Opportunities for Introducing Food Ingredients and Additives to the Chinese Market

With a population of over 1.3 billion (~20% of the global population) and the prospect of continued opening of the marketplace to international trade, there are great opportunities for growth in China’s food market. The Chinese government is currently highly focused on ensuring the safety and quality of its food supply, resulting in an increased demand for safe ingredients. The government is also in the process of overhauling the national food regulatory framework to create efficiencies in the thousands of often over-lapping standards and regulations that will hopefully reduce government red-tape and improve transparency of the approval process required for entry into the marketplace. This could be an excellent time to evaluate the potential expansion of your company into this new market.

In this light, we will discuss the regulatory requirements related to bringing to market novel food ingredients and food additives in China.

Novel food ingredients, regulated by the Ministry of Health (MOH) under the Novel Food Regulation (2007), include:

- 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; and
- Food materials of which original components and structures are changed due to new manufacturing techniques.

Companies applying for approval of a novel food will be required to submit a product dossier positioning the identity and safety of the ingredient with appropriate assays and testing procedures to the MOH. Additional testing in Chinese government-accredited agencies would be typically required for imported novel food. The time from initial review by an expert panel to final approval is in the range of 12 to 18 months. Novel food ingredients will be approved for specific food categories as per the MOH notices, but their labels cannot contain any stated or implied curative health claims or health functions.

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Regulated under the MOH Order 73 - *The Administration of New Food Additives*, provides for the requirements of any new food additives, including their definition as being technologically necessary and proven to be safe. In order to be added to foods, additives must be:

- found in the national food safety standards GB 2760 (list of allowable food additives), GB 14880 (list of allowable food additives used as food nutritional fortification substances), or the MOH list of additives; and
- within the scope of allowed applications and use levels.

New food additives, as well as expanded uses of existing additives, require approval by the MOH prior to addition to food. This will require a dossier outlining safety, technological efficacy, quality, testing, and country of origin certifications, amongst other elements. The preparation and testing phase of the process will typically take 8 to 12 months, while the approval process may take up to 12 months from dossier submission. The approval phase consists of a panel evaluation by the National Technical Committee on Food Additives, followed by approval by the MOH.

Any food additive listed in the standards (*i.e.*, GB 2760 and GB 14880) can be used without prior approval as long as the dose level does not exceed the allowable levels, the additive meets the established specifications, and is used in permitted applications. However, careful review of the standards is necessary as the lists are continuously evolving (addition of new additives, as well as removal of other additives).

For both novel foods and food additives, expertly positioned dossiers will be critical to an expedient approval process and faster entry into the market. Additionally, having on-the-ground support can assist in navigating the evolving regulatory climate in China. With extensive experience in Chinese regulations, and processes, as well as a new office in Beijing, Intertek Cantox is well-situated to address both of these needs. Don’t hesitate to contact us to explore the options that may open new growth horizons for your company!

Recent Publications


The Chinese market for functional (health) foods and dietary supplements is rapidly growing. There is substantial potential to successfully market functional foods and nutrient supplements in China, given the large aging population, an escalation in health care costs, and an increasing interest in achieving and maintaining health and a high quality of life. The demand and market value for health-promoting foods and dietary supplements are only expected to increase in China.

Functional foods are classified as either functional or nutrient supplements. According to The Provision for Functional Foods Administration (MOH, 1996), a functional food has special health functions, is suitable for consumption by special groups of people, has the function of regulating human body functions and is not used for therapeutic purposes. In 2005, the definition was extended by The Guideline for Registration of Functional Foods (SFDA, 2005) to include statements that functional foods have ability to supply vitamins or minerals and will not cause any harm, whether acute, sub-acute, or chronic. Functional foods can bear claims related to the 27 authorized functions, with a maximum of 2 claims for each product. A number of these functional claims, including blood pressure reduction, improvement of child growth, skin content function, and irradiation hazard protection are likely to be cancelled. Other function claims will be consolidated by combining similar claims. Functional food claims are specific to the finished product, rather than the ingredient. Nutrient supplements include single nutrient supplements and multi-component nutrient supplements, which are intended to supply vitamins or minerals (but not energy) or defend against nutrition deficiency.

