

(Unofficial Translation)

NOTIFICATION OF THE MINISTRY OF PUBLIC HEALTH

(NO. 443), B.E. 2566 (2023)

ISSUED UNDER THE FOOD ACT, B.E. 2522 (1979)

RE: ENZYMES USED IN FOOD PRODUCTION

Whereas it is expedient to amend the notification of the ministry of public health (No. 409), B.E. 2562 issued under the food act, B.E. 2522 Re: Enzymes used in food production.

By virtue of the provisions in paragraph one of section 5 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 The notification of the ministry of public health (No. 409), B.E. 2562 issued under the food act, B.E. 2522 Re: Enzymes used in food production shall be repeal.

Clause 2 Enzymes used in food production are food additives. They shall be the specifically controlled food.

Clause 3 In this Notification:

“Enzyme” means a protein used in the production of processed food, such as preparation of raw materials, processing, curing, transportation, or storage, that capable of catalyzing a specific biochemical reaction. 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.

“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 4 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 5 Enzymes used in food production shall comply with the qualities or standards as follows;

- (1) Enzyme activity must not less than 85 percent of the declared activity,
- (2) Lead must not more than 5 milligrams per kilogram,
- (3) Salmonella must absent in 25 grams,
- (4) Coliforms must not more than 30 per gram (MPN),
- (5) E. coli must absent in 25 grams,
- (6) Antibiotic activity must absent in microbial enzymes,
- (7) Mycotoxin must absent in enzymes are produced from fungal sources,
- (8) Absence of the production strain in 1 gram of the enzyme from a genetically modified microorganism,
- (9) Other qualities or standards (if any) prescribed by the Food and Drug Administration according the scientific opinion provided in the report from the risk assessment unit.

Clause 6 Applications of enzymes in food production shall follow:

- (1) The conditions of use specified in the Schedule 1 annexed to this Notification
- (2) The functional uses specified in specification of enzyme preparation according to the JECFA Combined Compendium of Food Additive Specifications,
- (3) The conditions of use specified in the Notification of the Ministry of Public Health regarding food additives,

With respect to any use other than (1) (2) or (3), the approval of the Food and Drug Administration granted in accordance with technology justification. In this regard, the producer or importer must submit the data or information as specified in the Schedule 3 annexed to this Notification.

Clause 7 The use of food additives in enzyme preparations shall comply with the conditions set in the Schedule 4 annexed to this Notification.

In the case where a food additive not listed in the Schedule 4 is intended to be used, the Food and Drug Administration shall consider granting an approval in accordance with the Notification of the Ministry of Public Health on food additives.

Clause 8 the use of material for immobilization or supportive materials for immobilized enzyme shall comply with the Schedule 5 annexed to this Notification.

In the case where a material not listed in the Schedule 5 is intended to be used, the Food and Drug Administration shall consider granting an approval in accordance with specification approved in the country where done the safety assessment according to the international guideline.

Clause 9 The analytical method shall be in accordance with those prescribed in the Schedule 5 annexed to this Notification.

Clause 10 producer or importer of enzymes for 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 11 The use of container or packaging for enzymes used in food production shall comply with the Notification of the Ministry of Public Health on food containers.

Clause 12 The labelling of enzymes used in food production shall comply with the Notification of the Ministry of Public Health regarding food additives.

The labelling of food product which enzyme used during production shall comply with the Notification of the Ministry of Public Health on labelling of prepackaged food.

Clause 13 This notification shall not apply to:

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

Clause 14 This Notification shall come into force as from the day following the date of its publication in the Government Gazette.

Given on the 15 July 2023

Mr. Satit Pitutacha,
Deputy Minister for Minister of Public Health

Schedule 1

Annexed to the Notification of The Ministry of Public Health (No. 443), B.E. 2566 (2023) Issued under the Food Act, B.E. 2522 (1979)

Re: Enzymes Used in Food Production

Names of Enzymes Used in Food Production

No.	Enzyme Nomenclature ⁽¹⁾	Enzyme Name ⁽²⁾	Source	Condition of Use	Maximum Use Level
1	EC 1.1.3.4	Glucose Oxidase	<i>Aspergillus oryzae</i> BECH 2 containing gene from <i>Aspergillus niger</i>	Processing aid for catalyzing the oxidation of glucose to hydrogen peroxide and gluconolactone in the production process of baked goods and pastry products.	GMP
2	Glucose Oxidase and Catalase as follows;				
	EC 1.1.3.4	Glucose Oxidase	<i>Aspergillus niger</i> , var.	(1) Antioxidation; (2) Processing aid for catalyzing the oxidation of glucose in: <ul style="list-style-type: none"> ● food products made from milk and eggs, e.g., cheese, beverages, and salad dressings, ● pastas and noodles and like products, ● baked goods and pastry products, ● cooked rice and processed rice products, ● food products made from wheat flour or rice flour (<i>Oryza sativa</i> L.), e.g. Steamed breads and buns. 	GMP
	EC 1.11.1.6	Catalase	<i>Aspergillus aculeatus</i>		

No.	Enzyme Nomenclature ⁽¹⁾	Enzyme Name ⁽²⁾	Source	Condition of Use	Maximum Use Level
3	EC 1.1.3.5	Hexose Oxidase or HOX	<i>Chondrus crispus</i> expressed in <i>Hansenula polymorpha</i>	Processing aid for catalyzing the oxidation of hexoses in: (1) production of bread to strengthen the gluten network, (2) production of shredded cheese, potato chips, egg white powder and whey protein to prevent maillard reactions, (3) production of cottage cheese and tofu to made curd, (4) production of ketchup, mayonnaise, and salad dressings to scavenge oxygen.	GMP
4	EC 1.10.3.2	Laccase	<i>Myceliophthora thermophile</i> expressed in <i>Aspergillus oryzae</i>	Processing aid for preventing off-flavors from the reaction of oxygen and fatty acids, amino acids, proteins, or alcohols during a beer production process (brewing).	GMP
5	EC 1.11.1.6	Catalase	Beef liver <i>Micrococcus lysodeicticus</i>	Processing aid in the production of food containing milk and eggs e.g., cheese, salad dressings, as well as beverages, to get rid of hydrogen peroxide.	GMP
6	EC 2.3.2.13	Protein-glutamine γ -glutamyltransferase or Transglutaminase	<i>Streptoverticillium mobaraense</i> var.	Processing aid for improve functional properties of protein in food such as:	GMP

