1998年には、“再生ＰＥＴを食品接触用途に利用する工程—単純化された試験法（チャレンジテスト）によるフィジビリテイースタデイ[14)]”と題する論文で、ＦＤＡのガイドラインによる再生工程の評価試験法をより実施しやすい方法に改善する提案をした。この欧州式再生工程評価法についてはＦＤＡも認めており、実際にスイスのビューラー社の超洗浄式再生工程は、この方法によってＦＤＡのＮＯＬを取得した。

1999年には、“使用済ボトルからの再生ＰＥＴの食品接触用途－食品関連法規への適合の最終的な証拠[15)]”と題する論文で、チャレンジテストの結果を総括している。また、同年には“使用済再生ＰＥＴを食品容器に使用するための分析的スクリーニングと評価[16)]”と題する論文で、実際の再生工場で製造された再生フレークが含有する不純物を分析する方法とその比較評価法を示し、ＥＵのプロジェクト[18)]にも採り入れられている。

### ３．２．２　欧州のガイドライン

再生プラスチックなどの食品容器包装への使用に関するEU指令の原案は法制局で凍結されているといわれるが、EU指令の原案に相当する内容と言われているガイドラインが存在する。即ち、前項で述べたタスクフォースのメンバーが1998年に国際生命科学研究所(ILSI)の名で、“Recycling of Plastics for Food Contact Use（食品包装材のリサイクルに関するガイドライン）[17)]”を発表した。以下にそのまとめの部分を転載する。

1　個々の、またはあらゆるタイプのプラスチックのリサイクル工程は、その性質により異なったものとなる。それ故に個々の工程は別個に査定する必要があり、また本ガイドラインが設定した基準に適合することを示さねばならない。

2　食品用途のプラスチックだけが、リサイクルの原料供給源として適している（化学分解法による場合は例外であるが)。それ故に再生工程は非食品グレードのプラスチックを除去する能力を示さなくてはならない。選別の最低の効率はケースバイケースで決定されるが、９９％以上でなければならない。

3　再生工程に対するチャレンジ試験は、その工程の適当な個所で汚染されていない原料供給源と一緒に代用化学物質を導入して実施されなければならない。代用化学物質の最終測定（例えば溶出試験）は最終の材料又は製品、最終の再生材料または製品自身を製造する前に再生されたプラスチックについて実施されねばならない。

4　チャレンジ試験は、次のような物質を使用して実施するものとする。これらは色々なタイプの化学物質とプラスチックに対する性質が異なるものをカバーしていると同時に消費者が入手し得る化学品のタイプをシュミレーションしている。
トリクロロエタン：極性、揮発性
ベンゾフェノン：極性、不揮発性
トルエン、クロロベンゼン：非極性、揮発性
フェニルシクロヘキサン：非極性、不揮発性
メチルパルメート（またはメチルステアレート）：有機金属化合物の代用物質

5　チャレンジ試験で導入される代用化学物質の濃度は、実際に起き得る最悪の汚染よりも十分に過剰なレベルでなければならない。これらの代用化学物質はチャレンジ試験の製品に充填する（又はテスト用のフレークを暴露する）為に、次のように規定され、使用者が強く要求する最大量以上の混合物（カクテル）として使用するものとする：
１%トリクロロエタン、１%ベンゾフェノン、１０%トルエン、１%クロロベンゼン、
１%フェニルシクロヘキサン、１%メチルパルメート（ステアレート）
通常の必要条件は、代用化学物質に汚染されたテスト製品の100%に対するものとするが、実際にありそうな汚染発生率の証明をベースにそれを緩和またはレベルを下げることが認められる。

6　再生工程の認証を得るには、最初はチャレンジ試験を実施しなくてはならない。規定されているパラメータの変更を提案する場合は、その変更提案に対して最も適切な試験でその性質に焦点を絞ったチャレンジ試験を再度実施しなければならない。これらの臨界的なパラメータは工程認証の時に確認されるが、例えば次のようなものを含む：ソースコントロール、選別と排除機構、洗浄方法、超洗浄方法、加熱、混合/希釈、機能性バリア。

7　チャレンジ試験が5項に規定された濃度の代用化学物質を使用して実施した後、再生されたプラスチックから食品に起き得る汚染量のポテンシャルは、次のいずれかの方法で立証するものとする：
- 再生されたプラスチック中の代用化学物質を定量して、100%食品に移行すると仮定して推定する。
- 再生されたプラスチック中の代用化学物質を定量して、食品への移行量を有効性が確認されたモデルで予測する。
- 実際に使用される食品と使用条件下で、溶出試験を実施する。
- EC Directive 82/711/EEC(5) または改正規則に規定された溶出試験法により溶出試験を実施する。

8　代用化学物質を導入したチャレンジ試験の結果は、4項の物質を準備し、5項の濃度で、7項に定めた試験条件で実施され、分析方法論での検出限界において、“検出しない”ことを示さなくてはならない。信頼すべき分析法では、検出限界はあらゆる分析技術上の誤差を含めて10μg/kg（10ppb）である。

このガイドラインの内容は、米国ＦＤＡの規制方法に極めて近似したものであり、中心となっているのはソースコントロールとチャレンジテスト（再生工程の能力の検証）の結果による個別審査である。

