

# Food additives in China

If you are exporting food to China, you must check that food additives used to make it are permitted.

- 1. Find out the international code for the food additive(s) you use
- 2. Check it against the list of permitted food additives
- 3. If it is not on the list, consider applying for it to be added
- 4. Label the food additive correctly

Sensitivity to food additives in China is part of the widespread concern over food safety. Particularly as the majority of reported food safety incidents are the result of criminal contamination with illegal additives—as was the case in the melamine scandal of 2008. More insidious is the general public's fear that to economise on costs, Chinese producers add more chemicals than are necessary. The average packaged food in China will often contain more additives than its equivalent in Europe. In an attempt to address these concerns, Chinese regulators have a strict focus on food additives. European producers will have little difficulty in complying with China's food additive requirements including labelling, however, as approved additives are harmonised with international standards. It should be noted that registering a new additive may be a costly process better addressed through a food organisation or association rather than individual companies.

# 1. Background

Both China and the European Union use the Codex Alimentarius international standards as the basis of their food additive legislation. Codex Alimentarius is based on advice from the Joint Expert Committee for Food Additives of the World Health Organisation and the Food and Agriculture Organisation, both organs of the United Nations.

The high level of harmony between European and Chinese regulations for permitted food additives and their maximum quantities or residue levels means that European exporters can expect a high level of certainty that they fully comply with Chinese requirements. International food additives standards are updated regularly. The Ministry of Health therefore also occassionally releases updates to its regulations. At the time of writing the latest update was in 2012. Exporters need to be aware that the information must be obtained from the most recent update, which refers to the 2011 regulations, rather than the regulations themselves. European food with permitted additives which are labelled correctly, and meet all other requirements not related to food additives, can expect to pass through customs and quarantine and into the Chinese market.

Foods that contain additives that are not included in China's lists must be approved by the Chinese authorities. Requests to add new food additives are usually undertaken by Chinese industy bodies. It is rare for foreign corporations to undertake this process, but they are permitted to do so.

The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) references Codex Alimentarius as the international consensus on food safety standards. As WTO members, both China and the European Union are bound to be guided by these common standards. Though countries are permitted to implement additional guiding rules to reflect local conditions, but they can be challenged if they are not scientifically justified.

# 1.1. China

Permitted Chinese food additives are listed in the regulation GB 2760-2011 [Doc01]<sup>1</sup>[Doc02]<sup>2</sup>.

In accordance with international practice, Chinese food additives regulation is based on the principle that they are technically necessary and proven to be safe. Food additives can only be used if they are covered in the national food safety standards, within the list of allowable food additives of the Ministry of Health, and within the scope of allowed applications and dosage levels.

Food additives that do not meet these criteria need to be registered as new food additives. The process is detailed below.

Food additives should not be intended to cover up food rancidness, quality defects (in the food itself or during processing) or be used for adulteration or falsification, or reduce the nutritional value of food. Levels of food additives should be as low as possible. Unless a residue level is specified, food processing aids used in the course of food processing should be removed.

1.2. Europe

<sup>&</sup>lt;sup>1</sup> Relevant documents can be provided by the EU SME Centre upon request at <u>enquiries@eusmecentre.org.cn</u>

<sup>&</sup>lt;sup>2</sup> Relevant documents can be provided by the EU SME Centre upon request at <u>enquiries@eusmecentre.org.cn</u>

Permitted food additives are listed in Annex II of Regulation (EC) No 1333/2008. The Regulation brings together in a single legislative act all types of food additives, including colours and sweeteners. The regulation also lists 12 substances or types of substance which are not considered to be food additives.

Under European legislation, food additives must be authorised before they can be used in foods. Since 2002, the European Food Safety Authority (EFSA) has overseen the regulation of food additives. Authorisation follows safety assessment by the EFSA.

The present regulatory framework has its origins in the reforms of December 2008, which, when they entered into force in January 2010, consolidated all food additives legislation previously covered by different directives.

In addition to the EU Regulation, other laws regulating food additives in the EU are:

- Regulation EU 257/2010 programme for the re-evaluation of approved food additives
- Directive 94/35/EC sweeteners for use in foodstuffs
- Directive 94/36/EC colours for use in foodstuffs
- Directive 95/2/EC food additives other than colours and sweeteners
- Directive 2008/60/EC purity criteria for sweeteners in foodstuffs
- Directive 2008/84/EC purity criteria for food additives other than colours and sweeteners
- Directive 2008/128/EC purity criteria for colours used in foodstuffs

The Regulation on the common authorisation procedure for additives, enzymes and flavourings began to be fully applicable in the course of 2011 when its implementing measures entered into force.

By December 2020 the EFSA is required to have re-evaluated all food additives which were authorised before 20 January 2009.<sup>3</sup>

# 2. Regulations and technical requirements

# Principal Chinese regulations and implementing rules

Food additives in China are governed by the *Food Safety Law of the People's Republic of China*, which came into effect on 1 June 2009, replacing the *Food Hygiene Law*. It contains provisions that confirm and strengthen governmental control and oversight regarding food additives. The Food Safety Law defines food additives as:

any synthetic or natural substance used to improve the quality, colour, fragrance, flavour of food, and used to add to the food or put together with the food for preventing spoilage, maintaining freshness or as required for processing technology.

