

Notification

Withdrawal of 80 food additives, which are no longer distributed in Japan, from the List of the Existing Food Additives

Purpose

The Ministry of Health, Labour and Welfare (hereinafter referred to as “MHLW”) intends to withdraw 80 food additives from the List of the Existing Food Additives.¹

Currently these 80 food additives have been found to be no longer distributed in Japan and are supposed to be withdrawn from the List and consequently will be prohibited for use on and after 18 May 2011 at the latest. These 80 food additives are identified in Ministry of Health, Labour and Welfare Notification No. 215, which was issued on 18 May 2010, for comments from public.

Background

According to Article 2-3 of the Supplementary Provisions of Law No.101 of 1995 (Law to Partially Revise the Food Sanitation Law and Nutrition Improvement Law ²), the Minister of Health, Labour and Welfare is responsible for its risk management decision to withdraw food additives from the List of the Existing Food Additives in the Ministry of Health and Welfare Announcement No. 120, 1996, when it is determined that food additives concerned, or preparations or foods containing them are no longer marketed. Such decision should be made, taking into account thoroughly the actual situation of the sale, manufacturing, import, processing, use, storage, and display of the substances.

In this decision making process, the Minister publishes a notification listing food additives concerned intended to be withdrawn, for the purpose of seeking public comments. According to the provision and process above, 70 additives have been withdrawn in the past 7 years since 2003.

In the identification of the 80 food additives mentioned above, the MHLW took into consideration carefully outcome of a survey carried out in 2009 addressing substances in the situation that their distribution was unknown.

The survey was aimed at examining the situation on sale, manufacturing, import, processing, use, storage, and display of such substances in the market in Japan. Through a thorough analysis of the survey result, the MHLW concluded that they were no longer distributed in the domestic market. Individual names of 80 food additives are identified in the attachment..

¹ “Existing food additives” refer to non-synthetic food additives that were marketed or used on the date of the amendment of the Food Sanitation Law (May 24, 1995) and that appear in the List of Existing Food Additives.

² The Nutrition Improvement Law is the present Health Promotion Law.

Criteria for the selection of the 80 substances for withdrawal³ are as follows:

- a. Those whose distribution was not confirmed in Japan;
- b. Those whose distribution was confirmed but whose use as food additives was not confirmed⁴; and
- c. Those for which requests for withdrawal were filed by their manufacturers: Catechin, Crayfish colour, Copal resin, Sphingolipid (bovine brain), and Dammar resin.

The MHLW submitted a report containing the result of the survey on the 80 food additive-list and the conclusion above to the Subcommittee on Food Additives, a consultative body assigned by the Minister. The Subcommittee considered them and agreed to give the following advice to the Minister, which was suggesting that it would be appropriate to withdraw these 80 additives from the List the List of the Existing Food Additives.

Action to be taken

Following the issuance of the Notification No.215 on 18 May 2010, the MHLW should take its decision making process. This process includes seeking public comment during a six-month period. Timeline of this process is as follows:

1. On May 18 2010: Published the Notification No.215 listing food additives for withdraw.
 - ◆ **Comment period (6 months, including WTO notification)**
 Those who claim to modify the list should submit an application to the MHLW with documents which prove actual distribution of the additives concerned, or preparations or food containing them in the market in Japan.
2. November 17 2010: Due date for comment submission.
3. In another six month period, the List of the Existing Food Additives will be revised to

³ Natural flavoring agents, which are obtained from animals and plants or mixtures of thereof for flavoring to food, are outside the scope of this activity.

⁴ As mentioned in the background, the use of these substances is not prohibited as long as they are used as ingredients of food commodities.

formally withdraw these additives. The List will come into force on 18 May 2011 at the latest. Thereafter, the use of them as food additives is prohibited.

