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## ANNEX

The Annex to Directive 95/31/EC is amended and corrected as follows:

- The following text concerning E 968 erythritol is inserted after E 967 xylitol:

<b>E 968 ERYTHRITOL</b>	
<b>Synonyms</b>	Meso-erythritol, tetrahydroxybutane, erythrite
<b>Definition</b>	Obtained by fermentation of carbohydrate source by safe and suitable food grade osmophilic yeasts such as <i>Moniliella pollinis</i> or <i>Trichosporonoides megachilensis</i> , followed by purification and drying
Chemical name	1,2,3,4-Butanetetrol
Einecs	205-737-3
Chemical formula	C <sub>4</sub> H <sub>10</sub> O <sub>4</sub>
Molecular weight	122,12
Assay	Not less than 99 % after drying
<b>Description</b>	White, odourless, non-hygroscopic, heat-stable crystals with a sweetness of approximately 60-80 % that of sucrose.
<b>Identification</b>	
A. Solubility	Freely soluble in water, slightly soluble in ethanol, insoluble in diethyl ether.
B. Melting range	119-123 °C
<b>Purity</b>	
Loss on drying	Not more than 0,2 % (70 °C, six hours, in a vacuum desiccator)
Sulphated ash	Not more than 0,1 %
Reducing substances	Not more than 0,3 % expressed as D-glucose
Ribitol and glycerol	Not more than 0,1 %
Lead	Not more than 0,5 mg/kg

- The text concerning E 954 saccharin and its Na, K and Ca salts is replaced by the following:

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**E 954 SACCHARIN AND ITS Na, K AND Ca SALTS**


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**(I) SACCHARIN****Definition**


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Chemical name	3-Oxo-2,3-dihydrobenzo(d)isothiazol-1,1-dioxide
Einecs	201-321-0
Chemical formula	C <sub>7</sub> H <sub>5</sub> NO <sub>3</sub> S
Relative molecular mass	183,18
Assay	Not less than 99 % and not more than 101 % of C <sub>7</sub> H <sub>5</sub> NO <sub>3</sub> S on the anhydrous basis
<b>Description</b>	White crystals or a white crystalline powder, odourless or with a faint, aromatic odour, having a sweet taste, even in very dilute solutions. Approximately between 300 and 500 times as sweet as sucrose
<b>Identification</b>	
Solubility	Slightly soluble in water, soluble in basic solutions, sparingly soluble in ethanol
<b>Purity</b>	
Loss on drying	Not more than 1 % (105 °C, two hours)
Melting range	226-230 °C
Sulphated ash	Not more than 0,2 % expressed on dry weight basis
Benzoic and salicylic acid	To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears
o-Toluenesulphonamide	Not more than 10 mg/kg expressed on dry weight basis
p-Toluenesulphonamide	Not more than 10 mg/kg expressed on dry weight basis
Benzoic acid p-sulfonamide	Not more than 25 mg/kg expressed on dry weight basis
Readily carbonisable substances	Absent
Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Selenium	Not more than 30 mg/kg expressed on dry weight basis
Lead	Not more than 1 mg/kg expressed on dry weight basis.
<b>(II) SODIUM SACCHARIN</b>	

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<b>Synonyms</b>	Saccharin, sodium salt of saccharin
<b>Definition</b>	
Chemical name	Sodium o-benzosulphimide, sodium salt of 2,3-dihydro-3-oxobenzisulphonazole, oxobenzisulphonazole, 1,2-benzisothiazolin-3-one-1,1-dioxide sodium salt dihydrate
Einecs	204-886-1
Chemical formula	C <sub>7</sub> H <sub>4</sub> NNaO <sub>3</sub> S·2H <sub>2</sub> O
Relative molecular mass	241,19
Assay	Not less than 99 % and not more than 101 % of C <sub>7</sub> H <sub>4</sub> NNaO <sub>3</sub> S on the anhydrous basis
<b>Description</b>	White crystals or a white crystalline efflorescent powder, odourless or with a faint odour, having an intensely sweet taste, even in very dilute solutions. Approximately between 300 and 500 times as sweet as sucrose in dilute solutions
<b>Identification</b>	
Solubility	Freely soluble in water, sparingly soluble in ethanol
<b>Purity</b>	
Loss on drying	Not more than 15 % (120 °C, four hours)
Benzoic and salicylic acid	To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears
o-Toluenesulphonamide	Not more than 10 mg/kg expressed on dry weight basis
p-Toluenesulphonamide	Not more than 10 mg/kg expressed on dry weight basis
Benzoic acid p-sulphonamide	Not more than 25 mg/kg expressed on dry weight basis
Readily carbonisable substances	Absent
Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Selenium	Not more than 30 mg/kg expressed on dry weight basis