<sup>&</sup>lt;sup>3</sup>See the EFSA website <u>here</u>.

Article 63 of the Food Safety Law requires that for the import of new food additives or new food related products, the importer must submit an application and relevant materials to the executive department of health under the State Council.

The law established the Food Safety Commission, a body charged with principal authority for overseeing food safety in China which reports to the State Council (China's cabinet). It is still in its formative stages.

The Food Safety Commission will coordinate and supervise the main authorities currently responsible for food safety in China. These include:

- Ministry of Agriculture
- General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)
- State Administration for Industry and Commerce
- Ministry of Health
- State Food and Drug Administration (SFDA)

*Measures for the Administration of New Food Additives (Order number 73 of the Ministry of Health)* are published by the Ministry of Health. They set out the process of applying for permission to use food additives that are not listed. This process is discussed in detail below.

*GB* 2760-2011 Food Safety National Standards for the Usage of Food Additives specifies the basic principles for the usage of food additives, food additive types, application scope and maximum allowable dose level. It contains lists of:

- approved food additives, application scope and maximum allowable dose level;
- list of food additives that should be used properly according to the needs of production;
- food types that are not subject to the proper use rules;
- allowable natural flavours;
- food additives auxiliaries without restrictions;
- food additives auxiliaries with restricted scope;
- food enzyme preparations.

The lists are supplemented by announcements from the Ministry of Health outlining newly permitted additives. The most recent at the time of writing was released on August 23, and can be found here  $[Doc30]^4$ .

*GB* 14880-2012 Food Safety National Standards for the Usage of Nutritional Enrichment  $[Doc32]^5$  lists the allowable food additives for use as food nutrition enrichments and their maximum levels.

*GB* 7718-2011 Food Safety National Standards—General Rules for the Labelling of Prepackaged Foods sets out labelling requirements.

<sup>&</sup>lt;sup>4</sup> Relevant documents can be provided by the EU SME Centre upon request at <u>enquiries@eusmecentre.org.cn</u>

<sup>&</sup>lt;sup>5</sup> Relevant documents can be provided by the EU SME Centre upon request at <u>enquiries@eusmecentre.org.cn</u>

# Technical committees

Organisation	Contact information
Codex Committee on Food Additives	http://www.codexalimentarius.org/committees-task-
	forces/en/?provide=committeeDetail&idList=9
Codex Committee on Food Import and Export Inspection and Certification Systems	http://www.codexalimentarius.org/committees-task-
	forces/en/?provide=committeeDetail&idList=5
Joint FAO/WHO Expert Committee on Food Additives (JECFA)	http://www.who.int/foodsafety/chem/jecfa/en/index.html
International Standards Organisation (ISO) TC/034 Food Products	http://isotc.iso.org/livelink/livelink/open/tc34
Codex Committee on Food Additives and Contaminants (CCFAC) (EU)	http://ec.europa.eu/food/fs/ifsi/eupositions/ccfac/ccfac_index_en.html

Laws and standards<sup>6</sup>

Chinese	English	URL
中华人民共和国食品安全法	Food Safety Law	[Doc04]
中华人民共和国进出口商品检验法	Import and Export Commodity Inspection Law	[Doc31]
食品添加剂新品种管理办法(卫生部令 第73号)	Measures for the Administration of New Food Additives (Order number 73 of Ministry of Health)	[Doc05 CH]
GB 2760-2011 食品安全国家标准 食品添加剂使用标准	Food Safety National Standards for the Usage of Food Additives	[Doc01] [Doc02]
GB 14880-2012 食品营养强化剂使用标准	Food Safety National Standards for the Usage of Nutritional Enrichment	[Doc32]
GB 26687—2011 复配食品添加剂通则	General Rules on Compound Food Additives	[Doc06 CH]

<sup>&</sup>lt;sup>6</sup> Relevant documents can be provided by the EU SME Centre upon request at <u>enquiries@eusmecentre.org.cn</u>

GB 7718-2011 食品安全国家标准一预包装食品标签通则	Food Safety National Standards—General Rules for the Labelling of Prepackaged Foods.	[Doc34]
国家质检总局 卫生部关于进口食品,食品添加剂检验有关适用标准问题的公告	Ministry of Health Notice on the relevant standards for imported food and food additives	[Doc07 CH]
进出口食品添加剂检验检疫监督管理工 作规范	Measures for the supervision, management of quarantine and inspection of the import and export of food additives	[Doc08 CH]
关于批准焦磷酸一氢三钠等 5 种食品添加剂新品种的公告(卫生部公告 2012 年 第 15 号)	Ministry of Health Notice 15 2012 (new food additives)	[Doc30]

Guideline: Food additives in China

#### 3. How to comply with food additive requirements

## **3.1.Foods with approved additives**

## Confirmation

To confirm a food additive is permitted in China, exporters need to know the Codex INS number of their food additive. Codex INS numbers are based on European E numbers, and in almost all cases will be the same. Exporters can confirm this by consulting the Codex Alimentarius list  $[Doc33]^7$  of INS numbers. Once the INS number for the food additive is known, it can be checked against the list of permitted food additives in the Chinese regulation GB 2760-2011  $[Doc01]^8$ .

