Revised: September 1999

SECTION H

Environmental Assessment for Food Additive Petition Terephthalate - Isophthalate Polymers

EN

1. ***Date:*** 14 September 1999 (This revision supersedes earlier versions dated 22 January 1999, 31 October 1996, and 27 February 1995.)

2. ***Name of petitioner***: BP Amoco Chemical Company

3. ***Address:*** Correspondence on this Environmental Assessment should be sent to:

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4. ***Description of the Proposed Action:***

4.A. ***Requested approval.*** BP Amoco Chemical Company (BP Amoco)[1] proposes that the existing regulation at 21 *CFR* 177.1630 be modified to permit the safe use of poly(ethylene terephthalate)-poly(ethylene isophthalate) copolymers (PET/PEI or PETI) for single and repeated use food contact applications, with from 83 to 97 weight percent of the polymer units derived from ethylene terephthalate. BP Amoco proposes that terephthalate/isophthalate copolymers be permitted for use as the base polymer in the fabrication of food packaging containers under a wide range of use conditions, as specified in Section A of this petition. Isophthalate-modified PET is currently approved for food-contact use for copolymers containing 0 to 3% ethylene isophthalate polymer units by weight and for copolymers containing 17-23% ethylene isophthalate polymer units.

Amoco's original environmental assessment (EA) was submitted in February 1995. On January 18, 1996, FDA commented on this EA in a "guidance document" stating that additional information, clarifications and corrections were required. Amoco developed and submitted a response to these documents on October 31, 1996. The January 1999 revised EA discussed new potential market applications identified in mid 1998. The current revision responds to FDA comments dated August 24, 1999.

4.B. ***Intended Market for Food Packaging***. BP Amoco expects that terephthalate/isophthalate copolymers will compete with existing food-packaging applications, particularly in use as beverage containers and thermoformed sheet packaging from amorphous poly(ethylene terephthalate), abbreviated as "APET". Beverage applications include, carbonated soft drinks, non-pasteurized beer, sports drinks or isotonics, still mineral waters, carbonated waters (including new-age drinks), cold-filled teas, and

[1]BP Amoco Chemical Company is the successor to Amoco Chemical Company, following the merger of British Petroleum with Amoco in late 1998. For convenience, actions and references predating the merger will continue to refer to "Amoco."

aseptically-filled (cold-filled) juices. PETI resin applications in cups or formed sheet packaging include disposable clear drinking cups, blister packaging, clear clamshell packaging and tubs or deli cups.

BP Amoco believes that these uses are primarily characterized as "single-use" although, in practice, some containers may be re-used by consumers. For the purposes of this environmental assessment, BP Amoco assumes that all uses of the proposed polymers will be in single-use applications. This assumption would overestimate any potential environmental impacts and thus is a conservative assumption.

This environmental assessment is based on the estimated change in market for food-contact uses for terephthalate/isophthalate polymers that BP Amoco believes reasonable following FDA approval of this petition.

The largest food contact application currently in use is in isophthalate-modified polyethylene terephthalate bottles, especially for carbonated soft drinks (CSD). This use was envisioned by American Enka and Goodyear Tire & Rubber Co., who submitted Food Additive Petitions 5B3871 and 5B3884 in 1985 seeking approval of 0 to 2% and 0 to 3% isophthalate content, respectively. FDA found that there would be no significant environmental impact from approval of those petitions, issuing a regulation approving 0 to 3% use on September 1, 1987.

A previous Food Additive Petition was submitted by 3M, who received approval of 17 to 23% isophthalate in response to FAP 0B2567. The primary application envisioned was for temperature-resistant oven films for food contact applications.

This present petition seeks to modify the approved isophthalate content to include the 3 to 17% range. BP Amoco provides a market estimate in the Confidential Appendix V of this petition. The estimates assume sufficient time for acceptance of the product in the market, which is taken to be about 5 years after FDA approval.

The current technologies to make plastic food packaging materials are suitable for making PETI copolymer packages, so many food packagers would probably not need to make significant process changes or investments. BP Amoco has been optimistic in the development of market estimates, however, the lack of market acceptability or dramatic economic shifts might alter market penetration in ways that BP Amoco cannot reasonably anticipate.

BP Amoco believes that the proposed food additive will compete with and potentially replace applications that currently use glass, aluminum, and PET in beverage containers and amorphous PET thermoformed sheet. The anticipated applications include a variety of beverage containers and several package shapes made from APET sheet.

Each type of application is discussed below, along with a description of the significant factors that affect the potential feasibility and acceptance of isophthalate-containing polymers in that market.

Beverage Containers

PET modified with purified isophthalic acid (PIA) has become the standard for commercial grade bottle resin throughout most of the world. Currently, "standard PET" is defined as the commercially available bottle-grade PET resin modified with low levels of ethylene isophthalate ranging from 1 to 3 percent.[2] As used in this EA, "higher level isophthalates" refers to PETI copolymer with ethylene isophthalate content from 3 to 17 wt%. BP Amoco has used a 10% isophthalate copolymer (PETI-10) as a representative composition for testing the suitability of PETI copolymers for specific applications, however, resin suppliers like to differentiate their products, so compositions are likely to vary.

Increasing the percentage of isophthalic acid in PET:

1) reduces a bottle's permeability to gases (carbon dioxide and oxygen) thus increasing product shelf life;
2) reduces the rate of thermal crystallization in thicker cross sections, making it possible to create perfectly clear, high performance bottles with intriguing shapes.
3) allows for the processing at lower temperatures during injection molding of bottle preforms, creating the potential to reduce both acetaldehyde production and cycle times (operating costs). Elevated levels of acetaldehyde can impart an unpleasant taste in still and carbonated bottled waters.

These three performance advantages lead to potential applications of PETI-10 (i.e., PET modified with 10% isophthalate) in non-pasteurized beer, fruit juice, cold fill teas, sports drinks (isotonics), and still and carbonated water. A potential application of PETI-5 (i.e. PET modified with 5% isophthalate) is being forecasted for the soft drink markets.

Modification levels of 10% or less are expected to meet the needs of most resin manufacturers. Resin manufacturers will balance the incremental improvements in properties and process by increasing isophthalate content against the costs of different resin compositions. Costs for increased isophthalate content increase as a linear function of the proportion of isophthalate vs. terephthalate. Once a desired performance or processing ability is attained, container manufacturers have no need to increase isophthalate levels. For example, once an adequate shelf life is attained, no additional costs are necessary. Or, once acetaldehyde levels are reduced below taste and odor thresholds, no further processing improvements would be desired. Consequently, manufacturers would reach a balancing point where no further isophthalate modification would be desired. In addition, physical properties of isophthalate-modified PET show a plateau, i.e., a decreasing rate of improvement with additional isophthalate content. BP Amoco studies and discussions with customers suggest that PETI-10 is likely to be the maximum practical level of isophthalate needed to achieve the desired improvements in bottle applications.

Soft Drinks - Increasing isophthalate content in soft drink containers with 16 oz to 2 liter capacity has the potential to allow bottle-fillers to optimize their bottling/distribution systems (due to increased shelf life). This increase will also facilitate the fabrication of containers with proprietary shapes and improve bottle fabrication economics. Consequently, we have assumed significant penetration for higher level isophthalates in these applications.

Beer - Containers with higher isophthalate content may be ideal as a primary packaging material for non-pasteurized beer when used in multi-layer constructions. This is because of their improved carbon dioxide barrier properties combined with ease of fabrication. The size of the potential market is limited by the market share (<25%) of non-pasteurized beer and by the high price sensitivity of most off-premise

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[2] Amoco Chemicals, "Bottle Enhancements: Extending the Performance of PET with Amoco® PIA", Bulletin PK-1, Chicago, Illinois. September, 1998. (Reference Tab 1)

marketing channels, such as grocery stores, drug stores and mass merchandisers. Our forecast assumes that higher level isophthalate containers will be limited to less price sensitive markets such as single serve containers sold mostly in convenience stores as well as certain on-premise markets such as concession sales, where the advantages of lightweighting, an unbreakable bottle and rapid service are critical. Higher-level isophthalate copolymers will replace glass, cans and paper cups (on-premise venues) in these market channels.

Still Water - A significant portion of premium still water sold in the United States is imported from Europe. Taste is very critical for these particular products and the presence of acetaldehyde imparts an unpleasant flavor to still waters. Higher-level isophthalate copolymers offer the brand owner the opportunity to minimize the presence of acetaldehyde in their products. Consequently, our forecast assumes that one of the major imported brands converts their production to high-level isophthalate copolymers over the next five years. Higher level isophthalates will replace PET which is currently used in these markets.

Carbonated Water (New Age Beverages) – PET containers have limited acceptance within the carbonated water market (including lightly carbonated fruit beverages) due to the inadequate carbon dioxide barrier properties of PET. Our forecast assumes that a significant proportion of 16 oz and larger glass containers will be replaced by higher level isophthalate.

Cold Fill Teas - An increasing proportion of the ready to drink tea market has already converted to cold fill processes and is packaged in 12 oz cans. This segment of the market is rapidly growing, but its price sensitivity inherently limits the size of the potential market for plastics. However, ready to drink teas are also available in glass containers (16-24 oz) and plastic containers (32 oz and larger) which are currently hot filled. Our forecast assumes that PET with > 3% isophthalate levels will provide the shelf life needed to allow use of plastics in smaller size packages (16-24 oz) and that at least one of the major brands will elect to convert their operations to fill these plastic packages via the cold fill techniques currently used for 12 oz cans.

Sports Drinks (Isotonic) - Over the past several years, there has been a proliferation of new flavors and package types introduced into this market. About 10% of the total isotonics market consists of slower moving flavors packaged in plastic 32 oz and higher which could benefit from the additional shelf life higher isophthalate containers would provide. Our forecast assumes that one of the major brand owners converts their packaging for these flavors to higher level isophthalates and converts their operations to cold filling to permit their use.

Cold Fill 100% Fruit Juice - Over the past several years, there has been a major move to the use of cold filling techniques to permit the packaging of fruit juices in plastic. One of the factors that has limited this conversion is the need to use preservatives because of PETs inadequate barrier properties, particularly in smaller sizes. Our forecast assumes that higher isophthalate levels will allow sufficient shelf life to permit one of the other major brand owners to convert from glass to plastic using cold fill techniques.

Sheet Applications

Currently, APET sheet applications consist of package shapes used for packages containing bakery products, salad and delicatessen items, cheese and dairy products, shortenings and margarines, refrigerated sauce and pasta, and sliced meats.

In addition to PET, other packaging materials may be used, including polystyrene (PS), polypropylene (PP), high-density polyethylene (HDPE), multilayer plastic materials or paper/paperboard.

In order to identify what materials are currently in use, a survey of two large Chicago area food stores was made.[3] The deli, bakery, sliced meat, refrigerated food and dairy sections of these stores were checked to identify the types of packaging material in use. In addition, other sections of one store were checked to identify the use of PET in non-bottle applications. SPI resin codes were used to identify the type of plastic material.

The intent was to document the types of materials used and not to identify the relative shelf space of specific products or other quantitative market information. Consequently, packages of different styles were sought instead of trying to document all products in a similar package. For example, there are a variety of prepackaged salads in 16 oz deli cups; rather than record all types of salad in the same style cup, only one type was noted. It is likely that some products dominate their market, increasing the predominance of one type of package material. However, such information was not sought or recorded.

This survey, although only semi-quantitative, found several patterns:

- Current PET packages tend to be the higher-priced or gourmet items. Lower priced materials, such as PS or HDPE, appear to dominate in most applications.

