UPDATE 2013

The Safety of Styrene-Based Polymers for Food-Contact Use 2013

Submitted to: U.S. Food and Drug Administration (FDA) Food Additive Master File (FAMF) Update

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I. Introduction

This report provides an update on estimated dietary exposure to styrene from the use of polystyrene food-contact articles in the United States. To accomplish this objective, a survey was used to collect data from polystyrene resin suppliers on the amount of polystyrene used in food-contact applications. The survey also collected data on residual levels of styrene in the types of polystyrene used to make these articles. The data has been used to do the following, as presented in this report:

- Recalculate/update a valid Consumption Factor (CF) for polystyrene for use of the resins in contact with food;
- Compare the current data to the recalculation of the polystyrene CF that was reported by K. Cassidy and S. Elyashiv-Barad of FDA in a 2007 journal article;¹
- Estimate the expected migration of styrene from the polystyrene products fabricated from the resins; and
- Calculate dietary exposure to styrene from the food-contact uses of polystyrene.

II. Survey

In July 2012, a third party electronically submitted survey forms regarding polystyrene usage to 7 resin supplier companies.² The survey submitted to these companies asked them to confidentially report to the third party survey manager 2011 data regarding the total pounds of polystyrene supplied and their intended food-contact applications, as well as the corresponding residual styrene levels. Information was requested for general purpose polystyrene (GPPS), high impact polystyrene (HIPS), polystyrene foam (PS), and expandable polystyrene (EPS) foam. Companies were asked to provide poundage and residual information for the following categories of food-contact applications:

- General Purpose Polystyrene (GPPS)/Oriented Polystyrene (OPS)
 - o produce baskets
 - o pie containers
 - o cookie trays

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¹ K. Cassidy and S. Elyashiv-Barad, *US FDA's Revised Consumption Factor for Polystyrene Used in Food-Contact Applications*, 24(9) FOOD ADDITIVES & CONTAMINANTS, 1026-31 (2007).

In addition, survey forms also were transmitted to 24 converter companies, *i.e.*, companies that purchase polystyrene from resin supplier companies and "convert" the raw resin into articles or materials used as parts of articles. We note that one of the resin suppliers also is a converter. Because the third party received responses from all of the polystyrene manufacturing companies and approximately 38% of the converter companies (responses were received from 9 of the 24 converter companies to which the survey forms were transmitted), this report is based primarily on the responses of the suppliers. Generally, the information obtained from the suppliers was consistent with the information received from the converters.

- o deli hinged take-out containers
- o bakery cake domes
- o cutlery (disposable serviceware)
- o plates, bowls, platters (disposable serviceware)
- o cups (disposable serviceware)
- High Impact Polystyrene (HIPS)
 - yogurt containers
 - creamers
 - o cold drink cups
 - o lids
 - o single-service condiment containers
 - o plates (single-service and reusable)
 - o stirrers
- Polystyrene Foam
 - o meat/poultry trays (prepackaged and store packaged)
 - o cold drink cups
 - o hot drink cups
 - o single-service plates/bowls
 - o hinged take-out containers
 - o school lunch and other food service trays
 - o other foam sheet (i.e., egg cartons and fruit and vegetable trays)
- Expanded Polystyrene (EPS) Foam
 - o cups and containers
 - o coolers (grape and fish boxes)

By November 2012, the completed surveys were received from all 7 resin companies. The following is a summary of the composite results received, including the total resin poundage values and weighted average residual styrene levels.

Table 1: Aggregated Survey Results

GPPS Application	Pounds	Residual Styrene (ppm)
Cookie trays	34,795,180	153
Cutlery	241,831,398	446
Deli hinged	182,378,357	155
Dome lids	29,671,049	232
Plates, bowls, platters	116,189,850	230
Other▲	141,904,167	1079

^{▲ -} When the number of responses received for polystyrene applications were insufficient to mask the data consistent with antitrust guidelines and protect the identity of the responding companies, the third party survey manager grouped those responses into the "other" category.

