

■ Revision of Specifications and Standards to Update the Official Compilation of Food Additives

The government of Japan will revise the existing specifications and standards for food additives.

Summary

Japan prohibits the sale of food additives that are not designated by the Minister of Health, Labour and Welfare (“the Minister”) under Article 12 of the Food Sanitation Act (“the Act”). In addition, when specifications or standards for food additives are stipulated pursuant to Article 13 of the Act, the sale of those additives are prohibited unless they meet the specifications or the standards.

The specifications and standards established based on Article 13, paragraph (1) of the Act are stipulated in the Specifications and Standards for Foods, Food Additives, Etc. (Public Notice of the Ministry of Health and Welfare No. 370 of 1959, “the Public Notice”). The Public Notice contains general notices, general tests, and reagents and solutions required for the testing of food additives as well as compositional specifications for additives and standards for the storage, manufacturing, and use thereof.

On the other hand, the Act requires the Minister and the Prime Minister, in Article 21 of the Act, to prepare the Official Compilation of Food Additives containing compositional specifications and standards for food additives based on Article 13, paragraph (1). In 1960 the first edition of the compilation was prepared. Since then, the compilation had been updated regularly until the publication of the ninth edition in 2018.

In March 2023, in response to a request from the Minister, the Committee on Food Additives of the Food Sanitation Council that is established under the Pharmaceutical Affairs and Food Sanitation Council discussed whether it is adequate to revise the specifications and standards for food additives to update the official compilation of food additives.

The committee concluded that the Minister should revise the specifications and standards based on Article 13 of the Act.

Process to prepare the tenth edition of the Official Compilation of Food Additives

In June 2018, the MHLW held the first session of the Committee on Preparing the Tenth Edition of the Official Compilation of Food Additives. By February 2022, the MHLW had 12 sessions to deliberate on the Tenth Edition of the Official Compilation of Food Additives. Based on the results of the discussions, the MHLW invited opinions on

revision of specification and standards of foods and food additives. Considering the opinions, the MHLW prepared the draft of the Tenth Edition of the Official Compilation of Food Additives. (For details, see Attachment.) Also, based on the consideration, some specifications and standards have already been published as Addenda 1 and 2 to the Ninth Edition.

Attachment

Outline of the Draft Tenth Edition of the Official Compilation of Food Additives

1. Establish specifications for 45 existing food additives.

Annex 1. Substances for which specifications are to be newly established

2. Concerning some monographs for which one monograph applies to plural similar substances with different specifications according to the form or constituent, specify each substance as an independent monograph by separating them. The modification is targeted at 2 designated additives, 5 existing food additives, and 2 food additive preparations.

Annex 2. Substances for which specifications are to be individually established according to the form and constituent

3. Modify specifications for 105 designated additives (128 specification categories), 59 existing additives (86 specification categories), and 2 food additive preparations (3 specification categories). This is to improve testing procedures, increase the testing accuracy, and change reagents to be used. In addition, this is to align descriptions—including substance names, structural formulae, terms, examples, and calculation formulae—with those based on the IUPAC (International Union of Pure and Applied Chemistry) nomenclature.

Annex 3. Substances for which specifications are to be modified

4. In section B “General Tests,” specify new testing methods including “Elemental Analysis” in the wake of the development of science and technology. Modify 16 existing testing methods stipulated in the section. This is to improve testing techniques, to change reagents and test apparatus used, and to unify the wordings and descriptions. Also delete “Methoxy Determination” because there are no longer substances that require this testing method.

5. In section C “Reagents, Solutions, and Other Reference Materials,” add new reagents in line with the establishment of new testing methods and compositional specifications. In addition, change description items for consistency of the description of specifications for reagents, including addition, modification, or deletion of items.

6. Delete infrared reference spectra in section C “Reagents, Solutions, and Other Reference Materials,” and specify each reference spectrum in the corresponding monograph in section D “Monographs.”

7. In sections E “Standards for Manufacturing” and F “Standards for Use,” delete the words “sand” to make specifications more accurate. And clearly represent the names of all the substances covered by the words “any other similar water-insoluble mineral substance.”