**List of Existing Food Additives To Be Withdrawn
(As of May 2010)**

No.	Name of substance name	Reference No. in the List of Existing Food Additives)
1	<i>N</i> -Acetylglucosamine (<i>N</i> -アセチルグルコサミン)	11
2	Arabino galactan (アラビノガラクトン)	21
3	Alkanet colour (アルカネット色素) A substance which is obtained from alkanet roots and whose main component is alkanin.	23
4	Aloe vera extract (アロエベラ抽出物) A substance which is obtained from aloe leaves and whose main components are polysaccharides.	28
5	Sweet potato carotene (イモカロテン) A substance which is obtained from the tuberous roots of sweet potatoes and whose main component is carotene.	37
6	Japanese styrax benzoin extract (エゴノキ抽出物) A substance which is obtained from the exudation of <i>ansoku-ko-no-ki</i> trees (<i>Styrax Benzoin</i> DRY.) and whose main component is benzoic acid.	44
7	Ellagic acid (エラグ酸)	46
8	Krill colour (オキアミ色素) A substance which is obtained from krill shells or eyes and whose main component is astaxanthin.	49
9	Oligo- <i>N</i> -acetylglucosamine (オリゴ- <i>N</i> -アセチルグルコサミン)	52
10	Oligoglucosamine (オリゴグルコサミン)	54
11	Cacao carbon black (カカオ炭末色素) A substance which is obtained from the seed coats of cacao beans and whose main component is carbon.	61
12	Gastric mucin (ガストリックムチン)	65

	A substance which is obtained from mammals' gastric mucosae and whose main components are mucopolysaccharides.	
13	Catechin (カテキン)	70
14	Crayfish colour (カニ色素) A substance which is obtained from crayfish shells or eyes and whose main component is astaxanthin.	72
15	Aloe extract (キダチアロエ抽出物) A substance which is obtained from the leaves of Kidachi aloe (<i>Aloe arborescens</i> MILL.) and whose main components are polysaccharides.	94
16	Phellodendron bark extract (キハダ抽出物) A substance which is obtained from the bark of phellodendron trees (<i>Phellodendron amurense</i> RUPR.) and whose main component is berberine.	100
17	Gutta hang kang (グッタハンカン) A substance which is obtained from the exudation of gutta hang kang trees (<i>Palaquium leiocarpum</i> BOERL.) and whose main components are amyirin acetate and polyisoprenes.	113
18	Green tuff (グリーンタフ)	116
19	Mulberry bark extract (クワ抽出物) A substance which is obtained from the rhizome skins of mulberry and whose main components are stilbene derivatives and flavonoids.	133
20	Gentian root extract (ゲンチアナ抽出物) A substance which is obtained from gentian roots or rhizomes and whose main components are amarogentin and gentiopicroside.	136
21	Enzymatically modified licorice extract (酵素処理カンゾウ) A substance which is obtained by adding glucose to licorice extract (refer to No. 88 Licorice extract) using cyclodextrin glucosyltransferase and whose main components are α -glucosylglycyrrhizic acids.	140
22	Enzymatically modified tea extract (酵素処理チャ抽出)	141

	物) A substance which is obtained by adding glucose to tea extract (refer to No. 232 Tea extract) using cyclodextrin glucosyltransferase.	
23	Enzymatically hydrolyzed coix extract (酵素分解ハトムギ抽出物) A substance which is obtained by enzymatically hydrolyzing the seeds of Job's tears (<i>Coix lacryma-Jobi var. ma-yuen</i> STAPP).	147
24	Copal resin (コーパル樹脂) A substance which is obtained from the exudation of copal trees and whose main component is agathenedicarboxylic acid.	155
25	Cobalt (コバルト)	156
26	Resin of depolymerized natural rubber (ゴム分解樹脂) A substance which is obtained from rubber (refer to No. 159 Rubber) and whose main components are diterpenes, triterpenes and tetraterpenes.	160
27	Enzymatically decomposed rice bran (コメヌカ酵素分解物) A substance which is obtained from defatted rice bran and whose main components are phytic acid and peptides.	162
28	Bamboo grass colour (ササ色素) A substance which is obtained from the leaves of bamboo grass and whose main component is chlorophyll.	165
29	Cane wax (サトウキビロウ) A substance which is obtained from cane stems and whose main component is myricyl palmitate.	166
30	Sandarac resin (サンダラック樹脂) A substance which is obtained from the exudation of sandarac trees and whose main component is sandaracopimaric acid.	171
31	Shikon colour [Lithospermum root colour] (シコン色素)	180

