

L.N. 92 of 2008

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

Permitted Food Additives (Amendment) Regulations, 2008

IN exercise of the powers conferred by article 10 of the Food Safety Act, the Minister of Health, the Elderly and Community Care has made the following regulations:—

1. (1) The title of these regulations is the Permitted Food Additives (Amendment) Regulations, 2008, and they shall be read and construed as one with the Permitted Food Additives Regulations, 2005 hereinafter referred to as “the principal regulations”. Citation and commencement.
L.N. 54 of 2005.

(2) These regulations shall enter into force on the 15th February, 2008.

2. (1) Regulations 3 and 4 and 6 to 10 implement the provisions of Directive 2006/52/EC of the European Parliament and of the Council amending Directive 95/2/EC on food additives other than colours and sweeteners and Directive 94/35/EC on sweeteners for use in foodstuffs, of the 5th July, 2006: Scope.

Provided that as from the 15th February 2008, trade in and use of products complying with these regulations shall be permitted and trade in and use products which do not comply with these regulations shall be prohibited; however products placed on the market or labelled before the 15th August, 2008 which do not comply with these regulations may be marketed until stocks are exhausted.

(2) Regulation 5 implements the provisions of Commission Directive 2006/129/EC of 8th December, 2006.

3. Regulation 3.1.3 shall be substituted by the following:

Amends regulation
3 of the principal
regulations.

“*carriers*, including carrier solvents, are substances used to dissolve, dilute, disperse or otherwise physically modify a food additive or flavouring without altering its function (and without exerting any technological effect themselves) in order to facilitate its handling, application or use;”.

Amends regulation
4 of the principal
regulations.

4. In regulation 4.8 of the principal regulations “weaning foods” shall be substituted by “processed cereal-based foods and baby foods”.

Amends regulation
6 of the principal
regulations.

5. Regulation 6.1 of the principal regulations shall be substituted by the following:

“6.1 The additives permitted for use by these regulations must satisfy the purity criteria laid down by Commission Directive 96/77/EC as amended by Directives 98/86/EC, 2000/63/EC, 2001/30/EC, 2002/82/EC, 2003/95/EC, 2004/45/EC and 2006/129/EC. A list of the food additives for which purity criteria have been established is given in the Seventh Schedule ”.

Amends the First
Schedule to the
principal
regulations.

6. The First Schedule to the principal regulations shall be amended as follows:

(a) in the introductory note, the following note is added:

“4. The substances listed under numbers E 400, E 401, E 402, E 403, E 404, E 406, E 407, E 407a, E 410, E 412, E 413, E 414, E 415, E 417, E 418 and E 440 may not be used in jelly mini-cups, defined, for the purpose of these regulations, as jelly confectionery of a firm consistence, contained in semi-rigid mini-cups or mini-capsules, intended to be ingested in a single bite by exerting pressure on the mini-cups or mini-capsule to project the confectionery into the mouth.”; and

(b) in the table, the following row is inserted:

“E 462	Ethyl cellulose;”.
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Amends the Second
Schedule to the
principal
regulations.

7. The Second Schedule to the principal regulations shall be amended as follows:

(a) The row for “ripened cheese” is substituted by the following:

“Ripened cheese	E 170 Calcium carbonate E 504 Magnesium carbonates E 509 Calcium chloride E 575 Glucono-delta-lactone	<i>quantum satis</i>
	E 500ii Sodium hydrogen carbonate	<i>quantum satis (only for sour milk cheese);”;</i>

(b) In the row for “*Pain courant français*” after the words “*Pain courant français*” the following words are added:

“*Friss búzakenyér, fehér és félbarna kenyerek.*”;

(c) In the row for “*Foie gras, foie gras entier, blocs de foie gras*” after the words “*Foie gras, foie gras entier, blocs de foie gras*” the following words are added:

“*Libamáj, libamáj egészben, libamáj tömbben.*”;

8. The Third Schedule to the principal regulations shall be amended and corrected as follows:

Amends the Third Schedule to the principal regulations.

