

# Food Chemical News

This Week's On the Front  
Burner Contributors  
David J. Ettinger and  
Mitzi Ng Clark



Weekly in-depth coverage of food regulations, additives, microbiology, contaminants and feed

It seems like the only food regulatory news to come out of Japan in recent months deals with the concern of radiation-contaminated food, but that's not the case, as the food regulatory experts at Keller and Heckman illustrate in the following contributed column.

## Navigating Japan's Food Packaging Regulations

By David J. Ettinger & Mitzi Ng Clark

Japan offers one of the greatest opportunities in the world for exporters of food products and food packaging materials.

Japan's consumer food and beverage sectors are enormous, having a value of about \$700 billion, according to a USDA Foreign Agricultural Service Global Agricultural Information Network (GAIN) report published last year. In fact, roughly 25% of Japanese income is spent on food, compared to about 15% by North Americans, as indicated in a report issued this year by Canada's Agri-Food Trade Service.

Coupled with an efficient food distribution system, and significant emphasis on food safety and the aesthetic value and quality of packaging, Japan continues to garner significant global attention as a source of potential marketing opportunities, particularly in the food packaging arena. A critical component to marketing in Japan is ensuring compliance of food packaging with the regulatory scheme in place for these materials.

The regulatory scheme for food packaging materials in Japan combines government regulations, based on the Food Sanitation Law of 1947, and industry standards that have been voluntarily established by industry trade associations.

Japan's Food Sanitation Law sets forth a general safety standard that covers not only food, but also includes food additives, food packaging materials, and equipment. As it relates to food-contact materials, the legislation prohibits the sale of equipment

or packages containing toxic or harmful substances. Additionally, the Food Sanitation Law introduces an enforcement component that includes inspection of domestic food-business facilities, import notification requirements, monitoring and testing, and the imposition of penalties.

To date, Japan does not maintain a so-called "positive list" of materials that are permitted for use in manufacturing articles that contact food, nor does it require premarket approval or review of food-contact substances prior to their use in the marketplace. Nonetheless, the Food Sanitation Law authorizes the Japanese Ministry of Health, Labor, and Welfare (MHLW), under the Pharmaceutical and Food Safety Bureau, Department of Food Safety, Standards and Evaluation Division, to establish specifications for food containers and packaging, as well as for raw materials used to manufacture such articles.

Three different types of specifications for containers and packaging materials have been established, namely: (1) general specifications that apply to all containers and packaging; (2) material-specific standards; and (3) certain specifications that apply to the end-use application for the packaging.

Material specific standards exist for metal cans, glass/ceramic/enamel articles, and rubber articles, including nursing apparatuses. Standards also exist for synthetic polymers generally, as well as for specific resins, e.g., polyvinylchloride, polyethylene, polypropylene, polystyrene, polyvinylidene chloride, polyethylene terephthalate, and polycarbonate. These standards include information on end tests

that are aimed at ensuring that the materials meet various specifications, e.g., heavy metals and total non-volatile extractives.

### Other key players in Japanese food regulation

In May 2003, in response to several events in Japan impacting food safety, such as the outbreak of bovine spongiform encephalopathy (BSE) and microbial contamination in various foods, the Japanese Parliament passed the Food Safety Basic Law. This law led to the establishment of a new Cabinet Office, the Food Safety Commission (FSC).

The FSC functions independently from the MHLW and is comprised of four commissioners who are experts on food safety and charged with the responsibility of conducting risk assessments. More specifically, the FSC's mission is to: (1) conduct risk assessments using scientific information and knowledge and provide its conclusions to the relevant ministries, for example, the MHLW, to implement risk management; (2) communicate its risk assessments and recommendations to interested stakeholders—such as consumers and business operators—via public meetings, its website, and other forms of public media; and (3) respond to foodborne outbreaks and emergencies by getting information out to the public and coordinating with relevant ministries. To assist with its mission, the FSC is supported by expert committees, e.g., the Food Additives Expert Committee.

In addition to the governmental standards and specifications in place, Japan has many voluntary standards developed by

## On the Front Burner

Japanese trade associations that ultimately serve as another vehicle for marketing various food packaging materials.

These voluntary standards are widely respected in Japan and, in fact, customers will often require a supplier to have its product sanctioned by the appropriate trade association before a sale can be made. Some of the most respected trade associations in Japan include the Japan Hygienic Olefin and Styrene Plastics Association (JHOSPA), the Japan Hygienic PVC Association (JHPA), the Japan Hygienic Association of Vinylidene Chloride (JHAVDC), and the Japan Paper Association (JPA).

