China's NHFPC Releases Key Food Packaging Standards

On September 29, 2015, China's National Health and Family Planning Commission (NHFPC) released a number of long-awaited draft Standards relating to food packaging materials on its website for public comment. The original announcement is available (in Chinese) at the following location: http://www.nhfpc.gov.cn/sps/s3593/201509/342e1a7b15d24c3781230c49ee1c6ba.shtml

Comments on these various Standards will be accepted by NHFPC until October 31, 2015.

Although the announcement included various Standards applicable to direct food additives, this Alert is intended to summarize the key Standards relating to food-contact materials in China. The announcement included several Standards that have been under development for some time and serve to consolidate a large number of existing National Standards (also known as “GB” Standards) relating to food-contact materials. These include the following Standards:

Standard Name

Food-Contact Use Paper, Paperboard and Paper Products
Food-contact Use Metal Materials and Products
Food-contact Use Rubber Materials and Products
Food-contact Use Plastic Resins
Food-contact Use Plastic Materials and Products
Food-contact Use Coatings and Coating Layers

The consolidation of these requirements from the myriad of different GB Standards that have been in place in China in past years is a welcome change for industry as it will greatly facilitate understanding by industry and, thus, regulatory compliance. We provide below a general summary regarding the key Standards.

Standard on Food-contact Use Plastic Resins ("Resin Standard") The Resin Standard pertains to resins (polymer) and polymer blends used to produce plastic articles for food contact applications, as well as plastic intermediates and thermoplastic elastomers. The Standard largely consolidates the approvals for plastic resins included in the List of 107 Resins that was published in response to the 2010 “Clean-up” procedures and prior GB Standards for food-contact resins, including those for Nylon 6 (GB 16331), polystyrene (GB 9692), polypropylene (GB 9693), polyethylene (GB 9691), PVC (GB 4803), PVdC (GB 15204), unsaturated polyester and glass fiber reinforced plastics (GB 13115), PET (GB 13114), and polycarbonate (GB 13116). The Standard includes various testing specifications relating to the overall migration limit (OML), potassium permanganate (KMnO4) consumption, heavy metals (as
lead), and certain sensory parameters.

**Standard on Food-contact Use Plastic Materials and Products ("Articles Standard")**

This Standard applies to food-contact plastic articles that will contact foods or which may potentially transfer their components to food during food production, processing, packaging, transportation, storage and use. These include plastic materials and products made only of plastics, multilayered plastic materials and products, multilayer materials, and thermoplastic elastomers. This Standard consolidates a number of Standards currently in place in China that apply to finished plastic articles (i.e., GB 16332, GB 9689, GB 17326, GB 9688, GB 9681, GB 14944, GB 9687, GB 17327, GB 14942, GB 9690 and GB 13113).

Consistent with the Resin Standard, the Articles Standard includes specifications relating to the OML, KMnO4 consumption, heavy metals (as lead), discoloration, and certain sensory parameters. The Standard also specifies that such articles must comply with any applicable specific migration limits (SML) or maximum residual limits (QM) set forth in the Resin Standard for component polymers.

In addition, the Articles Standard requires that such products be labeled in accordance with the requirements set forth under the **General Safety Requirements for Food Contact Materials and Articles**, which was announced for public comment on August 4, 2015. In particular, the Articles Standard states that label, instructions or enclosed documents must mark the materials subject to the requirements in Appendix A to Resin Standard and the plastic products made of polymer mixtures must be marked to note the main polymer materials.

**Standard on Food-Contact Use Coatings and Coating Layers ("Coatings Standard")**

This Standard will replace eight existing GB standards on individual types of food-contact coatings (GB 4805-1994, GB 7105-1986, GB 9680-1988, GB 9682-1988, GB 9686-2012, GB 11676-2012, GB 11677-2012, and GB 11678-1989). The scope of this Standard covers coatings applied to the direct food contact surface of food-contact materials and articles to form a layer/film in such a way as to create a protective layer and/or to impart technical performance. This language is expected to directly impact the interpretation of clearances on GB 9685 for “coatings.” Regulations applicable to coatings in other jurisdiction do not specify that the coating material must be in direct contact with food. Such regulations thereby permit the use of listed substances in the production of secondary coating layers separated from food. The new Coatings Standard appears to take a more restrictive approach, meaning that substances approved on GB 9685 for use in “coatings” would only permitted for use in the formulation of coatings on the food-contact surface of packaging materials.