Annex 1. Substances for which specifications are to be newly established

Substance Name	
English	Japanese
Agrobacterium Succinoglycan	アグロバクテリウムスクシノグリカン
Artemisia Seed Gum	サバクヨモギシードガム
Aspergillus Terreus Glycoprotein	アスペルギルスステレウス糖たん白質
Branched Cyclodextrin	分岐シクロデキストリン
Calcinated Coral Calcium	造礁サンゴ焼成カルシウム
Calcinated Sea Urchin Shell Calcium	うに殻焼成カルシウム
Calcinated Whey Calcium	乳清焼成カルシウム
Cane Wax	サトウキビロウ
Capsicum Water-soluble Extract	トウガラシ水性抽出物
Carpophore Derived Mannentake Extract (Fruiting body)	レイシ抽出物
Chicle	チクル
Coffee Bean Extract (Paste, Liquid)	生コーヒー豆抽出物（ペースト品、液体品）
Crude Potassium Chloride (Sea Water)	粗製海水塩化カリウム
Elemi Resin	エレミ樹脂
Enzymatically Hydrolyzed Guar Gum	グァーガム酵素分解物
Enzymatically Modified Lecithin	酵素処理レシチン
Essential Oil Removed Fennel Extract	精油除去ウイキョウ抽出物
Gallic Acid	没食子酸
Gentian Root Extract	ゲンチアナ抽出物
Glucosamine	グルコサミン
Heptane	ヘプタン
Horseradish Extract	セイヨウワサビ抽出物
Hyaluronic Acid	ヒアルロン酸
Jamaica Quassia Extract	ジャマイカカッシア抽出物
Japan Wax	モクロウ
Jelutong	ジェルトン
Licorice Oil Extract	カンゾウ油性抽出物
Mevalonic Acid	メバロン酸
Myrrh	ミルラ
Phytin (Extract)	フィチン（抽出物）
Quercetin	クエルセチン
Rice Bran Wax	コメヌカロウ
Rosemary Extract (Water Insoluble)	ローズマリー抽出物（非水溶性）
Rosemary Extract (Water Soluble)	ローズマリー抽出物（水溶性）
Rosin	ロシン
Rumput Roman Extract	カワラヨモギ抽出物
Sandalwood Red	シタン色素
Shellac Wax	シェラックロウ
Smoke Flavourings / Wood Vinegar / Liquid Smoke	くん液
Sodium Chloride-decreased Brine (Saline Lake)	塩水湖水低塩化ナトリウム液
Spice Extracts	香辛料抽出物
Tea Extract	チャ抽出物
Trehalose	トレハロース
Urushi Wax	ウルシロウ
Vegetable Carbon Black	植物炭末色素

Annex 2. Substances for which specifications are to be individually established according to the form and constituent

Substance Name		Substance Category			Substances with Independent Specifications in the 10th Edition					
English	Japanese	Existing Additive	Designated Additive	Preparation	English	Japanese	English	Japanese	English	Japanese
Annatto Extract	アナトー色素	✓			Annatto Extract (Norbixin)	アナトー色素(ノルビキシン)	Annatto Extract (Bixin)	アナトー色素(ビキシン)		
Asparaginase	アスパラギナーゼ		✓		Asparaginase (<i>A. niger</i> ASP-72-derived)	アスパラギナーゼ (<i>A. niger</i> ASP-72株由来)	Asparaginase (<i>A. oryzae</i> NZYM-SP-derived)	アスパラギナーゼ (<i>A. oryzae</i> NZYM-SP株由来)		
Baking Powder	合成膨張剤			✓	Baking Powder (Single)	合成膨張剤(一剤式)	Baking Powder (Duplex)	合成膨張剤(二剤式)	Baking Powder (Ammonia)	合成膨張剤(アンモニア系)
Ion Exchange Resin	イオン交換樹脂		✓		Ion Exchange Resin (granule)	イオン交換樹脂(粒状)	Ion Exchange Resin (powder)	イオン交換樹脂(粉状)	Ion Exchange Resin (suspension)	イオン交換樹脂(懸濁液)
Kansui	かんすい			✓	Kansui (Solid)	かんすい(固形)	Kansui (Liquid)	かんすい(液状)	Kansui (Diluted Powder)	かんすい(希釈粉末)
Licorice Extract	カンゾウ抽出物	✓			Licorice Extract (Crude)	カンゾウ抽出物(粗製物)	Licorice Extract (Purified)	カンゾウ抽出物(精製物)		
Phytic Acid	フィチン酸				Phytic Acid (Liquid)	フィチン酸(液体品)	Phytic Acid (Powder)	フィチン酸(粉末品)		
Shellac	シェラック	✓			Shellac (White Shellac)	シェラック(白シェラック)	Shellac (Purified Shellac)	シェラック(精製シェラック)		
Vegetable Sterol	植物性ステロール	✓			Vegetable Sterol (High Concentration Free Sterol)	植物性ステロール (遊離体高濃度品)	Vegetable Sterol (Low Concentration Free Sterol)	植物性ステロール (遊離体低濃度品)		