(1) Part A is amended as follows:

(a) in the table “Sorbates, benzoates and p-hydroxybenzoates”, the rows for “E 216 Propyl p-hydroxybenzoate” and “E 217 Sodium propyl p-hydroxybenzoate” are deleted;

(b) the following rows from the table for foodstuffs are deleted:

“Shrimps, cooked				2 000		
Crayfish tails, cooked, and prepacked marinated cooked molluscs	2 000					
Liquid dietary food supplements						2 000;”;

(c) the following rows are added to the table for foodstuffs:

“Crustaceans and molluscs, cooked		1 000		2 000		
Food supplements as defined in L.N. 239 of 2003 supplied in liquid form				2 000		

”;

(d) the words “Dietetic food intended for special medical purposes” are substituted by the words “Dietary foods for special medical purposes as defined in the Dietary Foods for Special Medical Purposes Regulations, 2001”;

L.N. 309 of 2001.

(2) in Part B, the table for foodstuffs is amended as follows:

(a) the row for “crustaceans and cephalopods” is substituted by the following:

“Crustaceans and cephalopods:	
- fresh, frozen and deep-frozen	150 ⁽¹⁾
- crustaceans, <i>Penaeidae</i> , <i>Solenoceridae</i> , <i>Aristaeidae</i> family:	
- up to 80 units	150 ⁽¹⁾
- between 80 and 120 units	200 ⁽¹⁾
- over 120 units	300 ⁽¹⁾
Crustaceans and cephalopods	
- cooked	50 ⁽¹⁾
- cooked crustaceans, <i>Penaeidae</i> , <i>Solenoceridae</i> , <i>Aristaeidae</i> family	
- up to 80 units	135 ⁽¹⁾
- between 80 and 120 units	180 ⁽¹⁾
- over 120 units	270 ⁽¹⁾
⁽¹⁾ in edible parts”;	

(b) the entry “Starches (excluding starches for weaning foods, follow-on formulae and infant formulae)” is substituted by:

“Starches (excluding starches in infant formulae, follow-on formulae and processed cereal-based foods and baby foods).”; and

(c) the following rows are added:

<i>“Salsicha fresca”</i>	450
Table grapes	10
Fresh lychees	10 (measured on edible parts).”; and

(3) in Part C the table for E 249, E 250, E 251 and E 252 is substituted by the following:

“E No	Name	Foodstuff	Maximum amount that may be added during manufacture (expressed as NaNO ₃)	Maximum residual level (exposed as NaNO ₃)
E 249	Potassium nitrite (x)	Meat products	150mg/kg	
E 250	Sodium nitrite (x)	Sterilised meat products (Fo > 3,00) (y)	100mg/kg	
		Traditional immersion cured meat products (1): <i>Wiltshire bacon</i>		
				175mg/kg

		(1.1); <i>Entremeada, entrecosto, chispe, orelheira e cabeça (salgados)</i> <i>Toucinho fumado (1.2);</i> and similar products <i>Wiltshire ham (1.1); and similar products</i>		100mg/kg
		<i>Rohschinken, nassgepökelt (1.6);</i> and similar products		50mg/kg
		<i>Cured tongue (1.3)</i>		50mg/kg
		Traditional dry cured meat products (2):		
		Dry cured bacon (2.1); and similar products		175mg/kg
		Dry cured ham (2.1); <i>Jamón curado, paleta curada, lomo embuchado y cecina (2.2);</i> <i>Presunto, presunto da pá and paio do lombo</i>		100mg/kg

		(2.3); and similar products <i>Rohschinken, trockengepökelt</i> (2.5); and similar products		50mg/kg
		Other traditionally cured meat products (3): <i>Výsočina Selský salám Turistický trvanlivý salám Poličan Herkules Lovecký salám Dunajská klobása Paprikáš</i> (3.5); and similar products <i>Rohschinken, trocken- /nassgepökelt</i> (3.1); and similar products <i>Jellied veal and brisket</i> (3.2)	180mg/kg	50mg/kg
E 251 E 252	Potassium nitrate ⁽¹⁾ Sodium nitrate ⁽²⁾	Non-heat-treated meat products	150mg/kg	
		Traditional immersion cured meat products (1): <i>Kylmäsavustettu poronliha/ Kalltrökt renkött</i> (1.4);	300mg/kg	

