

Translation

NOTIFICATION OF THE MINISTRY OF PUBLIC HEALTH
(NO. 409), B.E. 2562 (2019)
ISSUED UNDER THE FOOD ACT, B.E. 2522 (1979)
RE: ENZYMES USED IN FOOD PRODUCTION*

Whereas it is expedient to prescribe enzymes used in food production as food additives in conformity with the requirements of quality or standards set forth in the General Specification and Considerations for Enzyme Preparations used in Food Processing proposed by the Food and Agriculture Organization's Expert Committee on Food Additives;

By virtue of the provisions of section 5 paragraph one and section 6 (1), (2), (4), (5), (6), (7), (9) and (10) of the Food Act, B.E. 2522 (1979), the Minister of Public Health hereby issues the Notification as follows:

Clause 1. Enzymes used in food production that are food additives shall be specifically controlled food.

Clause 2. In this Notification:

“Enzyme” means protein derived from plants, animals or microorganisms which is used in the production of processed food, such as preparation of raw materials, processing, curing, transportation, or storage. It shall include enzyme preparations and immobilized enzymes.

“Enzyme preparation” means a product consisting of one or more types of enzymes which may contain other materials, such as preservatives, stabilizing agents, diluents or carriers, to preserve or prolong the shelf life of the enzymes. It shall also include immobilized enzymes.

“Immobilized enzyme” means an enzyme which has been made insoluble by a chemical or physical process, such as attaching it on support materials, or enlarging its molecular structure through chemical bonding or without chemical bonding which results in solidification of the enzyme to allow the enzyme to be separated from the production process and be reusable.

* Published in the Government Gazette, Vol. 136, Part 203 d, Special Issue, page 17, dated 15th August B.E. 2562 (2019).

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“Processing aid” means any substance or material which is not used for consumption as a food ingredient but is used in the production of processed food, preparation of raw materials or ingredients of food to fulfil a technological purpose during the processing, and which may result in the non-intentional but unavoidable presence of such substance or derivatives thereof as residues in the final product.

Clause 3. An enzyme used in food production must be derived from plant, animal or microbial sources as listed in the Schedule 1 annexed to this Notification or as specified in the JECFA Combined Compendium of Food Additive Specifications.

In the case where it is not listed under paragraph one, the Food and Drug Administration shall consider granting an approval in accordance with the recommendations of the Food Committee. In this regard, the producer or importer shall also submit a report on safety assessment as well as the detailed information as required by the Schedule 2 annexed to this Notification to assist the consideration.

Clause 4. Enzymes used in food production shall comply with the qualities or standards as follows:

(1) having activity that is not less than 85 percent of the enzyme activity notified;

(2) not detecting any genetically modified microorganism in 1 gram, in case of enzymes obtained from a genetically modified microorganism;

(3) conforming to any quality or standard conditions as follows:

(3.1) conforming to those prescribed in the Combined Compendium of Food Additive Specifications;

(3.2) conforming to those prescribed in the General Specification and Considerations for Enzyme Preparations Used in Food Processing as follows:

(a) detecting not more than 30 coliforms per gram by MPN method;

(b) not detecting any E. coli in 25 grams;

(c) not detecting any Salmonella in 25 grams;

(d) detecting not more than 5 milligrams of lead per kilogram;

(e) not detecting any antibiotic;

(3.3) conforming to those prescribed in the Notification issued by the Food and Drug Administration with consent of the Food Committee.

Clause 5. The use of enzymes in food production shall comply with any of the following conditions:

(1) The conditions of use specified in the Schedule 1 annexed to this Notification or the functional uses specified in the JECFA Combined Compendium of Food Additive Specifications shall be complied.

(2) The conditions of use specified in the Notification of the Ministry of Public Health on food additives or the latest version of the Codex General Standard for Food Additives.

(3) With respect to any use other than (1) and (2), the approval of the Food and Drug Administration granted in accordance with the recommendations of the Food Committee must be obtained. In this regard, the producer or importer must submit the detailed information on necessity as specified in the Schedule 3 annexed to this Notification.

Clause 6. The use of food additives in enzyme preparations or immobilized enzymes shall comply with the criteria set forth in the Schedule 4 annexed to this Notification.

In the case where a food additive not listed under paragraph one is intended to be used, the Food and Drug Administration shall consider granting an approval in accordance with the recommendations of the Food Committee. If there is no requirement of quality or standard existed for the food additive, the producer or importer shall submit a report on safety assessment of such food additive as prescribed by the Notification of the Ministry of Public Health on food additives.

Clause 7. The analytical method shall be in accordance with those prescribed in the Schedule 5 annexed to this Notification.

Clause 8. A person producing or importing for distribution enzymes used in food production must comply with the Notification of the Ministry of Public Health on production practices, production equipment and utensils, and storage of food.

Clause 9. The use of containers for enzymes used in food production shall comply with the Notification of the Ministry of Public Health on food containers.

Clause 10. The labelling of enzymes used in food production shall comply with the Notification of the Ministry of Public Health on food additives.

The labelling of enzyme-processed food shall comply with the Notification of the Ministry of Public Health on labelling of prepackaged food.

Clause 11. A producer or an importer of enzymes used in food production and a producer or an importer of enzyme-processed food who is licensed prior to the date

this Notification comes into force shall duly comply with this Notification within two years from the date this Notification comes into force.

Clause 12. This Notification shall not apply to:

- (1) enzymes used as food ingredients for the purposes of nutrition or other health benefits;
- (2) enzymes used in the production of food additives;
- (3) enzymes occurring naturally from the use of microorganisms during fermentation of food.

Clause 13. This Notification shall come into force as from the day following the date of its publication in the Government Gazette.

Given on the 9th day of July B.E. 2562 (2019)

Piyasakol Sakolsatayadorn

Minister of Public Health

Schedule 1

Annexed to the Notification of The Ministry of Public Health (No. 409), B.E. 2562 (2019) Issued under the Food Act, B.E. 2522 (1979)

Re: Enzymes Used in Food Production

List of Names of Enzymes Used in Food Production

No.	Code	Name of Enzyme	Source of Enzyme	Condition of Use	Maximum Use Level
1	EC 1.1.3.4	Glucose oxidase or β -D-Glucose: oxygen 1-oxidoreductase	<i>Aspergillus oryzae</i> BECH 2 containing gene from <i>Aspergillus niger</i>	Processing aid for catalyzing the oxidation of glucose sugars to yield hydrogen peroxide and gluconolactone in the production process of bakery products and baked goods	GMP
2	EC 1.1.3.4 and EC 1.11.1.6	Glucose oxidase and catalase	<i>Aspergillus niger</i> , var.	(1) Oxidation inhibitor (2) Processing aid for catalyzing the oxidation of glucose sugars in food products containing milk and eggs, e.g., cheese, beverages, and salad dressings	GMP
3	EC 1.1.3.5	Hexose oxidase or HOX	<i>Hansenula polymorpha</i> containing gene from <i>Chondrus crispus</i>	Processing aid catalyzing the oxidation of hexoses in food production, such as: (1) production of bread dough to strengthen the gluten network (2) production of shredded cheese, potato chips, egg white powder and whey protein isolates to minimize Maillard reactions	GMP

No.	Code	Name of Enzyme	Source of Enzyme	Condition of Use	Maximum Use Level
				(3) production of cottage cheese and tofu to facilitate curd formation (4) production of ketchup, mayonnaise, and salad dressings to scavenge oxygen	
4	EC 1.10.3.2	Laccase, urishiol oxidase, or p-diphenol oxidase	<i>Aspergillus oryzae</i> containing gene from <i>Myceliophthora thermophile</i>	Processing aid for preventing off-flavors from the reaction between oxygen and fatty acids, amino acids, proteins, or alcohols during a beer production process	GMP
5	EC 1.11.1.6	Catalase or hydrogen-peroxide oxidoreductase	Bovine liver	Processing aid in the production of food containing milk and eggs as raw materials, e.g., certain cheese, salad dressings, as well as beverages, to get rid of hydrogen peroxide	GMP
			<i>Micrococcus lysodeicticus</i>		
6	EC 2.3.2.13	Transglutaminase or protein-glutamine γ -glutamyltransferase	<i>Streptoverticillium mobaraense</i> var.	Processing aid in the production of food of which raw materials contain protein, such as: (1) minced cooked meat products and fishery products, e.g., meatballs and sausages (2) products containing milk as raw materials, e.g., yogurt, cheese, and milk ice cream	GMP