- Clear PET was used in a range of food packaging types, as blister packaging (e.g., solid shortening sticks, bakery containers, delicatessen containers), tubs (e.g., dried fruit and nuts) or cups (disposable cups, chicken salad lunch kit).

- PET was only found in applications where clear display of the package contents were desired. No PET was used in applications where the contents were not displayed, such as margarine or yogurt. Colored PET was used only in the bottom of clamshell or two-piece packaging with a clear top.

- PP was the most frequently used material for deli cups used for prepackaged individual servings and delicatessen counter sales. Refrigerated sauces, such as for pasta, were also packaged in PP. Several cheese and dairy products were in PP, as were some yogurt products. Clear PP was used for deli and sauce applications and white or colored PP was used for the cheese and dairy products.

- HDPE was used in delicatessen and margarine tubs as well as several cheese and dairy products. Lids for salad bar and delicatessen cups were most frequently HDPE.

- PS was frequently used for bakery products, salad bar packaging and yogurt containers.

- "Other" plastic packaging was found for some sliced meat brands that use a formed sheet backing (blister pack). Refrigerated pasta also was in formed sheet packages sometimes labeled with the "Other" code.

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[3]M.C. Harrass, September 1996. "Market Survey Report" (Reference Tab 2)

- Aluminum appeared only in foil lids over resin cups, as part of a laminate (cream cheese) or in a tab top package (rendered fat, whipped cream cheese).

- Virtually no vinyl (polyvinyl chloride or PVC) was identified in these applications. One cheese product, Farmer's cheese, was in a vinyl package.

- Paper/paperboard applications were very limited. Whipped butter, was in paper/paperboard tubs. Large (5 pound) prepackaged salads were found in gable paperboard cartons.

- Low-density polyethylene (LDPE) was found only in bags, such as used for produce, bakery, or groceries.

FDA[4] noted that Amoco did not include polyvinylidene chloride (PVDC), PVC, LDPE or linear low-density polyethylene (LLDPE) among materials expected to be replaced by the proposed food additive. FDA cited *Modern Plastics* articles in January 1994 (pp. 74-75) and January 1995 (pp. 64-66) and an older reference (Calvin J. Benning, *Plastics Films for Packaging*, 1983, p. 55) as evidence that these materials are used in plastic sheet and film.

BP Amoco does not dispute that PVDC, PVC, LDPE or LLDPE have applications in food contact sheet and film. However, the food store survey suggests that these materials are not abundant in the types of applications where thermoformed amorphous PETI sheet would be competitive. The above materials have significant use as flexible films and bags, but the PETI sheet is not a comparable application.

One source of confusion is that film and sheet applications are not routinely nor consistently distinguished or subdivided in the information available. US EPA[5] does not provide a separate category for film and sheet applications, instead having the categories of "Other plastic containers", "Bags, sacks and wraps", and "Other plastics packaging" (US-EPA, 1994, Table 7, p. 43). Nor does EPA include PVDC or LLDPE among the materials it tracks. The *Modern Plastics* 1995 article (p. 64) distinguishes between food from non-food use of LLDPE, LDPE and HDPE film but does not do so for sheet; PVC has a single relevant category "packaging" and PVDC is not mentioned. The film applications are subdivided somewhat in a companion journal, *Modern Plastics International* (January 1994), but not for sheet applications. Because the envisioned applications for the PETI copolymer are thermoformed sheet, details about film applications are not relevant to this petition.

There are a variety of products currently used in food packaging applications, but a relatively small fraction is used in sheet applications. Table H-1 shows EPA's estimates of food packaging products in the municipal waste stream.[6]

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[4]In a letter dated January 18, 1996, FDA commented on Amoco's original Environmental Assessment dated 27 February 1995.

[5]U.S. Environmental Protection Agency (US-EPA), 1994. "Characterization of Municipal Solid Waste in the United States: 1994 Update." Office of Solid Waste and Emergency Response, Washington, DC. EPA/530-R-94-02. NTIS # PB95-147690.

[6]U.S. Environmental Protection Agency (US-EPA), 1997. "Characterization of Municipal Solid Waste in the United States: 1996 Update." Office of Solid Waste and Emergency Response,

Table H-1. Selected Materials Generated in the Municipal Waste Stream
Values are in millions of pounds. Source: , US-EPA, 1997, Table 18.

Type of Product	1980	1990	1993	1995
Glass Beer & Soft Drink Bottles	13480	11280	10960	10240
Glass Wine & Liquor Bottles	4900	4060	3920	3580
Glass Food/Other Bottles & Jars	9560	8320	9660	9240
Combined Glass:	**27940**	**23660**	**24540**	**23060**
Aluminum Beer & Soft Drink Cans	1700	3100	3220	3160
Aluminum Foils and Closures	760	660	700	700
Aluminum:	**2460**	**3760**	**3920**	**3860**
Paper/paperboard wrapping	400	220	180	140
Other paper/paperboard packaging	1700	2040	2080	2240
Combined Paper/paperboard	**2100**	**2260**	**2260**	**2380**
Plastic Soft Drink Bottles	520	860	1120	1320
Plastic Milk Bottles	460	1060	1080	1260
Plastic Other Containers	1780	2860	3220	2500
Plastic Wraps	1680	3060	3640	3440
Other Plastics Packaging	1580	4080	4560	4540
Combined Plastics:	**6020**	**11920**	**13620**	**13060**

BP Amoco considers the details of the specific applications anticipated by this petition to be confidential. However, the EPA figures shown in Table H-1 overestimate potential uses for isophthalate-containing polymers associated with this petition because isophthalate-containing polymers will not compete with all the packaging products listed. Confidential Appendix V identifies the applications identified by BP Amoco anticipated by this petition.

Market estimates of various plastic resins are published by *Modern Plastics*. Table H-2 shows selected market applications for PET. Estimated sales of PET and its copolymers exceeded 3.9 billion pounds in 1995, including exports, according to *Modern Plastics* (January 1996).

Washington, DC. EPA/530-R-97-015.

Table H-2. Major markets for Polyethylene Terephthalate
Values are in million pounds. Source: *Modern Plastics*, January 1993, January 1994, January 1995, January 1996, January 1998.

Market	1991	1993	1995	1997
Blow molding				
Soft-drink bottles	793	1015	1540	1828
Custom bottles (cosmetics, toiletries, pharmaceuticals, food, liquor)	403	560	880	1322
Extrusion				
Film (excluding magnetic)	550	562	680	*
Magnetic recording film	90	94	102	*
Ovenable trays	50	57	65	55
Coating (for ovenable board)	13	15	17	18
Sheeting (blisters, cups, food trays, etc.)	87	112	154	130
Strapping	36	40	43	*
Exports 318	280	440	396	
TOTAL	2340	2735	3921	3748

* Not Reported

BP Amoco projects that the market for the PETI copolymers that are the subject of this petition will be a small fraction of the current and future markets for PET (detailed in the Confidential Appendix V of this petition). PET is manufactured by many companies in the U.S., including Eastman Chemical, Shell, Trevira (Hoechst Celanese) and DuPont (ICI). U.S. production capacity of PET in 1998 exceeds 5.4 billion pounds. Due to a number of expansions and new producers, production capacity is expected to increase to approximately 6.3 billion pounds in the year 2002. Table H-3 shows major producers of PET and their capacities for bottle-grade resin.

Table H-3. Major Producers of Bottle-Grade Polyethylene Terephthalate
Values are in million pounds of capacity at U.S. facilities. Sources: *Chemical Data Inc.*, March 1993, February 1994, *Chem. & Eng. News*, 7/18/94, *Plastics News*, 8/8/94, Container Consulting Inc., "North American PET Supply Demand", 1/98.

Supplier	1990	1994	1996	1998	2000	2002
Trevira (Hoechst Celanese)	250	594	841	1179	1190	1190
DuPont (ICI)	125	165	312	325	325	325
Shell / Goodyear	490	581	737	935	935	935
Eastman	920	1342	1862	2056	2265	2320
Wellman	0	78	190	490	970	1065
Nan Ya Plastics	0	0	240	480	480	480
TOTAL	**1860**	**2760**	**4280**	**5465**	**6165**	**6315**

Consumption	1990	1992	1994	1997
Total	1508	2100	2280	3220

4.C. ***Location of Production.***

FDA has revised its environmental regulations, effective July 29,1997 and has advised[7] BP Amoco that the agency no longer routinely asks that information about environmental introductions resulting from the production of an FDA-regulated substance. FDA suggested that BP Amoco remove all discussion that relates to production of the subject copolymers. FDA also advised BP Amoco to determine whether any extraordinary circumstances pertain to the manufacture of the subject copolymers.

FDA defined "extraordinary circumstances" to include situations where (1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal State or local environmental agencies and the emissions may harm the environment; (2) a proposed action threatens a violation of Federal State or local environmental laws or requirements (40 *CFR* 1508.27(b)(10)); and (3) production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Fauna and Flora to be endangered or threatened or wild fauna or flora that are entitled to special protection under some other Federal law.

BP Amoco had previously described information about locations of production in Section 4.C.i of its previous EAs and had provided information about environmental introductions from sites of production in Section 6.A. This complied with the previously required format for EAs and included responses to questions asked by FDA in 1996.

To respond to FDA's advice reflecting its revised environmental regulations, BP Amoco has determined that there are no extraordinary circumstances that pertain to the manufacture of the subject copolymers. (1) The circumstances of emissions are adequately addressed by existing emission requirements,

[7] Letter from Julius Smith, FDA to Mary Michaels, BP Amoco, August 24, 1999.

including occupational. There are no emissions that would be significantly different than those produced by current production of polyethylene terephthalate/polyethylene isophthalate (PETI) copolymers. (2) No laws or regulations pertaining to threatened or endangered species would be threatened. The proposed action involves no alterations of the physical environment, such as construction or harvesting of natural resources. (3) Production associated with the proposed action would not affect species or critical habitat of species entitled to special protection under Federal law. No trade of flora or fauna is involved.

FDA advised that BP Amoco should remove all discussion in the EA that relates to production of the subject copolymers. Consequently the text in Sections 4.C.i and 4.C.ii of the January 1999 EA has been removed.

4.D. ***Locations of Use.*** The production of food packaging articles using the proposed food additive is expected to occur in facilities that are presently involved in fabricating food contact articles from polymers or copolymers. There are hundreds of such facilities and BP Amoco is not able to identify that a specific facility will produce food packaging containing the proposed food additive. Consequently, BP Amoco is not able to describe the environments where such production may take place. These probably can be described as light industrial facilities that may be located in rural, urban or industrial areas.

4.E. ***Locations of Disposal.*** Food-packaging materials made from the proposed food additive are expected to be used in patterns corresponding to national population density and will be widely distributed across the country. Consequently, disposal will occur nationwide with the materials ultimately being deposited in landfills, incinerated, or possibly recycled where PET recycling programs are in place.

Environments potentially affected by disposal would be watersheds or groundwater receiving leachate from land disposal sites and areas subject to air emissions from landfills and incineration sites. BP Amoco believes that the types of food packaging that will use the proposed food additive are likely candidates for post-consumer recycling programs. The proposed PETI material is expected to be compatible with current PET recycling.

5. ***Identification of chemical substances that are the subject of the proposed action.***

The proposed food additives are terephthalate/isophthalate copolymers containing 3 to 17% ethylene isophthalate content by weight. BP Amoco has described the chemical nature of the materials and the anticipated technical improvements due to the terephthalate/isophthalate copolymers in Section A of this petition. BP Amoco expects that the improved technical properties of the polymers, combined with the polymer's compatibility with current processing technologies, will permit substitution of the polymers for currently used materials with no significant disruption of food packager's processing.