HIPS Application	Pounds	Residual Styrene (ppm)
Cold drink cups	354,817,193	396
Lids	233,006,326	409
Plates	127,451,641	207
Other [▲]	176,714,959	1219
PS Foam Application	Pounds	Residual Styrene (ppm)
Hinged take out containers	224,607,072	345
Meat/poultry trays	245,394,344	371
School lunch/food service trays	49,436,957	385
Single-service plates/bowls	187,934,742	458
Other [▲]	23,172,720	718
EPS Foam Application	Pounds	Residual Styrene (ppm)
Cups and containers	305,391,230	71
Other [▲]	9,735,000	586

^{▲ -} When the number of responses received for polystyrene applications were insufficient to mask the data consistent with antitrust guidelines and protect the identity of the responding companies, the third party survey manager grouped those responses into the "other" category.

III. Consumption Factor Update

The postulated dietary consumption of a substance depends on the potential level in food (*e.g.*, a value derived from migration studies or calculations intended to reflect the results of migration studies) on the fraction of an individual's diet likely to contact packaging materials containing the substance. FDA employs the term, "Consumption Factor" (CF), to describe the portion of the diet likely to contact specific packaging materials. A CF is the ratio of the weight of food contacting a specific packaging material to the weight of all food packaged. FDA has established default CF values both for packaging material categories (*e.g.*, metal, glass, polymer, and paper) and for specific polymers. In addition, to account for the variable nature of food contacting each packaging material, FDA has developed Food-Type Distribution Factors (f_T) for each packaging material to indicate the fraction of the food contacting each material that is aqueous, acidic, alcoholic, and fatty. Using these parameters, along with the experimentally or mathematically determined potential migration levels, the possible dietary exposure to a component of food-contact articles can be determined.

FDA's current default CF and f_T values are set forth in Appendix IV of the Agency's "Guidance for Industry: Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations" (April 2002; December 2007). The Agency clearly indicates in its "Chemistry Recommendations," however, that it will rely on these values only as default values and is prepared to substitute alternative CF values where valid data are

available that justify the use of a more precise estimate. This report presents refined CF values in accordance with FDA's guidance.

FDA has established a default CF value of 0.14 for polystyrene. The 0.14 CF for polystyrene was established with the issuance of the current version of the "Chemistry Recommendations," and this 0.14 polystyrene CF was, in turn, based on the details set forth in the Cassidy and Elyashiv-Barad article.

The poundage values obtained in the current survey were used to calculate an updated set of CFs for polystyrene, using the same approach as set forth in the Cassidy and Elyashiv-Barad article cited above. More specifically, the following assumptions were employed in these calculations:

- Density: 1.04 g/cm³ for GPPS and HIPS, and 0.05 g/cm³ for PS foam and EPS foam
- Thickness: 0.025 cm (0.01 in) for GPPS and HIPS, and 0.51 cm (0.2 in) for PS foam and EPS foam
- Food-to-surface area ratio: FDA's default assumption for food packaging generally of 10 g food/in²
- Daily food intake per person: FDA's default assumption of 3000 g food/person/day
- US Population: 311,000,000 for 2011 (the year of the survey)³

As an example, the sub-CF for GPPS used in the "Cookie trays" application is calculated to be 0.0027 based on the following:

Sub-CF = $(34,795,180 \text{ lb/year}) \times (454 \text{ g/lb}) \times (10 \text{ g food/in}^2) \div [(1.04 \text{ g/cm}^3) \times (0.01 \text{ in}) \times (16.4 \text{ cm}^3/\text{in}^3) \times (365 \text{ days/year}) \times (311,000,000 \text{ people}) \times (3000 \text{ g food/person/day})] = 0.0027$

In a similar manner, sub-CF values for each of the surveyed applications have been calculated, and the results summarized below.

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In the 2007 Cassidy and S. Elyashiv-Barad article, FDA used the US population data for the year 2000 (282 million people) because the Agency relied upon poundage data from 2000.