No.	Code	Name of Enzyme	Source of Enzyme	Condition of Use	Maximum Use Level
				(3) food products containing wheat dough as ingredients, e.g., pasta, wonton wrappers, egg noodles, as well as baked goods with wheat dough (4) food products containing soybeans as ingredients, e.g., tofu, soy proteins, and texturized vegetable proteins	
7	EC 2.4.1.18	Branching glucosyltransferase, 1,4- α -glucan branching enzyme, or branching glycosyltransferase	<i>Bacillus subtilis</i> containing gene from <i>Rhodothermus obamensis</i>	(1) flour treatment agent (2) Processing aid to obtain modified starch with improved functional properties	GMP
8	EC 3.1.1.3	Lipase, or triglycerin lipase, tributyrase, glycerol ester hydrolase, tributyrinase, triacylglycerol ester hydrolase, or triacylglycerol acylhydrolase	(1) Forestomach of calves and lambs (2) Edible animal pancreatic tissues	(1) Flavoring agent (2) Processing aid for breaking apart triglycerides or fatty acid esters in the production of cheese or for improving quality of fat	GMP
			<i>Ogataea polymorpha</i> containing gene from <i>Fusarium heterosporum</i>	Processing aid for catalyzing the breaking of ester bonds of triglycerides, lipids, or fatty acids in food products, e.g., bakery products, pasta, noodles, or food products containing egg yolk as raw material, as well as in oil degumming	GMP
			<i>Candida cylindrace</i>	Processing aid for hydrolyzing ester bonds of triacylglycerol molecules	GMP

No.	Code	Name of Enzyme	Source of Enzyme	Condition of Use	Maximum Use Level
				to obtain monoglycerides, diglycerides or glycerol and free fatty acids in bakery food products or other food products containing milk as raw material, as well as modification of fat and oil	
9	EC 3.1.1.4	Phospholipase A2 or phosphatidylcholine-2-acylhydrolase	<i>Streptomyces violaceoruber</i> AS-10 containing gene from <i>S. violaceoruber</i> IFO 15146	Processing aid for strengthening the properties of emulsifier of phospholipids or lecithins in food products, such as bakery products, emulsified sauce products, e.g., mayonnaise, salad dressing, and cream that do not contain egg yolks or soybeans	GMP
10	Pectinase, i.e.:				
	EC 3.1.1.11	(1) Pectin esterase or pectin methylesterase	<i>Aspergillus niger</i> , var.	Processing aid for breaking apart pectin to yield oligosaccharides in the production of food or beverages containing pectin, e.g., fruit juice or wine	GMP
	EC 3.2.1.15	(2) Polygalacturonase			
	EC 4.2.2.10	(3) Pectin lyase or pectin depolymerase			
11	EC 3.1.1.32	Phospholipase A1	<i>Aspergillus oryzae</i> containing gene from <i>Fusarium venenatum</i>	Processing aid for breaking down sn-1 ester bond of iacylphospholipids to form 2-acyl-1-lysophospholipids and free fatty acids to reduce the loss of fat and milk solids which are ingredients in the production of cheese	GMP

No.	Code	Name of Enzyme	Source of Enzyme	Condition of Use	Maximum Use Level
12	EC 3.1.3.8	Phytase or 3-phytase	<i>Aspergillus niger</i> containing gene from <i>A. Niger</i>	Processing aid for breaking apart myo-inositol hexakisphosphate (phytate) to give inositol pentaphosphate (IP5) and further to give a mixture of myo-inositol diphosphate (IP2), myo-inositol monophosphate (IP1) and free orthophosphate, to degrade phytate in food products containing cereal grains and legumes	GMP
13	EC 3.1.4.3	Phospholipase C, lecithinase C, lipophosphodiesterase C, or phosphatidase C	<i>Pichia pastoris</i> containing phospholipase C gene	Processing aid for breaking down phosphodiester bonds at the sn-3 position in glycerophospholipids including phosphatidyl-choline, phosphatidylethanolamine, and phosphatidylserine to yield 1,2-diacylglycerol and phosphate esters, in refining vegetable oils	GMP
14	EC 3.1.26.5	Ribonuclease P or RNase P	<i>Penicillium citrinum</i>	Processing aid for hydrolyzing phosphodiester linkages of RNA (ribonucleic acid) to yield 5'monophosphate nucleotides, in the production of yeast extracts	GMP
15	EC 3.2.1.1	Carbohydrase, diastase, ptyalin, or glycogenase	<i>Bacillus licheniformis</i>	(1) Flour treatment agent (2) Processing aid for breaking apart polysaccharides in the production process of food or beverages	GMP

No.	Code	Name of Enzyme	Source of Enzyme	Condition of Use	Maximum Use Level
				containing cereals, starch, vegetables, and fruits, e.g., vegetable juice, fruit juice, sugar, honey, confectioneries, candies, and bakery products	
16	EC 3.2.1.1	Alpha-amylase, diastase, ptyalin, or glycogenase	<i>Aspergillus oryzae, var.</i> <i>Bacillus subtilis</i> containing gene from <i>Bacillus megaterium</i> <i>Bacillus stearothermophilus</i> <i>Bacillus subtilis</i> containing gene from <i>Bacillus stearothermophilus</i> <i>Bacillus subtilis</i> <i>Bacillus licheniformis</i> <i>Bacillus amyloliquefaciens</i>	(1) Flour treatment agent (2) Processing aid for breaking apart polysaccharides in food products containing polysaccharides or starch, e.g., syrup, baked goods, alcoholic beverages, and beer	GMP
17	EC 3.2.1.1	Alpha-amylase (thermostable)	<i>Bacillus licheniformis</i> containing gene from <i>B. licheniformis</i>	Processing aid for breaking apart starch molecules in food products of which raw materials contain starch, e.g., syrup, ethanol, alcoholic beverages, and beer	GMP
18	EC 3.2.1.1	Alpha-amylase and glucoamylase	<i>Aspergillus oryzae, var.</i>	(1) Flour treatment agent (2) Processing aid for breaking apart starch molecules in the production of food containing cereals, flour, and vegetables as raw materials, e.g., beverages, sugar, confectioneries, candies,	GMP

No.	Code	Name of Enzyme	Source of Enzyme	Condition of Use	Maximum Use Level
				sweets, bakery products, and honey	
19	Carbohydrase, i.e.:				
	EC 3.2.1.1	(1) Alpha-amylase or glycogenase	<i>Rhizopus oryzae, var.</i>	Processing aid in the production of food or beverages of which raw materials contain starch, glycogen, or pectin, e.g., fruit juice, syrup, and sugar	GMP
	EC 3.2.1.15	(2) Pectinase			
EC 3.2.1.3	(3) Glucoamylase, amyloglucosidase, or glucan 1,4-alpha-glucosidase				
20	Malt carbohydrase or malt, i.e.:				
	EC 3.2.1.1	(1) Alpha-amylase, glycogenase, or diastase	Malt obtained from the germination of barley	Processing aid for catalyzing the breaking of starch or glycogen in the production of food and beverages of which raw materials contain starch or glycogen, e.g., beer, baked goods, alcoholic beverages, or syrup	GMP
EC 3.2.1.2	(2) β -amylase, glycogenase, or diastase				
21	Mixed microbial carbohydrase and protease, i.e.:				
	EC 3.2.1.1	(1) Alpha-amylase	<i>Bacillus subtilis, var.</i>	Processing aid in the production of food or beverages, such as the production of syrup from starch, alcoholic beverages, beer, glucose, bakery products, fish products, meat products, and protein hydrolysates to catalyze: (1) the breaking apart of polysaccharides to yield dextrins and oligosaccharides	GMP
	EC 3.4.21.14	(2) Microbial serine proteinase	<i>Bacillus amyloliquefaciens</i>		
EC 3.4.24.4	(3) Microbial metalloproteinases				

