Guidance for Industry

Use of Recycled Plastics in Food Packaging: Chemistry Considerations

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition (CFSAN)
August 2006

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I. INTRODUCTION

The purpose of this document is to highlight the chemistry issues that FDA recommends that a manufacturer of recycled plastic consider during the manufacturer's evaluation of a recycling process for producing material suitable for food-contact applications. This document supersedes the December 1992 "Points to Consider for the Use of Recycled Plastics in Food Packaging: Chemistry Considerations." The possibility that chemical contaminants in plastic materials intended for recycling may remain in the recycled material and could migrate into the food the material contacts is one of the major considerations for the safe use of recycled plastics for food-contact applications. Other aspects of plastics recycling, such as microbial contamination and structural integrity of the recycled plastic, are also important, but are not discussed in this document.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

Historically, glass, steel, aluminum, and paper have been recycled for food-contact use. Post-consumer use contamination has not been a major concern with glass and metals. These materials are generally impervious to contaminants and are readily cleaned at the temperatures used in their recycling. In addition, pulp from reclaimed fiber in paper and paperboard may be used for food-contact articles provided it meets the criteria in Title 21 of the *Code of Federal Regulations*, Section 176.260 (Pulp from reclaimed fiber).

Manufacturers of food-contact articles made from recycled plastic are responsible for ensuring that, like virgin material, recycled material is of suitable purity for its intended use and will meet all existing specifications for the virgin material. These requirements, which are described in 21 *CFR*, Parts 174 through 179, serve as the framework for the testing protocol and evaluation procedures outlined in this guidance document. In particular, §174.5 (General provisions applicable to indirect food additives), subparagraph (a)(2) states, "Any substance used as a component of articles that contact food shall be of a purity suitable for its intended use."

Several general methodologies exist by which plastic packaging can be recycled, and each presents distinct issues regarding the contaminant residues that may be present in post-consumer material. The agency presents below a preliminary discussion of the basic types of recycling and identifies specific concerns associated with each type. This guidance then describes a recommended approach for estimating the maximum level of a chemical contaminant in the recycled material that would result in an estimated daily intake (EDI) that does not exceed 1.5 micrograms/person/day (0.5 ppb dietary concentration (DC)), the level that FDA would generally consider to be of negligible risk for a contaminant migrating from recycled plastic. Finally, the guidance recommends a protocol for developing chemistry data that would be useful for evaluating the adequacy of a recycling process to remove chemical contaminants. FDA notes that the testing protocol and evaluation procedures recommended in this guidance may change as new knowledge is acquired.

The following changes to the testing protocol and evaluation procedures that were previously recommended in the December 1992 "Points to Consider for the Use of Recycled Plastics in Food Packaging: Chemistry Considerations" are included in this document:

- Lowering from 1 ppb to 0.5 ppb the DC that FDA would generally consider to be of negligible risk for a contaminant migrating from recycled plastic. These DCs correspond to EDIs of 3 micrograms/person/day and 1.5 micrograms/person/day, respectively.
- Increasing the number of recommended options for surrogate contaminants for use in evaluating a recycling process.
- Eliminating the recommendation to include a heavy metal contaminant in the surrogate testing of recycling processes for polyethylene terephthalate (PET).
- Providing recommendations to address secondary recycling of plastics for cases in which plastic containers from non-food-contact applications (those that originally contained, e.g., household cleaners, soaps, shampoos, or motor oil) are included in the post-consumer feedstock.
- Eliminating all data recommendations for tertiary recycling processes for PET and polyethylene naphthalate (PEN).
- Recommending the use of 0.05 as the default consumption factor (CF) for any plastic recycled for food-contact use.

Although not required by law or regulation, recyclers of plastics intended for the manufacture of food-contact articles are invited to submit information on their recycling process to FDA for evaluation and comment. Please send submissions to the Office of Food Additive Safety (OFAS) at the address given on the cover of this guidance.

III. RECYCLING PROCESSES

In 1991, the Environmental Protection Agency (EPA) introduced a nomenclature that describes the three distinct approaches to the recycling of plastic packaging materials. Primary recycling (1°) refers to the use of pre-consumer industrial scrap and salvage to form new packaging, a common practice in industry. Secondary recycling (2°) refers to the physical reprocessing (e.g., grinding and melting) and reformation of post-consumer plastic packaging materials. Tertiary recycling (3°) involves subjecting post-consumer plastic packaging to chemical treatment whereby its components are isolated and reprocessed for use in manufacture.