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Lead	Not more than 1 mg/kg expressed on dry weight basis
<b>(III) CALCIUM SACCHARIN</b>	
<b>Synonyms</b>	Saccharin, calcium salt of saccharin
<b>Definition</b>	
Chemical name	Calcium o-benzosulphimide, calcium salt of 2,3-dihydro-3-oxobenzisulfonazole, 1,2-benzisothiazolin-3-one-1,1-dioxide calcium salt hydrate (2:7)
Einecs	229-349-9
Chemical formula	$C_{14}H_8CaN_2O_6S_2 \cdot 3\frac{1}{2}H_2O$
Relative molecular mass	467,48
Assay	Not less than 95 % of $C_{14}H_8CaN_2O_6S_2$ on the anhydrous basis
<b>Description</b>	White crystals or a white crystalline powder, odourless or with a faint odour, having an intensely sweet taste, even in very dilute solutions. Approximately between 300 and 500 times as sweet as sucrose in dilute solutions
<b>Identification</b>	
Solubility	Freely soluble in water, soluble in ethanol
<b>Purity</b>	
Loss on drying	Not more than 13,5 % (120 °C, four hours)
Benzoic and salicylic acid	To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears
o-Toluenesulphonamide	Not more than 10 mg/kg expressed on dry weight basis
p-Toluenesulphonamide	Not more than 10 mg/kg expressed on dry weight basis
Benzoic acid p-sulphonamide	Not more than 25 mg/kg expressed on dry weight basis
Readily carbonisable substances	Absent
Arsenic	Not more than 3 mg/kg expressed on dry weight basis

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Selenium	Not more than 30 mg/kg expressed on dry weight basis
Lead	Not more than 1 mg/kg expressed on dry weight basis
<b>(IV) POTASSIUM SACCHARIN</b>	
<b>Synonyms</b>	Saccharin, potassium salt of saccharin
<b>Definition</b>	
Chemical name	Potassium o-benzosulphimide, potassium salt of 2,3-dihydro-3-oxobenzisulphonazole, potassium salt of 1,2-benzisothiazolin-3-one-1,1-dioxide monohydrate
Einecs	
Chemical formula	$C_7H_4KNO_3S \cdot H_2O$
Relative molecular mass	239,77
Assay	Not less than 99 % and not more than 101 % of $C_7H_4KNO_3S$ on the anhydrous basis
<b>Description</b>	White crystals or a white crystalline powder, odourless or with a faint odour, having an intensely sweet taste, even in very dilute solutions. Approximately between 300 and 500 times as sweet as sucrose
<b>Identification</b>	
Solubility	Freely soluble in water, sparingly soluble in ethanol
<b>Purity</b>	
Loss on drying	Not more than 8 % (120 °C, four hours)
Benzoic and salicylic acid	To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears
o-Toluenesulphonamide	Not more than 10 mg/kg expressed on dry weight basis
p-Toluenesulphonamide	Not more than 10 mg/kg expressed on dry weight basis
Benzoic acid p-sulphonamide	Not more than 25 mg/kg expressed on dry weight basis
Readily carbonisable substances	Absent

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Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Selenium	Not more than 30 mg/kg expressed on dry weight basis
Lead	Not more than 1 mg/kg expressed on dry weight basis

