

DIRECTIVES

COMMISSION DIRECTIVE 2010/37/EU

of 17 June 2010

amending Directive 2008/60/EC laying down specific purity criteria on sweeteners

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

criteria need to be adapted to reflect the limits for individual heavy metals of interest, where appropriate.

Having regard to the Treaty on the Functioning of the European Union,

(4) Directive 2008/60/EC should therefore be amended accordingly.

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives⁽¹⁾ and in particular Article 30(5) thereof,

(5) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

After consulting the European Food Safety Authority (EFSA),

HAS ADOPTED THIS DIRECTIVE:

Whereas:

Article 1

Annex I to Directive 2008/60/EC is amended in accordance with the Annex to this Directive.

(1) Commission Directive 2008/60/EC⁽²⁾ laying down specific purity criteria on sweeteners sets out the purity criteria for the sweeteners for use in foodstuffs listed in European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in Foodstuffs⁽³⁾.

Article 2

(2) The European Food Safety Authority (EFSA) assessed the information on the safety in use of neotame as a sweetener and flavour enhancer and expressed its opinion of 27 September 2007⁽⁴⁾. On the basis of the proposed uses, it has been considered appropriate to permit the use of this food additive. It is therefore necessary to adopt specifications for this food additive which is allocated E 961 as E number.

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 March 2011 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

(3) It is necessary to take into account the specifications and analytical techniques for additives as set out in the Codex Alimentarius drafted by the Joint Expert Committee on Food Additives (JECFA). In particular, the specific purity

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

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

⁽¹⁾ OJ L 354, 31.12.2008, p. 16.

⁽²⁾ OJ L 158, 18.6.2008, p. 17.

⁽³⁾ OJ L 237, 10.9.1994, p. 3.

⁽⁴⁾ Scientific opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the European Commission on neotame as a sweetener and flavour enhancer. *The EFSA Journal* (2007) 581, 1-43.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 17 June 2010.

For the Commission

The President

José Manuel BARROSO

 ANNEX

In Annex I to Directive 2008/60/EC the following entry E 961 is inserted after the entry E 959:

E 961 — NEOTAME**Synonyms**

N-[N-(3,3-dimethylbutyl)-L- α -aspartyl]-L-phenylalanine 1-methyl ester,
N(3,3-dimethylbutyl)-L-aspartyl-L-phenylalanine methyl ester

Definition

Neotame is manufactured by reaction under hydrogen pressure of aspartame with 3,3-dimethylbutyraldehyde in methanol in presence of a palladium/carbon catalyst. It is isolated and purified by filtration, where diatomaceous earth may be used. After solvent removal via distillation, neotame is washed with water, isolated by centrifugation and finally vacuum dried

CAS No

165450-17-9

Chemical name

N-[N-(3,3-dimethylbutyl)-L- α -aspartyl]-L-phenylalanine 1-methyl ester

Chemical formula

$C_{20}H_{30}N_2O_5$

Molecular weight

378,47

Description

white to off-white powder

Assay

Not less than 97,0 % on the dried basis

Identification

Solubility

4,75 % (w/w) at 60 °C in water, soluble in ethanol and ethyl acetate

Purity

Water content

Not more than 5 % (Karl Fischer, sample size 25 $\pm$ 5 mg)

pH

5,0 – 7,0 (0,5 % aqueous solution)

Melting range

81 °C to 84 °C

N-[(3,3-dimethylbutyl)-L- α -aspartyl]-L-phenylalanine

Not more than 1,5 %

Lead

Not more than 1 mg/kg'
