

Food, Drug, and Cosmetic Packaging Materials Committee Highlights and Accomplishments 2018

For over 60 years, PLASTICS' Food, Drug, and Cosmetic Packaging Materials Committee (FDCPMC) has been working with government officials, scientific institutions, and industry partners worldwide to develop science-based regulations that protect public health, support innovation, and enhance trade in packaging technologies designed to preserve and protect the global food supply. Throughout its history, the Committee has made such notable contributions as ushering through U.S. Congress legislative changes that authorized FDA to implement the Food Contact Notification Program, sponsoring scientific evaluations underpinning FDA's Threshold of Regulation, and participating in nearly every major rulemaking related to food contact materials around the world. Here is a snapshot of the Committee's most recent accomplishments.

Government Affairs Subcommittee

- FDA decided to exercise enforcement discretion for importers of food contact substances under the Foreign Supplier Verification Programs rule, citing as its basis points the FDCPMC and Food Packaging Coalition have repeatedly emphasized to the agency – that food contact substances are already subject to a comprehensive regulatory framework, are unlikely to introduce microbiological contamination into the food supply, and pose a low risk to consumers.
- Owing in large part to advocacy by the FDCPMC and Food Packaging Coalition, Congress appropriated sufficient funds and directed FDA to continue operating the Food Contact Notification program throughout FY 2019.
- During the January 2018 government shutdown, FDA acted in accordance with the Food Packaging Coalition's request for Food Contact Notifications (FCNs) pending at the time to be suspended rather than receive letters of objection. This is a welcome change from the October 2013 government shutdown, when FDA required notifiers to refile FCNs and start the 120-day review period anew when the government reopened.
- The FDCPMC provided extensive recommendations to FDA to update its *Guidance for Industry: Preparation of Premarket Submissions for Food Contact Substances: Chemistry Recommendations*. These included a request that FDA clarify migration testing requirements for certain conditions of use, permit the use of alternative food simulants in certain migration testing scenarios, and add to the Guidance those consumption factors that FDA has derived since the original publication.
- FDA invited the FDCPMC to provide the agency recommendations to improve the efficiency of the Food Contact Notification (FCN) program. Work is now underway to provide ideas and to create educational opportunities for FDA staff to learn about packaging innovations and manufacturing processes.

International Subcommittee

- The FDCPMC filed comments on Food Safety and Standards Authority of India's (FSSAI) Draft "Food Safety and Standards (Packaging) Regulation, 2018," strongly urging FSSAI to permit the use of food contact materials that are compliant with more comprehensive regulations in the United States and/or European Union, at least until the Indian Standards are updated to provide appropriate specifications for all food contact materials that are currently on the market in India and throughout the world.
- The FDCPMC provided recommendations to the Vietnamese government to improve the National Technical Regulations on the Safety Limits of Synthetic Resin Implement, Container and Packaging in Direct Contact with Foods and the Safety Limits of Container-Packages of Milk and Milk Products (QCVN 12-1:2017/BYT).
- The FDCPMC China Work Group provided the Chinese government recommendations for revision of GB 31604.1 *National Food Safety Standard on General Rules for Migration Testing for Food Contact Materials and Articles*.
- The FDCPMC MERCOSUR Initiative was again represented at the MERCOSUR Food Commission's first three quarterly meetings of 2018. PLASTICS has also empowered Brazil's ABIQUIM to serve as a local partner representing the Brazilian industry on food contact materials regulatory issues.

Program Subcommittee

- The Program Subcommittee organized the June 11-13, 2018, Food Packaging Summit, which attracted 104 participants from government and industry. The Summit opened with a special workshop on Proposition 65 responsibilities for suppliers of food contact materials. It continued with presentations from U.S. FDA officials and industry experts.

Medical and Personal Care Products Subcommittee

(in collaboration with PLASTICS Pharmaceutical and Medical Device Applications Committee)

- After two meetings and subsequent communications with the FDCPMC, FDA postponed the deadline for Type III Drug Master Files to be submitted in the electronic Common Technical Document (eCTD) format until May 5, 2019. FDA has indicated its willingness to work with PLASTICS on alternative electronic submission formats for Type III DMFs.

Technical Subcommittee

- Project Passport published updated versions of the following resources:
 - *Guideline for Risk Communication for the Global Food Contact Supply Chain*
 - *SVHC, Authorization, Restriction – Use of Industry Data to Trigger Regulatory Action under EU REACH*
 - *Considerations for Packaging Suppliers Regarding the Declaration of Major Allergens and Gluten*
 - *Good Manufacturing Practice Guideline for the Plastic Food Packaging Supply Chain*

FDCPMC Communications

- The FDCPMC continues issuing “Friday Updates” to keep our members informed on developing regulatory issues.
- The FDCPMC provided members with timely reviews of regulatory developments, including:
 - a. Funding status of FDA’s Food Contact Notification Program
 - b. FDA’s decision to exercise enforcement discretion for FSMA Foreign Supplier Verification Program rule
 - c. Alleged microplastics in bottled water – related studies, media coverage, and talking points
 - d. OEHHA NSRL for vinylidene chloride
 - e. European Commission directive on single-use packaging
 - f. CA Safer Consumer Products Regulations - Food packaging included in DTSC’s final 2018-2020 Priority Product Work Plan
 - g. GFSI Benchmarking Requirements v 7.2
 - h. Washington State legislative ban of PFAS in food packaging
 - i. NGO Food Additive Petition on phthalates out of abeyance
 - j. Meeting with USP regarding Biocompatibility Standards
 - k. FDA postponement of deadline for Type III DMF submissions to meet eCTD filing requirements
 - l. NTP draft report on CLARITY-BPA Study
 - m. European Commission final rule on BPA in food contact coatings and varnishes
 - n. CPSC revised Final Rule on Determinations Regarding Certain Plastics
 - o. 9th Amendment to the Plastics Regulation
 - p. India’s draft Food Safety and Standards (Packaging) Regulation, 2018