

Food, Drug, and Cosmetic Packaging Materials Committee Highlights and Accomplishments 2018 - 2019

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.

- The FDCPMC provided Health Canada information and contacts to address the agency's questions about the possible presence and safety of microplastics in bottled water and about nanomaterials used in food contact applications.
- The FDCPMC is working with PLASTICS' EHS+ Committee and Recycling Committee to participate in the European Commission's public consultation addressing the interface between product, chemical, and waste legislation.

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 China Work Group commented on the revised draft GB 9683 Standard for Composite Food Contact Materials and Articles.
- The FDCPMC China Work Group responded to extensive surveys issued by Shanghai FDA to inform the revision process for the *National Food Safety Standard on Food-contact Use Plastic Resins* (GB 4806.6-2016) and the *National Food Safety Standard on Food-contact Use Plastic Materials and Articles* (GB 4806.7-2016). Our recommendations included to keep the Standards separate instead of combining them, to clarify that testing requirements apply to final articles and not to resins or masterbatches, and to amend the aggressive n-hexane extractables testing protocol that polyolefins in use safely worldwide continually fail.
- 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. PLASTICS is filing comments on public consultations in the four MERCOSUR Member States on Proposed Resolution 05/18,

revoking GMC Resolution No. 32/07 on the positive list of additives for use in food contact plastics.

- The FDCPMC is compiling a list of food contact substances used in Japan that do not yet appear on the Japanese government's proposed legally-binding positive list.

Program Subcommittee

- The Program Subcommittee organized the 14th Biennial International Symposium on Worldwide Regulation of Food Packaging, June 11-14, 2019 in Baltimore, MD. Experts from government, industry and scientific institutions around the world convened to discuss regulatory issues surrounding global marketing of food packaging materials, efforts to manage those issues, and emerging priorities

Medical and Personal Care Products Subcommittee

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

After two meetings with FDCPMC member companies and Keller & Heckman legal counsel, FDA published a new draft guidance outlining the eCTD submission requirements for Drug Master Files (DMFs). The new guidance includes a proposal that FDA will permanently exempt Type III DMFs from the eCTD requirements. Although the proposal suggests that the eCTD format will still be recommended for Type III DMFs where possible, the Agency decided to amend the guidance to permanently exempt Type III DMFs from the eCTD requirements.

Technical Subcommittee

- A Technical Subcommittee member representative presented "*Good Manufacturing Practice Guideline for the Plastic Food Packaging Supply Chain*" at AICM's 2018 Food Contact Forum in Beijing.
- FDCPMC, in collaboration with Eagle Certification, provided a webinar on the Food Safety Modernization Act (FSMA) to members of the Institute of Packaging Professionals (IoPP). The webinar explained how rules to implement the FSMA apply to manufacturers along the supply chain for packaged food, a subject of considerable confusion in the marketplace.
- The Technical Subcommittee and FDCPMC staff are monitoring scientific studies on microplastics in the environment, actions by government authorities, media coverage, and industry activities related to microplastics. Information gathered to date has been shared with various regulators worldwide who have requested assistance determining

what is known and what is not yet known about microplastics on the basis of sound scientific investigations.

- 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 issued a response to the American Academy of Pediatrics July 23, 2018, Statement on Food Additives and Child Health.
- The FDCPMC provided members with timely reviews of regulatory developments, including:
 1. Funding status of FDA’s Food Contact Notification Program
 2. FDA’s decision to exercise enforcement discretion for FSMA Foreign Supplier Verification Program rule
 3. Alleged microplastics in bottled water – related studies, media coverage, and talking points
 4. OEHHA NSRL for vinylidene chloride
 5. European Commission directive on single-use packaging
 6. CA Safer Consumer Products Regulations - Food packaging included in DTSC’s final 2018-2020 Priority Product Work Plan
 7. GFSI Benchmarking Requirements v 7.2
 8. Washington State legislative ban of PFAS in food packaging
 9. NGO Food Additive Petition on phthalates out of abeyance
 10. Meeting with USP regarding Biocompatibility Standards
 11. FDA postponement of deadline for Type III DMF submissions to meet eCTD filing requirements
 12. NTP draft report on CLARITY-BPA Study

13. European Commission final rule on BPA in food contact coatings and varnishes
14. CPSC revised Final Rule on Determinations Regarding Certain Plastics
15. 9th Amendment to the Plastics Regulation
16. India's draft Food Safety and Standards (Packaging) Regulation, 2018
17. 11th Amendment to the Plastics Regulation
18. Court opinion on motion to dismiss GRAS lawsuit
19. A summary of the Food Safety Commission of Japan's *Guidelines for Assessment of Human Health Effects of Foods from Food Apparatus, Containers and Packages*, finalized in May of 2019
20. Opportunity to submit to U.S. Embassy Japan a list of food contact substances that are not included on the Japanese government's proposed legally binding positive list
21. Opening of MERCOSUR Member State public consultations on Proposed Resolution 05/18, revoking GMC Resolution 32/07 on additives for use in food contact plastics
22. OEHHA proposed MADL for n-hexane
23. U.S. FDA's amendment to the food additive regulations to no longer permit use of seven synthetic flavoring substances
24. Thailand's proposal to transform voluntary standards for various food contact materials into mandatory standards subject to enforcement in 2019