The Coatings Standard also contains requirements on raw materials, sensory testing, and certain physicochemical specifications (OML, KMnO4 consumption, heavy metals, etc.). Though the Chinese authorities previously considered the inclusion of a “monomers list” in the appendix to the Standard, the announced draft has also taken a more restrictive approach. Specifically, Appendix A contains a list of 110 permitted resins. These include 101 polymers in the List of 107 Resins, and those permitted under the pre-existing GB coatings standards noted above. Notwithstanding this language, it would seem that substances approved for use in “coatings” on GB 9685 may likewise be used in the manufacture of coatings used in direct food-contact applications.

**Standard on Food-Contact Use Paper, Paperboard and Paper Articles ("Paper Standard")**
This Standard will replace the Hygienic Standard on Raw Paper for Food Packaging Use (GB11680-1989) and the Hygienic Standard on Food Containers Made of Plant Fibers (GB 19305-2003). The scope of this Standard captures paper, paperboard, paper articles as well as pulp molded articles used for food packaging applications. The Paper Standard sets requirements on raw materials used, sensory tests, physical and chemical specifications, residue and migration specifications, and microbial specifications for food-contact paper materials. In this regard, the Standard specifies that additives used in paper food packaging must comply with China's GB 9685 Standard. The Paper Standard also specifies the unique requirements for performing migration testing on paper filters, and provides for screening and/or alternative testing methods in scenarios where standard migration testing would not be suitable.

Standard on Food-Contact Use Rubber Materials and Articles ("Rubber Standard")

This Standard will replace the existing Hygienic Standard for Rubber Products Directly Exposed to Foodstuffs (GB 4806.1-1994). The Standard applies to food contact materials and articles composed primarily from natural or and synthetic rubber, excluding pacifiers and food-contact silicone rubber products. The Rubber Standard contains physicochemical specifications, which include overall migration, potassium permanganate consumption, heavy metals (as lead), as well as the migration of N-nitrosamines and zinc. Finished rubber products must be labeled in accordance with the requirements set forth under the General Safety Requirements for Food Contact Materials and Articles.

Notably, Appendix A to the draft Rubber Standard includes a positive list of the polymers permitted for use in synthetic rubber. For each polymer, the Appendix provides its CAS Registry Number, common name, SML/QM, as well as other use restrictions. Interestingly, although the scope of the Standard indicates that it does not apply to silicon rubbers, the final 6 substances listed in the Appendix (No. 31 to 36) are, in fact, silicones and siloxanes (e.g., polydimethylsiloxane).

Testing Method Standards Relevant to Food-Contact Materials

In addition, the announcement also contained various testing method Standards that pertain to the determination of residual impurities and/or their migration from food-contact materials (FCM). Such Standards generally track international testing methods (e.g., those established by ISO, OECD, ASTM, etc.) and should, upon their finalization, be relied upon by testing laboratories and industry to confirm the residual content and/or migration of these impurities in packaging materials. The Standards included in this announcement include the following:

- Food-contact materials and articles Determination of sulfur dioxide content in wooden material
- Food-contact materials and articles Determination of 1,3-xylylenediamine
- Food-contact materials and articles Determination of 1,3-butadiene
- Food-contact materials and articles Determination of 1-octene and tetrahydrofuran migration
- Food-contact materials and articles Determination of acrylonitrile monomer content and migration
Food-contact materials and articles Determination of terephthalic acid migration

Food-contact materials and articles Determination of ethylene oxide and propylene oxide content

Food-contact materials and articles Determination of triethylamine and tri-n-butylamine content

Food-contact materials and articles Determination of free phenols content and migration

Food-contact materials and articles Determination of vinyl acetate migration

Food-contact materials and articles Determination of ethylenediamine and hexamethylene diamine migration

We will be reporting on more details about each of these Standards in future China Regulatory Matters! updates. Should you have any additional questions or if we may be of further assistance in any way, please do not hesitate to contact us.