



Supplementary News

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New Developments for European Functional Foods: How Will They Affect You?

In Europe, vitamins, minerals, and other substances that have a history of use in foods have been permitted under *Regulation (EC) 1925/2006* with relative ease. However, Germany recently requested that the procedures outlined under Article 8 of *Regulation (EC) 1925/2006 (the Regulation)* be initiated by the Standing Committee of the Food Chain and Animal Health (SCoFCAH) to control the addition of omega-3 fatty acids and several botanicals and their preparations to foods.

Under Article 8, the Commission or Member States may request that an "other substance", defined as a substance other than a vitamin or mineral that has a nutritional or physiological effect, be listed in Annex III of *the Regulation* should the addition of a substance to foods greatly exceed its consumption in comparison to a balanced and varied diet and/or represents a potential risk to consumers. Following an evaluation by the European Food Safety Authority (EFSA), the substance may be placed in Annex III, Part A or Part B if the substance's use is to be prohibited or permitted with specified conditions, respectively. Alternatively, should additional scientific uncertainty persist regarding the safety of the ingredient, the substance may be listed in Annex III, Part C. The Commission has up to 4 years to render a decision on the use of an ingredient within Part C, based on opinions from EFSA and on safety and exposure data submitted by interested parties.

Without any rules in place to implement Article 8, however, the Commission cannot yet accept Germany's request to add omega-3 fatty acids or the botanicals to Annex III. Therefore, a draft regulation clearly defining a substance's eligibility for listing in Annex III and the responsibilities of the Commission, Member States, EFSA, and any interested parties is to be presented to SCoFCAH in July 2011. Several key provisions in Article 8 need to be clearly defined to determine whether an "other substance" can be listed in Annex III. Under *the Regulation*, and re-iterated in the draft

regulation, substances are eligible for listing in Annex III if they are "added to" or "used in the manufacture of" foods. Substances without a history of use in food, such as some of the botanical substances proposed by Germany, may not fall within the scope of Article 8. Other key aspects include defining *greatly exceeds* and *balanced and varied diet*.

In the most recent draft of the proposed regulation, the estimated consumption of the substance will be evaluated on a case-by-case basis to determine if its consumption is greatly exceeded. Additionally, a balanced and varied diet is defined as excluding the "intake of food supplements and foods to which vitamins and minerals and other substances have been added." In Germany's request to list omega-3 fatty acids in Annex III, the Federal Institute for Risk Assessment concluded that the daily consumption of omega-3 fatty acids from fortified foods may be double or triple the amount reasonably expected from a balanced and varied diet, determined by including the intake of omega-3 fatty acids from fortified foods. However, other Member States are striving to increase intakes of omega-3 fatty acids in their populations and in some cases, doubling the intake may be required to meet nutritional targets.

With the Commission moving quickly to finalise a regulation on implementing Article 8, it appears that an interesting and complex debate on whether omega-3 fatty acids and certain botanicals do in fact meet the eligibility criteria may be required. If so, EFSA will be asked to evaluate. As a result of Germany's request to initiate procedures for controlling "other substances" added to foods, substances that have traditionally been added to foods without any checks may now be restricted, controlled, or require industry to submit scientific data to support the substance's safe use in foods. This new regulatory development may have far reaching effects in the food industry.



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Upcoming Events

UNPA - NDI Guidance and Food Safety Seminar

July 26 - 27, 2011
Salt Lake City UT
http://unpa.com/z_uploads/pdf/c3a8d7490630b3a7d318abb791fc9dc5.pdf

Natural Products Expo East

Sept. 21 – 24, 2011
Baltimore, Maryland
<http://www.expoeast.com/expoeast2011/public/enter.aspx>

NUCE

Oct. 5 – 7, 2011
Milan, Italy
http://www.nuce.pro/en_lfm/index_nce.asp

Health Ingredients Japan

Oct. 5 - 7, 2011
Tokyo, Japan
Visit us at booth: 1-210.
<http://www.hijapan.info/eng/info/hi.html>

SupplySide West

Oct. 10 - 14, 2011
Las Vegas, Nevada
Visit us at booth: 16096
<http://www.supplysideshow.com/2011/west/>

CHFA Expo East

Oct. 13 - 14, 2011
Toronto, Ontario
<http://www.chfa.ca/en-us/events/expoeast.aspx>

Food Ingredients Europe

Nov. 29 - Dec. 1, 2011
Paris, France
Visit us at booth: 4A37
<http://fieurope.ingredientsnetwork.com/about-us>

Do you have some exciting research data on one of your products or an upcoming event?

Find out how you can highlight it in our newsletter by sending an email to:
food@cantox.com

FDA's Draft NDI Guidance: Taking Industry in a New Direction?