Table 2: Sub-CF Values⁴

Applications		Sub-CF
GPPS Applications	Produce baskets	0.0012
	Pie containers	0.0016
	Cookie trays	0.0027
	Deli hinged	0.0143
	Dome lids	0.0023
	Cutlery	0.0189
	Plates, bowls, platters	0.0091
	Cups	0.0083
HIPS Applications	Yogurt containers	0.0046
	Creamers	0.0021
	Cold drink cups	0.0277
	Lids	0.0182
	Single-service condiment containers	0.0071
	Plates	0.0100
PS Foam Applications	Meat/poultry (pre-packaged)	0.0136
	Meat/poultry trays (store packaged)	0.0063
	Cold drink cups	0.0006
	Hot drink cups	0.0006
	Single-service plates/bowls	0.0153
	Hinged take out containers	0.0183
	School lunch/food service trays	0.0040
	Other foam sheet	0.0007
EPS Foam Applications	Cups and containers	0.0248
	Coolers (grape and fish boxes)	0.0008

We note that FDA, in its 2007 Cassidy and Elyashiv-Barad article, excluded certain polystyrene food-contact resin poundage from the total used in the calculations used to establish the CF values. More specifically, the article states, "we did not include consumption values for certain disposable articles ... such as cups, plates, bowls, and cutlery items." As noted above, FDA's term "Consumption Factor" (CF) describes the fraction of the daily diet expected to contact specific packaging materials (*i.e.*, food sold in packages), and does not necessarily include food that contacts articles used by consumers. Thus, by convention, FDA does not include in its CFs certain disposable materials or articles used by consumers where the food is not sold in the disposable materials or articles. Thus, so that the re-calculation of the CF for polystyrene will be parallel to that calculated by FDA in 2007, the following applications would not have been encompassed in FDA's 2007 calculation and, therefore, also are being excluded here:

• GPPS: cutlery; plates, bowls, platters; cups

• HIPS: cold drink cups; single-service condiment containers; plates

We note that Table 2 individually lists the consumption factors for polystyrene applications that were aggregated into the "other" categories in Table 1.

 PS foam: cold drink cups; hot drink cups; single-service plates/bowls; school lunch/food service trays

• EPS foam: no exclusions

Based on the foregoing, a refined table of sub-CFs, principally for the purpose of updating FDA's overall "official" polystyrene CF for food packaging applications, is summarized below. We note that the polystyrene applications described in Table 3 are identical to the applications included in the 2007 Cassidy and Elyashiv-Barad article.

Table 3: Refined Sub-CFs

Applications		Sub-CF
GPPS Applications	Produce baskets	0.0012
	Pie containers	0.0016
	Cookie trays	0.0027
	Deli hinged	0.0143
	Dome lids	0.0023
HIPS Applications	Yogurt containers	0.0046
	Creamers	0.0021
	Lids	0.0182
PS Foam Applications	Meat/poultry (pre-packaged)	0.0136
	Meat/poultry trays (store packaged)	0.0063
	Hinged take out containers	0.0183
	Other foam sheet	0.0007
EPS Foam Applications	Cups and containers	0.0248
	Coolers (grape and fish boxes)	0.0008

Thus, the totals of the sub-CFs for each polystyrene resin type and for polystyrene, based on the refined sub-CFs in the table above, are summarized below. The sub-CF totals included in the table below include only the applications included in the 2007 Cassidy and Elyashiv-Barad article.

