



# F18/17: China Health Food Regulations

## Food Products

2/05/2017

For Your Information

### 1 Requirements for health food products in China

- (1) Health foods to be sold in China are required to comply with relevant laws, regulations and standards, including but not limited to:
  - a) China Food and Drug Administration (CFDA) filing and registration requirements,
  - b) CFDA schedules for permissible health claims and raw materials,
  - c) relevant standards, such as GB Standard for Natural and Health Foods (GB 16740-2014<sup>1</sup>) and GB Standard for Nutrition Labelling of Prepackaged Foods (GB 28050-2011<sup>2</sup>), and
  - d) other relevant requirements such as China's Food Safety Law and Advertising Law.
- (2) It is recommended that exporters liaise with their importer or agent for specific details on filing/registration and compliance with relevant laws, regulations and standards.
- (3) **Health foods** as defined in China's GB 16740-2014 are foods (including dietary supplements) which are claimed to have certain specific health functions or can supplement certain vitamins and/or minerals, and are suitable for certain people to help them improve body functions without therapy, and will bring no acute, subacute or chronic harm to the human body.
- (4) China recognises two types of health foods:
  - a) **Nutritional supplements** refers to products whose purpose is to supplement nutrients such as vitamins and minerals. The functions include supplementing insufficient dietary intakes, prevention of nutritional deficiency, and lowering the risk of chronic and degenerative diseases.
  - b) **Functional health foods** refers to products with claims of specific health functions. They are defined as being suitable for consumption by specific groups of people and have the effect of regulating human bodily functions, but are not used for the purpose of treating diseases.

### 2 CFDA filing and registration requirements

- (1) CFDA's *Measures for Health Food Registration and Filing*<sup>3</sup> has been in force since 1 July 2016.
- (2) Nutritional supplements to be imported into China are subject to pre-export filing with CFDA.
- (3) Functional health foods to be imported into China are subject to pre-export registration with CFDA.

<sup>1</sup> An unofficial translation available can be found in this document: <http://www.mpi.govt.nz/document-vault/14401>

<sup>2</sup> An unofficial translation available can be found in this document: <http://www.mpi.govt.nz/document-vault/14371>

<sup>3</sup> CFDA *Measures for Health Food Registration and Filing*: <http://www.sfda.gov.cn/WS01/CL1197/145380.html>

- (4) Filing and registration require differing levels of documentation for approval. The process can be lengthy and extensive, particularly for the registration process where clinical trials are required (ie evidence to substantiate health claims which are made).
- (5) All health foods are required to comply with CFDA's schedule of permissible functional health claims (see Appendix 1) as well as CFDA's schedule of raw materials approved for use in health food production<sup>4</sup> (see Appendix 2). Both schedules are in the process of being finalised in batches and are subject to periodic reviews and updates by CFDA.
- (6) CFDA has released a list of approved vitamins and minerals permitted for use in nutritional supplements along with specific dosage limits.
- (7) The following information are relevant to both filing and registration applications:
  - a) Application for filing and registration will need to be authorised by the manufacturer, translated into Chinese, and notarised by a notarisation agency in China.
  - b) Imported health food products are also required to be marketed or sold in the country of production for at least one year before being eligible for pre-export registration or filing in China. Alternatively, the manufacturer can provide evidence of the product being sold in foreign markets and safety of the product for human consumption.
  - c) Testing and clinical trials will be required and must be conducted by CFDA accredited agencies in China<sup>5</sup>.

## 2.1 Imported functional health food products (excluding nutritional supplements)

- (1) Registration will apply to functional health food products to be imported into China (excluding nutritional supplements). CFDA has published details<sup>6</sup> and guidance<sup>7</sup> on the approval process for health foods requiring registration.
- (2) Functional health foods must only make one of the 27 CFDA approved claims (Appendix 1). Any functional claims outside of the list of permissible functions will require assessment and approval by CFDA.
- (3) Ingredients must be within the scope of the CFDA prescribed raw material list for health foods which is being revised. The current list is attached in Appendix 2.
- (4) MPI understands all functional health foods are required to go through the registration process which takes 1-3 years (depending on functional claim made) and is very costly. The process includes animal and in some cases human trials as part of the testing as well as toxicology, efficacy, composition and hygiene.
- (5) The registration process for functional health foods with claims outside of the 27 CFDA approved claims are likely to be longer.
- (6) The application for registration of health foods to be imported into China has 20 sections. The application form and online registration portal can be accessed on the CFDA website: <http://www.sfda.gov.cn/WS01/CL0128/25209.html>.
  - a) Sections 2 to 5 of the application relate to general information of the applicant and the product to be registered.

