Regulation and Clearance Procedures for Food Packaging Materials in the People's Republic of China

**NOTICE:** The Chinese Ministry of Health (MOH) recently released the official guidelines and clearance procedures for unapproved food-contact substances currently in use in China, and is now accepting applications via what we have termed a “grandfathering” process. Chinese authorities are now accepting applications for the use of un-cleared substances and for expanded uses of currently approved substances. The deadline for these submissions will be June 1, 2010.

While procedures for clearing new, *i.e.*, not in current use, food-contact substances will be forthcoming, it is unclear when this formalized approval process will become official, and there may be a significant period of time after June 1 during which no submissions will be possible. Accordingly, we strongly urge companies interested in obtaining an explicit clearance for substances lacking a suitable regulatory status in China to take advantage of the currently available procedures and submit applications by the June 1 deadline, which are described in more detail below.  

I. Overview of Food Packaging Regulation in China

Food-packaging materials in China are regulated pursuant to the *Food Safety Law of the People's Republic of China* (P.R.C.). The Food Safety Law was passed by the National People's Congress and became effective on June 1, 2009 and now governs all issues of food quality and food safety in the P.R.C. In conjunction, Articles 36 and 62 of the Food Safety Law prohibit the importation, use or purchase of food-related products (e.g., food packaging materials, food-related utensils, equipment, etc.) not complying with an applicable Chinese Food Safety Standard. This provision further requires that food producers establish product verification systems detailing the specification and supplier information for food-related products, which are to be maintained for 2 years. Violations can result in substantial penalties, including fines on the order of 5 to 10 times the total value of the commodity sold provided that the total value exceeds 10,000 Renminbi.[i]

In this regard, China has developed a number of hygienic standards for a number of polymeric materials that are commonly used to produce food-contact articles, including polyethylene, polypropylene, polystyrene, polyvinyl chloride, polyethylene terephthalate, nylon, and polycarbonate. These Standards are promulgated by the Chinese MOH, and enforcement against non-complying products is carried out by the General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ). Generally, the standards for the resins establish physical and chemical requirements for the material (e.g., weight loss upon drying, combustion residue, and extractions using n-hexane), while the application-specific standards set forth migration limits and performance criteria for finished containers and packaging.

China is in the process of revising many of its existing Food Safety Standards (e.g., hygienic standards, testing standards, etc.) relating to food packaging materials, some of which are well out of date, to ensure harmonization with the new Food Safety Law. For example, China's Hygienic Standard for Food Packaging Paper (食食食食食食食食食食食食, GB 11680-1989) has been in place since 1989 and is currently being revised by a designated working group. In the meantime, however, existing standards are considered to be enforceable Food Safety Standards that must be complied with under the Food Safety Law provisions noted above. In recent months, substantial attention has been focused on China's “Hygienic Standards for Uses of Additives in Food Containers and Packaging Materials”
(食品接触材料，GB 9685-2008), which currently provides a positive list of additives permitted for use in food containers and packaging materials.[ii] An amendment to this Standard became effective on June 1, 2009, which now permits the use of 959 food additives in the manufacture of food packaging.

Notwithstanding this expansion of GB 9685, Chinese authorities were well aware that there are numerous substances in current use in China which, while safe for their intended use, were not explicitly cleared under an applicable Food Safety Standard. Accordingly, in May of 2009, industry was informally advised that the MOH would consider “provisional approval” of a number of unapproved materials currently in use in the P.R.C. for purposes of granting a temporary status for such substances. The draft “Interim Measures on Administrative Permission of New Species of Food Related Products” were published for comment on May 6, 2009 with the intent to provide for the clearance of products currently in use in China. However, these procedures remained unofficial as of the June 1, 2009 effective date for the Food Safety Law and GB 9685, and the official procedures still have not been released.

Thus, in order to prevent severe market disruptions by effectively prohibiting such substances, the MOH and five other PRC agencies issued a June 5, 2009 Joint Announcement indicating that there would be a one year transitional period, lasting until June 1, 2010, before enforcement actions began. The June 5 Announcement was ambiguously worded, but indicated that during the transitional period industry would be expected to conduct “self-examination” and reporting of materials in current use. This transition policy was intended to avoid a crush of approval applications for substances in use but not listed under an applicable Food Safety Standard in China. While the specific contours of the self-reporting and notification procedures remained uncertain, the June 5 Announcement strongly inferred that continued marketing would be permitted for those products currently in use in China for which an application for approval via the Ministry’s forthcoming “self-reporting” procedures would be submitted. These procedures are described in more detail below. II. Procedures for Clearing Unapproved Food-Contact Substances and Materials Currently in Use in China

