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King & Spalding is pleased to provide this first edition of the International Food Law Gazette, a publication of our Food & Beverage Group. For decades, King & Spalding has closely advised leading food, beverage and dietary supplement companies, food industry trade associations, restaurants, retailers, and other businesses in the food supply chain on their most difficult and complex matters in the U.S. and Europe. Lawyers in our dedicated Food & Beverage Group have deep expertise in the areas of FDA and EU regulatory law, trade/WTO law, commercial and product liability litigation, as well as corporate and financial transactions.

The articles in this publication cover various issues and developments in the U.S. and EU that are of particular interest to the food and beverage industry. We hope you enjoy our first edition!

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Countries Continue to Voice Concerns over New and Existing Food and Beverage Regulations at the World Trade Organization Meeting on Technical Barriers to Trade in June 2015

Jasper M. Wauters, Geneva

At the Technical Barriers to Trade (TBT) Committee meeting of the World Trade Organization (WTO) on June 17-18, 2015, WTO Members continued to question other Members' new and existing regulatory measures affecting the food and beverage industries.[1] Members use these meetings to flag and discuss concerns about technical regulations affecting products and services that they believe hinder international trade and

adversely impact competitive opportunities. The types of measures discussed range from new product standards and regulations to labeling and packaging requirements that affect a diverse range of industries.

Regulations concerning food and beverages are a key focus of these meetings. In fact, at the June 2015 meeting, 17 regulatory measures directly or indirectly affecting the food and beverage industries were discussed, representing almost half of all trade concerns that were raised at the two-day meeting.

Unnecessarily restrictive labeling and packaging regulations, product standards and requirements, ingredient regulations, and marketing and sales restrictions are the types of measures typically discussed at these TBT meetings. Members often question the evidence supporting the measure, and inquire about the possibility of adopting less restrictive alternative measures to ensure, as required by the WTO agreements, that technical regulations are not more trade restrictive than necessary. Oral statements as well as written questions to which answers are expected to be provided explain the nature and extent of the concerns over proposed or adopted measures. Some examples of measures that were discussed at the last TBT Committee meeting included:[2]

- Chile – Proposed amendment to the Food Health Regulations (Supreme Decree No. 977/96)
- Chinese Taipei – GMO Labeling
- European Union – Proposed modification of Regulation (EC)1829/2003 referring to genetically modified organisms
- India – Food Safety and Standards Regulation – Food labeling requirements
- Kingdom of Saudi Arabia – Decree on the sale and marketing of energy drinks
- Mexico – Standard on non-alcoholic and soft drinks
- Peru – Act to Promote Healthy Eating Among Children and Adolescents
- Russian Federation – Draft on Technical Regulation of Alcohol Drinks Safety

Notifications of proposed regulatory measures affecting the food and beverage industries are made to the WTO on an almost daily basis. Monitoring such notifications and identifying potential legal avenues for challenging unnecessarily strict standards and requirements have proven to be effective in engaging with interested Members and getting such measures on the agenda of the Committee. Doing so can put diplomatic pressure on the governments proposing these measures to conduct a proper impact assessment and to examine alternative measures.

The next meeting of the WTO Committee on Technical Barriers to Trade will be held on November 4-5, 2015, and again will likely be addressing many food and beverage-related regulatory measures.

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[1] https://www.wto.org/english/news_e/news15_e/tbt_15jun15_e.htm.

[2] A list of all specific trade concerns of the June 2015 meeting is available at https://www.wto.org/english/news_e/news15_e/STC_list_e.pdf.

German Federal Supreme Court: Admissibility of Designation "Energy & Vodka" for Alcoholic Mixed Beverages

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The German Federal Supreme Court issued a decision on whether a company can advertise an energy drink and vodka mixed beverage with the designation "Energy & Vodka."

On October 9, 2014, the German Federal Supreme Court (Bundesgerichtshof – BGH) held that it is permissible to use the term "ENERGY & VODKA" for an alcoholic mixed beverage. According to the court, the term "Energy" is not classified as a "claim" under Art. 2 para. 2 no. 1 of Regulation (EC) No 1924/2006 on nutrition and health claims made on food[1] ("Health Claims Regulation"). The court explained that the term "Energy" does not imply that the food product itself has particular characteristics, but merely provides objective information about the characteristics of a class of food products.

Facts of the Case

The claimant was an industry association known as the "Protective Association of the Spirits Industry" (Schutzverband der Spirituosen-Industrie e.V.). The defendant distributed alcoholic and non-alcoholic beverages, including mixed beverages containing vodka and one other ingredient.