No.	Enzyme Nomenclature ⁽¹⁾	Enzyme Name ⁽²⁾	Source	Condition of Use	Maximum Use Level
				<ul style="list-style-type: none"> ○ minced cooked meat products and fishery products, e.g., meatballs and sausages, ○ products made from milk e.g., yogurt, cheese, and milk ice cream, ○ food products made from wheat flour e.g., pasta, wonton wrappers, egg noodles, as well as baked goods, ○ food products made from soybeans e.g., tofu, soy proteins, and vegetable proteins. 	
7	EC 2.4.1.18	1,4- α -glucan branching enzyme) or Branching glucosyltransferase	<p><i>Rhodothermus obamensis</i> expressed in <i>Bacillus subtilis</i></p> <hr/> <p><i>Geobacillus stearothermophilus</i> TRBE 14</p>	<p>(1) flour treatment agent,</p> <p>(2) Processing aid in the production of;</p> <ul style="list-style-type: none"> ○ modified starch to improve functional properties, ○ food products containing flour or starch e.g., <ul style="list-style-type: none"> - pastas noodles and like products, - cooked rice and rice products - pastries and baked goods - steamed breads and buns, - cooked fishery products containing flour and starch, - cooked meat products containing flour and starch. 	GMP

No.	Enzyme Nomenclature ⁽¹⁾	Enzyme Name ⁽²⁾	Source	Condition of Use	Maximum Use Level
8.	EC 2.4.1.24	1,4-alpha-glucan 6-alpha-glucosyltransferase or Transglucosidase	<i>Aspergillus niger, var.</i> <i>Aspergillus niger</i> expressed in <i>Trichoderma reesei RL-P37</i>	Processing aid in the production of Isomalto-oligosaccharide (IMO)	GMP
9	EC 3.1.1.3	Triacylglycerol lipase or Lipase	Rumen of calves or lambs Pancreatic tissue of the edible animals Fusarium heterosporum expressed in <i>Ogataea polymorpha</i> <i>Candida cylindracea</i> <i>Aspergillus niger</i> <i>Candida Antarctica</i> expressed in <i>Aspergillus niger MLxN26</i> <i>Rhizopus niveus</i> <i>Rhizopus oryzae</i> <i>Thermomyces lanuginosus</i> expressed in <i>Aspergillus oryzae PFJo 480</i>	(1) flavour enhancer (2) Processing aid for hydrolysis of triglycerides or fatty acid esters in the production of; ○ cheese or other milk products, ○ fat and oil products, ○ food products containing egg yolk. ○ pastries and baked goods, ○ pasta and noodles ○ cooked rice and rice products Immobilized enzyme use as a processing aid in fat and oil products e.g., margarine, modified fat products, beers and malt extracts.	GMP
10	EC 3.1.1.4	Phospholipase A2	<i>Streptomyces violaceoruber</i> expressed in <i>Streptomyces violaceoruber AS-10</i>	Processing aid to enhance emulsifying properties of phospholipids or lecithins in food products, such as baked goods, emulsified sauce products, e.g., mayonnaise, salad dressing, and cream that contain egg yolks or soybeans.	GMP

No.	Enzyme Nomenclature ⁽¹⁾	Enzyme Name ⁽²⁾	Source	Condition of Use	Maximum Use Level
11	EC 3.1.1.5	Lysophospholipase	<i>Aspergillus niger</i> expressed in <i>Aspergillus niger</i> C2948-1505-10	Processing aid for hydrolysis of L- α -lyso-phospha-tidylcholine to Glycerophosphocholine and free fatty acids in the production of flour and starch processing, syrup and glucose syrup, fat and oil processing and pastries and baked goods.	GMP
12	Pectinase as follows;				
	EC 3.1.1.11	(1) Pectin esterase	<i>Aspergillus niger</i> , var. <i>Aspergillus aculeatus</i>	Processing aid for hydrolysis of pectin to oligosaccharides in the production of food and beverages containing pectin such as fruit juice or wine	GMP
	EC 3.2.1.15	(2) endo – polygalacturonase			
	EC 4.2.2.10	(3) Pectin lyase			
13	EC 3.1.1.32	Phospholipase A1	<i>Fusarium venenatum</i> expressed in <i>Aspergillus oryzae</i> <i>Talaromyces leycettanus</i> expressed in <i>Aspergillus niger</i> 279- C2948-1	Processing aid for hydrolysis of sn-1 ester bond of iacylphospholipids to 2-acyl-1-lysophospholipids and free fatty acids in the production of; <ul style="list-style-type: none">○ Cheese○ Fat and oils	GMP
14	EC 3.1.3.8	3-phytase or Phytase	<i>Aspergillus niger</i> expressed in <i>Aspergillus niger</i>	Processing aid for hydrolysis of myo-inositol hexakisphosphate (phytate) to inositol pentaphosphate (IP5) and further to give a mixture of myo-inositol diphosphate (IP2),	GMP

No.	Enzyme Nomenclature ⁽¹⁾	Enzyme Name ⁽²⁾	Source	Condition of Use	Maximum Use Level
				myo-inositol monophosphate (IP1) and free orthophosphate in order to degrade phytate found in plant derived foods, particularly cereal grains and legumes, in order to improve mineral bioavailability.	
15	EC 3.1.4.3	Phospholipase C	<i>Pichia pastoris</i> containing phospholipase C gene	Processing aid for breaking down phosphodiester bonds at the sn-3 position in glycerophospholipids including phosphatidylcholine, phosphatidylethanolamine, and phosphatidylserine to 1,2-diacylglycerol and phosphate esters, in refining process of vegetable oils.	GMP
16	EC 3.1.26.5	Ribonuclease P	<i>Penicillium citrinum</i>	Processing aid for hydrolyzing phosphodiester linkages of RNA (ribonucleic acid) to 5' monophosphate nucleotides, in the production of yeast extracts.	
17	EC 3.2.1.1	alpha-Amylase or Glycogenase	<i>Bacillus licheniformis</i> <i>Aspergillus oryzae, var.</i> <i>Bacillus megaterium</i> expressed in <i>Bacillus subtilis</i>	(1) Flour treatment agent (2) Processing aid for hydrolyzing polysaccharides in the production of food or	GMP

