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The Safety of Styrene-based Polymers for Food-contact Use 2002

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The purpose of this report is to provide an update on an estimate of dietary exposure to styrene from the use of polystyrene food-contact articles, as compared to an estimate that was reported by Lickly *et al*.[1] Specifically, Lickly *et al*. reported that the estimated daily intake (EDI) for styrene from the use of polystyrene in food-contact applications was 9 μg/person/day. Furthermore, the purpose of this report is to compare the EDI with the acceptable daily intake (ADI) for styrene to demonstrate the safe use of polystyrene in contact with food.

Background

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) and 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; the 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 for both packaging categories (e.g., metal, glass, polymer, and paper) and specific polymers. In addition, to account for the variable nature of food contacting

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[1] Lickly, T.D., Breder, C.V., and Rainey, M.L., 1995, "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*, **21**, 406-417. This report describes the method used to estimate potential exposure to styrene undertaken by the Ad Hoc Styrene Migration Task Group of SPI's Food, Drug, and Cosmetic Packaging Materials Committee (FDCPMC) and summarized in "The Safety of Styrene-Based Polymers for Food-Contact Use," issued on April 14, 1993.

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 Recommendation," (April 2002). 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.

It is always important to use appropriate CF values to estimate possible exposure when presenting data to FDA in a food additive petition or another data file. However, it is even more critical to use CF values that are as well defined as possible for elucidating potential exposure to components of well-established plastics. The alternative is to rely on the default CF values, which are based on reasonable estimates of the total use of a given material but do not reflect refinements for specific uses. The use of refined CF values in lieu of the default values can permit more accurate estimates of potential exposure to be calculated based on the specific "real-life" uses.

FDA's has established a default CF value of 0.1 (i.e., 10% of the diet) for polystyrene; the 0.1 CF for polystyrene was established with the issuance of the prior version of the "Chemistry Recommendations," which was entitled "Recommendations for Chemistry Data for Indirect Food Additive Petitions," issued in June 1995. Prior to 1995, the polystyrene CF had a value of 0.08 (8%).[2] The paper published by Lickly *et al*. constituted an estimation of the dietary exposure of styrene from the use of food-contact polystyrene based on two fundamental considerations: (1) it included a refinement of the 0.08 polystyrene CF (*i.e.*, the CF in effect until June, 1995), based on industry survey data on the uses of polystyrene in food-contact applications, and (2) it was based on diffusion modeling of migration of styrene from polystyrene to the contacted food. Both of these considerations will be addressed below with regard to their impacts on the current dietary exposure to styrene from the use of polystyrene in contact with food.

Refined Polystyrene Consumption Factors

To address the validity of the polystyrene CF refinement, survey data once again have been employed. In deriving the refined polystyrene CF values, Lickly *et al*. employed two sources of information: data published in the January 1991 issue of *Modern Plastics* and data from a 1990 Franklin Associates study conducted for the Foodservice and Packaging Institute.

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2 The polystyrene CF increased from 0.08 to 0.1 with the issuance of the revised set of guidelines in June 1995. It is important to recognize that, as noted in the 1995 "Recommendations for Chemistry Data for Indirect Food Additive Petitions," changes in the CF values, including that for polystyrene, were made to round the previous values up or down to achieve values having one decimal figure. Thus, this change does not reflect the acquisition of actual food-contact use data on any of the materials for which CF values have been modified, including polystyrene.

These poundage data were employed by Lickly *et al*. by assuming that FDA's total default polystyrene CF was correct and using the data to refine the CF by subdividing the total CF in accordance with the distribution of poundage amongst the polystyrene food-contact applications. Thus, the validity of the approach employed by Lickly *et al*. with regard to the refined CF values may be assessed by considering the relative changes in these refinement categories over time.