The subject of this petition are poly(ethylene terephthalate/isophthalate) copolymers (CAS Numbers 24938-04-3, 130758-99-5, 26427-53-2, 26006-30-4 and 25135-73-3), in which the finished copolymer may contain from 83 to 97 weight percent ethylene terephthalate.

Other names for the terephthalate/isophthalate copolymer include:

- ethylene terephthalate-isophthalate copolyester,
- 1,3-benzene dicarboxylic acid, polymer with dimethyl-1,4-benzene dicarboxylic acid and 1,2-

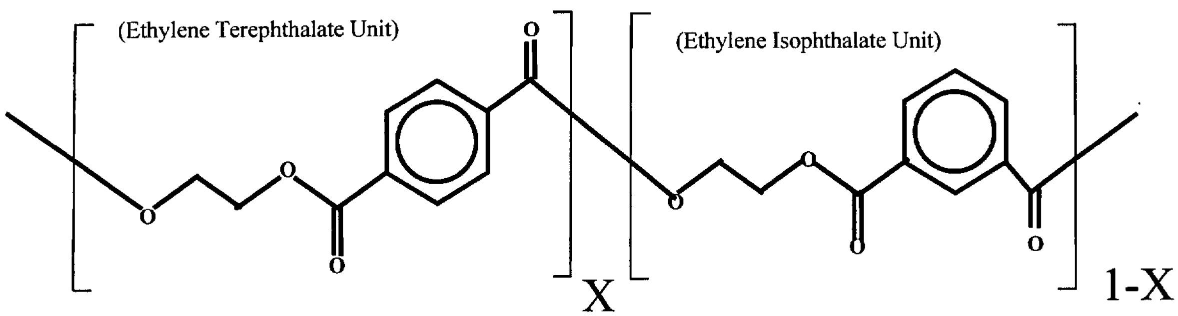
ethanediol,

- poly(ethylene terephthalate)-poly(ethylene isophthalate) copolymer, and
- ethylene glycol terephthalate-ethylene glycol isophthalate copolymer.

The chemical structure for the copolyesters is best described as ethylene glycol connected by ester linkages to either terephthalic acid or isophthalic acid in a random manner with terephthalic acid comprising 83-97 weight percent of the acid content and isophthalic acid comprising 3 to 17 weight percent of the acid content. Figure H-1 shows the diagrammatic molecular structure. Box 1 describes the nomenclature applied to the PETI copolymers in this document.

Figure H-1 Structure of PETI Copolymers

PETI copolymers are based on repeating units of ethylene terephthalate and ethylene isophthalate units. The PETI copolymers that are within the scope of this petition have X ranging from 83 to 97%.



The average molecular weight range is 19,000 to 40,000 g/mole, as determined from inherent viscosity (IV) of the copolymer range of 0.55 to 1.0 dl/g. Typical properties for PETI copolymer are:[8] glass transition temperature, T_g, of 77 to 83 °C, and melt temperature, T_m, of 221 to 250 °C (although variations of 2 to 5 °C might be expected in interlaboratory comparisons).

PETI copolymers are formed by either esterification or transesterification followed by polycondensation of terephthalic acid or dimethyl terephthalate, and isophthalic acid or dimethyl isophthalate, with ethylene glycol, during which water or methanol is removed from the reactor vessel. The relative composition of PETI is controlled by adjusting the ratio of acids or dimethyl compounds.[9]

A related polymer is the homopolymer of terephthalate. Polyethylene terephthalate (CAS 25038-59-9 and 9003-68-3) is also known as 1,4-benzene-dicarboxylic acid, polymer with 1,2-

[8] Bauer, C.W. 1999. "SIBU - PET-X Thermal Properties" BP Amoco Chemical Company. (Reference Tab 3).

[9] Bakker, M. (Editor), 1986 "Thermoplastic Polyesters" in The Wiley Encyclopedia of Packaging Technology, John Wiley & Sons, New York. pp. 512-514. (Reference Tab 4)
Radian Corp., 1986, pp. 325-332. (Reference Tab 5)

ethanediol, abbreviated as PET or PETE, and has the generic molecular formula $(C_8H_4O_2.C_2H_4O_2)_x$. PET is a medium-density (about 1.33 g/cm^3) resin with a relatively high melting point (ca.248-260°C), depending on what copolymer modifications are used. PET polymers for food contact are presently regulated under 21 *CFR* 177.1630 and are presently used for a variety of single-use and repeat-use food contact applications. Specifications for allowable additives and impurities are included in FDA regulations. Clarity, strength and good barrier properties contribute to widespread use of PET in food packaging. PET has numerous uses in applications not regulated by FDA such as in non-food containers, fibers and films (see Table H-2 above).

Copies of selected Material Safety Data Sheets (MSDSs) for these types of materials are attached to this environmental assessment.[10]

Box. 1 Nomenclature for Isophthalate-modified PET

Description of the level of isophthalate modification in this document reflects the relative fractions of ethylene terephthalate and ethylene isophthalate in the copolymer. Because the molecular weights of the terephthalate and isophthalate moieties are the same (i.e., they are isomers), the mole fraction equals the weight fraction. For example, PETI-10 refers to a copolymer with 10% of the polymer units derived from isophthalic acid and 90% of the polymer units derived from terephthalic acid. This material may also be called a 10% isophthalate copolymer. As depicted in Fig. H-1, PETI-10 would be a copolymer with 10% of the polymeric units being ethylene isophthalate. This convention is used in this document and seems most consistent with FDA's regulatory description of these types of materials (21 *CFR* 177.1630).

A slightly different approach would be taken if determining the fraction of isophthalic acid moiety in the copolymer. Since the polymer units consist of ethylene isophthalate (see Fig. H-1) and ethylene terephthalate, the weight % of isophthalic moiety is 0.6875 of the mole fraction of the ethylene isophthalate. Consequently, a PETI-10 copolymer would have 6.875 wt% isophthalic moiety present in the polymer.

A third approach applies when calculating how much isophthalic acid and terephthalic acid is required to produce a certain mass of copolymer. Reflecting the condensation reaction with ethylene glycol, 865 grams of acid (combination of terephthalic and isophthalic acids) is required to produce 1 kg of copolymer. Consequently, a 1 kg of PETI-10 copolymer would consume 86.5 g of isophthalic acid and 778.5 g of terephthalic acid. Stated another way, a PETI-10 copolymer would have 8.65 wt % isophthalic acid used per polymer weight. This calculation was used in determining the volume of isophthalic acid production associated with this petition (Confidential Appendix V).

[10] MSDS are attached as Reference Tab 6.

6. ***Introduction of substances into the environment.***

6.A. ***Introductions at Sites of Production.***
FDA advised that BP Amoco may remove all discussion in the EA that relates to production of the subject copolymers unless there are extraordinary circumstances. As discussed in Section 4.C, no extraordinary circumstances apply and consequently the text in Section 6.A of the January 1999 EA has been removed.

6.B. ***Introductions at Sites of Use and Disposal.*** The maximum yearly market volumes for the proposed applications are provided in the Confidential Appendix V of this petition. They constitute a very small fraction (less than 1 percent) of current uses of polyester polymers.

Environmental releases at sites of use of the terephthalate/isophthalate polymers, i.e., sites where the material is used to manufacture a food package, are likely to be restricted by economic incentives and minimized by process controls and waste minimization efforts. The production of food packaging using the proposed food additive is expected to occur in facilities that are presently involved in PET container fabrication. There are a variety of such facilities and BP Amoco is not able to identify that a specific facility will produce food packaging using the proposed food additive. Consequently, BP Amoco is not able to describe the environments where such production may take place. These probably can be described as light industrial facilities that may be located in a rural, urban or industrial areas.

BP Amoco believes that the use of the proposed food additive is unlikely to have an adverse effect on these workplaces, their air emissions or the disposal of any manufacturing wastes because of the similarity of the proposed food additive to existing food additives used in similar packaging applications. Air emissions would be minimal, including possible off-gassing of any volatile residuals in the polymers, accelerated by heating during the production process. One potential emission is acetaldehyde, but the lowered melting point of the proposed food additive is expected to reduce acetaldehyde formation (relative to PET processed at higher temperatures without isophthalate modification). Since the chemistry and manufacture of the subject food additive is essentially the same as that for currently used isophthalate-modified PET, any such air emissions would be the same as presently emitted from processing modified PET polymers into food packaging. Solid production wastes would be minimal, possibly including off-spec batches of polymer. Some of these might be reusable as feedstock to the extruder. Other solid wastes could be sold to lower value markets, e.g., strapping or fibers, or disposed in approved licensed facilities as non-hazardous waste.

BP Amoco has no data about what rates of wastage or environmental introduction are likely at sites of use. Users may determine that material may be reused on-site (pre-consumer recycling). If disposal is required, then the waste may be handled as normal municipal solid waste, and disposal will occur via landfilling or incineration.

Environmental releases at sites of disposal of the polymers would be minimal. FDA considers that disposal via landfilling may result in migration of oligomers via leaching into the environment. Potential migrations from landfilled terephthalate/isophthalate polymers are summarized below, but are discussed in the Confidential Appendix V of the petition because the estimation procedure uses the confidential market estimate. FDA considers that incineration of some food-packaging materials may release problematic air emissions. BP Amoco believes that incineration of subject polymers are not expected to release problematic air emissions. Combustion products of the incinerated terephthalate/isophthalate polymers are summarized below, but are discussed in the Confidential Appendix V because the estimation procedure uses the confidential market estimate.

6.B.i. **Estimated Disposal Pattern.** FDA requires an estimate of the fractions of the used food packaging that will be disposed of via landfilling, incineration and recycling.[11] This estimate is prepared by considering the amounts likely to be recycled from post-consumer waste, then allocating the remaining fraction to landfilling and incineration based on national patterns of disposal, calculated by FDA to be 80% landfilling and 20% incinerated, as the following indicate:

Fraction incinerated	$(f_{incinerated}) = 20\% \times (1 - f_{recycled})$
Fraction landfilled	$(f_{landfilled}) = 80\% \times (1 - f_{recycled})$

The fractions of food packaging that are projected to enter recycling, landfill and incineration waste streams were estimated using the US-EPA's projection for a 30% recovery of containers in the year 2000 (US EPA, 1997). The fraction landfilled and incinerated are then calculated using the above FDA projections.

FDA approval of higher level isophthalates could result in competitive replacement of the currently used packaging materials in affected applications. Since isophthalate is currently seen in the PET recycling stream, the overall changes that might result from FDA approval of this current petition are relatively small and thus no significant impact can reasonably be seen.

To quantify the changes in municipal solid waste (MSW), the mass of packaging materials replaced by PETI products was calculated. Each container predicted to be made of PETI polymers associated with this petition was taken to replace one container made of the competing materials. These numbers were multiplied by the anticipated container weight to estimate the mass of competing material not present in solid waste.

Anticipated container weights were derived using the historical patterns of lightweighting--using less material to make a container with a given volume capacity. This resulted in the following estimates: PE and laminate plastics, -10% per 5 years; glass, -5% per 5 years; metal, -3% per 5 years.[12] These factors were used to anticipate the weight of containers in the future. The number of units was multiplied by container unit weight, e.g., the weight of a bottle, to obtain a total mass of material affected. The values from these calculations are provided in the confidential Market Estimate (Appendix V).

6.B.ii. **Disposal by Recycling.** BP Amoco expects that PET food-contact containers and articles containing 3 – 17% isophthalate can also be readily recycled. Isophthalate-modified PET bottles are currently in the market and are processed efficiently in the PET recycling stream.