No.	Enzyme Nomenclature ⁽¹⁾	Enzyme Name ⁽²⁾	Source	Condition of Use	Maximum Use Level
			<i>Bacillus stearothermophilus</i> <i>Bacillus stearothermophilus</i> expressed in <i>Bacillus subtilis</i> <i>Bacillus subtilis</i> <i>Bacillus licheniformis</i> <i>Bacillus amyloliquefaciens</i> <i>Bacillus licheniformis</i> expressed in <i>Bacillus licheniformis</i> <i>Bacillus stearothermophilus</i> expressed in <i>Bacillus licheniformis</i> SJ10402	beverages containing starch, grain, cereals, vegetables, and fruits e.g., <ul style="list-style-type: none"> ○ vegetable juice and fruit juice ○ cereal-based beverage, legumes and nut milk ○ confectioneries and candies ○ pastries and baked goods ○ alcoholic beverages, beer and ethanol ○ sugar, syrup and sweetener ○ fiber ○ Processed fruit- and vegetable products 	
18	alpha-amylase or glucoamylase as follows;		<i>Aspergillus oryzae, var.</i>	(1) Flour treatment agent (2) Processing aid for hydrolyzibg polysaccharides in food products containing polysaccharides or starch, e.g., sugar, desert, syrup, candy, confectionary, baked goods, alcoholic beverages, and beer.	GMP
EC 3.2.1.1	alpha-amylase or glycogenase				
EC 3.2.1.3	glucan 1,4- α -glucosidase or glucoamylase				

No.	Enzyme Nomenclature ⁽¹⁾	Enzyme Name ⁽²⁾	Source	Condition of Use	Maximum Use Level
19	Carbohydrase as follows;				
	EC 3.2.1.1	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 3.2.1.3	glucan 1,4- α -glucosidase or glucoamylase			
	EC 3.2.1.15	pectinase			
20	Malt Carbohydrase or Malt as follows;				
	EC 3.2.1.1	alpha-Amylase or glycogenase	Malt is the product of controlled germination of barley	Processing aid for catalyzing of starch or glycogen in the production of food and beverages of which raw materials contain starch or glycogen, e.g., beer, pastry and baked goods, alcoholic beverages, or syrup.	GMP
	EC 3.2.1.2	beta-Amylase			

No.	Enzyme Nomenclature ⁽¹⁾	Enzyme Name ⁽²⁾	Source	Condition of Use	Maximum Use Level
21	Mixed Microbial Carbohydrase and Protease as follows;				
	EC 3.2.1.1	Alpha-amylase or glycogenase	<i>Bacillus subtilis, var</i>	Processing aid for hydrolyzing polysaccharides to dextrans and oligosaccharides or hydrolyzing polypeptides to small molecule in the production of food or beverages such as syrup, alcoholic beverages, beer, glucose, baked goods, fishery products, meat products, and protein hydrolysates.	GMP
	EC 3.4.21.14	Microbial serine proteinase as follows;	<i>Bacillus amyloliquefaciens</i>		
	EC 3.4.21.62	subtilisin			
	EC 3.4.21.63	oryzin			
	EC 3.4.21.64	endopeptidase K			
	EC 3.4.21.65	thermomycolin			
	EC 3.4.21.67	endopeptidase So			
	EC 3.4.24.4	Microbial metalloproteinases as follows;			
	EC 3.4.24.25	aeromonolysin			
	EC 3.4.24.26	pseudolysin			
	EC 3.4.24.27	thermolysin			
	EC 3.4.24.28	bacillolysin			
	EC 3.4.24.29	aureolysin			
	EC 3.4.24.30	coccolysin			
	EC 3.4.24.31	mycolysin			
	EC 3.4.24.32	β -lytic metalloendopeptidase			
	EC 3.4.24.39	deuterolysin			
	EC 3.4.24.40	serralysin			

No.	Enzyme Nomenclature ⁽¹⁾	Enzyme Name ⁽²⁾	Source	Condition of Use	Maximum Use Level
22	EC 3.2.1.2	beta-amylase	<i>Ipomoea batatas</i>	Processing aid for hydrolyzing 1,4-alpha-D-glucosidic of amylose and amylopectin in the production of; <ul style="list-style-type: none"> ○ Maltose syrup ○ Pastry and baked goods ○ Alcoholic beverages 	GMP
			<i>Glycine max</i>		
			<i>Bacillus flexus</i> expressed in <i>Bacillus licheniformis</i> AN1063		
23	EC 3.2.1.3	glucan 1,4-alpha-glucosidase or glucoamylase	<i>Aspergillus niger</i> , var	Processing aid for catalizing of polysaccharides in food products of which raw materials contain polysaccharides or starch, e.g., syrup, corn syrup, dextrose, fruit juice, pastry and baked goods, alcoholic beverages, or beer.	GMP
			<i>Aspergillus aculeatus</i>		
			<i>Trichoderma reesei</i> expressed in		
			<i>Trichoderma reesei</i>		
			<i>Aspergillus niger</i>		
			<i>Aspergillus oryzae</i>		
<i>Aspergillus niger</i> expressed in					
<i>Aspergillus niger</i> C40-1					
24	Cellulases as follows;				
	EC 3.2.1.4	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, or wheat products.	GMP
	EC 3.2.1.6	Endo- 1,3(4)-beta-glucanase			
EC 3.2.1.8	Endo-1,4- beta-xylanase				

No.	Enzyme Nomenclature ⁽¹⁾	Enzyme Name ⁽²⁾	Source	Condition of Use	Maximum Use Level
25	Cellulases as follows;				
	EC 3.2.1.4	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, or wheat products.	GMP
	EC 3.2.1.74	Glucan-1,4- β -glucosidase or Exo-1,4- β -D-glucosidase	<i>Trichoderma reesei</i>		
	EC 3.2.1.91	Cellulose 1,4- β -cellobiosidase or Exo-cellobiohydrolase			
	EC 3.2.1.6	endo -1,3(4) - β - glucanase or β -glucanase			
26	EC 3.2.1.6	endo-1,3- β -glucanase or beta-glucanase	<i>Aspergillus niger</i> , var.	Processing aid for catalyzing glucans which are polysaccharides of glucose, in the production of food or beverages, e.g., fruit juices, beer, or cheese.	GMP
			<i>Aspergillus aculeatus</i>		
27	Beta-glucanase as follows;				
	EC 3.2.1.6	Endo-1,3-beta-glucanase	<i>Trichoderma harzianum</i>	Processing aid for catalyzing glucans which are polysaccharides of glucose, in the production of food or beverages, e.g., fruit juices, wine, beer, or vegetable oils.	GMP
	EC 3.2.1.58	Exo-1,3-beta-glucanase			