The claimant petitioned to forbid the defendant from distributing a mixed beverage containing vodka with the product designation "Energy & Vodka," arguing that the product designation is both a nutritional and health claim, in violation of the Health Claims Regulation.

Rationale for the Decision

The German Federal Supreme Court denied the claimant's request for injunctive relief based on Art. 4 para. 3 subpara. 2 of Regulation (EC) No 1924/2006. According to the court, the term "Energy" is not a "claim" under Art. 2 para. 2 no. 1 of Regulation (EC) No 1924/2006.

According to Art. 2 para. 2 no. 1 of Regulation (EC) No 1924/2006, "claim" means any message or representation in any form which states, suggests, or implies that a food has particular characteristics.

According to the court, a "claim," as defined under Art. 2 para. 2 no. 1 of Regulation (EC) No 1924/2006, does not exist when the message or representation merely refers to a characteristic of a food that is inherent to all food products within that same product category. In such a case, there is no steering effect that justifies the restriction.

In the view of the court, the product designation “ENERGY & VODKA” does not imply that the beverage itself has special characteristics. The stimulating effect referred to under the designation “Energy” is merely a feature inherent to all energy drinks and is not a unique characteristic of the specific product.

In line with recital 5 of Regulation (EC) No 1924/2006, however, generic descriptors (denominations) that have traditionally been used to flag a unique characteristic of a class of foods or beverages that could imply an effect on human health, such as “digestive” or “cough drops,” should be exempt from the application of this Regulation.

It remains to be seen whether future cases will follow this decision of the German Federal Supreme Court.

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[1] BGH, judgment dated 9 October 2014 – I ZR 167/12, *available at* http://juris.bundesgerichtshof.de/cgi-bin/rechtsprechung/document.py?Gericht=bgh&Art=en&sid=6c604127b5359e08deba05d187e254c4&nr=69298&pos=0&anz=1&Blank=1.pdf.

Food Safety and Recalls – A Global Challenge: Manufacturers Can Reap Long-term Benefits from Short-term Compliance Adjustments

Smitha G. Stansbury, Washington, D.C.

MCC interviews Smitha G. Stansbury, a partner in the FDA and Life Sciences practice group of King & Spalding, resident in the firm's Washington, D.C. office. Ms. Stansbury focuses her practice in the areas of FDA-regulated food safety and food labeling. This interview was first published in the Metropolitan Corporate Counsel*, April 2015 issue.*

MCC: What issues are top of mind for your clients in the food and beverage industry?

Stansbury: My clients include global food and beverage manufacturers, distributors, food industry trade associations, and retailers such as grocery stores. In 2015, food safety continues to be a hot topic as the U.S. Food and Drug Administration (FDA) works to implement the FDA Food Safety Modernization Act (FSMA). This groundbreaking piece of legislation was enacted in 2011, and is intended to help FDA better prevent, detect, and respond to food safety incidents. The legislation was passed, in part, due to concerns over some highly publicized foodborne illness outbreaks and associated product recalls.

Under a court order, FDA is expected to issue a number of final rules over the next 12 months that implement certain key FSMA provisions. Specifically, in the next few months, FDA is expected to issue final rules related to hazard analysis and preventive controls for human and animal food, produce safety, foreign-supplier verification programs, and the accreditation of third-party auditors. In 2016, FDA is expected to issue additional rules related to intentional adulteration and the sanitary transportation of food.

These rules will have a significant impact on the way entities in the food supply chain conduct their businesses. For example, registered food facilities will be required to have written food safety and food defense plans, maintain additional food safety-related records, and verify that their suppliers are producing food in compliance with FDA requirements. Similarly, certain farms will be required to follow new minimum standards for the safe production and harvesting of produce. There will be a far greater focus on the steps taken by companies to evaluate product hazards and to prevent them from occurring.

It should also be noted that FSMA provides FDA with additional enforcement authorities, such as mandatory recall authority and the authority to suspend a food facility's registration. The suspension of registration is significant since it means that food from that facility may not be introduced into interstate or intrastate commerce, and may not be imported or exported. FSMA also enhances FDA's existing administrative detention authority, gives FDA access to a broader range of food records, and tasks FDA with increasing its inspections of both domestic and foreign-registered food facilities. FDA has requested significant additional funding from Congress for 2016 to help with the implementation of FSMA.

Over the next couple of years, due to increased product monitoring, testing and recordkeeping under FSMA, I would not be surprised to potentially see a temporary increase in product recalls as companies are better able to identify and uncover product issues. In the long run, however, FDA, Congress, the food industry, and the general public are hopeful that FSMA will help greatly reduce the number and severity of foodborne illnesses and associated product recalls as companies institute better preventive controls throughout the food supply chain.

