EU ASIA COOPERATION
on (PHYTO-) SANITARY (SPS) and
FOOD SAFETY REGULATION

# COMPARISON OF HYGIENE LEGISLATION AND FOOD SAFETY STANDARDS

For foods for special dietary purposes and health foods

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# CONTENT

# INTRODUCTION

The overall objective of the project is to contribute to understand and facilitate the trade in health food between the European Union and the People's Republic of China by a systematic comparison of standards applicable to bee products.

By identifying matching provisions – or any discrepancies in legal requirements – the work is hoped to contribute to the streamlining and simplification of approval and verification procedures in the trade of these products.

# LIST OF CHINESE NATIONAL STANDARDS ASSESSED

| | |
|---|---|
| **GB 16740-2014** | Health Food |
| **GB 17405- 1998** | Good manufacture practice on health food |
| **GB 14880-2012** | National Food Safety Standard for the Use of Nutritional Fortification Substances in Foods |

# RESULTS AND CONCLUSIONS

Health food refers to foods that claim to have specific health functions or for the supplementation with micronutrients (vitamins, minerals, other biological active substances, botanicals). Impact of health food is to support and supplement the normal diet. The labelling, presentation and advertising must not attribute the property of preventing, treating, or curing a human disease, or refer to such properties.

"Health food" is the name of the certain food category which is specially used in China. "Health food" includes different categories of food than those prescribed by the EU legislative framework.

Regulatory approaches in the area of Health Foods in China and the European Union (EU) differ substantially. Therefore, the comparison of the respective rules is rather difficult.

Chinese standards are completely different from European ones. The European legislative framework is divided into the several categories. In line with the EU legislative frameworks, "health food" can cover:

- Food/nutritional supplements;
- Addition of vitamins and minerals and certain other substances to foods;
- Food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control; and
- Including labelling and nutritional and health claims on foods.

In the comparison of the differences between Chinese and European legislation, all categories, conditions, labelling and highlighting of nutritional and/or health claims and connection to health were shown.

Also, comparison of good manufacturing practice on health food with EU legislation and Implementing rules and comparative evaluation was also carried out.

EU requirements on Health Food are similar/equivalent to Chinese requirements.

# 1 SUMMARY COMPARISON

| Subject | Evaluation result |
|---|---|
| Health foods regulated as a specific category | No category of 'Health Foods" regulated as such under EU law. |
| Even if in the Chinese National Standard GB 16740-2014 health foods are defined as "*Food products that claim and have specific health functions or are intended to be supplemented with vitamins and minerals. That is, foodstuffs that are suitable for consumption by specific groups of people, have the function of regulating the body, are not intended to treat diseases and do not cause any acute, sub-acute or chronic harm to the human body*" there are doubts as to what the scope of the category includes.<br>At least, the category comprises functional health foods, food supplements, foods for Special Medical Purposes. There are doubts whether foods for infants and young children in good health enter in that definition | Under EU law there are different legislative frame for following:<br>1. Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements<br>2. Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods<br>3. Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods<br>4. Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health<br>5. all relevant regulations related to health claims referring to children's development and health<br>6. Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control<br>7. all relevant regulations which come from the Regulation 609/2013 |
| Health foods can make a number of claims which are defined on the basis of the beneficial effect. For any new claimed effect there must be an application according to a determined procedure and the submission of required data. | Under EU legislation frame claims are authorised based on the food / ingredient / substance that the product contains and the beneficial effect the food/ingredient/substance confers to the body. Main is the Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. In Annex I all nutritional claims are named, and in other legislation are health claims. |

| Subject | Evaluation result |
|---|---|
| Health foods regulated as a specific category | No category of 'Health Foods" regulated as such under EU law. |
| Chinese National Standard **GB 16740-2014** Health Food | There are discrepancies between the China and EU requirements throughout all documents.<br>There is no corresponding category of foods in the EU Food Regulations nor is the term 'Health Foods' defined in any EU legal measure.<br>In line with the EU legislative frameworks, "health food" can be:<br>- food/nutritional supplements.<br>- addition of vitamins and minerals and certain other substances to foods.<br>- food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control,<br>- including labelling and nutritional and health claims on foods. |
| Chinese National Standard **GB 17405- 1998** Good manufacture practice on health food | There are discrepancies between the China and EU requirements in legislation frame. ~~documents.~~<br>The most relevant EU Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs lays down general rules for food business operators on the hygiene of foodstuffs, taking particular account of the following principles:<br>a) primary responsibility for food safety rests with the food business operator;<br>b) it is necessary to ensure food safety throughout the food chain, starting with primary production;<br>c) it is important, for food that cannot be stored safely at ambient temperatures, particularly frozen food, to maintain the cold chain;<br>d) general implementation of procedures based on the HACCP principles, together with the application of good hygiene practice, should reinforce food business operators' responsibility;<br>e) guides to good practice are a valuable instrument to aid food business operators at all levels of the food chain with compliance with food hygiene rules and with the application of the HACCP principles;<br>f) it is necessary to establish microbiological criteria and temperature control requirements based on a scientific risk assessment;<br>g) it is necessary to ensure that imported foods are of at least the same hygiene standard as food produced in the Community or are of an equivalent standard.<br>This Regulation applies to all stages of production, processing, and distribution of food and to exports, and without prejudice to more specific requirements relating to food hygiene.<br>Also applicable is Guidance document Commission Notice 2016/C 278/01 with more detailed requirements on this subject (personnel, health status), which are also mentioned in Guidance document Commission Notice 2022/C 355/01, Annex I, Examples of GHP. |

| Subject | Evaluation result |
|---|---|
| Health foods regulated as a specific category | No category of 'Health Foods" regulated as such under EU law. |
| Chinese National Standard **GB 14880-2012** National Food Safety Standard for the Use of Nutritional Fortification Substances in Foods | Under EU law following Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods can be relevant for this Chinese National Standard GB 14880-2012, e.g., National Food Safety Standard for the Use of Nutritional Fortification Substances in Foods.<br>In EU Regulation are restrictions on the addition of vitamins and minerals, as following:<br>1. unprocessed foodstuffs, including, but not limited to, fruit, vegetables, meat, poultry, and fish.<br>2. beverages containing more than 1,2% volume of alcohol.<br>Additional restrictions for other foods or food categories may be adopted via comitology procedure.<br>The purposes of addition are somehow more limited compared to the EU and follows a bit more the relevant Codex Alimentarius General Principles |

# 2 DETAILED ANALYSIS

## 2.1 NATIONAL STANDARD ON HEALTH FOOD PRODUCTS GB 16740-2014

| Chinese National Standard GB 16740-2014 | EU legislation | Implementing rules and comparative evaluation |
|---|---|---|
| **National standard 16740-2014 Point 2.1** defines Health Food as:<br>"Food products that claim and have specific health functions or are intended to be supplemented with vitamins and minerals. That is, foodstuffs that are suitable for consumption by specific groups of people, have the function of regulating the body, are not intended to treat diseases and do not cause any acute, sub-acute or chronic harm to the human body".<br>Interpreting this definition, Health Foods seem to be divided in:<br><br>**1) Functional health foods:** food products that claim to have a health function/physiological effect (beneficial effect?) on the human body.<br><br>**2) Nutritional supplements:** Health food that provides vitamins and/or minerals only. | **EU Regulation 1924/2006 on nutrition and health claims**<br>The concept in the EU is that all foods are functional because they provide nutrients and other substances that are or may be necessary for the functioning of the body. But foods can make a claim (see below), provided such claim is substantiated by generally accepted scientific data.<br>In the EU the corresponding products, **Food Supplements**, are regulated by **Directive 2002/46.** They may contain vitamins, minerals, and other substances with a nutritional or physiological effect. This Directive concerns food supplements marketed as foodstuffs and presented as such. These products shall be delivered to the ultimate consumer only in a pre-packaged form.<br>This Directive shall not apply to medicinal products as defined by Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.<br>The Directive 2002/46 sets a definition and includes specific provisions for the composition and labelling of food supplements. It also includes an Annex of the vitamins and minerals and their sources which may be used in the manufacture of these products:<br>- vitamins and minerals listed in Annex I,<br>- and the forms listed in Annex II.<br>The Annex can be updated through a specified procedure. | Discrepancy can be found between the Chinese and EU requirements in all documents.<br>There is no corresponding category of foods in the EU Food Regulations nor is the term 'Health Foods' defined in any EU legal measure.<br>In comparison with the EU legislation framework and Chinese GACC web site vitamin-supplements-china-gacc-registration_functional-foods-health-foods-gacc-registration_how-to-export-functional-foods-health-foods-to-china-GACC-AQSIQ-CIQ-CCIC-Cifer-Singlewindow (foodgacc.com), under "health food" can cover the following:<br>- food/nutritional supplements.<br>- addition of vitamins and minerals and certain other substances to foods.<br>- food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control,<br>- including labelling and nutritional and health claims on foods. |

| Chinese National Standard GB 16740-2014 | EU legislation | Implementing rules and comparative evaluation |
|---|---|---|
| **The Health Food Raw Materials Directory** includes the following vitamins and minerals.<br>Vitamins: Vitamin A, Vitamin D, Vitamin E, Vitamin K, Vitamin B1, Vitamin B2, Niacin, Pantothenic acid, Vitamin B6, Folic acid, Vitamin B12, Biotin, Vitamin C, choline<br>Minerals: Calcium, Magnesium, Iron, Copper, Zinc, Manganese, Potassium, Selenium.<br>In accordance with current Chinese regulations, there are 28 health functions available for functional health food.<br>**One category refers to the provision of vitamins and minerals.**<br><br>The other health functions for which a health food can make a **health claim** are:<br>Immune system, antioxidant effect, memory improvement, alleviation of eye fatigue, excretion of lead, throat clearance, improving sleep, facilitating milk secretion, alleviating feeling tired (fatigue), enhancing anoxia endurance, assisting irradiation hazard protection, weight control, improving child growth, increasing bone density, improving nutrition anaemia, protection of liver from chemical damage/injury, eliminating acne, eliminating skin pigmentation, improving moisture of skin, improving oil content of skin, regulating/balancing gastrointestinal flora, facilitating digestion, facilitating defecation, protection of gastric mucosa, reduction of lipids in the blood, reduction in blood sugar, reduction of blood pressure. | The **Annex I of Directive 2002/46** lists the following:<br>- Vitamins: Vitamin A, Vitamin D, Vitamin E, Vitamin K, Vitamin B1, Vitamin B2, Niacin, Pantothenic acid, Vitamin B6, Folic acid, Vitamin B12, Biotin, Vitamin C<br>- Minerals: Calcium, Magnesium, Iron, Copper, Iodine, Zinc, Manganese, Sodium, Potassium, Selenium, Chromium, Molybdenum, Fluoride, Chloride, Phosphorus, Boron<br>**In the Annex II** is the list of vitamin and mineral substances/forms which may be used in the manufacture of food supplements.<br>This list is amended with several new regulations related to new chemical forms of vitamins and minerals. Those are following:<br>- Directive 2006/37/EC<br>- Regulation (EC) No 1170/2009<br>- Regulation (EU) No 2015/414<br>- Regulation (EU) No 1161/2011<br>Also, the identification of permitted preparations of vitamins and minerals to be used in food supplements was made possible by the work carried out by EFSA who evaluated the safety and bioavailability of nutrient sources proposed for addition to the list of permitted substances in Annex II of the food supplements Directive and approval in the form of new regulations.<br>The denominations of vitamins and minerals reported in the Annex I are those relevant for the nutritional declaration of food supplements.<br>The denominations of vitamins and minerals reported in Annex II are those relevant for the list of ingredients.<br>Purity criteria, specified by Community legislation for the use of these substances in the manufacture of foodstuffs for purposes other than food supplements, shall apply. | |

| Chinese National Standard GB 16740-2014 | EU legislation | Implementing rules and comparative evaluation |
|---|---|---|
| The Chinese provisions therefore have defined the function areas for which health claims and reduction of disease risk claims can be made. New function claims can be added on the request of an operators under defined provisions.<br><br>Nutritional supplements can be marketed after going through a procedure of filing and provided the substances included are in the Health Raw Materials Directory.<br><br>Products bearing health claims in the defined permitted areas (see above) must apply to go through a registration procedure which includes the submission of the scientific data that substantiate the claim.<br><br>New categories of claims may be added on the request of an operator who has to submit a dossier for evaluation including among others the scientific studies substantiating the health claim.<br>A draft to update those rules has been published in August 2022 and is in consultation. | If purity criteria are not specified, generally acceptable purity criteria recommended by international bodies shall be applicable and national rules setting stricter purity criteria may be maintained.<br>Important to notice is that setting maximum amounts of vitamins and minerals in food supplements is not established. Therefor some member states in EU may set the maximum amounts at national level on the basis of the criteria laid down in Article 5 of Directive 2002/46/EC.<br>To ensure that significant amounts of vitamins and minerals are present in food supplements, minimum amounts per daily portion of consumption as recommended by the manufacturer shall be set, as appropriate. In the Annex XIII, part A of the Regulation No.1169/2011 on the provision of food information to consumers are daily refence intakes for adults with quantities of vitamins and minerals which can be declared and their nutrient reference values (NRV).<br>Minimum amount per day is important as condition for nutritional and health claim.<br>The corresponding provision in EU legislation would be a permitted nutrition claim* included in the Annex of Regulation 1924/2006. It should be noted that the list of nutrition claims allowed in the EU is much wider than claims referring to vitamins and minerals.<br><br>* '**nutrition claim**' means any claim which states, suggests or implies that a food has particular beneficial nutritional properties due: (a) the energy (calorific value) it (i) provides, (ii) provides at a reduced or increased rate, or (iii) does not provide; and/or (b) the nutrients or other substances it (i) contains, (ii) contains in reduced or increased proportions, or (iii) does not contain.<br>Nutritional claims are following: Low energy, Energy-reduced, Energy-free, Low-fat, Fat-free, Low-saturated fat, Saturated fat-free, Low sugar, Sugar-free, With no added sugar, Low sodium/salt, Very low sodium/salt, Sodium-free or salt-free, | |