No.	Enzyme Nomenclature ⁽¹⁾	Enzyme Name ⁽²⁾	Source	Condition of Use	Maximum Use Level
28	Mixed β -glucanase Cellulase and Xylanase as follows;				
	EC 3.2.1.6	endo -1,3(4) - β - glucanase or β -glucanase	<i>Rasamsonia emersonii</i>	Processing aid for catalyzing β -D glucans, cellulose, lichenin, and xylans which are the components of cell walls of cereal, grains, vegetables, and fruits in the production of food or beverages, e.g., rice products, alcoholic beverages or beer.	GMP
	EC 3.2.1.4	Cellulase			
	EC 3.2.1.8	endo-1,4- β -xylanase or Xylanase			
29	Mixed Xylanase or β -Glucanase or Mixed β -Glucanase and Xylanase as follows;				
	EC 3.2.1.6	beta-Glucanase	<i>Hunicola insolens</i> <i>Disporotrichum dimorphosporum</i>	Processing aid for catalyzing beta-glucans or xylans contained in cell walls of rice, grains, vegetables, and fruits or pentosans and other gums in the production of food and alcoholic beverages, e.g., beer, and the fermentation of other food products.	GMP
	EC 3.2.1.8	endo-1,4- β -xylanase or Xylanase	<i>Disporotrichum dimorphosporum</i> <i>Aspergillus niger var.</i>		
30	EC 3.2.1.7	Inulinase	<i>Aspergillus niger var.</i>	Processing aid for catalyzing (2 \rightarrow 1)- β -D-fructosidic linkage of Innulin in the production of oligofructose.	GMP

No.	Enzyme Nomenclature ⁽¹⁾	Enzyme Name ⁽²⁾	Source	Condition of Use	Maximum Use Level
31	EC 3.2.1.8	endo-1,4-beta-xylanase or Xylanase	<i>Bacillus subtilis</i> expressed in <i>Bacillus subtilis</i>	Processing aid for catalyzing xylosidic linkages of arabinoxylans of arabinoxylans to oligosaccharides in the production of; <ul style="list-style-type: none"> ○ Pastry and bakery products, ○ Alcoholic beverage and beer. 	GMP
			<i>Thermomyces lanuginosus</i> expressed in <i>Fusarium venenatum</i>		
			<i>Thermomyces lanuginosus</i> expressed in <i>Aspergillus Oryzae</i> JaL 339		
			<i>Aspergillus aculeatus</i> expressed in <i>Aspergillus oryzae</i> MT 2181-2.3 Ek4		
32	Hemicellulase as follows;				
	EC 3.2.1.8	Endo-1,4-beta-xylanase	<i>Aspergillus niger, var.</i>	Processing aid for hydrolyzing polysaccharide and hemicelluloses which are components of plant cell walls in the production of food, e.g., instant coffee, bread pastry and bakery products.	GMP
	EC 3.2.1.37	Xylan 1,4-beta-xylosidase			
	EC 3.2.1.55	non-reducing end alpha -L- arabinofuranosidase or alpha- L-Arabinofuranosidase	<i>Aspergillus aculeatus</i>		
	EC 3.2.1.4	Cellulase			
	-	Galactomannanase			
33	EC 3.2.1.20	Alpha-glucosidase	<i>Aspergillus niger</i>		GMP

No.	Enzyme Nomenclature ⁽¹⁾	Enzyme Name ⁽²⁾	Source	Condition of Use	Maximum Use Level
			<i>Aspergillus niger</i> expressed in <i>Trichoderma reesei</i> RL-P37	Processing aid for catalyzing polysaccharides in food products of which raw materials contain polysaccharides, e.g., <ul style="list-style-type: none"> ○ sugar, syrup, including oligosaccharides and sweeteners ○ pastas noodles and like products ○ cooked rice and rice products ○ bread and bun ○ baked goods ○ Heat-treated processed comminuted meat, poultry, and game products e.g meatballs, or breakfast sausages ○ Cooked fish and fish products ○ Seasoned flour. 	
34	EC 3.2.1.23	Beta-Galactosidase or Lactase	<i>Kluyveromyces lactis</i> <i>Bacillus circulans</i> ATCC 31382 <i>Papiliotrema terrestris</i> AE-BLC <i>Bifidobacterium bifidum</i> expressed in <i>Bacillus licheniformis</i> PP3930	Processing aid for catalyzing (transgalactosylation) lactose in food products containing milk as raw materials that hydrolyse of terminal non-reducing β -D-galactose residues in β -D-galactosides.	GMP

No.	Enzyme Nomenclature ⁽¹⁾	Enzyme Name ⁽²⁾	Source	Condition of Use	Maximum Use Level
35	EC 3.2.1.26	β-Fructofuranosidase or Invertase	<i>Saccharomyces cerevisiae</i>	Processing aid for catalyzing sucrose to glucose and fructose in the production of food containing sugar, e.g., candies, sweets, chocolate, including pastries	GMP
36	Carbohydrase as follows;				
	EC 3.2.1.26	β-Fructofuranosidase or Invertase	<i>Saccharomyces species</i>	Processing aid in the production of food of which raw materials contain sucrose or lactose, e.g., ice cream, candies, or food products containing milk as raw materials.	GMP
	EC 3.2.1.23	Beta-Galactosidase or lactase			
37	EC 3.2.1.39	glucan endo-1,3-beta-D-glucosidase or glucanase	<i>Streptomyces violaceoruber</i> expressed in <i>Streptomyces violaceoruber</i> 1326	Processing aid in the production of yeast extract, beer and alcoholic beverages.	GMP
38	EC 3.2.1.41	Pullulanase or pullulan 6-α-glucanohydrolase	<i>Bacillus deramificans</i> expressed in <i>Bacillus subtilis</i> A164 <i>Bacillus deramificans</i> expressed in <i>Bacillus licheniformis</i> HyGe 486	Processing aid for catalyzing starch in the production of food and food ingredients e.g, maltotriose, high fructose corn syrup, alcoholic beverages and beer.	GMP

No.	Enzyme Nomenclature ⁽¹⁾	Enzyme Name ⁽²⁾	Source	Condition of Use	Maximum Use Level
39	EC 3.2.1.60	glucan 1,4- α -maltotetrahydrolase or Maltotetrahydrolase	<i>Pseudomonas stutzeri</i> expressed in <i>Bacillus licheniformis</i>	Processing aid in the production of food of which raw materials contain starch, e.g., pastries and baked goods.	GMP
40	EC 3.2.1.68	Isoamylase or Debranching enzyme	<i>Pseudomonas anmyloderamosa</i>	Processing aid for catalyzing of glycogen, amylopectin, and dextrans in food products containing flour or starch.	GMP
41	EC 3.2.1.133	Glucan1,4- α -maltohydrolase or Maltogenic Amylase	<i>Bacillus stearothermophilus</i> expressed in <i>Bacillus subtilis</i>	Processing aid for catalyzing of amylose, amylopectin, or other glucose polymers in the production of food containing flour, starch or sugar, e.g., high maltose corn syrup or pastries and baked goods.	GMP
42	Protease as follows;				
	EC 3.4.11	(1) Aminopeptidase	<i>Aspergillus oryzae, var.</i>	(1) Flavor enhancer, (2) Flour treatment agent, (3) Stabilizer, (4) Processing aid in the production of food e.g., meat and fish products, beverages, broths and soup, baked goods, food products containing milk as ingredients, cooked rice and rice product.	
	EC 3.4.21	(2) Serine endopeptidases			
	EC 3.4.23	(3) Aspartic endopeptidases			