3. The text concerning E 955 sucralose is replaced by the following:

<b>E 955 SUCRALOSE</b>	
<b>Synonyms</b>	4,1',6'-Trichlorogalactosucrose
<b>Definition</b>	
Chemical name	1,6-Dichloro-1,6-dideoxy- $\beta$ -D-fructofuranosyl-4-chloro-4-deoxy- $\alpha$ -D-galactopyranoside
Einecs	259-952-2
Chemical formula	C <sub>12</sub> H <sub>19</sub> Cl <sub>3</sub> O <sub>8</sub>
Molecular weight	397,64
Assay	Content not less than 98 % and not more than 102 % of C <sub>12</sub> H <sub>19</sub> Cl <sub>3</sub> O <sub>8</sub> calculated on an anhydrous basis.
<b>Description</b>	White to off-white, practically odourless crystalline powder.
<b>Identification</b>	
A. Solubility	Freely soluble in water, methanol and ethanol Slightly soluble in ethyl acetate
B. Infrared absorption	The infrared spectrum of a potassium bromide dispersion of the sample exhibits relative maxima at similar wave numbers as those shown in the reference spectrum obtained using a sucralose reference standard
C. Thin layer chromatography	The main spot in the test solution has the same R <sub>f</sub> value as that of the main spot of standard solution A referred to in the test for other chlorinated disaccharides. This standard solution is obtained by dissolving 1,0 g of sucralose reference standard in 10 ml of methanol
D. Specific rotation	$[\alpha]_{D}^{20} = + 84,0^{\circ}$ to $+ 87,5^{\circ}$ calculated on the anhydrous basis (10 % w/v solution)
<b>Purity</b>	

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Water	Not more than 2,0 % (Karl Fischer method)
Sulphated ash	Not more than 0,7 %
Other chlorinated disaccharides	Not more than 0,5 %
Chlorinated monosaccharides	Not more than 0,1 %
Triphenylphosphine oxide	Not more than 150 mg/kg
Methanol	Not more than 0,1 %
Lead	Not more than 1 mg/kg

4. The text concerning E 962 salt of aspartame-acesulfame is replaced by the following:

#### **E 962 SALT OF ASPARTAME-ACESULFAME**

<b>Synonyms</b>	Aspartame-acesulfame, aspartame-acesulfame salt
<b>Definition</b>	The salt is prepared by heating an approximately 2:1 ratio (w/w) of aspartame and acesulfame K in solution at acidic pH and allowing crystallisation to occur. The potassium and moisture are eliminated. The product is more stable than aspartame alone
<b>Chemical name</b>	6-Methyl-1,2,3-oxathiazine-4(3H)-one-2,2-dioxide salt of L-phenylalanyl-2-methyl-L- $\alpha$ -aspartic acid
<b>Chemical formula</b>	C <sub>18</sub> H <sub>23</sub> O <sub>9</sub> N <sub>3</sub> S
<b>Molecular weight</b>	457,46
<b>Assay</b>	63,0 % to 66,0 % aspartame (dry basis) and 34,0 % to 37 % acesulfame (acid form on a dry basis)
<b>Description</b>	A white, odourless, crystalline powder
<b>Identification</b>	
A. Solubility	Sparingly soluble in water, slightly soluble in ethanol
B. Transmittance	The transmittance of a 1 % solution in water determined in a 1 cm cell at 430 nm with a suitable spectrophotometer using water as a reference, is not less than 0,95, equivalent to an absorbance of not more than approximately 0,022
C. Specific rotation	$[\alpha]_{D^{20}} = + 14,5^{\circ}$ to $+ 16,5^{\circ}$ Determine at concentration of 6,2 g in 100 ml formic acid (15N) within 30 min of preparation of the solution. Divide the calculated specific rotation by 0,646 to

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	correct for the aspartame content of the salt of aspartame-acesulfame
<b>Purity</b>	
Loss on drying	Not more than 0,5 % (105 °C, four hours)
5-Benzyl-3,6-dioxo-2-piperazineacetic acid	Not more than 0,5 %
Lead	Not more than 1 mg/kg