Table 4: Refined Sub-CF Totals

Application	CF
GPPS	0.0221
HIPS	0.0249
PS Foam	0.0389
EPS Foam	0.0256
Overall	0.1115

IV. Styrene Migration Calculations

The migration levels of styrene from polystyrene to the contacted food, when used in the applications enumerated above, were estimated using the diffusion modeling approach employed

previously by Lickly *et al.*⁵ Specifically, the Lickly *et al.* paper set forth the following migration equations for estimating migration of styrene to food, as follows.

$$M_{t} = c_{P,0} \alpha K_{P,F} \left(1 - e^{Z^{2}} \operatorname{erfc} Z \right)$$
(1)

$$M_{t} = 2c_{P,0}\sqrt{D_{p}t/\pi} \tag{2}$$

where:

 $M_t = migration$ at time t in $\mu g/cm^2$

 $Z = (D_P t)^{1/2} / \alpha K_{P,F}$

erfc = error function c (complementary error function)

 $c_{P,0}$ = initial concentration of migrant in polymer

 α = volume of food (or simulant) in mL/cm²

 D_P = diffusion coefficient of migrant in polymer

t = time of food contact in seconds

 $K_{P,F}$ = partition coefficient of migrant between polymer and food

As noted in Lickly *et al.*, equation (1) is best suited in instances in which equilibrium partitioning may have an effect on migration, such as is the case involving contact with aqueous foods. In all other cases (such as migration to fat/oil or short exposure times to aqueous foods), the more simplified equation (2) is appropriately used. In instances in which a sequence of times and temperatures is appropriate to represent the use conditions of a polymer (such as polystyrene) in contact with food, the following equation is appropriate.

$$M_t = 2C_{P,0}\sqrt{1/\pi} \left[\sqrt{D_{P1}t_1 + D_{P2}t_2} \right] \tag{3}$$

With respect to a determination of $K_{P,F}$ (the partition coefficient of styrene between polymer and food), Lickly *et al.*, sets forth the following regression equation explicitly for styrene partitioning between GPPS or HIPS and aqueous food.

$$Log K = 2.2725 - 1773.9(1/T)$$
(4)

where T is the temperature in degrees Kelvin.

Finally, Lickly *et al.*, sets forth the following regression equations for calculating the diffusion of styrene through polystyrenes:

GPPS:
$$\log D_P = 2.724 - 4932(1/T)$$
 (5)

HIPS:
$$\log D_{\rm P} = 1.9407 - 4623.7(1/{\rm T})$$
 (6)

PS Foam and EPS Foam:
$$\log D_P = 4.543 - 4407.6(1/T)$$
 (7)

Lickly, T.D., Breder, C.V., and Rainey, M.L., A Model for Estimating the Daily Dietary intake of a Substance from Food-Contact Articles: Styrene from Polystyrene Food-Contact Polymers, REGULATORY TOXICOLOGY AND PHARMACOLOGY, 1995, **21**, 406-417.

Most of the applications addressed in the current survey are comparable, or identical, to those also addressed in Lickly *et al.*, and, consequently, the same times and temperatures were used in the current evaluation as those employed by Lickly *et al.* In addition, the same proportions of subdivision for sub-uses in a given category as employed by Lickly *et al.* also were used in the current evaluation. For example, deli-hinged take out containers, for which a single sub-CF was calculated, was further subdivided into uses for aqueous food (50% of the uses, or a factor of 0.5) and fatty food (a factor of 0.5).

However, there are several applications covered in the current survey that were not included in the previous evaluation by Lickly *et al.*, and, consequently, the following conditions were employed, using similar times and temperatures as those employed by Lickly *et al.*

- GPPS bakery cake domes: 7 days at 24°C.
- HIPS creamers: 60 days at 24°C.
- HIPS cold drink cups: 1 hour at 24°C.
- HIPS single-service condiment containers: 50% aqueous (factor of 0.5) and 50% fatty (factor of 0.5), both 1 hour at 24°C.
- Other foam sheet (egg cartons and fruit and vegetable trays): 10 days at 4.4°C.
- EPS coolers (grape and fish boxes): 10 days at 4.4°C.

Thus, the following conditions and "subdivision factors" were employed in the calculations.

