In these troubled times of recession in Europe and North America, there is a potential beacon of business growth and profitability that the food and food ingredient industry are beginning to explore for now and the future. China is the land of opportunity; we all know that, given the size of the market and the increasing demand for Western style products and with the health food sector shackled with endless regulatory burdens, especially in the EU, the industry is looking for alternative markets. But what does that mean, as China is not without a few of its own? So before heading off in the Asian direction, it is important that you first understand the rules.

Limited in Claims

One of the most important difference to the EU regulatory process and the first thing to understand if you are interested in approaching the Chinese market with a health food ingredient and make claims is that it is the finished product level at which they are regulated. There is a list of very limited structure/function claims that can be made on some vitamins and minerals, however new health claim approvals are not permitted for the ingredient itself but are granted for use by your customers incorporating your ingredients in to finished supplements and foods. It is the finished product marketer that must apply for a functional food approval and there is a clearly defined regulatory procedure along with specific data requirements that are required for submission purposes.

So although, you may have a lot of your own study data and even an approved health claim in the EU for your own specific ingredient, these studies alone will not be sufficient and likely will only provide corroborative evidence for an application in China. Furthermore, some studies required for Chinese health claim purposes conducted on the specific food products are required to be undertaken in China.

In China, “The Provisions for Functional Food Administration” are issued by the Ministry of Health and the term “functional food” means that a food has special health functions or is able to supply vitamins and minerals. Furthermore, these products are targeted towards special groups of people, aiming to regulate human body functions but cannot be used for therapeutic purposes. As such these products are also required to demonstrate both safety and efficacy according to defined criteria. In effect, the regulation is a licensing process, with similar requirement to that of a medicine in the EU that both risk and benefit are assessed together and a registration is granted for the product.

Authorized Functions for Functional Food Claims in China

(Highlighted in green likely to be cancelled; Highlighted in bold likely to be combined)

1. Enhancing Immune Function
2. Assisting Blood Lipids Reduction Function
3. Assisting Blood Sugar Reduction Function
4. Anti-oxidation Function
5. Assisting Memory Improvement Function
6. Alleviating Eye Fatigue Function
7. Alleviating Lead Excretion Function
8. Clear the Throat Function
9. Assisting Blood Pressure Reduction Function
10. Sleep Improvement Function
11. Facilitating Milk Secretion Function
12. Alleviating Physical Fatigue Function
13. Enhancing Anoxia Endurance Function
14. Assisting Irradiation Hazard Protection Function
15. Reducing Weight Function
16. Improving Child Growth Function
17. Increasing Bone Density Function
18. Improving Nutritional Anaemia Function
19. Assisting the Protection Against Chemical Injury of Liver Function
20. Eliminating Acne Function
21. Eliminating Skin Chloasma (melasma) Function
22. Improving Skin Water Content Function
23. Improving Skin Oil Content Function
24. Regulating Gastrointestinal Tract Flora Function
25. Facilitating Digestion Function
26. Facilitating Faeces Excretion Function
27. Assisting the Protection of Gastric Mucosa Function
Health & Wellness

Now we get even more defined when it comes to both the safety and the efficacy requirements. The claims you can make must come from the list detailed in the box.

**Mandatory Studies**

So once you have selected your claim, then you must go to a state laboratory (the tests can only be done at a state laboratory) to conduct the mandatory studies on the finished products. The tests are laid out in the so-called “Green Book” of “Technical Standards for Testing and Assessment of Health Food.”

The protocols described in the Green Book are very detailed, including the number of subjects, duration of intervention, inclusion/exclusion criteria, endpoints to be measured, and so on. The rationale behind these protocols, however, is unclear. Of note, there appears to be an emphasis on animal testing to support claims, as the majority of claims in China require efficacy testing in animals alone or in combination with human studies. Once these studies are complete, assuming they are successful, you are ready to begin the submission process by submitting the data and samples to the National Health and Family Planning Commission (NHFPC, formerly the Ministry of Health). The NHFPC will review and decide if additional data is needed. Following provision of that data and registration documents and further review NHFPC will issue an approval of the product and it is registered via with the Chinese Food and

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**Figure 1: Informal Evaluation to Determine the Likelihood of Achieving Chinese Regulatory Approval**
Drug Administration (CFDA). To try to streamline the process, Intertek is recommending first conducting an informal evaluation by experts within the field in China to determine the likelihood of achieving approval or if additional studies are required to be completed (see figure 1). The whole process can take up to 2 years from start to finish in theory but you must also take into account that the state laboratories are always very busy! So taking a step back and comparing to the EU we can summarize as follows.

1. The EU has, in effect, an ingredient specific procedure for health claims, whereas claims in China are product specific.
2. You can transfer a product to another party but you cannot licence and rebrand the same product to another company without repeating the studies. One product, one set of studies.
3. Revenue is limited therefore to the product itself but the cost of conducting studies is less in China because they are all done in state labs.
4. The EU has lots of guidance, however China has clearly laid down criteria for successful claims.
5. Health claims in the EU must be substantiated by human studies, whereas in China, the majority of claims may be supported by animal data.
6. The EU has independent scientific experts in the form of EFSA, while in China the National Health and Family Planning Commission experts are “in-house.”

If you want to get approval for ingredients that are not approved elsewhere, beware because evidence of previous use and international regulatory approval is to be provided in the application documents. China also has its own Novel Food legislation which we will explain in more detail in our next article.

Nigel Baldwin and Sandy Lin are Directors of Intertek’s food safety consulting business in Europe and China, respectively. nigel.baldwin@intertek.com; sandy.lin@intertek.com; www.intertek.com/food

At the PLMA Trade Show held in Amsterdam (May 28-29), nutrineo, the private label specialist, will present customer-tailored ready-to-drink products. It offers services for a rapidly growing market segment that attracts not only athletes but also lifestyle consumers.

“We provide expertise and ideas for sports nutrition and weight management products. And we support our customers by offering them strong technological know-how, scientific findings, current market information and professional project management. Trends have become an important driving force for innovation,” explains Simone Tückmantel, Sales Manager at nutrineo. Since the beginning of 2013, the company has been expanding its range of powdered products to include ready-to-drink items such as protein shakes in trendy flavors. nutrineo is the health food unit of Uelzena eG, newly established in 2012. nutrineo’s team claims to ensure the creation of products with optimum protein content and fabulous flavors in a multitude of packaging formats.