No.	Code	Name of Enzyme	Source of Enzyme	Condition of Use	Maximum Use Level
				(2) the breaking apart of polypeptides to yield peptides of lower molecular weight	
22	EC 3.2.1.3	Glucoamylase, amyloglucosidase, γ -amylase, lysosomal α -glucosidase, acid maltase, exo-1,4- α -glucosidase, glucose amylase, γ -1,4-glucan glucohydrolase, acid maltase, or 1,4- α -D-glucan	<i>Aspergillus niger, var.</i> <i>Trichoderma reesei</i> containing gene from <i>Trichoderma reesei</i> <i>Aspergillus niger</i> <i>Aspergillus oryzae</i> <i>Aspergillus niger</i> C40-1 containing <i>Aspergillus niger</i> CBS 120.49	Processing aid for breaking apart polysaccharides in food products of which raw materials contain polysaccharides or starch, e.g., syrup, corn syrup, dextrose, fruit juice, baked goods, alcoholic beverages, or beer	GMP
23	Cellulase, i.e.:				
	EC 3.2.1.4	(1) Cellulase or endo-1,4-beta-glucanase	<i>Penicillium funiculosum</i>	Processing aid in the production of food or beverages of which raw materials contain cellulose polysaccharides, e.g., fruit juices, alcoholic beverages, wine, beer, vegetable oils, malt extract products from barley, or wheat products	GMP
	EC 3.2.1.6	(2) Endo-1,3(4)-beta-glucanase			
	EC 3.2.1.8	(3) Endo-1,4-beta-xylanase			
24	Cellulase, i.e.:				
	EC 3.2.1.4	(1) Cellulase or endo-1,4- β -glucanase	<i>Trichoderma longibrachiatum</i>	Processing aid in the production of food or beverages of which raw materials contain cellulose polysaccharides, e.g., fruit juices, alcoholic beverages, wine, beer, vegetable oils, malt extract products from barley, or wheat products	GMP
	EC 3.2.1.74	(2) Exo-1,4- β -D-glucosidase or glucan-1,4- β -glucosidase			
	EC 3.2.1.91	(3) Exocellobiohydrolase or cellulose 1,4- β -cellobiosidase	<i>Trichoderma reesei</i>		
	EC 3.2.1.6	(4) β -glucanase			

No.	Code	Name of Enzyme	Source of Enzyme	Condition of Use	Maximum Use Level
25	EC 3.2.1.6	Beta-Glucanase or endo-1,3- β -glucanase	<i>Aspergillus niger, var.</i>	Processing aid for breaking apart glucans which are polysaccharides of glucose, in the production of food or beverages, e.g., fruit juices, beer, or cheese	GMP
26	Beta-Glucanase, i.e.:				
	EC 3.2.1.6	(1) Endo-1,3-beta-glucanase	<i>Trichoderma harzianum</i>	Processing aid for breaking apart glucans which are polysaccharides of glucose, in the production of food or beverages, e.g., fruit juices, beer, or cheese	GMP
EC 3.2.1.58	(2) Exo-1,3-beta-glucanase				
27	Mixed β -glucanase, cellulase, and xylanase, i.e.:				
	EC 3.2.1.6	(1) β -glucanase	<i>Rasamsonia emersonii</i>	Processing aid for catalyzing the degradation of β -D glucans, cellulose, lichenin, and xylans which are components of cell walls of grains, rice, vegetables, and fruits, in the production of food or beverages, e.g., the processing of rice grains, and the production of alcoholic beverages or beer	GMP
	EC 3.2.1.4	(2) Cellulase			
EC 3.2.1.8	(3) Xylanase				
28	Mixed xylanase, β -glucanase, or mixed β -glucanase and xylanase, i.e.:				
	EC 3.2.1.6	(1) Beta-glucanase	<i>Hunicola insolens</i>	Processing aid for catalyzing the hydrolysis of beta-glucans or xylans contained in cell walls of rice grains, grains, vegetables, and fruits, or pentosans and other gums in the	GMP
EC 3.2.1.8	(2) Xylanase	<i>Disporotrichum dimorphosporum</i>			

No.	Code	Name of Enzyme	Source of Enzyme	Condition of Use	Maximum Use Level
				production of food and alcoholic beverages, e.g., beer, and the fermentation of other food	
29	EC 3.2.1.8	Xylanase, beta-1,4-Dxylan xylanohydrolase, endo-1,4-beta-xylanase, beta-D xylanase, or beta-xylanase	<i>Bacillus subtilis</i> containing gene from <i>Bacillus subtilis</i> <i>Fusarium venenatum</i> containing gene from <i>Thermomyces lanuginosus</i>	Processing aid for catalyzing the breaking of xylosidic linkages of arabinoxylans to yield small oligosaccharides to increase dough stability of baked goods	GMP
30	Hemicellulase, i.e.:				
	EC 3.2.1.8	(1) Endo-1,4-beta-xylanase	<i>Aspergillus niger, var.</i>	Processing aid for catalyzing the hydrolysis of hemicelluloses which are components of plant cell walls in the production of food, e.g., instant coffee, bread, including baked goods	GMP
	EC 3.2.1.37	(2) Xylan 1,4-beta-xylosidase			
	EC 3.2.1.55	(3) Alpha-L-Arabinofuranosidase			
	EC 3.2.1.4	(4) Cellulase			
	-	(5) Galactomannanase			
31	EC 3.2.1.20	Alpha-glucosidase or Alpha-D-glucoside glucohydrolase	<i>Aspergillus niger</i>	Processing aid for breaking apart polysaccharides in food products of which raw materials contain polysaccharides, e.g., sugar, syrup, including oligosaccharides and sweeteners	GMP
32	EC 3.2.1.23	Lactase, beta-galactosidase, or β -D-galatoside galactohydrolase	<i>Kluyveromyces lactis</i>	Processing aid for breaking apart lactose in food products containing milk as raw materials	GMP
33	EC 3.2.1.26	Invertase, carbohydrase, or saccharase	<i>Saccharomyces cerevisiae</i>	Processing aid for breaking apart sucrose to yield glucose and fructose in the production of food	GMP

No.	Code	Name of Enzyme	Source of Enzyme	Condition of Use	Maximum Use Level
				containing sugar, e.g., candies, sweets, chocolate, including pastries	
34	Carbohydrase, i.e.:				
	EC 3.2.1.26	(1) β -fructofuranosidase, invertase, or saccharase	<i>Saccharomyces species</i>	Processing aid in the production of food of which raw materials contain sucrose sugar or lactose sugar, e.g., ice cream, candies, or food products containing milk as raw materials	GMP
EC 3.2.1.23	(2) β -galactosidase or lactase				
35	EC 3.2.1.41	Pullulanase, pullulan α -1,6-glucanohydrolase, amylopectin 6-glucanohydrolase, bacterial debranching enzyme, α -dextrin endo-1,6-glucosidase, debranching enzyme, or R-enzyme	<i>Bacillus subtilis</i> A164 containing gene from <i>Bacillus deramificans</i> LMGP 13056	Processing aid for catalyzing the hydrolysis of starch in the production of food, e.g., maltotriose, high fructose corn syrup, including the brewing of alcoholic beverages and beer	GMP
			<i>Bacillus licheniformis</i> containing gene from <i>Bacillus deramificans</i>		
36	EC 3.2.1.60	Maltotetrahydrolase, exo-maltotetrahydrolase, or 1,4-alpha-D-glucan maltotetrahydrolase	<i>Bacillus licheniformis</i> containing gene from <i>Pseudomonas stutzeri</i>	Processing aid for catalyzing the breaking of starch in the production of food of which raw materials contain starch, e.g., baked goods	GMP
37	EC 3.2.1.68	Isoamylase, debranching enzyme, or α -1,6-glucan hydrolase	<i>Pseudomonas anmyloderamosa</i>	Processing aid for breaking apart glycogen, amylopectin, and dextrans in food products containing starch	GMP
38	EC 3.2.1.133	Maltogenic amylase	<i>Bacillus subtilis</i> containing gene from <i>Bacillus stearothermophilus</i>	Processing aid for catalyzing the breaking of amylose, amylopectin, or other glucose polymers in the production of food containing	GMP