### ３．２．３　欧州連合プロジェクト

その後、欧州連合はＥＵ契約番号 FAIR-CT-98-4318[18] で、“リサイクル性”プロジェクトを立ち上げた。このプロジェクトはドイツのフラウホーファ食品技術、包装大学のウエブサイト＊で見ることができ、前述のフランツ博士がコーディネータを務めている。そして、食品包装へのリサイクル材料の安全な使用をテーマとする３部門から成る再生支援プログラムである。　　＊URL=http://www.ivv.fgh.de/fair/index/html

第１部門　食品に直接接触する用途のＰＥＴリサイクルの基準
第２部門　食品に直接又は/及び間接接触する再生紙及び板紙の有用性
第３部門　食品に間接接触する機能性バリアで防護された再生プラスチックの有用性

このプロジェクトは 1999 年 1 月に発足し、３カ年計画で実施されており、間もなく終了の予定である。このプロジェクトの目的は、米国の産業界がＦＤＡ規則を盾として合法的に再生プラスチックを利用できるので競争力が増しているのに対して、欧州の産業界も法制度の見直しを図り、欧州委員会（ECC）に実際的に有効な推奨基準を提案することを目標としている。そして、“リサイクルにおいていかに包装材料の安全な使用を確保するか？”という課題に力点がおかれている。

例えば、第１部門“ＰＥＴ”では、

1）欧州の食品市場から回収された再生 PET 中の汚染物質の性質と量の概要を統計学的に把握すること、
2）そのデータを PET の実在の拡散と移行のモデルに適用して、リサイクルプラスチックから食品へ移行する汚染物質の消費者への暴露量の平均値と最大値をモデル化し予測すること、
3）再生工程の洗浄効率を評価する試験の条件と最低の要求水準を確立すること、
4）食品包装材料内に存在するリサイクル PET を検知する試験法を提供すること

の４項目の極めて論理性の高い方法論の構築を目標に掲げて作業が進められている。

既に、欧州市場の各種の再生工程から集められた PET フレーク、約 900 ロットが分析され、未使用のボトルと比較されて統計的に主成分分析が施されて、まもなく詳細が発表されるという。このプロジェクトの終了後、ＥＵはリサイクルプラスチックに対する法規制を構築するものと期待される。

このように米国に比較するとＥＵの総括的な法規制が遅れていることから、各国で独自の規制を行っているところもある。 ドイツでは Bundesinstitut fur gesundheitlichen Verbrauchershutz und Veterinarmedizin (BgVV) がガイドライン[19] を発表しており、ホームページ＊で見ることができる。これは、３．２．１項で示した英国およびドイツの“再使用及び再生プラスチックの食品容器に関する見解”の延長線上にあるが、米国ＦＤＡの再生工程の評価方法を取り入れて、より具体的なものとなっている。当然ながら、３．２．２

項の“欧州のガイドライン[17]”と基本的に一致した内容である（添付資料２）。

＊URL=http://www.bgvv.de/index.e.htm

欧州の事業者たちは、フラウエンホーファ食品技術・包装技術大学のフランツ博士の指導により、自社の再生工程をＦＤＡに申請し始めており、既に４社がＮＯＬを取得している。また、スイスでは、食品保健省の認可の下で、米国のURRC社（ＮＯＬ取得済）の超洗浄方式の再生工程を事業化して、ボトルからボトルへのリサイクル（直接接触）が始まっている。

# 第４章　まとめ

現在、世界中で１年間に６５０万トンもの飲料用ＰＥＴボトルが使用され廃棄されている。欧米諸国をはじめ地球上の殆どの国で利用され、その廃棄物を資源として有効利用するために、それを応用する分野でも研究開発から事業化への流れが進んでいる。しかし、廃棄源である飲料ボトルから、再び食品用途へ、特に飲料ボトルへという完全な循環型リサイクルの事業化については、食品衛生安全性の確保に課題があり、これまで順調ではなかった。再生されたＰＥＴ原料の主たる用途は繊維原料であり、色々な用途分野で開発、事業化の努力がされてきた。しかし、どこの国でも元の用途に戻すべきという社会的責任論を含めて、食品容器包装は重要なターゲットと考えられ、欧米諸国では長年にわたり官民が協力しての取り組みがなされてきた。

わが国でも飲料用ＰＥＴボトルの需要量は年間40万トンに達しており、しかも法規制による分別回収なので、回収率は40%を超えているものと見られている。従って、再生原料の供給量も急増しており、その安定的な用途先が“繊維製品”をはじめ非食品の用途だけということでは、いずれはシステム破綻の恐れがあると考えられる。

わが国の関係業界の手により、“ボトルからボトル”、“ボトルからトレイ”と称する食品容器から再び食品容器への輪をつなぐ方向への努力がなされてきた。容器包装廃棄物からリサイクルされた再生材を食品用途に使用するにはその安全性の確保が不可欠であり、わが国の法制度から見れば、食品衛生法の各条項とその規格基準への適合が第一に考慮すべき事項であることは言うまでもない。