No.	Enzyme Nomenclature ⁽¹⁾	Enzyme Name ⁽²⁾	Source	Condition of Use	Maximum Use Level
43	EC 3.4.21.1	Chymotrypsin or Serine Protease with Chymotrypsin Specificity	<i>Nocardiosis prasina</i> expressed in <i>Bacillus Licheniformis</i>	Processing aid for catalyzing protein such as casein, whey, soy protein, soy protein, wheat gluten or corn gluten in the production of hydrolyzed proteins from vegetable or animal source.	GMP
44	EC 3.4.21.4	Trypsin or Serine Protease with Trypsin Specificity	<i>Fusarium oxysporum</i> expressed in <i>Fusarium venenatum</i> extracts of porcine or bovine pancreas.	Processing aid for catalyzing polypeptides, amides, and esters to small peptide molecules in the production of food e.g., pastry and baked goods, meat products, and protein hydrolysates.	GMP
45	EC 3.4.21.4 EC 3.4.21.62	Subtilisin or Protease	<i>Bacillus licheniformis</i>	Processing aid for hydrolyzing of proteins to peptide (short chain of amino acid) or amino acids in the production of food e.g., protein extracts from animal or plant, milk protein, soup and sauce, and like products.	GMP
46	EC 3.4.21.63	Oryzin or Protease	<i>Aspergillus melleus</i> P-52	Processing aid for hydrolyzing of proteins to peptide (short chain of amino acid) or amino acids in the production of food e.g., milk protein, flavouring agent and yeast extract.	GMP

No.	Enzyme Nomenclature ⁽¹⁾	Enzyme Name ⁽²⁾	Source	Condition of Use	Maximum Use Level
47	EC 3.4.21	Endopeptidase or Acid prolyl endopeptidase or Prolyl endoprotease or Proline endopeptidase	<i>Aspergillus niger</i> expressed in <i>Aspergillus niger</i>	Processing aid for hydrolyzing of proteins to peptide (short chain of amino acid) at carboxylic side of proline in the production of food and beverage e.g., beer or protein hydrolysate from animal and plant.	GMP
48	Papain as follows;				
	EC 3.4.22.2	(1) Papain	<i>Carica papaya (L.) (Fam. Caricaceae)</i>	(1) Flavor enhancer	GMP
EC 3.4.22.6	(2) Chymopapain	(2) Processing aid for catalyzing of polypeptides, amides, esters, leucine, or glycine to small peptide molecules in the production of food or beverages, e.g., beer or food products containing meat as raw materials, cereal products including protein hydrolysates.			
49	EC 3.4.22.3	Ficain	The latex of <i>Ficus</i> sp.	Processing aid for catalyzing of polypeptides in the production of food of which raw materials contain protein, e.g., meat products, beverages, and baked goods.	GMP

No.	Enzyme Nomenclature ⁽¹⁾	Enzyme Name ⁽²⁾	Source	Condition of Use	Maximum Use Level
50	EC 3.4.22.4	Bromelain as follows;			
	EC 3.4.22.32	Stem bromelain	Stem cell or fruit of;	(1) Flavor enhancer, (2) Flour treatment agent, (3) Stabilizer, (4) Processing aid for catalyzing polypeptides, amides, and esters in the food of which raw materials contain protein, e.g., meat products, cereal products, or protein hydrolysates, and beer.	GMP
	EC 3.4.22.33	Fruit bromelain	(1) Pineapple (<i>Ananas comosus</i>) or (2) Red pineapple (<i>Ananas bracteatus</i> (L))		
51	EC 3.4.23.1	Avian Pepsin	the forestomach (proventriculum) of chicken or turkey.		
52	Pepsin as follows;				
	EC 3.4.23.1	(1) Pepsin A	Pig stomach	Processing aid for catalyzing of polypeptides including those with linkages adjacent to aromatic or L-leucine residues yielding 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) Gastricsin or Pepsin C			

No.	Enzyme Nomenclature ⁽¹⁾	Enzyme Name ⁽²⁾	Source	Condition of Use	Maximum Use Level
53	EC 3.4.22.4	Chymosin or Rennin or Rennet	<i>Escherichia coli</i> K-12 containing Prochymosin A Gene	Processing aid for catalyzing casein in clotting of milk for cheese production.	GMP
			<i>Aspergillus niger</i> var. <i>Awamori</i> containing Prochymosin B Gene		
			<i>Kluyveromyces lactis</i> containing Prochymosin B Gene		
			Aqueous extracts made from the fourth stomach of calf, kid or lamb		
			Aqueous extracts made from the fourth stomach of bovine animals, goats and sheep.		
			<i>Rhizomucor</i> species		
54	Rhizopuspepsin protease and triacylglycerol lipase				
	EC 3.4.23.21	Rhizopuspepsin protease	<i>Rhizopus niveus</i>	Processing aid in the production of; <ul style="list-style-type: none"> ○ Cooked rice or semi-cooked rice ○ Fat and oils 	GMP
	EC 3.1.1.3	Triacylglycerol lipase or Triacylglycerol acylhydrolase			

No.	Enzyme Nomenclature ⁽¹⁾	Enzyme Name ⁽²⁾	Source	Condition of Use	Maximum Use Level
55	EC 3.4.24.27	Thermolysin or Thermolysin Protease	<i>Geobacillus stearothermophilus</i>	Processing aid for catalyzing 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
56	EC 3.4.24.28	Bacillolysin or Anilozyme P 10	<i>Bacillus amyloliquefaciens</i> AE-NP	Processing aid for catalyzing peptide bond of protein to short chain protein and amino acid in the production of for example yeast extract, milk products, soybean milk, rice milk, oat milk, seasoning powder or condiments and eggshell membrane extract.	GMP
57	EC 3.5.1.1	Asparaginase	<i>Aspergillus niger</i> expressed in <i>Aspergillus niger</i>	Processing aid in the production of food to reduce Acrylamide from the reaction of Asparagine and reducing sugar during baking or frying.	GMP
			<i>Aspergillus oryzae</i> expressed in <i>Aspergillus oryzae</i>		
58	EC 3.5.1.2	Glutaminase	<i>Bacillus amyloliquefaciens</i>	Processing aid for catalyzing L-glutamine in the production of seasoning or condiments.	GMP
59	EC 3.5.1.44	Protein- glutamine glutaminase	<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 baked goods, pasta, noodle, cereal products, seasoning derived from yeast, or food products contained egg.	GMP