With the much anticipated release of draft guidance on what classifies as a new dietary ingredient (NDI) and when a notification should be filed with the United States Food and Drug Administration (FDA), industry groups have been quick to react stating their concerns on how the additional guidance will affect the dietary supplement industry. But is this guidance a negative impact or will it create a level playing field for everyone while ensuring that consumer safety is protected?

In Section IV of the guidance, the FDA takes readers through a series of questions and answers aimed at presenting several situations in which an ingredient may be classified as an NDI and whether an NDI notification is required. Keeping consistent with their previous opinions on whether ingredients and components of conventional foods would be defined as an NDI (e.g., dietary ingredients marketed after October 15, 1994 and with no history of use in the U.S. prior to October 15, 1994, regardless if they have been marketed outside of the U.S.), the FDA offers further nuggets of information on how an ingredient will be classified as an NDI.

In the draft guidance, FDA mentions several manufacturing processes that have been determined by the FDA to chemically alter a dietary ingredient and thereby create an NDI. These processes include breaking or creating chemical bonds such as hydrolysis or esterification, removing some components of a hydroalcoholic or water extract, using a different solvent for extraction, using high temperature baking or cooking for ingredients that do not normally undergo this process, applying nanotechnology, changing agricultural or fermentation conditions, and using a botanical ingredient at a different life stage than previously used. Furthermore, the FDA has limited the definition of an NDI, excluding synthetic duplicates of herbal or other botanical constituents and extracts. With these further definitions on what makes a dietary ingredient "new," several ingredients that have previously been thought to be "old" dietary ingredients may now be defined as "new" or not permitted for use at all.

The FDA also has provided further clarifications on when an NDI notification is required. Although the FDA has not changed their opinion drastically on when a NDI notification is required, they have confirmed that self-determined Generally Recognized as Safe (GRAS) opinions are acceptable alternatives to filing NDI notifications. This means that if the NDI is used under the same conditions as those specified in the self-GRAS determination, the FDA is likely to conclude that there are sufficient data to support the safety of the NDI. Additionally, although ingredients only marketed outside the U.S. would be defined as NDIs, a notification to the FDA may not be required to assure the safety of the ingredient. The FDA, however, has recommended that manufacturers that fall within both scenarios confer with the agency to confirm whether the available evidence is sufficient to support the ingredient's safety. Moreover, the FDA has clearly emphasized the requirement for each manufacturer of a dietary supplement to submit his own notification demonstrating the safety of his NDI and product, as the safety for a particular ingredient or product may rely on the confidential manufacturing details that are not required to be made public once the notification is listed on the FDA's website. No more can one manufacturer use another's notification to demonstrate the safety of his ingredient or product.

It is clear from FDA's opinions expressed in the new draft guidance document and the response from industry groups that pre-market notification activities around dietary supplements in the U.S. are going to change. As the NDI guidance is in draft format, interested parties are invited to submit their comments to the FDA by October 3, 2011 for consideration in the final guidance document. Although the FDA's guidance document removes many of the gray areas surrounding dietary ingredients and dietary supplement, how the increased clarification and guidance will impact the industry is yet to be seen.

Did You Know...

On December 8, 2010, the United States Food and Drug Administration (FDA) released a Proposed Rule related to the use, in or on the labeling and advertising of foods and dietary supplements, of the authorized health claim related to phytosterols and risk of coronary heart disease. The Proposed Rule amends the use of the authorized health claim pertaining to phytosterols and reduced risk of coronary heart disease in several ways, including:

- Requiring that only phytosterols esterified with food-grade fatty acids be used in dietary supplements;
- Increasing the efficacious intake of phytosterols to 2.0 g/day;
- Eliminating the requirement that the daily dietary intake of phytosterols be consumed in 2 separate servings (*i.e.*, the delivery of the entire dose in a single serving has been found to be efficacious);
- Increasing the minimum amount of phytosterols per reference amount customarily consumed (RACC) to 0.5 g/day; and
- Expanding the types of food that may bear the claim to include a broader range of foods, so long as:
 1. Use of the phytosterols in the food has been submitted to the FDA in a Generally Recognized as Safe (GRAS) notification;
 2. The conditions of use are consistent with the eligibility requirements for the health claim; and
 3. The Agency has no further questions to the notification submitted.

The Proposed Rule of December 8, 2010 was supposed to have come into effect on February 21, 2011; however, on February 18, 2011, the FDA released another Proposed Rule, indicating that it would extend the deadline for compliance until February 21, 2012.

This means that by February 21, 2012, use of the authorized health claim related to consumption of phytosterols and reduced risk of coronary heart disease must be in compliance with the conditions laid out in 21 CFR § 101.83 or the Proposed Rule.

If you would like more information on the Proposed Rule, please contact Cantox Health Sciences International, An Intertek Company.

We're here to help!

Proposed Changes to Dietary Supplement Labeling in the U.S.