しかし、未使用の原料で製造された食品用容器はポジテイブリスト（ＰＬ）適合の保証ができるが、一般廃棄物からの資源の場合は、収集、再生工程における不純物に対する管理が不明の場合が多く、すべての不純物を同定することは難しい。従って、間接的な方法論と個別の評価方法の組み合わせで安全性を証明する必要がある。又、プラスチック素材の場合はポリマー別に性質や製造技術が異なり、リサイクルに向いているもの、向かないものなどかなりの差があるので、一般的な方法論では通用しない。

そこで、最もリサイクルに適しているポリマーと言われるポリエチレンテレフタレート（ＰＥＴ）を中心に、欧米等におけるリサイクル包装材の使用状況、法的な状況、安全性確保のための基準、ガイドライン、認可状況等を調査した。

米国ではプラスチック容器包装等のリサイクル事業は、民間ベースで推進されており連邦政府の規制や援助はない。しかし、再生材の食品用途での使用については食品衛生安全性を規制する必要があるとして、早くからＦＤＡが対策を講じてきた。即ち、現行の法制度の運用において、かなり大胆な理論と柔軟な対処を行って、事業者個別の再生工程（原料）の申請を受理して、審査して認可する制度を確立した。政府機関であるＦＤＡ自体が“再生プラスチックの食品用途への使用に関するガイドライン”を提案し、審査基準を設けて申請を受理してきた。昨年末までに72件の個別企業の申請に対して、

承認のＮＯＬを発行している。そのうち、ＰＥＴに関する件数は46件とほぼ2/3を占めている。

そのうち物理的再生法のものが32件、化学的再生法のものが14件である。初期の物理的再生法による工程は殆んどが食品接触不可の条件付認可であり、機能性バリアの使用による認可であった。しかし、1997年以降、特に超洗浄法による申請ではあるが、食品と直接接触して使用することを認められた工程が約12件もある。もちろん、化学的再生法によるものはすべて食品との直接接触が認められており、今後は申請手続きを義務化しないで食品用途への使用を認める方針である。

一方、一般法による法体系の欧州各国ではあるが、イギリス、ドイツ、スイス、フランスなどが中心となって、米国と欧州のギャップを埋める努力を懸命に続けている。そして、米国ＦＤＡの方法論と規制基準に類似した欧州におけるガイドラインを国際生命科学協会（ＩＬＳＩ）欧州が発表しているが、これが現在準備中のＥＵ指令（原案）の骨格であると言われている。欧州連合(ＥＵ)は、リサイクルの支援のために再生プラスチックの食品用途での使用を目指す研究プロジェクトを組織して推進している。まもなく、1999年に始まったこのプロジェクトは終了し、それをベースに法制度の整備を図ると見られている。その間、国別ではイギリス、ドイツ、スイスは独自の法規制を行っている。

わが国では“容器包装リサイクル法”により、ＰＥＴボトルをはじめとするプラスチック容器包装のリサイクル事業が推進されている。しかも使用済の飲料ＰＥＴボトルを再び食品容器包装へ使用する生産技術はほぼ確立しており、食品衛生安全面での規制は、食品衛生法第９条による製造者責任だけと考えられる。欧米では安全性の確認を優先し、まずはスイス、オーストラリア等数カ国で機能性バリアを利用した３層構造のボトルが使用されてきた。また、ケミカルリサイクルによる再利用も一時は実施されていたが、再生樹脂の安全性を確保すればコストパフォーマンスがネックとなり伸び悩んできた。そのため、欧米の企業は超洗浄法のシステムに期待していると考えられ、既にスイス、オーストラリアでは、超洗浄方式の再生原料による直接接触のボトルが使用されている。

現在、わが国では“ボトルからトレイ”が経済的にも成立するので、食品接触の用途への利用も望まれており、“ボトルからボトル”もＦＤＡのＮＯＬを取得した企業がケミカルリサイクルにより事業を開始する段階に来ており、わが国としての法規制を早急に構築しなければない時期が来ている。関係業界においても、自主的に再生ＰＥＴの食品用途への使用に向けて生産技術の開発、安全性確認の試験、自主規制基準の施行が進められており、国としても再生プラスチックを食品容器に再使用する際の安全性を確保するための法規制の枠組みを検討していく必要があると考えられる。

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## 添付資料

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“Points to Consider for the Use of Recycled Plastics in Food Packaging: Chemistry Considerations”

（2）ドイツ BgVV の再生プラスチックに関するガイドライン
“Use of mechanically recycled plastic made from polyethyleneterephthalate(PET) for the manufacture of articles into contact with food.”

（3）PET ボトルのケミカルリサイクルに関する FDA の見解
“Memorandum from Division of Food Contact Substance Notification Review Chemistry Group1; Submission dated 4/27/01(CTS#75517) from Keller & Heckmann: Need for surrogate testing data in the review of tertiary recycling processes for PET.”

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Premarket Approval
Chemistry Review Branch
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# Points to Consider for the Use of Recycled Plastics in Food Packaging: Chemistry Considerations

This informal guidance was developed to assist manufacturers of food packaging in evaluating processes for producing packaging from post-consumer recycled plastic. The law, regulations and specific letters take precedence over these informal considerations. Comments on this document are encouraged.