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<sup>4</sup> CFDA Schedule of Raw Material Permissible to be used in Health Foods: <http://www.sda.gov.cn/WS01/CL1160/>

<sup>5</sup> CFDA accredited agencies: <http://www.sda.gov.cn/WS01/CL1158/>

<sup>6</sup> CFDA Notice on the Detailed Rules for Examination and Approval of Health Food Registration (2016 version): <http://www.sda.gov.cn/WS01/CL0847/166399.html>

<sup>7</sup> CFDA Health Food Registration Application Service Guide: <http://www.sda.gov.cn/WS01/CL0087/167894.html>

- b) Sections 6 to 13 relate to the research, description, labelling and testing of the product and production processes.
  - c) Sections 14 to 18 relate to evidence of the product being sold in its originating country, relevant standards, and processing requirements in the originating country.
  - d) Samples are also required to be provided as part of the application process.
- (7) The period of validity for each registration approval is five years, which must be extended before expiry if the product is to continue to be sold in the Chinese market. The renewal should be applied at least three months before its expiry.

## 2.2 Imported nutritional supplements

- (1) Filing with CFDA is required for nutritional supplements such as vitamins and minerals.
- (2) Ingredients used in nutritional supplements must comply with CFDA's prescribed raw material schedule<sup>8</sup>. CFDA will begin accepting filing applications for nutritional supplements with permissible raw materials and claims to be exported to China from 1 May 2017<sup>9</sup>.
- (3) Under the new requirements, nutritional supplements only require filing with CFDA and do not need to be registered as functional health foods. As part of the filing process, products are required to undergo testing for hygiene, stability and composition, which is expected to take around 120 days.
- (4) MPI understands the entire filing process is expected to take 8 to 12 months.
- (5) If ingredients or functions proposed are outside the current list of permissible raw materials and functional claims, the product will be required to go through the registration process.
- (6) CFDA consulted on the *Details for implementing health food filing*<sup>10</sup> (closed on 28 February 2017).

## 3 Compositional requirements and health claims

- (1) Food products which utilised ingredients listed in CFDA's schedule of raw materials approved for use in health food production, and use claim(s) listed in CFDA's schedule of permissible functional health claims will be considered health foods, and are required to have scientific evidence to support the functional health claims which are made.
- (2) Raw materials not included in the CFDA *Schedule of Raw Material Permissible to be used in Health Foods* may be used if adequate supporting evidence is provided and approved. Any newly approved health food raw material will be made public.
- (3) Foods that do not meet CFDA's health food definition may be considered pre-packaged foods. Exporters are advised to liaise with importer on the applicable standards and requirements.
- (4) Nutritional and content claims are allowed for pre-packaged foods in accordance with GB Standard for Nutrition Labelling of Prepackaged Foods (GB 28050-2011) and GB Standards for Uses of Nutritional Fortification Substances in Foods (GB 14880-2012).
- (5) MPI understands that claims of a particular health function of nutritional strengthened foods (eg "fortified with calcium") cannot be made on general food products exported to China.

