All Wrapped Up: China Finalizes Long-Awaited Standards for Food Packaging

On November 18, 2016, China’s National Health and Family Planning Commission (NHFPC) finalized the following Standards applicable to food-contact materials marketed in the People’s Republic of China in its announcement No. 15/2016:

- GB 9685-2016 Standard on the Uses of Additives in Food-Contact Materials and Articles
- GB 4806.1-2016 Standard on General Safety Requirements for Food-contact Materials and Articles
- GB 4806.6-2016 Standard on Food-contact Use Plastic Resins
- GB 4806.7-2016 Standard on Food-contact Use Plastic Materials and Articles
- GB 4806.8-2016 Standard on Food-Contact Use Paper, Paperboard and Paper Articles
- GB 4806.9-2016 Standard on Food-contact Use Metal Materials and Articles
- GB 4806.10-2016 Standard on Food-contact Use Coatings and Coating Layers
- GB 4806.11-2016 Standard on Food-contact Use Rubber Materials and Articles
- GB 5009.156-2016 Standard on Pre-treatment Methods for Migration Test of Food-Contact Materials and Articles

China has long maintained National Standards (also known as “GB” Standards) for food packaging, but these new Standards serve as a major step forward in the evolution of its food-contact regulatory scheme. These Standards also contain some additional changes from the draft versions that we will address in the coming weeks as needed.

In the meantime, we provide below a brief discussion of the final Standards, which will take effect on April 19, 2017 (except GB 4806.1-2016 and GB 9685-2016, of which the effective date is 6 months later, i.e., October 19, 2017).

**GB 9685-2016**

As noted in our prior CRM Alert (China Publishes Draft Amendment to the GB 9685 Hygienic Standard), a draft amendment to the GB 9685 Standard was released in January 2015. The final published Standard now incorporates more than 340 new approvals that were issued since the issuance of the prior version of the Standard (GB 9685-2008). These new listings arise from administrative approvals published in response to petitions filed under the 2010 “clean-up” procedures[2] and the current Management Rules for the Administrative Approval of New Varieties of Food Related Products.[3] In addition, existing clearances for more than 200 other listed additives have been expanded. The amended GB 9685 adopts a new format, with separate tables in Appendix A for the additives permitted in different packaging materials. For example, Table A.1 applies to additives used in plastics and Table A.2 pertains to additives in coatings and coating layers. The new Standard also has separate Appendices for the total specific migration limit (SML(T)) (Appendix B), SMLs for metal elements (Appendix C), polymer resin abbreviations (Appendix D), and a list of all permitted additives sorted by CAS number (Appendix E).

Perhaps most importantly, the amended GB 9685 Standard contains a number of categorical clearances that now permit the use of a number of unlisted substances. Article A.13(a) now allows the use of direct food additives...
ood additives listed in Table A.2 of China's General Standard for Use of Food Additives (GB 2760) in food packaging materials. However, Article 3.5 states that when used as additives of food-contact materials and articles, substances listed in GB 2760 should not have any technical effect to food with which they are in contact. GB 9685 Article A.13(b) of the amended Standard permits the use of sodium, potassium and calcium salts, including acidic salts and double salts, of acids, alcohols and phenols listed within Appendix A for use in food contact materials, provided that they comply with the restrictive requirements for the corresponding acid, alcohol or phenol. For example, if the listed acid were subject to an applicable SML, the sodium, potassium and calcium salts could be used, but would still be required to meet that limit. Further, the Standard clarifies that polymers having a molecular weight over 1000 daltons and which have been separately cleared in China for food-contact use may also be used as additives in food packaging. General Safety Requirements for Food-Contact Materials and Articles ("General Safety Standard") China's General Safety Standard (GSS) was notified to the World Trade Organization (WTO) in May 2015,[4] and announced for domestic comment in June 2015.[5] Per its title, the Standard applies to all food packaging materials and requires that they be safe and suitable for their intended use. The Standard also defines "non-intentionally added substances" (NIAS), and requires producers of food packaging materials to perform safety assessments to ensure their safety.[6] This language suggests that explicit approvals are not required for NIAS provided that the manufacturer performs an assessment and confirms safety. Most importantly, the GSS formally adopts the functional barrier doctrine in China. A definition of "functional barrier" has also been provided in Article 2.14, which is "a barrier in food-contact materials, made of one layer or multi-layer materials, that prevents the materials behind it from migrating to food to ensure that the migration of non-permitted substance to food is no more than 0.01 mg/kg, and the food-contact materials and articles comply with the requirements in Articles 3.1 and 3.2[7] when they are in contact with food under recommended conditions of use." Consistent with the EU Plastics Regulation,[8] Article 3.6 of the GSS permits the use of unlisted substances used behind a barrier provided that the substance migrates at less than 0.01 mg/kg, and is not a carcinogen, mutagen, reproductive toxin (CMR) or nano substance. This is a critical development that helps to bring China's food-contact regulations into line with more practical and modern requirements in other jurisdictions. Material Standards Our prior CRM Alert (China's NHFPC Releases Key Food Packaging Standards) detailed the draft Standards applicable to the following food-contact materials, which largely remain unchanged:

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

China currently maintains a myriad of GB Standards relevant to these packaging materials. The announcement of these new Standards consolidates and normalizes existing Standards and should thereby facilitate industry understanding and compliance. Certain of these Standards not only establish testing requirements for the material but also provide the explicit clearances for individual substances that can be used in the material. For example, the Standard on Food-contact Use Plastic Resins includes a list of 102 permitted polymer resins in Table A.1; this list is derived from prior GB Standards as well as
as the List of 107 Resins, which was published in response to the 2010 "clean-up" procedures.[9] Similarly, the
Standard on Food-contact Use Coatings and Coating Layers also includes a list of 105 base resins permitted for use
in coatings. **Testing Standards** The NHFPC announcement also contains final testing method Standards that pertain
to the determination of residual impurities and/or their migration from food-contact materials. Such Standards
generally track international testing methods (e.g., those established by ISO, OECD, ASTM, etc.) and will
ultimately be relied upon by testing laboratories and industry to confirm the residual content and/or migration of
these impurities in packaging materials. As noted above, these Standards will take effect in April and October of
2017 and will greatly improve the organization of China's food packaging Standards. This is another step taken by
the Chinese authority toward a more modern system of regulating food-contact materials.

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[6] See Article 3.5 of the GSS Standard. Article 3.1 requires that the materials migrating from food contact materials and articles to foods should be limited to an amount not endangering human health. Article 3.2 stipulates that when in contact with foods, food contact materials and articles should not cause any change of food composition, structure or colour, flavour and other properties, and should not produce technological effects of the food (except with special regulations). See Recital 28 and Article 13(2) of Regulation (EU) No. 10/2011, available at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0010&from=EN