MCC: Under what circumstances might a recall be considered?

Stansbury: With respect to FDA-regulated products in the U.S., recalls are generally considered when a company becomes aware that a product it has manufactured or distributed is "adulterated" or "misbranded," and is in violation of the Federal Food, Drug, and Cosmetic Act (FFDCA). For example, recalls often occur when a company becomes aware that a food contains an undeclared allergen, such as peanuts, or when a food is contaminated with a harmful bacteria (such as salmonella, E. coli, or listeria) or virus (such as norovirus in shellfish). Food and beverage recalls are also conducted for a variety of other reasons, such as chemical contamination, the presence of foreign objects, such as metal or glass, defective packaging, and/or misbranded labeling.

FDA classifies product recalls into three different classes, Class I, II and III, depending upon the severity of the potential health hazard. Class I recalls involve situations where there is a reasonable probability that use of, or exposure to, a violative product will cause serious adverse health consequences or death (such as when salmonella is found in a ready-to-eat food). Class II recalls involve situations where use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote (such as the presence of certain foreign objects in food). Finally, Class III recalls involve violative products that are not likely to cause adverse health consequences (such as low levels of pesticide residue in food or certain product labeling violations).

MCC: What is the typical corporate communication chain for uncovering product issues? At what point do you get involved in product recalls?

Stansbury: Potential product issues can be identified by companies through both internal and external sources. A company, for example, may uncover an issue on its own through regular product quality monitoring or testing. A potential product issue could also be brought to a company's attention by regulatory agencies, such as state or local health departments, FDA, the United States Department of Agriculture (USDA), and/or the Centers for Disease Control and Prevention (CDC). These agencies all have a role in identifying, investigating and responding to foodborne illness outbreaks and other food safety-related issues. Companies can also learn of product problems from their ingredient suppliers or from their customers. Responsible companies will work quickly to investigate the potential problem, identify the source of any issue, bracket the extent of the problem,

take corrective action to ensure that the problem does not reoccur, and if needed, initiate a product recall in a quick and effective manner.

Different companies use their outside counsel in different ways with respect to product recalls, depending upon the size of the company and the degree to which they already have an experienced internal team in place. In many instances, I am involved long before an incident occurs by helping companies develop or update a written recall plan so that they can act quickly if and when they have to execute a product recall. In other situations, I am brought in after a potential product issue has been identified to assist the company and its recall team in evaluating whether a product is violative and/or a "reportable food" for purposes of submitting a report to FDA's Reportable Food Registry (RFR); provide insight on FDA's legal requirements and expectations for product recalls; review any draft communication documents; and/or coordinate interactions with FDA.

MCC: Discuss some best practices for being prepared to execute a recall.

Stansbury: It is very important that food and beverage companies plan and prepare for product recalls and have adequate insurance in place, since even the most responsible of companies may find themselves having to conduct a recall at some point. Companies should, for example, become familiar with FDA's existing regulations and guidance documents related to product recalls, and should have a written recall plan and a recall team in place well in advance of a product problem. The recall team should be a cross-functional team with representatives from, among other things, manufacturing, quality assurance, logistics and distribution, public relations, scientific experts, legal and accounting. Companies should also test their recall plans by conducting mock recalls to identify any potential stumbling blocks in their ability to recall violative goods. Resolving any issues in advance makes all the difference when a company is called upon to quickly and effectively execute a product recall.

In addition to being prepared to execute a recall, it is important that all food and beverage companies take steps to prevent incidents from occurring in the first place by securing the manufacturing and distribution process. Manufacturers should, for example, conduct a hazard analysis and establish preventive controls, monitor and verify that those preventive controls are working, and take corrective actions as needed. Companies should also verify that their domestic and foreign suppliers are delivering high-quality and safe products, establish a food defense plan to protect against intentional adulteration, and take steps to ensure that food is being transported in a sanitary manner. FDA's soon-to-be-released final rules under FSMA are expected to make many of these activities mandatory – including the development and maintenance of a written recall plan.

MCC: Would you say that this is a shared goal among regulators and companies? What are the stakes for the industry?

Stansbury: The food industry and regulators share a common goal of ensuring the safety of the American food supply. No one wants consumers to get sick from the food they consume. Although the requirements of FSMA

may appear to be onerous, they are expected to be beneficial not only for the public by helping to prevent foodborne illnesses, but also for the food industry as a whole. When a product recall occurs, particularly in the context of a foodborne illness outbreak, it can have significant financial implications for the entity that produced the contaminated product given the costs associated with a product recall, lost sales and any resulting products liability lawsuits.

