

Updating Packaging Factors used to estimate dietary exposure to food contact substances

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FDA

Abstract

FDA's safety assessment for premarket approval of food contact substances (FCS) relies on evaluating probable dietary exposure to the FCS, its constituents, and its impurities from the proposed use and other authorized uses of the FCS, and ensuring that they are supported by the available toxicological information. Probable dietary exposure is typically determined by combining migrant levels in food with information on packaging uses. For single use packaging, FDA recommends using packaging factors (PF), which includes consumption factors (CF) and food-type distribution factors (FT), to estimate dietary exposures to migrants from the intended use of the FCS. FDA developed many of the PFs contained in the 2007 Chemistry Guidance for premarket submissions for FCSs over 40 years ago and may no longer reflect the current packaging market. As part of updating the 2007 Chemistry Guidance, FDA has drafted updated PFs using several data sources, focusing primarily on the Euromonitor International (EI) data on consumer goods, specifically food poundage data in Packaging and Packaged Food. EI captures data according to their own defined categories and organizational structure. As such, FDA had to restructure the data to remove duplication and recategorize the data to align with FDA packaging type definitions.

Data Curation. FDA removed information not relevant to the assessment.

- FDA removed all data that was not food poundage, data from years other than 2016, and columns that are the same across all data sets such as Region (North America) and Country (USA).
- EI organizes the data according to hierarchal levels (0-5). Increasing hierarchal level number corresponds to more specific description of the food or beverage, but EI does not break down all categories to level 5. FDA defined the lowest levels for the EI food types and removed all higher category data to avoid including duplicative food poundage data.
- EI organizes the data by pack type groups and their sub-categories, pack types. FDA selected for the specific pack types and removed duplicate information, such as total packaged food poundage for each food type.

Modification. EI data includes food poundage totals for both the primary and the secondary packaging of a food item. FDA manually corrected the packaging totals to account for the secondary packaging.

NOTE: FDA definitions of primary and secondary packaging differ from EI, so FDA had to manually review every instance of secondary packaging to correct the data.

Categorization

- FDA manually reviewed and assigned FDA food types and food categories for all the EI food categories; *this allows for calculation of the food type distribution factors.*
- FDA manually reviewed and mapped the EI pack types and pack type groups to the FDA general packaging categories according to the food contact surface as the EI assignments do not necessarily align with FDA's categories. *This allowed for calculation of packaging factors for the FDA general packaging categories.*
- Most of EI pack types do not include polymer identify information. FDA identified if the food contact surface was a polymer, its identity and added that information to the dataset. *This allowed for calculation of polymer specific packaging factors.*

Calculations.

- FDA calculated the CF and f_T s for the general packaging categories (Table 2) and for specific polymers (Table 3). The CF and f_T equations are shown in Figure 1.

Introduction

FDA's safety assessment for premarket approval of food contact substances (FCS) relies on evaluating probable dietary exposure to the FCS, including all constituents, as a result of the proposed use and other authorized uses, and ensuring that such dietary exposures are supported by the available toxicological information.

Probable dietary exposure is typically determined by combining migrant levels in food with information on packaging uses. For single use packaging, FDA recommends the use of packaging factors (PF), which includes consumption factors (CF) and food-type distribution factors (f_T), to estimate dietary exposures to the various migrants from the intended uses of the FCS. PFs describe the fraction of the daily diet expected to contact specific packaging materials and the specific types of food that make up that fraction (see Figure 1). Many of the PFs contained in the 2007 Chemistry Guidance for FCSs (see Table 1) were developed over 40 years ago. With the recent technological innovations in the food packaging industry, FDA's PFs are long overdue for an update.

FDA is in the process of updating the 2007 Chemistry Guidance (*Guidance for Industry: Preparation of Premarket Submissions for Food Contact Substances (Chemistry Recommendations)*), with the additional goal of updating all the PFs at one time.

NOTE: The updated PFs in this poster are DRAFT and not currently for use in regulatory assessments.

