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Food Health Claims: Challenges for ASEAN Manufacturers

Within the food industry, all eyes are currently turned toward the European Union, because after December 14, 2012, new limitations will be introduced for acceptable health claims on food products.

Regulation No. 1924/2006 of the European Parliament and of the Council of December 20, 2006, on Nutrition and Health Claims Made on Foods (the Regulation) has changed the scope of the interpretation of health claims in the European Union. Initially, each country was entitled to have its own set of acceptable claims, but growing inconsistencies between countries made it difficult for manufacturers to sell their products.

European Regulation

In an attempt to harmonize the rules, the Regulation was adopted. It defined health claims as “any claim that states, suggests, or implies that a relationship exists between a food category, a food or one of its constituents and health” (Article 2 Definition 5). Such claims should not:

- ❑ “Be false, ambiguous, or misleading.
- ❑ Give rise to doubt about the safety and/or the nutritional adequacy of other foods.
- ❑ Encourage or condone excess consumption of food.
- ❑ State, suggest, or imply that a balanced and varied diet cannot provide the appropriate quantities of nutrients in general. . . .
- ❑ Refer to changes in bodily functions which could give rise to or exploit fear in the consumer . . .”

As these restrictions are common in most countries in the world, they are not the reason why companies have raised concerns about this Regulation. The key issue is that the Regulation has provided specific conditions with regard to health claims applicable to products launched in Europe. For example, health claims will only be permitted if certain information is included in the labeling, presentation, or advertising, such as “a statement indicating the importance of a varied and balanced diet and healthy lifestyle” or “the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect.”

The Regulation has set up a process by which companies are able to submit their proposed health claims for approval by the Commission. However, companies must submit generally accepted scientific evidence and ensure that the claim can be well understood by the average consumer. Of the 44,000 claims submitted, only 222 had been approved as of May 2012 according to Commission Regulation No. 432/2012, which established a list of permitted health claims made on foods, except for those claims referring to the reduction of disease or disease risk and to children’s development and health.

Surprisingly, some claims that were widely used in the past and approved by several national health agencies have been rejected, such as claims regarding prebiotics and probiotics products. The arguments raised by the Commission were that the scientific evidence provided by the submitting companies was not sufficient for this type of product. The main industries affected are currently raising their concerns with the Commission.

ASEAN Perspective

For companies set up within ASEAN, implementation of the Regulation will have a significant impact. Although most countries follow Codex Alimentarius and its Guidelines for use of Nutrition and Health Claims, discrepancies still exist between member countries as ASEAN has not yet implemented harmonized legislation on this particular topic. For example, a Malaysian company planning to sell its products in Thailand, Singapore, and the EU would face three different sets of requirements as some countries have even implemented a positive list of nutrition function claims. In another example, Thailand would not accept other function claims, contrary to Malaysia and Singapore, while the Singaporean authorities would authorize a disease risk reduction claim which would not be admissible in Malaysia or in Thailand.

Focusing on the examples of Thailand, Malaysia, and Singapore helps to highlight the differences among the interpretations of health claims in ASEAN, and thus the difficulties encountered by ASEAN companies to sell their products both within the region and overseas.

Thailand Experience

In Thailand, health claims are not described as clearly in legal terms compared to the EU, and interpretation is generally on a case-by-case basis. Section 40 of the Food Act refers indirectly to health claims and states that “no one shall advertise the benefits, qualities, or efficacies of foods which are false or which are misleading, without getting prior approval from the Thai Food and Drug Administration (FDA).” The Notices of the FDA regarding “Bases on Food Advertisement” provide the requirements for food advertisements and for some specific food categories. However, only nutrition claims have specific acceptable guidelines in place set up by the Thai FDA (Notification of the Ministry of Public Health (MoPH) No. 182 of 1998 re: Nutrition Labeling).

An order of the Thai FDA No. 403/2551 (2008), “Consideration for Granting Permission to Make Health Claims for Probiotics in Food Products,” states that health claims are authorized for such products if they are backed with scientific evidence sufficient for the permission to use these types of claims. For other products, such as weight control products and other products falling into the Specially Controlled Food category, the process is similar, but might be more cumbersome.

Additionally, the first regulation specially targeting health claims has recently been implemented, and health claims for probiotics were clarified in the Notification of the MoPH regarding “Use of Probiotics in Food” dated June 27, 2011. A health claim means “a displaying of a picture, photograph, invented mark, mark, trademark, or any statement on the label which is related to the food, food components, or nutrients concerned with health, either directly or indirectly.”

