Regulatory considerations for exporters of food contact materials

This expert focus, prepared by Jeffrey A. Keithline and Herb Estreicher of Keller and Heckman, outlines South Korea’s regulatory scheme for food contact materials and guides companies through the regulatory requirements for exporting FCM’s to South Korea.

The entry into force of the US/Korea trade agreement on 15 March 2012 heralded many new opportunities for US companies to sell American-made goods to South Korean customers. The EU and South Korea are also important trading partners and hence there is likely to be increasing competition to gain a foothold in the Korean market.

Both raw materials and finished food contact materials will play an important part in this competition given the substantial investment made by companies in both the EU and the US on innovative packaging. Fortunately, establishing a suitable food contact status under South Korean law should be relatively straightforward for both EU and US companies because the South Korean regulatory scheme shares many common features with those in place in the EU and US. A greater challenge for substances used to produce food contact articles is posed by The Act on the Registration and Evaluation of Chemicals (K-REACH), which enters into force on 1 January 2015.

Korea’s FCM Regulatory Scheme

According to the US Department of Agriculture (USDA), South Korea has historically modelled its regulatory system for food and food related products on the US system. However, in recent years, the “regulatory system has been increasingly influenced by the European food safety model”. Of note, South Korean regulators often cite the consumers’ right to know as the justification for increased regulatory requirements, and this forms the basis for many legislative proposals.

South Korea’s Food Sanitation Act establishes the legal basis for food safety related work conducted by the Ministry of Health and Welfare (MHW) and the Ministry of Food and Drug Safety (MFDS). Until recently, the food sanitation laws were administered by the South Korean Food and Drug Administration (KFDA). KFDA was elevated to ministerial level and renamed in March 2013, and MFDS was granted legislative authority under the new food safety legislation to implement guidelines. MFDS’s main role is to protect public health and safety, including the safety of food products. Under the Act, MFDS is responsible for enforcing the law, as well as establishing regulations, standards and specifications for domestic and imported foods including livestock products, functional foods, food additives, food packaging, containers and equipment. The MFDS also establishes testing methods and specifies maximum residue levels for agricultural chemicals and veterinary drugs, irradiated food, and contaminants.

Although substances used in the manufacture of food utensils, packaging, and containers are not considered food additives under the Food Sanitation Act, Article 2 of the Act indicates that substances that are used to sterilise or disinfect the surface of food contact materials do fall within the “food additive” definition because they may indirectly transfer to food. Under Article 8 of the Act, the manufacture, import, or sale of apparatus, containers or packages that contain poisonous or harmful materials that are likely to cause harm to humans is prohibited. Article 9 of the Act authorises MFDS to establish regulations, standards, and specifications for food packaging materials including requirements for the raw materials used in their manufacture. The manufacture, import, or sale of containers and packages that fail to comply with these standards and specifications is prohibited under the Act.

1. See USDA Foreign Agriculture Service, FAIRS Country Report: Republic of Korea-Food and Agricultural Import Regulations and Standards, GAIN Report no. KSI359 (December 26, 2013) available online
In December 2013, the Food Additive Standards Division of MFDS published updated standards for food packaging, ‘Standards and Specifications for Utensils, Containers and Packaging for Food Products’. The updated standards replace chapter 7 of South Korea’s ‘Food Code’, ‘Standards and Specifications for Equipment and Container/Packaging’. The updated standards have not yet been incorporated into the latest publication of the Korean Food Code, but are published separately, and are available in English here.

The new standards and specifications have four sections:

» general rules;
» common standards and specifications, including manufacturing standards and usage specifications;
» specifications for individual materials; and
» general test methods.

The second section on manufacturing standards bans the use of di-(2-ethylhexyl)phthalate (DEHP) unless no possibility exists that it will migrate into food, and imposes a limit of 100mg/kg of lead, cadmium, mercury, and hexavalent chromium in utensils, containers, and packaging.

The manufacturing standards prohibit the use of printing inks on the food contact side of utensils, containers, and packaging. They specify that printing inks applied to the non-food contact side must be sufficiently dry to comply with certain migration limits. Further, in the case of benzophenone, this substance must not migrate at levels greater than 0.6 mg/L. In the case of inks used to print the non-food contact side of flexible printing, residual toluene from ink compounds should be no greater than 2mg/ m2.