Table 5: Subdivision Factors

Application	Food Type	Conditions	CF	Factor
GPPS (OPS)				
produce baskets	aqueous	4.4°C/7 d	0.0012	1
pie containers	aqueous	4.4°C/30 d	0.0016	1
cookie trays	aqueous	24°C/60 d	0.0027	1
deli hinged take-out containers	aqueous	24°C/1 hr	0.0143	0.5
	fatty	24°C/1 hr		0.5
bakery cake domes	aqueous	24°C/7 d	0.0023	1
cutlery (disposable serviceware)	aqueous	24°C/1 hr	0.0189	0.6754
	aqueous	54°C/1 hr		0.0754
	fatty	24°C/1 hr		0.2246
	fatty	54°C/1 hr		0.0246
plates, bowls, platters (disposable	aqueous	4.4°C/1 hr	0.0091	0.3
serviceware)	aqueous	24°C/1 hr		0.3
	aqueous	54°C/1 hr		0.3
	fatty	4.4°C/1 hr		0.033
	fatty	24°C/1 hr		0.033
	fatty	54°C/1 hr		0.033
cups (disposable serviceware)	aqueous	24°C/1 hr	0.0083	1

HIPS				
yogurt containers	fatty	66°C/30 min + 4.4°C/60d	0.0046	1
creamers	fatty	24°C/60 d	0.0021	1
cold drink cups	aqueous	4.4°C/1 hr	0.0277	1
Lids	aqueous	24°C/1 hr	0.0182	1
single-service condiment	aqueous	24°C/1 hr	0.0071	0.5
containers	fatty	24°C/1 hr		0.5
plates (single-service and reusable)	aqueous	4.4°C/1 hr	0.01	0.3
	aqueous	24°C/1 hr		0.3
	aqueous	54°C/1 hr		0.3
	fatty	4.4°C/1 hr		0.033
	fatty	24°C/1 hr		0.033
	fatty	54°C/1 hr		0.033
PS Foam				
meat/poultry trays – prepackaged	fatty	4.4°C/10 d	0.0136	1
meat/poultry trays – store	fatty	4.4°C/10 d	0.0063	1
packaged				
cold drink cups	aqueous	24°C/1 hr	0.0006	1
hot drink cups	aqueous	54°C/1 hr	0.0006	1
single-service plates/bowls	aqueous	24°C/1 hr	0.0153	0.425
	aqueous	54°C/1 hr		0.425
	fatty	24°C/1 hr		0.075
	fatty	54°C/1 hr		0.075
hinged take-out containers	aqueous	24°C/1 hr	0.0183	0.125
	aqueous	54°C/1 hr		0.375
	fatty	24°C/1 hr		0.125
	fatty	54°C/1 hr		0.375
school lunch and other food	aqueous	24°C/1 hr	0.004	0.5
service trays	fatty	24°C/1 hr		0.5
other foam sheet	aqueous	4.4°C/10 d	0.0007	1
EPS Foam				
cups and containers	aqueous	24°C/1 hr	0.0248	0.25
	aqueous	54°C/1 hr		0.75
coolers (grape and fish boxes)	fatty	4.4°C/10 d	0.0008	1

V. Calculated Levels of Styrene Migration and Dietary Exposure

As discussed above and depicted in the table above, the levels of styrene migration and corresponding dietary exposures have been calculated. For the sake of demonstrating how the calculations were performed, included below are examples of the calculations performed that cover: (1) fatty food contact (PS Foam meat/poultry trays - prepackaged), (2) a short duration of aqueous food contact (GPPS deli hinged take-out containers), and (3) a long duration of contact with aqueous food (GPPS produce baskets).