| Chinese National Standard GB 16740-2014 | EU legislation | Implementing rules and comparative evaluation |
|---|---|---|
| | Source of fibre, High fibre, Source of protein, High protein, Source of (name of vitamin/s) and/or (name of mineral/s), High (name of vitamin/s) and/or (name of mineral/s), Contains (name of the nutrient or other substance), Increased (name of the nutrient), Reduced (name of the nutrient), Light/lite, Naturally/natural.<br>Additional **Commission Regulation (EU) No 116/2010** of 9 February 2010 amending Regulation (EC) No 1924/2006 of the European Parliament and of the Council with regard to the list of nutrition claims with following nutritional claims: "Source of omega-3 fatty acids", "High omega-3 fatty acids", "High monounsaturated fat", "High polyunsaturated fat", "High unsaturated fat"<br><br>'**Health claim**' means any claim that states, suggests, or implies that a relationship exists between a food category, a food or one of its constituents and health.<br>267 health claims are today authorised in the EU according to the EU Register on health claims and Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health.<br>There are 11 approved health claims referring to children's development and health in separate legislation frame.<br>'**Reduction of disease risk claim**' means any health claim that states, suggests, or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease.<br>(The last three function claims in the Chinese list could correspond to the EU **reduction of disease risk claims**)**.**<br><br><u>The EU provisions are food/nutrient/substance based and allow the authorisation of claims for beneficial effects on undetermined functions or risk factors of a disease</u>. | |

| Chinese National Standard GB 16740-2014 | EU legislation | Implementing rules and comparative evaluation |
|---|---|---|
| | In the EU **food supplements Directive 2002/46, all food supplements** can be marketed provided they are in conformity with the provisions of **Directive 2002/46**. Member States of the EU may require a notification that the product is placed on the market. This should consist of a letter to the competent authority and a copy of the label of the product.<br><br>In the EU a product bearing an authorised health claim and **meeting the conditions of use** set for the claim, can be placed on the market. In some rare cases, a 5-year period of protection of the scientific data on the basis which the claim has been authorised applies.<br><br>A similar procedure for the authorisation of health claims exists in the EU comprising the submission of a dossier to a Member State which transmits it to EFSA for evaluation. If the evaluation by EFSA is positive the Commission, then proceeds with the authorisation of the health claim.<br><br>Relevant provisions are named in **Regulation 1924/2006 on nutrition and health claims.** | |
| **National standard 16740-2014 <u>Point 3.1</u> Raw materials and excipients**<br>The raw materials and excipients shall comply with the corresponding food standards and relevant regulations. | For vitamins and minerals purity criteria provisions are set in Article 4.2, 4.3 and 4.4 of **Directive 2002/46** on food supplements and in Article 5 of **Regulation 1925/2006** on addition of vitamins and minerals and other substances to foods. | Guidance document Commission Notice 2022/C 355/01, Annex I, 34. Raw materials<br>a) Consideration should be given not only to the supply of raw materials themselves but also to the supply of additives, processing aids, packaging material and food contact material. |

<table>
<tr><th>Chinese National Standard GB 16740-2014</th><th>EU legislation</th><th>Implementing rules and comparative evaluation</th></tr>
<tr>
<td>
National standard 16740-2014 <u>Point 3.4 and 3.5</u> Contaminant limits and mycotoxin limits<br><br>
Compliance with limits in GB2762, or in their absence with limits below<br><br>
Table 2 Pollutant limits
<table>
<tr><td>Item</td><td>Indicator</td><td>Test method</td></tr>
<tr><td>Lead [a](Pb)/(mg/kg)</td><td>2.0</td><td>GB 5009.12</td></tr>
<tr><td>Total arsenic [b] (As) / (mg/kg)</td><td>1.0</td><td>GB/T 5009.11</td></tr>
<tr><td>Total mercury [c](Hg)</td><td>0.3</td><td>GB/T 5009.17</td></tr>
<tr><td colspan="3">[a] Lead ≤ 5.0mg/kg for bagged tea preparations; lead ≤ 0.5mg/kg for liquid products; lead ≤ 0.3mg/kg for solid or semi-solid health food for infants and children; lead ≤ 0.02mg/kg for liquid health food for infants and children.<br>[b] total arsenic of liquid products ≤ 0.3mg/kg; total arsenic of infant health food ≤ 0.3mg/kg.<br>[c] Total mercury is not measured for liquid products (except for infant health food); total mercury for infant health food ≤ 0.02mg/kg.</td></tr>
</table>
</td>
<td>
Commission Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as last amended by Commission Regulation 696/2014 sets limits for different contaminants by food category.<br>
There is new Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006. It is important to check in consolidated version comprising the latest amendment. Also, it is important to check each contaminant and mycotoxin limit regarding specific food category.<br>
Commission Regulation (EU) 2023/465 of 3 March 2023 amending Regulation (EC) No 1881/2006 as regards maximum levels of arsenic in certain foods. New limits for arsenic (inorganic arsenic for 3.5.1 to 3.5.4 and total arsenic for 3.5.5) are now applicable. This Regulation 2023/465 is included in the Regulation 2023/915.
</td>
<td>Certain food contaminants are listed in different Regulations for specific food categories</td>
</tr>
</table>

| Chinese National Standard GB 16740-2014 | EU legislation | Implementing rules and comparative evaluation |
|---|---|---|

**National standard 16740-2014 Point 3.6 Microbiological limits**

Microbiological limits should be in accordance with the provisions of GB29921 of the corresponding food category and the corresponding food category of the national food safety standards, without the provisions of the corresponding food category should be in accordance with the provisions of Table 3.

**Table 3 Microbiological limits**

| Item | Sampling plan [a]nd limits | | Test method |
|---|---|---|---|
| | Liquid products | Solid or semi-solid products | |
| Total number of colonies/(CFU/g or mL) ≤ | $10^3$ | $3x10^4$ | GB 4789.2 |
| Coliform bacteria (MPN/g or mL) ≤ | 0.43 | 0.92 | GB 4789.3 MPN counting method |
| Moulds and yeasts (CFU/g or mL) ≤ | 50 | | GB 4789.15 |
| Staphylococcus aureus ≤ | 0/25g(mL) | | GB 4789.10 |
| Salmonella ≤ | 0/25g(mL) | | GB 4789.4 |

[a] Sampling and handling of samples is carried out according to GB 4789.1.

[b] Not applicable to products with active strains (aerobic and partly anaerobic probiotics) in the final product.

**Commission Regulation (EC) No 2073/2005** on microbiological criteria for foodstuffs sets relevant limits in food categories.

Article 4:

1. Food business operators shall perform testing as appropriate against the logical criteria set out in Annex I, when they are validating or verifying the correct functioning of their procedures based on HACCP principles and good hygiene practice.

EU legislation requires food business operators to perform testing and collect samples as part of the HACCP programme and during the slaughter process. Testing has to be done in laboratories designated by the competent authority. These laboratories can locate elsewhere. Regulation (EU) 2017/625, Articles 37, 38 and 39 lay down the requirements for the designation, obligations, and audits of official laboratories. Article 40 deals with the designation of Trichinella laboratories. Prevention and protection against fire hazards are laid down in other legislation.

Certain microbiological criteria and limits are listed in different Guidance and Regulations for specific food categories

| Chinese National Standard GB 16740-2014 | EU legislation | Implementing rules and comparative evaluation |
|---|---|---|
| **National standard 16740-2014 Point 3.7 Food additives and nutritional fortificants**<br><br>3.7.1 The use of food additives should comply with the provisions of GB2760. | **Relevant E**U **Regulation 1333/2008** on food additives. Also, Commission Regulation (EU) No **1131/2011** of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council with regard to steviol glycosides. | Certain food additives are listed in different Regulations for specific food categories |
| 3.7.2 The use of nutritional fortificants shall comply with GB 14880 and/or relevant regulations | For the food fortification the **Regulation EU 1925/2006** on the addition of vitamins and minerals and certain other substances to foods is valid. The provisions of this Regulation regarding vitamins and minerals shall not apply to food supplements covered by Directive 2002/46/EC.<br>Nutrients or ingredients are added to food in order to "*enrich*" or "*fortify*" the food in question, so as to add or emphasize particular nutritional characteristics. A wide range of nutrients and other ingredients are used in food manufacturing, including (*but not limited to*): Vitamins, Minerals including trace elements, Amino acids, Essential fatty acids, Fibre, Various plants, and herbal extracts.<br>There are some restrictions on the addition of vitamins and minerals according to this Regulation 1925/2006.<br>Also, purity criteria are named for vitamins and minerals.<br>Conditions for the addition of vitamins and minerals as well labelling, presentation, and advertising of foods to which vitamins and minerals have been added shall not include any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients.<br>Annexes I and II include the vitamins and minerals and their sources which may be used in the manufacture of foods.<br>Regarding **Article 8 of Regulation 1925/2006** there is the procedure for some substances which can be prohibited, restricted or under Community scrutiny. Following that there are new regulations:<br>1. Commission Regulation (EU) **2015/403** of 11 March 2015 amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards Ephedra species and Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille) | |

| Chinese National Standard GB 16740-2014 | EU legislation | Implementing rules and comparative evaluation |
|---|---|---|
| | 2. Commission Regulation (EU) **2019/650** amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille) places Yohimbe bark and its preparations originating from Yohimbe (*Pausinystalia yohimbe* (K. Schum.) Pierre ex Beille) in Part A of Annex III.<br>3. Commission Regulation (EU) **2021/468** of 18 March 2021<br>amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards botanical species containing hydroxyanthracene derivatives<br>4. Commission Regulation (EU) **2019/649** of 24 April 2019 amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards trans fat, other than trans fat naturally occurring in fat of animal origin<br>5. Commission Regulation (EU) **2022/860** of 1 June 2022 amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards monacolins from red yeast rice<br>6. COMMISSION REGULATION (EU) **2022/2340** of 30 November 2022<br>amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards green tea extracts containing (-)-epigallocatechin-3-gallate | |
| **National standard 16740-2014 <u>Point 4</u> Other**<br><br>**Labelling:** The labelling should comply with the relevant regulations. | In the EU horizontal rules applicable to all foods apply (Regulation EU 1169/2011), while specific rules in Directive 2002/46, Regulation 1924/2006 and Regulation 1925/2006 may add or derogate from the provisions of Regulation EU 1169/2011<br><br>All chemical forms of vitamins and minerals are regulated with **Commission Regulation (EC) No 1170/2009** of 30 November 2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements.<br>Firstly, chemical forms are in annexes of Directive 2002/46 and Regulation 1925/2006. | All health claims and Conditions of use are explained above, that means there are 267 health claims till today authorised in the EU according to the EU Register on health claims and Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health. |

| Chinese National Standard GB 16740-2014 | EU legislation | Implementing rules and comparative evaluation |
|---|---|---|
| The Chinese authorities pay great attention to the supervision of health food labels. Main contents of the label shall be consistent with that of the registration/filing approval certificate. Moreover, on 20 August 2019, SAMR issued the *Guideline on Warning Statements for Health Food Labelling*, which has entered into force on January 1st, 2020. The following labelling requirements shall be focused on:<br>• It is forbidden to claim that the product is to prevent or treat any disease. And the warning statement of "health food is not drug and cannot replace drug to treat disease" shall be printed on the prominent position of label.<br>Note also that the definition comprises the following part relevant to labelling/presentation of the products: "…are not intended to treat diseases …"<br>• Production date and expiry date must be indicated in the order of "year/month/date".<br>• Complaint hotline and hotline service time shall be marked. The font of complaint hotline shall be same with the font of health function. | Those annexes are amended by:<br><br>1. **Directive 2006/37/EC** amending Annex II of Directive 2002/46/EC<br>2. **Commission Regulation (EC) No 1170/2009** of 30 November 2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements. There is list of form only for food (Vitamin formulations and mineral substances which may be added to foods) and the list in Annex II of forms only for food supplements (Vitamin and mineral substances which may be used in the manufacture of food supplements)<br>3. **Commission Regulation (EU) No 1161/2011** of 14 November 2011 amending Directive 2002/46/EC of the European Parliament and of the Council, Regulation (EC) No 1925/2006 of the European Parliament and of the Council and Commission Regulation (EC) No 953/2009 as regards the lists of mineral substances that can be added to foods<br>4. **Commission Regulation (EU) No 119/2014** of 7 February 2014 amending Directive 2002/46/EC of the European Parliament and of the Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards chromium enriched yeast used for the manufacture of food supplements and chromium (III) lactate tri-hydrate added to foods<br>5. **Commission Regulation (EU) 2015/414** of 12 March 2015 amending Directive 2002/46/EC of the European Parliament and of the Council as regards (6S)-5-methyltetrahydrofolic acid, glucosamine salt used in the manufacture of food supplements<br>6. **Commission Regulation (EU) 2017/1203** of 5 July 2017<br>amending Directive 2002/46/EC of the European Parliament and of the Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards organic silicon (monomethylsilanetriol) and calcium phosphoryl oligosaccharides (POs-Ca®) added to foods and used in the manufacture of food supplements.<br>7. **Commission Regulation (EU) 2023/1065** of 1 June 2023<br>amending Annex II to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards nicotinamide riboside chloride added to foods | There are 11 approved health claims referring to children's development and health in separate legislation frame. |

| Chinese National Standard GB 16740-2014 | EU legislation | Implementing rules and comparative evaluation |
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| | According to Art 4(8) of the Report "the use of substances with nutritional or physiological effects other than vitamins and minerals in food supplements study undertaken for DG Sanco, European Commission " on 05 December 2008 there are categories of substances other than vitamins and minerals chosen in the Report and includes:<br>- amino acids.<br>- enzymes.<br>- pre- and probiotics.<br>- essential fatty acids.<br>- botanicals and botanical extracts.<br>- miscellaneous bioactive substances.<br><br>Regulation EU 1169/2011 provides that subject to certain derogations, the labelling of food shall not attribute to any food the property of preventing, treating, or curing a human disease, nor refer to such properties.<br>Depending on the product a 'use by …' or 'best before …' date should appear on the labelling.<br>Regarding food supplements the labelling, presentation and advertising must not attribute to food supplements the property of preventing, treating, or curing a human disease, or refer to such properties.<br><br>There are some specific **rules according to Directive 2002/46 and** the labelling shall bear the following particulars:<br>a) the names of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances.<br>b) the portion of the product recommended for daily consumption.<br>c) a warning not to exceed the stated recommended daily dose.<br>d) a statement to the effect that food supplements should not be used as a substitute for a varied diet.<br>e) a statement to the effect that the products should be stored out of the reach of young children. | |