With respect to colourants, only those permitted as food additives are allowed, unless the colourant is melted glaze, glass, or enamel, or unless it can be shown that there is no migration of the colourant into the food. A ban on di-n-butylphthalate (DBP), benzyl-n-butylphthalate (BBP), and bisphenol A (BPA) in infant feeding bottles (including bottle nipples) is set out in the usage specifications subsection of the standards.

In December 2013, two new common manufacturing standards were added. Specifically, MFDS sanctioned the use of substances authorised by the US Food and Drug Administration (i.e., in 21 C.F.R. Part 170-199) for lubrication of food machines and utensils. In addition, MFDS indicated that recycled resins produced from the chemical depolymerisation and purification of polyethylene terephthalate (PET) and polyethylene naphthalate (PEN) may be used in the manufacture of food utensils, containers, and packaging.

The third section on specifications for individual materials is divided into subsections on:

» synthetic resins;
» cellophane;
» rubber;
» paper or processed paper;
» metal;
» wood;
» glass, ceramic, porcelain enamel and pottery; and
» starch.

The subsection on synthetic resins identifies 38 synthetic resins. The resin standards include a number of resins that are commonly used in food packaging applications, such as polyethylene (PE), polypropylene (PP), polystyrene (PS), and polylactide (PLA). Definitions are provided for the resins, which, in some cases, indicate the permitted monomers used to produce the resin. The resin standards also include limits on residual levels of some starting materials and other impurities, such as heavy metals. The standards include limits on extractable total non-volatile residue and specific migration specifications for some substances; however, it is important to note that the resin standards do not include positive lists for additives. (As noted above, a number of substances, such as certain phthalate plasticisers, are prohibited in the manufacture of food contact applications, but unlike the analogous legislation in the US or the EU, there is no binding positive list of additives that are permitted for use in the manufacture of plastics.) The standards and specification also identify the test methods that must be used to demonstrate compliance with the specifications.

The regulation on food contact paper notes that fluorescent whitening agents shall not be detected, which suggests that optical brighteners are prohibited in the manufacture of food contact paper. Although some optical brighteners are permitted for use in the US, it is common in Asian countries to prohibit such use.
The fourth section (of the new standards and specifications) on general test methods includes analytical tests for determining the level of certain individual metals, directions for preparing migration test solutions for specific food contact materials, an analytical test to determine the migration level of colourants, and a test to measure BPA. Testing guidelines are developed by the National Institute of Food and Drug Safety Evaluation (NIFDA), a research institute that conducts risk assessments and advises MFDS. The solvents and time/temperature conditions used in the testing are chosen based on the intended use of the packaging material, and are similar to those specified in other Asian countries such as Japan, Taiwan, and China.

If a company is interested in using a resin or other material that is not subject to a standard, the company may submit information to the MFDS to develop a new standard. Information on the composition of the material of interest, its method of manufacture, and intended use conditions must be submitted. In addition, information on manufacturing specifications and methods must be submitted to obtain approval of the new standard. Although South Korea has its own regulations for food contact materials that differ somewhat from other jurisdictions, demonstrating compliance with the standards and specifications should not be difficult for materials that comply with the requirements of Japan, the US, or the EU.

K-REACH
Article 3(7) of K-REACH excludes from its scope food, food additives, equipment, containers, and packages as defined under Article 2, paragraphs 1, 2, 4, and 5 of the Food Sanitation Act. Substances used as raw materials for containers and packages fall outside of the exclusion, as the terms containers and packages are defined as the finished good used to contain or wrap the food. As a consequence substances used to produce food contact materials in South Korea will be subject to K-REACH including the registration requirements for new substances and existing substances, where required. Because the REACH regulation in the EU also requires registration of substances used in food contact applications, EU companies may have an advantage over their US counterparts in being able to service the South Korean market because EU companies may already possess much of the data that would be needed for registration under K-REACH. The importation of finished food contact articles from the US should not be impacted, however, by K-REACH.

Herb Estreicher and Jeffrey A. Keithline, Partners Keller & Heckman LLC.

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