Materials and Methods

To calculate PFs, we used data from Euromonitor International (EI), an independent research company, who provides an online database called Passport, that specializes in information on consumer goods in 80 countries. FDA purchased Passport data from EI for the relevant food contact industries: Packaging and Packaged Food in the United States. Relevant to our purposes, they reported data on the annual retail food poundage in the United States for foods by the type of packaging generally, such as metal, glass, and paper, and specifically, such as bottles and trays. EI captures data according to their own defined categories and organizational structure. As such, FDA had to restructure the data to remove duplication and recategorize the data to align with FDA packaging type definitions.

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Calculations.

- FDA calculated the CF and f_T s for the general packaging categories (Table 2) and for specific polymers (Table 3). The CF and f_T equations are shown in Figure 1.

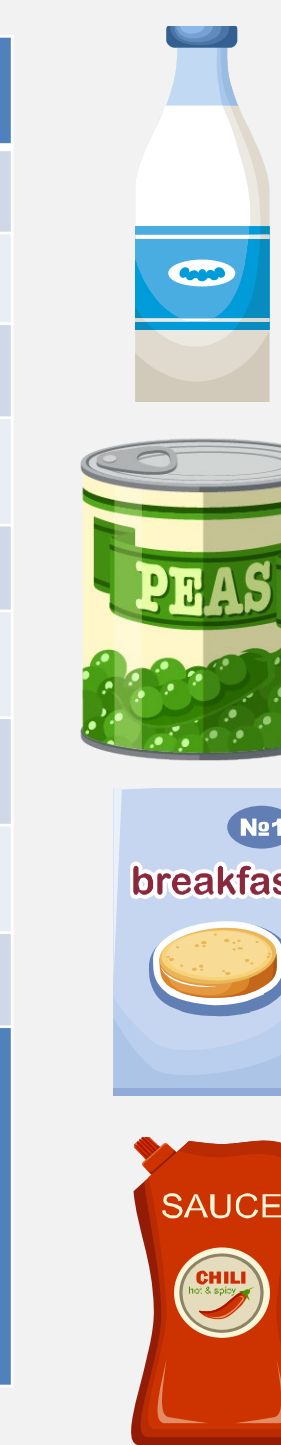


Results and Discussion

Table 1. Current Packaging Factors (CF and f_T s) for General Packaging Categories from the 2007 Chemistry Guidance

General Packaging Category	CF	Food type distribution factors (f_T)			
		Aq.	Acidic	Al.	Fatty
Glass	0.1	0.08	0.36	0.47	0.09
Metal-uncoated	0.03	0.54	0.25	<0.01 ^a	0.20
Metal- polymer coated	0.17	0.16	0.35	0.40	0.09
Paper-uncoated and clay coated	0.1	0.57	<0.01 ^a	<0.01 ^a	0.41
Paper- polymer coated	0.2	0.55	0.04	<0.01 ^a	0.40
Polymers	0.4	0.49	0.16	<0.01 ^a	0.34
All Polymers ^b	0.8				

^a- 1% or less
^b- originates from summing CFs for metal-polymer coated, paper-polymer coated, and polymer



CF - The fraction of the daily diet expected to contact specific packaging materials

$$CF(\text{paper}) = \frac{\sum \text{Mass food (paper)}}{\sum \text{Mass all foods (all packaging)}}$$

f_T - Distribution of packaging use among food types for each packaging material

$$\text{Paper } f_T(\text{aq}) = \frac{\sum \text{Mass aq. food in paper}}{\sum \text{Mass food (paper)}}$$

Figure 1. Equations and definitions for consumption factors (CFs) and food type distribution factors (f_T s), using aqueous foods in paper packaging as an example.

Analysis.

The current PFs for the general packaging categories are shown in Table 1. The draft updated PFs for the general packaging categories are shown in Table 2 and the draft updated PFs for specific polymers are shown in Table 3. We note the following about the consumption of foods packaged in various materials when comparing the current and updated CFs:

- Overall the use of polymer packaging for food has increased.
- Food packaged in polymer coated metal has increased, which appears to correlate to an increase in the use of metal beverage bottles and a decrease in foods packaged in glass.
- The use of paper packaging for food has decreased when comparing uncoated, clay coated and polymer coated paper in Table 1 to uncoated paper, coated paper and liquid cartons in Table 2.