EPA has projected recycling rates for a variety of materials. Figures for recycling rates of used food packaging ("recovered" in US-EPA's terminology), are shown in Table H-4, as provided by US-EPA

[11]Food and Drug Administration, Environmental Impact Staff, Center for Food Safety and Applied Nutrition, 1993. "New Polymeric Food-Packaging Materials: Key Environmental Issues." Draft. (Reference Tab 7)

[12] The patterns were derived from data in EPA (1992) and confidential industry information.

Table H-4. Recycling of Selected Products in the Municipal Waste System

Values are in percent recovery. Source: US-EPA, 1994, Table 21 (for 1990-1993 data) and US-EPA, 1997, Tables 21 (for 1995 data) and B-1 (for 2000 projection). Negligible recycling is shown as "--" if less than 50,000 tons was recovered. Projection for 2000 uses EPA's 30% overall recycling scenario.

Type of Product	1990	1991	1992	1993	1995	2000
Glass Beer & Soft Drink Bottles	33.2%	25.6%	28.3%	29.4%	32.6%	
Glass Wine & Liquor Bottles	10.0%	20.7%	23.5%	24.3%	26.3%	
Glass Food/Other Bottles & Jars	12.7%	19.6%	20.5%	19.4%	21.6%	
Overall Rate for Glass	*22.0%*	*19.6%*	*20.5%*	*24.6%*	*27.2%*	*30.0%*
Steel Beer & Soft Drink Cans	26.7%	44.4%	50.0%	57.1%	--	
Steel Food & Other Cans	23.2%	31.0%	39.8%	47.8%	56.8%	
Overall Rate for Steel	*23.5%*	*30.8%*	*39.1%*	*46.3%*	*54.4%*	*61.5%*
Aluminum Beer & Soft Drink Cans	63.2%	62.2%	67.9%	63.4%	62.7%	
Overall Rate for Aluminum	*53.2%*	*52.3%*	*56.9%*	*53.0%*	*51.8%*	*69.0%*
Paper/paperboard milk cartons	--	--	--	--	--	
Paper/paperboard folding cartons	--	13.0%	15.0%	14.2%	20.2%	
Overall Rate-Paper/paperboard	*37.3%*	*39.6%*	*41.8%*	*44.2%*	*52.3%*	*57.8%*
Plastic Soft Drink bottles	32.6%	35.6%	41.2%	41.1%	45.5%	55.0%
Plastic Milk Bottles	3.8%	14.3%	23.1%	23.6%	30.2%	35.0%
Plastic Other Containers	1.2%	4.0%	4.3%	4.7%	12.8%	15.0%
Plastic Bags and Sacks	3.2%	1.1%	2.1%	1.9%	3.4%	
Plastic Wraps	2.0%	0.6%	1.1%	1.6%	2.3%	
Other Plastic Packaging	0.9%	0.5%	0.4%	0.4%	0.9%	6.0%
Overall Rate for Plastics	*3.6%*	*4.4%*	*5.8%*	*6.2%*	*9.7%*	*14.0%*

(1997). Of the categories used by EPA, the following seem most likely to describe the products where PETI copolymers will compete: "Glass containers", "Aluminum Packaging", and "Other plastic containers" or "Other plastics packaging." Within these categories, EPA data indicates that: "Glass Beer and Soft Drink Bottles" had a recycling rate in 1995 of 32.6% while "Aluminum Beer and Soft Drink Cans" had a rate of 62.7%.[13] Also, in 1995, "Other containers" made from PET had a recycling rate of 12.1% while those of HDPE had a recycling rate of 17.1%.[14] All other polymers noted (PVC, LDPE, PS, Other resins) had a negligible recovery rate. Among the "Other plastics packaging" group, only PP had a non-negligible recovery rate of 3.8%. A footnote in Table 7 of the EPA document states: "Other plastic packaging includes coatings, closures, caps, trays, shapes, etc."

Currently, soft-drink bottles are recycled the most extensively among plastic food packaging materials. Milk bottles and other containers are recycled somewhat less extensively, and other plastics packaging the least extensively. Published recycling rate targets have been set at 50-60% by various policy-making

[13] US-EPA, 1997, Table 21, p. 73.

[14] US EPA, 1997, Table 7, p. 41.

groups. One published projection predicted that the mass of PET containers collected would almost double from 1991 to 1996 (Modern Plastics, October, 1993, p. 79). Market demand for recycled polyester has been increasing, which supports higher recycling rate projections.

PET recycling actually involves several distinct types of recovery. Some states have bottle deposits that encourage bottle return and recycling. Curbside collection is the other major source of recovered PET. Curbside collection requires that materials recovery facilities (MRFs) sort and bale the collected materials, usually segregating glass, aluminum, steel and some plastics from the collected post-consumer materials.

The overall PET recycling rate in 1997 was 27%[15], about the same as in 1993.[16] Recent recycling rates have declined from rates of about 40% in 1995 and 32% in 1996. The 1997 change reflects a significant increase (16%) in sales of PET bottles and jars, with a minimal change (-1%) in the mass of PET recycled. According to the 1998 NAPCOR/APC report, the increased sales came from 20oz. carbonated soft drinks, family size juice and juice drinks, isotonic products, still waters, and dairy drinks. The highest PET recovery rates occur in states that have bottle deposits. These rates (for carbonated soft drink bottles) approach 80% and the resulting material is the most consistent, i.e. has the fewest contaminants. Where curbside collection programs occur, carbonated soft drink bottles are recovered at rates of about 40%. The bottle deposits do not apply to most custom bottles, so these containers are not recovered at nearly the same rate. Because custom bottles are less recognizable than soft drink bottles in sorting programs, curbside collection of custom bottles achieves about 4-6% recovery rate.

EPA (1997) projected recycling rates (for year 2000) that would achieve overall recycling of 30% and 35%. For the 30% overall recycling rate, 55% recycling of soft drink bottles was projected, along with rates of 15% for other containers (e.g., custom bottles), and 6% for other plastics packaging (e.g., sheet). Using these projections and the market estimates for each type of PETI application, BP Amoco estimates that the overall recovery rate from containers within the scope of FAP 5B 4455 would be intermediate between EPA's soft drink bottle and other container recycling rate projections (Confidential Appendix V, Table V-7.A.). BP Amoco views these EPA recycling rates as likely to overestimate isophthalate content in the recycling stream following FDA action, when considering our market estimates and the recycling rates.

FDA approval of the subject materials might actually improve the recycling of plastics by increasing the types of food articles containing PET, which is currently one of the most recycled plastics. The compatibility of rPET with increased isophthalate content is further discussed in section 9 of this environmental assessment. Also, conventional techniques to sort colored (amber or brown) from clear containers will produce (1) a clear rPET stream and (2) a brown rPETI stream composed virtually entirely of beer bottles. Significant uses of clear and green recycled PET include spinning into fiber and making containers. Reported uses of recycled PET have ranged from about 500 to 600 million pounds in

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[15] R. A. Bennett, R.W. Beck, and Associated Services Group (ASG), August, 19, 1998: "1997 PET Recycling Rate Information Released" Prepared for The national Association for Plastic Container Recovery (NAPCOR), Charlotte, NC. (Reference Tab 8)

[16]PCI (Xylenes & Polyesters) Ltd. 1993. "North America PET Recycling Supply/Demand Report 1993/94." Devonshire House, 66 Church St., Leatherhead, Surrey, KT22 8DJ, England (Confidential report)

the last few years.[17] Recycling demand is expected to exceed supply for the next several years[18] so that interest in expanding PET recycling is likely to continue. The presence of isophthalate-containing polymers in currently recycled PET demonstrates the feasibility of handling such materials. FDA approval of the subject petition will not increase the fraction of isophthalate present in this recycling stream to a level greater than that currently approved for food contact use.[19]

Beer bottle recycling. With the introduction of a plastic beer bottle by Miller Brewing Co. in late 1998, PET-based amber bottles may be anticipated to become part of the PET recycling stream.[20] For purposes of estimating recycling rates of beer bottles made from copolymers within the scope of this petition, BP Amoco has assumed a recovery rate less than EPA's estimate for soda bottles, but exceeding EPA's estimate for "other containers." (Confidential Appendix V).

BP Amoco anticipates that recovery of these beer bottles is encouraged by several factors, including (1) required deposits in certain areas, (2) an easily identifiable product profile, so consumers can readily learn to include with recyclables in curbside programs, (3) an existing PET recycling infrastructure that can adapt to include compatible materials, (4) industry awareness and sensitivity to the need for recycling new packaging systems, (5) market pressure for, and acceptance of, a recyclable bottle, and (6) political pressure to increase overall recycling rates and volumes. Illustration of several of these points comes from reactions to the new plastic beer bottles, where both public environmental concerns and packaging industry innovations have been identified. Shell, a major producer of PET resins, acknowledged concerns about how the brown bottle color and non-PET barrier layers impact sales of recycled PET to the textile industry.[21] Eastman, another major producer of PET resins, recently announced a depolymerization technology to handle all barrier materials now in use, with reference to plastic beer bottles.[22]

While able to anticipate in general how recycling of amber plastic beer bottles will be resolved, BP Amoco is not able to predict the details. Implementation of depolymerization technology or growth of new markets for reclaimed materials is unlikely to precede an increase in supply of amber plastic bottles. Some issues anticipated with recycling amber PETI beer bottles may be the same as for other competitive systems, such as the amber color, metal caps and applied labels. These issues are not caused

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[17]R. A. Bennett (University of Toledo, College of Engineering), 1996. "Research to determine the 1995 amount of post consumer PET bottles recycled, PET recycling rate and end use markets." Prepared for The National Association for Plastic Container Recovery (NAPCOR), Charlotte, NC. (Reference Tab 9)

[18]Powell, J., 1993. "The ever-changing PET recycling market." *Resource Recycling*, October. pp. 26-31.

[19]Amoco calculated that the change in isophthalate content in PET recycling streams resulting from approval of this petition would not increase the average isophthalate content above the currently permitted 3% level (Confidential Appendix V).

[20] "Miller Launches Expanded Test of Plastic Beer Bottles" 11/02/1998. Viewed at http://news.packagingnetwork.com/industry-news/19981102-1841.html on 3 September 1999.
[21] "Shell Sees Burgeoning Market for PET to Package Beverages." August 9, 1999. *Modern Plastics Online*. Viewed at http://www.modplas.com/news/week/990809.htm on 3 September 1999.
[22] "Technology boosts PET recyclability." *Modern Plastics Online*. Viewed at http://www.modplas.com/news/month_099/gr09.htm on 3 September 1999.

by FDA approval of PETI copolymers, however. In fact, the compatibility of isophthalate modified PET with other PET means that problems of material incompatibility, such as expected for nylon or ethylene vinyl alcohol (EVOH) materials used as barrier layers in multi-layer containers, are not an issue. In Section 9.A.i.a, BP Amoco discusses how the PET recycling infrastructure may be expected to change to accommodate recycling of PET-based beer bottles.

Variability of recycling rate estimates. Before leaving this discussion of recycling rates, the variability of rates as reported in EPA's Characterizations should be noted. Inspection of Table H-4 for the plastic materials from 1990-1995 suggests that these data are quite variable: the coefficients of variation range from 42% to 46% for the "Plastic Other Containers," "Plastic Bags and Sacks," "Plastic Wraps" and "Other Plastic Packaging."[23]

If one compares EPA's 1994 report with the previous 1992 version, various recycling rate predictions have changed notably. To achieve a 30% overall recycling rate in the year 2000, EPA projected recycling of "Other plastic containers" to be 35% in its 1992 report, but 30% in its 1994 update. For "Other plastics packaging", the 1992 report sought a recycling rate of 11.2%, but dropped this to 5.0% in the 1994 report (US-EPA, 1992, Table B-2; US-EPA, 1994, Table B-1).