JHOSPA was established in 1973 and is comprised of resin and additive manufacturers, converters, distributors and food companies. JHOSPA publishes a set of voluntary standards titled, "Self-Restrictive Requirements on Food-Contacting Articles Made of Polyolefins and Certain Polymers," which include a "positive list" of certain polymers, additives and colorants for use in food containers, packaging materials, and utensils.

To date, JHOSPA has developed voluntary standards for 30 basic polymers commonly used in food-contact applications. The JHOSPA list of polymers goes beyond the number of polymeric standards established by the MHLW.

The "positive list" for additives was initially established by JHOSPA by listing additives that were permitted in select foreign countries (e.g., the United States) for use in food-contact applications. New substances can be added to JHOSPA's positive list by filing a petition; however, only members of JHOSPA are permitted to file a petition, which makes new filings difficult for non-members, such as foreign entities. For non-members who wish to pursue a filing, sponsorship by a JHOSPA member is required.

JHPA was established in 1967 and is composed of member companies that manufacture ingredients of PVC and finished PVC products. JHPA's positive list, along with criteria for registering

substances on the list, is set forth in "JHP Recommended Substances." Industry can turn to this "positive list" to identify substances that have been petitioned and reviewed for use in PVC, along with standards for materials used in making PVC.

### Positive list for substances in food-contact paper

JPA was established in 1997. In May 2007, the association established its "Voluntary Standard of Paper and Paperboard Intended for Use in Food Contact," which is intended to provide its members with voluntary standards, e.g., limits on heavy metal substances, to promote the safe use of paper and paperboard for use in food-contact containers and packages.

In September 2010, JPA announced that it will establish a positive list for materials used in food-contact paper. JPA is in the process of performing risk assessments on over 1,900 substances that were submitted by industry.

Once completed, the results of these risk assessments will be made available to the public and listed on JPA's positive or negative list. A listing on JPA's negative list would ban its use in the manufacture of food-contact paper and paperboard.

In May of this year, JPA began accepting registrations for new chemical substances. As part of this process, applicants are required to submit

information on the substance, including safety and exposure data.

### Will Japan follow China to a positive list system?

While Japan's regulation of food packaging materials has evolved over the past 60 years, it is a system that foreign companies often find difficult to penetrate. As noted above, oftentimes one must be a member of a particular trade association or seek sponsorship from an existing member in order to obtain a voluntary standard on a food packaging material. Unless the foreign entity has a sister company, joint venture, or other connection to a business operation in Japan, it can be a real challenge to obtain a new standard.

With China's recent shift to a "positive list" system, eyes are now beginning to shift toward Japan to see if it will follow suit. While Japanese authorities have suggested an interest in moving toward a positive list system, it is low on their priority list. However, should the Japanese government move toward such a system, the process of getting a substance on a positive list would, presumably, be open to the world, so that membership in or sponsorship from a trade association member would no longer be required. This would certainly be a welcome opportunity for foreign entities looking to enter Japan's \$700 billion food and beverage market.

## ABOUT THE AUTHORS



**David J. Ettinger** ([ettinger@khlaw.com](mailto:ettinger@khlaw.com)) is a partner in the Washington, D.C. office of Keller and Heckman LLP. He represents domestic and foreign corporations in the area of food and drug law. He specializes in counseling clients on product development and product protection of food and drug packaging in the United States, Asia, the European Union, Canada, and South America. In addition to practicing in the firm's Washington office, in 2006-2007, Ettinger was the U.S. resident partner in Keller and Heckman's Brussels office where he counseled clients on global food packaging matters.



**Mitzi Ng Clark** ([clark@khlaw.com](mailto:clark@khlaw.com)) is an associate in the Washington, D.C., office of Keller and Heckman LLP. She practices in the area of food and drug law, with an emphasis on food packaging. She assists domestic and international corporations in establishing a suitable regulatory status for products under the laws and regulations administered by the FDA and other federal and state agencies. She also counsels clients on a broad range of global food-contact matters, including ones in Canada, the European Union, the Pacific Rim and Latin America. She has a background in epidemiology and disease research.

Permission to reproduce this column was granted by Food Chemical News, the leading source of news and analysis in relation to food regulations. Now included with your subscription: The Food Chemical News Guide, a database, updated weekly, with information about thousands of food chemicals. For more information or to subscribe to this product, go to [www.foodchemicalnews.com](http://www.foodchemicalnews.com). Or contact our customer service department by calling 888-732-7070, Option 2, or writing [agra.enquiries@informa.com](mailto:agra.enquiries@informa.com)