No.	Code	Name of Enzyme	Source of Enzyme	Condition of Use	Maximum Use Level
				starch or sugar, e.g., high maltose glucose syrup or baked goods	
39	Protease, i.e.:				
	EC 3.4.11	(1) Aminopeptidases	<i>Aspergillus oryzae</i> , var.	(1) Flavoring agent (2) Flour treatment agent (3) Stabilizing agent (4) Processing aid in the production of food, e.g., meat and fish products, beverages, broths and soup, or bakery products, including food products containing milk as ingredients	GMP
	EC 3.4.21	(2) Serine endopeptidases			
	EC 3.4.23	(3) Aspartic endopeptidases			
40	EC 3.4.21.1	Serine protease with chymotrypsin specificity, chymotrypsins A and B, α -chymar ophth, chymar ophth, avazyme, chymar, chymotest, enzeon, quimar, quimotrase, α -chymar, α -chymotrypsin A, or α -chymotrypsin	<i>Bacillus Licheniformis</i> with gene from <i>Nocardiopsis prasina</i>	Processing aid for breaking apart protein like casein, whey, soy protein isolate, soy protein concentrate, wheat gluten or corn gluten in the production of partially or extensively hydrolyzed proteins of vegetable or animal origin.	GMP
41	EC 3.4.21.4	Trypsin, serine protease with trypsin specificity, α -trypsin, β -trypsin, cocoonase, parenzyme, parenzymol, tryptar, trypure, pseudotrypsin, tryptase, tripcellim, or sperm receptor hydrolase	<i>Fusarium venenatum</i> with gene from <i>Fusarium oxysporum</i>	Processing aid in the production of hydrolyzed proteins of vegetable and animal origin	GMP
			extracts from porcine or bovine pancreas	Processing aid for breaking apart polypeptides, amides, and esters to yield peptides of lower molecular weight, in the production of food,	GMP

No.	Code	Name of Enzyme	Source of Enzyme	Condition of Use	Maximum Use Level
				e.g., baked goods, meat products, and protein hydrolysates	
42	EC 3.4.21.62	Protease or subtilisin	<i>Bacillus licheniformis</i>	Processing aid for catalyzing the hydrolysis of proteins to yield peptides of shorter length or amino acids in the production of food, e.g., protein extracts from meat or fishery products, soup products, sauce, and similar products, or protein products other than soy protein	GMP
43	Papain, INS 1101 (ii), i.e.:				
	EC 3.4.22.2	(1) Papain, papaya peptidase I, or cysteine proteinase	Fruit of papaya (<i>Carica papaya</i> (L)) (Fam. <i>Caricaceae</i>)	(1) Flavoring agent (2) Processing aid for catalyzing the breaking of polypeptides, amides, esters, leucine, or glycine to yield peptides of lower molecular weight, in the production of food or beverages, e.g., beer, food products containing meat as raw materials, precooked cereals, and protein hydrolysates	GMP
	EC 3.4.22.6	(2) Chymopapain or cysteine proteinase			
44	EC 3.4.22.3	Ficin	Latex of tropical fig trees (<i>Ficus</i> sp.)	Processing aid for breaking apart polypeptides in the production of food of which raw materials contain	GMP

No.	Code	Name of Enzyme	Source of Enzyme	Condition of Use	Maximum Use Level
				protein, e.g., meat products, beverages, and bakery products	
45	EC 3.4.22.4 including EC 3.4.22.32 and EC 3.4.22.33	Bromelain	<i>Ananas comosus</i>	(1) Flavoring agent, flour treatment agent, or stabilizing agent	GMP
			<i>Ananas bracteatus</i> (L)	(2) Processing aid for breaking apart polypeptides, amides, and esters in the food of which raw materials contain protein, e.g., meat products, precooked cereals, or protein hydrolysates, including beer	
46	EC 3.4.2.1	Avian pepsin	Forestomach (proventriculus) of chicken or turkey	Processing aid for breaking apart polypeptides to yield peptides of lower molecular weight, and clotting of milk in cheese making	GMP
47	Pepsin, i.e.:				
	EC 3.4.23.1	(1) Pepsin A	Porcine stomach	Processing aid for breaking apart polypeptides including linkages adjacent to aromatic or L-leucine residues to yield peptides of lower molecular weight, in the production of food of which raw materials contain protein, e.g., cheese, fish products, or protein hydrolysates	GMP
	EC 3.4.23.2	(2) Pepsin B			
EC 3.4.23.3	(3) Pepsin C				
48	EC 3.4.23.4	Chymosin A, rennin, milk-clotting enzyme, chymosin, chymosin A, or aspartyl protease	<i>Escherichia coli</i> K-12 containing prochymosin A gene	Processing aid for breaking apart milk casein into smaller molecules	GMP

No.	Code	Name of Enzyme	Source of Enzyme	Condition of Use	Maximum Use Level
				in clotting of milk for cheese production	
49	EC 3.4.23.4	Chymosin B, rennin, milk-clotting enzyme, chymosin, chymosin B, or aspartyl protease	<i>Aspergillus niger var. awamori</i> containing prochymosin B gene <i>Kluyveromyces lactis</i> containing prochymosin B gene	Processing aid for breaking apart milk casein into smaller molecules in clotting of milk for cheese production	GMP
50	EC 3.4.23.4 including EC 3.4.23.6 and EC 3.4.23.23	Rennet	Gastric extracts made from the fourth stomach of calf, kid, or lamb <i>Rhizomucor</i> species	Processing aid in the production of cheese	GMP
51	EC 3.4.24.27	Thermolysin protease, <i>Bacillus thermoproteolyticus</i> neutral proteinase, thermoase, thermoase Y10, or TLN	<i>Geobacillus stearothermophilus</i>	Processing aid for catalyzing the breaking down of peptide bonds of proteins to yield smaller amino acids, i.e., the production of yeast extracts or protein concentrate, to use as flavoring agent in food, e.g., condiments, ready-to-eat soup, or soy sauce	GMP
52	EC 3.5.1.1	Asparaginase, L-asparaginase, or α -asparaginase	<i>Aspergillus niger</i> containing gene from <i>Aspergillus niger</i> <i>Aspergillus oryzae</i> containing gene from <i>Aspergillus oryzae</i>	Processing aid to reduce the formation of acrylamide from the reaction between asparagine and reducing sugars during baking or frying	GMP
53	EC 3.5.1.2	Glutaminase or L-glutamine aminohydrolase	<i>Bacillus amyloliquefaciens</i>	Processing aid for breaking apart L-glutamine in the production of flavoring agents or condiments	GMP

No.	Code	Name of Enzyme	Source of Enzyme	Condition of Use	Maximum Use Level
54	EC 3.5.1.44	Protein-glutaminase or protein-L-glutamine amidohydrolase	<i>Chryseobacterium proteolyticum</i> strain 9670	Processing aid in the production of food of which raw materials contain protein, e.g., milk products, meat products, fish products, as well as bakery products, pasta, noodle, cereal products, seasoning products from yeast, or food products that are not ingredients	GMP
55	EC 3.5.4.6	AMP deaminase or AMP aminohydrolase	<i>Aspergillus melleus</i>	Processing aid in the production of yeast extract	GMP
56	EC 4.1.1.5	Alpha-acetolactate decarboxylase	<i>Bacillus subtilis</i> containing gene from <i>Bacillus brevis</i>	Processing aid in the production of beer or alcoholic beverages	GMP
58	EC 5.3.1.5	Glucose isomerase, xylose isomerase, or D-xylose aldose-ketoseisomerase	<i>Actinoplanes missouriensis</i> <i>Bacillus coagulans</i> <i>Streptomyces olivaceus</i> <i>Streptomyces olivochromogen</i> <i>Streptomyces rubiginosus</i> <i>Streptomyces violaceoniger</i> <i>Streptomyces rubiginosus</i> containing gene from <i>S. rubiginosus</i> <i>Streptomyces murinus</i> DSM 3252	Processing aid in the production of food of which raw materials contain starch, e.g., high fructose corn syrup and other fructose syrups	GMP