	A substance which is obtained from the roots of <i>murasaki</i> (<i>Lithospermum erythrorhizon</i> SIEBOLD et ZUCCARINI) and whose main component is shikonin.	
32	Jamaica quassia extract (ジャマイカカッシア抽出物) A substance which is obtained from the trunks/branches or bark of Jamaica quassia trees and whose main components are quassin and neoquassin.	185
33	Calcinated calcium (焼成カルシウム) Calcinated calcium is defined as a substance which is obtained by calcinating sea urchinshells, shells, coral, whey, bones or eggshells and whose main components are calcium compounds. This time, calcinated calcium obtained from sea urchinshells will be expected to be withdrawn.	187
34	Sclero gum [Scleroglucan] (スクレロガム) A substance which is obtained from the culture fluid of <i>Sclerotium gluconicum</i> and whose main components are polysaccharides.	193
35	Sphingolipid (スフィンゴ脂質) Sphingolipid is defined as a substance which is obtained from bovine brains or rice bran and whose main components are sphingosine derivatives. This time sphingolipid obtained from bovine brains will be expected to be withdrawn.	197
36	Sesamol (セサモリン)	203
37	Sesbania gum (セスバニアガム) A substance which is obtained from sesbania seeds and whose main components are polysaccharides.	205
38	Sorva [Leche caspi] (ソルバ) A substance which is obtained from the exudation of sorva trees and whose main components are amyris acetate and polyisoprenes.	212
39	Sorvinha (ソルビンハ) A substance which is obtained from the exudation of sorvinha trees (<i>Couma utilis</i> MUELL.) and whose main components are amyris acetate and	213

	polyisoprenes.	
40	L-Sorbose (L-ソルボース)	214
41	Tannin (extract) (タンニン (抽出物)) Tannin is defined as a substance which is obtained from Japanese persimmon fruits, chestnut astringent skins, Japanese gall, tamarind seed coats, angelica powder, nutgall or silver wattle bark and whose main components are tannin and tannic acid. This time, tannin obtained from chestnut astringent skins or tamarind seed coats is expected to be withdrawn.	226
42	Dammar resin (ダンマル樹脂) A substance which is obtained from the exudate of trees of <i>Shorea</i> spp., <i>Hopea</i> spp., or <i>Agathis</i> spp. and whose main components are resin and polysaccharides.	227
43	Tea seed saponin (チャ種子サポニン) A substance which is obtained from tea seeds and whose main components are saponins.	231
44	Chilte (チルテ) A substance which is obtained from the exudation of chilte trees (<i>Chidoscolus elasticus</i> LUNDELL) and whose main components are amyryne acetate and polyisoprenes.	233
45	Tunu (ツヌー) A substance which is obtained from the exudation of tunu trees (<i>Castilla fallax</i> COOK) and whose main components are amyryne acetate and polyisoprenes.	235
46	Depolymerized natural rubber (低分子ゴム) A substance which is obtained by decomposing the exudation of para rubber trees and whose main components are polyisoprenes.	238
47	Tourmaline (電気石)	244
48	Cholesterol (動物性コレステロール) A substance which is obtained from fish oil or lanolin (refer to No. 395 Lanolin) and whose main component is cholesterol.	248

49	Dokudami extract (ドクダミ抽出物) A substance which is obtained from the leaves of <i>dokudami</i> (<i>Hauttuyniae coradata</i> THUNB.) and whose main component is isoquercitrin.	249
50	Triacylglycerol lipase (トリアシルグリセロールリパーゼ)	258
51	Quassia extract (ニガキ抽出物) A substance which is obtained from the trunks/branches or bark of <i>nigaki</i> trees (<i>Picrasma quassioides</i> BENN.) and whose main component is quassin.	268
52	Niger gutta (ニガーグッタ) A substance which is obtained from the exudation of niger gutta trees (<i>Ficus platyphylla</i> DELILE.) and whose main components are amyirin acetate and polyisoprenes.	269
53	Absinth extract (ニガヨモギ抽出物) A substance which is obtained from the whole absinth grass and whose main components are sesquiterpenes.	270
54	Nystose (ニストース)	271
55	Olibanum (ニユウコウ) A substance which is obtained from the exudation of olibanum trees and whose main components are α - and β -boswellic acids.	273
56	Garlic extract (ニンニク抽出物) A substance which is obtained from garlic bulbs and whose main components are allylsulfides.	275
57	Paffia extract (パフィア抽出物) A substance which is obtained from the roots of paffia (<i>Paffia iresinoides</i> SPRENGEL) and whose main components are ecdysteroids and saponins.	281
58	Isodonis extract (ヒキオコシ抽出物) A substance which is obtained from the stems or leaves of <i>hiki-okoshi</i> (<i>Isodon japonicus</i> HARA) and whose main component is enmein.	288