In addition, non-offending producers of food products that fall within the same product category of a recalled food could also be impacted. For example, according to a 2012 U.S. Government Accountability Office (GAO) report, the 2006 outbreak of E. coli linked to fresh spinach from California caused an estimated $100 million loss to the spinach industry as a whole. Similarly, following the 2008-2009 outbreak of salmonella associated with peanuts, general demand for peanut products reportedly declined for several months. The food industry benefits when its members are required to establish and follow robust food safety protocols.

MCC: Let's delve into specifics. What are the elements of a good recall plan?

Stansbury: Recall plans can and will vary depending upon the company, but they should always reflect FDA's regulations and guidance related to product recalls, which can be found in 21 C.F.R. §§ 7.40-7.59, and FDA's "Guidance for Industry: Product Recalls, Including Removals and Corrections."

A good recall plan will have a means of tracking all of the company's action steps as they occur, such as when a potential product problem was identified, how the initial risk was evaluated, when production was stopped, and how wholesalers were notified. A good recall plan will also have, among other things, a master list of all relevant names and contact information for the members of the recall team, any outside advisors and key regulatory contacts; a list for evaluating whether an issue presents a health problem; a plan for how the company will quickly obtain the necessary records and secure the product; a plan for obtaining the list of basic information that would be provided to FDA (such as identity of the product, distribution information, reason for recall, health hazard evaluation and recall strategy); and drafts of any communication documents such as press releases. FDA's proposed rule on preventive controls for human food would require registered food facilities to establish and maintain a written recall plan.

MCC: What about recordkeeping practices?

Stansbury: Robust recordkeeping practices and sufficient product coding/lot numbers can help companies quickly identify the source and scope of a product problem and better track, trace and recall particular products in the event of a product emergency. Detailed manufacturing, processing and testing records can help show, for example, that a tainted ingredient was only used in specific lots of product that were manufactured on a specific date at one production facility. This type of information can help limit the scope and cost of a product recall.

MCC: These are emotional issues for consumers. When disaster strikes and a company has to recall a product, what are some effective strategies for managing the reputational consequences?

Stansbury: Consumers rightfully expect the foods and beverages they consume to be safe and lawful. Even the most diligent of companies, however, may find themselves needing to conduct a product recall. From a reputational standpoint, companies will be able to better regain consumer trust if they quickly and correctly identify the source of a product problem, take appropriate corrective actions to help prevent the issue from occurring again in the future, work cooperatively with FDA and/or other regulatory agencies to conduct an effective product recall, and have adequate infrastructure and staffing in place to respond to what may be a large number of consumer inquiries related to the product recall. A company that does not appear to have a good handle on the problem, is at odds with the relevant agency, or is otherwise unresponsive or disorganized will not be viewed favorably by the public.

MCC: What's the difference between a company-initiated recall and one initiated by the FDA?

Stansbury: Most recalls are company-initiated voluntary recalls. These are situations where a company identifies a product problem, or hears of a product problem by FDA or others, and decides on its own initiative to conduct a recall of the violative product. It is important to note that a "recall" is defined in 21 C.F.R. § 7.3(g) to mean a firm's removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action. A product recall does not include a market withdrawal or a stock recovery.

In addition to firm-initiated voluntary recalls, FDA can also specifically request that a company conduct a voluntary recall. Specifically, under 21 C.F.R. § 7.45, FDA may request a firm to initiate a voluntary recall if the distributed product presents a risk of illness or injury or gross consumer deception, the firm has not initiated a recall of the product, and an agency action is necessary to protect the public health and welfare. In such situations, FDA will generally notify the firm; identify the specific violation, the health hazard classification of the violative product, and the recall strategy; and provide other appropriate instructions for conducting the recall.

Finally, FSMA provided FDA with mandatory recall authority. Under 21 U.S.C. § 350l, if a company does not voluntarily recall a product, FDA may order a product recall when there is a reasonable probability that an article of food is adulterated, or misbranded with respect to allergen labeling, and the use of or exposure to the article will cause serious adverse health consequences or death. There is nothing in this new authority that limits the agency's ability to request a voluntary recall or to issue an order to cease distribution or to recall under any other provision of the FFDCA. FDA's mandatory recall authority is expected to be used in relatively narrow circumstances given that the vast majority of companies will voluntarily recall a product when requested by FDA.

MCC: In closing, please expand on the nature of the relationship between regulators and the food and beverage industry.