Schedule 2

Annexed to the Notification of The Ministry of Public Health (No. 409), B.E. 2562 (2019)

Issued under the Food Act, B.E. 2522 (1979)

Re: Enzymes Used in Food Production

List of Information or Evidence on Safety Assessment Considerations

No.	Information	Description
1	Information on characteristics of enzyme	
1.1	Name and group of enzymes	Identify the chemical name, common name, trade name, synonym, and acronym.
1.2	Enzyme code under universal system	For example, EC Number, IUBMB number, INS number, or CAS number (if any)
1.3	Components of enzyme structure	In case of an enzyme derived from an organism that does not have any historical use in food-based application or a genetically modified organism, the following detailed information shall be provided: (1) Molecular mass; (2) Subunit structure; (3) Amino acid sequence.
1.4	Impurities that may occur during the production process	Describe the result of analysis of contaminants, e.g., heavy metals, mycotoxins, which may occur during the production process, and identify the methods for preventing or removing the contaminants, including the methodology for analyzing such contaminants.
1.5	Properties of enzyme	Describe the details related to: (1) Active principles, enzymatic properties to substrate, e.g., bonds or position of the substrate that will be digested by the enzyme, reaction and yields, and required cofactors; (2) Suitable conditions for enzymatic activities; (3) Subsidiary or side activities resulting from enzymatic activity, and method for detecting such subsidiary activities (if any).
1.6	Reactions and fate of enzyme in food	Describe the reaction that occurs when using the enzyme in the food production process, the reaction between the enzyme and substances in the food during the process of production, cooking or preparation of food, and the method for removing, eliminating, or inactivating the enzyme.
1.7	Analytical method of enzyme activity	Describe the enzyme analytical method which is standard and universally recognized by referring to that specified in the Combined Compendium of Food Additive Specification or Food Chemical Codex. Such assay must have the following characteristics:

No.	Information	Description
		(1) Specificity; (2) Limit of detection or limit of quantitation (LOD or LOQ); (3) Accuracy; (4) Precision. In the case where the analytical method does not conform to the specification, a document describing the analytical method together with the certification of equivalency must be attached.
1.8	Standard quality specifications of enzyme determined by the producer	Standard quality specifications should be consistent with those specified in the General Specifications and Considerations for Enzyme Preparations Used in Food Processing, and must at least consist of the following information: (1) Enzyme nomenclature and source; (2) Active component; (3) Physical description; (4) Activity of enzyme and unit of measurement; (5) conditions of use, including recommended method of application; (6) Limits of contaminants; (7) Packaging and storage.
2	Source of enzyme and production process	
2.1	Source of enzyme:	Identify production organism or donor organism, as the case may be;
	(1) In cases of enzymes from animal sources	Identify the scientific name, as well as parts of the animal from which the enzyme is extracted.
	(2) In cases of enzymes from plant sources	Identify the plant's scientific name, as well as parts of the plant from which the enzyme is extracted.
	(3) In cases of enzymes from microbial sources	Identify the species and strain, and specific details of the strain of microorganism, such as data relating to toxigenicity, pathogenicity, edibility, production of antimicrobials, as well as the method for preserving type cultures and for preventing the mutation of type cultures used in each lot of production.
	(4) In cases of enzyme from genetically modified microorganism	The following detailed information must be provided: 1. Details of the genetically modified microorganism, i.e.: 1.1 Type of the genetically modified microorganism (bacteria, yeast, or filamentous fungi); 1.2 Strain of the genetically modified microorganism; 1.3 Nature of genetic modification; 1.4 Purpose of genetic modification;

No.	Information	Description
		<p>1.5 Risk of the genetically modified microorganism.</p> <p>2. Details of the recipient/host microorganism</p> <p>2.1 Scientific name;</p> <p>2.2 Common name (if any);</p> <p>2.3 Taxonomic classification;</p> <p>2.4 Accession number or details identified with the culture repository;</p> <p>2.5 History of use, cultivation, strain development, and traits that may adversely impact human health;</p> <p>2.6 Genotypes and phenotypes relevant to its safety (The data should cover the microbial strains that are close or related to the recipient microorganism):</p> <p>2.6.1 Toxigenicity;</p> <p>2.6.2 Production of antibiotics;</p> <p>2.6.3 Resistance to antibiotics;</p> <p>2.6.4 Pathogenicity to healthy humans or animals;</p> <p>2.6.5 Immunological impacts;</p> <p>2.6.6 Genetic stability of the recipient microorganism.</p> <p>3. Details of the donor microorganism</p> <p>3.1 In the case where an organism is the donor, the following shall be identified:</p> <p>3.1.1 Scientific name;</p> <p>3.1.2 Common name (if any);</p> <p>3.1.3 Taxonomic classification;</p> <p>3.1.4 Accession number or entry identified with the culture repository;</p> <p>3.1.5 Information on food safety;</p> <p>3.1.6 Genotypes and phenotypes relating to safety:</p> <ul style="list-style-type: none"> - Toxigenicity; - Production of antibiotics; - Resistance to antibiotics; - Pathogenicity to healthy humans or animals; - Immunological impacts. <p>3.2 In the case of synthetic DNA not existed in nature, the following shall be identified:</p> <p>3.2.1 Functions and roles of the synthetic DNA;</p> <p>3.2.2 Base sequence of the synthetic DNA.</p> <p>4. Details of genetic modification procedure</p> <p>4.1 Gene transfer method;</p> <p>4.2 Information of the DNA used in the modification:</p>

No.	Information	Description
		<p>4.2.1 Target gene that controls the desired characteristics, with the identification of potential harms to the expressed nucleotide sequence and amino acid sequence;</p> <p>4.2.2 Marker gene;</p> <p>4.2.3 Promotor;</p> <p>4.2.4 Terminator;</p> <p>4.2.5 Other relevant factors, such as other genes that may be affected by the function of this gene.</p> <hr/> <p>5. Characterization of genetic modification</p> <p>5.1 Information on genetic modification in the genetically modified microorganism</p> <p>5.1.1 Characterization and details of the added, inserted, or deleted DNAs, or modified genetic materials, including plasmids or other carriers used to transfer the desired DNAs, with an analysis of its potential for mobilization;</p> <p>5.1.2 Number of DNA insertion sites;</p> <p>5.1.3 Organization of the modified genetic materials at each insertion, modification or deletion site, and number of DNA copies at each insertion site;</p> <p>5.1.4 Open reading frames within the inserted DNA or created by the contiguous DNA in the chromosome or in a plasmid;</p> <p>5.1.5 Possibility of creating potentially harmful proteins, such as reported allergenicity of the nucleotide sequence or amino acid sequence;</p> <p>5.2 Information on products from the expression of the gene in the genetically modified microorganism</p> <p>5.2.1 Products obtained from the genetic modification (a protein or an untranslated RNA) or other information, such as an analysis of transcripts or expression products to identify any new substances that may be present in the food;</p> <p>5.2.2 Functions of the product resulting from the genetic modification;</p> <p>5.2.3 Phenotypic details of the new traits;</p> <p>5.2.4 Level and site of expression of the gene product and metabolites resulting from the gene product:</p>