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| | Also:<br>1. the amount of the nutrients or substances with a nutritional or physiological effect present in the product shall be declared on the labelling in numerical form. The units to be used for vitamins and minerals shall be those specified in Annex I of Directive 2002/46/EC. Rules for implementing this paragraph may be specified in accordance with the procedure referred to in Article 13(2).<br>2. The amounts of the nutrients or other substances declared shall be those per portion of the product as recommended for daily consumption on the labelling.<br>3. Information on vitamins and minerals shall also be expressed as a percentage of the reference values mentioned (%NRV), as the case may be, in the Annex XIII of the Regulation 1169/2011.<br>It is important to notice that the labelling, presentation, and advertising of food supplements shall not include any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.<br>All health claims and Conditions of use are explained above. | |
| Chinese National Standard on Determination of Vitamin B12 in Health Food GB 16740-2014 and<br><br>Chinese National Standard on Determination of Determination of thiamine hydrochloride, pyridoxine hydrochloride, niacin, niacinamide and caffeine in health food GB/T 5009.197-2003<br><br>These Standards provide specific methodologies for the analysis of certain vitamins in Health Foods. | It should be noted that official controls on the territory of EU Member States are the competence of national controlling authorities, although the different authorities coordinate activities with the European Commission. | The EU legislation in general does not set methods of analysis of vitamins and minerals and other substances.<br>Consequently, the national reference laboratories set their methodology taking into account scientific and technological developments, available scientific equipment, and relevant costs.<br>It should also be noted that scientific and technological developments in the area take place at a pace that the regulators would not be able to follow. |

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| On the internet there are reference to rules on infant formula and foods for special medical purposes (information and summary of rules on FSMP (see below) from consultant sites) but specific texts were not available. | In the EU there are Specific rules on foods for infants and young children, foods for special medical purposes and total diets for weight control according to **Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013** on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control.<br><br>**Former Directive 2009/39/EC** of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses lays down general rules on the composition and preparation of foods that are specially designed to meet the particular nutritional requirements of the persons for whom they are intended. The majority of the provisions laid down in that Directive date back to 1977 and need to be reviewed. Directive 2009/39/EC establishes a common definition for 'foodstuffs for particular nutritional uses', and general labelling requirements, including that such foods should bear an indication of their suitability for the nutritional purposes being claimed.<br><br>The general compositional and labelling requirements laid down in Directive 2009/39/EC are complemented by a number of non-legislative Union acts, which are applicable to specific categories of food. In that respect, harmonised rules are laid down in Commission Directives 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction and 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes. Similarly, Commission Directive 2006/125/EC lays down certain harmonised rules with respect to processed cereal-based foods and baby foods for infants and young children. Commission Directive 2006/141/EC lays down harmonised rules with respect to infant formulae and follow-on formulae and Commission Regulation (EC) No 41/2009 lays down harmonised rules concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten.<br><br>Experience shows that certain rules included in, or adopted under, Directive 2009/39/EC are no longer effective in ensuring the functioning of the internal market. Therefore, the concept of 'foodstuffs for particular nutritional uses' should be abolished and Directive 2009/39/EC should be replaced by Regulation 609/2013/EC. To simplify the application of this act and to ensure consistency of application throughout the Member States, this act is in the form of a Regulation. | It is not clear from the definition of Health Foods whether the category comprises foods for infants and young children, foods for weight control and foods for special medical purposes.<br>The part of the definition 'That is, foodstuffs that are suitable for consumption by specific groups of people, …' may imply that such foods are included in the scope of the Standard.<br>Accordingly, this section explains all categories named in the Regulation for Food for Specific Groups, labelling requirements, chemical forms of vitamins and minerals and specific parts of legislation. |

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| | A limited number of categories of food constitute a partial or the sole source of nourishment for certain population groups. Such categories of food are vital for the management of certain conditions and/or are essential to satisfy the nutritional requirements of certain clearly identified vulnerable population groups. Those categories of food include infant formula and follow-on formula, processed cereal-based food and baby food, and food for special medical purposes. That's why new Regulation focuses on the general compositional and information requirements for those categories of food, taking into account Directives 1999/21/EC, 2006/125/EC, and 2006/141/EC.<br><br>New **Regulation 609/2013** of the European Parliament and the Council on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control enter into force in July 2013, but with some exceptions.<br><br>Substances belonging to the following categories of substances may be added to one or more of the categories of food referred to in Article 1(1) of the Regulation 609/2013, provided that these substances are included in the Union list set out in the Annex and comply with the elements contained in the Union list in accordance with paragraph 3 of this Article:<br>a) vitamins<br>b) minerals<br>c) amino acids<br>d) carnitine and taurine<br>e) nucleotides<br>f) choline and inositol<br><br>**The Union list** contains the following elements:<br>a) the category of food referred to in Article 1(1) to which substances belonging to the categories of substances listed in paragraph 1 of this Article may be added.<br>b) the name, the description of the substance and, where appropriate, the specification of its form.<br>c) where appropriate, the conditions of use of the substance.<br>d) where appropriate, the purity criteria applicable to the substance. | |

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| | **Purity criteria** established by Union law applicable to food, which apply to the substances included in the Union list when they are used in the manufacture of food for purposes other than those covered by this Regulation, shall also apply to those substances when they are used for purposes covered by this Regulation unless otherwise specified in this Regulation.<br><br>**Specific parts of the legislation** which are part of Regulation 609/2013 are following:<br>1. instead Directive 2006/141/EC on infant formulae and follow-on formulae new regulation is Commission Delegated **Regulation 2016/127** on infant formulae (IF) and follow-on formulae (FoF)<br><br>2. instead Directive 1999/21/EC<br>on food for special medical purposes (FSMPs) new Regulation is Commission Delegated **Regulation (EU) 2016/128** as regards the specific compositional and information requirements for food for special medical purposes (FSMPs)<br><br>3. Commission Directive 96/8/EC on foods intended for use in energy-restricted diets for weight reduction covered: a) products presented as a replacement for the whole of the daily diet b) products presented as a replacement for one or more meals of the daily diet.<br>It is replaced with Commission Delegated **Regulation (EU) 2017/1798** for total diet replacement products for weight control. Main scope is that it is applicable only for the total daily diet products.<br><br>In Commission Delegated **Regulation 2016/127** on infant formulae (IF) and follow-on formulae (FoF) - ***'Infant formula'*** means food intended for use by infants during the first months of life and satisfying by itself the nutritional requirements of such infants until the introduction of appropriate complementary feeding<br>***'Follow-on formula'*** means food intended for use by infants when appropriate complementary feeding is introduced, and which constitutes the principal liquid element in a progressively diversified diet of such infants. | |

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| | In Commission Delegated **Regulation (EU) 2016/128** as regards the specific compositional and information requirements for food for special medical purposes (FSMPs) there are <u>three categories</u>:<br>a) nutritionally complete food with a standard nutrient formulation.<br>b) nutritionally complete food with a nutrient-adapted formulation specific for a disease, disorder, or medical condition.<br>c) nutritionally incomplete food with a standard formulation or a nutrient adapted formulation specific for a disease, disorder, or medical condition.<br><br>There is flexibility for composition:<br>- General requirement that formulation is based on sound medical and nutritional principles and the product's use is safe, beneficial, and effective based on generally accepted scientific evidence<br>- Minimum and maximum amounts of micronutrients (for FSMPs for adults and infants)<br>- FSMPs intended for infants to comply with compositional requirements for formulae for healthy infants but derogations allowed where required by the intended use.<br><br>In **Regulation (EU) 2017/1798** 'Total diet replacement for weight control 'means food specially formulated for use in energy reduced diets for weight reduction which when used as instructed by the food business operator replaces the whole daily diet. **Total diet replacement for weight control** products may contain other ingredients than the substances listed in Annex I only if their suitability has been established by generally accepted scientific data. | |

## 2.2 NATIONAL STANDARD GB 17405- 1998 GOOD MANUFACTURE PRACTICE ON HEALTH FOOD

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| **4 Personnel** | **Regulation (EC) No 852/2004**[1], Annex II, Chapter I, 9. Where necessary, adequate changing facilities for personnel are to be provided.<br><br>Regulation (EC) No 852/2004, Annex II, Chapter VIII, every person working in a food-handling area is to maintain a high degree of personal cleanliness and is to wear suitable, clean and, where necessary, protective clothing.<br><br>Regulation (EC) No 852/2004, Annex II, Chapter I:<br>3. An adequate number of flush lavatories are to be available and connected to an effective drainage system. Lavatories are not to open directly into rooms in which food is handled.<br>4. An adequate number of washbasins is to be available, suitably located and designated for cleaning hands. Washbasins for cleaning hands are to be provided with hot and cold running water, materials for cleaning hands and for hygienic drying. Where necessary, the facilities for washing food are to be separate from the hand-washing facility. | More detailed requirements on this subject (changing room) are mentioned in the Guidance document Commission Notice 2016/C 278/01, Annex I, 2.1:<br>g) The specific clothes changing room(s) should be clean and ordered, not used as a refectory or a smoking room, and should facilitate a separation between normal clothing, clean work clothing and used work clothing. |

[1] **Regulation (EC) No 852/2004 of the European parliament and the council of 29 April 2004 on the hygiene of foodstuffs**

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| 4.1 Health food manufacturers must have technical personnel with relevant professional knowledge in medicine (or biology, food science) and management personnel with production and organisational skills appropriate to the health food products they produce. The proportion of full-time technical personnel shall not be less than 5% of the total number of employees.<br>4.2 The head of the enterprise in charge of technology must have a college degree or above or a corresponding degree and have experience in the production and quality and health management of health food products.<br>4.3 The person in charge of the production and quality management of health food shall be a full-time employee with a college degree or above or a corresponding education level appropriate to the profession he/she is engaged in, capable of organizing production or quality management in accordance with the requirements of this Code, and competent to make correct judgement and deal with practical problems arising in the production and quality management of health food.<br>4.4 Health food manufacturers must have full-time quality control personnel. Quality inspection personnel must have secondary school education or above; procurement personnel should master the knowledge and skills to identify and select the side bar to meet the quality and health requirements.<br>4.5 Practitioners must undergo education on health regulations and corresponding technical training before they start work, and enterprises should establish training and assessment files. The person in charge of the enterprise and the person in charge of the production and quality management department should also receive professional training on health food from the health supervision department at or above the provincial level and obtain a qualified certificate. | **Regulation (EC) No 852/2004**, Annex II, Chapter VIII<br>1. Every person working in a food-handling area is to maintain a high degree of personal cleanliness and is to wear suitable, clean and, where necessary, protective clothing.<br>2. No person suffering from or being a carrier of a disease likely to be transmitted through food or afflicted, for example, with infected wounds, skin infections, sores or diarrhoea is to be permitted to handle food or enter any food-handling area in any capacity if there is any likelihood of direct or indirect contamination. Any person so affected and employed in a food business and who is likely to come into contact with food is to report immediately the illness or symptoms, and if possible, their causes, to the food business operator.<br><br>Regulation (EC) No 852/2004, Annex II, Chapter XII<br>Food business operators are to ensure:<br>1. that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity. | More detailed requirements on this subject (personnel, health status) are mentioned in the Guidance document Commission Notice 2016/C 278/01, Annex I, 2.9:<br>a) Personnel should be aware of hazards from gastro-intestinal infections, hepatitis, and wounds with appropriate exclusion from food handling or suitable protection; relevant health problems should be reported to the manager. Special consideration should be given to temporary workers who might be less familiar with potential hazards.<br><br>More detailed requirements on this subject (personnel, hygiene) are mentioned in the Guidance document Commission Notice 2016/C 278/01, Annex I, 2.9:<br>c) Hands should be washed (+ disinfected) regularly, as a minimum, before starting to work, after using the lavatory, after breaks, after rubbish disposal, after coughing or sneezing, after handling of raw materials, …<br>. |

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| 4.6 Practitioners must undergo health checks and obtain health certificates before they are allowed to work and must undergo health checks once a year thereafter.<br>4.7 Practitioners must do their personal hygiene according to the requirements of GB14881. | 2. that those responsible for the development and maintenance of the procedure referred to in Article 5(1) of this Regulation (= HACCP programme) or for the operation of relevant guides have received adequate training in the application of the HACCP principles; and<br>3. compliance with any requirements of national law concerning training programmes for persons working in certain food sectors. | d) Hair covers (and beard snoods) should be considered and appropriate clothing with high degree of cleanliness, minimum of pockets, absence of jewellery and watches.<br>e) Eating, drinking and/or smoking rooms should be separated and clean.<br>More detailed requirements on this subject (visitors) are mentioned in the Guidance document Commission Notice 2016/C 278/01, Annex I, 2.9:<br>g) The number of visitors should be minimized. Visitors should wear appropriate protective clothing, provided by the Food Business Operator. |

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| **5 Design and facilities**<br>5.1 Design<br>The overall design of the health food plant, the general design of the plant and facilities, the building and sanitary facilities should be in accordance with the requirements of GB 14881. | **Regulation (EC) No 852/2004**, Annex II, Chapter I, 2. states:<br>The layout, design, construction, siting, and size of food premises are to:<br>(a) permit adequate maintenance, cleaning and/or disinfection, avoid or minimise air-borne contamination, and provide adequate working space to allow for the hygienic performance of all operations.<br>(b) be such as to protect against the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces.<br>(c) permit good food hygiene practices, including protection against contamination and, in particular, pest control; and<br>(d) where necessary, provide suitable temperature-controlled handling and storage conditions of sufficient capacity for maintaining foodstuffs at appropriate temperatures and<br>designed to allow those temperatures to be monitored and, where necessary, recorded. | The EU Commission has prepared a Commission notice (2022/C 355/01) to be used as a guidance document for food business operators to facilitate and harmonise the implementation of the EU requirements on PRPs and HACCP-based procedures by providing practical guidance. It helps food business operators to implement EU requirements after establishment of specific adaptations and without prejudice to their primary responsibility in matter of food safety. |