In an attempt to prevent further confusion between foods and dietary supplements, U.S. Senator Rick Durbin, D-Illinois, is proposing to introduce the Dietary Supplement Labeling Act, which calls for an improvement in the quality of label information for dietary supplements, a register for dietary supplement products with the U.S. Food and Drug Administration (FDA), and a definition for the term "conventional food" to better differentiate conventional foods from dietary supplements in the context of the Federal Food, Drug, and Cosmetic Act.

The bill, released June 30th, proposes that manufacturers of dietary supplements submit a registration that includes a description of each dietary supplement product, a list of all ingredients, and a copy of the label 30 days after a new or reformulated dietary supplement is introduced on the market and after a supplement product is discontinued. Additionally, the bill proposes that the safety of dietary supplement ingredients and proprietary blends of ingredients, including a list of ingredients that could cause potentially serious adverse events, drug interactions, contraindications, or potential risks to vulnerable populations, be reviewed by the Institute of Medicine (IOM). Within 2 years of the IOM's completed safety report, the bill further states that a list of mandatory warning label requirements should be drafted, and in the case of proprietary blends of ingredients, the weight per serving would be provided on the label.

Although many of the proposed actions in the Dietary Supplement Labeling Act are similar to current required actions under the Dietary Supplement Health and Education Act (DSHEA), industry groups such as the American Herbal Products Association (AHPA), the Natural Products Association (NPA), the Council for Responsible Nutrition (CRN) and the Alliance for Natural Health have criticized the bill as being misguided, disingenuous, bureaucratic, expensive, and redundant. Meanwhile, manufacturers including the makers of Inko's White Tea Energy, MODJO Natural Beverage Supplement, and Golazo energy drink have released positive comments on the bill, stating the extra paperwork may lead to more honest companies, fair competition, and no worries for companies that are already FDA compliant.

The bill is currently being reviewed by the Committee on Health, Education, Labor, and Pensions.



Headlines from Around the World

As of May 1, the **European Directive 2004/24/EC** regarding therapeutic herbal medicine products (TMHP) came into full enforcement, ending the 7-year transition period. Although several member states have commented that the majority of the affected products are in compliance, in the UK only 211 applications for registration have been submitted to the Medicines and Healthcare Products Regulatory Agency and less than 50% have been granted registration. As a result of the low registration rates, the Alliance for Natural Health Europe is in the process of launching a legal challenge on the THMP Directive to help protect THMPs.

Health Canada released a Notice of Intent (NOI) in the Canada Gazette, Part I to amend Schedule F of the Food and Drugs Regulations adding quinine, its salts and derivatives except in oral dosage form that provides 50 mg or less of quinine base per dosage unit or per daily dose. This means that oral products containing less than 50 mg quinine per day would be regulated as a natural health product.

The **Codex Committee on Fats and Oils** has adopted a proposal to develop a standard for fish oils. The Codex Alimentarius Commission is expected to endorse the proposal in July, and the standard will cover oils from fish, shellfish, and cephalopods but will exclude algae and marine mammal sources.

China has drafted an amendment on the regulation of food nutrition enhancers. Highlights of the draft include a more unified classification system of foods to which enhancers can be added, a list of approved chemical ingredients, and more current standards for nutrition enhancers in infant foods.

Due to the increased numbers of energy drinks available in the Australian and New Zealand markets, the **Australia and New Zealand Food Regulation Ministerial Council** have requested that the Policy Guideline on the Addition of Caffeine to Foods undergo a comprehensive re-evaluation. During the review, the Ministerial Council will consider the global developments in caffeinated products and regulatory approaches being taken in comparable markets.

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We're Here to Help!

In today's competitive supplement and functional food marketplace, developing a product that will meet the needs and wants of consumers is key to success. The use of health claims helps manufacturers to highlight the benefits of their products to consumers. However, as the demand for supplement products and functional foods increase, regulators are tightening up their requirements for product safety, efficacy, and quality. Developing a product formulation that provides a competitive advantage while having the appropriate scientific data to substantiate product safety and health claims will ensure timely approval in various jurisdictions. Cantox Health Sciences International, an Intertek Company (Cantox) can help!

In the area of product formulation assistance, Cantox:

- Performs literature searches identifying data relevant to the product;
- Conducting feasibility assessments and providing recommendations to meet regulatory requirements for safety, efficacy, and quality;
- Identifies doses and conditions of use that are considered safe and effective;
- Conducts exposure assessments to determine the anticipated consumption of the medicinal/active ingredients, as necessary;
- Provides guidance to ensure that the product formulation will meet regulatory requirements in International jurisdictions;
- Provides guidance to meet quality standards; and,
- Designs, places, and monitors pre-clinical and clinical studies to ensure completeness of the safety and/or efficacy database, as necessary.

For more information please contact us at food@cantox.com.



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