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THE EUROPEAN UNION**

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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 Lysozyme (E 1105) in beer |

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Delegations will find attached Commission document D019483/02.

Encl.: D019483/02



EUROPEAN COMMISSION

Brussels, **XXX**  
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**[...]**(2012) **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 Lysozyme (E 1105) in beer**

(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 Lysozyme (E 1105) in beer**

(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) and Article 30(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) That list 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<sup>2</sup>.
- (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 authorisation of the use of Lysozyme (E 1105) as a preservative in beer was submitted and has been made available to the Member States.
- (5) Most breweries use sterile filtration or pasteurisation of their beers to prevent bacterial spoilage during storage of the beer before consumption. For some specialty beers, like the top-fermenting beers with re-fermentation, for instance cask-conditioned beer and bottle-conditioned beer, such treatments are not possible because the present viable micro-organisms are part of the production process of those beers. Lysozyme (E 1105) has been proven to be a suitable antibacterial agent for brewing purposes and it is effective in inhibiting lactic acid bacteria added to finished beers.

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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.

- (6) Lysozyme (E 1105) belongs to the group of additives for which no acceptable daily intake has been specified<sup>3</sup>. This implies that it does not represent a hazard to health at the levels necessary to achieve the desired technological effect. It is therefore appropriate to allow the use of Lysozyme (E 1105) for the preservation of beers that will not receive either pasteurisation or sterile filtration.
- (7) According to Commission Directive 2008/84/EC of 27 August 2008 laying down specific purity criteria on food additives other than colours and sweeteners<sup>4</sup>, Lysozyme (E 1105) is obtained from hen's eggs whites. Eggs and products thereof are listed in Annex IIIa to Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs<sup>5</sup>. The presence of this enzyme in beers needs to be indicated on the labelling in accordance with the requirements of the said Directive.
- (8) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission is to seek the opinion of the European Food Safety 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 use of Lysozyme (E 1105) as a preservative in beer 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 European Food Safety Authority.
- (9) 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<sup>6</sup>, 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 Lysozyme (E 1105) in beers before that date, it is necessary to specify an earlier date of application with regard to that food additive.
- (10) Therefore, Annex II to Regulation (EC) No 1333/2008 should be amended accordingly.
- (11) 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.

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<sup>3</sup> Report from the Commission on Dietary Food Additive Intake in the European Union, COM(2001) 542 final.

<sup>4</sup> OJ L 253, 20.9.2008, p. 1.

<sup>5</sup> OJ L 109, 6.5.2000, p. 29.

<sup>6</sup> OJ L 295, 12.11.2011, p. 1.

## *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**

In Part E of Annex II to Regulation (EC) No 1333/2008 the following entry is inserted in the food category 14.2.1 "beer and malt beverages" after the entry for E 962:

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|  |        |          |                      |  |   |  |
|--|--------|----------|----------------------|--|---|--|
|  | E 1105 | Lysozyme | <i>quantum satis</i> |  | only in beers that will not receive either pasteurisation or sterile filtration | Period of application:<br>From [the date of entry into force of this Regulation] |
|--|--------|----------|----------------------|--|---|--|

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