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| 5.2.1 The plant should be reasonably laid out in accordance with the production process and the required cleanliness level, and the production operations in the same plant and adjacent plants should not interfere with each other. | Regulation (EC) No 853/2004, Article 4 states that establishments handling products of animal origin shall not operate unless the competent authority has approved them following an on-site visit.<br>Article 4, 1.<br>Food business operators carrying out primary production and those associated operations listed in Annex I shall comply with the general hygiene provisions laid down in part A of Annex I.<br>Annex I, II, 3 a) states:<br>a) measures to control contamination arising from the air, soil, water, feed, fertilisers, veterinary medicinal products, plant protection products and biocides and the storage, handling, and disposal of waste.<br>Article 4, 2.<br>Food business operators carrying out any stage of production, processing, and distribution of food after those stages to which paragraph 1 applies (see Article 4.1.) shall comply with the<br>general hygiene requirements laid down in Annex II. Chapter I<br>of Annex II states:<br>Food premises are to be kept clean and maintained in good repair and condition.<br>Regulation (EC) No 852/2004, Annex II, Chapter I, 8 states:<br>Drainage facilities are to be adequate for the purpose intended. They are to be designed and constructed to avoid.<br>the risk of contamination. Where drainage channels are fully or partially open, they are to be so designed as to ensure that waste does not flow from a contaminated area towards or into<br>a clean area, in particular an area where foods likely to present a high risk to the final consumer are handled. | Guidance document Commission Notice 2022/C 355/01, Annex I, Examples of GHP<br>3.1 Infrastructure:<br>a) When assessing the risk from the location and surrounding areas, the proximity of potential sources of contamination, water supply, wastewater removal, power supply, access for transport, climate, possible flooding, … should be taken into account. This should also be considered for primary production (fields). |

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| 5.2.2 The cleanliness level must be divided according to the production process and health and quality requirements, in principle into general production area and 100,000 level area. 100,000 level clean area should be installed with corresponding purification air conditioning facilities with filtration devices. | Regulation (EC) No 852/2004, Annex II, Chapter I, 10:<br>Cleaning agents and disinfectants are not to be stored in areas where food is handled.<br>Regulation (EC) No 852/2004, Annex II, Chapter II, 2:<br>Adequate facilities are to be provided, where necessary, for the cleaning, disinfecting and storage of working utensils and equipment. These facilities are to be constructed of corrosion-resistant materials, be easy to clean and have an adequate supply of hot and cold water. | Guidance document Commission Notice 2022/C 355/01, Annex I, Examples of GHP<br>3.1 Infrastructure:<br>g) The specific clothes changing room(s) should be clean and ordered, not used as a refectory or a smoking room. A separation between normal clothing, clean work clothing and used work clothing should be facilitated.<br>h) Toilets should not open directly to food handling areas. Preferably water flushing with use of foot/arm pedals should be present and reminders to wash hands and strategically placed signs informing about the obligation, when applicable, to remove protective clothing before using the toilets.<br>i) Hand washing facilities should be positioned conveniently between toilets/changing rooms and the food handling area, not excluding the possible need for additional wash hand basins in production areas near workstations; disinfectants, soap and towels for single use should be available; installations blowing warm air should only be present in rooms without food and non-hand-operable taps are desirable.<br>f) Clearly defined storage facilities should be available for raw material, and receptacles for food and packaging materials. Only products that may be added to food (e.g., additives) should be stored in the area with the food, excluding common storage with toxic products (e.g., pesticides). |

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| The cleanliness level of the plant and the number of air changes are shown in Table 1.<br>**Table 1**<br>Cleanliness level \| Dust number/$m^3$ ≥0.5μm \| Dust number/$m^3$ ≥5μm \| Number of living microorganisms / $m^3$ \| Number of air changes / h<br>Class 10000 \| ≤350 000 \| ≤2 000 \| ≤100 \| ≥20 times<br>Class 100 000 \| ≤3 500 000 \| ≤20 000 \| ≤500 \| ≥15 times | | The Guidance document Commission Notice 2016/C 278/01 Annex I lay down the:<br>Prerequisite programs (PRPs)<br>2.8 Water and air control<br>a) Regular own microbiological and chemical analysis of water directly in contact with food (unless community potable water) should be carried out. Factors such as the source, intended use of the water, etc. will determine the frequency of analysis. |
| 5.2.4 The purification level must meet the need for air purification for the production and processing of health food products. The production of tablets, capsules, pills, and oral liquids that cannot be sterilised in the final container should use a clean plant of class 100,000. | Regulation (EC) No 852/2004, Annex II, Chapter I,<br>5. There is to be suitable and sufficient means of natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area is to be avoided. Ventilation systems are to be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.<br>6. Sanitary conveniences are to have adequate natural or mechanical ventilation | |

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| 5.2.5 The plant, equipment layout and process flow shall be reasonably articulated, and the building structure shall be perfect and able to meet the requirements of production process and quality and hygiene; the plant shall have sufficient space and places to place equipment and materials; the storage room for intermediate products and products to be packed shall be compatible with the production requirements.<br><br>5.2.6 The temperature and relative humidity of the clean plant shall be compatible with the requirements of the production process. | **Regulation (EC) No 852/2004**, Annex II, Chapter I:<br>5. There is to be suitable and sufficient means of natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area is to be avoided. Ventilation systems are to be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.<br>6. Sanitary conveniences are to have adequate natural or mechanical ventilation. | The Guidance document Commission Notice 2016/C 278/01 Annex I lay down the:<br>Prerequisite programs (PRPs)<br>2.8 Water and air control<br>a) Regular own microbiological and chemical analysis of water directly in contact with food (unless community potable water) should be carried out. Factors such as the source, intended use of the water, etc. will determine the frequency of analysis.<br><br>More detailed requirements on this subject (ventilation) are mentioned in the Guidance document Commission Notice 2016/C 278/01, Annex I, 2.8:<br>d) Ventilation systems are kept clean, so that they do not become a source of contamination. For high risk/care areas requiring air control, the implementation of positive air pressure systems and appropriate air filtering systems should be considered. |

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| 5.2.7 Sewage, hand washing, and other hygienic cleaning facilities installed in the clean room shall not cause pollution to the production of health food.<br>5.2.8 Buffering facilities shall be provided between plants of different cleanliness levels and between plants and passages. Passages for personnel and materials shall be set up respectively in accordance with the cleanliness level.<br>5.2.9 Pre-treatment of raw materials (e.g., extraction, concentration, etc.) shall be carried out in premises appropriate to their production scale and process requirements, and equipped with the necessary ventilation, dust removal and temperature reduction facilities. Pre-processing of raw materials shall not be carried out in the same production plant as the production of finished products.<br>5.2.10 The production of health food shall have a preparation room, the cleanliness level of which shall be consistent with the requirements of the production process.<br>5.2.11 The air purification facilities and equipment in the clean room shall be regularly maintained and appropriate measures shall be taken during the maintenance process so as not to cause contamination to the production of health food products.<br>5.2.12 The production of fermented products shall have a special fermentation workshop, and there shall be special equipment corresponding to fermentation and spraying.<br>5.2.13 All production tools and equipment that are in direct contact with raw materials and intermediate products shall be made of materials that meet the requirements of product quality and hygiene. | Regulation (EC) No 852/2004, Annex II, Chapter II, 1<br>In rooms where food is prepared, treated, or processed (excluding dining areas and those premises specified in<br>Chapter III, but including rooms contained in means of transport) the design and layout are to permit good food hygiene practices, including protection against contamination.<br>between and during operations.<br>(c) ceilings (or, where there are no ceilings, the interior surface of the roof) and overhead fixtures are to be constructed and finished so as to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable mold and the shedding of particles. | |

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| **6 Raw materials**<br>6.1 The purchase and use of raw materials required for the production of health food should be formulated as a system of acceptance, storage, use and inspection, and be the responsibility of a person.<br>6.2 Raw materials must comply with food hygiene requirements. The variety, source, specification, and quality of raw materials should be consistent with the approved formula and product corporate standards.<br>6.3 Procurement of raw materials must be in accordance with the relevant provisions to obtain a valid inspection report form; raw materials that are new food resources need to obtain the Ministry of Health approval certificate (copy).<br>6.4 to bacteria by artificial fermentation of mycelium or mycelium and fermentation products and mixtures of micro-ecological raw materials must obtain strain identification reports, stability reports and strains do not contain drug-resistant factors to prove the information.<br>6.5 algae, animals and animal tissues and organs as raw materials, must obtain the species identification report. If a single active substance is extracted from animals or plants or if biological or chemical synthesis is used as raw material, a test report on the physical and chemical properties and content of the substance should be obtained.<br>6.6 containing stimulants or hormones of raw materials, should be obtained for its content test report; by radioactive radiation of raw materials, should be obtained for the relevant information on the dose of irradiation. | Regulation 178/2002 provides in Art 18:<br>Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing.<br>animal, or any substance intended to be, or expected to be, incorporated into a food or feed.<br>Commission Regulation (EC) No 1935/2004 provides general principles of safety and inertness for all Food.<br>Contact Materials and sets out a harmonised legal EU framework.<br>Art. 11 of Reg 178/2002 and Art 10 of Reg 852/2004 provide that any supplies from Third countries must comply with the EU food law. As EU food business<br>operators, importers must verify that these conditions are met.<br><br>Regulation (EC) No 852/2004, Annex II, Chapter IX A food business operator is not to accept raw materials or ingredients, other than live animals, or any other material used in processing products, if they are known to be, or might reasonably be expected to be, contaminated with parasites, pathogenic microorganisms or toxic, decomposed or foreign substances to such an extent that, even after the food business operator had hygienically applied normal sorting | The guidance document (Commission Notice 2016/C 278/01) Annex I, 2.10 Raw materials states:<br>a) Consideration should be given not only to the supply of raw materials themselves but also to the supply of additives, processing aids, packaging material and food contact material.<br>b) A strict supply policy, containing agreement on specifications (e.g., microbiological) and hygiene assurance and/or requesting a certified quality management system can be taken into account in the extent of details on the PRPs and HACCP plan of the establishment itself.<br>c) Apart from agreements with and possible auditing of the supplier, a number of issues might give a good indication on the reliability of the supplier such as homogeneity of delivered goods, compliance with agreed delivery period, accuracy of information added, sufficient shelf life or freshness, use of clean and suitably equipped transportation, hygiene awareness of the driver and other food |

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| 6.7 The means of transport of raw materials, etc. should meet health requirements. According to the characteristics of raw materials, should be equipped with appropriate insulation, refrigeration, freshness, rain and dust protection and other facilities to ensure quality and health needs. The transport process should not be mixed with toxic and harmful substances in the same vehicle or the same container.<br>6.8 After the purchase of raw materials on the source, specifications, packaging conditions for preliminary inspection, according to the provisions of the acceptance system to fill in the storage account, card, storage should be applied to the quality inspection department to take samples for testing.<br>6.9 All kinds of raw materials should be stored off the floor according to the pending inspection, qualified, unqualified partition, and have obvious signs; qualified spare should also be stored separately according to different batches, the same library shall not store raw materials that affect each other's flavour.<br>6.10 temperature, humidity and special requirements for raw materials should be stored in accordance with the prescribed conditions; general raw materials storage sites or warehouses, the ground should be flat, easy to ventilate, with rodent, insect-proof facilities.<br>6.11 The storage period of raw materials should be developed, using the principle of first-in, first-out. Unqualified or expired raw materials should be marked and dealt with early.<br>6.12 Mycelium made from artificial fermentation of bacteria or micro-ecology as raw materials should be strictly controlled strain preservation conditions, strains should be regularly screened, purified, identified, when necessary, to prevent contamination of miscellaneous bacteria, strain degradation and mutation of toxic production. | and/or preparatory or processing procedures, the final product would be unfit for human consumption.<br><br>Regulation (EC) No 852/2004, Annex II, Chapter IX<br>2. Raw materials and all ingredients stored in a food business are to be kept in appropriate conditions designed to prevent harmful deterioration and protect them from contamination.<br>3. At all stages of production, processing and distribution, food<br>is to be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.<br>4. Adequate procedures are to be in place to control pests.<br>Adequate procedures are also to be in place to prevent domestic animals from having access to places where food is prepared, handled, or stored (or, where the competent authority so permits in special cases, to prevent such access from resulting in contamination).<br><br>Regulation (EC) No 852/2004, Annex II, Chapter IV<br>1. Conveyances and/or containers used for transporting foodstuffs are to be kept clean and | handlers transporting the food, correct temperature during transport, long term satisfaction, etc. Most of these issues should be part of a reception control. It may be necessary to be aware of previous cargoes of a transport vehicle in order to implement adequate cleaning procedures to reduce the likelihood of cross contamination.<br>d) Storage conditions at the establishment itself should take into account any instructions provided by the supplier, 'first in, first out' or 'first expire, first out'. principles, accessibility for inspection from all sides (e.g., not placed directly on the ground, against walls, …) |

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| | maintained in good repair and condition to protect foodstuffs from contamination and are,<br>where necessary, to be designed and constructed to permit adequate cleaning and/or disinfection.<br>2. Receptacles in vehicles and/or containers are not to be used for transporting anything other than foodstuffs where this may result in contamination. 3. Where conveyances and/or containers are used for transporting anything in addition to foodstuffs or for transporting different foodstuffs at the same time, there is, where necessary, to be effective separation of products. | |
| **7 Production process**<br>7.1 Development of production operating procedures | EU legislation: Regulation (EC) No 852/2004, Article 1:<br>This Regulation lays down general rules for food business operators on the hygiene of foodstuffs and shall apply to<br>all stages of production, processing, and distribution of food and to exports. | |
| 7.1.1 The factory shall, according to the requirements of this Code and taking into account the production process characteristics of its own products, formulate production process procedures and job operation procedures. The production procedure shall meet the requirements of no loss, destruction, transformation and harmful intermediates of the efficacy components in the processing of health food products, and its content shall include the product formula, the preparation of each component, the main technical conditions of the finished product processing and the quality and hygiene | Regulation (EC) No 852/2004, Article 6<br>2. In particular, every food business operator shall notify the appropriate competent authority, in the manner that the latter requires, of each establishment under its control that carries out any of the stages of production, processing and distribution of food, with a view to the registration of each such establishment. | |

