

Chinese food (additive) industry: manufacturing licence is now required

The Chinese General Administration of Quality Supervision, Inspection and Quarantine (“AQSIQ”) published the *Rules of Administration and Supervision on Production of Food Additives* (“Rules”) on 4 April 2010 (to be entered into force on 1 June 2010).

Serving as one of the follow-up measures of the *PRC Food Safety Law*, these new Rules will enhance the administrative supervision of the Chinese food additive industry. Starting from 1 June 2010, all manufacturers producing food additives in China will be subject to manufacturing licence control by AQSIQ; in the past, the regulation of food additive production under hygiene regulations was not as strict. In future, the manufacture of food additives will not be permitted in China without such a manufacturing licence.

In addition to food additive manufacturers, the above Rules are also important for those in industries which make use of food additives, such as food manufacturers. Food manufacturers may be sanctioned with fines or even cessation of activities or cancellation of their food manufacturing licence if they have not kept evidence of compliance of their food additive supplier with the Rules.

1. General rules

The Rules are the underlying rules governing the manufacture of food additives which have been already listed in the approved food additives list issued by the Ministry of Health (“MOH”) or in national food safety standards. To produce food additives which are not included in the current list of approved food additives or national standards, prior approval of the MOH is required, so that this new food additive can be added into the list (according to *Administrative Measures on the New Variety of Food Additives effective as of 30 March 2010*). Therefore, the approval of new food additives is not governed by the Rules.

Importing food additives is subject to different rules. Usually, apart from the Chinese labelling rules and import inspection procedures, no special licence is required if the imported food additive is already included in the above list. Otherwise, in order to import a food additive into China, it is necessary to apply for the approval to add the new food additive into the above list according to the above *Administrative Measures on the New Variety of Food Additives*.

2. Hygiene Licence vs Manufacturing Licence

Before the *Food Safety Law* came into force, the manufacture of food additives in China was subject to the hygiene licence regime. According to the *Food Hygiene Law* (effective on 30 October 1995 and abolished on 1 June 2009) as well as the *Administrative Measures on the Food Hygiene Licence* (effective on 25 December 1995 and abolished on 1 May 2010), all manufacture and use of food additives had to meet certain hygienic standards. A hygiene licence shall be granted to those manufacturers of food additives who meet the hygienic standards and will be valid

for 4 years, after which it can be renewed. Currently, the hygienic standards are GB 2760-2007 (*Hygienic Standards for the Use of Food Additives*).

Due to the abolition of the *Food Hygiene Law* and the *Administrative Measures on the Food Hygiene Licence*, the hygiene licence regime has been replaced by the manufacturing licence regime under the *Food Safety Law*. The manufacturing licence is valid for five years, renewable 6 months before its expiry.

3. Jurisdiction

The provincial department in charge of quality inspection and supervision is responsible for issuing manufacturing licence for food additives.

4. Prohibition of manufacture without manufacture licence

In the past, manufacturers could start trial manufacturing and trial distribution before they obtained the hygiene licence. However, under the Rules, no trial manufacturing or distribution is authorised. A food additives manufacturing licence is a prerequisite for each food additives manufacturer to carry out its manufacturing activities.

5. Approval procedure

The application and approval procedure is summarised as follows:

- (1) the applicant applies for the manufacturing licence by submitting a series of documents stipulated in the Rules;
- (2) the authorities accept the application documents or reject the application documents or ask the applicant to modify and provide supplementary documents;
- (3) the authorities examine the application documents and organise on-site inspection;
- (4) if the on-site inspection is passed, the authorities then select samples for testing by an authorised inspection institute;
- (5) if the testing is also passed, the authorities issue an authorisation decision, and the manufacturing licence shall be granted 10 days after the issue of such a decision.

The whole approval procedure shall be 60 days, sample testing time excluded.

6. Filing

The provincial department in charge of quality and supervision shall file a list of manufacturing licences to the AQSIQ for record and the list is available to the public.

7. Modification of manufacturing licence

A manufacturing licence must be modified, and the approval procedure detailed above will need to be repeated, under any of the following circumstances:

- Additional food additives to be manufactured which are not covered in the initial licence;
- Major modification of conditions of manufacturing, inspection, techniques or process by the manufacturer; or
- Change of related laws, regulations, and standards and upon request of the authorities.

8. Manufacturers' obligations

The Rules provide a chapter specifically stipulating the obligations of manufacturers, including:

- inspection obligations before the delivery from the factory;
- inspection of raw materials, packaging and equipment;
- putting into place a quality management system (records shall be kept for at least two years or the guarantee period, whichever is longer);
- obligations in relation to labelling;
- obligations in case of subcontracting; and
- recall obligations.

9. Preliminary comments

It is noted that an earlier draft of the Rules did not mention compound food additives. Compound food additives are composed of more than two different food additives which were expressly mentioned in the defunct *Administrative Measures relating the Hygiene of Food Additives*. The disclosure of the composition of compound food additives was a heated topic during the public consultation phase, since many Chinese companies feared that this would risk their know-how related to compound food additives being disclosed to others. However, no obligation related to compound food additives is provided in the Rules. It is expected that new rules relating to compound food additives will be issued by AQSIQ.

It is not clear whether the hygienic licence issued under the previous regime will be still valid after the Rules come into force. It is probable that these licences will remain valid and upon expiration of the existing hygienic licences, food additive manufacturers would then need to apply for new manufacturing licence. However, no clear provisions are stipulated in the Rules.

The manufacturers' obligations stipulated by the Rules are very general and hard to implement. For instance, no obligation to stop manufacturing in a recall procedure is provided. The Rules only require manufacturers to report to the authorities so as to explain the recall procedure that has been followed and disposal of food additives that have been recalled.

Additional detailed implementing rules are necessary, so as to make the Rules enforceable in practice.