



Food UPDATE

Novel Foods - Food Additives - Functional Foods - Food Ingredients

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Proposition 65: The Reality

What is Proposition 65?

The Office of Environmental Health Hazard Assessment (OEHHA) within the California Environmental Protection Agency (CalEPA) publishes a continuously updated list of chemicals that are "known to the state to cause cancer or reproductive toxicity", for the purposes of the Safe Drinking Water and Toxic Enforcement Act of 1986, also known as Proposition 65. This proposition was voted into the state law by the people of California in 1986 to inform citizens about the products they use and the chemicals they are exposed to. Employers knowingly exposing employees or citizens to chemicals or manufacturers that produce consumer products that contain chemicals found in the Proposition 65 list of chemicals, must provide a label warning employees/consumers that the product or site contains such a chemical. This law also prohibits the discharge of listed chemicals into sources of drinking water. Failure to provide warnings can result in civil penalties of up to \$2,500 per day for each violation. However, overall costs to defendants are usually much higher when attorneys' fees and costs and settlement fees are factored in.

Many of the chemicals have exposure limits (No Significant Risk Levels [NSRLs] for cancer-causing chemicals and Maximum Allowable Dose Levels [MADLs] for reproductive toxins) derived by CalEPA, based on available test data or conclusions provided by authoritative bodies (e.g. International Agency for Cancer Research [IARC], National Toxicology Program [NTP]). These will typically relate to a daily dose and in some cases factor in different routes of exposure where available (oral, dermal, inhalation). In situations where it can be shown, through the use of exposure modeling, that the use of the consumer product would not result in exposures to the chemical at doses above the NSRL or MADL (or generally not result in increased risk), no warning labels are required.

How is it Enforced?

Proposition 65 is enforced through litigation via the California Attorney General's Office. Any district attorney, consumer advocacy group, private citizen or law firm can file a lawsuit against a company failing to provide adequate warnings. However, prior to the filing of the lawsuit, the plaintiff must submit to the defendant a "60-Day Notice" indicating that they are in violation of Prop 65 and that they have 60 days to take corrective action. If the case goes to trial and the defendant is found guilty and required to pay a fine, the attorney filing the suit will be awarded 25% of the penalties paid (25% is used by the department for further funding of enforcement and 50% goes to the Hazardous Substance Account in the General Fund). When originally established, Proposition 65 proved expensive to the state in terms of hiring health officers and then enforcing this regulation. As a result, this was handed over to the civil courts to handle. Although it appeared to be a cost-effective method of enforcing a regulation that most citizens were in favor of, in the end it may not be very reasonable or fair to manufacturers/employers.

Of note, this system has led to a number of lawsuits by so called "bounty-hunter lawyers" that seek out evidence of violations and then press the defendants to settle out of court, which is likely to be more lucrative than 25% of the fines (plus time in court, etc). With easy to use and more affordable detection techniques, detecting the mere presence of some chemicals can be quite easy, while the burden to prove that levels are only present in trace levels or not a safety concern is on the manufacturer (defendant), which can be prohibitive.

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Overall, OEHHA indicates, in recent changes to their website, that Proposition 65 is more of a “right to know” law, than an actual product safety law. In other words, just because a product contains a warning, does not mean that the product is necessarily unsafe in all instances.

How does this apply to the food industry?

These regulations not only apply to consumer products and work environments – it will also relate to foods as well, as any food product containing a listed chemical must also bear a warning label if present in excess of the Safe Harbor Level established exposure limits. Commonly seen warnings include those on alcoholic beverages (related to harm to the fetus). A few examples of big cases include cheese and the presence of diethylhexyl phthalate allegedly migrating from packaging materials, canned tuna and methyl mercury, and lead in candies from Mexico. Interestingly, most of these were settled out of court. Lead, in particular, has been the chemical at the center of many 60-day notices often for products such as dietary supplements, herbal products, in addition to traditional foods (e.g. as of January 1, 2011, out of 89 notices filed for alleged lead violations, 41 notices have been filed against dietary supplement companies).