5. The text concerning E 965 (i) maltitol is replaced by the following:

<b>E 965 (i) MALTITOL</b>	
<b>Synonyms</b>	D-Maltitol, hydrogenated maltose
<b>Definition</b>	
Chemical name	( $\alpha$ )-D-Glucopyranosyl-1,4-D-glucitol
Einecs	209-567-0
Chemical formula	C <sub>12</sub> H <sub>24</sub> O <sub>11</sub>
Relative molecular mass	344,31
Assay	Content not less than 98 % of D-maltitol C <sub>12</sub> H <sub>24</sub> O <sub>11</sub> on the anhydrous basis
<b>Description</b>	Sweet tasting, white crystalline powder
<b>Identification</b>	
A. Solubility	Very soluble in water, slightly soluble in ethanol
B. Melting range	148 to 151 °C
C. Specific rotation	[ $\alpha$ ] <sub>D</sub> <sup>20</sup> = + 105,5° to + 108,5° (5 % w/v solution)
<b>Purity</b>	
Water	Not more than 1 % (Karl Fischer method)
Sulphated ash	Not more than 0,1 % expressed on dry weight basis
Reducing sugars	Not more than 0,1 % expressed as glucose on dry weight basis
Chlorides	Not more than 50 mg/kg expressed on dry weight basis
Sulphates	Not more than 100 mg/kg expressed on dry weight basis
Nickel	Not more than 2 mg/kg expressed on dry weight basis



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Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Lead	Not more than 1 mg/kg expressed on dry weight basis

6. The text concerning E 965 (ii) maltitol syrup is replaced by the following:

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**E 965 (ii) MALTITOL SYRUP**

<b>Synonyms</b>	Hydrogenated high-maltose glucose syrup, hydrogenated glucose syrup
<b>Definition</b>	A mixture consisting of mainly maltitol with sorbitol and hydrogenated oligo- and polysaccharides. It is manufactured by the catalytic hydrogenation of high maltose-content glucose syrup or by the hydrogenation of its individual components followed by blending. The article of commerce is supplied both as a syrup and as a solid product
<b>Assay</b>	Content not less than 99 % of total hydrogenated saccharides on the anhydrous basis and not less than 50 % of maltitol on the anhydrous basis
<b>Description</b>	Colourless and odourless, clear viscous liquids or white crystalline masses
<b>Identification</b>	
A. Solubility	Very soluble in water, slightly soluble in ethanol
B. Thin layer chromatography	Passes test
<b>Purity</b>	
Water	Not more than 31 % (Karl Fischer)
Reducing sugars	Not more than 0,3 % (as glucose)
Sulphated ash	Not more than 0,1 %
Chlorides	Not more than 50 mg/kg
Sulphate	Not more than 100 mg/kg
Nickel	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg

7. The text concerning E 966 lactitol is replaced by the following:

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**E 966 LACTITOL**

<b>Synonyms</b>	Lactit, lactositol, lactobiosit
<b>Definition</b>	

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Chemical name	4-O-β-D-Galactopyranosyl-D-glucitol
Einecs	209-566-5
Chemical formula	C <sub>12</sub> H <sub>24</sub> O <sub>11</sub>
Relative molecular mass	344,32
Assay	Not less than 95 % on the dry weight basis
<b>Description</b>	Sweet-tasting crystalline powders or colourless solutions. Crystalline products occur in anhydrous, monohydrate and dihydrate forms
<b>Identification</b>	
A. Solubility	Very soluble in water
B. Specific rotation	[α] <sub>D</sub> <sup>20</sup> = + 13° to + 16° calculated on the anhydrous basis (10 % w/v aqueous solution)
<b>Purity</b>	
Water	Crystalline products; not more than 10,5 % (Karl Fischer method)
Other polyols	Not more than 2,5 % on the anhydrous basis
Reducing sugars	Not more than 0,2 % expressed as glucose on dry weight basis
Chlorides	Not more than 100 mg/kg expressed on dry weight basis
Sulphates	Not more than 200 mg/kg expressed on dry weight basis
Sulphated ash	Not more than 0,1 % expressed on dry weight basis
Nickel	Not more than 2 mg/kg expressed on dry weight basis
Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Lead	Not more than 1 mg/kg expressed on dry weight basis