No.	Information	Description
		<p>- In cases of Gram-negative bacteria, the gene product shall be identified as either intracellular or periplasmic;</p> <p>- In cases of eukaryotic microorganisms, it shall be identified as either organellar or secreted;</p> <p>5.2.5 Amount of the inserted gene product if the expressed gene alters the level of a specific endogenous mRNA;</p> <p>5.2.6 The absence of a gene product or the absence of alterations in metabolites related to gene products in the case where it is the intended result of the genetic modification;</p> <p>5.3 Other information, namely:</p> <p>5.3.1 Whether the arrangement of genes used in the gene transfer has been conserved, or the rearrangement occurs after the insertion;</p> <p>5.3.2 Whether the change in the amino acid sequence resulting from the genetic modification affects the post-translational protein modification or affects the structure and function of the protein;</p> <p>5.3.3 Whether the intended effect has been achieved, is stable, and can be inherited consistent with laws of inheritance;</p> <p>5.3.4 Whether the new trait is expressed as expected and targeted to the appropriate cellular location at a level that is consistent with the regulatory gene controlling the expression;</p> <p>5.3.5 Effects on the recipient/host microorganism resulting from the genetic modification procedure;</p> <p>5.3.6 Information on the identity and expression pattern of any new fusion proteins.</p> <p>6. Limitation and assessment of the presence of genetically modified microorganisms and gene components in the final product</p> <p>6.1 Description of the method or procedure for eliminating genetically modified microorganisms and DNA from the desired product;</p> <p>6.2 Result of the examination of cells of the genetically modified microorganism;</p> <p>6.3 Result of the examination of gene components.</p>
2.2	Enzyme production method or process	Details related to raw materials used in the production process or fermentation process, and controlled

No.	Information	Description
		conditions, e.g., temperature, quantity of nutrients, quantity of gases, name of chemicals used in the fermentation process, purification method, with a chart showing the enzyme production process.
2.3	Immobilization procedure (if any)	Steps and details of the enzyme immobilization procedure, substances used for the immobilization, including properties and characteristics of the substances.
3	Information on safety	
3.1	In cases of an enzyme from a source with no historical use as food for consumption or in food production process, or an enzyme from a genetically modified organism, the following detailed information on its safety shall be provided.	
3.1.1	Studies related to sub-chronic toxicity	Information from a study in which the test is designed, as the case may be, in accordance with the Organization for Economic Co-operation and Development (OECD Guideline 408, 2000a), as follows: <ul style="list-style-type: none"> - Repeated Dose 90-Day Oral Toxicity Study in Rodents, or - Repeated Dose 90-Day Oral Toxicity Study in Non-Rodents.
3.1.2	Result of genotoxicity assessment	Information relating to the bacterial mutation test (Ames test, OECD Guideline 471) or mouse lymphoma tk assay, and chromosomal aberration/micronucleus assay (OECD Guideline 476).
3.1.3	Allergenicity	Information on similarities of amino acid sequence and/or structure of the enzyme and the amino acid sequence of proteins known to be allergens or other toxic substances, by comparing them in at least 2 databases provided that the databases used must be up to date but no later than 3 years from the date of submission of the information.
3.1.4	Dietary exposure and description of risk	<ol style="list-style-type: none"> 1. Assessment of extensive exposure shall be made from the following information: <ul style="list-style-type: none"> - Consumption per capita data at the mean and 97.5th percentile based on food consumption data of Thailand in 7 age ranges in respect of which every type of food used in the assessment shall be listed; - Data on the maximum use level of enzyme recommended for each type of food as calculated in mg (TOS)/kg of food. 2. Nature of risk based on the calculation of the margin of expose (MOE) by comparing the dietary exposure value to the point of departure value, i.e., NOEL, NOAEL, or benchmark dose level obtained from sub-chronic oral toxicity studies

No.	Information	Description
3.1.5	Acceptable daily intake (ADI)	Determination of the acceptable daily intake (ADI) by referencing at least the following information: <ul style="list-style-type: none"> (a) No observed effect level (NOEL) or no observed adverse effect level (NOAEL); (b) Safety factor in the calculation; (c) Data on toxicological versus physiological responses; (d) MOE value.
3.2	In cases of an enzyme from a source with historical use as food for consumption or in food production process	
3.2.1	Plant or animal	Provide documents or evidence showing that the enzyme is derived from an edible part of a plant or an animal.
3.2.2	Microorganism	Provide documents or evidence showing that the microorganism has historical use as food or evidence showing that the microorganism has passed safety assessment and been permitted to be used in the production of food, e.g., Qualified Presumption of Safety (QPS) document, or Bulletin of International Dairy federation (IDF),
4	Report on assessment results or relevant legal documents (if any)	
4.1	Report on the results of safety assessment or opinions from safety assessment agencies of other countries	Report on the results of safety assessment or opinions from safety assessment agencies of other countries, e.g., South Korea, Canada, European Union, United States of America, Japan, Australia, or New Zealand.
4.2	Other relevant documents	For example, response letters or permission documents from a government, or patent documents containing the technical details or production method of the enzyme.

Schedule 3

Annexed to the Notification of The Ministry of Public Health (No. 409), B.E. 2562 (2019)

Issued under the Food Act, B.E. 2522 (1979)

Re: Enzymes Used in Food Production

Information on Necessity Considerations

No.	Document	Additional Description
1	Information on characteristics of enzyme	
1.1	Name and group of enzymes	Identify the chemical name, common name, trade name, synonym, and acronym
1.2	Enzyme code under universal system (if any)	Identify the CAS number, EC Number, IUBMB number, or INS number.
1.3	Properties of enzyme	Describe the information relating to: (1) Active principles, enzymatic properties to substrate, e.g., bonds or position of the substrate that will be digested by the enzyme, reaction and yields, and required cofactors; (2) Suitable conditions for enzymatic activities; (3) Subsidiary or side activities caused by enzymatic activities in unsuitable conditions, and method for detecting such subsidiary activities.
2	Summary relating to technology justification of using enzymes in the production process, and annexes	
2.1	Technology justification of using enzymes in the production of each type of food applied for use	Information on research and credible reference documents that show the efficiency and necessity of using the enzymes, with the identification of the quantity as calculated in TOS and the purposes of use or their technological functions in the production
2.2	Information related to food-based application	Provide details, characterization, and methods of using the enzymes in the food production process in a detailed manner, including the detailed production process that affects the activation or inactivation of the enzyme, or the removal of the enzymes from the food product.
2.3	Other relevant legal documents (if any)	- Laws or regulations showing that the enzyme is allowed to be used in the food products in a country with a credible safety assessment system, e.g., European Union, Australia, New Zealand, United States of America, and Japan - Patent documents

Schedule 4

Annexed to the Notification of The Ministry of Public Health (No. 409), B.E. 2562 (2019) Issued under the Food Act, B.E. 2522 (1979)

Re: Enzymes Used in Food Production

List of Food Additives Permitted to be Used in Enzyme Preparations or Immobilized Enzymes

INS No.	Name of Food Additive	Maximum Use Level	Maximum Residue Limit in Beverages	Maximum Residue Limit in Other Food Products
INS 170 (i)	Calcium carbonate	GMP	GMP	GMP
INS 200	Sorbic acid	20,000 mg/kg (use alone or in combination; calculated as sorbic acid)	Not exceeding 10 mg/liter	Not exceeding 20 mg/kg
INS 202	Potassium sorbate			
INS 210	Benzoic acid	(1) 5,000 mg/kg (use alone or in combination; calculated as benzoic acid) (2) 12,000 mg/kg (rennet enzyme only)	Not exceeding 0.85 mg/liter	Not exceeding 1.7 mg/kg
INS 211	Sodium benzoate		Not exceeding 2.5 mg/liter (in whey beverages containing rennet enzyme)	Not exceeding 5 mg/kg (in rennet-based cheese)
INS 214	Ethyl-p-hydroxybenzoate or ethylparaben	2,000 mg/kg (use alone or in combination; calculated as benzoic acid)	Not exceeding 1 mg/liter	Not exceeding 2 mg/kg
INS -	Sodium ethyl p-hydroxybenzoate			
INS 218	Methyl p-hydroxybenzoate or methylparaben			
INS -	Sodium methyl p-hydroxybenzoate			
INS 220	Sulfur dioxide	(1) 2,000 mg/kg (in the form of single substance or mixture with free sulfur dioxide (SO ₂))	Not exceeding 2 mg/liter	Not exceeding 2 mg/kg
INS 221	Sodium sulfite			
INS 222	Sodium hydrogen sulfite			