- PS Foam meat/poultry trays prepackaged: The time and temperature of contact used for this application is 4.4°C (277.4°K) for 10 days. Using equation (7), the diffusion coefficient is calculated to be 4.5 x 10⁻¹² cm²/sec. Using equation (2), along with this diffusion coefficient, the time (10 days, equivalent to 864000 seconds), the residual styrene concentration (352 parts per million (ppm)), and the "standard" PS foam density (0.05 g/cm³), the migration is calculated to be 25.3 ppb. Finally, using the calculated migration along with the CF for PS Foam meat/poultry trays prepackaged (0.0136) and the "subdivision factor" for PS Foam meat/poultry trays prepackaged (1), the dietary concentration (DC) for styrene from this application is calculated to be 0.3438 parts per billion (ppb).⁶
- GPPS deli hinged take-out containers (aqueous): The time and temperature of contact used for GPPS deli hinged take-out containers used in contact with aqueous foods is 24°C (297°K) for 1 hour. Using equation (5), the diffusion coefficient is calculated to be 1.3 x 10⁻¹⁴ cm²/sec. Using equation (2), along with this diffusion coefficient, the time (1 hour, equivalent to 3600 seconds), the residual styrene concentration (155 ppm), and the "standard" GPPS density (1.04 g/cm³), the migration is calculated to be 0.81 ppb. Finally, using the calculated migration along with the CF for GPPS deli hinged take-out containers (0.0143) and the "subdivision factor" for GPPS deli hinged take-out containers (aqueous) (0.5), the DC for styrene from this application is calculated to be 0.0058 ppb. ⁷
- GPPS produce baskets: The time and temperature of contact used for GPPS produce baskets is 4.4°C (277.4°K) for 7 days. Using equation (4), the equilibrium partition coefficient is calculated to be 7.55 x 10⁻⁵ and, using equation (5), the diffusion coefficient is calculated to be 8.8 x 10⁻¹⁶ cm²/sec. Using equation (1), along with these partition and diffusion coefficients, the time (7 days, equivalent to 604800 seconds), the residual styrene concentration (195 ppm), and the "standard" GPPS density (1.04 g/cm³), the migration is calculated to be 3.41 ppb. Finally, using the calculated migration along with the CF for GPPS produce baskets (0.0012) and the "subdivision factor" for GPPS produce baskets (1), the DC for styrene from this application is calculated to be 0.3438 ppb.⁸

The migration levels and DCs for all of the applications have been calculated in a similar manner, as summarized below.

^{6 (1)} \times (0.0136) \times (25.3 ppb) = 0.3438 ppb.

⁷ $(0.5) \times (0.0143) \times (0.81 \text{ ppb}) = 0.0058 \text{ ppb}.$

^{8 (1)} \times (0.0012) \times (3.41 ppb) = 0.0041 ppb.

Table 6: Migration Levels and DCs

Application	Food Type	Conditions	Migration (ppb)	DC (ppb)
GPPS (OPS)				
produce baskets	Aqueous	4.4°C/7 d	3.41	0.0041
pie containers	Aqueous	4.4°C/30 d	6.91	0.0110
cookie trays	Aqueous	24°C/60 d	30.2	0.0815
deli hinged take-out containers	Aqueous	22°C/1 hr	0.81	0.0058
	Fatty	24°C/1 hr	0.81	0.0058
bakery cake domes	Aqueous	24°C/7 d	15.6	0.0360
cutlery (disposable serviceware)	Aqueous	24°C/1 hr	2.32	0.0296
	Aqueous	54°C/1 hr	13.4	0.0191
	Fatty	24°C/1 hr	2.32	0.0098
	Fatty	54°C/1 hr	13.4	0.0062
plates, bowls, platters (disposable	Aqueous	4.4°C/1 hr	0.31	0.0008
serviceware)	Aqueous	24°C/1 hr	1.20	0.0033
	Aqueous	54°C/1 hr	6.91	0.0189
	Fatty	4.4°C/1 hr	0.31	0.0001
	Fatty	24°C/1 hr	1.20	0.0004
	Fatty	54°C/1 hr	6.91	0.0021
cups (disposable serviceware)	Aqueous	24°C/1 hr	3.61	0.0300
HIPS				
yogurt containers	Fatty	66°C/30 min + 4.4°C/60d	46.6	0.2141
Creamers	Fatty	24°C/60 d	91.6	0.1923
cold drink cups	Aqueous	4.4°C/1 hr	0.78	0.0216
Lids	Aqueous	24°C/1 hr	2.85	0.0519
single-service condiment containers	Aqueous	24°C/1 hr	2.37	0.0084
	Fatty	24°C/1 hr	2.37	0.0084
plates (single-service and reusable)	Aqueous	4.4°C/1 hr	0.41	0.0012
	Aqueous	24°C/1 hr	1.44	0.0043
	Aqueous	54°C/1 hr	7.48	0.0244
	Fatty	4.4°C/1 hr	0.41	0.0001
	Fatty	24°C/1 hr	1.44	0.0005
	Fatty	54°C/1 hr	7.48	0.0025

