

Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (Text with EEA relevance)

## CHAPTER V

### TRANSITIONAL AND FINAL PROVISIONS

#### *Article 17*

#### **Establishment of the Community list of food enzymes**

1 The Community list of food enzymes shall be drawn up on the basis of applications made pursuant to paragraph 2.

2 Interested parties may submit applications for the inclusion of a food enzyme in the Community list.

[<sup>F1</sup>The deadline for submitting such applications shall be 42 months after the date of application of the implementing measures laid down in accordance with Article 9(1) of Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.]

3 The Commission shall establish a Register of all food enzymes to be considered for inclusion in the Community list in respect of which an application complying with the validity criteria to be laid down in accordance with Article 9(1) of Regulation (EC) No 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings] has been submitted in accordance with paragraph 2 of this Article (hereinafter referred to as the Register). The Register shall be made available to the public.

The Commission shall submit the applications to the Authority for its opinion.

4 The Community list shall be adopted by the Commission in accordance with the procedure laid down in Regulation (EC) No 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings], once the Authority has issued an opinion on each food enzyme included in the Register.

However, by way of derogation from that procedure:

- a Article 5(1) of Regulation (EC) No 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings] shall not apply to the Authority's adoption of its opinion;
- b the Commission shall adopt the Community list for the first time after the Authority has delivered its opinion on all the food enzymes listed in the Register.

5 If necessary, any appropriate transitional measures for the purposes of this Article which are designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(3).

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**Changes to legislation:** There are outstanding changes not yet made to Regulation (EC) No 1332/2008 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

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### Textual Amendments

- F1** Substituted by [Commission Regulation \(EU\) No 1056/2012 of 12 November 2012 amending Regulation \(EC\) No 1332/2008 of the European Parliament and of the Council on food enzymes with regard to transitional measures \(Text with EEA relevance\)](#).

## Article 18

### Transitional measures

- 1 Notwithstanding Articles 7 and 17 of this Regulation, the Community list shall, when drawn up, include the following food enzymes:
- a E 1103 Invertase and E 1105 Lysozyme, stating the conditions governing their use as specified in Annex I and Part C of Annex III to Directive 95/2/EC;
  - b Urease, beta-glucanase and lysozyme for use in wine in accordance with Regulation (EC) No 1493/1999 and the implementing rules for that Regulation.
- 2 Food enzymes, food enzyme preparations and food containing food enzymes placed on the market or labelled before 20 January 2010 which do not comply with the provisions of Articles 10 to 12 may be marketed until their date of minimum durability or use-by-date.

## Article 19

### Amendments to Directive 83/417/EEC

In Directive 83/417/EEC, in Annex I, Section III(d), the indents shall be replaced by the following:

- rennet meeting the requirements of Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes<sup>(1)</sup>;
- other milk-coagulating enzymes meeting the requirements of Regulation (EC) No 1332/2008.

## Article 20

### Amendment to Regulation (EC) No 1493/1999

In Regulation (EC) No 1493/1999, the following paragraph shall be added to Article 43:

3. Enzymes and enzymatic preparations used in the authorised oenological practices and processes listed in Annex IV shall meet the requirements of Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes<sup>(2)</sup>.

## Article 21

### Amendments to Directive 2000/13/EC

Directive 2000/13/EC is hereby amended as follows:

1. Article 6(4) shall be amended as follows:

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- (a) point (a) shall be replaced by the following:
  - (a) “Ingredient” shall mean any substance, including additives and enzymes, used in the manufacture or preparation of a foodstuff and still present in the finished product, even if in altered form.;
  - (b) in point (c)(ii), the introductory word ‘additives’ shall be replaced by ‘additives and enzymes’;
  - (c) in point (c)(iii), the words ‘additives or flavouring’ shall be replaced by ‘additives or enzymes or flavourings’;
- 2. the following indent shall be added to Article 6(6):
  - enzymes other than as referred to in paragraph 4(c)(ii) shall be designated by the name of one of the categories of ingredients listed in Annex II, followed by their specific name,.

#### *Article 22*

#### **Amendments to Directive 2001/112/EC**

In Directive 2001/112/EC, in Annex I, Section II(2), the fourth, fifth and sixth indents shall be replaced by the following:

- Pectolytic enzymes meeting the requirements of Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes<sup>(3)</sup>;
- Proteolytic enzymes meeting the requirements of Regulation (EC) No 1332/2008;
- Amylolytic enzymes meeting the requirements of Regulation (EC) No 1332/2008.

#### *Article 23*

#### **Amendment to Regulation (EC) No 258/97**

In Regulation (EC) No 258/97, the following point shall be added to Article 2(1):

- (d) food enzymes falling within the scope of Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes<sup>(4)</sup>.

#### *Article 24*

#### **Entry into force**

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

Article 4 shall apply from the date of application of the Community list. Until that date, national provisions in force concerning the placing on the market and use of food enzymes and food produced with food enzymes shall continue to apply in the Member States.

Articles 10 to 13 shall apply from 20 January 2010.

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- (1) [OJ L 354, 31.12.2008, p. 7.](#)
- (2) [OJ L 354, 31.12.2008, p. 7.](#)
- (3) [OJ L 354, 31.12.2008, p. 7.](#)
- (4) [OJ L 354, 31.12.2008, p. 7.](#)

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**Changes and effects yet to be applied to :**

- Regulation applied (with modifications) by [S.I. 2023/959 reg. 4\(a\)Sch. 1](#)

**Changes and effects yet to be applied to the whole legislation item and associated provisions**

- Signature words omitted by [S.I. 2019/860 reg. 78](#)
- Art. 1(a) word substituted by [S.I. 2019/860 reg. 56\(b\)](#)
- Art. 3(2)(c) inserted by [S.I. 2019/860 reg. 58](#)
- Art. 3(2)(c) words substituted in earlier amending provision S.I. 2019/860, reg. 58 by [S.I. 2020/1504 reg. 18\(12\)](#)
- Art. 11(1)(g) words substituted by [S.I. 2019/860 reg. 69](#)
- Art. 15A inserted by [S.I. 2019/860 reg. 72](#)
- Art. 15A(1)(c) omitted in earlier amending provision S.I. 2019/860, reg. 72 by [S.I. 2020/1504 reg. 18\(13\)\(a\)](#)
- Art. 15A(3) words substituted in earlier amending provision S.I. 2019/860, reg. 72 by [S.I. 2020/1504 reg. 18\(13\)\(b\)\(i\)](#)
- Art. 15A(3)(b) words substituted in earlier amending provision S.I. 2019/860, reg. 72 by [S.I. 2020/1504 reg. 18\(13\)\(b\)\(ii\)](#)
- Art. 15A(3)(d) omitted in earlier amending provision S.I. 2019/860, reg. 72 by [S.I. 2020/1504 reg. 18\(13\)\(b\)\(iii\)](#)
- Art. 15A(3)(d) words substituted by [S.I. 2019/1013 reg. 77\(a\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/1013 revoked immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 21(e))
- Art. 15A(4)(d) omitted in earlier amending provision S.I. 2019/860, reg. 72 by [S.I. 2020/1504 reg. 18\(13\)\(c\)](#)
- Art. 15A(5) inserted by [S.I. 2019/1013 reg. 77\(b\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/1013 revoked immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 21(e))
- Art. 17(4)(b) word substituted by [S.I. 2019/860 reg. 75\(d\)\(ii\)\(bb\)](#)
- Art. 17(4)(b) words substituted by [S.I. 2019/860 reg. 75\(d\)\(ii\)\(aa\)](#)