

CHINA REGULATION

How to Navigate the Chinese Novel Food Hurdles

In this second in the series, a look at the regulatory environment for the novel food approval of new food ingredients in China.

by Nigel Baldwin and Sandy Lin

In the April/May 2013 issue of *TWOFI*, we discussed that functional food approvals in China are product rather than ingredient specific. Thankfully that is not the case for novel foods. Like in the European Union, before a new food ingredient can be used to add to a functional food it must be approved as safe first. The Novel Food Regulation was published in July, 2007 by the Ministry of Health (MOH), and came into force on December 1, 2007. Under the Regulation, "Novel Food" means:

- Animals, plants and microorganisms that are not eaten conventionally in China;
- Food materials separated from animals, plants and microorganisms, which are not

eaten conventionally in China;

- New species of microorganisms used in food processing;
- Food materials of which original components and structures are changed due to new manufacturing techniques.

The Regulation is divided into four basic sub-Regulations:

1. Administrative Measures
2. Administrative Permission - Application and Acceptance
3. Guideline for Research and Development
4. Safety Assessment Procedure

Application Procedure

The application procedure is similar to that for a functional food approval in

that the dossier is submitted and evaluated by an expert committee who make recommendations for any additional data and then a final approval is issued by the Ministry of Health, renamed as National Health and Family Planning Commission. Like the EU, it is around a 2 year process, from when you have you completed safety tests ready for submission.

The dossier itself comprises 9 sections:

1. Application form of hygiene administration permit of novel food
2. Research and development report and safety research reports
3. Brief summary of production process and flow chart
4. Product specification
5. Status on research and application in China and abroad, as well as related safety evaluation documents
6. Product label and instructions and sample (one piece or 30g)
7. Other materials helpful for assessment and review.
8. Certificate or document issued by authority to testify free production or free sales of the substances in the country of origin, or*
9. Historical justification of edible use in the country of origin*

Section 8 underlines one very important point. In China they do not normally expect to be the first country to approve a novel food, thus a fundamental part of the application is the demonstration of approvals elsewhere in the world. Like many countries they typically like to see approval already in the EU and/or the US. The rest of the documentation is pretty straight forward, however we again come

Table 1: Permitted List of Cultures for General Food (2010-4-22)

<i>Bifidobacterium</i>	<i>Lactobacillus</i>
<i>Bifidobacterium adolescentis</i>	<i>Lactobacillus acidophilus</i>
<i>Bifidobacterium animalis</i>	<i>Lactobacillus casei</i>
<i>Bifidobacterium bifidum</i>	<i>Lactobacillus cripatus</i>
<i>Bifidobacterium breve</i>	<i>Lactobacillus fermentum</i>
<i>Bifidobacterium infantis</i>	<i>Lactobacillus gasseri</i>
<i>Bifidobacterium lactis</i>	<i>Lactobacillus johnsonii</i>
<i>Bifidobacterium longum</i>	<i>Lactobacillus paracasei</i>
<i>Streptococcus</i>	<i>Lactobacillus plantarum</i>
<i>Streptococcus thermophilus</i>	<i>Lactobacillus reuteri</i>
	<i>Lactobacillus rhamnosus</i>
	<i>Lactobacillus salivarius</i>



› Abbott Essence 3 Growing-Up Milk Formula Powder (China).

SOURCE: INNOVAMARKET INSIGHTS

to the point that China has prescribed safety testing for novel food ingredients and, while there may be some allowances made for high quality studies done outside of China, you would have to conduct at least some of your safety studies in Chinese state laboratories.

These laboratories are very busy and often have a long waiting time before even starting studies. It is usually at step 2 of the application process that the specific additional studies are identified although the checklists are well documented and if you have no studies, don't even start until you have conducted them.

Once approved, the Novel Food is registered as a novel food ingredient. It is important to note that no claims or implications of curative effects and specific health functions of novel food ingredients are permitted.

Approvals are only for the categories of foods specified. Looking at the approvals to date, most exclude foods for infants and young children. This is an area of well documented extra concern and scrutiny in China.

One type of ingredient that China has applied novel food definition and approvals for more strictly than the European Union is that of probiotics. There are currently 11 permitted species for general food use and only 6 strains for infants and young children (see tables). Overall to date, looking at the number of applications it appears that while around a third of food applications have been for home produced food ingredients, none have gained approval since 2009. Indeed for all types of applications there appears so far to be a less than 50 percent success rate. Following new regulation, MOH will periodically announce the list of novel food which has been transformed to common food.

Tough Legislation

So in summary, the Chinese Novel Food Regulation has a

great deal of similarities with that of Europe in that both a scientific and regulatory process apply.

In China, of course, there is only one committee to apply to and there is not the potential intervention of another 26 countries and EFSA (which could be hundreds of scientists and in total), so at least the process is direct and straight forward.

They are both tough pieces of legislation with set scientific guidance (which is similar), but there also appears to be at least an element of pre-review permitted with a potential degree of flexibility and dialogue.

And on the face of it they take around the same time to complete. However, while parallel submission may be possible in theory, in practice China likes to see approval and free sale in other jurisdictions for imported foods first. That is pretty common across most Asian countries, as everyone likes to see a clean EFSA opinion. ▼

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► Firmus Follow-on Formula (China) with lactoferrin, probiotics, prebiotics, DHA, lactalbumin, walnut oil and lutein.

► China: Permitted Strains for Foods for Infants and Young Children General Food (2011-10-24)

1. *Lactobacillus acidophilus* *NCFM
2. *Bifidobacterium animalis* Bb-12
3. *Bifidobacterium lactis*
HN019
Bi-07
4. *Lactobacillus rhamnosus*
LGG
HN001

* for young children above 1 year old only