

# How the FCN 772 Substances are Fairing During China's Transition to New Plastic Food Packaging Rules

By Martha Marrapese, John Eldred and Devon Hill

The People's Republic of China's (PRC or China) regulatory scheme for food contact materials is evolving and will continue to do so in the foreseeable future. Food contact additives are governed by the *Hygienic Standard for Uses of Additives in Food Containers and Packaging Materials*, GB 9685-2008, which was finalized on Feb. 11, 2009. This scheme is supplemented by a set of national standards for certain polymers and other materials (i.e., a polyethylene

(PE) standard), as well as standards for food packaging articles made from specific polymers (i.e., a standard for PE articles).

## A Positive List System for Plastic Food Packaging

As part of updating the 2003 version of GB9685, the PRC decided to greatly expand the number of substances approved as food packaging additives

based on a number of criteria, including their clearance status in the United States, the European Union (EU) and Japan. Industry submitted proposals to the Ministry of Health (MOH) for additives it wanted listed and a list was developed.

In February 2009, a "positive list" of 959 food additives authorized for use in food packaging materials was issued. Listed additives are either: (1) authorized for use without restriction; or (2) listed with specifications pertaining to "Maximum Permitted Quantity," "Specific Migration Limit" and "Not Detectable." Any additive not on the list, or the use of which does not conform to those specified in the standard, is prohibited for use after June 1, 2009, when GB 9685-2008 officially became effective.

## RadTech's Nomination of FCN 772 Substances for Provisional Listing in China Allows for their Continued Use There

Due to the short time between when the positive list was issued and its planned implementation date, companies were allowed to notify the MOH of additional additives that are currently used in food contact plastics in China that were not included in the published revisions to GB9685. The notifications allowed these additional



additives to be placed on a provisional list permitted to be used after June 1, 2009, and until their evaluation by MOH is completed. To be included on the provisional list, (1) notifiers had to commit to supporting the nominated substances as needed in the process to be implemented going forward; (2) the additives needed to be cleared for use in the EU, U.S. or Japan; and (3) they had to be in current use in China in food contact applications. Radtech submitted a petition within the agreed upon timeframe for the substances cleared by the industry project that resulted in the U.S. Food and Drug Administration Food Contact Notification (FCN) 772. Based on present knowledge and belief, no other companies or organized entities stepped forward to support the FCN 772 substances (i.e., tripropylene glycol diacrylate, trimethylolpropane triacrylate, trimethylolpropane ethoxylate triacrylate, bisphenol A diglycidyl ether diacrylate, and the difunctional alpha-hydroxy ketone photoinitiator).

### Anticipated Petition Procedures

On May 6, 2009, the PRC published a draft of “Interim Measures on Administrative Permission of New Species of Food Related Products” for comment. The PRC issued an updated notice on its process on Dec. 4. The MOH released an administrative procedure on how to file petitions for unlisted food contact materials.

The PRC’s outlined procedures for submitting a petition to obtain approval include proposed data and document requirements for new food contact materials, specifically chemical property data; applications and conditions of use; manufacturing process; toxicological data; and a statement—along with supporting documents on the material’s clearance status in other countries. An estimate

of dietary exposure would also be required for food contact substances.

“Good laboratory practice (GLP)-compliant labs” or “labs accredited by the MOH” will need to conduct required toxicological or migration testing. It is hoped that the final standard will clarify what is meant by GLP and that something less than the formal GLP requirements in the U.S. will be accepted. The toxicological safety assessment requirements for new food packaging materials and containers; food production and operation tools; equipment; and processing additives would be based on the level of migration of the new materials to foods, such that:

- For migration levels less than 0.01 mg/kg, structural-activity analysis data and other safety data or literature would be provided;
- For migration levels between 0.01 and 0.05 mg/kg (including 0.05 mg/kg), data from three mutagenicity studies (i.e., Ames test, in vitro mammalian chromosome aberration test, or bone marrow cell micronucleus test) would be provided;
- For migration levels between 0.05 and 5 mg/kg (including 5 mg/kg), three mutagenicity studies and a 90-day rat sub-chronic toxicity study would be provided; and
- For migration levels between 5 and 60 mg/kg, data from an acute oral toxicity study; three mutagenicity studies; a 90-day rat oral sub-chronic toxicity study; a reproductive toxicity study (two-generation reproduction toxicity study and teratogenicity study); and a chronic toxicity and carcinogenicity study would be provided.