*This document supersedes the "Points to Consider" dated May, 1992. No substantive changes have been made.*

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The purpose of this document is to highlight the chemistry issues that manufacturers of recycled plastic should consider during the evaluation of a recycling process to produce material suitable for food-contact application. The possibility that chemical contaminants in plastic materials intended for recycling may remain in the recycled material and could migrate into the food it contacts is one of the major issues to be resolved before the safe use of recycled plastics for food contact can be assured. Other aspects of plastics recycling, such as microbial contamination and structural integrity, are also important, but will not be discussed in any detail in this document.

The suggestions expressed herein are expected to change as new knowledge is acquired and should not be regarded as fixed or all-inclusive. The general regulations under Part 177 of Title 21 of the Code of Federal Regulations (Indirect Food Additives: Polymers) and the requirements specified in 21 CFR 174.5 relating to good manufacturing practice serve as the framework for this document. In particular, 21 CFR 174.5(a)(2) states, "Any substance used as a component of articles that contact food shall be of a purity suitable for its intended use."

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 21 CFR 176.260.

Manufacturers of food-contact articles made from recycled plastic must assure that recycled material, like virgin material, is of suitable purity for food-contact use, and will meet all existing specifications for the virgin material. Several general methodologies exist by which plastic packaging can be recycled, and each introduces distinct concerns regarding the contaminant residues that may be present in post-consumer material. A preliminary discussion of the basic types of recycling is presented along with some specific concerns associated with each. Following this, an approach is described for estimating the maximum level of a chemical contaminant in the recycled material that would be acceptable and not compromise the public health. Finally, a protocol is suggested by which chemistry data can be developed that would be used to evaluate the adequacy of a recycling process to remove chemical contaminants.

## Recycling Processes

There are three distinct approaches to the recycling of post-consumer plastic packaging materials. The packaging may (1) be reused directly, (2) undergo physical reprocessing (e.g., grinding and melting) and reformation, or (3) be subjected to chemical treatment whereby its components are isolated and reprocessed for use in manufacture. The Environmental Protection Agency (EPA) has adopted a now widespread nomenclature that refers to physical reprocessing as secondary recycling (2°), and chemical processing as tertiary recycling (3°). "Primary recycling" (1°) refers to use of pre-consumer industrial scrap and salvage to form new packaging, a common occurrence in industry.

EPA considers "recycling" to be the processing of waste to make new articles. Since 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. Although EPA does not consider reuse to be a recycling process, using the 1°, 2°, and 3° conventions above, it could be considered "zeroth order" recycling. In simple rescue, 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.

### *Reuse*

Glass bottles have a long history of being reused. Milk, bottled water, beer, and soft drinks can be purchased in bottles that are returned, washed, sterilized, and then refilled. Plastic bottles used in this manner must be cleansed by washing and sanitizing so that contaminant residue levels (including any food residue) are low enough so as to not adulterate the food.

The reuse of plastic bottles presents several special concerns. Plastic bottles are more likely than glass to absorb contaminants that could be released back into food when the bottle is refilled. Analytical protocols may need to be developed to demonstrate that, after cleaning, contaminant levels are sufficiently low so that the contents of the refilled bottle would not be adulterated. In addition, while washing and sanitizing or sterilizing the bottles must be shown to be effective for removing contaminants to an acceptable level, the cleansing operation should not have an adverse effect on the integrity of the bottles. Bottles must retain structural integrity and be functional after each cycle of washing and reuse. Plans for reuse of plastic bottles could include, for example, a limit on the number of use cycles a bottle will undergo, an expiration date for the use of such articles, a visual inspection system for gross contamination and damaged bottles, or some combination of these approaches. A limit on the number of use cycles could be difficult to implement, requiring a method for monitoring the number of times a bottle has been reused.

Safety concerns with plastic bottles intended for reuse can be minimized in a variety of ways. The most important may be educating the consumer to avoid storing household chemicals such as garden pesticides and automotive fluids in reusable containers. Labeling the bottles, for example "Food Use Only", is one part of the education process. Requiring a deposit on the bottles could be a useful strategy; the consumer would be less likely to contaminate a bottle that required an investment. Devices, such as hydrocarbon "sniffers" or color scanners, could be a part of the screening process for chemical contaminants. Reusable containers, unlike those intended for recycling, would be returned directly to the store by the consumer or collected at the home by the distributor, thereby adding a measure of control over the source.

### *Pre-consumer Scrap:* **Primary Recycling**

Primary recycling of industrial scrap produced during the manufacture of food-contact articles 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) is acceptable, provided good manufacturing practices are followed. If the home scrap were collected from several different manufacturers, however, concern would arise that the level and type of adjuvants would not comply with existing regulations. Primary recycling will not be discussed further.

### *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 polymer, the ground, flaked, or pelletized resin is washed to remove contaminants. The size of the resin flakes or pellets could influence the effectiveness of the washing. Smaller particles would provide a greater surface area for enhancing the effectiveness of the wash. Different resins may also undergo different reforming conditions, such as different processing temperatures, the use of vacuum stripping, or other procedures, that could influence contaminant levels. 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 reformed plastic have been reduced to sufficiently low levels to assure that the resulting packaging would not adulterate food. To produce a resin with the desired qualities, however, additional antioxidants, processing aids, or other adjuvants may need to be added to the recycled resin. The type and total amount of additives would have to be consistent with existing regulations. Any adjuvants already in the plastic should not react during the recycling process to form unregulated additives. Recycled resins that require new additive or amounts of additives in excess of what is currently regulated would require a food additive petition for food-contact use.