MOH issued on December 4, 2009 a Circular on the Conduct of Food Packaging Material Clean-up Operations to various Chinese agencies regarding the production and use of unapproved food-contact materials. According to the Circular, companies are to assess the compliance of the food-contact materials currently in use in the P.R.C. and file submissions with the MOH to seek explicit approval for food-contact materials without a suitable status. The Circular set forth procedures for what we call “grandfather” approval of food contact substances – both additives and resins or polymers - currently-marketed in China.[iii] MOH is expected to publish two lists after review of the submissions by the Ministry’s technical experts. The first list will be titled, “List of Substances Which Can Be Used in Food Packaging Materials” (the so-called “positive list”),[iv] and the second list will be titled, “List of Substances Which are Prohibited for Use in Food Packaging Materials” (the so-called "negative list").[v]

According to the December 4 Circular, “serious actions will be taken against entities or personnel who continue to use the substances on the ‘List for Substances Which Are Prohibited for Use in Food Packaging Materials’ in food packaging materials and containers for manufactured or sold after the list is announced.” Based on this language, the circular implies that no enforcement action will be taken against non-compliant food-contact materials until the negative list is published. While there is no confirmed timeline for the publication of the negative list, the ambiguity concerning the timeline for its establishment allows for the possibility of a tacit extension the announced grace period.

On February 12, 2010 the Final MOH Guidance Documents for the “grandfathering” clearance were published on the
Nutrition and Food Safety Institute of the Chinese Center for Disease Control within MOH. This Guidance sets forth the data requirements and June 1, 2010 deadline for applications for approval of food packaging materials currently in use in the P.R.C. While the MOH may consider approving an application without all applicable data, this will be determined on a case-by-case basis. In short, an applicant will be able to demonstrate why certain data are not needed and if the MOH internal experts agree the substance will be approved. Approvals of such applications may well be delayed until the end of 2010, but the enforcement authorities have given strong (albeit informed) assurances that, absent a safety issue, currently marketed products can remain on the market until December 31, 2010.

In addition to evaluating the safety of a given substance, we understand that MOH will attach substantial weight to the existence of regulatory clearances for a given food-contact substance in the United States, European Union (EU), and Japan. It may be possible in certain instances to support a U.S. clearance via a "no migration" determination (i.e., by demonstrating that a substance is not reasonably expected to become a component of food) or that a substance is generally recognized as safe (GRAS) under its intended conditions of use. In addition, MOH will require that toxicity and migration data be provided where available.

As referenced above, there have been no indications from MOH as to when it will issue its final regulations on the process of seeking approval of new substances, i.e., those not currently marketed or used in China. It is possible that this will not occur until much later in 2010. Keller and Heckman LLP are attempting to ensure that such a mechanism be put into place by the June 1, 2010 deadline for “grandfather” applications. However, if no such procedure is in place for newly-marketed substances by that time, there will be no way to obtain approval, perhaps until next year, other than for substances qualifying for “grandfather” treatment. *

Should you have any questions regarding these developments, or if you require assistance in seeking approval for food-contact materials currently marketed in China, please contact Devon Hill at hill@khlaw.com or Mark Thompson at thompson@khlaw.com.

[i] See Article 85 of the Food Safety Law. Should the total value not exceed 10,000 RMB, fines are generally set at between 2,000 and 50,000 RMB.

[ii] GB 9685 clears the use of certain additives in various food contact polymers, coatings, adhesives, as well as paper and paperboard. These listings are often subject to specific migration limits (SML) which must be met under their intended conditions of use.

[iii] The circular provides details containing submissions for food-contact resins, and for “new species of food related products,” which is intended to cover all other food-contact products (i.e., “food packaging materials and containers,” “tools and equipment for food production and operation,” “additives for food contains, packaging materials, equipment and tools,” “detergents for food,” and “disinfectants for food”).

[iv] While the list of approved substances is referenced here as a “positive list,” we note that this will not serve as an exhaustive positive list, but rather a list of approved substances. In addition to the food contact materials and substances cleared in the current consolidated list (GB 9685-2008), the first positive list will include substances that are grandfathered according to the procedures noted in the recent circular.
[v] We note that, with regard to the negative list, the MOH has not provided any information on the form of a submission for materials that should be banned for food-contact uses; further, no explicit criteria have been established for determining which substances should be banned for these uses.