Stansbury: FSMA places significant new responsibilities on both FDA and the food industry to better ensure the safety of the United States food supply. The various controls and activities required by FSMA are expected to benefit not just the public health, but also the food industry as a whole, since all companies will be held to a higher food safety standard. There is hope that the stricter controls may result in fewer food safety incidents, greater consumer confidence, and fewer instances where non-offending producers are impacted by recalls that occur within their own product category. Under FSMA, industry is expected to work in partnership with FDA towards a common goal of providing safe food products to the American public.

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EU Food Information Regulation in Force

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In the European Union, the regulations on labeling and information of food products have been fully harmonized since December 2014.

On December 13, 2014, the new Regulation (EU) No 1169/2011 on the provision of food information to consumers[1] became effective.

Key changes:

- Improved legibility of information (minimum font size for mandatory information);
- Clearer and harmonized presentation of allergens (e.g., soy, nuts, gluten, lactose) on prepackaged foods (emphasis on allergens through font, style or background color) in the ingredient list;
- Mandatory allergen information for non-prepackaged foods, including those served in restaurants and cafes;
- Requires certain nutrition information for the majority of prepackaged, processed foods;
- Mandatory origin information for fresh meat from pigs, sheep, goats and poultry;
- Consistent labeling requirements for online, distance-selling, or in-store purchases;
- Requires listing of engineered nanomaterials in the ingredients;
- Requires specific information on the vegetable origin of refined oils and fats;
- Strengthened rules to prevent misleading practices;
- Requires disclosure of substitute ingredient for “imitation” foods;
- Requires clear indication of “formed meat” or “formed fish;” and
- Requires clear indication of defrosted products.

In order to help food business operators prepare for the new labeling requirements, certain transition measures were agreed upon: The obligation to provide nutrition information will become effective December 13, 2016. In

addition, foods placed on the market or labeled prior to December 13, 2014 that do not comply with the new regulatory requirements may continue to be sold until the stock is expended.

The European Commission plans to develop a system to ensure compliance with the new regulations. Specifically, the Commission plans to establish an EU database to maintain all mandatory labeling regulations that apply at the EU level and in the individual Member States. The database will be populated with these regulations throughout 2015.

The European Commission published a Q&A document[2] to answer a series of questions concerning the application of the Regulation.

The labeling requirements for food products are very strict. Uncertainties exist both with the enterprises and with the responsible authorities. We recommend careful review of food product labeling.

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[1] Regulation (EU) No 1169/2011, *available at* http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R1169&qid=1430834273603&from=EN.

[2] Questions and Answers on the application of the Regulation (EU) No 1169/2011 on the provision of food information to consumers, *available at* http://ec.europa.eu/food/safety/docs/labelling_nutrition-labelling_legislation-qanda_application_reg1169-2011_en.pdf.

Do the New European Union Rules on GMO Cultivation and Use Comply with Its Obligations under the World Trade Organization?

Jasper M. Wauters, Geneva

The European Union (EU) recently adopted new rules with respect to the approval of genetically modified organisms (GMOs)[1] for cultivation that allow Member States to ban or restrict GMO cultivation in their territory, even if such cultivation has been approved at the EU level.[2] In addition, the European Commission recently proposed new EU-wide rules for the use of food and animal feed products containing GMOs, which also give Member States more freedom to adopt national restrictions or prohibitions.[3]

GMO Cultivation

The new rules on GMO cultivation entered into effect on April 2, 2015. The EU seeks to disconnect the EU-wide approval process from individual Member State consent by implementing any restriction or prohibition at the EU level, at the stage of authorization or renewal of GMO applications. However, Member States will have the flexibility to adopt national cultivation restrictions or prohibitions on the basis of grounds distinct from and complementary to the EU risk assessment. National restrictions may be adopted on grounds relating to environmental or agricultural policy objectives, or other non-scientific compelling grounds such as town and country planning, land use, socio-economic impacts, coexistence and public policy.

European Commission Proposal for New Rules on Use of GMO Products

In addition to the recently adopted rules on GMO cultivation, the European Commission has also recently proposed new rules allowing Member States to adopt measures restricting or prohibiting the use in all or part of their territory of a GMO or a GM food and feed, provided that such measures are reasoned, based on compelling grounds in accordance with Union law, and are in line with the principles of proportionality and non-discrimination between national and non-national products. Although the proposal states that the relevant restrictions or prohibitions "should refer to the use and not to the free circulation and imports of genetically modified food and feed," the effect of this proposal would be to allow Member States to ban the sale and use of a GMO or a GM food and feed, thus rendering importation of these products pointless.