Just a few of the listed chemicals that may be found in foods or beverages include:

- 3-MCPD (3-monochloropropane-1,2-diol or 3-chloro-1,2-propanediol) is a contamination by-product found in elevated levels in soy sauces, although laboratory analyses have also detected it in breads, savory crackers, toasted biscuits, cheeses, doughnuts, burgers and salamis. It is typically found in foods containing acid-hydrolysed vegetable protein, which is added to foods to improve the “savory” flavor.
- Ethanol in alcoholic beverages –known to cause reproductive harm to the unborn fetus and cancer in cases of alcohol abuse.
- 4-MEI: (4-methylimidazole), is a contaminant formed in caramel colors, during manufacturing; caramel colors are used in a range of products, including pharmaceuticals, rubber, and certain food substances, such as soda beverages and soy sauces. 4-MEI is formed through the reaction between sugars and ammonia or ammonia-sulfite.
- Acrylamide: is a natural reaction product found in starchy foods that are fried, baked or roasted at temperatures above 120°C (248°F). The proposed mechanism involves asparagine and reducing sugars or reactive carbonyls.

It appears that doing business in California will continue to be difficult for some manufacturers as they navigate the minefield of product safety, litigation and those that seek to profit from the whole ordeal.

Regulatory News...

Health Canada's new legislation for allergen listing

In mid-February, Health Canada unveiled new legislation for the labelling of allergens in foods. The new Consumer Product Safety Act comes into force in August 2012 and requires industry to list all sources of known allergens or gluten on the product label. Cross-contaminations from pre-packaged goods fall outside of this jurisdiction. For more information, see the Health Canada Allergen Listing website (http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/2011/2011_23-eng.php).

Latest Article 13.1 Health Claim Opinions Released by EFSA

The European Food Safety Authority (EFSA) released the most recent batch of health claim opinions on April 8, 2011. Of the 338 claims evaluated in 63 opinions, 31 claims received a positive opinion. Of note, a favorable opinion was given for resistant starch and reduction of post-prandial glycemic and insulinemic responses. This opinion may spur the development of high-fiber foods and the inclusion of resistant starch in biscuits and cereals. Producers of sugar replacers also will benefit from a positive opinion for maintaining

tooth mineralization. Interestingly, caffeine was deemed to be beneficial for alertness and attention but not for energy expenditure or fat oxidation. In contrast, negative opinions included claims pertaining to quercetin, beta-carotene, or lutein and protection from oxidative damage, as well as claims linking fructo- or galacto-oligosaccharides to gastrointestinal health outcomes. Various strains of *Lactobacillus* and *Bifidobacterium* also were viewed unfavorably by EFSA for gastrointestinal and immunity claims.

Maximum residue limits

Effective March 1, 2011, the Council of Australian Governments Ministerial Taskforce on chemicals and plastics regulation made legislative changes which allow for quicker recognition of Maximum Residue Limits (MRLs) in food standards. This will reduce the lag between when the Australian Pesticides and Veterinary Medicines Authority (APVMA) approves a chemical product for use and the inclusion of appropriate MRLs in the Food Standards Code. Current APVMA-proposed draft MRL variations are open for comment.

The Emerging Role of Branched-Chain Amino Acids in Weight Management

As of 2008, 1.5 billion adults worldwide were overweight [*i.e.*, body mass index (BMI) ≥ 25 kg/m²], 500 million of whom were obese (*i.e.*, BMI ≥ 30 kg/m²). It has been predicted that by 2015, almost one third of the adult population of the world will be overweight or obese. Obesity and overweight are associated with increased risk of cardiovascular disease, diabetes, osteoporosis, certain types of cancer, disability, and premature death.

The use of high-protein, low-carbohydrate diets to facilitate weight loss is not a novel concept. Aside from providing fewer calories (due to the lower calorie content of proteins compared to carbohydrates), these diets have been suggested to play specific metabolic roles in weight management. Decreased intake of dietary carbohydrate and increased intakes of high-quality proteins have been shown to promote the utilization of fat rather than protein for energy during times of energy restriction and to enhance stabilization of blood glucose levels.

Leucine, isoleucine, and valine, the branched-chain amino acids (BCAA), account for over 20% of typical dietary protein intake. The other 17 amino acids are primarily metabolized in the liver, but since the liver lacks the aminotransferase enzyme required for BCAA metabolism, the BCAA are oxidized mainly in skeletal muscle. Thus, concentrations of BCAA in skeletal muscle tend to be proportional to dietary intakes.

It has been reported that leucine may contribute to weight management by playing key metabolic roles in skeletal muscle, including regulation of muscle protein synthesis, insulin signaling, and glucose use. The potential for leucine to participate in these metabolic functions is related to its availability in the skeletal muscle, and therefore, its dietary intake.