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Thus, it is interesting to observe that Thailand currently has, in practice, a recognized, strict approach toward health claims on food products. But contrary to the EU, Thailand still accepts most health claims for probiotic products if they are supported by scientific journals. Although a draft of the Notification on the Advertisement of Food will soon be published in the *Government Gazette*, there does not yet seem to be a move toward narrowing the types of claims acceptable for food products. A notification regarding “Health Claims and Warnings” and an announcement regarding “Scientific Substantiation of Health Claims” are also in the early stages of the drafting process.

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Malaysia Experience

The Malaysian Food Act of 1983, supported by the Food Regulation of 1985, amended in 2005 to encompass health and nutrition claims, is the main source of legislation in Malaysia covering health claims. Within ASEAN, Malaysia is the only country that makes nutrition labeling a requirement. A Guide to Nutrition Labeling and Claims has also been issued to assist companies in their advertisement process in Malaysia. Malaysia follows the Codex Alimentarius Guidelines for Use of Nutrition and Health Claims more closely than many other countries.

As in most ASEAN countries, nutrient claims and, more specifically, content claims, comparative claims, and nutrient function claims, are acceptable. There are no specific regulations on prebiotics and probiotics in Malaysia. Ingredients are permitted for use in health supplements and conventional food, but approval is required beforehand. Thus, prebiotics and probiotics claims are acceptable if such claims fall into the authorized claims by the Ministry of Health (e.g., “Bifidobacteria lactis helps foster a beneficial intestinal environment and may help to reduce the incidence of diarrhea”). The requirements for submitting a claim involve submitting sufficient scientific evidence (which includes five clinical trial approvals from other recognized countries), as well as ensuring that the claim is comprehensible for consumers.

Singapore Experience

The Singapore Food Regulations, supported by the Guide to Food Labeling and Advertisements, implement the scope of acceptability of health claims in Singapore. Under article 9 of the Food Regulations, false or misleading statements, words, brands, pictures, or marks purporting to indicate the nature, stability, quantity, strength, purity, composition, weight, origin, age, effects, or proportion of the food or any ingredients are not allowed to be used on food labels and advertisements, unless otherwise specified. Singapore also prohibits the use of:

- ❑ Claims for therapeutic or prophylactic action.
- ❑ Claims which could be interpreted as advice of a medical nature from any person.
- ❑ Claims that a food will prevent, alleviate, or cure any disease or condition affecting the human body.

- ❑ Claims that health or an improved physical condition may be achieved by consuming any food.

One particularity of Singapore is that risk-related claims are acceptable; similarly, in the EU, a list of acceptable nutrient function claims has been implemented. In order to obtain approval, a company would have to establish, among other requirements, that essential nutrients with established recommended intakes are of nutritional importance, and that the claim is sufficiently generally accepted by the scientific community and is understandable to consumers.

The Guide to Food Labeling and Advertisements also includes the acceptability of the claim, “prebiotics promote the growth of good Bifidus bacteria to help maintain a healthy digestive system.” Thus, like in Thailand, claims on probiotics and prebiotics are acceptable. Companies can also state that a product “helps to suppress/fight against harmful bacteria in the digestive system, thereby helping to maintain a healthy digestive system.”

Future Expectations

Clearly, ASEAN companies are faced with a challenge if each country in which they are planning to sell their products requires different analysis and/or proof of their claims.

The Codex Alimentarius (prepared jointly by the United Nations and the World Health Organization) and the World Trade Organization, among others, are working toward harmonizing the rules. ASEAN countries have prepared a set of guiding principles for food control systems, which include the Common Guidelines for the Labeling of Prepackaged Foodstuffs.

Another step toward harmonization was taken recently. In early September 2012, the ASEAN countries announced that they have agreed in principle to impose uniform standards in regard to health claims. The objective is to implement these regulations by 2015, but a draft is not yet available.

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agencies and try to participate in the drafting of the new standards. One of the significant points of discussion will be to ensure the complete harmonization of claims for prebiotics and probiotics products. It is important for the industry to learn the lessons of the EU Regulation and to work closely with regulators to ensure that the harmonized rules have a reasonable degree of continuity with the currently accepted interpretations. ⚖️