In line with the cultivation rules, the new proposal for the authorization to use GMO products maintains a single scientific risk-management system at the EU level and gives each Member State the power to ban the use of EU-approved GMO products on their territory on the basis of grounds other than risks to human and animal health and the environment, including for non-scientific reasons. In fact, the new proposal expressly states that to avoid any interference with the EU's risk assessment related competences, "Member States should not be authorized to use grounds which are related to risks to health and to the environment which should be dealt with in accordance with the procedure already established in Regulation (EC) No 1829/2003."[4] Thus, once a GMO has been authorized for use as food or animal feed in the European Union, an individual Member State can still

decide to opt out or restrict that particular GMO from being used in their territory provided such decision is based on compelling, non-health grounds and is proportionate and non-discriminatory.[5]

Under the existing rules, in place since 2003, Member States can only adopt national restrictions, so called emergency measures, to prevent the use in their territory of GMO products authorized at the EU level if there is scientific evidence demonstrating that the product is likely to pose a serious risk to human or animal health or to the environment.

If the European Commission proposal is adopted and the rules enter into force, the European Union would have a consistent set of rules regarding GMOs for both cultivation and for food and feed, which would allow Member States to regulate GMOs on the basis of individual concerns other than health protection.

Are the EU's New Rules Consistent with its WTO Obligations?

While the EU believes the new rules on GMO cultivation will improve the process for authorizations, concerns have been raised over their consistency with the EU's obligations as a Member of the WTO.

When announcing its new proposal, the European Commission stated that any measure adopted by Member States needs to be compatible with the internal market and "consistent with the EU's international obligations - of which the EU's WTO obligations are an integral part."[6] The European Commission did not provide details as to how this could be done given the authorization granted to Member States to ban, for non-health related reasons and on non-scientific grounds, GMO products that are found to be scientifically "safe" by the EU regulator.

Indeed, under the relevant rules of the WTO, in particular the SPS Agreement, the EU and its Member States have committed to certain obligations in respect of sanitary and phytosanitary measures (SPS measures), such as laws, regulations or requirements applied, among others, to protect human, animal or plant life or health from pests, diseases, or disease-causing organisms and to prevent or limit other damage to a country from the entry, establishment or spread of pests. Such SPS measures can only be imposed if they are *necessary to protect human, animal or plant life or health*, are *based on scientific principles* and are *not maintained without sufficient scientific evidence*. Furthermore, these measures must be based on an appropriate assessment of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations. They cannot be more trade restrictive than necessary to achieve the appropriate level of protection.

Allowing Member States to adopt individual bans on GMO products (as proposed by the European Commission) would likely qualify as an SPS measure, as evidenced by the WTO's findings in the *EC – Biotech* case. The same is likely to be true for the already adopted rules allowing Member States to restrict or prohibit the cultivation of GMOs. Indeed, the findings of the WTO panel in *EC – Biotech* with respect to certain of the

Member State's safeguard measures, which also concerned cultivation, suggest that cultivation measures would also be considered covered by the disciplines in the SPS Agreement.

If the use and cultivation-related rules qualify as an SPS measure, they must comply with all of the WTO's obligations requiring, among others, a scientific justification and a proper risk assessment. This scientific risk assessment continues to be conducted at the EU level by the relevant authorities. However, under the new rules, a positive risk assessment would not mean that the GMO product could be used or the GMO could be cultivated in every Member State. These products will be subject to a second, non-scientific layer of scrutiny at the Member State level. The broad range of "town and country planning, land use, socio-economic impacts, coexistence and public policy" grounds appears to effectively allow Member States to disregard their WTO obligations. It is highly questionable whether such non-scientific "public policy" grounds are permissible for a trade-restrictive measure that is justified as a measure taken to protect the spread of disease and to protect human, animal or plant health.

It seems that the EU is further developing the "public morals" argument it previously raised to justify a ban on seal products under the general rules of the WTO's General Agreement on Tariffs and Trade and the Agreement on Technical Barriers to Trade. This ban was challenged by Norway and Canada in the WTO *EC – Seals* dispute. In that case, the WTO upheld the public morals defense, finding only a violation of the rules because of the discriminatory application of the EU seals ban. Whether a similar conclusion would be reached in the context of an SPS challenge of the GMO ban remains to be seen. The specific language of the SPS Agreement and the well-established jurisprudence with respect to the need for a scientific justification of SPS measures seems to suggest otherwise.

Conclusions

Although the new GMO-related rules seek to disconnect the EU-wide approval process from individual Member State consent, thus limiting the risk of delays for implementation in at least some Member States, it seems to have replaced one problematic situation with another. In situations where a GMO-crop is authorized at an EU level, after having passed an individual and scientific risk assessment, a Member State would nevertheless be allowed to restrict or prohibit cultivation and use in its territory for reasons unrelated to the protection of human, animal or plant life or health. Allowing Member States to ban GMOs from their territory for reasons other than health protection, without scientific evidence and absence of a proper risk assessment, or even in direct contradiction of the risk assessment conducted at the EU level demonstrating an absence of risk, appears to be highly problematic under relevant WTO law which imposes specific obligations for SPS measures that are even stricter than those imposed on technical regulations and standards.