As there is not a readily available update for the Franklin Associates study, data from subsequent issues of *Modern Plastics* have been used to address the changes in the annual poundage of polystyrene used in food-contact applications. These data are summarized below in Tables 1 (for polystyrene used in food packaging applications) and Table 2 (for polystyrene used in disposables applications.) In summarizing these data, two observations must be made. First, the years included in the tables range from 1991 to 1999 – the first year in the range (1991) is the year of the issue of *Modern Plastics* from which the data evaluated by Lickly *et al*. were taken and the end of the range (1999) is the last year that *Modern Plastics* included the same categories of uses of polystyrene as in 1991.[3] Second, three categories included by Lickly *et al*. were not reported in *Modern Plastics* during any years of the range;[4] the categories not included in *Modern Plastics* are not included in Tables 1 and 2. Abbreviations used in the tables include those for general purpose polystyrene (GPPS), impact polystyrene (HIPS), polystyrene foam (PS foam) and expanded polystyrene foam (EPS foam).

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[3] Specifically, the 2000, 2001, and 2002 issues of *Modern Plastics* employ polystyrene categories that do not allow a comparison with the categories reported in prior years.

[4] These categories are "Aseptic food containers, "Food service trays," and "Other foam sheet."

Table 1. Annual Poundage for Polystyrene Used in Packaging Food-Contact Applications

Packaging Category	Million Pounds (By Year Reported)[a]								
	1991	**1992**	**1993**	**1994**	**1995**	**1996**	**1997**	**1998**	**1999**
GPPS	-	-	-	-	-	-	-	-	-
Produce baskets	24	22	21	27	31	31	33	35	39
Oriented film and sheet	245	240	270	285	305	322	332	368	380
HIPS	-	-	-	-	-	-	-	-	-
Dairy containers	150	142	155	158	171	179	189	195	200
Blow molded items	10	9	9	10	10	10	10	10	12
PS Foam	-	-	-	-	-	-	-	-	-
Stock food trays	191	185	200	204	214	225	221	242	245
Egg cartons	60	55	52	50	55	61	62	65	67

a The year indicated is year of the January issue of *Modern Plastics* cited.

Table 2. Annual Poundage for Polystyrene Used in Disposables Food-Contact Applications

Disposables Category	Million Pounds (By Year Reported)[a]								
	1991	**1992**	**1993**	**1994**	**1995**	**1996**	**1997**	**1998**	**1999**
GPPS	-	-	-	-	-	-	-	-	-
Flatware, cutlery	100	90	88	90	97	94	96	103	108
HIPS	-	-	-	-	-	-	-	-	-
Tumblers and glasses	90	80	76	96	102	97	98	100	103
Vending and portion cups	260	255	290	293	305	310	326	335	340
Dishes, cups, bowls	58	55	55	63	68	63	66	70	75
Plates and bowls	45	40	48	52	57	59	64	76	80
Closures	96	91	94	105	117	113	118	123	127
Lids	110	110	130	136	145	152	160	175	180
PS Foam	-	-	-	-	-	-	-	-	-
Cups (non-thermoformed)	40	40	50	51	55	57	59	62	65
Single service plates	140	135	154	160	174	181	176	183	188
Single service hinged containers	125	100	105	108	112	118	117	120	127
EPS Foam	-	-	-	-	-	-	-	-	-
Cups and containers	153	148	153	167	185	179	189	201	205

a The year indicated is year of the January issue of *Modern Plastics* cited.

A review of Tables 1 and 2 indicate that, while there have modest increases in the polystyrene categories, virtually all of the applications have increased and in a roughly proportionate manner. Thus, one may conclude that, as the polystyrene poundages for food-contact applications have maintained an approximately proportionate increase, the apportionment employed by Lickly *et al*. is valid in light of the time that has past since the study performed by Lickly *et al*. was performed. Therefore, the CF values employed by Lickly *et al*. are still valid.

Migration Calculations

To estimate migration of styrene to the contacted food, the approach that was employed by Lickly *et al*. was to perform calculations based on the principles of diffusion. Summarized below are the equations employed by Lickly *et al.* and described in detail therein.