A secondary recycling process presents some unique problems that *may* 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. Where effective source control could be established, however, the problem of commingling post-consumer food-contact materials with other post-consumer plastics would be minimized or eliminated. Nevertheless, even if all the resin were from food-contact materials, limitations on food type or condition of use could be compromised. That is, an additive regulated for use with aqueous food or for refrigerated use, only, could be incorporated into packaging intended for high-temperature use with fatty foods. The result would be a food-contact article that does not comply with regulations. 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 ester (PETE) soda bottle.

Submissions to the Agency involving 2° recycling should address these concerns by incorporating appropriate information regarding controls on the source of the recycled resin, use limitations on the recycled packaging (such as use at room temperature or below), or food-type restrictions (such as dry or aqueous foods only).

### *Chemical Reprocessing:* **Tertiary Recycling**

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.

The primary goal in this type of recycling is the regeneration of purified starting materials. The use of additional adjuvants in tertiary recycling would have to comply with the regulations.

## The Use of a Functional 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. Such use would not present a concern about potential contaminant migration into food as long as the recycled resin was separated from the food by an effective barrier made from a regulated virgin resin or other appropriate material, e.g., an aluminum film.

To demonstrate that a regulated virgin resin functions as an effective barrier to migration of contaminants, the recycler should first subject intentionally contaminated resin (see below) to the recycling process. The recycled resin should then be incorporated into the finished article using virgin resin as the functional barrier, and extraction studies should be performed with food-simulating solvents to demonstrate the effectiveness of the virgin resin as a functional barrier. (See the Recommendations for Chemistry Data for Indirect Food Additive Petitions, June, 1995, from CRB {Recommendations}.) If other data are available that establish sufficient impermeability of a given thickness of a particular resin under anticipated time/temperature use conditions, those data could serve to replace extraction experiments.

## Exposure to Contaminants

Bottles intended to be reused would be sterilized, and 2° or 3° recycling involves conditions (either high temperature, solvent baths, or both) that would effectively sterilize the material. Therefore, exposure to microbiological contaminants should not be of concern.

Acute exposure to chemical contaminants from food containers produced from plastic that has been processed by 2° or 3° recycling is expected to 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 carcinogenic substance (or any other substance that may constitute a chronic health hazard) 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 further recycling will result in dilution of the carcinogen (or any contaminant, for that matter,) a very low steady-state concentration of certain carcinogens could conceivably develop in the recycled material over the long term. Therefore, the potential exists that a consumer could be exposed to low concentrations of a particular carcinogen over a long period of time. In order to develop criteria for deciding what levels of contaminants in the recycled material would be acceptable and not compromise the public health, consideration has been given to the question of carcinogenic risk in a probabilistic way rather than on a compound-by-compound basis.

The establishment of an acceptable upper-limit dietary exposure level to chemical contaminants can form the basis of Good Manufacturing Practice with respect to recycled material. To accomplish this it is necessary to determine the residual concentration of a contaminant that corresponds to an acceptable upper limit of dietary exposure. Preliminary thinking in the Center for Food Safety and Applied Nutrition suggests that dietary exposures to contaminants from recycled food-contact articles on the order of 1 ppb or less generally are of negligible risk. The following exercise illustrates the calculation of the maximum residual level in the plastic for a contaminant of PETE that would contribute no more than 1 ppb to the daily diet.

In the case of PETE, a density of 1.4 g/cm$^3$ and an assumed container thickness of 20 mils gives a package with a mass-to-surface area ratio of 460 mg/in$^2$. Further assumptions include: 10 g of food contacts one square inch of container, a consumption factor (CF) of 0.05, and a food-type distribution factor ($f_T$) of 1.0 (the aqueous $f_T$ for PETE is 0.97) reflecting the use of PETE almost exclusively in beverage bottles (see our "Recommendations"). The relationship between dietary concentration and the CF, $f_T$, and migration level from package to food is:

$$\mathbf{CF \cdot <M> = CF \cdot \sum_{i=1}^{4} (M \cdot f_T)_i = dietary\ concentration}$$

where M is the concentration of migrant into a food-simulating solvent, i, where i represents the four simulated food types: aqueous, acidic, alcoholic, and fatty foods. Using the parameters noted above leads to:

1 ppb in the diet = 0.05(M)(1.0)

and M = (1 x $10^{-9}$g contaminant/g food) / (0.05)

= 2 x $10^{-8}$g contaminant/g food.

Then, (460 x $10^{-3}$g packaging/in$^2$) / (10 g food/in$^2$) = 0.046 g packaging/g food

4.3 x $10^{-7}$ g contaminant/g packaging,

or 430 ppb of contaminant in the packaging material. In other words, if a contaminant were present at 430 ppb in the PETE 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 PETE), the concentration of the contaminant in the daily diet would be 1 ppb.