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| monitoring points of key processes, such as the temperature, pressure, time, pH value and quality index of intermediate products in the finished product processing. The job operating procedures should stipulate specific operational requirements for each major production process and clarify the job responsibilities of each workshop, process and individual.<br><br>7.1.2 The production technology and management personnel of each production workshop shall keep records of each batch of products from raw material preparation, intermediate product output, product quality and hygiene indicators in accordance with the control items and inspection requirements of each key process in the production process. | | |
| 7.2.1 Before production, raw materials must be strictly inspected to check the name, specifications, and quantity, for mould, insects, mixed with foreign substances or other abnormal sensory properties, does not meet the requirements of quality standards, shall not be put into use. Any raw materials with a storage period shall not be used after the expiry date. Liquid raw and auxiliary materials should be filtered to remove foreign matter; solid raw and auxiliary materials need to be crushed, sieved should be crushed to the required fineness.<br><br>7.2.2 The workshop receives raw and auxiliary materials according to the production needs, and calculates, weighs, and feeds them correctly according to the recipe. | Regulation (EC) No 852/2004, Annex I lay down general hygiene rules for primary production | |

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| 7.3.1 Before dosing the product, check that the dosing kettle and container pipes are clean and meet the standards required by the process. Fermenters, vessels, and pipelines used for production using the fermentation process must be thoroughly cleaned and disinfected before they can be used for production. A record of the cleaning and disinfection of the apparatus should be kept every shift.<br>7.3.2 Production operations should be reasonably articulated, with quick and easy transfer to prevent cross-contamination. The processes of raw material handling, intermediate product processing, cleaning and disinfection of packaging materials and containers, packaging and inspection of finished products should be set up separately. The same workshop should not produce different products at the same time; containers for different processes should be clearly marked and should not be mixed.<br>7.3.3 Production operators should strictly follow the different requirements of the general production area and the clean area to improve personal hygiene. When there is a possibility of product contamination due to job transfer, work clothes, shoes and hats must be changed and disinfected again. Work clothes, hats and shoes used in the clean area must be strictly cleaned and disinfected, changed daily, and only allowed to be worn in the clean area, not taken out of the area.<br>7.3.4 Raw and auxiliary materials entering the production area must enter through the material channel. All materials entering the clean plant or workshop must be removed from the outer packaging, if the outer packaging cannot be removed, they must be scrubbed clean or replaced with indoor packaging barrels.<br>7.3.5 The raw and auxiliary materials in the preparation process must be mixed evenly, and the heating temperature and time must be strictly controlled if the materials need to be hot-melted, hot-taken or concentrated (evaporated). If the intermediate products need to be adjusted in terms of content, pH and other technical parameters, the content, pH, relative density, and preservatives must be re-determined and rechecked after adjustment.<br>7.3.6 All process operations shall be carried out in good condition in accordance with the process requirements. Where filtration is required in the production of oral liquids, beverages and other liquid products, care should be taken to use filtering materials that do not shed fibres and meet hygiene requirements. If solid products such as | EU legislation: Regulation (EC) No 852/2004, Annex II,<br>Chapter IV<br>4. Bulk foodstuffs in liquid, granulate or powder form are to be transported in receptacles and/or containers/tankers<br>reserved for the transport of foodstuffs. Such containers are to be marked in a clearly visible and indelible fashion, in one or more Community languages, to show that they are used for the transport of foodstuffs or are to be marked ‘for foodstuffs only’.<br>6. Foodstuffs in conveyances and/or containers are to be so placed and protected as to minimise the risk of contamination. | |

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| capsules, tablets and punches need to be dried, the temperature and time of the drying room (oven) should be strictly controlled to prevent melting and deterioration of the particles; equipment for mashing, tablet pressing, sieving or granulation should be made of materials that meet hygienic requirements and be regularly cleaned and maintained to avoid contamination by rust and metal pollutants.<br>7.3.7 The pressing of tablets, the dispensing of capsules, the filling of punches and liquid products should be carried out in a clean room, where the temperature and humidity of the operating room should be controlled. The manual dispensing of capsules should be carried out in a Plexiglas enclosure with the appropriate cleanliness level and the operating table should not be lower than 0.7m<br>7.3.8 Prepared material shall be placed in clean, closed containers and entered in time for the filling, pressing, or dispensing of capsules, etc. and shall not be stored beyond the prescribed period. | | |
| 7.4.1 Food containers, packaging materials, detergents and disinfectants that comply with hygiene standards and hygiene management practices shall be used.<br>7.4.2 The raw materials used, such as empty capsules and sugar coatings, must meet hygienic requirements and the use of non-edible colours is prohibited.<br>7.4.3 All kinds of glass bottles (tubes), plastic bottles (tubes), bottle caps, bottle pads, bottle stoppers, aluminium-plastic packaging materials, etc. used for product packaging should be cleaned, dried, and sterilised by appropriate methods, and should be placed in a clean room for cooling after sterilisation. After sterilization, they should be cooled in a clean room and set aside. Storage time exceeding the specified period should be rewashed and sterilized. | Regulation (EC) No 852/2004, Annex II, Chapter X<br>1. Material used for wrapping and packaging are not to be a source of contamination.<br>2. Wrapping materials are to be stored in such a manner that they are not exposed to a risk of contamination.<br>3. Wrapping and packaging operations are to be carried out so as to avoid contamination of the products.<br>4. Wrapping and packaging material re-used for foodstuffs is to be easy to clean and, where necessary, to disinfect | |

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| 7.5 Sterilisation of products<br>7.5.1 Effective sterilisation or sterilisation equipment and methods should be used for sterilisation of all types of products. For products that need to be sterilised and cannot be sterilised by hot pressing, methods such as fine filtration, microwave and irradiation can be used according to different processes and food hygiene requirements to ensure the sterilisation effect. When irradiation sterilisation methods are used, the absorbed dose and time of irradiation should be strictly controlled in accordance with the provisions of the Measures for the Hygienic Management of Irradiated Food.<br>7.5.2 Reliability verification of the uniformity and repeatability of the temperature in the sterilisation or sterilisation device should be done regularly, and the temperature and pressure testing instruments should be regularly calibrated. Accurate records of temperature, pressure and time shall be kept during sterilisation or sterilisation operations. | Regulation (EC) No 852/2004, Annex II, Chapter VI:<br>1. Food waste, non-edible by-products and other refuse are to be removed from rooms where food is present as<br>quickly as possible, so as to avoid their accumulation.<br>2. Food waste, non-edible by-products and other refuse are to be deposited in closable containers, … These containers are to be of an appropriate construction, kept in sound condition, be easy to clean and, where necessary, to disinfect.<br>3. Adequate provision is to be made for the storage and disposal of food waste, non-edible by-products, and other refuse. Refuse stores are to be designed and managed in such a way as to enable them to be kept clean and, where necessary, free of animals and pests.<br>4. All waste is to be eliminated in a hygienic and environmentally friendly way in accordance with Community legislation applicable to that effect and is not to constitute a direct or indirect source of contamination.<br><br>Regulation (EC) No 852/2004, Article 5: 1. Food business operators shall put in place, implement, and maintain a permanent procedure or procedures based on the HACCP principles. 2. The HACCP principles referred to in paragraph 1 consist of the following: … (g) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f). | |

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| 7.6 Filling or filling of products<br>7.6.1 Each batch of product to be filled or stuffed should be checked for quality, the output rate should be calculated and checked against the actual output rate. If there is a significant discrepancy, the cause must be identified and, after a reasonable explanation has been reached and it has been confirmed that there are no potential quality incidents, the product shall be treated as normal only after approval by the quality management.<br>7.6.2 The filling of liquid products and the granulation, pressing and filling of solid products shall be carried out in a clean area in accordance with the appropriate requirements. With the exception of capsules, the filling and stuffing of products shall be carried out by automatic mechanical devices and not by hand.<br>7.6.3 Filling equipment, needles, pipes, etc. shall be checked for cleanliness, disinfection, or sterilisation with fresh distilled water before filling.<br>7.6.4 The operator must always check the quality of the semi-finished product after filling and sealing and adjust the filling (sealing) machine at any time to ensure the quality of filling and sealing.<br>7.6.5 For products requiring sterilisation, the time from filling and sealing to sterilisation shall be controlled within the time limits required by the process regulations.<br>7.6.6 Light inspection shall be carried out after filling and sealing of oral ampoules, straight glass bottles and other bottled liquid preparations. The rejected products should be marked with name, specification and batch number and placed in clean containers for disposal by special persons.<br>7.7.1 The packaging materials and labels of health food shall be kept by a person, and each batch of product labels shall be issued and received by instruction, and records shall be kept of the packaging materials destroyed.<br>7.7.2 The quality of printing or labelling should be checked at any time during the printing or labelling process of semi-finished products that have passed the light inspection and inspection. The printing should be clear; the sticker should be correctly and firmly attached.<br>7.7.3 No non-food related items shall be placed in the finished product packaging.<br>7.7.4 The maximum pressure (weight) should be indicated on the outer packaging of the product. | Regulation (EC) No 853/2004, Annex III, Section IX, Chapter III, Wrapping and packaging.<br>Sealing of consumer packages must be carried out immediately after filling in the establishment where the last heat treatment of liquid products takes place by means of sealing devices that prevent contamination. The sealing system must be designed in such a way that, after opening, the evidence of its opening remains clear and easy to check. | |

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| 7.8.1 Product labelling must comply with the requirements of the Regulations on Health Food Labelling and GB7718. | **Regulation EU 1169/2011** provides that subject to certain derogations, the labelling of food shall not attribute to any food the property of preventing, treating, or curing a human disease, nor refer to such properties.<br>Depending on the product a 'use by …' or 'best before …' date should appear on the labelling.<br>Regarding food supplements the labelling, presentation and advertising must not attribute to food supplements the property of preventing, treating, or curing a human disease, or refer to such properties.<br>There are some specific rules according to **Directive 2002/46** and the labelling shall bear the following particulars:<br>(a) the names of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances.<br>(b) the portion of the product recommended for daily consumption.<br>(c) a warning not to exceed the stated recommended daily dose.<br>(d) a statement to the effect that food supplements should not be used as a substitute for a varied diet.<br>(e) a statement to the effect that the products should be stored out of the reach of young children.<br>Also:<br>1. the amount of the nutrients or substances with a nutritional or physiological effect present in the product shall be declared on the labelling in numerical form. The units to be used for vitamins and minerals shall be those specified in Annex I of Directive 2002/46/EC. Rules for implementing this paragraph | All relevant labelling provisions must be according to the applicable legislations. |

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| | may be specified in accordance with the procedure referred to in Article 13(2).<br>2. The amounts of the nutrients or other substances declared shall be those per portion of the product as recommended for daily consumption on the labelling.<br>3. Information on vitamins and minerals shall also be expressed as a percentage of the reference values mentioned (%NRV), as the case may be, in the Annex XIII of the Regulation 1169/2011.<br>It is important to notice that the labelling, presentation, and advertising of food supplements shall not include any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients in general | |
| 7.8.2 The printing of health food product instructions and labels shall be consistent with the content approved by the Ministry of Health. | In the EU food supplements Directive, all food supplements can be marketed and provided they are in conformity with the provisions of Directive 2002/46. | Member States of the EU may require a notification that the product is placed on the market. This should consist of a letter to the competent authority and a copy of the label of the product. |
| 8.2 Finished products should be stored in a manner and in an environment that is protected from light and rain, with temperature and humidity controlled within appropriate limits, and avoiding impact and vibration. | **Regulation (EC) No 852/2004**, Annex II, Chapter IX<br>Point 5. Raw materials, ingredients, intermediate products, and finished products likely to support the reproduction of pathogenic micro-organisms or the formation of toxins are not to be kept at temperatures that might result in a risk to health.<br>The cold chain is not to be interrupted.<br>Point 8. Hazardous and/or inedible substances, including animal feed, are to be adequately labelled and stored in separate and secure containers.<br><br>Regulation (EC) No 852/2004, Annex II, Chapter IV | |

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| | 1. Conveyances and/or containers used for transporting foodstuffs are to be kept clean and maintained in good repair and condition to protect foodstuffs from contamination and are, where necessary, to be designed and constructed to permit adequate cleaning and/or disinfection.<br>7. Where necessary, conveyances and/or containers used for transporting foodstuffs are to be capable of maintaining foodstuffs at appropriate temperatures and allow those temperatures to be monitored. | |
| 8.3 Products containing biologically active substances should be stored and transported in a cold chain with appropriate refrigeration measures. | Regulation (EC) No 852/2004, Annex II, Chapter IX<br>5. Raw materials, ingredients, intermediate products and finished products likely to support the reproduction of pathogenic micro-organisms or the formation of toxins are not. to be kept at temperatures that might result in a risk to health. The cold chain is not to be interrupted.<br>8. Hazardous and/or inedible substances, including animal feed, are to be adequately labelled and stored in separate and secure containers.<br><br>Chapter X<br>1. Material used for wrapping and packaging are not to be a source of contamination. 2. Wrapping materials are to be stored in such a manner that they are not exposed to a risk of contamination. 3. Wrapping and packaging operations are to be carried out so as to avoid contamination of the products. Where appropriate and in particular in the case of cans and glass jars, the integrity of the container's construction and its cleanliness is to be assured. | Many guides to good practice have been developed both as Community guides as well as National guides by each Member State. |

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| 8.4 Health food products stored at non-conventional temperatures (e.g., certain micro-ecological health food products) shall be stored and transported at the required temperature according to the different characteristics of the products.<br>8.5 The warehouse shall have an inspection system for receipt and delivery. The principle of "produce first, sell first" shall be implemented for finished products.<br>8.6 There should be stock records for incoming finished products; there should be shipping records for outgoing finished products, including at least batch number, shipping time, place, object, and quantity, etc., so that problems can be found and recovered in time. | Regulation (EC) No 852/2004, Annex II, Chapter IV<br>1. Conveyances and/or containers used for transporting foodstuffs are to be kept clean and maintained in good repair and condition to protect foodstuffs from contamination and are, where necessary, to be designed and constructed to permit adequate cleaning and/or disinfection.<br>7. Where necessary, conveyances and/or containers used for transporting foodstuffs are to be capable of maintaining foodstuffs at appropriate temperatures and allow those temperatures to be monitored. | Guidance document Commission Notice 2016/C 278/01, Annex I, 2. Examples of PRPs:<br>d) Storage conditions at the establishment itself should take into account any instructions provided by the supplier, 'first in, first out' or 'first expire, first out' principles, accessibility for inspection from all sides (e.g., not placed directly on the ground, against walls, …). |
| 9.1 The factory must set up an independent quality management organization that is compatible with the production capacity and directly under the leadership of the person in charge of the factory. Each workshop has a full-time quality supervisor, and each team has a part-time quality inspector, forming a complete and effective quality monitoring system, responsible for the quality supervision of the whole production process. | Regulation (EC) No 178/2002, Article 18 states:<br>1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing, and distribution.<br>2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal,<br>or any substance intended to be, or expected to be, incorporated into a food or feed. To this end, such operators shall have in place systems and procedures which allow for this information to be made avail-able to the competent authorities on demand. | Guidance document Commission Notice 2016/C 278/01, Annex II, Heading 3: Preliminary activities 3.1 Assembly of a multidisciplinary HACCP team This team, which involves all parts of the food business concerned with the product, should include the whole range of specific knowledge and expertise appropriate to the product under consideration, its production (manufacture, storage, and distribution), its consumption |