If the petition is for a polymer with an average molecular weight greater than 1,000 daltons, the toxicology data of the monomers also would need to

be provided. Applications must be in Chinese. Once an application is officially accepted, it will be reviewed by the MOH within 60 days. If any new data are required in the final rules that were not outlined in the proposal, applicants will have one year to provide it.

In the Dec. 4 notice, the MOH expects industry to conduct a “self-examination” and provide the MOH with an inventory of non-listed substances currently in use in China. The MOH is surveying Chinese producers of resins and food contact materials to determine the list of resins and food contact materials currently in use in China that are not on the positive list.

It is expected that it will be six months or more before the MOH is prepared to accept applications for formal approval of new substances.

### The Current Situation: A Transitional Period and Possible Grandfathering

A provisional list has not been publicly issued. The interim measures do not mention a “provisional list,” but it is believed that the PRC still intends to address the status of substances nominated to that list either through an abbreviated filing or a “grandfathering” process.

On June 5, the MOH and five other PRC agencies announced a one-year transitional period, lasting until June 1, 2010, before enforcement actions begin. During this time, the MOH is expected to decide whether additional substances in current use in China can be added to the positive list under another round of “grandfathering.” In contrast, the provisional list approach formally outlined by authorities in April 2009 would have required provisionally listed items to pursue formal approval.

The MOH will determine if the substances identified through the self-exam processes should also be added to GB 9685 through a “grandfathering”

procedure. It is possible that clearance status in the U.S., EU or Japan may be sufficient for this purpose; however, additional data and an abbreviated application for approval could be required. Following this final stage, only substances approved by the MOH may be used in China. All parties wishing to use new substances will be required to submit new petitions.

### Summary of the Present Status

What is clear at present is that:

1. There will be no enforcement actions against food packaging materials that are not listed in GB 9685 before June 1, 2010, and perhaps beyond this date, provided that they are not "toxic or harmful."
2. There may be more opportunities to add materials to the authorized GB 9685 "positive" list before formal enforcement.
3. With respect to substances which are candidates for "grandfathering," the MOH is focusing on the "grandfathering" process now, rather than creation of a provisional list. Such a focus is beneficial to industry because "grandfathered" substances will be approved without further need for an application. This would mean that RadTech may not need to follow up its provisional listing petition for the FCN 772 substances with additional filings.
4. Even if such substances are not added to GB 9685 through a "grandfathering" procedure, we expect that the authorities will allow sufficient time for such substances to become the subject of formal applications for approval before they would be required to be removed from the market.
5. Thus, with respect to provisional substances, industry must remain attentive. If nominated provisional substances are not supported

by the MOH either through "grandfathering" or abbreviated filings, industry will no longer be able to use the substances without resorting to the Chinese FCN procedure. It is, therefore, in industry's best interest to seek continued use of these substances through good faith participation in the MOH's process.

Additional announcements are anticipated which we expect will clarify the overall situation. ▀

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## FCN 772 Opens Food Packaging Market to UV/EB

Food Contact Notification (FCN) 772, approved by the FDA on March 7, 2008, is a great success for UV/EB technology. This industry-sponsored initiative resulted in FDA clearance of several commonly used multifunctional acrylates in a variety of food packaging applications. These substances are approved for use on their own, in combination with each other, or with other reactants, polymers, additives, pigments, etc., which are permitted for the intended use under 21 C.F.R. The substances covered by the FCN are: tripropylene glycol diacrylate; trimethylolpropane triacrylate; trimethylolpropane ethoxylate triacrylate; bisphenol A diglycidyl ether diacrylate; and, optionally, Esacure One photoinitiator, cured by either ultraviolet or electron beam irradiation. FCN 772 applies to uses of these substances as coatings or components of coatings on polymeric substrates; paper and paperboard; metal substrates; or as a component in adhesives. Note that only companies listed in the FCN as the notifiers and their customers may rely on the clearance to manufacture food-packaging materials and the acrylates and photoinitiators must be supplied by an FCN-listed company. For more information, contact one of the listed suppliers found at <http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=fcslisting&id=772>.