In instances where equilibrium partitioning may have an effect, such as with aqueous foods, migration may be generally estimated as

$$M_t = C_{P0}\alpha K(1 - e^{Z^2} \text{ erfc } Z) \quad (1)$$

where

$Z = (D_p t)^{½} / \alpha K$
M_t = migration at time t in g/cm^2
C_{P0} = initial residual concentration of substance in polymer in g/cm^3
α = volume of food simulant in mL/cm^2
K = partition coefficient for substance between polymer and food simulant
D_p = diffusion coefficient of substance in the polymer
t = time of food contact in seconds
erfc = error function

In Lickly *et al.*, a simpler relationship than that expressed in equation (1) was employed, since the solution of the error function term (1 - e^{Z^2} erfc Z) is a laborious procedure. Instead, the amount of migration into aqueous foods was determined as:

$$M_t = M_t^{*} C_{P0} \alpha K \qquad (2)$$

where M_t^{*} is obtained by calculating Z (which is equal to $(D_p t)^{½} / \alpha K$, as noted above) and determining M_t^{*} as described by Lickly *et al*.

Where equilibrium partitioning has little effect, such as with the migration of most organic substances into food oil or where there are very short exposure times to aqueous foods, equation (1) is reduced to:

$$M_t = 2C_{P0}(D_p t/\pi)^{½} \qquad (3)$$

Finally, in instances in which packaged food will experience two distinct temperatures during the overall time in which the food will be in the package, *e.g.*, where the packaged food will first be sterilized for a short period of time followed by long-term shelf storage, the total migration of the substance from both phases may be expressed as:

$$M_t = M_{t1} + M_{t2} \qquad (4)$$

where the subscripts 1 and 2 indicate first and second stages of temperature exposure.

The value of M_{t1} is calculated using equation (3) above, while the value of M_{t2} may be calculated as:

$$M_{t2} = 2C_{P01}(1/\pi)^{½}[(D_{p1}t_1 + D_{p2}t_2)^{½} - (D_{p1}t_1)^{½}] \qquad (5)$$

Thus, the solutions to equations (2) through (5) require that values for t (time), C_{P0} (initial concentration of the substance), α (volume of food simulant), K (partition coefficient for the substance between polymer and food simulant), and D_p (diffusion coefficient of the substance in the polymer) be known. While values for t, C_{P01}, and α are defined by the use parameters, values for K and D_p must be determined for a given substance and polymer system. To assess whether the migration calculations performed by Lickly *et al.* may be considered still valid, each of these parameters is address.

The anticipated time and temperature of contact between the food and polystyrene for the polystyrene food-contact applications has not changed. For this reason, the parameters that rely upon time (t) and temperature (K and D_p) have not changed. Likewise, the nature of the food-contact applications has not change – consequently, the food volume parameter (α) has not changed. The only remaining parameter is the initial styrene concentration (C_{P0}).

In performing the calculations, Lickly *et al.* assumed that the residual styrene concentration was 500 parts per million (ppm). To assess the validity of this assumption, a survey of all of the domestic polystyrene producers was undertaken in 2001. In early 2002 the collected information was assessed and validated. This survey has revealed that the average residual styrene contents of GPPS, HIPS and foam (PS foam and EPS foam together) are approximately 300 ppm, 450 ppm, and 260 ppm, respectively. These values are all somewhat lower than the assumed valued used by Lickly *et al.* (500 ppm). Thus, one may conclude that the residual styrene levels in polystyrene for food-contact applications are comparable to (or even slightly lower than) the level employed by Lickly *et al*.

Therefore, as all of the parameter values included in the migration calculations are comparable to (or slightly lower than) the values employed by Lickly *et al*., the migration values calculated by Lickly *et al*. are still valid. Hence, the estimated daily intake (EDI), as reported by Lickly *et al*., is considered to be 9 μg/person/day.

Conclusion

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 μg/person/day. Therefore, calculated EDI (9 μg/person/day) is four orders of magnitude less than the ADI.