

**2004 No.2601**

**FOOD, ENGLAND**

**The Miscellaneous Food Additives (Amendment) (England)  
Regulations 2004**

<i>Made</i>	- - - -	<i>5th October 2004</i>
<i>Laid before Parliament</i>		<i>8th October 2004</i>
<i>Coming into force</i>		<i>29th October 2004</i>

The Secretary of State, in exercise of the powers conferred upon him by sections 16(1) (a), 17(1), 26(1) and (3) and 48(1) of, and paragraph 1 of Schedule 1 to, the Food Safety Act 1990(a) and now vested in him(b) and having had regard in accordance with section 48 (4A) of that Act to relevant advice given by the Food Standards Agency, and after consultation both as required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(c) and in accordance with section 48(4) and (4B) of that Act, makes the following Regulations:

**Title, commencement and application**

1. These Regulations—

- (a) may be cited as the Miscellaneous Food Additives (Amendment) (England) Regulations 2004;
- (b) shall come into force on 29th October 2004;
- (c) shall apply in relation to England only.

**Amendment of the Miscellaneous Food Additives Regulations 1995**

2. The Miscellaneous Food Additives Regulations 1995(d) shall be amended in accordance with regulations 3 and 4 below.

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(a) 1990 c.16

(b) Functions formerly exercisable by “the Ministers” (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraphs 7 and 8 of Schedule 5 to the Food Standards Act 1999 (c. 28) and paragraphs 12 and 21 of that Schedule amend sections 17(1) and 48 of the 1990 Act. Functions of “the Ministers” so far as exercisable in relation to Wales were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672) as read with section 40(3) of the 1999 Act and those functions so far as exercisable in relation to Scotland were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (c. 46) as read with section 40 (2) of the 1999 Act. Regulation 13(4) of S.I. 2000/656 expressly authorises the Secretary of State to amend or revoke existing Regulations made or having effect as if made by the Minister of Agriculture, Fisheries and Food (whether with others or not) under the Food Safety Act 1990.

(c) OJ No. L31, 1.2.2002, p.1.

(d) S.I. 1995/3187, relevant amendments are S.I. 1997/1413, S.I.1999/1136, S.I. 2001/60 and S.I. 2001/3775.

3. In paragraph (1) of regulation 2 (interpretation), in the definition of “Directive 96/77/EC”(a) for the words “and Commission Directive 2002/82/EC” there shall be substituted the following words —

“; Commission Directive 2002/82/EC(b) Commission Directive 2003/95/EC(c) and Commission Directive 2004/45/EC(d)”.

4. In regulation 11, after paragraph (1D), there shall be inserted the following paragraph—

“(1E) In any proceedings for an offence in contravention of regulation 3(1) where it is alleged that a food additive failed to satisfy the purity criteria for that additive, it shall be a defence for the accused to show either—

- (a) that the food additive concerned is E431-E436, or polyethylene glycol 6000 and the food additive or food concerned was put on the market or labelled before 1<sup>st</sup> November 2004; or
- (b) that the food additive concerned is E407, E407a, E1517 or E1519 and the food additive or food concerned was put on the market or labelled before 1<sup>st</sup> April 2005;

and that that matter constituting the offence would not have constituted an offence under these Regulations if the amendments made to them by regulation 3 of the Miscellaneous Food Additives (Amendment) (England) Regulations 2004 had not been in force when that matter occurred.”

Signed by authority of the Secretary of State for Health

5th October 2004

*Melanie Johnson*  
Parliamentary Under Secretary of State  
Department of Health

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(a) OJ No. L339, 30.12.1996, p.1.  
(b) OJ No. L292, 28.10.2002, p.1.  
(c) OJ No. L283, 31.10.2003, p.71.  
(d) OJ No. L113, 20.4.2004, p.19.

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations, which apply to England, implement Commission Directive 2003/95/EC(**a**) and Commission Directive 2004/45/EC(**b**), both of which amend Commission Directive 96/77/EC(**c**) laying down specific purity criteria on food additives other than colours and sweeteners. Directive 96/77/EC was implemented by amendment(**d**) to the Miscellaneous Food Additives Regulations 1995(**e**).

In particular these Regulations provide for purity criteria as outlined in the Annexes to Commission Directives 2003/95/EC and 2004/45/EC in relation to the following additives:

E251 Sodium Nitrate

E431 Polyoxyethylene (40) Stearate

E432 Polyoxyethylene Sorbitan Monolaurate (Polysorbate 20)

E433 Polyoxyethylene Sorbitan Monooleate (Polysorbate 80)

E434 Polyoxyethylene Sorbitan Monopalmitate (Polysorbate 40)

E435 Polyoxyethylene Sorbitan Monostearate (Polysorbate 60)

E436 Polyoxyethylene Sorbitan Tristearate (Polysorbate 65)

E459 Beta-Cyclodextrin

Polyethylene Glycol 6000

E407 Carrageenan

E407a Processed Eucheuma seaweed

E907 Hydrogenated Poly-1-decene

E1517 Glyceryl Diacetate

E1519 Benzyl Alcohol

A regulatory impact assessment has not been prepared in respect of these Regulations as the instrument will have no effect on the costs of business. A transposition note setting out how the main elements of Directives 2003/95/EC and 2003/45/EC are transposed into domestic law has been prepared and placed in the library of each House of Parliament. Copies may be obtained from the Novel Foods Additives and Supplements Division of the Food Standards Agency, Aviation House, 125 Kingsway, London WC2B 6NH.

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(a) OJ No. L283, 31.10.2003, p.71.

(b) OJ No. L113, 20.4.2004, p.19.

(c) OJ No. L339, 30.12.1996, p.1.

(d) In S.I. 1997/1413.

(e) S.I. 1995/3187, relevant amendments are S.I. 1997/1413, S.I.1999/1136, S.I. 2001/60 and S.I. 2001/3775.

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STATUTORY INSTRUMENTS

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