INS No.	Name of Food Additive	Maximum Use Level	Maximum Residue Limit in Beverages	Maximum Residue Limit in Other Food Products
INS 223	Sodium metabisulfite	(2) 5,000 mg/kg (enzyme used for beer industry only) (3) 6,000 mg/kg (beta-amylase enzyme from barley only) (4) 10,000 mg/kg (papain enzyme in solid form only)		
INS 224	Potassium metabisulfite			
INS 250	Sodium nitrite	500 mg/kg	Use in enzyme for beverage production is prohibited	Not exceeding 0.01 mg/kg
INS 260	Acetic acid	GMP	GMP	GMP
INS 261 (i)	Potassium acetate	GMP	GMP	GMP
INS 262 (i)	Sodium acetate	GMP	GMP	GMP
INS 263	Calcium acetate	GMP	GMP	GMP
INS 270	Lactic acid	GMP	GMP	GMP
INS 281	Sodium propionate	GMP	Not exceeding 50 mg/liter	GMP
INS 290	Carbon dioxide	GMP	GMP	GMP
INS 296	Malic acid	GMP	GMP	GMP
INS 300	Ascorbic acid, L-	GMP	GMP	GMP
INS 301	Sodium ascorbate	GMP	GMP	GMP
INS 302	Calcium ascorbate	GMP	GMP	GMP
INS 304	Ascorbyl palmitate or vitamin C palmitate	GMP	GMP	GMP
INS-	Tocopherol-rich extract	GMP	GMP	GMP

INS No.	Name of Food Additive	Maximum Use Level	Maximum Residue Limit in Beverages	Maximum Residue Limit in Other Food Products
INS 307a	D-alpha-tocopherol concentrate or vitamin E	GMP	GMP	GMP
INS 307b	Tocopherol concentrate, mixed or vitamin E	GMP	GMP	GMP
INS 307c	DL-alpha-Tocopherol	GMP	GMP	GMP
INS 322 (i)	Lecithin	GMP	GMP	GMP
INS 325	Sodium lactate (solution)	GMP	GMP	GMP
INS 326	Potassium lactate (solution)	GMP	GMP	GMP
INS 327	Calcium lactate	GMP	GMP	GMP
INS 330	Citric acid monoanhydrate	GMP	GMP	GMP
INS 331 (i)	Sodium dihydrogen citrate or monosodium citrate	GMP	GMP	GMP
INS 331 (iii)	Trisodium citrate or sodium citrate	GMP	GMP	GMP
INS 332 (i)	Potassium dihydrogen citrate	GMP	GMP	GMP
INS 332 (ii)	Tripotassium citrate or potassium citrate	GMP	GMP	GMP
INS 333 (iii)	Calcium citrate	GMP	GMP	GMP
INS 334	L(+)-Tartaric acid	GMP	GMP	GMP
INS 335 (ii)	Sodium L(+)-tartrate or sodium dextro-tartrate	GMP	GMP	GMP
INS-	Potassium tartrates	GMP	GMP	GMP
INS 337	Potassium sodium L(+)-tartrate	GMP	GMP	GMP

INS No.	Name of Food Additive	Maximum Use Level	Maximum Residue Limit in Beverages	Maximum Residue Limit in Other Food Products
INS 350 (i)	Sodium hydrogen DL-malates	GMP	GMP	GMP
INS 350 (ii)	Sodium DL-malates	GMP	GMP	GMP
INS 338	Phosphoric acid	10,000 mg/kg (in the form of phosphorus pentoxide)	GMP	GMP
INS 339 (i)	Sodium dihydrogen phosphate	50,000 mg/kg (in the form of single substance or mixture with phosphorus pentoxide)	GMP	GMP
INS 339 (ii)	Disodium hydrogen phosphate			
INS 339 (iii)	Trisodium phosphate			
INS 340 (i)	Potassium dihydrogen phosphate			
INS 340 (ii)	Dipotassium hydrogen phosphate			
INS 340 (iii)	Tripotassium phosphate			
INS 341 (i)	Calcium dihydrogen phosphate			
INS 341 (ii)	Calcium hydrogen phosphate			
INS 341 (iii)	Tricalcium phosphate			
INS 343 (i)	Magnesium dihydrogen phosphate			
INS 343 (ii)	Magnesium hydrogen phosphate			
INS 343 (iii)	Trimagnesium phosphate			
INS 343 (iv)	Magnesium dihydrogen diphosphate			
INS-	Potassium malate	GMP	GMP	GMP
INS 352 (ii)	Calcium DL-malate or DL-Monocalcium malate	GMP	GMP	GMP
INS-	Calcium tartrate (E 354)	GMP	GMP	GMP
INS 380	Triammonium citrate	GMP	GMP	GMP

INS No.	Name of Food Additive	Maximum Use Level	Maximum Residue Limit in Beverages	Maximum Residue Limit in Other Food Products
INS 400	Alginic acid	GMP	GMP	GMP
INS 401	Sodium alginate	GMP	GMP	GMP
INS 402	Potassium alginate	GMP	GMP	GMP
INS 403	Ammonium alginate	GMP	GMP	GMP
INS 404	Calcium alginate	GMP	GMP	GMP
INS 406	Agar	GMP	GMP	GMP
INS 407	Carrageenan	GMP	GMP	GMP
INS 407a	Processed eucheuma seaweed	GMP	GMP	GMP
INS 410	Carob bean gum, locust bean gum, or carob bean gum (clarified)	GMP	GMP	GMP
INS 412	Guar gum or guar gum (clarified)	GMP	GMP	GMP
INS 413	Tragacanth	GMP	GMP	GMP
INS 414	Gum Arabic, Acacia gum, or Arabic gum	GMP	GMP	GMP
INS 415	Xanthan gum	GMP	GMP	GMP
INS 417	Tara gum	GMP	GMP	GMP
INS 418	Gellan gum	GMP	GMP	GMP
INS 420 (i)	Sorbitol, d-glucitol, d-sorbitol, sorbit, or sorbol	GMP	GMP	GMP
INS 421	Mannitol	GMP	GMP	GMP
INS 422	Glycerol or glycerine	GMP	GMP	GMP
INS 428	Edible gelatin	GMP	GMP	GMP

INS No.	Name of Food Additive	Maximum Use Level	Maximum Residue Limit in Beverages	Maximum Residue Limit in Other Food Products
INS 440	Pectins	GMP	GMP	GMP
INS 450 (i)	Disodium pyrophosphate	50,000 mg/kg (in the form of single substance or mixture with phosphorus pentoxide)	GMP	GMP
INS 450 (ii)	Trisodium diphosphate			
INS 450 (iii)	Tetrasodium pyrophosphate			
INS 450 (v)	Tetrapotassium pyrophosphate			
INS 450 (vi)	Dicalcium pyrophosphate			
INS 450 (vii)	Calcium dihydrogen diphosphate			
INS 450 (ix)	Magnesium dihydrogen diphosphate			
INS 451 (i)	Pentasodium triphosphate			
INS 451 (ii)	Pentapotassium triphosphate			
INS 452 (i)	Sodium polyphosphate			
INS 452 (ii)	Potassium polyphosphates			
INS 452 (iii)	Sodium calcium polyphosphate			
INS 452 (iv)	Calcium polyphosphate			
INS 452 (v)	Ammonium polyphosphate			
INS-	Sodium metaphosphate, insoluble or Insoluble sodium polyphosphate			
INS 460 (i)	Microcrystalline cellulose or cellulose gel	GMP	GMP	GMP
INS 460 (ii)	Powdered Cellulose	GMP	GMP	GMP
INS 461	Methyl cellulose	GMP	GMP	GMP
INS 462	Ethyl cellulose	GMP	GMP	GMP