## Labelling

Foods which contain approved food additives must be labelled correctly.

The Ministry of Health is currently developing standards on food additive labelling. The draft indicates that "Food Additive" must be prominently placed on the label. The names of food additives must be consistent with GB 2760 or GB 14880 or notices issued by the Ministry of Health providing updates. Each additive must be declared in a descending order of the content of each ingredient. The scope of use and the allowable dosage of a food additive as well as its application method must also be given. In case of compound additives, the quantity of each food additive must be indicated in a descending order. However, the content of each ingredient for a compound food additive does not need to be given in case of non-retail sales of food additives.

When food additives are used in prepackaged food for direct delivery to consumers, they must be indicated on the label in descending order of their weights added in the process of manufacture or preparation of the food. The names of those food additives shall be declared in general names in accordance with GB 2760. The content of each ingredient does not need to be declared. This labelling requirement is specified in *GB* 7718-2011 Food Safety National Standards—General Rules for the Labelling of Prepackaged Foods.

Food additives listed in GB 2760 and GB 14880 can be used without prior approval as long as the dosage is appropriate. Lists are constantly changing, however. These are updated by the Ministry of Health and can be found [here].

# 3.2 New food additives

An individual or organisation intending to produce, operate, use or import a new food additive must apply for a license from the Ministry of Health.

New food additives are regulated by Order 73 of the Ministry of Health—The Measures for The Administration of New Food Additives, which came into force on March 10, 2010. This law has replaced The Measures for Hygienic Administration of Food Additives issued on 28 March 2002.

<sup>8</sup> Relevant documents can be provided by the EU SME Centre upon request at <u>enquiries@eusmecentre.org.cn</u>

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<sup>&</sup>lt;sup>7</sup> Relevant documents can be provided by the EU SME Centre upon request at <u>enquiries@eusmecentre.org.cn</u>

The following materials must be submitted:

- common name, function category, dose level and application scope of the additive;
- documents or certificates to prove technical necessity and use effect;
- quality specification requirements, production techniques and testing method for the food additive, as well as the method or instruction to test the additive in food;
- safety assessment materials, including raw materials or sources, chemical structure and physical properties, production techniques, toxicology safety assessment documents or testing reports on toxicology, and testing reports on quality specifications;
- samples of labelling, instructions and food additive product;
- documents of other countries (regions) or international organizations allowing production and use of (the additive) that are helpful to the safety assessment.

Some documents can be waived for the applications of enlarged application scope or dose levels.

After receiving applications, the Ministry of Health organises experts from relevant fields to perform a technical review on the technical necessity and safety assessment materials of the new food additive variety and produce a conclusion about the technical review within 60 days. Exporters should be aware that this timeline is in addition to lab analysis. If the Ministry of Health requires further information, the sixty day period will recommence after it is provided. Since any additional request for information restarts the clock, this process can potentially last months or years.

Based on the conclusion of the technical review, the Ministry of Health shall grant a licence to the new food additive variety that is technically necessary and meets the food safety requirements and shall include it in the list of allowable food additives for publication.

For additives that lack technical necessity or fail to meet food safety requirements, the Ministry of Health shall reject the application and provide a written justification.

Registering a new food additive in China can be a lengthy and costly process. It is more likely to be undertaken by large food multinational than a small or medium food enterprise. The State Food and Drug Administration also welcomes applications from food groups or associations, so that the cost can be borne across a larger group of companies.

Lex Europa	European Union law and regulations search
eur-lex.europa.eu	engine
Standardisation Administration of the People's	SAC is responsible for drafting and revising laws
Republic of China	and regulations for the purpose of
www.sac.gov.cn/sac_en/	standardisation. Source of Chinese legislation
	and regulations.
International Standards Organisation	ISO develops and publishes international
www.iso.org	standards.
US Department of Agriculture Foreign	Publishes reports on changes in Chinese
Agriculture Service	regulations regarding food, including food
www.fas.usda.gov	packaging.
CIRS Reach	CIRS is a China-accredited hazardous substance
www.cirs-reach.com	research firm which publishes guidelines on
	Chinese standards

4. Resources



The EU SME Centre assists European SMEs to export to China by providing a comprehensive range of free, hands-on support services including the provision of information, confidential advice, networking events and training. The Centre also acts as a platform facilitating coordination amongst Member State and European public and private sector service providers to SMEs.

The Centre's range of free services cover:

• Business Development – provision of market information, business and marketing advice

• Legal – legal information, 'ask the expert' initial consultations and practical manuals

• Standards – standards and conformity requirements when exporting to China

• HR and Training - industry and horizontal training programmes

• Access to a service providers directory and information databases

• Hot-desking – free, temporary office space in the EU SME Centre to explore local business opportunities

• Any other practical support services to EU SMEs wishing to export to or invest in China.



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