EPA considers "recycling" to be the processing of waste to make new articles. Because bottles intended for reuse are not made to be discarded and become waste, reuse is not considered recycling by EPA. Rather, reuse is regarded simply as one form of source reduction, i.e., minimizing the amount of material entering the environment. In simple reuse, the package remains intact and is reused in its original form. In secondary and tertiary recycling, the original package is destroyed and new packaging is formed from the remains. This guidance focuses on the recycling of plastic packaging materials, and reuse will not be discussed further.

A. PRE-CONSUMER SCRAP: PRIMARY RECYCLING

Primary recycling is the recycling of industrial scrap produced during the manufacture of food-contact articles and is not expected to pose a hazard to the consumer. The recycling of this scrap ("home scrap" as defined by the EPA in 56 *FR* 49992, Oct. 2, 1991) is acceptable, provided good manufacturing practices are followed. If the home scrap is collected from several different manufacturers, however, FDA recommends that the recycler consider whether the level and type of adjuvants in the recycled plastic would comply with existing approvals.

B. PHYSICAL REPROCESSING: SECONDARY RECYCLING

Physical reprocessing involves grinding, melting, and reforming plastic packaging material. The basic polymer is not altered during the process. Prior to melting and reforming, the ground, flaked, or pelletized polymer is generally washed to remove contaminants. The size of the polymer flakes or pellets can influence the effectiveness of the washing. Smaller particles provide a greater surface area for enhancing the effectiveness of the wash. Different polymers may also undergo different reforming conditions, such as different processing temperatures, the use of vacuum stripping, or other procedures, that could influence contaminant levels. In some cases, during the grinding or melting phases, the reprocessed material may be blended with virgin polymer.

Recyclers must be able to demonstrate that contaminant levels in the reformed plastic have been reduced to sufficiently low levels to ensure that the resulting packaging is of a purity suitable for its intended use. To produce a polymer with the desired qualities, however, additional antioxidants, processing aids, or other adjuvants may need to be added to the recycled polymer. The type and total amount of these additives must comply with existing authorizations, and any adjuvants already in the plastic may not react during the recycling process to form substances whose safety has not been evaluated by the FDA. Use in the recycled polymer of a new additive or an amount of an approved additive in excess of what is currently authorized for the virgin polymer would require a food contact notification (FCN) or food additive petition (FAP) (see the Food Ingredients and Packaging Approval and Notifications Programs).

A secondary recycling process presents some unique challenges that *might* cause it to be inappropriate for the production of food-contact articles, particularly if the recycler had little or no control over the waste stream entering the recycling facility (e.g., commingling of food-contact and non-food-contact materials). Where effective source control or sorting procedures can be established, however, the potential for post-consumer food-contact materials to be recycled together with other post-consumer plastics will be minimized or eliminated. Nevertheless, even if all the incoming post-consumer polymer were comprised of food-contact materials, limitations on food type or conditions of use could be compromised in the finished recycled product. For example, an additive approved for use only in contact with aqueous food or only for refrigerated use could be incorporated into packaging intended for high-temperature use with fatty foods. The resulting food-contact article would not comply with existing approvals. This concern may be mitigated by development of sorting procedures that result in reprocessing of only a single characteristic container, e.g., a polyethylene terephthalate (PET) soda bottle.

Given the foregoing, FDA recommends that 2° recyclers address these concerns by, for example, implementing controls on the source of the post-consumer polymer, adequate sorting procedures for the incoming post-consumer material, use limitations on the finished recycled packaging (such as use at room temperature or below), or food-type restrictions (such as dry or aqueous foods only). In any submissions to FDA regarding 2° recycling processes, a discussion of these types of actions would be very helpful in FDA's evaluation of the processes.

C. CHEMICAL REPROCESSING: TERTIARY RECYCLING

The primary goal of tertiary recycling is the regeneration of purified starting materials. Chemical reprocessing may involve depolymerization of the used packaging material with subsequent regeneration and purification of resulting monomers (or oligomers). The monomers are then repolymerized and the regenerated or reconstituted polymer is formed into new packaging. Regenerated monomer, polymer, or both may be blended with virgin materials. The regeneration process may involve a variety of monomer/polymer purification steps in addition to washings, such as distillation, crystallization, and additional chemical reaction.

IV. EXPOSURE TO CHEMICAL CONTAMINANTS

The FDA believes that acute consumer exposure to chemical contaminants from food containers produced from plastic that has been processed by 2° or 3° recycling will be extremely low because of the low concentrations of contaminant residues in the recycled polymers (see below). It is possible, however, that traces of a toxic substance could be carried through a 2° or 3° recycling process, become a part of the packaging, and migrate into food in contact with the packaging. Although subsequent recycling of the packaging will result in dilution of the toxin, a very low steady-state concentration of certain toxins could conceivably develop in the recycled material over the long term. Therefore, there is a potential for a consumer to be exposed to low concentrations of a particular toxin over a long period of time. In order to develop a recommendation for the maximum acceptable level(s) of residual contaminants in the recycled material, FDA has considered the question of risk in a probabilistic way rather than on a compound-by-compound basis.