Annex 3. Substances for which specifications are to be modified

Substance Name		Substance Category			Category of the Specifications to Be Revised						
English	Japanese	Existing Additive	Designated Additive	Preparation	Definition	Content	Description	Identification	Purity	Assay	Other
Acetone	アセトン		✓							✓	
Active Carbon	活性炭	✓							✓		
Adipic Acid	アジピン酸		✓							✓	
Alginate Acid	アルギン酸	✓								✓	
Aluminium Ammonium Sulfate	硫酸アルミニウムアンモニウム		✓						✓		
Aluminium Potassium Sulfate	硫酸アルミニウムカリウム		✓						✓		
L-Arabinose	Ｌ-アラビノース	✓							✓		
L-Arginine L-Glutamate	Ｌ-アルギニンＬ-グルタミン酸塩		✓					✓			
L-Ascorbic Acid	Ｌ-アスコルビン酸		✓								Specific Rotation
L-Ascorbyl Palmitate	Ｌ-アスコルビン酸パルミチン酸エステル		✓							✓	
L-Ascorbyl Stearate	Ｌ-アスコルビン酸ステアリン酸エステル		✓							✓	
Aspartame	アスパルテーム		✓						✓		
Bees Wax	ミツロウ	✓							✓		
Calcinated Bone Calcium	骨焼成カルシウム	✓			✓						
Calcinated Eggshell Calcium	卵殻焼成カルシウム	✓			✓						
Calcinated Shell Calcium	貝殻焼成カルシウム	✓			✓						
Calcium Acetate	酢酸カルシウム		✓						✓		
Calcium Carbonate II	炭酸カルシウム II		✓						✓		
Calcium Carbonate I	炭酸カルシウム I		✓						✓		
Calcium Carboxymethylcellulose	カルボキシメチルセルロースカルシウム		✓						✓		
Calcium Chloride	塩化カルシウム		✓						✓		
Calcium Hydroxide	水酸化カルシウム		✓						✓		
Calcium Lactate	乳酸カルシウム		✓						✓		
Calcium L-Ascorbate	Ｌ-アスコルビン酸カルシウム		✓								Specific Rotation
Calcium Oxide	酸化カルシウム		✓						✓		
Calcium Propionate	プロピオン酸カルシウム		✓						✓		
Calcium Silicate	ケイ酸カルシウム		✓					✓		✓	Loss on Ignition
Calcium Stearoyl Lactylate	ステアロイル乳酸カルシウム		✓						✓		
Calcium Sulfate	硫酸カルシウム		✓								CAS Registry Number
Caramel III (Ammonia caramel)	カラメル III	✓							✓		
Caramel I (Plain caramel)	カラメル I	✓							✓		
Caramel II (Sulfite caramel)	カラメル II	✓							✓		
Carbon Dioxide	二酸化炭素		✓						✓		
Carob Bean Gum / Locust Bean Gum	カロブビーンガム	✓							✓		
Chinese Bayberry Extract	ヤマモモ抽出物	✓							✓		