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<sup>8</sup> CFDA *Health Food Raw Material Schedule and Permissible Health Claim schedule for Health Foods*: <http://www.sda.gov.cn/WS01/CL0087/168507.html>

<sup>9</sup> CFDA *Notification relating to Health Food Filing*: <http://www.sda.gov.cn/WS01/CL0087/169229.html>

<sup>10</sup> *Details for Implementing Health Food Filing (Draft for consultation)*: <http://www.sfda.gov.cn/WS01/CL0782/169362.html>

## 4 Labelling requirements

- (1) Article 78 of China's Food Safety Law (2016) prohibits food product labels to state freedom from prohibited or unapproved ingredients/substances in China, eg labels cannot have "not containing" or "not added" claims that emphasise the product does not use or contain prohibited or unapproved substances (including GMO ingredients). As stated in clause 3 (4) of this FYI, content and nutritional claims are permitted for pre-packaged foods in accordance with GB Standard for Nutrition Labelling of Prepackaged Foods (GB 28050-2011); for example, statements such as "zero sugar" and "not containing saturated fat" are permitted as both sugar and saturated fat are permitted content/substances in food.
- (2) MPI understands that recent amendments to China's Advertising Law further restrict what can be used to market health foods including:
  - a) Assertions or guarantee of efficacy and safety;
  - b) Mentioning disease prevention or cures;
  - c) Claiming or implying the product is essential for ensuring health;
  - d) Comparing it with drugs or other health food; and
  - e) Using endorsements

### Contact for further information

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### Disclaimer

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## Appendix 1: CFDA permissible functional claims

Sourced from <http://www.sda.gov.cn/WS01/CL1163/>

Note: This list is only guidance and is subject to change.

- Enhancing immune function
- Aiding blood lipids reduction
- Aiding blood sugar reduction
- Increasing antioxidants
- Improving memory
- Relieving body fatigue
- Relieving eye fatigue
- Facilitating lead excretion
- Clearing throat
- Aiding blood pressure reduction
- Improving sleep
- Increasing milk secretion
- Improving endurance during anoxia
- Aiding protection against irradiation
- Aiding weight loss
- Improving growth and development
- Increasing bone density
- Improving nutritional anaemia
- Aiding protection against chemical liver injury
- Removing acne
- Removing chloasma/melasma
- Improving skin moisture
- Improving skin oil content
- Regulating enteric bacteria flora
- Facilitating digestion
- Improving constipation
- Aiding protection against gastric mucosa

## Appendix 2: List of substances considered as food and drug, substances permitted to be used in health foods, and substances prohibited in health foods.

Unofficial translation from information sourced from  
<http://www.nhfpc.gov.cn/zwgkzt/wsbysj/200810/38057.shtml>

Note: The lists are only guidance and are subject to change.

### Substances both as food and drug (按笔划顺序排列 in order of strokes)

Table 1: Substances approved for use as both a food and a drug		
	Chinese	English
1	丁香	Cloves
2	八角茴香	Star anise
3	刀豆	Beans
4	小茴香	Fennel
5	小蓟	Thistle
6	山药	Yam
7	山楂	Hawthorn
8	马齿苋	Purslane
9	乌梢蛇	Dry body of <i>Zaocys dhumnades</i> (black striped snake)
10	乌梅	Dried <i>Fructus mume</i> (dark plum)
11	木瓜	Papaya
12	火麻仁	Semen Cannabis (ripe fruit of <i>Cannabis sativa</i> )
13	代代花	Seville orange flower (bitter orange)
14	玉竹	<i>Polygonatum odoratum</i> (Solomon's seal)
15	甘草	Licorice
16	白芷	<i>Radix Angelicae dahuricae</i> (Dahurian Angelica Root)
17	白果	Gingko nuts
18	白扁豆	semen dolichoris (Hyacinth bean, Egyptian kidney bean)
19	白扁豆花	semen dolichoris flowers
20	龙眼肉 (桂圆)	Longan flesh (longan fruit)
21	决明子	<i>Semen cassia</i> (cassia seed)
22	百合	Lily bulbs
23	肉豆蔻	Nutmeg