Limitations of Draft updated Packaging Factors

- Assignments of the food contact surface to specific polymer types for specific packaging types were predominately made on the basis marketing reports rather than direct analysis.
- Only addresses packaging layers that touch food.
- Does not include fresh meat, fish, & poultry or fresh fruits & vegetables
- Does not include food consumed at restaurants or comparable retail establishments.
- Does not include caps, closures or liners.

Table 2. Draft updated Packaging Factors (CF and f_T s) for General Packaging Categories

General Packaging Category	CF	Food type distribution factors (f_T)						
		Aq.	Acidic	LA	HA	Fat	Fat-dry	Dry
Glass	0.07	0.04	0.17	0.66	0.08	0.04	<0.01 ^d	<0.01 ^d
Metal-uncoated	0.01	0.17	0.05	0.27	<0.01 ^d	0.12	0.20	0.19
Metal-coated	0.21	0.09	0.53	0.33	<0.01 ^d	0.05	0.00	0.00
Paper-uncoated	0.03	0.27	<0.01 ^d	<0.01 ^d	<0.01 ^d	0.21	0.33	0.18
Paper-coated ^c	0.01	0.00	0.78	<0.01 ^d	<0.01 ^d	0.22	<0.01 ^d	<0.01 ^d
Liquid Cartons	0.03	0.61	0.29	0.02	<0.01 ^d	0.08	0.01	<0.01 ^d
Polymer-Flexible ^c	0.11	0.28	<0.01 ^d	0.03	<0.01 ^d	0.27	0.19	0.23
Stand-up Pouches	0.01	0.13	0.40	0.03	<0.01 ^d	0.18	0.12	0.15
Polymer-Rigid	0.52	0.55	0.37	<0.01 ^d	0.01	0.05	0.02	0.01

^c- Polymer flexible does not include Stand-up Pouches; Paper-coated does not include Liquid Cartons

^d- 1% or less as per 2007 Chemistry guidance

Table 3. Draft updated Packaging Factors (CF and f_T s) for Polymers

Polymer	CF	Food type distribution factors (f_T)						
		Aq.	Acidic	LA	HA	Fatty	Fatty-dry	Dry
PET	0.38	0.47	0.46	<0.01 ^a	0.01	0.05	0.01	<0.01 ^a
HDPE	0.11	0.73	0.17	<0.01 ^a	<0.01 ^a	0.01	0.01	0.08
LDPE	0.10	0.53	0.14	0.01	<0.01 ^a	0.23	0.02	0.08
LLDPE	<0.01 ^a	<0.01 ^a	<0.01 ^a	1.00	<0.01 ^a	<0.01 ^a	<0.01 ^a	<0.01 ^a
PP	0.05	0.29	0.04	<0.01 ^a	<0.01 ^a	0.02	0.53	0.12
PO	0.01	0.16	<0.01 ^a	<0.01 ^a	<0.01 ^a	0.73	<0.01 ^a	0.11
PS	0.03	0.51	<0.01 ^a	<0.01 ^a	<0.01 ^a	0.34	0.12	0.03
Total Polymer ^b	0.69							

^a-CF and f_T values reported as less than 1% as per 2007 Chemistry guidance

^b-Total polymer does not include not include metal-coated

Future Work.

- Revising the Packaging Factors (CF and f_T s) to include fresh meat, fish, & poultry and/or fresh fruits & vegetables
- Calculating other use specific packaging factors, for example, beverage cans, food cans, adhesives

Abbreviations: Aq., aqueous food; Al., alcoholic food; LA, low alcohol food; HA, high alcohol food; Fat, fatty food; fat-dry, fatty-dry food; PET, poly(ethylene terephthalate); HDPE, high density polyethylene; LDPE, low density polyethylene; LLDPE, linear low density polyethylene; PO, polyolefin; PS, polystyrene;

Conclusion

In conclusion, using data from EI, we have calculated updated packaging factors (CFs and f_T s) for the general packaging categories, for specific polymers, and for beverage and food cans. While there are some limitations, we recommended the draft updated PFs be considered for inclusion in the update to the *Guidance for Industry: Preparation of Premarket Submissions for Food Contact Substances (Chemistry Recommendations)*.