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| | 3. Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied.<br>This information shall be made available to the competent authorities on demand.<br>4. Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions.<br>Regulation (EC) No 178/2002, Article 19 states:<br>1. If a food business operator considers or has reason to believe that a food which it has imported, produced,<br>processed, manufactured, or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where?<br>the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if.<br>necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection. | and the associated potential hazards and should also involve as much as possible the higher management levels. The team should get the full support of the management who should consider itself owner of the HACCP plan and overall Food Safety Monitoring System. |
| 9.2.1 The quality management organization must formulate a perfect management system, which shall include the following contents.<br>a) Management system for raw and auxiliary materials, intermediate products, finished products and unqualified products. | Regulation (EC) No **852/2004**, Annex II, Chapter XII<br>Food business operators are to ensure:<br>1. that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity. | |

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| b) management system for raw material identification and quality inspection, inspection of intermediate products, inspection technical procedures for finished products, such as quality specifications, inspection items, inspection standards, sampling, and inspection methods, etc.<br>c) A system for retaining samples for observation and a laboratory management system.<br>d) A system for verification of the operation of the production process.<br>e) Clearance management system.<br>(f) various original records and batch production records management system.<br>(g) file management system.<br><br>9.2.2 The above management systems shall be practical, easy to operate and easy to check. | 2. that those responsible for the development and maintenance of the procedure referred to in Article 5(1) of this Regulation (= HACCP programme) or for the operation of relevant guides have received adequate training in the<br>application of the HACCP principles; and<br>3. compliance with any requirements of national law concerning training programmes for persons working in certain food sectors<br><br>Also: **Regulation 178/2002** Article 17 Responsibilities<br>1. Food and feed business operators at all stages of production, processing, and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met. | |
| 9.3 Inspection rooms and laboratories must be set up to suit the type of products produced, and should have the rooms, instruments, equipment, and devices required for the inspection of raw materials, semi-finished products, and finished products, and be regularly identified so that they are always in good condition. | Regulation (EC) No 852/2004, Annex II, Chapter V:<br>1. All articles, fittings and equipment with which food comes into contact are to:<br>(b) be so constructed, be of such materials and be kept in such good order, repair, and condition as to minimise any risk of contamination; | |

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| 9.4.1 Must be set up in accordance with the provisions of the state or relevant departments quality inspection personnel, batch by batch identification and quality inspection of raw materials, unqualified must not be used.<br>9.4.2 The storage place of raw materials must be checked and managed, and places where the storage conditions do not meet the requirements must not be used.<br><br>9.5 Quality management of the processing process<br>9.5.1 Key quality and hygiene control points in the processing process are to be identified and at least the following links are to be monitored and recorded.<br>9.5.1.1 The name and weight (or volume) of the input material.<br>9.5.1.2 Technical parameters such as temperature, pressure, time, and pH in the active ingredient extraction process.<br>9.5.1.3 The yield and quality specifications of the intermediate products.<br>9.5.1.4 Output rates and quality specifications for finished products.<br>9.5.1.5 The hygienic condition of inner packaging materials in direct contact with food.<br>9.5.1.6 Technical parameters for the method of sterilisation of finished products. | Regulation 178/2002 Article 17 Responsibilities<br>Also apply.<br>1. Food and feed business operators at all stages of production, processing, and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met. | Guidance document Commission Notice 2016/C 278/01, Annex II, heading 10: Documentation and record keeping.<br>Efficient and accurate record keeping is essential to the application of HACCP-based procedures.<br>HACCP-based procedures should be documented in the HACCP-plan and continuously supplemented by records on findings.<br>Documentation and record keeping should be appropriate to the nature and size of the operation and sufficient to assist the business to verify that the HACCP-based procedures are in place and being maintained. Documents and records should be kept for a sufficient period of time beyond the shelf life of the product for traceability purposes, for the regular revision of the procedures by the FBO and to allow the competent authority to audit the HACCP-based procedures. Documents should be signed by a responsible reviewing official of the company. Recommended documentation includes:<br>- PRPs applied, working instructions, standard operational procedures, control instructions.<br>- Description of the preparatory stages (before 7 principles).<br>- Hazard analysis.<br>- CCP (+/- oPRPs) identification.<br>- Critical limit determination.<br>- Validation activities.<br>- Corrective actions anticipated.<br>- Description of planned monitoring and verification activities (what, who, when).<br>- Record forms.<br>- Modifications to the HACCP-based procedures.<br>- Supporting documents (generic guides, scientific evidence, …). |

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| 9.5.2 Important production equipment and measuring instruments shall be regularly serviced and thermometers and manometers used for sterilization equipment shall be serviced at least once every six months and records of the servicing shall be made.<br><br>9.5.3 The production environment shall be monitored and the temperature, humidity, air purification and other indicators of the key process environment shall be regularly monitored.<br><br>9.5.4 The ability to monitor the water used for production should be available and monitored on a regular basis.<br><br>9.5.5 Any abnormalities found during the quality management process should be promptly identified and recorded and corrected. | | Record examples are:<br>- Outcome of CCP monitoring activities.<br>- Observed deviations and executed corrective actions.<br>- Outcome of verification activities.<br><br>Records should be kept for an appropriate period of time. That period should be long enough to ensure information to be available in case of an alert that can be traced back to the food in question. For certain foods the date of consumption is certain. For instance, in food catering, consumption takes place shortly after the time of production. For food for which the date of consumption is uncertain, records should be kept for a reasonably short period after the expiry date of the food. Records are an important tool for the competent authorities to allow verification of the proper functioning of the food businesses' FSMS. A simple record-keeping system can be effective and easily communicated to employees. It may be integrated into existing operations and may use existing paperwork, such as delivery invoices and checklists to record, for example, product temperatures. |

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| 9.6.1 The finished product must be inspected batch by batch for sensory, hygienic, and quality indicators and must not be allowed to leave the factory if unqualified.<br>9.6.2 Should have the ability to test the main efficacy factors or efficacy ingredients of the products and test the efficacy factors or main efficacy ingredients of the products produced by each feeding, those who fail shall not leave the factory.<br>9.6.3 Each batch of products should be retained, retained samples should be stored in a dedicated sample library (or area), according to species, batch number classification storage, and has a clear sign.<br>9.6.4 Product stability experiments shall be conducted on a regular basis.<br>9.6.5 The packaging materials, signs and instructions of the products must be inspected and those that are not qualified shall not be used.<br>9.6.6 The storage conditions of the finished product warehouse shall be checked and managed, and any warehouse that does not meet the storage conditions shall not be used. | Regulation (EC) No 852/2004, Article 5<br>1. Food business operators shall put in place, implement, and maintain a permanent procedure or procedures based on the HACCP principles | |

| Chinese National Standard GB 17405-1998 Good manufacture practice on health food | EU legislation | Implementing rules and comparative evaluation |
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| 9.7.1 Detailed records should be kept of quality comments made by users and adverse reactions arising from use, and investigations should be carried out and records kept for inspection.<br>9.7.2 Complete quality management files must be established, with filing cabinets and file managers, and various records classified and filed, and kept for 2 to 3 years for inspection.<br>9.7.3 A comprehensive inspection of production and quality shall be carried out on a regular basis to verify the various operating procedures and job responsibility systems in production and management. Adjustments shall be made to problems identified during inspection or verification, and the production quality of products shall be reported to the health administration on a regular basis. | Regulation (EC) No 852/2004, Article 5<br>(f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively.<br>The verification of effective self-controls is a key objective of official controls in food establishments:<br><br>Regulation (EU) 2017/625, Article 14<br>Official control methods and techniques shall include the following as appropriate:<br>(a) an examination of the controls that operators have put in place and of the results obtained.<br>(b) an inspection of:<br>(i) equipment, means of transport, premises and other places under their control and their surroundings.<br>(ii) animals and goods, including semi-finished goods, raw materials, ingredients, processing aids and other products used for the preparation and production of goods or for feeding or treating animals.<br>(iii) cleaning and maintenance products and processes.<br>(iv) traceability, labelling, presentation, advertising, and relevant packaging materials including materials intended to come into contact with food.<br>(c) controls on the hygiene conditions in the operators' premises.<br>(d) an assessment of procedures on good manufacturing practices, good hygiene practices, good farming practices, and of procedures based on the principles of hazard analysis critical control points (HACCP).<br>(e) an examination of documents, traceability records and other records which may be relevant to the assessment of compliance with the rules referred to in Article 1(2), including, where appropriate, documents | |

| Chinese National Standard GB 17405-1998 Good manufacture practice on health food | EU legislation | Implementing rules and comparative evaluation |
|---|---|---|
| | accompanying food, feed and any substance or material entering or leaving an establishment.<br>(f) interviews with operators and with their staff; (g) the verification of measurements taken by the operator and other test results.<br>(h) sampling, analysis, diagnosis, and tests.<br>(i) audits of operators.<br>(j) any other activity required to identify cases of non-compliance. | |

## 2.3 National standard GB 14880-2012 Food Safety Standard for the Use of Nutritional Fortification Substances in Foods

| **National standard GB 14880-2012** Food Safety Standard for the Use of Nutritional Fortification Substances in Foods | **EU legislation** | **Implementing rules and comparative evaluation** |
|---|---|---|
| This Standard specifies the fundamental purposes of nutritional fortification in foods, the requirements of using nutritional fortification substances, the selection requirements for fortifiable food categories and application requirements for nutritional fortification substances.<br>This Standard is applicable to the application of nutritional fortification substances in foods, unless otherwise stated in national laws and regulations and/or standards | For the food fortification the Regulation EU 1925/2006 on the addition of vitamins and minerals and certain other substances to foods is valid. The provisions of this Regulation regarding vitamins and minerals shall not apply to food supplements covered by Directive 2002/46/EC. | |
| Nutrient<br>The substances which have specific physiological effects in foods and are required and able to maintain the growth, development, activity, reproduction, and normal metabolism, including protein, fat, carbohydrate, mineral substances, and vitamin, etc. | According to Regulation EU 1925/2006 nutrients or ingredients are added to food in order to "enrich" or "fortify" the food in question, so as to add or emphasize particular nutritional characteristics.<br>Only vitamins and/or minerals listed in Annex I, in the forms listed in Annex II, may be added to foods, subject to the rules laid down in this Regulation.<br>Vitamins and minerals in a form that is bio-available to the human body may be added to foods, whether or not they are usually contained therein. | This standard is fundamentally similar to the EU text, which is restricted to naming the nutrients. Apart from the named substances in the Chinese Standard the EU definition of nutrients includes fibre. |

| **National standard GB 14880-2012** Food Safety Standard for the Use of Nutritional Fortification Substances in Foods | **EU legislation** | **Implementing rules and comparative evaluation** |
|---|---|---|
| Other nutritional ingredients<br>Other food compositions which have nutrition and/or physiological functions except nutrients | According to Regulation EU **1925/2006**<br>'Other substance' means a substance other than a vitamin or a mineral that has a nutritional or physiological effect, and include trace elements, amino acids, essential fatty acids, fibre, various plants, and herbal extracts etc. | Similar to EU |
| Foods for special diets<br>Food made by special process or formula in order to meet special physical/psychological conditions and/or meet special diet demands under the conditions of diseases or disorder. The contents of nutrients and/or other nutritional ingredients in these foods are obviously different from comparable ordinary foods. | Commission Delegated Regulation (EU) **2016/128** as regards the specific compositional and information requirements for food for special medical purposes (FSMPs).<br>Substances belonging to the following categories may be added to one or more of the categories of food (referred to in Article 1(1) of the Regulation 609/2013) and provided that these substances are included in the Union list set out in the Annex of the Reg.609/2013.<br>Only in food for special medicinal purposes is allowed to add following statement 'For the dietary management of …' where the blank shall be filled in with the disease, disorder, or medical condition for which the product is intended. | This describes Foods for Special Medical Purposes (FSMPs). The description differs from the definition of FSMPs under EU law but a specific Chinese text with definitions and other particulars for FSMPs has not been identified. |
| Fundamental Purposes of Nutritional Fortification<br>Make up the nutrient loss caused during normal process and storage of foods.<br>In a given territorial scope, where the intake of some nutrients for a large scale of crowd is low or lacked, the caused poor health effects may be improved by fortification.<br>The nutrient intake level for some crowd is low or lacked because of the dietary habit and/or other causes, the caused poor health effects may be improved by fortification.<br>Replenish and adjust the contents of nutrients and/or other nutritional ingredients in foods for special diets. | The Regulation EU **1925/2006** harmonises the provisions laid down by law, regulation or administrative action in Member States which relate to the addition of vitamins and minerals and of certain other substances to foods, with the purpose of ensuring the effective functioning of the internal market, whilst providing a high level of consumer protection. | The list of purposes for fortification is more restricted that under EU law. Follows more Codex Alimentarius General Principles on the issue.<br>According to EU legislation Food for Special Medical Purposes (FSMPs) is very different from fortified foods. |