The point being made is not that the EPA estimates are flawed, but that the values are highly variable. This is a limitation of the technique and means that even large numeric differences may reflect variability of the driving input parameters as much as they suggest a real change. Because the recycling rate drives FDA's disposal pattern, this variability extends throughout the related sections of this environmental assessment.

6.B.iii. **Disposal via Landfilling.** FDA requires an estimate of the quantity of each substance (e.g., oligomers) that could leach from the landfilled food packaging material into the environment during the first year following disposal of the material. This estimate is to be determined from the annual market volume, the percent of this volume expected to enter landfills, and the amount of each substance that could migrate from the polymer, expressed as a weight percent of the polymer.

The amount of terephthalate/isophthalate products that would be landfilled is estimated in Confidential Appendix V because it directly reflects market volumes. A comparison of new PETI applications within the scope of FAP 5B 4455 shows that landfill volumes are slightly less than the volume needed by the competitive materials, i.e., glass, aluminum and paper and plastics. In other words, net landfill volume needs would decrease. The overall decrease is slight compared to current US volumes of 319 cu yd/yr (less than 0.10%) so BP Amoco does not believe this is a significant change. (See Section 9.A.ii. for additional discussion of landfill volume).

Concentrations of chemicals in landfill leachate that might result from landfill disposal of food packaging materials containing the proposed food additive are particularly difficult to estimate because of the large number of assumptions involved. BP Amoco notes that PETI has been used for many years: approval of the petition would not be expected to change the types of chemicals that might leach from landfill sites containing food packaging that contains PETI complying with current FDA approvals.

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[23]Coefficients of variation (CV) are calculated as the standard deviation divided by the mean for a set of numbers. For example, for "Plastic Other Containers" the mean of the years 1990-1993 is 3.55% with standard deviation of 1.59%, giving a CV of 1.59/3.55 = 44.9%.

An estimate of the amount of material available to enter landfill leachate uses the following equation:

$$\text{Chemical (mass) in leachate} = MV \times f_{landfilled} \times f_{leachable}$$

6.B.iii.a. *MV (Market volume).* BP Amoco provides a confidential market volume in the Confidential Appendix V of this petition.

6.B.iii.b. *Fraction to be landfilled (* $f_{landfilled}$*).* The net percent of terephthalate/isophthalate polymers subject to this petition expected to enter landfills is about 50%, i.e., 80% of the materials not recycled.

6.B.iii.c. *Estimated percent extractable in leachate (* $f_{leachable}$*).* The amount of extractables in any solvent that simulates landfill leachate has not been determined. Landfill leachate has been described as "a very strong wastewater."[24] Typical pH is reported to be 6, ranging from pH 5.3 to 8.5, with total organic carbon of 1,500 to 20,000 mg/L, typically 6,000 mg/L (or 0.6% TOC). This low organic content suggests that leachate should be considered an aqueous solvent rather than an organic solvent. Because terephthalate/isophthalate polymers are insoluble in water, the leachable fraction constitutes no more than a fraction of a percent by weight of the used food packaging material in a landfill.

Extraction studies using solvents to simulate foods are reported elsewhere in this petition (Appendix VI). They provide a very conservative estimate of the material potentially available for leaching in landfills. These tests are done under exaggerated temperature conditions and with relatively strong solvents in order to predict how much material might migrate from food-packaging into food. If the migrating material is instead assumed to remain with the packaging and be available for leaching into landfill leachate, then these tests may be used to estimate the amount of material that might enter a landfill leachate. Several terephthalate/isophthalate polymers were tested with different solvents. The highest value obtained under any condition suggests that less than 0.01% may migrate in leachate, as shown using the following approach.

The extraction tests used test plaques that were 3.175 mm (1/8 inch) thick (reported in Appendix VI). The density of the plaques was between 1.33 and 1.4 g/cm^3, so the least dense value for PET (1.33 g/cm^3) was used (to overestimate the resulting rate of extraction). Multiplying these gives a mass per unit area of the test plaques of 0.422 g/cm^2. Since there are 6.45 cm^2 per in^2, this is equivalent to 2.72 g/in^2. The greatest concentration of total extractables was 50.9 micrograms per in^2, obtained in 8% ethanol, 120°F, at 240 hours, from a 83% terephthalate/
17% isophthalate polymer (reported in Appendix VI of this petition). Converting 50.9 micrograms per in^2 to grams per in^2 gives 50.9×10^{-6} g/in^2. Expressed as a percent of initial mass per area (2.72 g/in^2) the fraction of total extractable material is 0.0000187, or less than 0.01%.[25]

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[24]Glysson, E.A., in R.A. Corbitt (Ed.) Standard Handbook of Environmental Engineering. McGraw-Hill Publ. Co. 1989. p. 8.126

[25]Note that this material would comply with current regulations because it contained 17% isophthalate. Copolymers of 5% and 10% isophthalate were tested and had less non-volatile extractables. Consequently, the proposed food additive material would have less potentially leachable material than a currently approved formulation.

6.B.iii.d. *Estimated Landfill Leachate Concentration Maximum.* To estimate the potential concentrations in landfill leachate, BP Amoco developed an upper-bound estimate using calculations contained in a US-EPA report to Congress, titled "The Report to Congress, Waste Disposal Practices and Their Effects on Ground Water" by the Office of Water Supply and the Office of Solid Waste Management.[26] The estimate is an upper-bound estimate because it assumes that: (1) all water-soluble materials are extracted from landfilled food packaging within the first year after deposition, (2) all leachate in a landfill escapes without containment or treatment, and (3) no attenuation or biodegradation of chemical concentrations in leachate occurs as the leachate moves through the soil before reaching ground- or surface-waters.

Using the confidential market volume, BP Amoco has estimated that the concentration of extractable material that might migrate into landfill leachate is below 50 parts per billion (see Confidential Appendix V). This value is derived from the fraction estimated to be disposed in landfills and an upper-bound conservative estimate of the fraction that may migrate into leachate (<0.01%).

EPA regulations require new MSW landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water, and to have ground water monitoring systems (40 CFR 258). Groundwater monitoring of existing active MSW landfills constructed before October 9, 1993 is required and corrective actions are required as appropriate. Consequently, leachate from the subject additive is not expected to migrate to surface water where it might impact aquatic or terrestrial life.

BP Amoco believes that this evaluation shows there would be no significant concentrations of chemicals expected to enter the environment with landfill leachate as a result of FDA approval of this petition.

6.B.iv. **Disposal via Incineration**. About 13% of the food-packaging materials resulting from FDA approval of this petition are likely to be incinerated. This is the balance after recycling and landfilling. The products of complete combustion of the proposed food additive are water and carbon dioxide. Incineration of food packaging made from the proposed food additive would constitute substantially less than 0.1% of current incineration rates, according to US-EPA (1997) figures.

US-EPA has not included net carbon dioxide emissions from waste incineration in its inventory of US greenhouse gas emissions.[27] Total US emissions of carbon dioxide in 1994 are estimated to be 5.2 billion metric tons (1.0×10^{13} lbs). Incineration of food packaging made from the proposed food additive would constitute less than 0.0001% of the estimated 1994 carbon dioxide emissions.

The proposed food additive would compete with and possibly replace glass, aluminum, paper and other plastic materials. To the extent this occurs, there would be a reduction in total incinerator ash because of the non-combustible nature of glass and aluminum. The products of incineration of the proposed food

[26]The document was published by its principal author, D.W. Miller, as "Waste Disposal Effects on Ground Water: A Comprehensive Survey of the Occurrence and Control of Ground-water Contamination Resulting from Waste Disposal Practices," Premier Press, Berkeley, CA (1980).

[27]U.S. Environmental Protection Agency, 1995. "Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-1994." Office of Policy, Planning and Evaluation, EPA-230-R-96-006. Washington, DC. p. 84.

additive (water, carbon dioxide) are the same as the products of incineration of the plastics (e.g., PET, multilayer polypropylene, multilayer PET) that may be replaced. This combination leads to a net increase in water and carbon dioxide from incineration of the increased plastics. Also, the decrease in glass and aluminum incineration leads to a decrease in slug and ash being landfilled.

7. ***Fate of emitted substances in the environment:***

7.A. ***Air.*** None of the scenarios for item 6, introduction of substances into the environment, includes any significant changes in introduction of substances into the air. The materials potentially introduced into the air are minimal and are all currently used in food packaging.

7.B. ***Freshwater, estuarine, and marine ecosystems.*** Using the confidential market and other information, BP Amoco estimates that aquatic exposures to water soluble extractables from terephthalate/isophthalate polymers would not exceed 50 parts per billion. The extractives are minimal and are identical to those extracted from currently regulated PETI copolymers.[28]

7.C. ***Terrestrial.*** No significant releases into terrestrial environments are expected. Littering may occur, but the relative amount of food packaging littered is small and only poorly quantifiable, if at all. Any chemical substances entering the terrestrial environment would be virtually the same as currently available from food-contact and non-food contact applications of PET.

8. ***Environmental effects of released substances:***

No data are available on the environmental effects of substances expected to be emitted to the environment as a result of the use or disposal of products containing the additive. The proposed food additive consists of high molecular weight polymers whose molecular size limits their biological availability. The polymers do not have surface charges, so surface membrane effects are unlikely. In addition the extremely low environmental concentrations in aquatic environments (see item 7) reflects very low potential exposure. Consequently, for compounds of this nature and at the very low exposures possible, BP Amoco believes there are no significant environmental effects that would result from FDA approval of the proposed food additive.

9. ***Use of resources and energy:***

The proposed food additive will use natural resources and energy of types and amounts similar to those used by the materials with which it will compete and may replace. The PETI copolymers are manufactured from products derived from crude oil, natural gas and coal, so land use and mineral use are those associated with the production of hydrocarbon materials. However, these are the same materials used to produce the materials potentially replaced by the proposed food packaging material. No effects are anticipated on any endangered or threatened species or upon property listed or eligible for listing in the National Register of Historic Places.

9.A. ***Solid Waste Management Strategies.*** The approval of the proposed food additive is not expected to cause any significant changes[29] on solid waste management strategies, including recycling programs.

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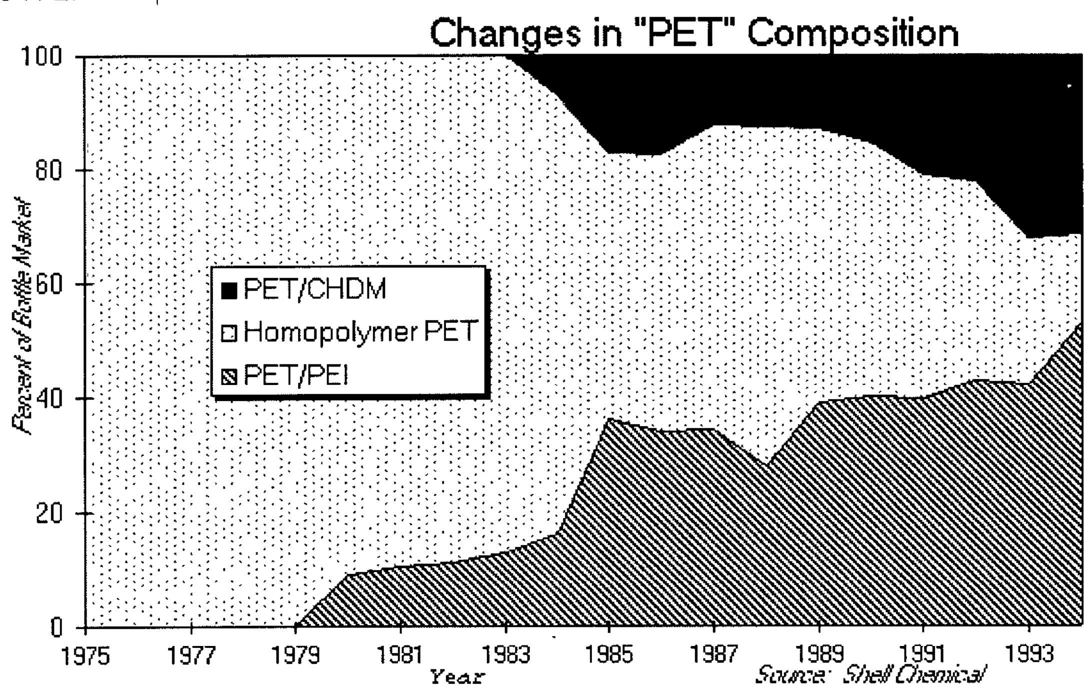
[28]FDA letter dated January 18, 1996, p. 6.

