

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criteria on sweeteners (Text with EEA relevance) (repealed)

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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⁽¹⁾ and in particular Article 30(5) thereof,

After consulting the European Food Safety Authority (EFSA),

Whereas:

- (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⁾.
- (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.
- (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 criteria need to be adapted to reflect the limits for individual heavy metals of interest, where appropriate.
- (4) Directive 2008/60/EC should therefore be amended accordingly.
- (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,

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

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IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.*

Article 2

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.

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*.

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 ₂ O 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 ± 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

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- (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.