		<i>Wiltshire bacon and Wiltshire ham</i> (1.1); <i>Entremeada, entrecosto, chispe, orelheira e cabeça (salgados), Toucinho fumado</i> (1.2); <i>Rohschinken, nassgepökelt</i> (1.6); and similar products	250mg/kg
		<i>Bacon, Filet de bacon</i> (1.5); and similar products <i>Cured tongue</i> (1.3)	250 mg/kg without added E 249 or E 250 10 mg/kg
		Traditional dry cured meat products (2): <i>Dry cured bacon and Dry cured ham</i> (2.1); <i>Jamón curado, paleta curada, lomo embuchado y cecina</i> (2.2); <i>Presunto, presunto da pá and paio do lombo</i> (2.3); <i>Rohschinken, trockengepökelt</i> (2.5); and similar products	250mg/kg
		<i>Jambon sec, jambon sel sec et autres pièces</i>	250 mg/kg without added E 249 or

- (*) When labelled "for food use", nitrite may be sold only in a mixture with salt or a salt substitute.
- (^y) Fo-value 3 is equivalent to 3 minutes heating at 121 °C (reduction of the bacterial load of one billion spores in each 1000 cans to one spore in a thousand cans).
- (^z) Nitrates may be present in some heat-treated meat products resulting from natural conversion of nitrites to nitrates in a low-acid environment.
- 1 Meat products are immersed in curing solution containing nitrites and/or nitrates, salt and other components. The meat products may undergo further treatments e.g. smoking.
 - 1.1 Meat is injected with curing solution followed by immersion curing for 3 to 10 days. The immersion brine solution also includes microbiological starter cultures.
 - 1.2 Immersion cured for 3 to 5 days. Product is not heat-treated and has a high water activity.
 - 1.3 Immersion cured for at least 4 days and pre-cooked.
 - 1.4 Meat is injected with curing solution followed by immersion curing. Curing time is 14 to 21 days followed by maturation in cold-smoke for 4 to 5 weeks.
 - 1.5 Immersion cured for 4 to 5 days at 5 to 7 °C, matured for typically 24 to 40 hours at 22 °C, possibly smoked for 24hrs at 20 to 25 °C and stored for 3 to 6 weeks at 12 to 14 °C.
 - 1.6 Curing time depending on the shape and weight of meat pieces for approximately 2 days/kg followed by stabilisation/maturation.
- 2 Dry curing process involves dry application of curing mixture containing nitrites and/or nitrates, salt and other components to the surface of the meat followed by a period of stabilisation/maturation. The meat products may undergo further treatments e.g. smoking.
 - 2.1 Dry curing followed by maturation for at least 4 days.
 - 2.2 Dry curing with a stabilisation period of at least 10 days and a maturation period of more than 45 days.
 - 2.3 Dry cured for 10 to 15 days followed by a 30 to 45 day stabilisation period and a maturation period of at least 2 months.
 - 2.4 Dry cured for 3 days + 1 day/kg followed by a 1 week post-salting period and an ageing/ripening period of 45 days to 18 months.
 - 2.5 Curing time depending on the shape and weight of meat pieces for approximately 10 to 14 days followed by stabilisation/maturation.
- 3 Immersion and dry cured processes used in combination or where nitrite and/or nitrate is included in a compound product or where the curing solution is injected into the product prior to cooking. The products may undergo further treatments e.g. smoking.
 - 3.1 Dry curing and immersion curing used in combination (without injection of curing solution). Curing time depending on the shape and weight of meat pieces for approximately 14 to 35 days followed by stabilisation/maturation.
 - 3.2 Injection of curing solution followed, after a minimum of 2 days, by cooking in boiling water for up to 3 hours.
 - 3.3 Product has a minimum 4-week maturation period and a water/protein ratio of less than 1,7.
 - 3.4 Maturation period of at least 30 days.
 - 3.5 Dried product cooked to 70 °C followed by 8 to 12 day drying and smoking process. Fermented product subject to 14 to 30 day three-stage fermentation process followed by smoking.