No.	Enzyme Nomenclature ⁽¹⁾	Enzyme Name ⁽²⁾	Source	Condition of Use	Maximum Use Level
60	EC 3.5.4.6	AMP deaminase	<i>Aspergillus melleus</i>	Processing aid in the production of yeast extract.	GMP
61	EC 4.1.1.5	Acetolactate Decarboxylase	<i>Bacillus brevis</i> expressed in <i>Bacillus subtilis</i>	Processing aid in the production of beer or alcoholic beverages.	GMP
62	EC 5.3.1.5	Xylose isomerase or Glucose isomerase	<i>Actinoplanes missouriensis</i>	Processing aid in the production of food of which raw materials contain starch or flour, e.g., high fructose corn syrup and other fructose syrups.	GMP
			<i>Bacillus coagulans</i>		
			<i>Streptomyces olivaceus</i>		
			<i>Streptomyces olivochromogen</i>		
			<i>Streptomyces rubiginosus</i>		
			<i>Streptomyces violaceoniger</i>		
			<i>Streptomyces rubiginosus</i> expressed in <i>Streptomyces rubiginosus</i>		
<i>Streptomyces murinus</i> DSM 3252					

Note:

(1) number of enzyme classified by the Enzyme Commission of International Union of Biochemistry and Molecular Biology (IUBMB).

(2) Accepted name, systematic name or other name of enzyme classified by the Enzyme Commission of IUBMB.

Schedule 2

Annexed to the Notification of The Ministry of Public Health (No. 443), B.E. 2566 (2023)

Issued under the Food Act, B.E. 2522 (1979) Re: Enzymes Used in Food Production

List of information or evidence for safety assessment.

No.	Information required	Details
1	Description and enzyme characterizations	
1.1	Name of enzyme(s)	Accepted name, systematic name or other name of enzyme classified by the International Union of Biochemistry and Molecular Biology (IUBMB).
1.2	Number(s)	EC/IUBMB number; CAS number (where appropriate).
1.3	Enzyme structure	Enzyme structure which include; (1) Molecular weight(s) (2) Amino acid sequence(s)
1.4	Historical use(s) in food-based applications	Evidence of commercial food use, including from the parent strain or other strains in the lineage.
1.5	Characteristic of enzyme(s)	Include; (1) All reactions catalyzed both active principle and any secondary activities including their products and co-factor or co enzyme, (2) conditions under which catalysis occurs (e.g. pH, temperature), (3) subsidiary or side activities (where appropriate).
1.6	Reactions and fate of enzyme in food.	Explain the enzyme active. How is enzyme inactive or removed?
1.7	The measurement of enzyme activity	Explain the measurement of enzyme activity according to the reaction catalyzed by individual enzymes and are usually reference to the method recommended in the Combined Compendium of Food Additive Specification or Food Chemical Codex. The method for enzyme activity measurement should be; (1) specificity,

No.	Information required	Details
		<p>(2) provide the Limit of detection and the limit of quantitation,</p> <p>(3) accuracy, and</p> <p>(4) precision.</p> <p>In case where the method of enzyme activity measurement is difference from the method provide in the document mentioned aboved, the producer should certify the performance of that method.</p>
1.8	Description and Impurities of Enzyme	Explain the appearance of enzyme product and attach the analytical report of such as heavy metal and mycotoxin which can occur during enzyme production. It shuld include the meathod of analysis.
1.9	Proposed specification of enzyme or enzyme preparation	<p>The specicication should comply with the safety requirement established in the notification of MOPH on enzyme for use in food production or the General Specifications and Considerations for Enzyme Preparations used in Food Processing. It should include;</p> <p>(1) Enzyme Nomenclature and source</p> <p>(2) Active Component</p> <p>(3) Physical discription</p> <p>(4) Enzyme Activity and Measure Unit</p> <p>(5) Condition of Use and Use instruction</p> <p>(6) Impurities (including heavy metal, mycotoxin and microbial aspects)</p> <p>(7) Packing and storage condition.</p>
2	Detail of production organism and enzyme production	
2.1	Source of enzyme	Identify genus, species (and strain) of the production organism;
	(1) Enzyme devired from animal	Identify scientific name and part of the production animal.
	(2) Enzyme devired from plant	Identify scientific name and part of the production plant

No.	Information required	Details
	(3) Enzyme derived from microorganism	Identify genus, species, and strain of the production microorganism including the characterization such as information relating to toxigenicity, virulence for human, other potential concern, history of use in food, culture collection, and the certificate of the collection control which the strain is held.
	(4) Enzyme derived from genetically modified microorganism (GMM)	<p>Should include;</p> <ol style="list-style-type: none"> 1. Details of the genetically modified microorganism, i.e.: <ol style="list-style-type: none"> 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; 1.5 Hazard characterization of the genetically modified microorganism. 2. Details of the recipient/host microorganism <ol style="list-style-type: none"> 2.1 Scientific name; 2.2 Common name (if any); 2.3 Taxonomy classification; 2.4 Accession number or culture collection; 2.5 History of use, cultivation, strain development, and toxigenicity or other potential concerns; 2.6 Genotypes and phenotypes relevant to safety; Toxigenicity, Antibiotic activity, Pathogenicity, Immunological impacts, genetic stability or genetic movement. 3. Details of the donor microorganism <ol style="list-style-type: none"> 3.1 In the case where an organism is the donor, the following shall be identified: <ol style="list-style-type: none"> 3.1.1 Scientific name; 3.1.2 Common name (if any); 3.1.3 Taxonomic classification;

No.	Information required	Details
		<p>3.1.4 Accession number or identified number from the culture collection;</p> <p>3.1.5 Information relating on food safety;</p> <p>3.1.6 Genotypes and phenotypes relating to; Toxigenicity, production of antibiotics, antibiotic activity, pathogenicity and immunological impacts.</p> <p>3.2 In the case of using synthetic DNA, 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 strand.</p> <p>4. Details of genetic modification procedure;</p> <p>4.1 Gene transfertation method</p> <p>4.2 Information of the DNA used in the modification:</p> <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> <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>