INS No.	Name of Food Additive	Maximum Use Level	Maximum Residue Limit in Beverages	Maximum Residue Limit in Other Food Products
INS 463	Hydroxypropyl cellulose	GMP	GMP	GMP
INS 464	Hydroxypropyl methyl cellulose	GMP	GMP	GMP
INS 465	Methyl ethyl cellulose	GMP	GMP	GMP
INS 466	Sodium carboxymethyl cellulose	GMP	GMP	GMP
INS 469	Sodium carboxymethyl cellulose, enzymatically hydrolyzed	GMP	GMP	GMP
INS-	Sodium, potassium, and calcium salts of fatty acids	GMP	GMP	GMP
INS-	Magnesium salts of fatty acids	GMP	GMP	GMP
INS-	Mono- and diglycerides of fatty acids	GMP	GMP	GMP
INS 472a	Acetic and fatty acid esters of glycerol or acetic acid esters of mono- and diglycerides	GMP	GMP	GMP
INS 472b	Lactic and fatty acid esters of glycerol or lactic acid esters of mono- and diglycerides	GMP	GMP	GMP
INS 472c	Citric and fatty acid esters of glycerol or citric acid esters of mono- and diglycerides	GMP	GMP	GMP
INS- (E 472d)	Tartaric acid esters of mono- and diglycerides of fatty acids	GMP	GMP	GMP

INS No.	Name of Food Additive	Maximum Use Level	Maximum Residue Limit in Beverages	Maximum Residue Limit in Other Food Products
INS 472e	Diacetyltartaric and fatty acid esters of glycerol, diacetyltartaric acid esters of mono- and diglycerides, or Mixed acetic and tartaric acid esters of mono- and diglycerides of fatty acids	GMP	GMP	GMP
INS 473	Sucrose esters of fatty acids	50,000 mg/kg	Not exceeding 25 mg/l	Not exceeding 50 mg/kg
INS 473a	Sucrose oligoesters Type I and Type II Type I: Sucrose fatty acid esters (high-esterified) or sucrose oligoesters (high-esterified) Type II: Sucrose fatty acid esters or sucrose oligoesters			
INS 500 (i)	Sodium carbonate	GMP	GMP	GMP
INS 500 (ii)	Sodium hydrogen carbonate			
INS 500 (iii)	Sodium sesquicarbonate or sodium monohydrogen dicarbonate			
INS 501 (i)	Potassium carbonate	GMP	GMP	GMP
INS 501 (ii)	Potassium hydrogen carbonate			
INS 503 (i)	Ammonium carbonate	GMP	GMP	GMP
INS 503 (ii)	Ammonium hydrogen carbonate or ammonium bicarbonate			

INS No.	Name of Food Additive	Maximum Use Level	Maximum Residue Limit in Beverages	Maximum Residue Limit in Other Food Products
INS 504 (i)	Magnesium carbonate	GMP	GMP	GMP
INS 504 (ii)	Magnesium hydroxide carbonate			
INS 507	Hydrochloric acid	GMP	GMP	GMP
INS 508	Potassium chloride	GMP	GMP	GMP
INS 509	Calcium chloride	GMP	GMP	GMP
INS 511	Magnesium chloride	GMP	GMP	GMP
INS 513	Sulfuric acid	GMP	GMP	GMP
INS 514 (i)	Sodium sulfate			
INS 514 (ii)	Sodium hydrogen sulfate			
INS 515 (i)	Potassium sulfate	GMP	GMP	GMP
INS 516	Calcium sulfate	GMP	GMP	GMP
INS-	Ammonium sulphate	100,000 mg/kg	Not exceeding 50 mg/liter	Not exceeding 100 mg/kg
INS 524	Sodium hydroxide	GMP	GMP	GMP
INS 525	Potassium hydroxide	GMP	GMP	GMP
INS 526	Calcium hydroxide	GMP	GMP	GMP
INS 527	Ammonia solution, ammonium Hydroxide, or aqueous ammonia	GMP	GMP	GMP
INS 528	Magnesium hydroxide	GMP	GMP	GMP
INS 529	Calcium oxide	GMP	GMP	GMP
INS 530	Magnesium oxide	GMP	GMP	GMP
INS 551	Silicon dioxide, amorphous or silica	50,000 mg/kg (in powder form)	GMP	GMP
INS-	Fatty acids	GMP	GMP	GMP

INS No.	Name of Food Additive	Maximum Use Level	Maximum Residue Limit in Beverages	Maximum Residue Limit in Other Food Products
INS-	Gluconic acid	GMP	GMP	GMP
INS 575	Glucono delta-lactone	GMP	GMP	GMP
INS 576	Sodium gluconate	GMP	GMP	GMP
INS 577	Potassium gluconate	GMP	GMP	GMP
INS 578	Calcium gluconate	GMP	GMP	GMP
INS-	Glycine and its sodium salt	GMP	GMP	GMP
INS-	L-cysteine	10,000 mg/kg	Not exceeding 5 mg/l	Not exceeding 10 mg/kg
INS 938	Argon	GMP	GMP	GMP
INS 939	Helium	GMP	GMP	GMP
INS 941	Nitrogen	GMP	GMP	GMP
INS 942	Nitrous oxide	GMP	GMP	GMP
INS 948	Oxygen	GMP	GMP	GMP
INS-	Hydrogen	GMP	GMP	GMP
INS 965 (i)	Maltitol	GMP	GMP	GMP
INS 965 (ii)	Maltitol syrup			
INS 966	Lactitol	GMP	GMP	GMP
INS 967	Xylitol	GMP	GMP	GMP
INS 1200	Polydextroses	GMP	GMP	GMP
INS 1400	Dextrins, roasted starch	GMP	GMP	GMP
INS 1404	Oxidized starch	GMP	GMP	GMP
INS 1405	Starches, enzyme treated	GMP	GMP	GMP
INS 1410	Monostarch phosphate	GMP	GMP	GMP

INS No.	Name of Food Additive	Maximum Use Level	Maximum Residue Limit in Beverages	Maximum Residue Limit in Other Food Products
INS 1412	Distarch phosphate	GMP	GMP	GMP
INS 1413	Phosphated distarch phosphate	GMP	GMP	GMP
INS 1414	Acetylated distarch phosphate	GMP	GMP	GMP
INS 1420	Starch acetate	GMP	GMP	GMP
INS 1422	Acetylated distarch adipate	GMP	GMP	GMP
INS 1440	Hydroxy propyl starch	GMP	GMP	GMP
INS 1442	Hydroxy propyl distarch phosphate	GMP	GMP	GMP
INS 1450	Starch sodium octenyl succinate	GMP	GMP	GMP
INS 1451	Acetylated oxidized starch	GMP	GMP	GMP
INS 1520	Propylene glycol	500 g/kg	1,000 mg/kg (in single form or use in combination with triethyl citrate, glyceryl diacetate (diacetin) and glyceryltriacetate; triacetin, except liqueur)	3,000 mg/kg (in single form or use in combination with triethyl citrate, glyceryl diacetate (diacetin) and glyceryltriacetate; triacetin)
INS -	PolyEthyleneimine; PEI	GMP	GMP	GMP
INS 558	Bentinite	GMP	GMP	GMP
INS -	Diatomaceous earth, diatomaceous Silica, or diatomite	GMP	GMP	GMP
INS -	Maltodextrin	GMP	GMP	GMP

Schedule 5

Annexed to the Notification of The Ministry of Public Health (No. 409), B.E. 2562 (2019)

Issued under the Food Act, B.E. 2522 (1979)

Re: Enzymes Used in Food Production

Technical Methods for the Analysis of Enzymes

1. The analytical method for measuring the activity of an enzyme must be in accordance with the Combined Compendium of Food Additive Specifications: Analytical methods, test procedures and laboratory solutions used by and referenced in the food additive specifications.

In the case where the analytical method used for measuring the activity of an enzyme does not conform to paragraph one, the producer or importer must submit the detailed information on the analytical method together with the certification of equivalency of the measurement method and the method so prescribed.

2. The method for analyzing other quality or standards must be any of the following:

(1) A method prescribed by a national agency or an international organization on standards or published in a universally recognized document, manual, or publication.

(2) A method that has accurate and appropriate performance characteristics and of which the test results are validated as accurate and appropriate by a laboratory conducting a collaborative study in accordance with the criteria that conform to those of a generally accepted international agency or by a laboratory which has a single laboratory validation system consistent with universally accepted criteria, provided that the assessment results must be a document or evidence which can be verified under the latest version of the ISO/IEC 17025 standard quality system.