[29]"Significant changes" in this context is taken to mean a change that is probably measurable, that

9.A.i. **Recycling.** Materials very similar to the proposed food additive are currently being successfully recycled. The primary difference between currently recycled PET bottles containing isophthalic acid and the proposed food packaging material is the percent isophthalate. Studies have shown that terephthalate/isophthalate copolymers are compatible with the existing PET recycling stream and that it is appropriate to include these materials with recycled PET. The inclusion of additional amber containers in the recycling stream may require some control over the colored materials in the waste stream to remove those materials which are incompatible with certain downstream processes. The means to accomplish this will be no different than needed for recently introduced multilayer amber beer bottles[30] or for other rapidly growing markets which utilize amber PET. These other markets include liquor, prune and apple juice, Worcestershire and other sauces, and cough medicines, which have all been part of the recycled PET stream for many years. This will be discussed further in section 9.A.i.b.

Figure H-2.



is, a change that would exceed the variability inherent in the components. This meaning is consistent with that used by Franklin Associates who conclude, based upon 23 years of experience in analyzing resource and energy data, that a difference of less than 25% in calculated product systems' air and waterborne emissions, industrial solid waste, and post-consumer solid waste by volume, are insignificant. For energy and postconsumer solid waste by weight, Franklin Associates considers differences less than 10% to be insignificant. (Franklin Associates, Ltd, 1989, "Comparative Energy and Environmental Impacts for Soft Drink Delivery Systems: Final Report." Prepared for the National Association for Plastic Container Recovery, Charlotte, NC. Also see Franklin Associates, Ltd, 1994, "REPAQ™: Resource and Environmental Profile Analysis Query" Manual. Prairie Village, KS.)

[30] *USA Today*, October 30, 1998, "Miller taps plastic for beer anywhere" Money Section, p.1.

Rather than a static market comprised entirely of homogeneous material, recycled PET (rPET) is a dynamic, changing market whose composition reflects the polymers that comply with 21 *CFR* 177.1630, 177.1315, and 177.1345. Since about 1980, the proportion of homopolymer PET has continually decreased. Figure H-2 shows how the abundance of PET copolymers and modified PET has increased in bottle resins.[31] In the 1970s, the PET market was dominated by high inherent viscosity (IV) PET that was unmodified by other additives. Lower IV homopolymer PET then captured the market. However, use of isophthalate-modified PET began in 1980, soon followed by use of 1,4-cyclohexane dimethanol (CHDM)-modified PET. Use of these copolymers has increased to where the copolymers dominate the market at present. The changes in composition have modified resin properties such as shifting melt points, thermal stability, viscosity, crystallinity rates, and color.[32] Recycling processes have continued to accommodate these changes in source materials.

The isophthalate levels in PET copolymers are expected to continue to shift upwards. Work done to date[33], indicates that increasing isophthalate levels provides improved bottle processing and properties. Market demand and customer needs call for higher converter speeds, new and unique bottle shapes, lightweighting, and thicker preforms. Increases in isophthalate content leads to lower injection molding temperatures, a broader blowmolding process window, increased shelf-life (improved barrier properties). Many of these characteristics associated with increased isophthalate levels were previously discussed.

Another event suggesting an upcoming increase in isophthalate levels in the rPET stream is the scheduled completion of Eastman Chemical's new isophthalic acid plant in 1999, suggesting that Eastman will move, at least in part, from its current PET modifier, , to .[34]

Based on numerous tests, communications and feedback from customers, the isophthalate levels used in BP Amoco's market analysis appear reasonable and provide desired characteristics and allow for ease of manufacture. BP Amoco believes the actual modification levels may vary as customers better define their desired characteristics.

9.A.i.a. *PET Recycling Infrastructure.* Isophthalate-containing polymers would be incorporated into products such as some carbonated soft drink (CSD) bottles and other beverage containers that are easily recognized by consumers. These containers are among the most frequently recovered plastic package

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[31] This figure was developed from information provided by Shell Chemical Company in the Environmental Assessment for FAP 5B4450, Figure VII-3.

[32] *Chemical Week*, Nov. 23, 1994, "Polyester Resin Growth Fuels demand for Modifiers: Making a more obedient PET." p. 32.

Mitchell, A.K., "Polyethylene Terephthalate: Traditional container outlets thrive while new uses come to the fore," , *Modern Plastics*, Mid-November 1994. pp. B-48-B50. (Reference Tab 10)

[33] For example: T. Moore, 1998. Wellman, Inc. USA, "Improved Bottle Processing with PIA. Increased reheat capacity opens process window", Presentation to Bev-Pak America's '98 meeting, April 6&7. (Reference Tab 11)

[34] *Chemical Market Reporter,* October 6, 1997, "Isophthalic Market Facing Oversupply: String of new plants and expansions are expected to kick product out of balance.", p. 5. (Reference Tab 12)

as shown in Tables H-~~7~~4 and H-~~8~~5.

The lower recovery rates reflected for sheet packaging is apparently due to the wide variety of materials used in this type of food packaging. Different materials such as polypropylene (PP) and polyethylene (PE) are used to make the same type of package. These materials may have a milky translucent appearance as compared to the clear PETI containers, making visual sorting of such containers feasible. In addition, difference in specific gravities between the lighter PP and PE and the denser PETI would allow mechanical separation via sink/float or hydrocyclone techniques. Market penetration of PETI sheet materials might encourage such sorting

An extensive infrastructure for recycling has developed over the years. Because the composition of PET has changed as different modifiers became plentiful, as shown in Figure H-2, and as resins with different IV were developed, we infer that the PET recycling infrastructure has adapted to changes in the composition of the polyester. As indicated in Table H-5 PET recycling depends heavily on CSD bottles collected through deposit and curbside collection mechanisms. BP Amoco, along with others in the industry, wish to ensure the integrity of the rPET stream and its suitability for use in recycle-content applications. To better characterize the infrastructure, Dr. M. Harrass and Dr. Greg Schmidt of Amoco prepared a detailed flow chart and analysis to describe the current pattern of PET recycling. That review is attached as a supplement to this FAP.[35]

The flow chart of the existing rPET is presented here as Figure H-3. Five types of activities are included in a thorough description of the PET recycling infrastructure: collecting, sorting, transporting, reclaiming, and reprocessing.[36] With the exception of transportation, these are shown in Figure H-3.A.

In describing the PET recycling infrastructure, one potential source of confusion is the overlapping roles played by various participants. For example, municipalities are often involved in collecting and initial sorting, although the operations are typically conducted, and often owned, by private firms.[37] Materials recovery facilities (MRFs) are central operations where commingled and/or source separated recyclables are processed mechanically or manually, with processing including separation and beneficiation to meet market specifications for sale.[38] Intermediate processing facilities (IPCs) are facilities that generally take in loose, source separated plastic bottles and densify them for shipment.[39] Plastics recycling

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[35] Excerpts from, "Recycling Polyethylene Terephthalate/Naphthalate (rPET/N) Food Packaging: A Flow Chart and Analysis (Non-confidential Version)", March 1997. (Reference Tab 13)

[36] P. Dinger, 1996. American Plastics Council (APC) Packaging Technical Committee, Presentation to SPI/PEN Committee meeting, August 6. (Reference Tab 14)

[37] Polk, T., and M. Knoll, "How MRFs and their clients share risks of fluctuating markets" in J. T. Aquino (ed.) Waste Age/Recycling Times' Recycling Handbook, Lewis Publishers, Boca Raton, pp. 114-126.

[38] CalRecovery and PEER Consultants, 1993. Materials Recovery Facility Design Manual, C. K. Smoley, CRC Press, Inc. Boca Raton, p. 1-1.

[39] Clean Washington Center, 1998 "Best Practices in PET Recycling" 999 Third Avenue, Suite 1060, Seattle, WA 98104. (Reference Tab 15)

facilities (PRFs) are operations that process lower quality commingled plastics and curbside rPET materials obtained from MRFs and IPCs with sortation being a typical activity. PET reclaimers (who obtain materials from MRFs and PRFs) are themselves often involved in sorting, reclaiming and reprocessing.

Table H-5. Post-consumer PET Recycling

The amount of post-consumer PET is given in millions of pounds. Percents are of the total PET. Source: *Modern Plastics*, Jan. 1995; *Modern Plastics International*, Jan. 1994; *Modern Plastics*, Jan. 1998

Sources of Post-consumer PET material

Material	1992		1993		1994		1997	
Soft drink bottles	310	(80%)	420	(93%)	480	(91%)	479	(79%)
Custom bottles	20	(5%)	30	(7%)	45	(9%)	64	(11%)
Non-packaging (mostly X-ray film)	59	(15%)*		*			62	(10%)
TOTAL	389		450		525		605	
Grand Total for all Plastics	913		1162		1339		1993	

Uses of Post-consumer PET

Material	1992		1993		1994		1997	
Fiberfill	189	(49%)	210	(47%)	240	(46%)	258	(43%)
Food bottles (via Depolymerization)	35	(9%)	25	(6%)	20	(4%)	24	(4%)
Non-food bottles	20	(5%)	35	(8%)	40	(8%)	65	(11%)
Strapping	20	(5%)	25	(6%)	35	(7%)	55	(9%)
Sheet	**		35	(8%)	40	(8%)	60	(10%)
Export	14	(8%)	25	(6%)	50	(10%)	120	(20%)
All Other	95	(24%)	95	(21%)	100	(19%)	28	(5%)
TOTAL	389		450		525		605	
Grand Total for all Plastics	915		1162		1339		1993	

Excluded from values for 1993 and 1994 in Modern Plastics report.
* Not distinguished from "All Other" uses, in Modern Plastics International report.
(Percentages may not add to 100% due to rounding.)