The regulatory framework for functional (health) foods in China is regulated by State Council, State and Drug Administration (SFDA). Efficacy and safety of the functional food must be evident from animal and/or clinical studies following pre-defined research protocols (The Green Book, Testing Standard for Testing & Assessment of Health Food 2003), conducted at testing agencies in China that are qualified by the SFDA. Other evidence from generally accepted (textbook) information and recommendations from national or international bodies or results from other clinical studies can also be used to support efficacious claims.

The Application Form for Registration of Domestic Functional Food is required for applicants who produce and sell their functional food in China and The Application Form for Registration of Imported Functional Food is required for applicants whose functional food is produced and sold in a foreign country but who wish to sell the product in China. The recipe formula of the product cannot be changed after it is registered. The application procedure in China involves four phases and can take almost two years to complete: 1) Applicator phase (application and relevant data are filed, and samples are provided); 2) Testing phase [Chinese accredited testing agency evaluates hygiene, stability, safety and function (8 – 12 months)]; 3) Report assessment phase (health food assessment committee performs an additional evaluation on product samples); and 4) Final approval phase [the SFDA approves the final product and issues a Certificate of Product Registration (phase 3 and 4, 6 – 12 months)].

It is noteworthy that the Certificate of Product Registration expires 5 years after the date of issue. In order to maintain functional food status, an Application Form for Domestic (or Imported) Functional Food Re-registration must be completed and submitted.

A solid understanding of functional food regulatory processes will ensure the approval and success of a functional (health) food in China. Working with experts in Chinese regulations will be key to entering this lucrative market. Let Intertek Cantox help you in achieving your market expansion goals for functional foods in China!
General Principle for Nutrition Labeling of Pre-packaged Food (GB 28050-2011) Updates

On July 11th, 2012, the Ministry of Health (MOH) published an official Q&A notice to further interpret General Principle for Nutrition Labeling of Pre-packaged Food GB 28050-2011, which will be effective as of January 1st, 2013.

This Q&A details basic status, application scope, nutrition tables, nutrition claims, and nutrient function claims, as well as the format of nutrition tables for pre-packaged food.

General Standard of Use of Nutritional Fortification Substance, GB 14880-2012 Updates

MOH recently published the new version of General Standard of Use of Nutritional Fortification Substance (GB 14880-2012), which will be officially effective on January 1st, 2013.

The new version of the national standard covers one main text and four appendices, in which the main text regulates the main purposes of nutrition fortification, requirements of nutritional fortification substances, and the principle for fortified food categories.

• Appendix A lists the type, application scope, and dosage of permitted nutritional fortification substances;
• Appendix B lists the source of permitted nutritional fortification compounds;
• Appendix C lists names and sources of permitted nutritional fortification compounds for foods for special dietary purpose; and
• Appendix D lists the food categories.

An Update on Administrative Measures on Novel Foods

MOH started to revise the current Administrative Measures on Novel Foods since September, 2011, but the final revised version is still pending for MOH approval, and is expected to be released in Q4, 2012 and effective in early 2013.

The relevant supporting regulations on novel foods have been under revision as well, including Safety Assessment Procedure for Novel Food and Hygiene Administrative Permission - Application and Acceptance of Novel Food.

Those regulations would be published together with the revised Administrative Measures on Novel Foods.

SFDA Revised and Published 9 Function Assessment Methods of Functional Foods

The State Food and Drug Administration (SFDA) recently revised and published 9 functional assessment methods for functional foods, including Anti-oxidation Function, Alleviating Eye Fatigue Function, Assisting Blood Sugar Reduction Function, Assisting Blood Lipids Reduction Function, Improving Nutritional Anemia Function, Alleviating Lead Excretion Function, Assisting the Protection of Gastric Mucosa Function, Reducing Weight Function, and Clear the Throat Function. To validate functional food applications, health food registration testing institutions will conduct function assessment tests according to the revised methods, which became effective on May 1st, 2012.