To recommend a maximum acceptable level for chemical contaminants in recycled food-contact articles that can form the basis of Good Manufacturing Practice with respect to recycled material, FDA has determined the residual concentration of a contaminant that corresponds to an acceptable upper limit of dietary exposure. Using the scientific analysis supporting the Threshold of Regulation approach to evaluating indirect food additives as a basis (see 21 *CFR* 170.39), FDA believes that EDIs of contaminants from recycled food-contact articles on the order of 1.5 micrograms/person/day (0.5 ppb DC) or less are generally of negligible risk. The following exercise illustrates the calculation of the maximum acceptable level in the plastic of a contaminant in PET that would result in an EDI of no more than 1.5 micrograms/person/day.

In the case of PET, combining its density of 1.4 g/cm^3 with an assumed container thickness of 0.50 mm (~0.02 in) gives a package with a mass-to-surface area ratio of 70 mg/cm^2 (450 mg/in^2). FDA further assumed the following: individuals consume 3 kg of food per day, 10 g of food contacts one square inch of container, a consumption factor (CF) of 0.05 for recycled PET,[2] and a food-type distribution factor (f_T) of 1.0 for all food types (see "Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations"). The relationships among EDI, DC, and the CF, f_T, and migration level from package to food are as follows:

$$\mathbf{DC = CF \cdot \langle M \rangle = CF \cdot \sum_{4i=1} (M \cdot f_T)_i}$$

$$\mathbf{EDI = DC \cdot 3\ kg\ food/person/day}$$

where M is the concentration of migrant in a food simulant, i, where i represents the four simulated food types: aqueous, acidic, alcoholic, and fatty foods. Use of the parameters noted above leads to:

$$DC = 0.5 \text{ ppb} = 0.05 \langle M \rangle = 0.05(M)(1.0)$$

and $$\langle M \rangle = (0.5 \times 10^{-9} \text{ g contaminant/g food}) \div (0.05)$$

$$= 1 \times 10^{-8} \text{ g contaminant/g food.}$$

Then, $$(450 \times 10^{-3} \text{ g packaging/in}^2) \div (10 \text{ g food/in}^2) = 0.045 \text{ g packaging/g food}$$

$$(1 \times 10^{-8} \text{ g contaminant/g food}) \div (0.045 \text{ g packaging/g food}) =$$

$$2.2 \times 10^{-7} \text{ g contaminant/g packaging,}$$

or 220 µg/kg of contaminant in the packaging material. In other words, if a contaminant were present at 220 µg/kg in the PET container made from the recycled material and if 100% migration of the contaminant into food were assumed (a conservative assumption for room-temperature applications of a high barrier material like PET), the DC of the contaminant would be 0.5 ppb (EDI: 1.5 micrograms/person/day).

The maximum acceptable level of a residual contaminant in a polymer that corresponds to an EDI equal to 1.5 micrograms/person/day will depend on the polymer density, polymer thickness, and CF. The table below reflects residue levels in several polymers that would result in an EDI of a contaminant of 1.5 micrograms/person/day. These calculations were done using a CF of 0.05 for each recycled polymer,[2] **a container wall thickness of 0.50 mm (~0.02 in)**, and the conservative assumptions that all food types are used with each polymer and that the finished article will consist of 100% recycled polymer.

Recycled Polymer	**Density, g/cm^3**	**Maximum Residue**
PET	1.4	220 µg/kg
Polystyrene	1.05	300 µg/kg
PVC	1.58	200 µg/kg
Polyolefins	0.965	320 µg/kg

Thus, to achieve EDIs below 1.5 micrograms/person/day for recycled containers of 0.50-mm thickness, individual chemical contaminants should not be present at levels greater than those given above. It must be emphasized that the calculated levels depend on the thickness of the packaging — the thicker the packaging, the lower the maximum residue levels must be to meet the 1.5 microgram/person/day EDI limit. If a specialized use for a recycled polymer can be documented, it may be possible to estimate a lower CF for use in calculating a maximum acceptable contaminant level. Finally, in cases in which recycled polymer is expected to be blended with virgin polymer, and thus, contaminants in the recycled polymer are diluted with virgin polymer, the maximum acceptable contaminant level calculated using the agency's recommended approach set out above may be divided by the fraction of recycled polymer in the blend.