24	肉桂	Cinnamon
25	余甘子	<i>Fructus phyllanthi</i> (Emblic Leafflower Fruit)
26	佛手	<i>Fructus citri sarcodactylis</i>
27	杏仁 (甜、苦)	Almond (sweet, bitter)
28	沙棘	Oleaster
29	牡蛎	Oysters
30	芡实	<i>Semen euryales</i> (Gorgon fruit seeds)
31	花椒	<i>Pericarpium zanthoxyli</i> (fruit of Sichuan pepper)
32	赤小豆	<i>Phaseolus calcaratus</i>
33	阿胶	Donkey-hide gelatin
34	鸡内金	Membrane of chicken gizzard
35	麦芽	Malt
36	昆布	Kelp
37	枣 (大枣、酸枣、黑枣)	Chinese dates ( <i>Fructus ziziphi jujubae</i> , <i>Zizyphus jujube</i> , <i>Dateplum persimmon</i> )
38	罗汉果	<i>Momordica grosvenori</i>
39	郁李仁	<i>Semen pruni</i> (prunes)
40	金银花	<i>Flos lonicerae</i> (honeysuckle)
41	青果	<i>Fructus canarii</i> (Chinese white olive)
42	鱼腥草	<i>Herba houttuyniae</i>
43	姜 (生姜、干姜)	Ginger (both fresh and dry)
44	枳椇子	<i>Semen hoveniae</i>
45	枸杞子	Chinese wolfberry
46	栀子	<i>Fructus gardeniae</i>
47	砂仁	<i>Fructus amomi</i>
48	胖大海	<i>Scaphium scaphigerum</i>
49	茯苓	<i>Poria cocos</i>
50	香橼	<i>Fructus citri</i>
51	香薷	<i>Herba moslae</i>

52	桃仁	Peach kernel
53	桑叶	Mulberry leaf
54	桑椹	Mulberry
55	桔红	<i>Exocarpium citri rubrum</i>
56	桔梗	<i>Radix platycodonis</i>
57	益智仁	<i>Semen amomi Amari</i>
58	荷叶	lotus leaves
59	莱菔子	<i>Semen raphani</i>
60	莲子	<i>Semen nelumbinis</i>
61	高良姜	Chinese ginger
62	淡竹叶	<i>Lophatherum gracile</i>
63	淡豆豉	<i>Semen sojae praeparatum</i>
64	菊花	Chrysanthemum
65	菊苣	Chicory
66	黄芥子	<i>Semen sinapis albae</i>
67	黄精	<i>Polygonatum canaliculatum</i>
68	紫苏	Basil
69	紫苏籽	<i>Perilla frutescens</i>
70	葛根	<i>Radix puerariae</i>
71	黑芝麻	Black sesame
72	黑胡椒	Black pepper
73	槐米	Pagodatree flower bud
74	槐花	<i>Flos sophorae</i>
75	蒲公英	Dandelion
76	蜂蜜	Honey
77	榧子	<i>Semen torreyae</i>
78	酸枣仁	<i>Semen Ziziphi spinosae</i>
79	鲜白茅根	Fresh cogongrass rhizome
80	鲜芦根	Fresh reed rhizome



81	蝮蛇	Viper
82	橘皮	Orange peel
83	薄荷	Mint
84	薏苡仁	<i>Semen coicis</i>
85	薤白	<i>Allii macrostemi bulbosus</i>
86	薤白	<i>Allii macrostemi bulbosus</i>
87	藿香	Wrinkled giant hyssop

**Substances can be used in health food (按笔划顺序排列 in order of strokes)**

<b>Table 2: Substances approved for use in Health Food</b>		
	<b>Chinese</b>	<b>English</b>
1	人参	Ginseng
2	人参叶	Ginseng leaf
3	人参果	<i>Monorchid herminium herb</i>
4	三七	Pseudo-ginseng
5	土茯苓	<i>Smilax glabra</i>
6	大蓟	Setose thistle
7	女贞子	<i>Fructus ligustri lucidi</i>
8	山茱萸	<i>Semen corni</i>
9	川牛膝	<i>Cyathnla capitata moq</i>
10	川贝母	<i>Fritillaria cirrhosa d. don</i>
11	川芎	<i>Ligusticum wallichii</i>
12	马鹿胎	Wapiti's fetus extract
13	马鹿茸	<i>Cervus elaphus Linnaeus</i>
14	马鹿骨	Red deer bones
15	丹参	<i>Radix salviae miltiorrhizae</i>
16	五加皮	Acanthopanax bark
17	五味子	<i>Fructus schisandrae chinensis</i>
18	升麻	<i>Rhizoma cimicifugae</i>
19	天门冬	<i>Radix asparagi</i>

