 213) in cooked shrimps in brine

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Delegations will find attached document D036749/02.

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Encl.: D036749/02



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(POOL/E3/2014/12151/12151-EN.doc)  
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[...](2014) **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 benzoic acid – benzoates (E 210 – 213) in cooked shrimps in brine**

(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 benzoic acid – benzoates (E 210 – 213) in cooked shrimps in brine**

(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),

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 updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008<sup>2</sup>, either on the initiative of the Commission or following an application.
- (3) A request to amend the Union list of food additives has been submitted by the Danish Seafood Association in order to increase the maximum permitted level of benzoic acid – benzoates (E 210 -213) in cooked shrimps in brine.
- (4) Annex II to Regulation (EC) No 1333/2008 sets maximum limits for the use of Sorbic acid – sorbates; Benzoic acid - benzoates (E 200 – 213) of 2000 mg/kg in semi-preserved fish and fisheries products including crustaceans, molluscs, surimi and fish / crustacean paste; cooked crustaceans and molluscs. In cooked crustaceans and molluscs the total maximum permitted level of Benzoic acid – benzoates (E 210 – 213) is furthermore 1000 mg/kg.
- (5) These maximum permitted levels in cooked and brined shrimps with pH of 5.6 to 5.7 should be sufficient to inhibit the growth of *Listeria monocytogenes* at cooling temperatures between 5 and 8 °C. However, small changes in the preserving parameters can result in growth of *Listeria monocytogenes*. A mathematical predictive

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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).

method has been developed at the Technological University of Denmark, to determine which level of benzoic acid benzoate (E 210 – 213) is needed<sup>3</sup>. According to that model the level of 1000 mg/kg of E 210 – 213 is not sufficient to prevent growth of *Listeria monocytogenes* in shrimps in brine at pH 5.8. In order to prevent growth of *Listeria monocytogenes* in these shrimps, both the model and tests show that the optimal combination of Benzoic acid - benzoates (E 210 – 213) and Sorbic acid - sorbates (E 200 – 203) is 1500 mg/kg and 500 mg/kg respectively.

- (6) In its report trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2012<sup>4</sup>, the European Food Safety Authority (the Authority) concluded that the number of listeriosis cases in humans increased slightly compared with 2011, and 1,642 confirmed human cases were reported in 2012. A statistically significant increasing trend in the Union was observed over the period 2008-2012, though only slowly increasing, along with a seasonal pattern. As in previous years, a high fatality rate (17.8 %) was reported among the cases. A total of 198 deaths due to listeriosis were reported by 18 Member States in 2012, which was the highest number of fatal cases reported since 2006. *Listeria monocytogenes* was seldomly detected above the legal safety limit for ready-to-eat foods at point of retail. Samples exceeding this limit were most often found in fishery products.
- (7) The Commission report on Dietary Food Additive Intake in the European Union<sup>5</sup> concluded that exposure to benzoic acid – benzoates could be up to 96 % of the ADI for young children and 84 % for adults based on the use at maximum permitted levels. At that time a maximum level in cooked shrimps of 2000 mg/kg was set for sorbic acid – sorbates in combination with benzoic acid – benzoates. This level was revised by Directive 2006/52/EC<sup>6</sup> when this authorisation was extended to all cooked crustaceans and molluscs, however with a maximum of 1000 mg/kg for benzoic acid – benzoates. It is therefore expected that the increase of this level to 1500 mg/kg, only for cooked shrimps in brine, will not lead to additional exposure that would be of safety concern.
- (8) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission is to seek the opinion of the 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. Since the authorisation of the use of benzoic acid - benzoates (E 210 – 213) in cooked shrimps preserved in brine 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.
- (9) Therefore, Annex II to Regulation (EC) No 1333/2008 should be amended accordingly.

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<sup>3</sup> <http://sssp.tuaqua.dk>

<sup>4</sup> The European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks in 2012, (EFSA Journal 2014;12(2):3547), <http://www.efsa.europa.eu/en/efsajournal/doc/3547.pdf>

<sup>5</sup> COM(2001) 542 final.

<sup>6</sup> Directive 2006/52/EC of the European Parliament and of the Council of 5 July 2006 amending Directive 95/2/EC on food additives other than colours and sweeteners and Directive 94/35/EC on sweeteners for use in foodstuffs (OJ L 204, 26.7.2006, p. 10–22).

(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 II 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*.

It shall apply from the moment of entry into force of this Regulation.

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*