59	Himematsutake extract (ヒメマツタケ抽出物) A substance which is obtained from the mycelium or fruit body of <i>hime-matsutake</i> (<i>Agricus blazei</i> MURR.) or its culture fluid.	295
60	Pimento extract (ピメント抽出物) A substance which is obtained from pimento fruits and whose main components are eugenol and thymol.	296
61	Hesperetin (ヘスペレチン)	331
62	Powdered annatto (ベニノキ末色素) A substance which is obtained from annatto seeds and whose main components are norbixin and bixin.	335
63	Venezuelan chicle (ベネズエラチクル) A substance which is obtained from the exudation of Venezuelan chicle trees and whose main components are amyirin acetate and polyisoprenes.	338
64	Pepper extract (ペパー抽出物) A substance which is obtained from pepper fruits and whose main components are feruperines.	339
65	Garden balsam extract (ハウセンカ抽出物) A substance which is obtained from the whole plant of garden balsam and whose main component is naphthoquinone.	348
66	Hokosshi extract (ホコッシ抽出物) A substance which is obtained from the seeds of <i>hokosshi</i> (<i>Psoralea corylifolia</i> O.KZE.) and whose main component is bakuchiol.	349
67	Massaranduba chocolate (マッサランドバチョコレート) A substance which is obtained from the exudation of massaranduba chocolate trees and whose main components are amyirin acetate and polyisoprenes.	359
68	Massaranduba balata (マッサランドババサラ) A substance which is obtained from the exudation of massaranduba balata trees and whose main components are amyirin acetate and polyisoprenes.	360
69	Methylthioadenosine (メチルチオアデノシン)	372

	A substance which is obtained from <i>Saccharomyces</i> spp. and whose main component is 5'-dehydroxy-5'-methylthioadenosine.	
70	Mousouchiku charcoal extract (モウソウチク炭抽出物) A substance which is obtained by extraction from the carbonized stems of <i>mousou-chiku</i> bamboo (<i>Phyllostachys heterocycla</i> MITF.).	377
71	Morin (モリン)	385
72	Montan wax (モンタンロウ) A substance which is obtained from brown coal or lignite and whose main components are esters of fatty acids and tetracosyl-triacontanyl alcohol or hexacosyltriacontanyl alcohol.	386
73	Vegetable oil soot colour (油煙色素) A substance which is obtained by burning vegetable oils and whose main component is carbon.	388
74	Eucalyptus leaf extract (ユーカリ葉抽出物) A substance which is obtained from eucalyptus leaves and whose main components are β -diketones.	389
75	Linter cellulose (リンターセルロース) A substance which is obtained from single cotton filament and whose main component is cellulose.	405
76	Leche de vaca (レッチュデバカ) A substance which is obtained from the exudation of leche de vaca trees (<i>Brosimum utile</i> (H.B.K.) PITT.) and whose main components are esters of amyrin.	410
77	Levan (レバン) A substance which is obtained from the culture fluid of <i>Bacillus subtilis</i> and whose main components are polysaccharides.	411
78	Lemon peel extract (レモン果皮抽出物) A substance which is obtained from lemon peels and whose main components are geraniol and citral.	412
79	Rosidinha (ロシディンハ) A substance which is obtained from the exudation of rosidinha trees (<i>Sideroxylon</i>) and whose main	416

	components are amyirin acetate and polyisoprenes.	
80	Wasabi extract (ワサビ抽出物) A substance which obtained from the rhizomes or leaves of <i>wasabi</i> (<i>Wasabia japonica</i> MATSUM.) and whose main component is isothiocyanate	419