PS Foam				
meat/poultry trays – prepackaged	Fatty	4.4°C/10 d	25.3	0.3438
meat/poultry trays – store packaged	Fatty	4.4°C/10 d	29.7	0.1873
cold drink cups	Aqueous	24°C/1 hr	2.64	0.0016
hot drink cups	Aqueous	54°C/1 hr	12.6	0.0076
single-service plates/bowls	Aqueous	24°C/1 hr	7.10	0.0462
	Aqueous	54°C/1 hr	34.0	0.2214
	Fatty	24°C/1 hr	7.10	0.0081
	Fatty	54°C/1 hr	34.0	0.0391
hinged take-out containers	Aqueous	24°C/1 hr	5.35	0.0122
	Aqueous	54°C/1 hr	25.6	0.1760
	Fatty	24°C/1 hr	5.35	0.0122
	Fatty	54°C/1 hr	25.6	0.1760
school lunch and other food service	Aqueous	24°C/1 hr	5.97	0.0119
trays	Fatty	24°C/1 hr	5.97	0.0119
other foam sheet	Aqueous	4.4°C/10 d	22.7	0.0159
EPS Foam				
cups and containers	Aqueous	24°C/1 hr	1.10	0.0068
	Aqueous	54°C/1 hr	5.28	0.0982
coolers (grape and fish boxes)	Fatty	4.4°C/10 d	42.1	0.0337

Based on the foregoing, the sum of the individual exposure contributions food packaging uses included in the Cassidy and Elyashiv-Barad 2007 article yields an updated dietary exposure for styrene of 1.66 ppb in the diet, and an updated styrene exposure of 2.20 ppb in the diet has been calculated for all polystyrene uses (*i.e.*, the sum of all of the above food-contact applications, including the applications excluded by Cassidy and Elyashiv-Barad).

VI. Analysis and Conclusions

Based on the data collected in the survey, an updated overall polystyrene CF of 0.1115 has been calculated. Furthermore, as demonstrated in Tables 2 and 3, the overall polystyrene 0.1115 CF has been subdivided into more specific categories; specifically, Table 3 contains the applications that were included in the Cassidy and Elyashiv-Barad 2007 article, but further sub-divided. Based on our analysis of the survey data, we respectfully suggest that the updated CF of 0.1115 be adopted for polystyrene, along with the major subdivisions for GPPS, HIPS, PS foam, and EPS foam.

Using the updated CFs for the specific uses, an updated dietary exposure for styrene of 1.66 ppb in the diet has been calculated for the food packaging uses included in the Cassidy and Elyashiv-Barad 2007 article, and an updated styrene exposure of 2.20 ppb in the diet attributable to food packaging has been calculated for all polystyrene uses. The latter is lower than the 3.0 ppb in the diet dietary concentration determined in the 1995 Lickly *et al.* paper.

As described in detail in *Toxicological Review of Styrene (CAS 100-42-5) Submitted to the Food and Drug Administration by the Styrene Information and Research Center November 18*, 2002,

the acceptable daily intake (ADI) for styrene is considered to be 90,000 μ g/person/day. The dietary concentration of 2.20 ppb of styrene attributable to food packaging using FDA's default assumption that an individual consumes a daily diet of 3.0 kilograms of food (all solids and liquids) results in an estimated daily intake (EDI) of 6.6 μ g/person/day (0.0066 mg/person/day). Therefore, the calculated EDI (6.6 μ g/person/day) is more than four orders of magnitude less than the ADI.