Substance Name		Substance Category			Category of the Specifications to Be Revised						
English	Japanese	Existing Additive	Designated Additive	Preparation	Definition	Content	Description	Identification	Purity	Assay	Other
Chlorous Acid Water	亜塩素酸水		✓							✓	
Citric Acid	クエン酸		✓						✓		
Cochineal Extract / Carminic Acid	コチニール色素	✓			✓				✓	✓	Color Value
Curcumin / Turmeric Oleoresin	ウコン色素	✓									Substance Name
Cyanocobalamin	シアノコバラミン	✓						✓			
L-Cysteine Monohydrochloride	Ｌ-システイン塩酸塩		✓							✓	
Dextranase	デキストラナーゼ	✓									Dextranase Activity Test
Diluted Benzoyl Peroxide	希釈過酸化ベンゾイル		✓							✓	
Disodium DL-Tartrate	DL-酒石酸ナトリウム		✓								Structural Formula Chemical Name
Disodium L-Tartrate	Ｌ-酒石酸ナトリウム		✓						✓		
Enju Extract / Japanese Pagoda Tree Extract	エンジュ抽出物	✓			✓				✓		Substance Name
Enzymatically Decomposed Lecithin	酵素分解レシチン	✓							✓		
Erythorbic Acid	エリソルビン酸		✓								Specific Rotation
Ethyl Acetate	酢酸エチル		✓			✓		✓		✓	Refractive Index Specific Gravity
Ferric Ammonium Citrate	クエン酸鉄アンモニウム		✓							✓	
Ferric Chloride	塩化第二鉄		✓						✓	✓	
Ferric Citrate	クエン酸鉄		✓							✓	
Ferric Pyrophosphate	ピロリン酸第二鉄		✓							✓	
Ferric Pyrophosphate Solution	ピロリン酸第二鉄液		✓							✓	
Ferrous Gluconate	グルコン酸第一鉄		✓						✓		
Ferrous Sulfate	硫酸第一鉄		✓							✓	
Gellan Gum	ジェランガム	✓							✓		
Glycerol	グリセリン		✓							✓	
Grape Skin Extract / Grape Skin Color	ブドウ果皮色素	✓							✓		
Guar Gum	グァーガム	✓							✓		
Heme Iron	ヘム鉄	✓								✓	
Higher Fatty Acid (Behenic Acid)	高級脂肪酸(ベヘニン酸)	✓							✓	✓	
Higher Fatty Acid (Lauric Acid)	高級脂肪酸(ラウリン酸)	✓							✓	✓	
Higher Fatty Acid (Myristic Acid)	高級脂肪酸(ミリスチン酸)	✓							✓	✓	
Higher Fatty Acid (Stearic Acid)	高級脂肪酸(ステアリン酸)	✓							✓	✓	
Higher Fatty Acid (Capric Acid)	高級脂肪酸(カプリン酸)	✓							✓	✓	
Higher Fatty Acid (Caprylic Acid)	高級脂肪酸(カプリル酸)	✓							✓	✓	
Higher Fatty Acid (Palmitic Acid)	高級脂肪酸(パルミチン酸)	✓							✓	✓	
High-Test Hypochlorite	高度サラシ粉		✓							✓	
L-Histidine Monohydrochloride	Ｌ-ヒスチジン塩酸塩		✓								CAS Registry Number
Hydrogen Peroxide	過酸化水素		✓						✓		
1-Hydroxyethylidene-1,1-diphosphonic Acid	1-ヒドロキシエチリデン-1,1-ジホスホン酸		✓						✓		
Hydroxypropyl Cellulose	ヒドロキシプロピルセルロース		✓			✓				✓	

Substance Name		Substance Category			Category of the Specifications to Be Revised						
English	Japanese	Existing Additive	Designated Additive	Preparation	Definition	Content	Description	Identification	Purity	Assay	Other
D-Sorbitol	D-ソルビトール		✓						✓		
DL-Tartaric Acid	DL-酒石酸		✓								Structural Formula Chemical Name
Terpineol	テルピネオール		✓					✓			
Thaumatococin	タウマチン	✓							✓		
DL-Threonine	DL-トレオニン		✓						✓		
Thujaplicin (Extract) / Hinokitiol (Extract)	ツヤプリシン(抽出物)	✓									Residue on Ignition
Titanium Dioxide	二酸化チタン		✓						✓		Loss on Ignition
Tripotassium Phosphate	リン酸三カリウム		✓							✓	
Vegetable Sterol (High Concentration Free Sterol)	植物性ステロール(遊離体高濃度品)	✓							✓		
Vegetable Sterol (Low Concentration Free Sterol)	植物性ステロール(遊離体低濃度品)	✓							✓		
Vegetable Tannin	植物タンニン	✓			✓	✓					
Welan Gum	ウェランガム	✓							✓		
Xanthan Gum	キサンタンガム	✓							✓		Ash
Xylanase	キシラナーゼ	✓									Xylanase Activity Test
D-Xylose	D-キシロース	✓						✓	✓	✓	
Yucca Foam Extract	ユッカフォーム抽出物	✓						✓		✓	