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[1] The term 'genetically modified organism' is defined in EU Directive 2001/18/EC, as amended, in two parts: (i) 'organism' means any biological entity capable of replication or of transferring genetic material; and (ii) 'genetically modified organism (GMO)' means

an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

[2] The DIRECTIVE (EU) 2015/412 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs), 13.3.2015, OJ L68/1.

[3] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory, 22.4.2015, COM(2015) 177 final, available at http://ec.europa.eu/transparency/regdoc/rep/1/2015/EN/1-2015-177-EN-F1-1.PDF.

[4] Recital (10) of the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory, 22.4.2015, COM(2015) 177 final.

[5] Article 1 of the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory, 22.4.2015, COM(2015) 177 final.

[6] See, "European Commission - Fact Sheet Review of the decision-making process on GMOs in the EU: Questions and Answers," available at http://europa.eu/rapid/press-release_MEMO-15-4779_en.htm, referring to Section 4.1 of the Explanatory Memorandum to the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory, 22.4.2015, COM(2015) 177 final.

New Health Claim on Carbohydrates Admitted in the EU

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In the European Union, health claims are strictly forbidden for all substances unless the European Commission has allowed them in the so-called "Union list" in accordance with Regulation (EC) No 1924/2006 on nutrition and health claims made on foods.[1] The authorized claims are published in Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods.[2]

With Commission Regulation (EU) 2015/7 of 6 January 2015 authorizing a health claim made on foods,[3] a new health claim on carbohydrates was included in the Union list of authorized health claims of Regulation (EU) No 432/2012. The newly admitted health claim provides:

> Carbohydrates contribute to the recovery of normal muscle function (contraction) after highly intensive and/or long-lasting physical exercise leading to muscle fatigue and the depletion of glycogen stores in skeletal muscle.

The claim may be used under the following conditions:

- The claim may only be used for foods that provide carbohydrates that are metabolized by humans (excluding polyols).
- Consumers must be informed that the beneficial effect is obtained by consuming carbohydrates, from all sources, at a total intake of 4 g per kg body weight, at doses, within the first 4 hours and no later than 6 hours, following highly intensive and/or long-lasting physical exercise that leads to muscle fatigue and depletion of glycogen stores in skeletal muscle.
- The claim may be used only for foods intended for adults who have performed highly intensive and/or long-lasting physical exercise that leads to muscle fatigue and depletion of glycogen stores in skeletal muscle.

Background

In December 2006, the European Council and the European Parliament adopted Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. The Regulation establishes harmonized rules across the European Union for the use of nutrition claims such as "low fat" and "high fiber" or health claims such as "reducing blood cholesterol."

This Regulation provides for implementation measures that ensure any claim made on food labeling, presentation, or marketing in the European Union is clear, accurate and based on evidence accepted by the collective scientific community.

The Commission established a Register of Nutrition and Health Claims to provide a comprehensive overview of authorized nutrition claims, as well as authorized, rejected, and pending health claims.[4]

There are approximately 260 authorized health claims, 2,000 rejected health claims, and 2,160 health claims that are still under examination. Of those health claims under examination, 2,095 are "on-hold claims" that have not yet been evaluated. Notably, 2,078 of the "on-hold claims" relate to plants and plant substances (so-called "botanicals"). The admissibility of health claims on botanicals has not yet been decided by the European Food Safety Authority (EFSA), but there are three actions pending before the European Court of First Instance regarding health claims on botanicals.

For further information on the admissibility of health claims, please see the European Commission's webpage on Health and Nutrition Claims.[5]

The European regulations on health and nutritional claims are very strict. Health and nutritional claims on food and beverage packaging and in advertising should be reviewed carefully.

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[1] Regulation (EC) No 1924/2006, *available at* http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1924-20121129&from=EN.

[2] Regulation (EU) No 432/2012, *available at* http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02012R0432-20150421&qid=1436201285078&from=EN.

[3] Regulation (EU) 2015/7 *available at* http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R0007&rid=1.

[4] Register of Nutrition and Health Claims, *available at* http://ec.europa.eu/nuhclaims/.

[5] European Commission on Health and Nutrition Claims, *available at* http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm.