V. SURROGATE CONTAMINANT TESTING

How may the ability of a ***2° or 3° recycling process*** to remove contaminants from plastic containers or packaging that has been subjected to consumer misuse or abuse (e.g., through storage of pesticides or automotive chemicals) be demonstrated? FDA recommends simulating consumer misuse by exposing virgin polymer (either in container form or as flake) to selected surrogate contaminants and then running the exposed or "challenged" polymer through the recycling process. Subsequent analysis of the processed polymer for the surrogate contaminants would provide a means to evaluate the efficacy of the recycling process.

A. CHOICE OF SURROGATES

The FDA recommends that recyclers use materials that have a variety of chemical and physical properties to simulate consumer misuse. In particular, FDA recommends that the surrogate contaminants represent "common" materials accessible to the consumer and include a volatile polar organic substance, a volatile non-polar organic substance, a non-volatile polar organic substance, a non-volatile non-polar organic substance, and a heavy metal salt (except for PET, see below). Examples of recommended surrogates are given below; FDA believes that one surrogate per category is sufficient for the testing.

Volatile Polar	**Non-Volatile Polar**
Chloroform	Benzophenone
Chlorobenzene	Methyl salicylate
1,1,1-Trichloroethane	
Diethyl ketone	**Non-Volatile Non-Polar**
	Tetracosane
Volatile Non-Polar	Lindane
Toluene	Methyl stearate
	Phenylcyclohexane
Heavy Metal	1-Phenyldecane
Copper(II) 2-ethylhexanoate	2,4,6-Trichloroanisole

Chloroform and toluene are components of cleaning solvents; benzophenone is a suitable substitute for non-volatile polar pesticides such as Diazinon; and tetracosane is a good representative for the long-chain hydrocarbons that comprise motor oil. A heavy metal salt such as copper(II) 2-ethylhexanoate, a substitute for the toxic salts commonly used in herbicides, would complete the range of properties noted.[3] OFAS is available to discuss the use of surrogates other than those listed in the table above.

In the case of PET, FDA does not recommend including a heavy metal salt in surrogate testing. In the PET recycling submissions reviewed over the past decade, migration of the heavy metal surrogate has never been detected in food simulants. FDA reviewed data for a number of heavy metal surrogates, including the metal salts calcium monomethylarsonate (an herbicide for crabgrass), copper acetoarsenite (Paris green), cadmium acetate, zinc stearate, and copper(II) 2-ethylhexanoate. The data show that,

unlike small organic molecules, metal salts do not sorb as readily into PET and also that the salts are more easily washed out of PET, probably because they simply adsorb to the PET surface. In one case, the heavy metal surrogate was incorporated into the resin by blending and still was not detected in migration experiments. FDA believes that the metal-containing substances to which consumers have access are primarily in the salt form, and even if this were not the case, it is unlikely that non-ionic organometallic species would behave any differently than the organic compounds represented by the four general surrogate categories.

To date, surrogate testing data for recycling processes for polymers other than PET are insufficient to support general conclusions about the behavior of heavy metals in those polymers. Therefore, FDA continues to recommend the use of a heavy metal surrogate in the testing of recycling processes for polymers other than PET.

B. CONTAMINATION OF THE PLASTIC

In order to test the recycling process, FDA recommends the following approach.

First, containers made of the virgin plastic of interest are contaminated or "challenged" by filling them with the surrogate contaminants, either "neat" or in "at use" concentrations, using a solvent such as hexane as a diluent. An alternative approach that would reduce the amount of potentially hazardous wastes would be to soak several kilograms of flaked virgin plastic of the type actually used in the recycling process in the selected contaminants at either "neat" or "at use" concentrations. A mixture, or "cocktail," of the contaminants could be used so long as the components of the "cocktail" do not react with each other. Agency recommendations for minimum concentrations of surrogates for a "cocktail" are shown in Table 1 below:

Table 1. Examples of Minimum Concentrations of Contaminants in a Surrogate Cocktail

Contaminant	Concentration
Chloroform (volatile polar)	10% v/v[a]
Toluene (volatile non-polar)	10% v/v
Benzophenone (non-volatile polar)	1% v/v
Tetracosane or Lindane (non-volatile non-polar)	1% w/w[b]
Copper(II) 2-ethylhexanoate (heavy metal)	1% w/w
Balance: 2-Propanol (as solvent for Cu(II) 2-ethylhexanoate)	10% v/v

Hexane or Heptane (as overall solvent for cocktail)	68% v/v

[a] v/v - volume of contaminant per unit volume of entire cocktail
[b] w/w - mass of surrogate per unit mass of entire cocktail

Once the bottles are filled or after the contaminants are thoroughly mixed with the flakes, the bottles or flakes should be stored sealed for two weeks at 40°C with periodic agitation. After the contaminants are drained and the bottles or flakes are rinsed, the concentration of each surrogate should be determined in the polymer. The challenged polymer should then be subjected to the proposed recycling process, and regenerated components or packaging material formed from the reprocessed polymer should be analyzed for residual contaminants. This approach represents a worst-case scenario, i.e., all material entering the recycling stream is assumed to be contaminated.

