THE
NATIONAL LAW REVIEW

FDA’s Approach to New Packaging Factor Database Explained at KH Seminar

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Wednesday, October 9, 2019

The U.S. Food and Drug Administration (FDA) is developing a comprehensive, updated database of packaging factors (PFs) for Food Contact Substance Notifications (FCNs). The new database will include PFs for 550 foods as compared to the PFs for 49 foods that are currently available, explained Jessica R. Cooper, Ph.D., Chemistry Team Lead in FDA’s Office of Food Additive Safety (OFAS), Division of Food Contact Substances (DFCS), at Keller and Heckman’s 20th annual Food Packaging Law Seminar, held September 24-25, 2019.

Data requirements for FCNs and food additive petitions require the notifier to estimate the potential consumer exposure to a food contact substance (FCS), or the estimated daily intake (EDI). First, a dietary concentration is estimated by multiplying the amount of the substance that is expected to migrate to food by the approximate fraction of the daily diet expected to contact materials containing that substance. Next, the EDI is determined by multiplying the concentration of the FCS in the daily diet by the total food intake (typically 3000 grams of food per person per day).

PFs are used to estimate the dietary concentration to an FCS used in single-use food packaging. PFs include both consumption factors (CFs)—the fraction of the daily diet expected to contact specific packaging materials—and food type distribution factors (fT)—the distribution of packaging use among food types aqueous (aq), acidic (ac),

alcoholic (al) and fatty (fat).

Current CFs were first developed almost 40 years ago in 1980, Dr. Cooper stated in explaining why FDA is re-evaluating PFs. She also noted that new food products, such as almond milk, kefir, and energy drinks, have been introduced since the current CFs were developed and that there have been recent technological advances in packaging.

FDA is using a comprehensive approach to developing updated PFs, Dr. Cooper said, noting that many of the current PFs were determined on an individual basis as information became available. She added that the Agency is using a variety of collection methods, such as market surveys using UPC codes or labels. The updated database also will link data from FDA's internal polymer packaging project to retail data and have detailed information on individual products.

As for the current status of the project, Dr. Cooper explained that FDA has determined preliminary PFs. The next steps are to complete data analysis, write-up the method that the Agency used, then publish a public notice in the *Federal Register* and allow for comments and for submission of additional data.

Dr. Cooper also discussed FDA's Center for Safety and Applied Nutrition (CFSAN) online submission module (COSM), which was launched on September 6, 2019. She explained that it integrates FDA guidance documents within the interface, allows faster data entry, and allows the user to save their progress and continue working on the submission at a later time. The COSM system automatically creates a formatted roadmap within a "zip" file that can be saved locally and submitted to FDA either on DVD/CD-ROM or electronically via FDA's electronic submissions gateway.