During periods of energy restriction, supplementation with BCAA or leucine alone is thought to improve body composition by attenuating loss of metabolically active lean body mass (*i.e.*, muscle protein) and enhancing loss of fat mass. Although the mechanisms by which these effects are achieved are not entirely clear, it has been proposed that leucine may attenuate loss of muscle protein by acting on an enzyme in the insulin signaling cascade, resulting in enhanced rates of protein synthesis.

It has been observed that diurnal rates of muscle protein synthesis are lowest after prolonged periods of fasting (*e.g.*, during sleep). After 30 hours of constant intravenous administration of radiolabeled leucine, rates of protein oxidation and synthesis in obese women were observed to be lowest upon awakening in the morning and highest following meals. Thus, it has been theorized that the most critical meal for protein consumption is breakfast.

Results from several clinical studies have demonstrated the potentially beneficial effects of high-protein diets providing supplementary leucine on body weight; however, additional research is needed to confirm these benefits and elucidate the mechanism of action. Given the emerging evidence that supports the role of BCAA in body composition and weight, it appears that consumers will have increasing options for managing their weight.

References will be made available upon request.

Upcoming Events

SupplySide East*

May 2 - 4, 2011

Secaucus, NJ, USA

Don't miss Dr. Andrea Wong's presentation on 'Ingredient Regulations in Japan, China and South Korea: Opportunities and Challenges'.

<http://www.supplysideshow.com/2011/east/>

Vitafoods*

May 10 - 12, 2011

Geneva, Switzerland

Visit us at booth SP04.

<http://www.vitafoods.eu.com/>

IFT*

June 11 - 14, 2011

New Orleans, LA, USA

Visit us at booth 5310.

<http://www.ift.org/>

NutrEvent*

June 15 - 16, 2011

Lille, France

Visit us at our booth.

<http://www.nutrevent.com/>

Natural Market Place

June 23 - 25, 2011

Las Vegas, NV, USA

<http://www.naturalmarketplaceshow.com/nm11/Public/enter.aspx>

Health Ingredients Japan*

October 5 - 7, 2011

Tokyo, Japan

Visit us at booth 1-210.

<http://www.hijapan.info/eng/info/hi.html>

* If you would like to set up a meeting during any of these events please contact us at:
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In Profile with...

Andrea Wong Ph.D.
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There is growing interest by the food and supplement industries to expand into the Asian marketplace because of the large market size, the Westernization of lifestyles, and the long-standing history of using foods and natural products for health promotion. However, the regulatory landscapes in Asian jurisdictions may be difficult to navigate.



To learn about the often complex regulatory processes involved in introducing ingredients to key markets in Asia, join us at SupplySide East in Secaucus, New Jersey (May 4th, 8:30 am) where Dr. Andrea Wong will be delivering a presentation entitled, "Ingredient Regulations in Japan, China, and South Korea: Opportunities and Challenges". Understanding the current regulatory framework and requirements will help you to better position your company to expand into these key markets and capitalize on future opportunities.

Dr. Wong has played a key role in numerous successful notifications and petitions evaluated by regulatory authorities in the various international jurisdictions. She has extensive experience in preparing documentation for health claim submissions, GRAS determinations, and novel food petitions. Her areas of expertise include the critical evaluation and interpretation of clinical and non-clinical study data used for health claim substantiation and safety assessments of food and feed ingredients, food additives, and dietary supplements. Please contact Dr. Wong (awong@cantox.com) for more information on her upcoming presentation or if you have questions about Asian food regulations.

Celebrating 25 Years of Success!

Cantox Strengths:

From its initial focus on servicing North American clients, Cantox Health Sciences International, now an Intertek company, has grown to serve a global clientele with our team of more than 85 professionals.

- We offer a one-stop shop, especially now with Intertek, with the breadth and depth of service that provide clients with the resources they need.
- We are highly ethical, relationship oriented, and deliver excellent value by doing only what is necessary to drive a successful outcome.
- The Cantox guiding principle has always been to help our clients achieve their milestones when bringing new products to market, or defending those already established.
- We ensure that clients benefit from successful outcomes, reduced time to market, and decreased costs.

While Intertek Cantox has grown to become one of the largest and most respected scientific consulting firms in the world, we are just as responsive to client needs today as we were 25 years ago. If you have any questions, or would like additional information about our services, we can be reached at info@cantox.com.



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