Upcoming Events

Vitafoods Asia
September 5 - 7, 2012
Asia World Expo, Hong Kong
(http://www.vitafoodasia.com/)

The 12th China International Food Exhibition
September 12 - 14, 2012
Guangzhou Jinhan Exhibition Centre, Guangzhou, China (http://www.gzspz.com/en/)

The 8th China Food Expo
October 26 - 29, 2012
New International Convention & Exposition Center, Chengdu, Sichuan, China (http://en.cfe.org.cn/)

FoodEx China 2012
November 22 - 24, 2012
Zhejiang World Trade International Exhibitor Center, Hangzhou, Zhejiang, China (http://www.foodexchina.com/en/)

Innovations in Beverages
September 11 - 13, 2012
Don’t miss Mr. Nigel Baldwin’s, Intertek Cantox, presentation on September 12, 2012 at 9:00 a.m.

SupplySide West
November 7 - 8, 2012
The Venetian Sands and Expo, Las Vegas, Nevada, USA (http://west.supplysideshow.com/)
Visit us at booth: 16084

Health Ingredients Europe
November 13 -15, 2012
Messe Frankfurt, Frankfurt, Germany (http://hieurope.ingredientsnetwork.com/)
Visit us at booth: D89
Complimentary Webinar on China’s Functional Food or Dietary Supplement Market on September 5, 2012

Learn ‘why’ and ‘how’ China is driving the global growth in the functional food and dietary supplement market, join us on September 5, 2012 for a free 30-minute webinar.

Topics to be addressed:
• The importance of functional foods and dietary supplements in Chinese society.
• Functional food and dietary supplement market size and trends in China.
• ‘Why’ and ‘how’ China is becoming one of the world’s largest consumer markets for functional foods and dietary supplements.

For more information, visit: http://www.intertek.com/events/2012/09-05-china-food-dietary-supplement-market-webinar/

Intertek Cantox Workshop: Beyond the Great Wall-How to Access the Food and supplement markets in China

Intertek Cantox is your passport to the vast and growing Chinese market. Hear directly from Chinese regulatory experts at our exciting one-day workshop. The workshop will be held in Arlington, Virginia, USA on September 21, 2012 and will be repeated in Geneva, Switzerland on October 16, 2012.

This informative workshop will outline the scientific and technical data requirements in China, consider timelines and costs of regulatory processes, and set forth the best approach to ensure timely and successful product approvals.

Who should participate?
This workshop is intended for scientific, regulatory, or marketing personnel who are considering expanding their marketing and sales initiatives into the lucrative Chinese market.

Why should you participate?
• To learn about the latest updates on regulatory processes in China
• To understand the requirements for introducing new food ingredients and additives in China
• To determine what is needed to have a claim for a functional food or dietary supplement approved in China
• To learn how to gain entry into the vast and growing Chinese market

Highlights include:
• A unique opportunity to hear directly from Chinese government experts
• An exceptional venue to network with industry and regulatory professionals

For registration details visit: http://www.intertek.com/food/consulting/2012-china-workshops/

For more information feel free to contact:
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In Profile with…
Ms. Lin (Sandy) Song

Ms. Lin (Sandy) Song is a member of the Food and Nutrition Group of Intertek Cantox, and plays a vital role in the expansion of Intertek Cantox’s food regulatory services in Asia, as the Director of our new office in Beijing, China.

Sandy Lin is a food and feed regulatory expert with qualifications that span 20 years of industry and regulatory experience working for large international food companies in China. She has developed and maintained networking relationships with the Chinese government authorities responsible for food safety, and with important food safety institutes and prominent trade associations, such as the Ministry of Public Health, State Food and Drug Administration Bureau, General Administration of Quality Supervision, Inspection and Quarantine, Ministry of Industry & Information Technology. Sandy Lin has also established excellent relationships with the Institute of Nutrition and Food Safety, the China National Food Safety Standard Committee, the International Life Science Institute (ILSI), China National Food Industry Association, China Association of Fragrance, the Flavour and Cosmetic Industry, and the China Dairy Industry Association.

International food companies and their ingredient suppliers recognize the importance of accessing the Asian marketplace as part of a global product approval strategy. With the launch of the Beijing office, Intertek Cantox now offers its clientele ready access to on-the-ground support in China, as well as regulatory expertise for neighbouring Asian markets.

Under Sandy Lin’s direction, the new Beijing office illustrates Intertek Cantox’s commitment to helping clients achieve their market expansion goals by delivering unparalleled experience as world leaders in the field of food regulatory compliance and new product approval.

For more information on any of our services contact us at: food.cantox@intertek.com