| **National standard GB 14880-2012** Food Safety Standard for the Use of Nutritional Fortification Substances in Foods | **EU legislation** | **Implementing rules and comparative evaluation** |
|---|---|---|
| Requirements of Using Nutritional Fortification Substances Utilization of nutritional fortification substances shall not result in intake excess or imbalance of nutrients or other nutritional ingredients, neither the metabolism abnormality of any nutrient and other nutritional ingredients. Utilization of nutritional fortification substances shall not encourage and lead the food consumption pattern against the national nutrition policies. The quality of nutritional fortification substances added to foods shall be able to be kept stable under specific conditions of storage, transportation and eating. The nutritional fortification substances added to foods shall not result in obvious bad changes of general characteristics of foods, such as colour, luster, flavour, smell and cooking characteristics. The content or effect of a certain nutritional ingredient shall not be exaggerated by the application of nutritional fortification substances to mislead and cheat consumers. | Article 4 of Regulation 1925/2006 have certain Restrictions on the addition of vitamins and minerals.<br>Vitamins and minerals may not be added to:<br>(a) unprocessed foodstuffs, including, but not limited to, fruit, vegetables, meat, poultry, and fish.<br>(b) beverages containing more than 1,2 % by volume of alcohol and provided that no nutrition or health claim is made.<br>Additional foods or categories of foods to which particular vitamins and minerals may not be added may be determined in accordance with the procedure referred to in Article 14(2) in the light of scientific evidence and taking into account their nutritional value.<br>Community provisions applicable to specified foods may provide for restrictions or prohibitions on the use of certain substances in addition to those laid down in this Regulation.<br>Regulation EU **1169/2011** provides that subject to certain derogations, the labelling of food shall not attribute to any food the property of preventing, treating, or curing a human disease, nor refer to such properties. | General principles in line with EU principles.<br>That means that also in Chinese National Standard is named that the labelling of food shall not attribute to any food the property of preventing, treating, or curing a human disease or like in Directive 46/2002 on the product has to be named following:<br>- a warning not to exceed the stated recommended daily dose.<br>- a statement to the effect that food supplements should not be used as a substitute for a varied diet.<br>- a statement to the effect that the products should be stored out of the reach of young children. |

| **National standard GB 14880-2012** Food Safety Standard for the Use of Nutritional Fortification Substances in Foods | **EU legislation** | **Implementing rules and comparative evaluation** |
|---|---|---|
| Selection Requirements of Fortification Food Categories Foods consumed universally by target population and obtained easily shall be selected for fortification. The consumption of foods as the fortification carriers shall be relatively stable. The foods which are advocated to reduce the eating amount in the diet guideline of China should not be used as the fortification carriers. | Commission Delegated Regulation (EU) **2017/1798** for total diet replacement products for weight control.<br>According to Regulation (EC) No 1924/2006 on nutrition and health claims made on foods and *Article 12* **Restrictions on the use of certain health claims,** the following health claims shall not be allowed:<br>(a) claims which suggest that health could be affected by not consuming the food;<br>(b) claims which make reference to the rate or amount of weight loss;<br>(c) claims which make reference to recommendations of individual doctors or health professionals and other associations not referred to in Article 11. | The EU Regulation have specific category “total diet replacement” which is related to diet and includes some specific provisions and requirements. It can be included in Chinese diet guideline. |
| 6 Application Rules of Nutritional Fortification Substances<br>See Table 1 | Commission Delegated **Regulation (EU) 2016/128** as regards the specific compositional and information requirements for food for special medical purposes (FSMPs).<br>Substances belonging to the following categories may be added to one or more of the categories of food (referred to in Article 1(1) of the Regulation 609/2013) and provided that these substances are included in the Union list set out in the Annex of the Reg.609/2013. | A long list of provisions for nutrients that may be added to which categories of foods and at what amounts. Such specific provisions in the EU exist only for food for special medical purposes. For food supplements and foods in general there are criteria based on risk assessment of the individual nutrients, but the EU has not yet set up maximum amounts for the addition of vitamins and minerals in foods or in food supplements. |

# APPENDIX A GB 14880-2012

**Standardized Appendix**

**Regulation on the use of nutritional fortification substances in foods**

| Nutrients | Classification of food | | Application amount/kg |
|---|---|---|---|
| | Food Codes | Classification/Name | |
| Vitamin A | 01.01.03 | Modified milk powder | 600-1000 μg/kg |
| | 01.03.02 | Modified milk powder (excluding milk powder used for pregnant women and | 3000-9000 μg/kg |
| | | Modified milk powder (for children) | 1200-7000 μg/kg |
| | | Modified milk powder (for pregnant women | 2000-10000 μg/kg |
| | 02.01.01.01 | Vegetable oil | 4000-8000 μg/kg |
| | 02.02.01.02 | Margarine and similar products | 4000-8000 μg/kg |
| | 03.01 | Ice cream and ice confectionery | 600-1200 μg/kg |
| | 04.04.01.07 | Grain flour (soybean flour only) and derived products | 3000-7000 μg/kg |
| | 04.04.01.08 | Soybean | 600-1400 μg/kg |
| | 06.02.01 | Rice | 600-1200 μg/kg |
| | 06.03.01 | Wheat/flour | 600-1200 μg/kg |
| | 06.06 | Ready-to-eat cereals, including oats and rolled oats | 2000-6000 μg/kg |
| | 07.02.02 | Foreign pastry | 2330-4000 μg/kg |
| | 07.03 | Biscuits | 2330-4000 μg/kg |
| | 14.03.01 | Milk containing drinks | 300-1000 μg/kg |
| | 14.06 | Solid beverage | 4000-17000 μg/kg |
| | 16.01 | Jelly | 600-1000 μg/kg |
| | 16.06 | Puffing food | 600-1500 μg/kg |
| B-carotene | 14.06 | Solid beverages | 3-6 mg/kg |
| Vitamin D | 01.01.03 | Modified milk powder | 10-40 μg/kg |
| | 01.03.02 | Modified milk powder (excluding milk powder used for pregnant women and children) | 63-125 μg/kg |
| | | Modified milk powder (for children) | 20-112 μg/kg |
| | | Modified milk powder (for pregnant women | 23-112 μg/kg |
| | 02.02.01.02 | Margarine and similar products | 125-156 μg/kg |
| | 03.01 | Ice cream and ice confectionery | 10-20 μg/kg |
| | 04.04.01.07 | Grain flour (soybean flour only) and derived products | 15-60 μg/kg |
| | 04.04.01.08 | Soybean | 3-15 μg/kg |
| | 06.05.02.03 | Lotus root starch | 50-100 μg/kg |
| | 06.06 | Ready-to-eat cereals, including oats and rolled oats | 12.5-37.5 μg/kg |
| | 07.03 | Biscuits | 16.7-33.3 μg/kg |
| | 07.05 | Other baked products | 10-70 μg/kg/kg |
| | 14.02.03 | Fruit and vegetable juices (Include fermented products) | 2-10 μg/kg |
| | 14.03.01 | Milk containing drinks | 10-40 μg/kg |
| | 14.04.02.02 | Flavored beverages | 2-10 μg/kg |
| | 14.06 | Solid beverages | 10-20 μg/kg |
| | 16.01 | Jelly | 10-40 μg/kg |
| | 16.06 | Puffing food | 10-60 μg/kg |

| Nutrients | Classification of food | | Application amount/kg |
|---|---|---|---|
| | Food Codes | Classification/Name | |
| Vitamin E | 01.01.03 | Modified milk powder | 12-50 mg/kg |
| | 01.03.02 | Modified milk powder (excluding milk powder used for pregnant women and | 100-310 mg/kg |
| | | Modified milk powder (for children) | 10-60 mg/kg |
| | | Modified milk powder (for pregnant women | 32-156 mg/kg |
| | 02.01.01.01 | Vegetable oils | 100-180 mg/kg |
| | 02.02.01.02 | Margarine and similar products | 100-180 mg/kg |
| | 04.04.01.07 | Grain flour (soybean flour only) and derived products | 30-70 mg/kg |
| | 04.04.01.08 | Soybean | 5-15 mg/kg |
| | 05.02.01 | Gum candy | 1050-1450 mg/kg |
| | 06.06 | Ready-to-eat cereals, including oats and rolled oats | 50-125 mg/kg |
| | 14.0 | Beverage (excluding beverages covered under 14.01,14.06) | 10-40 mg/kg |
| | 14.06 | Solid beverages | 76-180 mg/kg |
| | 16.01 | Jelly | 10-70 mg/kg |
| Vitamin K | 01.03.02 | Modified milk powder (for children) | 420-750 mg/kg |
| | | Modified milk powder (for pregnant women | 340-680 mg/kg |
| Vitamin B1 | 01.03.02 | Modified milk powder (for children) | 1.5-14 mg/kg |
| | | Modified milk powder (for pregnant women | 3-17 mg/kg |
| | 04.04.01.07 | Grain flour (soybean flour only) and derived products | 6-15 mg/kg |
| | 04.04.01.08 | Soybean | 1-3 mg/kg |
| | 05.02.01 | Gum candy | 16-33 mg/kg |
| | 06.02 | Rice and derived products (rice, rice vermicelli, rice cake) | 3-5 mg/kg |
| | 06.03 | Wheat flour and derived products | 3-5 mg/kg |
| | 06.04 | Grain flour (soybean flour only) | 3-5 mg/kg |
| | 06.06 | Ready-to-eat cereals, including oats and rolled oats | 7.5-17.5 mg/kg |
| | 07.01 | Bread | 3-5 mg/kg |
| | 07.02.02 | Foreign pastry | 3-6 mg/kg |
| | 07.03 | Biscuits | 3-6 mg/kg |
| | 14.03.01 | Milk containing beverages | 1-2 mg/kg |
| | 14.04.02.02 | Flavored beverages | 2-3 mg/kg |
| | 14.06 | Solid beverages | 9-22 mg/kg |
| | 16.01 | Jelly | 1-7 mg/kg |

| Nutrients | Classification of food | | Application amount/kg |
|---|---|---|---|
| | Food Codes | Classification/Name | |
| Vitamin B2 | 01.03.02 | Modified milk powder (for children) | 8-14 mg/kg |
| | | Modified milk powder (for pregnant women | 4-22 mg/kg |
| | 04.04.01.07 | Grain flour (soybean flour only) and derived products | 6-15 mg/kg |
| | 04.04.01.08 | Soybean | 1-3 mg/kg |
| | 05.02.01 | Gum candy | 16-33 mg/kg |
| | 06.02 | Rice and derived products (rice, rice vermicelli, rice cake) | 3-5 mg/kg |
| | 06.03 | Wheat flour and derived products | 3-5 mg/kg |
| | 06.04 | Grains flour (including soybean flour) and derived products (soybean flour only) | 3-5 mg/kg |
| | 06.06 | Ready-to-eat cereals, including oats and rolled oats | 7.5-17.5 mg/kg |
| | 07.01 | Bread | 3-5 mg/kg |
| | 07.02.02 | Foreign pastry | 3.3-7.0 mg/kg |
| | 07.03 | Biscuits | 3.3-7.0 mg/kg |
| | 14.03.01 | Milk containing drinks | 1-2 mg/kg |
| | 14.06 | Solid beverages | 9-22 mg/kg |
| | 16.01 | Jelly | 1-7 mg/kg |
| Vitamin B6 | 01.03.02 | Modified milk powder (excluding milk powder used for pregnant women and | 8-16 mg/kg |
| | | Modified milk powder (for children) | 1-7 mg/kg |
| | | Modified milk powder (for pregnant women | 4-22 mg/kg |
| | 06.06 | Ready-to-eat cereals, including oats and rolled oats | 10-25 mg/kg |
| | 07.03 | Biscuits | 2-5 mg/kg |
| | 07.05 | Other baked products | 3-15 mg/kg |
| | 14.0 | Beverages (excluding the foodstuffs mentioned in 14.01 and 14.06) | 0.4-1.6 mg/kg |
| | 14.06 | Solid beverages | 7-22 mg/kg |
| | 16.01 | Jelly | 1-7 mg/kg |
| Vitamin B12 | 01.03.02 | Modified milk powder (for children) | 10-30 µg/kg |
| | | Modified milk powder (for pregnant women | 10-66 µg/kg |
| | 06.06 | Ready-to-eat cereals, including oats and rolled oats | 5-10 µg/kg |
| | 07.05 | Other baked products | 10-70 µg/kg |
| | 14.0 | Beverages (excluding the foodstuffs mentioned in 14.01 and 14.06) | 0.6-1.8 µg/kg |
| | 14.06 | Solid beverages | 10-66 µg/kg |
| | 16.01 | Jelly | 2-6 µg/kg |

| Nutrients | Classification of food | | Application amount/kg |
|---|---|---|---|
| | Food Codes | Classification/Name | |
| Vitamin C | 01.02.02 | Flavoured fermented product | 120-240 mg/kg |
| | 01.03.02 | Modified milk powder (excluding milk powder used for pregnant women and children) | 300-1000 mg/kg |
| | | Modified milk powder (for children) | 140-800 mg/kg |
| | | Modified milk powder (for pregnant women | 1000-1600 mg/kg |
| | 04.01.02.01 | Canned fruits | 200-400 mg/kg |
| | 04.01.02.02 | Puree | 50-100 mg/kg |
| | 04.04.01.07 | Grain flour (soybean flour only) and derived products | 400-700 mg/kg |
| | 05.02.01 | Gum candy | 630-13000 mg/kg |
| | 05.02.02 | Sweets other than gum candy | 1000-6000 mg/kg |
| | 06.06 | Ready-to-eat cereals, including oats and rolled oats | 300-750 mg/kg |
| | 14.02.03 | Fruits and vegetable (pulp) juices | 250-500 mg/kg |
| | 14.03.01 | Milk containing drinks | 120-240 mg/kg |
| | 14.04 | Water-based flavoured beverages | 250-500 mg/kg |
| | 14.06 | Solid beverage | 1000-2250 mg/kg |
| | 16.01 | Jelly | 120-240 mg/kg |
| Niacin (or nicotinamide) | 01.03.02 | Modified milk powder (for children) | 23-47 mg/kg |
| | | Modified milk powder (for pregnant women | 42-100 mg/kg |
| | 04.04.01.07 | Grain flour (soybean flour only) and derived products | 60-120 mg/kg |
| | 04.04.01.08 | Soybean | 10-30 mg/kg |
| | 06.02 | Rice and derived products (rice, rice vermicelli, rice cake) | 40-50 mg/kg |
| | 06.03 | Wheat flour and derived products | 40-50 mg/kg |
| | 06.04 | Grain flour (including soybean flour) and derived products (soybean flour only) | 40-50 mg/kg |
| | 06.06 | Ready-to-eat cereals, including oats and rolled oats | 75-218 mg/kg |
| | 07.01 | Bread | 40-50 mg/kg |
| | 07.03 | Biscuits | 30-60 mg/kg |
| | 14.0 | Beverages (excluding the foodstuffs mentioned in 14.01 and 14.06) | 3-18 mg/kg |
| | 14.06 | Solid beverages (excluding soy milk powder) | 110-330 mg/kg |
| Folic acid | 01.01.03 | Modified milk powder | 400-1200 μg/kg |
| | 01.03.02 | Modified milk powder (excluding milk powder used for pregnant women and children) | 2000-5000 μg/kg |
| | | Modified milk powder (for children) | 420-3000 μg/kg |
| | | Modified milk powder (for pregnant women | 2000-8200 μg/kg |
| | 06.02.01 | Rice (washing-face rice only) | 1000-3000 μg/kg |
| | 06.03.01 | Wheat flour | 1000-3000 μg/kg |
| | 06.06 | Ready-to-eat cereals, including oats and rolled oats | 1000-2500 μg/kg |
| | 07.03 | Biscuits | 390-780 μg/kg |
| | 07.05 | Other baked products | 2000-7000 μg/kg |
| | 14.02.03 | Fruits and vegetable (pulp) juices | 157-313 μg/kg |
| | 14.06 | Solid beverages | 600-6000 μg/kg |
| | 16.01 | Jelly | 50-100 μg/kg |