- 3.6 Raw fermented dried sausage without added nitrites. Product is fermented at temperatures in the range of 18 to 22°C or lower (10 to 12 °C) and then has a minimum ageing/ripening period of 3 weeks. Product has a water/protein ratio of less than 1,7.'; and

(4) Part D is amended as follows:

- (a) the Note is substituted by: "The * in the table refers to the proportionality rule: when combinations of gallates, TBHQ, BHA and BHT are used, the individual levels must be reduced proportionally.";
- (b) row E 310 to E 321 and row E 310 to E 320 are substituted by the following:

"E 310	Propyl gallate	Fats and oils for the professional manufacture of heat-treated foodstuffs	200*(gallates, TBHQ and BHA, individually or in combination)
E 311	Octyl gallate	Frying oil and frying fat, excluding olive pomace oil	100*(BHT)
E 312	Dodecyl gallate		
E 319	Tertiary-butyl hydroquinone (TBHQ)	Lard; fish oil; beef, poultry and sheep fat	both expressed on fat
E 320	Butylated hydroxyanisole (BHA)	Cake mixes Cereal-based snack foods Milk powder for vending Machines	200 (gallates, TBHQ and BHA, individually or in combination)

E 321	Butylated hydroxytoluene (BHT)	Dehydrated soups and broths Sauces Dehydrated meat Processed nuts Pre-cooked cereals Seasonings and condiments	expressed on fat 200 (gallates and BHA, individually or in combination) expressed on fat
		Dehydrated potatoes	25 (gallates, TBHQ and BHA, individually or in combination)
		Chewing gum Food supplements as defined in L.N. 239 of 2003	400 (gallates, TBHQ, BHT and BHA, individually or in combination)
		Essential oils	1 000 (gallates, TBHQ and BHA, individually or in combination)
		Flavourings other than essential oils	100 * (gallates, individually or in combination) 200 * (TBHQ and BHA, individually or in combination);"

(c) the following row is added:

"E 586	4-Hexylresorcinol	Fresh, frozen and deep-frozen crustaceans	2 mg/kg as residues in crustacean meat;"
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9. The Fourth Schedule to the principal regulations shall be amended and corrected as follows:

Amends the Fourth
Schedule to the
principal
regulations.

(1) the row for E 385 is substituted by the following:

"E 385	<i>Calcium disodium ethylene diamine tetra-acetate (Calcium disodium EDTA)</i>	<i>Emulsified sauces</i>	<i>75 mg/kg</i>
		<i>Canned and bottled pulses, legumes, mushrooms and artichokes</i>	<i>250 mg/kg</i>
		<i>Canned and bottled crustaceans and molluscs</i>	<i>75 mg/kg</i>
		<i>Canned and bottled fish</i>	<i>75 mg/kg</i>
		<i>Spreadable fats as defined in Annexes B and C to Regulation (EC) No 2991/ 94 (*), having a fat content of 41 % or less</i>	<i>160 mg/kg</i>
		<i>Frozen and deep- frozen Crustaceans</i>	<i>75 mg/kg</i>
		<i>Libamáj, egészben és tömbben</i>	<i>250 mg/kg; "</i>
(*) OJ L 316, 9.12.1994, p. 2;"			

(2) the following row is inserted after the row for E 967:

"E 968	Erythritol	Foodstuffs in general (except drinks and those foodstuffs referred to in regulation 4.3 Frozen and deep-frozen unprocessed fish, crustaceans, molluscs and cephalopods Liqueurs	<i>quantum satis</i> <i>quantum satis</i> <i>quantum satis</i> For purposes other than sweetening;"
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(3) the following row is added:

"E 426	Soybean hemicellulose	Dairy-based drinks intended for retail sale	5 g/l
		Food supplements as defined in L.N. 239 of 2003	1,5 g/l 30 g/l
		Emulsified sauces	10 g/kg
		Pre-packaged fine bakery wares intended for retail sale	10 g/kg
		Pre-packaged ready to eat oriental noodles intended for retail sale	10 g/kg
		Pre-packaged ready to eat rice intended for retail sale	10 g/kg
		Pre-packaged processed potato and rice products (including frozen, deep frozen, chilled and dried processed products) intended for retail sale	10 g/kg
		Dehydrated, concentrated, frozen and deep-frozen egg products Jelly confectionery, except jelly mini-cups	10 g/kg;";

(4) in row E 468 the words “Solid dietary supplements” are substituted by the words “Food supplements as defined in Food Supplements Regulations, 2003 supplied in solid form”; L.N. 239 of 2003.

(5) in row E 338 to E 452 the words “Dietary supplements” are substituted by the words “Food supplements as defined in Food Supplements Regulations, 2003”;

(6) in row E 405, row E 416, row E 432 to E 436, row E 473 and E 474, row E 475, row E 491 to E 495, row E 551 to E 559, and row E 901 to E 904, the words “Dietary food Supplements” are substituted by the words “Food supplements as defined in Food Supplements Regulations, 2003”;

(7) in row E 1201 and E 1202 the words “Dietary food supplements in tablet and coated tablet form” are substituted by the words “Food supplements as defined in Food Supplements Regulations, 2003 in tablet and coated tablet form”;

(8) in row E 405, row E 432 to E 436, row E 473 and E 474, row E 475, row E 477, row E 481 and E 482, row E 491 to E 495 the words “Dietetic food intended for special medical purposes” are substituted by the words “Dietary foods for special medical purposes as defined in “Dietary Foods for Special Medical Purposes Regulations, 2001”;

(9) row E 1505 to E 1520 is substituted by the following:

“E 1505	Triethyl citrate	Flavourings	3 g/kg from all sources in foodstuffs as consumed or as reconstituted according to the instructions of the manufacturer; individually or in combination. In the case of beverages, with the exception of cream liqueurs, the maximum level of E 1520 shall be 1 g/l;
E 1517	Glyceryl diacetate (diacetin)		
E 1518	Glyceryl triacetate		

E 1520	(triacetin) Propan-1,2-diol (propylene glycol)		
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";and

(10) the following rows are added:

"E 1204	Pullulan	Food supplements as defined in L.N. 239 of 2003 in capsule and tablet form	quantum satis
		Breath freshening micro-sweets in the form of films	quantum satis
E 1452	Starch Aluminium Octenyl Succinate	Encapsulated vitamin preparations in food supplements as defined in L.N. 239 of 2003	35 g/kg in food supplement."

Amends the Fifth Schedule to the principal regulations.

10. The Fifth Schedule to the principal regulations shall be amended and corrected as follows:

(a) the following row is inserted after the row for E 967:

"E 968	Erythritol."	
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(b) the following row is inserted after the row for E 466:

"E 462	Ethyl cellulose.	
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"; and

(c) in the third column of the row for E 551 and E 552 the following sentence is added:

"For E 551: in E 171 titanium dioxide and E 172 iron oxides and hydroxides (max. 90 % relative to the pigment) ".

11. The Sixth Schedule to the principal regulations shall be amended as follows:

Amends the Sixth Schedule to the principal regulations.

(a) in the first, second and third paragraph of the introductory note “weaning foods” are substituted by “processed cereal-based foods and baby foods”;

(b) in Part 3, in the title, in row E 170 to E 526, row E 500, E 501 and E 503, row E 338, row E 410 to E 440, row E 1404 to E 1450 and row E 1451 “weaning foods” are substituted by “processed cereal-based foods and baby foods”; and

(c) in Part 4, the following is inserted after row E 472c:

“E 473	Sucrose esters of fatty acids	120 mg/l	Products containing hydrolysed proteins, peptides and amino acids.”.
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