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**Information Document on the Commission Directive 2009/163/EU amending  
Directive 94/35/EC of the European Parliament and of the Council on sweeteners  
for use in foodstuffs with regard to neotame**

***Scope***

Directive 94/35/EC of the European Parliament and of the Council of 30 June 1994 on sweeteners for use in foodstuffs lays down a list of sweeteners that may be used in the Union and the conditions for their use.

The European Food Safety Authority (EFSA) evaluated the safety of neotame as a sweetener and flavour enhancer and expressed its opinion of 27 September 2007. After considering all the data on stability, degradation products and toxicology, EFSA concluded that neotame is not of safety concern with respect to the proposed uses as a sweetener and flavour enhancer and established an acceptable daily intake (ADI) of 0–2 mg/kg bw/day. EFSA also noted that conservative estimates of neotame dietary exposure both in adults and children suggest that it is very unlikely that the ADI would be exceeded at the proposed use levels.

Neotame is a highly intense sweetener with a sweetness potency ranging from 7 000 to 13 000 times that of sucrose. It may be used as a replacement for sucrose or other sweeteners in a broad range of products. Neotame can be used alone or with other sweeteners. In addition, neotame can modify the flavour of foods and beverages.

It is necessary to amend the Annex of Directive 94/35/EC to permit the use of neotame in the same food applications as the other currently permitted intense sweeteners. Neotame should be assigned a new E number, namely E 961. In order to facilitate the marketing and use of this new sweetener, it is provided that products which comply with the provisions of this Directive may be marketed from the date of its entry into force.

In accordance with point 34 of the Interinstitutional agreement on better law-making, Member States are encouraged to draw up, for themselves and in the interests of the Union, their own tables, which will, as far as possible, illustrate the correlation between this Directive and the transposition measures, and to make them public.

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

***Sweeteners for use in Foodstuffs (Amendment) Regulations, 2010***

It is proposed to implement the requirements of this Directive as follows:

**1. Amends the Schedule to the principal regulations**

The Commission's website on Food may be found at:

[http://ec.europa.eu/enterprise/food/index\\_en.htm](http://ec.europa.eu/enterprise/food/index_en.htm)

***Who would be interested***

All operators dealing with food. This includes manufacturers, importers, distributors, retailers and catering establishments.

***Comments***

Your comments regarding this consultation document are kindly being requested.

Comments are to reach the Regulatory Affairs Directorate in writing or via email by

**Monday, 8<sup>th</sup> February, 2010**

Should any further information be required kindly contact the *Foodstuffs, Chemicals, Pesticides & Cosmetics Unit* (Regulatory Affairs Directorate) of the Malta Standards Authority using the following contact details:

Malta Standards Authority

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L.N. of 2010

**FOOD SAFETY ACT  
(CAP. 449)**

**Sweeteners for use in Foodstuffs (Amendment) Regulations, 2010**

IN exercise of the powers conferred by article 10 of the Food Safety Act, the Minister for Social Policy has made the following regulations:-

**Citation and commencement**

**L.N. 30 of 2005.**

1. (1) The title of these regulations is the Sweeteners for use in Foodstuffs (Amendment) Regulations, 2010 and they shall be read and construed as one with the Sweeteners for use in Foodstuffs Regulations, 2005, hereinafter referred to as the “principal regulations”.
- (2) These regulations shall enter into force on the 12<sup>th</sup> October, 2010.
- (3) Products which comply with the provisions of these regulations may be marketed from the date of entry into force of these regulations.

**Scope**

2. These regulations implement the provisions of Commission Directive 2009/163/EU amending Directive 94/35/EC of the European Parliament and of the Council on sweeteners for use in foodstuffs with regard to neotame.