Testing protocols may be submitted to OFAS for comment before any contamination studies are done. FDA recommends that all analyses be validated as discussed in the "Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations".

C. OTHER CONSIDERATIONS

If a proposed recycling process cannot be shown to remove contaminants to maximum acceptable levels under the scenario discussed above, then additional factors or limitations on use could justify a conclusion that the recycled package will not introduce contaminants into the diet at unacceptable levels. The following additional factors/limitations may result in an acceptable upper limit of dietary exposure: the use of a recycled/virgin blend, source controls, restricted uses, the fraction of contaminant that migrates into food or a food simulant, or the use of an effective barrier. FDA recommends that the effect of measured or mathematically modeled factors be supported by adequate documentation (e.g., studies on a specific source control program, studies on the actual extent of contaminated material entering the recycling stream, or information that demonstrates that the recycled polymer is separated from food contact by an effective barrier).

In cases where the post-consumer plastic feedstock is intended to consist of food containers only (i.e., containers that were used to package non-food substances such as household cleaners are intentionally excluded), FDA would consider data submitted by recyclers that show the extent of contaminated material entering the recycling stream as a result of consumer misuse in order to demonstrate or allow a prediction of the actual incidence of chemical contamination of recycled articles. FDA believes that, due to the incidental nature of potential consumer misuse of a food container and subsequent introduction of that container into the recycling stream, this information (if properly validated) can be factored into the exposure calculations to obtain more realistic values.

VI. PLASTIC CONTAINERS FROM NON-FOOD-CONTACT APPLICATIONS AS FEEDSTOCK

The 1992 "Points to Consider" was developed to address incidental contamination of food containers by consumers, following the original intended use of the containers. Containers with non-food contents (e.g., household cleaners, furniture polish, shampoos, soaps, pesticides, or motor oil) were purposely not addressed.

The amount of custom PET containers (i.e., containers other than soda bottles that are used to package specialty foods as well as non-food substances) collected via curbside programs has increased dramatically over the past several years[4] and is predicted to continue to increase ("Plastics," **1996**, and "Adding," **1996**). In addition, the use of PET in non-food containers is increasing ("PET," **1997**, and Schumacher *et al.*, **1997**). These trends indicate that the contamination introduced into post-consumer PET feedstock via non-food containers, as well as the probability that up to 100% of the post-consumer plastic feedstock might consist of non-food containers, are likely to increase. Therefore, FDA recommends that worst-case contamination assumptions be made for non-food containers entering the recycling stream (see below).

The FDA believes that the following two questions are relevant in determining the appropriateness of recycling non-food containers into new food containers by 2° processes:

1) Are the non-food container plastic, its adjuvants, and the adjuvant levels in the plastic currently authorized for use in contact with food? FDA believes that it is highly unlikely that 2° recycling processes will remove unapproved adjuvants (such as colorants or antioxidants) because these substances are incorporated into the polymer matrix during manufacture.

2) Can the levels of chemical contaminants introduced into the post-consumer feedstock by non-food containers, which can sorb relatively large amounts of chemicals from their contents over very long shelf lives, be sufficiently reduced so that finished recycled containers are suitable for food-contact use? FDA believes that it is likely that 2° recycling processes could remove residual amounts of non-food substances such as household cleaning solutions from non-food containers because these substances are simply sorbed into the container's surface.

These questions have been addressed for PET:

1) The FDA has received information from the plastics industry that verifies that all PET resin used to manufacture containers in the U.S. is authorized for food-contact use, i.e., food-grade PET is used to manufacture both food and non-food containers (see, for example, Phoenix, **1998**).

2) The FDA has used a mathematical model, based on Fick's law of diffusion, to predict the amount of a contaminant (represented by the surrogate contaminants described above)

that will sorb into a PET bottle during a period of one year at 25°C, the shelf life and use temperature of a typical non-food substance packaged in PET (see Appendix I). Because the model tends to overpredict sorption (see Appendix I), FDA's experimental sorption results and data from the literature have also been used to calculate the sorption of several surrogates into PET under these use conditions (Begley *et al.*, **2002**, and Demertzis *et al.*, **1997**). The PET sorption values for several surrogates are summarized in Table 2 below.

FDA recommends that recyclers who wish to include non-food PET containers in their feedstock establish that the concentrations of the surrogates in challenged PET flake, prior to its being run through their recycling process, are greater than or equal to the sorption values shown in Table 2. FDA does not recommend that this criterion be included in surrogate testing for a recycling process that uses only food containers as feedstock — simply exposing virgin flake or intact bottles to the surrogate cocktail for 2 weeks at 40°C is sufficient to model incidental misuse of containers by consumers.