For polymers other than PETE, the amount of residual contaminant that would result in an exposure greater than the proposed upper limit would vary. Using the consumption factors for food packaged in various polymers from our "Recommendations" and conservatively assuming all food types are used with each polymer, the following table gives examples of the residue levels in several polymers that would give a dietary concentration of a contaminant below 1 ppb (assuming a 20 mil thick container):

| **Polymer (density, g/cm$^3$)** | **CF** | **Maximum Residue** |
|---|---|---|
| PETE (1.4) | 0.05 | 430 ppb |
| Polystyrene (1.05) | 0.08 | 360 ppb |
| PVC (1.58) | 0.11 | 180 ppb |
| Polyolefins (0.965) | 0.33 | 96 ppb |

Thus, to achieve dietary concentrations below 1 ppb, individual chemical contaminants should not be present at, for example, greater than 430 ppb in PETE or 96 ppb in polyolefin containers. The maximum acceptable contaminant levels calculated using the above assumptions are within the capabilities of modern analytical techniques. It must be emphasized that the calculated maximum acceptable contaminant levels depend on the thickness of the packaging as well as the intended use (s). The CF's given above assume that 100% of the food-contact applications will use recycled resin. If a specialized use for the recycled resin can be documented, a lower CF may be used to calculate a maximum acceptable contaminant level. The contaminant limits calculated above also assume 100% recycled resin content in the finished article. In many instances, recycled resin is expected to be blended with virgin resin; this will have the effect of lowering the exposure to the contaminant.

The preceding discussion results from using a worst-case assumption for articles entering the recycling stream. Currently, data that demonstrate or allow a prediction of the actual incidence of contamination of recycled articles are not available. When such data become available, that information can be factored into the exposure calculations and resulting contaminant levels.

Reuse of plastic bottles would not present the same concerns of chronic, low-level exposure to contaminants. Even if a contaminated bottle entered the food stream, it would affect only one or a few consumers at a time before being returned, washed, and refilled. It is unlikely that the same bottle would return to the same consumer. It is also unlikely that the same contaminant would be present in another bottle subsequently obtained by the same consumer. Because the bottles remain intact between uses, contaminants would not be dispersed into other bottles as during recycling processes. Therefore, for reuse of plastic beverage bottles, safety concerns would focus on acute exposure to toxic contaminants, not chronic exposure as for recycled materials.

Concerns regarding acute exposure to contaminants from reuse of plastic bottles are, in fact, currently addressed, with respect to milk containers, in the FDA publication *Grade A Pasteurized Milk Ordinance--1989 Revision* (Public Health Service/Food and Drug Administration, Publication No. 229, p. 73)(1). Three points are relevant to the current considerations. Part 7.d. states, "A device shall be installed in the filling line capable of detecting in each container before it is filled, volatile organic contaminants in amounts that are of public health significance...Any container detected by the device as being unsatisfactory must be automatically made unusable to prevent refilling." Part 7.g., "The container shall not impart into the product pesticide residual levels or other chemical contaminants in excess of those considered acceptable under the Federal Food, Drug and Cosmetic Act, as amended and regulations issued thereunder." Part 7.h. concludes, "The phrase '**Use only for food**' shall appear on all containers." The ordinance also contains a list of cleaning and sanitizing criteria for multi-use plastic containers. These sanitation requirements for milk would be appropriate to reduce acute exposure to contaminants to levels low enough to protect the consumer for other applications where plastic containers may be reused.

## Chemical Contaminants Analysis

The ability of *2° or 3° recycling* to remove contaminants from plastic containers or packaging that has been subjected to consumer misuse or abuse, for example, through storage of pesticides or automotive chemicals, should be demonstrated. Consumer misuse can be simulated by exposing plastic packaging (either in container form or as flaked or ground resin) to selected surrogate contaminants. Following exposure of resin to the surrogate contaminants, the resin would be subjected to the recycling process. Subsequent analysis of the resin for those contaminants would demonstrate the efficacy of the recycling process.

The materials used for the simulation of consumer misuse should bracket a variety of chemical and physical properties. The model contaminants should be "common" materials accessible to the consumer and include a volatile nonpolar organic substance, a volatile polar organic substance, a nonvolatile nonpolar organic substance, and a nonvolatile polar organic substance. Examples of such materials would be toluene, chloroform, lindane, and diazinon, respectively. Toluene and chloroform may be components of cleaning solvents, while lindane and diazinon are common insecticides. A toxic salt, such as disodium monomethylarsonate (crabgrass killer), would complete the range of properties noted. The study should include a polymer-specific contaminant. For PETE, a solvent such as ortho-cresol, which is known to significantly swell the polymer, may be appropriate. For polystyrene, PVC, and polyolefins, a solvent such as acetone or trichloroethane may be appropriate.

If tests are to be performed in a commercial food-processing plant rather than in a laboratory separated from food processing or food packaging activities, the practicality of using toxic materials may be questioned. In such cases, the use of non-toxic model contaminants that have chemical and physical properties similar to the toxins suggested above may be used. Rather than lindane and diazinon, the use of vitamin A acetate as a nonpolar, nonvolatile model contaminant and benzophenone as a polar, nonvolatile contaminant would be acceptable. These are suggestions for the types of contaminants that should be investigated. The actual model contaminants used in any study should be discussed with the agency.