**Amends the Schedule to the principal regulations**

3. In the Schedule to the principal regulations immediately after item E 959, there shall be added the following entry for E 961:-

EC No	Name	Foodstuffs	Maximum usable dose
"E 961	Neotame	<b>Non-alcoholic drinks</b>	
		Water-based flavoured drinks, energy-reduced or with no added sugar	20 mg/l
		Milk- and milk-derivative-based or fruit-juice-based drinks, energy-reduced or with no added sugar	20 mg/l
		<b>Desserts and similar products</b>	
		Water-based flavoured desserts, energy-reduced or with no added sugar	32 mg/kg
		Milk- and milk derivative-based preparations, energy-reduced or with no added sugar	32 mg/kg
		Fruit- and vegetable-based desserts, energy-reduced or with no added sugar	32 mg/kg
		Egg-based desserts, energy-reduced or with no added sugar	32 mg/kg
		Cereal-based desserts, energy-reduced or with no added sugar	32 mg/kg
		Fat-based desserts, energy-reduced or with no added sugar	32 mg/kg
		Snacks: certain flavours of ready-to-eat, pre-packed, dry, savoury starch products and coated nuts	18 mg/kg
		<b>Confectionery</b>	
		Confectionery with no added sugar	32 mg/kg
		Cocoa or dried fruit-based confectionery, energy-reduced or with no added sugar	65 mg/kg
		Starch-based confectionery, energy-reduced or with no added sugar	65 mg/kg

	Cornets and wafers, for ice cream, with no added sugar	60 mg/kg
	<i>Essoblaten</i>	60 mg/kg
	Cocoa-, milk-, dried-fruit- or fat-based sandwich spreads, energy-reduced or with no added sugar	32 mg/kg
	Breakfast cereals with a fibre content of more than 15 %, and containing at least 20 % bran, energy-reduced or with no added sugar	32 mg/kg
	Breath-freshening micro-sweets, with no added sugar	200 mg/kg
	Strongly flavoured throat pastilles with no added sugar	65 mg/kg
	Chewing gum with no added sugar	250 mg/kg
	Energy-reduced tablet form confectionery	15 mg/kg
	Cider and perry	20 mg/l
	Drinks consisting of a mixture of a non-alcoholic drink and beer, cider, perry, spirits or wine	20 mg/l
	Spirit drinks containing less than 15 % alcohol by volume	20 mg/l
	Alcohol-free beer or with an alcohol content not exceeding 1,2 % vol.	20 mg/l
	Bière de table/Tafelbier/Table beer (original wort content less than 6 %) except for "Obergäriges Einfachbier"	20 mg/l
	Beers with a minimum acidity of 30 milli-equivalents expressed as NaOH	20 mg/l
	Brown beers of the " <i>oud bruin</i> " type	20 mg/l
	Energy-reduced beer	1 mg/l
	Edible ices, energy-reduced	26 mg/kg

	or with no added sugar	
	Canned or bottled fruit, energy-reduced or with no added sugar	32 mg/kg
	Energy-reduced jams, jellies and marmalades	32 mg/kg
	Energy-reduced fruit and vegetable preparations	32 mg/kg
	Sweet-sour preserves of fruit and vegetables	10 mg/kg
	<i>Feinkostsalat</i>	12 mg/kg
	Sweet-sour preserves and semi-preserves of fish and marinades of fish, crustaceans and molluscs	10 mg/kg
	Energy-reduced soups	5 mg/l
	Sauces	12 mg/kg
	Mustard	12 mg/kg
	Fine bakery products for special nutritional uses	55 mg/kg
	Foods intended for use in energy-restricted diets for weight reduction as referred to in Directive 1996/8/EC	26 mg/kg
	Dietary foods for special medical purposes as defined in Directive 1999/21/EC	32 mg/kg
	Food supplements as defined in Directive 2002/46/EC supplied in a liquid form	20 mg/kg
	Food supplements as defined in Directive 2002/46/EC supplied in a solid form	60 mg/kg
	Food supplements as defined in Directive 2002/46/EC based on vitamins and/or mineral elements and supplied in a syrup-type or chewable form	185 mg/kg
	Table top sweeteners	<i>quantum satis</i> .”.