No.	Information required	Details
		<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> <ul style="list-style-type: none"> - In cases of Gram-negative bacteria, the gene product shall be identified as either intracellular or periplasmic; - In cases of eukaryotic microorganisms, it shall be identified as either organellar or secreted; <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</p>

No.	Information required	Details
		<p>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/hose 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</p> <p>6.3 genetically modified microorganism;</p> <p>Result of the examination of gene components.</p>

No.	Information required	Details
2.2	Detail of manufacturing process	Details related to raw materials used in the production process or fermentation process, and controlled 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	Production of enzyme concentrate and preparation	Steps and details of the enzyme immobilization procedure, substances used for the immobilization, including properties and characteristics of the substances.
3	Toxicology study and assessment of potential allergenicity of enzyme	
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 ^{1,2} , the following detailed information on its safety shall be provided.	
3.1.1	Sub-chronic toxicity study	A subchronic oral toxicity study should be follow the guideline of the Organization for Economic Co-operation and Development (OECD Guideline 408, 2000a). the recommended study is - Repeated Dose 90-Day Oral Toxicity Study in Rodents, or - Repeated Dose 90-Day Oral Toxicity Study in Non-Rodents
3.1.2	Genotoxicity study	The recommended approach for genotoxicity study as the first step is Ames test (OECD Guideline 471) or mouse lymphoma tk assay and chromosomal aberration/ micronucleus assay (OECD Guideline 476)

1. The toxicity tests maybe waived for;

1.1 an enzyme produced by the production strain is identified as belonging to a species have long history of safe use and no concerns are raised by the genetic modification of self-cloning as case by case consideration,

1.2 an enzyme which it can be demonstrated that there is no carry-over of the enzyme TOS into the final food products (all products intent to use that enzyme).

2. In case of enzymes produced by a strain which have long history of safe use, it maybe acceptable for providing toxicity testing from the same strain, or a related strain, or a lineage of related strain.

No.	Information required	Details
3.1.3	Allergenicity studies	Comparison of the amino acid sequence and/or structural similarities of the enzyme with known allergens. The comparison must confirm at least from 2 database and not more than 3 year up to the date of information submission.
3.1.4	Estimated dietary exposure and risk characterization	<p>1. Dietary exposure assessment for worst case scenario based on following information:</p> <p>1.1 Food consumption across Thailand for mean and 97.5th percentile of 7 age-groups³ ,</p> <p>1.2 Conversion factor or processing factor calculated from standard recipe or refer to the information provided by the Food and Agriculture Organization of the United Nations,</p> <p>1.3 the maximum use level of enzyme recommended for each type of food as in mg (TOS)/kg of food.</p> <p>Risk characterization referred to as the MOE (margin of expose) which calculated as:</p> <p><i>MOE = Reference point / Estimated dietary exposure</i> <i>(Reference point: i.e., NOEL, NOAEL, or benchmark dose level obtained from sub-chronic oral toxicity studies)</i></p>
3.1.5	Calculation of Acceptable Daily Intake (ADI)	<p>Calculation of Acceptable Daily Intake (ADI) based on information;</p> <p>(a) Reference point such as No-observed-effect level (NOEL) or No-observed-adverse-effect level (NOAEL)</p> <p>(b) Safety factor or an uncertainty factor which the value depends on the toxic effect, the size and type of the population.</p>

3. Except for food products which there are available evidence to proves that there are no residues of enzyme components.

No.	Information required	Details
		(c) toxicological versus physiological responses (d) the margin of expose (MOE)
3.2	For microorganism which prefer to submit the toxicology studies of same species or same strain lineage shall also submit foolowing information;	
3.2.1	History of the micoorganism	History of the microorganism maybe refer to the status of that microorganism as define in the Qualified Presumption of Safety (QPS).
3.2.2	Amino acid squence of the enzyme.	Amino acid squence of the enzyme.
3.3	Enzymes derived from sources that are considered or presumed safe for consumption.	
3.3.1	Plant or animal	Describe about history of use of the part of that palnt or animal.
3.3.2	Micoorganisms	Provide the history of use as food or document showing the safety or permission of that microorganism to be used in the production of food, e.g., Qualified Presumption of Safety (QPS) document, or Bulletin of International Dairy federation (IDF).
4	Expert opinion or related regulation (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. 443), B.E. 2566 (2023)

Issued under the Food Act, B.E. 2522 (1979) Re: Enzymes Used in Food Production

List of information or evidence for technology justification consideration.

No.	Information required	Details of information required
1	Information on inzyme characterization.	
1.1	Name and enzyme classification	Identify the chemical name, common name, trade name, synonym, and acronym.
1.2	Number(s)	EC/IUBMB number; CAS number (where appropriate).
1.3	Enzym characterization	Describe the information relating to: (1)Active principles, enzyme properties and reaction; (2)conditions of use; (3)Subsidiary or side activities of enzyme activities, including the method for detecting such substance resulting from subsidiary activities.
2	Summary relating to technology justification of using enzymes in the production process, and annexes.	
2.1	A technological need of enzymes in the production of food	Information or documents to serve a well-defined technological function and the purposes of use in the production with the recommend use level as in TOS.
2.2	The use of enzyme in food production	Details of using enzyme in the food production, food production process method to activate, inactivate or remove of the enzymes from the final food product.
2.3	Related documents (if any)	- Regulations or certification of free sale showing that enzyme is allowed to be maeket or used for food products in a country or community e.g., European Union, Australia, New Zealand, United States of America, or Japan Patent documents.

Schedule 4

Annexed to the Notification of The Ministry of Public Health (No. 443), B.E. 2566 (2023)

Issued under the Food Act, B.E. 2522 (1979) Re: Enzymes Used in Food Production

Lists of permitted food additives used in enzyme preparation.