Plastic containers may be contaminated by filling with the model contaminants, either "neat" or in "at use" concentrations. An alternative that would reduce the amount of potentially hazardous wastes would be to soak several kilograms of flaked or ground plastic (the form actually used in the recycling process) in the selected contaminants, again either "neat " or with "at use" concentrations. A mixture, or "cocktail", of the contaminants often could be used. In this case, the components of the cocktail should not react with each other. Once the bottles are filled or after thoroughly mixing the contaminants with the flakes, the bottles or flakes should be stored sealed for two weeks at 40°C with periodic agitation. After draining the contaminants, the concentration of each should be determined. The contaminated resin 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.

For 3° recycling only, the material to be depolymerized may be spiked with contaminant. A spiking level for each contaminant of 0.1% (1000 ppm) by weight of resin being subjected to depolymerization is suggested as a reasonable worst-case level. Because 3° recycling involves regeneration and purification of monomers (or oligomers) it is expected that the amount of residual contaminant in the regenerated polymer will be significantly less than 500 ppb (see "Exposure to Contaminants"). Thus, this spiking protocol may be a relatively straightforward means of simulating worst-case consumer abuse and be useful for demonstrating the ability of the 3° recycling process to remove contaminants.

Testing protocols should be submitted to FDA for comment before any contamination studies are done. All analyses should be validated as discussed in our Recommendations for Chemistry Data for Indirect Food Additive Petitions.

If a proposed recycling process cannot be shown to remove contaminants to an acceptable upper-limit of dietary exposure under the 100% consumer contamination scenario discussed above, then additional justifiable factors could still lead to a conclusion that the recycled package will not introduce contaminants into the diet at unacceptable levels. Additional factors relevant to the determination of the upper-limit of dietary exposure include the use of recycled/virgin blend, source controls, restricted uses, the fraction of contaminant that migrates into food or a food stimulant, or the use of a functional barrier. Consideration of each additional factor must be supported by adequate documentation (e.g., studies on a specific source control program, actual extent of contaminated material entering the recycling stream, and research to demonstrate that the recycled resin is separated from food contact by a functional barrier).

## Conclusions

A general approach has been proposed for obtaining chemistry data that demonstrate the ability of a 2° or 3° recycling scheme to reduce chemical contaminants in recycled material to what may be considered acceptable levels. A recycling scheme reflecting GMP should produce a product that would result in a dietary exposure of the order of 1 ppb or less for any one chemical contaminant. Recycled material is expected to meet all specifications existing for the virgin material.

Contamination from consumer misuse is not the only consideration. The amounts and nature of any additives used in the recycling process must also be assessed by the recycler, and if the use of any additive is not consistent with current regulations, a food additive petition for its use in manufacturing a food-contact article is required.

For reuse of plastic bottles, the primary issues consist of adequate source controls, consumer education, package integrity over the lifetime of the container, and adequate cleaning and sanitation to eliminate chemical and microbial contaminants.

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## Footnote

1. Cleaning and sanitizing multiservice bottled water containers is also addressed in FDA's good manufacturing practice regulations for bottled water in 21 CFR Part 129.

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Bundesinstitut
für gesundheitlichen Verbraucherschutz und Veterinärmedizin

# Use of mechanically recycled plastic made from polyethylene terephthalate (PET) for the manufacture of articles coming into contact with food

*The Expert Group on Plastic Material for Food Contact of the Federal Institute for Health Protection of Consumers and Veterinary Medicine (BgVV) has dealt with the use of mechanically recycled plastic made from polyethylene terephthalate (PET) for the manufacture of articles coming into contact with food. As a result, the following opinion is stated:*

## 1 Legal situation and introduction

According to § 5 para 1 no. 1 of the German Act on Foods and Commodities (LMBG), mechanically recycled polyethylene terephthalate for food contact use must meet the same requirements as virgin PET as given in §§ 30 and 31 (1) of LMBG as well as those of the German Regulations on Commodities (Bedarfsgegenständeverordnung). No PET constituents are allowed to migrate into the food except they are considered to be safe with regard to consumers' health and acceptable with regard to affecting food odour and taste and only in such amounts which are technically unavoidable.

Manufacturers and distributors of such commodities coming into contact with food made from PET are fully responsible for the safety to health within the scope of the principles of good manufacturing practice and due diligence.

The Committee on Plastic Material for Food Contact of the Federal Institute for Health Protection of Consumers and Veterinary Medicine had already issued earlier an opinion on plastic articles for multiple use and on recycled plastics for the manufacture of articles for food contact [1].

The starting material for mechanical recycling is generally divided into three quality classes:

***Class 1:***

Materials remaining from production by the manufacturing or converting industry (primary recyclate) where their past history is known and which have always been under the control of the processor. If contamination can be excluded, this material is as suitable for direct contact with foodstuffs as new material.

***Class 2:***

Pure-grade but contaminated material (secondary recyclate) which had been used for food packaging for known applications and re-collected pure-grade by the utilizer, for instance via a deposit system or material collection. The utilizer does not usually have complete control of the plastic materials over the time period from its first use up to its return.

***Class 3:***

Non pure-grade and contaminated material (secondary recyclate) which had been used like class 2 material for certain applications also outside of the food packaging area and enters the recycling system via mixed plastics collection, for example such ones as operated by 'Duales System Deutschland' (DSD).