Table 2. Sorption of Surrogate Contaminants into PET After 365 Days at 25°C

Surrogate	Sorption Value (mg/kg)	Reference
Volatile, Polar		
Chloroform	4860	Begley *et al.*, **2002** (modeled value)
Chlorobenzene	1080	Demertzis *et al.*, **1997**[a]
1,1,1-Trichloroethane	1050	Demertzis *et al.*, **1997**[a]
Diethyl ketone	4860	Assumed to be the same as chloroform, based on similar molecular weights
Volatile, Non-Polar		
Toluene	780	Begley *et al.*, **2002**
Non-Volatile, Polar		
Benzophenone	49	Begley *et al.*, **2002**
Methyl salicylate	200	Begley *et al.*, **2002**
Non-Volatile, Non-Polar		
Tetracosane	154	Begley *et al.*, **2002** (modeled value)
Lindane	750	Begley *et al.*, **2002**

Methyl stearate	150	Assumed to be the same as tetracosane, based on preliminary FDA experimental results
Phenylcyclohexane	390	Demertzis *et al.*, **1997**[a]
1-Phenyldecane	170	Demertzis *et al.*, **1997**[a]
2,4,6-Trichloroanisole	1100	Based on value for lindane with molecular weight correction
[a]These values were measured at 40°C.		

In order to obtain the initial concentrations shown in Table 2, FDA recommends exposing PET flake rather than intact bottles to the surrogate solutions for at least 14 days at 40°C. The use of intact PET bottles in surrogate testing potentially can result in at least an order of magnitude less sorption of the surrogate contaminants than the values shown in Table 2, due to the lower surface area of a PET bottle compared to an equal mass of flake (Komolprasert and Lawson, **1995**). FDA also recommends that a surrogate cocktail contain, at a minimum, the concentrations of contaminants given in Table 1 above. Finally, FDA recommends that recyclers consider using higher concentrations of volatile surrogates such as chloroform in the cocktail to offset losses that could occur before the flake is analyzed.

FDA recommends that, in cases in which the starting concentrations are found to be lower than the values in Table 2, recyclers correct for the shortfall by multiplying the surrogate testing results by a simple factor. For example, if the actual starting concentration of toluene were 500 mg/kg, then the factor would be 1.6 ((780 mg/kg)/(500 mg/kg) = 1.6).

FDA recommends against analyzing actual batches of post-consumer plastics for potential chemical contaminants in order to refine exposure calculations because these analyses provide only a snapshot of the composition of curbside-collected plastic containers, and there is no guarantee that the composition of non-food containers in curbside recycling programs will remain the same over time.

Recyclers who have already had their PET recycling processes evaluated by FDA should not assume, based on the conclusions in this guidance document, that their letters from FDA apply to the use of non-food PET containers as feedstock. If these recyclers desire FDA's opinion on their use of non-food PET containers, they may ask FDA to reevaluate their surrogate testing data and issue a separate letter.

VII. THE USE OF AN EFFECTIVE BARRIER

The use of 2° or 3° recycled material as a non-food-contact layer of a multilayer food package is a potential application for recycled plastics. FDA believes that this use would

not present a concern about potential contaminant migration into food as long as the recycled polymer is separated from the food by an effective barrier made from virgin polymer or other appropriate material, e.g., an aluminum film. Based on experimental and mathematically modeled diffusion data obtained by the OFAS laboratory (and others) for three-layered coextruded PET films in which the center layer contained surrogate contaminants and the outer layers were comprised of virgin material (Piringer *et al.*, **1998**), FDA has determined that virgin PET is an effective barrier to contaminants that could potentially migrate from a recycled plastic inner layer under the following conditions:

1) at a thickness ≥ 25 µm (~0.001 in) at room temperature and below, and

2) at a thickness ≥ 50 µm (~0.002 in) at higher temperatures, including use as a dual-ovenable container for cooking food at 150°C for 30 min, provided that only food containers are used in the feedstock to manufacture the recycled layer.

In these cases, the presence of a virgin PET layer ensures that migration of a contaminant to food will result in an EDI no greater than 1.5 micrograms/person/day. The calculation assumes a consumption factor (CF) of 0.05 for recycled plastic packaging.[2] [Note: Although an EDI ≤ 1.5 micrograms/person/day for a contaminant is generally of negligible safety concern, a substance intentionally used as a component of a food-contact article is still subject to the food additive definition and might require FDA premarket approval via a food contact notification (see Preparation of Food Contact Notifications: Administrative) or a Threshold of Regulation submission (see Submitting Requests Under 21 CFR 170.39 Threshold of Regulation of Substances Used in Food Contact Articles), even if the EDI of the substance is ≤ 1.5 micrograms/person/day.]