INS No.	Name of the food additive	Maximum level in enzyme preparation	Maximum residue level in beverage	Maximum residue level in final food (except beverage)
INS 170(i)	Calcium carbonate	GMP	GMP	GMP
INS 200	Sorbic acid	20,000 mg/kg (singly or in combination expressed as sorbic acid)	10 mg/l	20 mg/kg
INS 202	Potassium sorbate			
INS 210	Benzoic acid	(1) 50,000 mg/kg (singly or in combination expressed as benzoic acid)	0.85 mg/l	1.7 mg/kg
INS 211	Sodium benzoate	(2) 12,000 mg/kg (in rennet)	2.5 mg/l (in whey-based beverages where rennet has been used)	5 mg/kg (in cheese where rennet has been used)
INS 214	Ethyl-p-hydroxybenzoate or Ethylparaben	2,000 mg/kg (singly or in combination expressed as free acid)	1 mg/l	2 mg/kg
INS -	Sodium ethyl p-hydroxybenzoate			
INS 218	Methyl p-hydroxybenzoate			
INS-	Sodium methyl p-hydroxybenzoate			

INS No.	Name of the food additive	Maximum level in enzyme preparation	Maximum residue level in beverage	Maximum residue level in final food (except beverage)
INS 220	Sulfur dioxide	(1) 2,000 mg/kg (singly or combination express as SO ₂) (2) 5,000 mg/kg (only in enzymes for brewing) (3) 6,000 mg/kg (only for beta-amylase derived from barley) (4) 10,000 mg/kg (only for papain in solid form)	2 mg/l	2 mg/kg
INS 221	Sodium sulfite			
INS 222	Sodium hydrogen sulfite			
INS 223	Sodium metabisulfite			
INS 224	Potassium metabisulfite			
INS 250	Sodium nitrite	500 mg/kg	No use	ไม่เกิน 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	ไม่เกิน 50 mg/l	GMP
INS 290	Carbon dioxide	GMP	GMP	GMP
INS 296	Malic acid	GMP	GMP	GMP
INS 300	Ascorbic acid	GMP	GMP	GMP

INS No.	Name of the food additive	Maximum level in enzyme preparation	Maximum residue level in beverage	Maximum residue level in final food (except beverage)
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 307a	d-alpha-Tocopherol Concentrate	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 No.	Name of the food additive	Maximum level in enzyme preparation	Maximum residue level in beverage	Maximum residue level in final food (except beverage)
INS-	Potassium tartrates	GMP	GMP	GMP
INS 337	Potassium sodium L (+) - tartrate	GMP	GMP	GMP
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 (expressed as P ₂ O ₅)	GMP	GMP
INS 339(i)	Sodium dihydrogen phosphate	50,000 mg/kg (singly or in combination expressed as P ₂ O ₅)	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-	Potassium malate	GMP	GMP	GMP

INS No.	Name of the food additive	Maximum level in enzyme preparation	Maximum residue level in beverage	Maximum residue level in final food (except beverage)
INS 352(ii)	Calcium DL-malate or DL-Monocalcium malate	GMP	GMP	GMP
INS-	Calcium tartrate	GMP	GMP	GMP
INS 380	Triammonium citrate	GMP	GMP	GMP
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 or 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 gum	GMP	GMP	GMP
INS 414	Gum Arabic or 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 or D-Glucitol or D-sorbitol or Sorbit or Sorbol	GMP	GMP	GMP
INS 420(ii)	Sorbitol syrup or D-Glucitol syrup	GMP		

INS No.	Name of the food additive	Maximum level in enzyme preparation	Maximum residue level in beverage	Maximum residue level in final food (except beverage)
INS 421	Mannitol	GMP	GMP	GMP
INS 422	Glycerol or Glycerine	GMP	GMP	GMP
INS 428	Edible Gelatin	GMP	GMP	GMP
INS 440	Pectins	GMP	GMP	GMP
INS 450(i)	Disodium diphosphate	50,000 mg/kg (singly or in combination expressed as P ₂ O ₅)	GMP	GMP
INS 450(ii)	Trisodium diphosphate			
INS 450(iii)	Tetrasodium diphosphate			
INS 450(v)	Tetrapotassium diphosphate			
INS 450(vi)	Dicalcium diphosphate			
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 No.	Name of the food additive	Maximum level in enzyme preparation	Maximum residue level in beverage	Maximum residue level in final food (except beverage)
INS 460(ii)	Powdered Cellulose	GMP	GMP	GMP
INS 461	Methyl cellulose	GMP	GMP	GMP
INS 462	Ethyl cellulose	GMP	GMP	GMP
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 No.	Name of the food additive	Maximum level in enzyme preparation	Maximum residue level in beverage	Maximum residue level in final food (except beverage)
INS- (E 472d)	Tartaric acid esters of mono- and diglycerides of fatty acids	GMP	GMP	GMP
INS 472e	Diacetyltartaric and fatty acid esters of glycerol or 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	25 mg/l	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 No.	Name of the food additive	Maximum level in enzyme preparation	Maximum residue level in beverage	Maximum residue level in final food (except beverage)
INS 503(i)	Ammonium carbonate	GMP	GMP	GMP
INS 503(ii)	Ammonium hydrogen carbonate or Ammonium bicarbonate			
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			
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			
INS 516	Calcium sulfate	GMP	GMP	GMP
INS-	Ammonium sulphate	100,000 mg/kg	50 mg/l	ไม่เกิน 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 No.	Name of the food additive	Maximum level in enzyme preparation	Maximum residue level in beverage	Maximum residue level in final food (except beverage)
INS 527	Ammonia solution or 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-	Fatty acids	GMP	GMP	GMP
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	5 mg/l	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 No.	Name of the food additive	Maximum level in enzyme preparation	Maximum residue level in beverage	Maximum residue level in final food (except beverage)
INS 965(i)	Maltitol	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 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 No.	Name of the food additive	Maximum level in enzyme preparation	Maximum residue level in beverage	Maximum residue level in final food (except beverage)
INS 1520	Propylene glycol	500 g/kg	1,000 mg/kg (single or incombination with Triethyl citrate, Glyceryl diacetate (diacetin) and Glyceryltriacetate; triacetin; exception of cream liqueurs)	3,000 mg/kg (single or incombination with Triethyl citrate, Glyceryl diacetate (diacetin) and Glyceryltriacetate; triacetin)
INS -	Maltodextrin	GMP	GMP	GMP

Schedule 5

Annexed to the Notification of The Ministry of Public Health (No. 443), B.E. 2566 (2023)

Issued under the Food Act, B.E. 2522 (1979) Re: Enzymes Used in Food Production

Lists of support materials used for immobilization of enzymes.

INS 551	Silicon dioxide, Amorphous or Silica
INS 558	Bentinite
INS -	PolyEthyleneimine; PEI
INS -	Diatomaceous Earth, Diatomaceous silica, Diatomite
INS -	polymethacryl-divinylbenzene copolymer or 2-Propenoic acid, 2-methyl-, butyl ester, polymer with diethenylbenzene, ethenylbenzene, ethenylethylbenzene and methyl 2-methyl-2-propenoate (CAS. 1204391-75-2)

Schedule 6

Annexed to the Notification of The Ministry of Public Health (No. 443), B.E. 2566 (2023)

Issued under the Food Act, B.E. 2522 (1979) Re: Enzymes Used in Food Production

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.