

U.S. FDA Makes Progress in Updating Packaging Consumption Factors for FCNs

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The U.S. Food and Drug Administration (FDA) is in the process of revising the default factors the Agency recommends using to estimate exposure to food contact substances (FCSs) in Food Contact Notifications (FCNs), including consumption factors (CFs) and food type distribution factors (fTs). In a June 8, 2022 presentation before the PLASTICS Industry Association, Dr. Allan Bailey, Chief of FDA's Chemistry Review Branch in the Division of Food Contact Substances (DFCS), indicated that FDA is considering a substantial increase to the CF for polyethylene terephthalate (PET), and a decrease to the CFs for paper and polystyrene (PS).

As [previously reported on Packaginglaw.com](#), these factors are an integral part of most FCNs, as they are used to estimate dietary intake levels for components of an FCS that are expected to migrate from a packaging material to food, which then informs FDA's assessment of the safety of the substance. FDA's CFs were first developed more than 40 years ago. Although incremental changes have occurred over the years, FDA has not comprehensively updated these packaging factors for many years. Because food packaging has changed substantially since the last "re-set" of the factors, FDA indicated that a comprehensive update to these factors is warranted.

Dr. Bailey's presentation to PLASTICS included a table of the current draft CFs and fTs under development by the Agency. Notably, FDA's draft proposes an increase in the CF for PET from 16% to 45.6%, almost triple the current CF, while the draft CFs for coated and uncoated paper have decreased by approximately an order of magnitude, from 20% and 10%, respectively, to 1.7% (excluding liquid cartons) and 1.6%. The Agency also shared draft CFs for food packaging made of glass and metal, as well as new categories of packaging, including liquid cartons and stand-up pouches. Importantly, the values presented by Dr. Bailey are considered by the Agency as a "work in progress."

Dr. Bailey explained that in developing the draft CFs, FDA has relied on data from Euromonitor International (EI), a market research group that maintains a database of industry information. This information allowed FDA to create an outline of the types of food and beverages sold in the U.S., along with the corresponding types of packaging. FDA was able to categorize the data by year, region, poundage, and sub-types of food to refine its CFs. Dr. Bailey stated that the EI database allowed FDA to take a "new approach" to revising the CFs, as previous approaches (primarily based on retail scanner data) presented challenges in creating accurate CFs.

Although FDA has made substantial progress on its latest draft, Dr. Bailey noted certain caveats affecting the accuracy of the draft CFs in their current form. For example, the draft CFs do not take into account packaging expected to contact fresh meats, fruits, and vegetables, or food consumed outside the home (e.g., at a restaurant). The new draft factors also do not account for consumption of tap water. Additionally, FDA's analysis did not include an assessment of the amount of food expected to contact caps, closures, liners, and secondary packaging (i.e., incidental contact with packaging outside of the immediate food contact layer). FDA encouraged industry to work with the Agency to ensure the accuracy of these newly derived factors, and to fill in the gaps in FDA's analysis.

Dr. Bailey did not provide a specific timeframe for the Agency to conclude its revision of the packaging factors. However, FDA has indicated that, when the revisions are complete, the revised packaging factors will be incorporated into FDA's [Guidance for Industry: Preparation of Premarket Submissions for Food Contact Substances \(Chemistry Recommendations\)](#) and released in DRAFT form for public comment.

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