To demonstrate that a given thickness of a virgin polymer functions as an effective barrier to the migration of contaminants, FDA recommends that the recycler subject intentionally contaminated polymer to the recycling process and incorporate the recycled polymer into a non-food-contact layer of a finished article, using virgin polymer as the barrier layer. FDA recommends that migration studies be performed with food simulants as described in the "Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations". If migration studies show that the EDI of individual contaminants would not exceed 1.5 micrograms/person/day, FDA would consider the virgin layer of the specified thickness to be an effective barrier to contaminants migrating from the non-food-contact layer of recycled material. If data from studies other than migration experiments establish that a given thickness of a particular polymer is sufficiently impermeable under anticipated time/temperature use conditions, those data could serve to replace migration experiments.

VIII. ELIMINATION OF DATA RECOMMENDATIONS FOR 3° RECYCLING PROCESSES FOR PET AND PEN

Based on a comprehensive review of all surrogate testing data submitted over the past decade for 3° recycling processes for PET and polyethylene naphthalate (PEN), FDA

concludes that 3° recycling of PET or PEN by methanolysis or glycolysis results in the production of monomers or oligomers that are readily purified to produce a finished polymer that is suitable for food-contact use. Both 3° processes will clean the polyester sufficiently to allow it to be considered of suitable purity, even assuming 100% migration of residual surrogate to food. This is a significant difference from the surrogate testing of 2° recycling processes. Secondary recycling processes often produce PET that is insufficiently cleaned to withstand 100% migration calculations for the residual surrogates. Under these circumstances, FDA recommends additional migration tests to demonstrate that the finished PET meets the 1.5 micrograms/person/day EDI limit.

Based on a determination that 3° recycling processes produce PET or PEN of suitable purity for food-contact use, FDA no longer recommends that such recyclers submit data for agency evaluation. Because 3° processes for polymers other than PET and PEN have not been the subject of FDA reviews, however, recyclers who wish to engage in 3° recycling of polymers other than PET and PEN are encouraged to submit data for evaluation.

APPENDIX 1. MODEL OF THE SORPTION OF SURROGATE CONTAMINANTS INTO PLASTIC

FDA recommends using the following equation from Crank (**1975**) to model the sorption, at a fixed temperature, of any substance (including surrogate contaminants) into plastic:

$$\frac{M_t}{M_\infty} = (1 + \alpha)\left[1 - \exp\left(\frac{\tau}{\alpha^2}\right) erfc\left(\frac{\tau}{\alpha^2}\right)^{1/2}\right]$$

(1)

$$\tau = \frac{Dt}{l^2}$$

(2)

In this equation, M_t and M_∞ are, respectively, the sorption (g surrogate/g plastic) at time t and the sorption at equilibrium (or "infinite" time), α is the ratio of the volume of the surrogate solution to the volume of the plastic, D is the diffusion coefficient (cm^2/s) of the surrogate in the plastic at a given temperature, t is the time in seconds, and *l* is the thickness of the plastic (cm). The full thickness is used for a single-sided experiment (i.e., a plastic bottle filled with surrogate solution) while half the thickness is used for a double-sided experiment (i.e., a plastic strip soaked in a surrogate solution).

In order to solve Eqn. 1 for M_t, a value for M_∞ is needed. In the absence of experimentally determined values, FDA recommends using the following equation derived from Crank (**1975**) to calculate M_∞:

$$M_\infty = \frac{a}{w} C_o \frac{1}{1 + \alpha}$$

(3)

In this equation, *a* is the volume of the surrogate solution (mL), *w* is the mass of the polymer (g), and C_o is the starting concentration of the surrogate in the solution (g/mL). FDA's version of this equation differs from Crank's in that the mass of the polymer is included in the denominator to obtain M_∞ in the units g surrogate/g plastic.

The following parameters were used for a typical non-food PET bottle: a 1-L capacity, a mass of 38.26 g, a density of 1.37 g/cm^3, and a wall thickness of 0.03 cm. The bottle's mass was divided by its density to obtain the volume of PET in contact with the surrogate solution. A 10% w/w concentration of each surrogate in solution was assumed to represent the maximum concentration of any given component of a non-food substance packaged in PET.[5] The densities of the surrogate and the remainder of the surrogate solution (assumed to be 1 g/cm^3) were used to calculate C°. The following diffusion coefficients were used for several surrogates in PET:

Surrogate	D (cm^2/s), 25°C	Reference
Chloroform	9.1 x 10^{-14}	Calculated with Piringer model (Baner *et al.*, **1996**)
Toluene	4.3 x 10^{-15}	Sadler *et al.*, **1996**
Benzophenone	4.8 x 10^{-14}	Calculated with Piringer model (Baner *et al.*, **1996**)
Lindane	1.6 x 10^{-14}	Calculated with Piringer model (Baner *et al.*, **1996**)
Tetracosane	1 x 10^{-16}	Sadler *et al.*, **1996**

In order to validate the model, the modeled results were compared with experimental measurements of toluene sorption into a PET strip (i.e., a two-sided experiment) made by Demertzis *et al.* (**1997**) after 15 and 40 days at 40°C. Sadler's D value of 3.92 x 10^{-14} cm^2/s for toluene at 40°C, which has been well characterized, was used in the model (Sadler *et al.*, **1996**). Specifications for the PET strip and the surrogate solution as given in the Demertzis article were also used. The results follow:

Time (days) at 40°C	Modeled Toluene Sorption from 16.7% (w/w) Soln.	Experimentally Measured Toluene Sorption from 16.7% (w/w) Soln. (Demertzis *et al.*, 1997)
15	3.1 mg/dm^2 of PET (750 mg/kg in PET)	3.5 mg/dm^2 of PET
40	5.1 mg/dm^2 of PET (1230 mg/kg in PET)	6.0 mg/dm^2 of PET

The excellent agreement of the modeled results with experimental measurements indicates that the model adequately predicts surrogate sorption into PET over time. However, the model tends to overpredict sorption when experimentally determined D or M_∞ values are not available and semi-empirical or theoretical values are used. The Piringer model, an empirical correlation based on the molecular weight of the migrant, was used to calculate D for chloroform, benzophenone, and lindane for input to the sorption model (see Baner *et al.*, **1996**). Comparisons of modeled D values with experimental measurements indicate that the Piringer model can overestimate D by several orders of magnitude (Baner *et al.*, **1996**). This discrepancy has been attributed to failure of the model to account for partitioning of the migrant between the solvent and polymer phases. Similarly, Eqn. 3 will generally overpredict M_∞ because it does not take into account partitioning of the migrant between the solvent and polymer phases (Crank, **1975**). Because the sorption model depends on D and M_∞, overestimates of these values will result in overestimates of sorption. Modeled results for a typical bottle are given in Table 3:

Table 3. Modeled Sorption of Surrogates into 1-L PET Bottles Filled with 10% w/w Surrogate Solutions after 365 days at 25°C

Surrogate	Modeled Sorption into PET, mg/kg
Chloroform	4860
Toluene	1000
Benzophenone	3390
Lindane	1920
Tetracosane	154

FDA believes that the modeled sorption value for chloroform is probably reasonable because there is very little partitioning of chloroform between the solvent and polymer phases. However, the measured sorption values for benzophenone and lindane have

shown the modeled values to be significant overestimates due to the need to rely on semi-empirical or theoretical D *and* M_∞ values (Begley *et al.*, **2002**).

APPENDIX 2. REFERENCES

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Endnotes

[1] This guidance has been prepared by the Division of Food Contact Notifications in the Center for Food Safety and Applied Nutrition (CFSAN) at the U.S. Food and Drug Administration.

[2] FDA will assume a default CF of 0.05 for any recycled polymer. Previously, FDA used a CF for both virgin and recycled PET of 0.05. Based on recent market data that demonstrated that, since 1990, virgin PET has captured a dramatically larger share of the food-packaging market, FDA increased the CF for virgin PET to 0.16. Such an increase in market share has not been observed for recycled PET, so FDA uses a CF for recycled PET of 0.05. Since PET is recycled into food containers at a higher rate than any other polymer, it can be assumed that the CF for any other recycled polymer will not exceed 0.05.

[3] Although FDA previously recommended testing with a polymer-specific surrogate, e.g., *ortho*-cresol, which is known to significantly swell PET, such data are no longer considered necessary because 1) the range of possible contaminant properties are already covered by the five surrogate categories selected, and 2) a consumer's storage of a polymer-specific solvent in a bottle would significantly degrade the bottle to the extent that it would be rejected during the sorting process.

[4] Of 280,000 tons of custom PET containers generated in 1993, 3.6% was recycled. Of 820,000 tons generated in 1999, 9.8% was recycled. See EPA, **1994**, and EPA, **1999**, under the "Other plastic containers" entries for PET.

[5] A search of a database of ingredients in household products (http://www.happi.com) shows that liquid detergents, shampoos, and hand cleaners might contain up to 30% long-chain fatty acids; however, these compounds are not expected to sorb into PET to any greater extent than lower molecular weight compounds from 10% solutions.

This document supercedes "Points to Consider for the Use of Recycled Plastics in Food Packaging: Chemistry Considerations", December 1992