State of California: Proposed Amendments to Proposition 65 Warning Regulations – Looking for Improvements in "Round Two"

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By the end of the summer, the State of California expects to issue the next (and presumably final) draft of its substantial revisions to regulations that require product warnings for exposures to substances the State considers to be carcinogenic or cause reproductive or developmental harm. The proposed amendments represent the first overhaul of these rules in more than 25 years; not surprisingly, they received focused attention from the business community, including food and beverage companies.

Background

California's Safe Drinking Water and Toxic Enforcement Action of 1986 (colloquially known as Proposition 65) requires businesses offering products or services in California to provide a "clear and reasonable" warning before exposing any person to more than a threshold level of one or more of roughly 800 listed chemicals.[1] The current regulations administered by the Office of Environmental Health Hazard Assessment (OEHHA) provide "safe harbor" warnings that businesses can rely upon to comply with the statute.[2]

The proposed amendments would make several key changes in the rules. First, in order to satisfy the statute's requirement to be "clear and reasonable," new warnings must state that the product "can expose you to a chemical …" known to the State to cause cancer or reproductive toxicity, rather than the current safe harbor language that simply states that the product "contains a chemical…." The proposal would also require warnings in multiple languages for certain product labels or signs. Further, the revised warnings for products that could expose a person to one or more identified chemicals above a threshold level would be required to identify those chemicals, by name, in the warning. Several of the chemicals include foods in the justification for naming those chemicals in the warning:

- Acrylamide appears on the list primarily because "given the popularity of acrylamide-containing foods, the potential for regular exposure is significant."[3]
- Foods are also listed prominently as a category of products for which "identification of arsenic exposures … can provide valuable information."[4]
- Foods are also listed as sources of exposure to other named chemicals – cadmium, formaldehyde, hexavalent chromium, lead and phthalates.[5]

The proposed amendments also provide tailored warnings for food products:

> "**WARNING**: Consuming this product can expose you to a chemical known to the State of California to cause cancer [and/or birth defects or other reproductive harm]. For more information go to http://www.p65warnings.ca.gov/food."[6]

Over the past several months, a variety of companies and groups offered comments and testimony on how OEHHA should revise the draft, and a number of these recommendations would improve the impact of the revised regulations on companies in the food and beverage industries.

Areas of Requested Improvement

A revised draft of the proposed amendments is anticipated in the next several weeks. Businesses in the food and beverage industries should look to the new draft to determine whether and how OEHHA has revised the proposal, including the following particular concerns:

- "Can expose" – Food and beverage companies are among the sectors whose products may contain listed substances that are not intentionally added to the product, but are inherently present. Commenters suggested reverting to the existing "may contain" text in recognition of the unique situation of such products.

- Clarification of the "Sell-Through" or Grandfathering Provision – The earlier proposal included a two-year transition period, but many stakeholders questioned its sufficiency and suggested either a longer period or that all products produced prior to the effective date should receive grandfathered status.

- Preservation of Warnings Approved in Settlements – Many existing products bear warnings derived in court-approved settlements. Commenters recommended explicit language in the amendments that preserves businesses' continuing ability to use such warnings.[7]

- Use of Off-Product Warnings – The proposed amendments recognize that a warning may qualify as "clear and reasonable" even if it does not appear in an on-product label. However, OEHHA also rejected off-product warnings that individuals must "seek out." Several commenters encouraged OEHHA to elaborate on this distinction.

- Multi-lingual Warnings – Commenters sought additional direction on what information would trigger the requirement to provide warnings in multiple languages.

- Supplemental Information – Under the proposal, businesses may provide additional information so long as it does not "contradict, dilute or diminish" the Proposition 65 warning; however, the proposal provides little guidance on what supplemental information is permissible. A range of commenters, particularly those subject to labeling rules from other agencies (e.g., FDA, USDA), articulated the need for additional discussion on this issue.

Regardless of their final form, these new regulations are expected to change the strategies that businesses use to comply with Proposition 65. Under the existing regulations, many businesses have found it easier simply to provide a Proposition 65 compliant warning rather than undertake the costly exposure assessment allowed under the rule to demonstrate that a product does not pose a significant risk. Businesses should assess the new draft to determine how any revisions impact their Proposition 65 procedures in light of the increased requirements and litigation potential expanded under the new regulations.

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[1] Cal. HSC § 25249 et seq.

[2] 27 CCR § 25601 et seq.

[3] Initial Statement of Reasons (ISOR), at 15 (Jan. 16, 2015).

[4] Id. at 16.

[5] Id. at 17-22.

[6] Proposed 27 CCR § 25608.2. Cited hyperlink is inactive as of the date of this publication.

[7] The ISOR uses labels on several food products as examples of settlement-derived warnings. *See* ISOR, at 30.