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Fig. H-3.A. Future PET+PETI Recycling Infrastructure: Overview

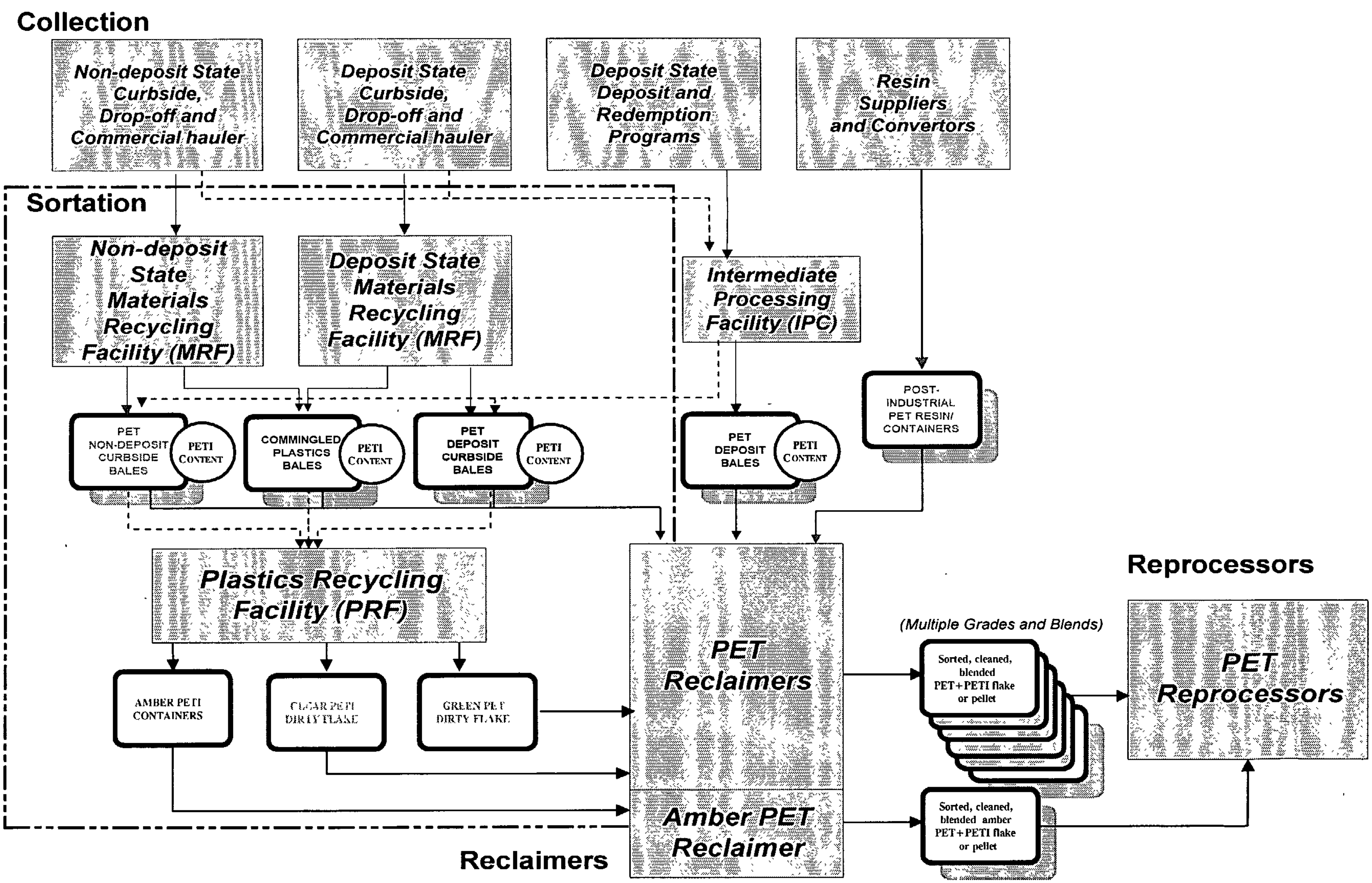

Fig. H-3.B. Future PET+PETI Recycling Infrastructure: Collection and Initial Sortation

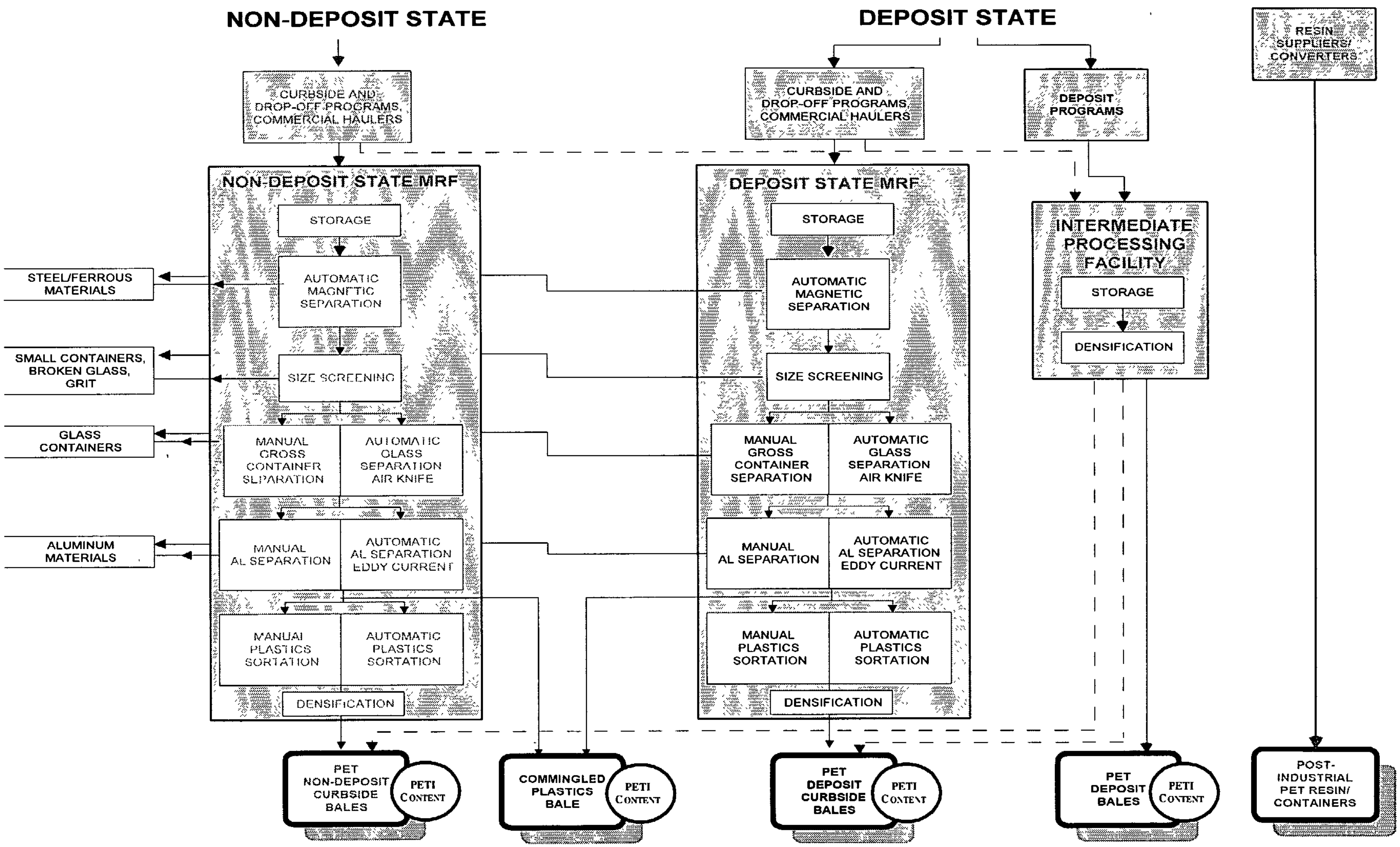

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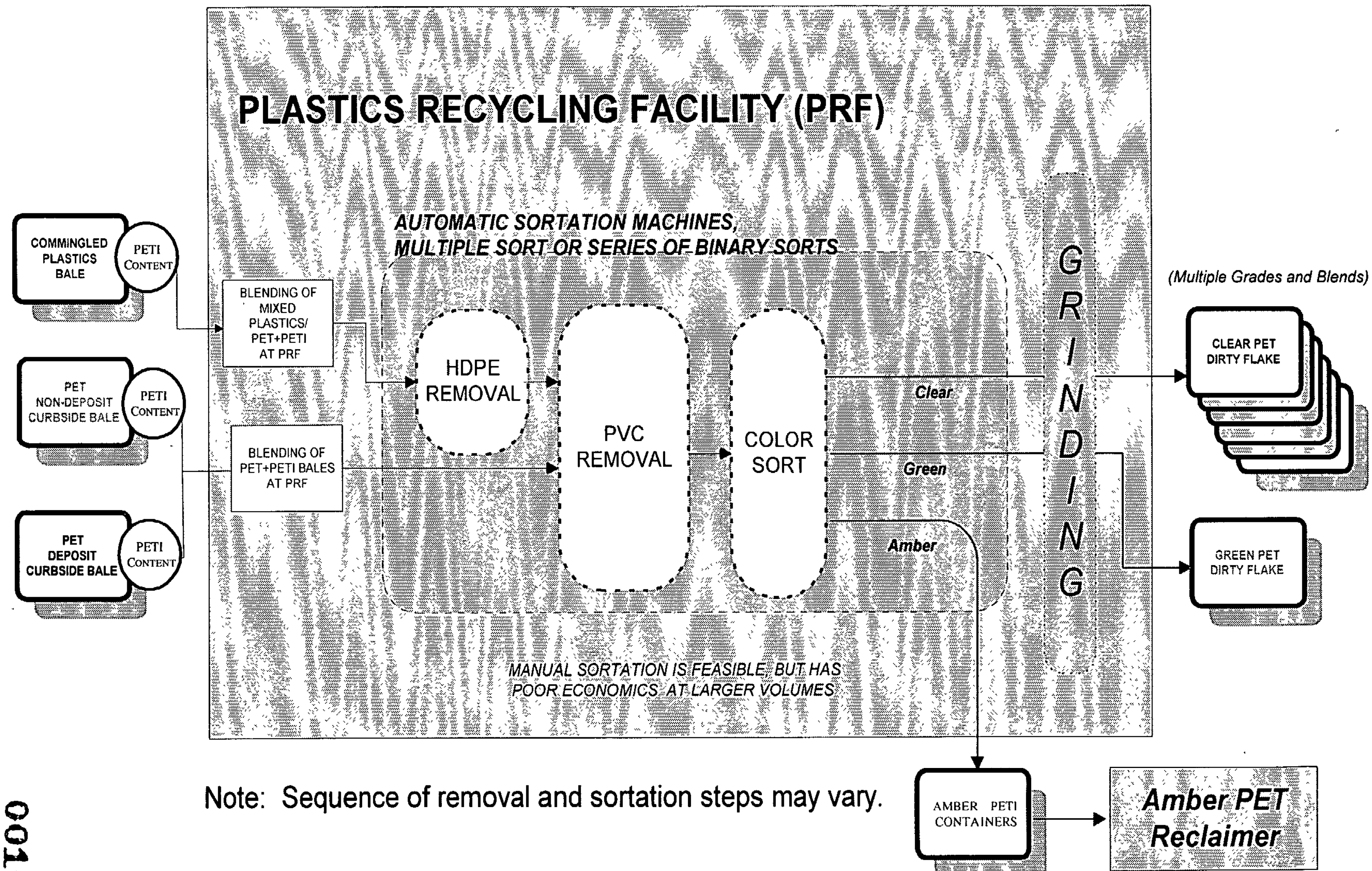
Fig. H-3.C. Future PET+PETI Recycling Infrastructure: Sortation



Note: Sequence of removal and sortation steps may vary.