20	天麻	Gastrodin
21	太子参	<i>Radix pseudostellariae</i>
22	巴戟天	<i>Morinda officinalis</i>
23	木香	<i>Radices saussureae</i>
24	木贼	<i>Equisetum hiemale</i>
25	牛蒡子	<i>Fructus arctii</i>
26	牛蒡根	Burdock root
27	车前子	<i>Semen plantaginis</i>
28	车前草	Plantain
29	北沙参	<i>Radix glehniae</i>
30	平贝母	Fritillary bulb
31	玄参	<i>Radix scrophulariae</i>
32	生地黄	<i>Radix rehmanniae recens</i>
33	生何首乌	<i>Crude polygonum</i>
34	白及	<i>Bletilla hyacinthina reichb</i>
35	白术	<i>Bighead atractylodes rhizome</i>
36	白芍	<i>Radices paeoniae alba</i>
37	白豆蔻	<i>Amomum cardamomum</i>
38	石决明	<i>Concha haliotidis</i>
39	石斛 ( 需提供可使用证明 )	<i>Dendrobium nobile</i> (permission of use should be provided)
40	地骨皮	<i>Cortex lycii radices</i>
41	当归	Angelica
42	竹茹	<i>Caulis bambusae in taeniam</i>
43	红花	Safflower
44	红景天	<i>Herba rhodiolae</i>
45	西洋参	American ginseng
46	吴茱萸	<i>Evodia rutaecarpa</i>
47	怀牛膝	<i>Radix achyranthis bidentatae</i>

48	杜仲	<i>Eucommia ulmoides</i>
49	杜仲叶	<i>Folium cortex eucommiae</i>
50	沙苑子	<i>Semen astragali complanati</i>
51	牡丹皮	Moutan bark
52	芦荟	Aloe species
53	苍术	<i>Rhizoma atractylodis</i>
54	补骨脂	<i>Fructus psoraleae</i>
55	诃子	<i>Fructus chebulae</i>
56	赤芍	<i>Red paeonia</i>
57	远志	Polygala root
58	麦门冬	<i>Radices ophiopogonis</i>
59	龟甲	Tortoise shell
60	佩兰	Eupatorium species
61	侧柏叶	<i>Cacumen biotae</i>
62	制大黄	Prepared rhubarb
63	制何首乌	<i>Radix Ppolygoni multiflori praeparata</i>
64	刺五加	<i>Aesculus wilsonii</i> Rehd
65	刺玫果	<i>Fructus Rosae Davuricae</i>
66	泽兰	<i>Herba lycopi</i>
67	泽泻	<i>Rhizoma alismatis</i>
68	玫瑰花	<i>Flos rosae rugosa</i>
69	玫瑰茄	Malvaceae <i>Hibiscus sabdariffa</i>
70	知母	<i>Rhizoma anemarrhenae</i>
71	罗布麻	Bluish dogbane
72	苦丁茶	Broadleaf holly leaf
73	金荞麦	Golden buckwheat rhizome
74	金樱子	<i>Fructus rosae laevigatae</i>
75	青皮	<i>Pericarpium citri reticulatae viride</i>
76	厚朴	<i>Mangnolia officinalis</i>

77	厚朴花	Flos magnoliae officinalis
78	姜黄	Turmeric
79	枳壳	Fructus aurantii
80	枳实	Fructus aurantii immaturus
81	柏子仁	Semen boitae
82	珍珠	Pearls
83	绞股蓝	Gynostemma pentaphylla
84	胡芦巴	Semen trigonellae
85	茜草	Semen trigonellae
86	葶苈	Radix rubiae
87	韭菜子	Long pepper
88	首乌藤	Semen allii tuberosi
89	香附	Caulis polygoni multiflori
90	骨碎补	Rhizoma cyperi, drynaria rhizome
91	党参	Codonopsis pilosula
92	桑白皮	Root bark of white mulberry
93	桑枝	Semen Cuscutae
94	浙贝母	Ramulus mori
95	益母草	Fritillaria thunbergii Miq
96	积雪草	Motherwort
97	淫羊藿	Hydrocotyle asiatica
98	菟丝子	Aceranthus sagittatus S. et Z
99	野菊花	Flos chrysanthemi indicis
100	银杏叶	Ginkgo leaf
101	黄芪	Astragalus mongholicus
102	湖北贝母	Hupei fritillary bulb
103	番泻叶	Folium sennae
104	蛤蚧	Gecko
105	越橘	Cowberry blueberry