In the past years, essential technological progress has been made in the area of decontamination of "post-consumer" plastics, in particular from the PET beverage bottle market. The development of modern recycling procedures increasingly allows cleaning and reconditioning of "post-consumer" recycled PET for being reused in direct food contact applications. In parallel, research carried out in connection with this technological development has provided an enormous increase in knowledge which allows today to assess with sufficient confidence and safety the extent of interaction processes of possible recyclate-specific contaminants between PET bottles and the infilled foodstuff [2].
In order to take account of these developments and in the absence of regulations in this new area of food packaging applications at a European level, guidelines have been elaborated as a supplement to the general opinion of the Plastics Committee from 1995. These guidelines shall assist the relevant industry implementing R&D developments in the field of PET recycling.

## 2 Guidelines for the use of recycled PET

### State of the art

In the manufacture of articles from primary plastics there is normally perfect control of the starting raw materials used. For secondary recyclate materials as in categories 2 and 3, complete control of the material is not possible. Here, it can be expected that substances are introduced which are untypical of polymers, above all components from the filled product from the first use but also from misuse by the consumer and that corresponding contamination of the secondary recyclate material occurs.

As is generally known, plastics can interact with organic chemicals. The extent of this interaction depends on the diffusion behaviour specific to polymers and the sorption properties of the plastic. These properties ultimately determine the potential risk of food contamination due to recycling. In relation to this aspect, PET possesses much more favourable material properties in comparison to other packaging plastics, such as polyolefins or polystyrene and is, therefore, much better suited for mechanical recycling for being reused in the commodity sector.

Recycling processes for the manufacture of recycled PET as a final product, which is safe from the angle of food legislation, must include processing steps which efficiently clean the plastic and eliminate substances which originate from the first use or possible misuse. It is therefore imperative in this highly sensitive field that the utilizer of secondary recyclate material demonstrates in a worst-case scenario that, even under the most unfavourable conditions, conformity with the Act on Foods and Commodities (LMBG) is ensured for the articles partially or completely manufactured from recycled material.

For the safe manufacture and use of commodities made from recycled PET the following points must be taken into consideration:

***I. Control of material recovery logistics***

***II. Testing and evaluation of the efficiency of cleaning steps in the recycling process***

***III. Analytical quality assurance***

**Ad I:**

The first use of the returned material and the proportion of foreign polymers is controlled by *material recovery logistics.* Only original food-grade PET shall be used as the raw material source for the recycling process. A deposit system for drink bottles or a controlled, pure-grade re-collection system normally fulfils the mentioned requirements for recovery control. If other re-collection systems are used, the sorting process must ensure the corresponding purity grade. Experience has shown that maximum fractions of foreign polymers of 1% are technologically attained when good manufacturing practices are adhered to. Under foreign polymers also pure-grade PET material which has not been used in its first application in contact with food is understood. Sufficient sorting efficiency is to be guaranteed by corresponding control measures.

***Guideline 1:*** *Use only food-grade PET quality as a raw material source. Ensure a sorting efficiency to provide purities of at least 99% excluding other PET qualities and foreign polymer fractions.*

**Ad II:**

The efficiency of the cleaning steps in the recycling process is checked and assured by a so-called "challenge test"[3]. For this test, organic chemicals with varying chemical and physical properties are introduced into the sorted (see above) returned PET material which is then recycled by the process to be assessed. The organic substances serve as model contaminants or so-called surrogates. A model food contact article is then manufactured using the regranulate contaminated in this way which is subjected to migration testing. Recommended chemicals are listed below which should be used as surrogates.

| | |
|---|---|
| *Recommended model contaminants:* | *Toluene, chlorobenzene, phenyl cyclohexane, benzophenone, methyl stearate.* |

The contamination must be carried out in such a way that sufficient amounts of chemicals can diffuse into the plastic material. It is recommended to work with a mixture of all chemicals. The initial concentration of the model contaminants to be used must be sufficiently high to establish a worst-case scenario with respect to the recycling system to be assessed or, if necessary, the modular cleaning step which is to be checked. With pure-grade re-collected PET, for example, a concentration in the range of 500 ppm (mg/kg) to 1000 ppm per model contaminant used is a sufficient initial condition for checking the entire process. An addition of too high initial concentrations can have a negative effect on the processablility of the contaminated material within the challenge test and may lead to technical difficulties during the manufacture of the regranulate and the model food contact article. According to the present state of knowledge, initial concentrations of 500 ppm to 1000 ppm include a safety factor in the range of 100 to 1000 with respect to really ocurring maximum initial concentrations of foreign substances in recycled PET which are PET untypical and do not originate from the previously filled foodstuff. By mixing single misused bottles, which may occur sporadically, with large amounts of fully uncontaminated returned PET material, there results an extremely high dilution effect as a rule.

The recycling process to be assessed by the challenge test must be able to remove the recycling-related substances introduced so efficiently that the finished product (regranulate) meets the requirements of food legislation. To guarantee this, the model article coming into contact with food that has been produced in the challenge test shall undergo migration testing. It should be noted that the conditions of the envisaged use of the article containing recycled material influence the extent of possible migration into food. The migration-determining parameters are contact time and temperature as well as the nature of the real filling product, in addition to the corresponding test conditions according to EU Directive 97/48/EC and EU Directive 85/572/EEC, respectively. With regard to the conditions of use it