| Nutrients | Classification of food | | Application amount/kg |
|---|---|---|---|
| | Food Codes | Classification/Name | |
| Pantothenic acid | 01.03.02 | Modified milk powder (for children) | 6-60 mg/kg |
| | | Modified milk powder (for pregnant women | 20-80 mg/kg |
| | 06.06 | Ready-to-eat cereals, including oats and rolled oats | 30-50 mg/kg |
| | 14.04.01 | Carbonated drinks | 1.1-2.2 mg/kg |
| | 14.04.02.02 | Flavoured drinks | 1.1-2.2 mg/kg |
| | 14.05.01 | Tea drinks | 1.1-2.2 mg/kg |
| | 14.06 | Solid beverages | 22-80 mg/kg |
| | 16.01 | Jelly | 2-5 mg/kg |
| Biotin | 01.03.02 | Modified milk powder (for children only) | 38-76 μg/kg |
| Chlorine | 01.03.02 | Modified milk powder (for children only) | 800-3000 mg/kg |
| | | Modified milk powder (for pregnant women only) | 1600-3400 mg/kg |
| | 16.01 | Jelly | 50-100 mg/kg |
| Inositol | 01.03.02 | Modified milk powder and modified cream powder (including flavoured milk powder and flavoured cream powder) | 210-250 mg/kg |
| | 14.02.03 | Fruits and vegetable (pulp) juices | 60-120 mg/kg |
| | 14.04.02.02 | Flavoured beverages | 60-120 mg/kg |
| **Minerals** | | | |
| Iron | 01.01.03 | Modified milk powder | 10-20 mg/kg |
| | 01.03.02 | Modified milk powder (excluding milk | 60-200 mg/kg |
| | | powder used for pregnant women and children) | |
| | | Modified milk powder (for children) | 25-135m mg/kg |
| | | Modified milk powder (for pregnant women | 50-280 mg/kg |
| | 04.04.01.07 | Grain flour (soybean flour only) and derived products | 46-80 mg/kg |
| | 05.02.02 | Sweets other than gum candy | 600-1200 mg/kg |
| | 06.02 | Rice and derived products (Rice, rice vermicelli, rice cake) | 14-26 mg/kg |
| | 06.03 | Wheat flour and derived products | 14-26 mg/kg |
| | 06.04 | Grain flour (soybean flour only) | 14-26 mg/kg |
| | 06.06 | Ready-to-eat cereals, including oats and rolled oats | 35-80 mg/kg |
| | 07.01 | Bread | 14-26 mg/kg |
| | 07.02.02 | Foreign pastry | 40-60 mg/kg |
| | 07.03 | Biscuits | 40-60 mg/kg |
| | 07.05 | Other baked products | 50-200 mg/kg |
| | 12.04 | Soy sauce | 180-260 mg/kg |
| | 14.0 | Beverages (excluding the foodstuffs mentioned in 14.01 and 14.06) | 10-20 mg/kg |
| | 14.06 | Solid beverages (excluding the food mentioned in 14.06.02) | 95-220 mg/kg |
| | 16.01 | Jelly | 10-20 mg/kg |

| Nutrients | Classification of food | | Application amount/kg |
|---|---|---|---|
| | Food Codes | Classification/Name | |
| Calcium | 01.01.03 | Modified milk powder | 250-1000 mg/kg |
| | 01.03.02 | Modified milk powder (for children) | 3000-7200 mg/kg |
| | | Modified milk powder (for pregnant women | 3000-6000 mg/kg |
| | 01.06 | Cheese | 2500-10000 mg/kg |
| | 03.01 | Ice cream and ice cream cake products | 2400-3000 mg/kg |
| | 04.04.01.07 | Grain flour (soybean flour only) and derived products | 1600-8000 mg/kg |
| | 06.02 | Rice and derived products (rice, rice vermicelli, rice cake) | 1600-3200 mg/kg |
| | 06.03 | Wheat flour and derived products | 1600-3200 mg/kg |
| | 06.04 | Grain flour (Including soybean flour) and derived products (soybean flour only) | 1600-3200 mg/kg |
| | 06.05.02.03 | Lotus root starch | 2400-3200 mg/kg |
| | 06.06 | Ready-to-eat cereals, including oats and rolled oats | 2000-7000 mg/kg |
| | 07.01 | Bread | 1600-3200 mg/kg |
| | 07.02.02 | Foreign pastry | 2670-5330 mg/kg |
| | 07.03 | Biscuits | 2670-5330 mg/kg |
| | 07.05 | Other baked products | 3000-15000 mg/kg |
| | 08.03.05 | Meat sausage | 850-1700 mg/kg |
| | 08.03.07.01 | Dry meat floss | 2500-5000 mg/kg |
| | 08.03.07.02 | Bak kwa products | 1700-2550 mg/kg |
| | 10.03.01 | Dehydrated egg products | 190-650 mg/kg |
| | 12.03 | Vinegar | 6000-8000 mg/kg |
| | 14.0 | Beverages (excluding the foodstuffs mentioned in 14.01 and 14.06) | 160-1350 mg/kg |
| | 14.02.03 | Fruits and vegetable (pulp) juices | 1000-1800 mg/kg |
| | 14.06 | Solid beverages | 2500-10000 mg/kg |
| | 16.01 | Jelly | 390-800 mg/kg |
| Zinc | 01.01.03 | Modified milk powder | 5-10 mg/kg |
| | 01.03.02 | Modified milk powder (excluding milk powder used for pregnant women and children) | 30-60 mg/kg |
| | | Modified milk powder (for children) | 50-175 mg/kg |
| | | Modified milk powder (for pregnant women | 30-140 mg/kg |
| | 04.04.01.07 | Grain flour (soybean flour only) and derived products | 29-55.5 mg/kg |
| | 06.02 | Rice and derived products (rice, rice vermicelli, rice cake) | 10-40 mg/kg |
| | 06.03 | Wheat flour and derived products | 10-40 mg/kg |
| | 06.04 | Grain flour (soybean flour only) | 10-40 mg/kg |
| | 06.06 | Ready-to-eat cereals, including oats and rolled oats | 37.5-112.5 mg/kg |
| | 07.01 | Bread | 10-40 mg/kg |
| | 07.02.02 | Foreign pastry | 45-80 mg/kg |
| | 07.03 | Biscuits | 45-80 mg/kg |
| | 14.0 | Beverages (excluding the foodstuffs mentioned in 14.01 and 14.06) | 3-20 mg/kg |
| | 14.06 | Solid beverages (excluding soy milk powder) | 60-180 mg/kg |
| | 16.01 | Jelly | 10-20 mg/kg |

| Nutrients | Classification of food | | Application amount/kg |
|---|---|---|---|
| | Food Codes | Classification/Name | |
| Selenium | 01.03.02 | Modified milk powder (excluding children) | 140-280 μg/kg |
| | | Modified milk powder (for children only) | 60-130 μg/kg |
| | 06.02 | Rice and derived products (rice, rice vermicelli, rice cake) | 140-280 μg/kg |
| | 06.03 | Wheat flour and derived products) | 140-280 μg/kg |
| | 06.04 | Grain flour (Including soybean flour) and derived products (soybean flour only) | 140-280 μg/kg |
| | 07.01 | Bread | 140-280 μg/kg |
| | 07.03 | Biscuits | 30-110 μg/kg |
| | 14.03.01 | Milk containing drinks | 50-200 μg/kg |
| Magnesium | 01.03.02 | Modified milk powder (excluding pregnant women and children) | 300-1100 mg/kg |
| | | Modified milk powder (for pregnant women only) | 300-2800 mg/kg |
| | 01.03.02 | Modified milk powder (for children only) | 300-2300 mg/kg |
| | 14.0 | Beverages (excluding the food mentioned in 14.01 and 14.04.01) | 30-60 mg/kg |
| | 14.06 | Solid beverages | 1300-2100 mg/kg |
| Copper | 01.03.02 | Modified milk powder (excluding pregnant women and children) | 3-7.5 mg/kg |
| | | Modified milk powder (for children only) | 2-12 mg/kg |
| | | Modified milk powder (for pregnant women only) | 4-23 mg/kg |
| Manganese | 01.03.02 | Modified milk powder (excluding pregnant women and children) | 0.3-4.3 mg/kg |
| | | Modified milk powder (for children only) | 7-15 mg/kg |
| | | Modified milk powder (for pregnant women only | 11-26 mg/kg |
| Potassium | 01.03.02 | Modified milk powder (excluding pregnant women and children) | 7000-14100 mg/kg |
| Phosphorous | 04.04.01.07 | Grain flour (soybean flour only) and derived products | 1600-3700 mg/kg |
| | 14.06 | Solid beverages | 1960-7040 mg/kg |

| Nutrients | Classification of food | | Application amount/kg |
|---|---|---|---|
| | Food Codes | Classification/Name | |
| **Others** | | | |
| **L-Lysine** | 06.02 | Rice and derived products (rice, rice vermicelli, rice cake) | 1-2 g/kg |
| | 06.03 | Wheat flour derived products | 1-2 g/kg |
| | 06.04 | Grain flour (Including soybean flour) and derived products (soybean flour only) | 1-2 g/kg |
| | 07.01 | Bread | 1-2 g/kg |
| **Taurine** | 01.03.02 | Modified milk powder | 0.3-0.5 g/kg |
| | 04.04.01.07 | Grain flour (soybean flour only) and derived products | 0.3-0.5 g/kg |
| | 04.04.01.08 | Soybean | 0.06-0.1 g/kg |
| | 14.03.01 | Milk containing beverages | 0.1-0.5 g/kg |
| | 14.04.02.01 | Beverage for special uses | 0.1-0.5 g/kg |
| | 14.04.02.02 | flavoured beverages | 0.4-0.6 g/kg |
| | 14.06 | Solid beverages | 1.1-1.4 g/kg |
| | 16.01 | Jelly | 0.3-0.5 g/kg |
| **L-carnitine** | 01.03.02 | Modified milk powder (excluding children usage) | 300-400 mg |
| | | Modified milk powder (for children only) | 50-150 mg/kg |
| | 14.02.03 | Fruit and vegetable (pulp) juices | 600-3000 mg/kg |
| | 14.03.01 | Milk containing drinks | 600-3000 mg/kg |
| | 14.04.02.01 | Products with special uses (for sports beverages only) | 100-1000 mg/kg |
| | 14.04.02.02 | Flavoured beverages | 600-3000 mg/kg |
| | 14.06 | Solid beverages | 6000-30000 mg/kg |
| **γ-linoelic acid** | 01.03.02 | Modified milk powder and modified cream powder (including flavoured milk powder and flavoured cream powder) | 20-50 g/kg |
| | 02.01.01.01 | Vegetable oil | 20-50 g/kg |
| | 14.0 | Beverages (excluding packaged drinking water mentioned in 14.01) | 20-50 g/kg |
| **Lutein** | 01.03.02 | Modified milk powder (for children only, measurements of liquids will be done after dilution) | 1620-2700 μg/kg |
| **Oligofructose** | 01.03.02 | Modified milk powder (For children and pregnant women) | ≤64.5 g/kg |
| **1,3-dioleoyl-2-palmitoyl-glycerol** | 01.03.02 | Modified milk powder (for children only, measurements of liquids will be done after dilution) | 24-96 g/kg |
| **Arachidonic acid (AA or ARA)** | 01.03.02 | Modified milk powder (for children only) | ≤1% (percentage of total fatty acids) |
| **DHA** | 01.03.02 | Modified milk powder (for children only) | ≤0.5% (percentage of total fatty acids) |
| | | Modified milk powder for pregnant women only) | 300-1000 mg/kg |
| **Lactoferrin** | 01.01.03 | Modified milk products | ≤1.0 g/kg |
| | 01.02.02 | flavoured fermented products | ≤1.0 g/kg |
| | 14.03.01 | Milk containing beverages | ≤1.0 g/kg |

| Nutrients | Classification of food | | Application amount/kg |
|---|---|---|---|
| | Food Codes | Classification/Name | |
| **Calcium casein peptide** | 06.0 | Rice and derived products (rice, rice vermicelli, rice cake) (excluding products covered under 06.01 and 07.0) | ≤1.6 g/kg |
| | 14.0 | Beverages (Excluding beverages covered in 14.01) | ≤1.6 g/kg (Usage can be increased after dilution for solid beverages |
| **Casein phosphopeptides** | 01.01.03 | Modified milk products | ≤1.6 g/kg |
| | 01.02.02 | flavoured fermented products | ≤1.6 g/kg |
| | 6.0 | Rice and derived products (rice, rice vermicelli, rice cake) (excluding products covered under 06.01 and 07.0) | ≤1.6 g/kg |
| | 14.0 | Beverages (excluding the foodstuffs mentioned in 14.01 and 14.06) | ≤1.6 g/kg(Usage can be increased after dilution for solid beverages |
| A The use of table A.1 is in accordance to the categorization number and name of product | | | |