106	槐实	Fructus Sophorae
107	蒲黄	Cattail pollen
108	蒺藜	Fructus Tribuli
109	蜂胶	Propolis
110	酸角	Tamarind fruit
111	墨旱莲	Eclipta
112	熟大黄	Prepared RADIX ET RHIZOMA RHEII
113	熟地黄	Prepared rehmannia root
114	鳖甲	Turtle shell

**Substance prohibited in health food (按笔划顺序排列 in order of strokes)**

<b>Table 3: Substances Prohibited for use in Health Food</b>		
	<b>Chinese</b>	<b>English</b>
1	八角莲	Dysosma versipelli
2	八里麻	Chinese Elder Her
3	千金子	Semen Euphorbiae Lathyridi
4	土青木香	Aristolochiae
5	山莨菪	Scopolia tangutica Maxim
6	川乌	Monkshood
7	广防己	Aristolochia fangchi
8	马桑叶	Chinese coriaria leaf
9	马钱子	Dog button
10	六角莲	Dysosma pleiontha
11	天仙子	Semen hyoscyami
12	巴豆	Tigilium
13	水银	Mercury
14	长春花	Catharanthus roseus
15	甘遂	Euphorbia kansui
16	生天南星	Unprocessed Rhizoma Arisaematis
17	生半夏	Unprocessed Rhizoma Pinelliae

18	生白附子	Unprocessed rhizoma typhonii
19	生狼毒	Unprocessed radix euphorbiae lantu
20	白降丹	Hydrargyrum chloratum compositum
21	石蒜	Short-tube lycoris
22	关木通	Caulis aristolochiae manshuriensis
23	农吉痢	crotalaria sessiliflora
24	夹竹桃	Nerium indicum Mill
25	朱砂	cinnabar
26	米壳 ( 罌粟壳 )	pericarpium papaveris (fructus papaveris)
27	红升丹	hydrargyrum oxydatum crudum
28	红豆杉	Chinese yew
29	红茴香	Illicium henryi Diels
30	红粉	HYDRARGYRI OXYDUM RUBRUM
31	羊角拗	Strophanthus divergens Grah
32	羊躑躅	Rhododendron molle G.Don
33	丽江山慈姑	Iphigenia indica Kunth et
34	京大戟	Radix Euphorbiae Pekinensis
35	昆明山海棠	tripterygium hypoglaucom hutch
36	河豚	globefish
37	闹羊花	Rhododendron molle G.Don
38	青娘虫	cantharis sinica
39	鱼藤	tuba root
40	洋地黄	digitalis
41	洋金花	flos daturae
42	牵牛子	Semen Pharbitidis
43	砒石 ( 白砒、红砒、砒霜 )	arsenolite (white arsenic, ARSENICUM SUBLIMATUM, arsenic)
44	草乌	radix aconiti agrestis
45	香加皮 ( 杠柳皮 )	Chinese silkvine bark (periplocae,cortex)

46	骆驼蓬	peganum harmala
47	鬼臼	podophyllum versipelle Hance
48	莽草	illicium anisatum L.
49	铁棒槌	A. Pendulum busch
50	铃兰	keiskei
51	雪上一枝蒿	short-pedicel aconite root
52	黄花夹竹桃	yellow oleander seed
53	斑蝥	cantharides
54	硫磺	brim stone
55	雄黄	realgar
56	雷公藤	Tripterygium wilfordii
57	颠茄	Atropa belladonna
58	藜芦	black false hellebore
59	蟾酥	Senso