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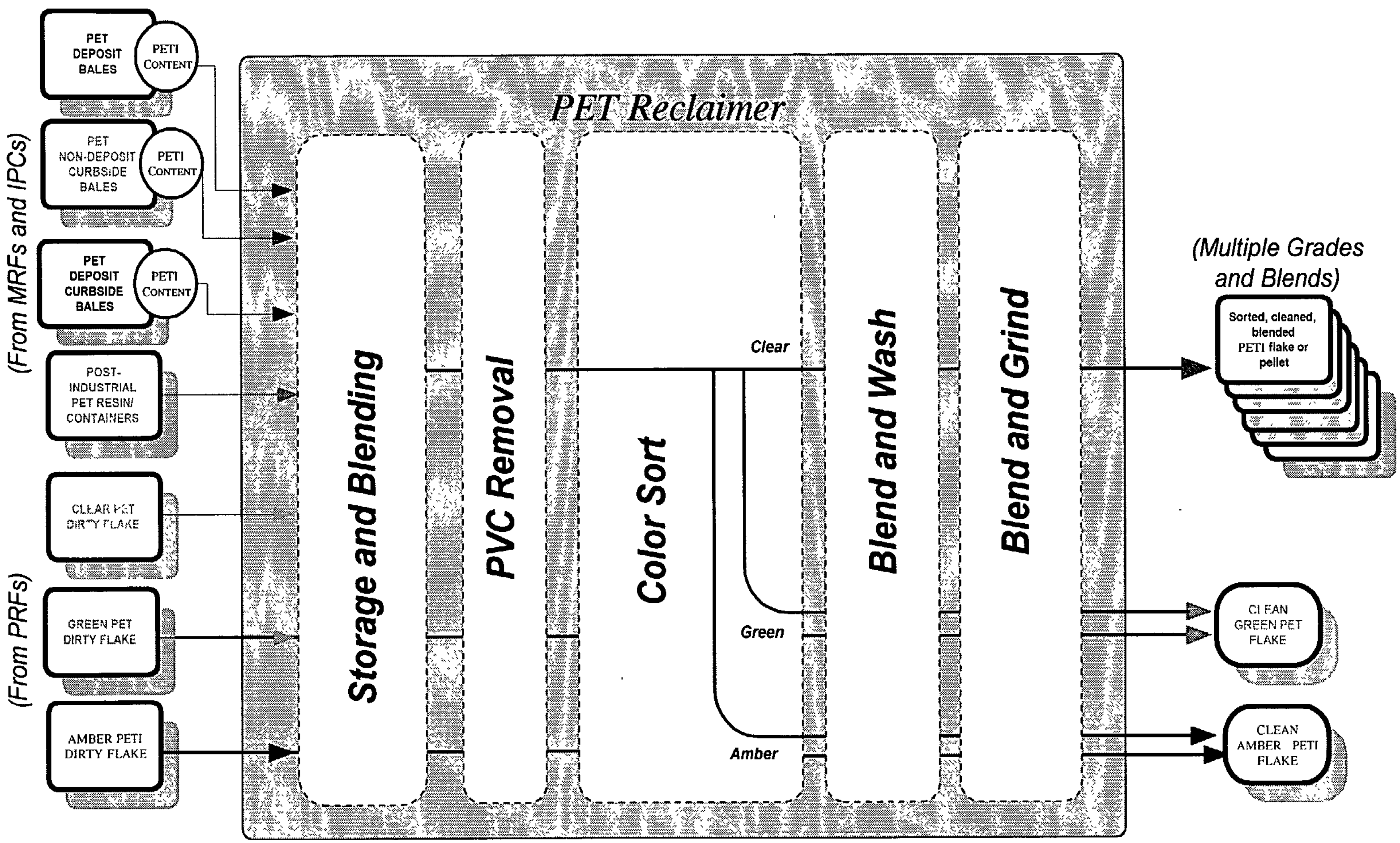
Fig. H-3.D. Future PET+PETI Infrastructure: Reclaimers



Note: Sequence of sortation steps may vary.

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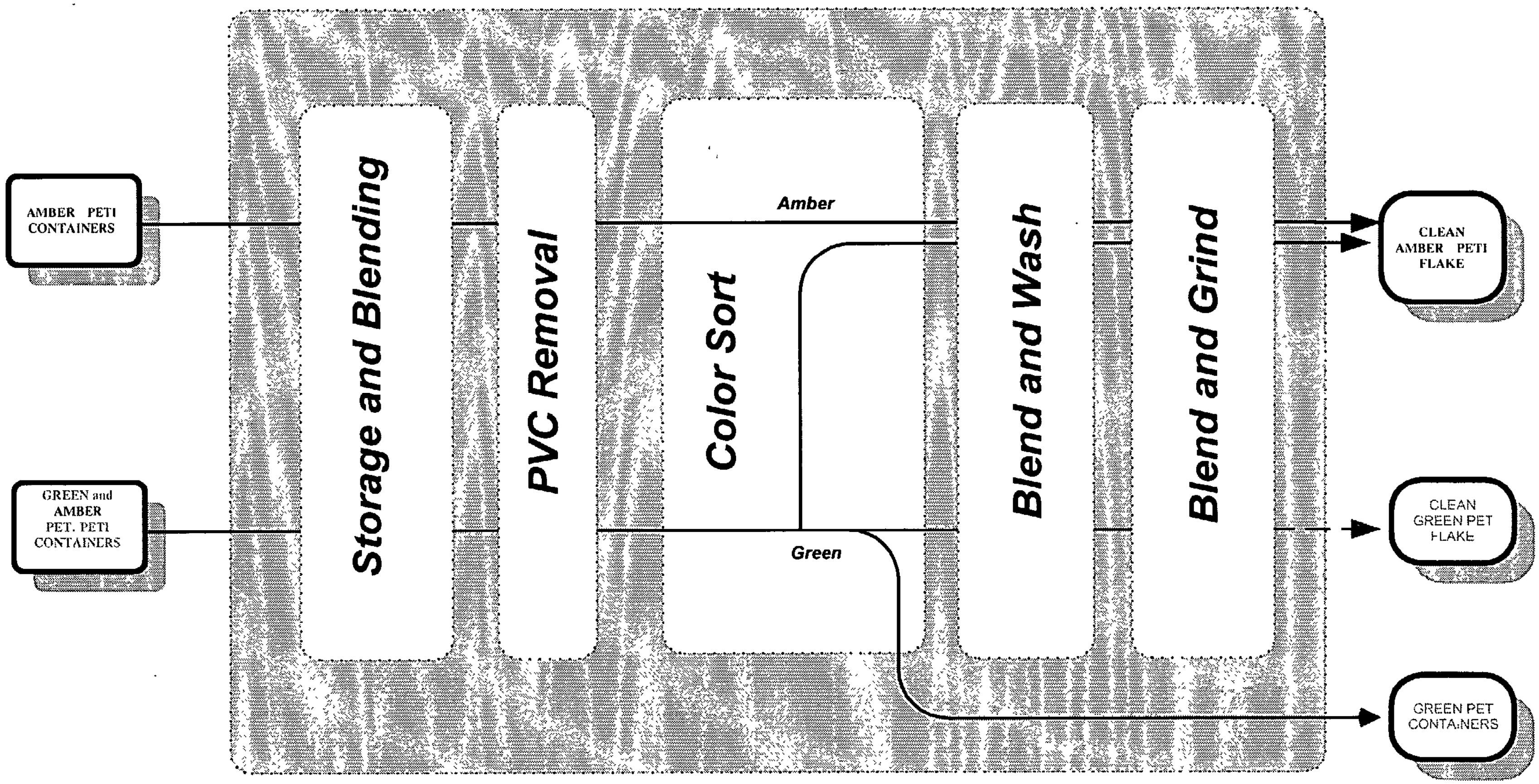
Fig. H-3.E. Future PET+PETI Infrastructure: Amber PET Reclaimer



Note: Sequence of sortation steps may vary.
Note: Green PET Containers may be returned to other PRFs or Reclaimers

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Figure H-3.A illustrates how MRFs, PRFs and PET reclaimers all participate in the sortation process. It also illustrates the four major types of post-consumer rPET bales in commerce: deposit bales, deposit curbside bales, non-deposit curbside bales, and commingled bales. Figure H-3.B focuses on the operations in typical MRFs. Figure H-3.C focuses on the operations in a PRF. Figure H-3.D focuses on the operations in a PET reclaimer and illustrates the variety of end products derived from various rPET sources. The major point shown by Figure H-3 is the variety of sources, pathways and products that typify the rPET infrastructure.

Awareness of the flow patterns in this infrastructure let Amoco differentiate between different types of rPET bales and develop estimates of how rPETI would distribute among deposit bales, deposit curbside bales, and non-deposit bales. The results of these analyses were described in Section 6.B.ii and in Confidential Appendix V.

9.A.i.b. *Changes in the PET Recycling Stream.* BP Amoco expects that the proposed food additive material is fully compatible with existing recycled PET applications. Isophthalate is currently present in recycled PET (see Shell Oil Co. MSDS for REPETE®80310 and above figure showing isophthalate use in PET bottles). Post-consumer plastic processors report that composition of their rPET feedstocks continuously vary, as do their sources for material. It is therefore common practice to make adjustments for this variable content. This adjustment process would accommodate the small increases in isophthalate-containing resins in the recycle stream due to approval of this petition, just as it has accommodated historical trends discussed previously

BP Amoco has made extensive contacts with companies involved in PET recycling and the uses of rPET. On the basis of this information the rPET flow-chart shown in Fig. H-3 incorporates the ongoing modifications to the PET recycling infrastructure to handle the rapidly growing amber PET stream.

As shown in the overview (Fig. H-3.A), the available recycled materials will include amber rPETI, clear rPETI and clear rPET. Removal of the colored (amber or brown) PETI beer bottles from clear rPET can be done by automated color sortation that is already in place (Fig. H-3.C.).

In Confidential Appendix V, BP Amoco estimated the levels of PETI expected in each type of rPET bale. This was calculated by determining, for each application, the mass of material, its predicted recovery rate, and percents going to different types of recycled PET (rPET) bales. The recovery (recycling) rates for isophthalate-containing applications were projected using EPA (1997) rates for 30% recovery projected for the year 2000.

FDA approval of this FAP would lead to an increase of approximately 0.4% isophthalate content in unsorted rPET bales. The current level of isophthalate expected to be in unsorted rPET bales is approximately 1.25%.[40] Color sortation would slightly reduce isophthalate levels in the clear rPET stream and the color rPET stream would contain the typical percent isophthalate content used in beer bottles.

One note regarding the calculation in the Confidential Appendix is the explicit attention to non-incremental

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[40] The currently permitted isophthalate content in PET bottles is 0-3%, and average isophthalate content in carbonated soft drink (CSD) bottles is approximately 2.0%. Current data suggest that about 65% of current PET beverage bottles use isophthalic acid. This information suggests that the overall isophthalate content of currently recycled CSD bottles is about 1.25%.

PET.[41] The large capacity CSD PET bottle market would include a significant amount of non-incremental PET. Calculations were structured so that PET is not "double-counted" in estimating total mass of rPET bales.

9.A.i.c. *Compatibility of rPETI with rPET processes and end uses.* The expected market for the subject polymer includes applications that are among those currently targeted for post-consumer programs, specifically beverage containers targeted in curbside recycling programs. However, as addressed in the Confidential Appendix V, introduction of an increased level of isophthalate in these programs is not expected to displace a sufficiently large fraction of currently recycled packaging and thus would not have a negative impact on those recycling streams.

PETI is already in the PET recycling stream; the proposed FDA approval would likely increase the level of isophthalate in future rPET streams. Consequently, an issue that could affect PET recycling is whether the incremental increase in isophthalate content is compatible with current PET recycling. In other words, will processors or end users be able to accept rPET that contains slightly higher levels of isophthalate?

The major end uses of rPET are in fiber and bottles as shown in Table H-5. Consequently, BP Amoco sponsored studies of how well increased isophthalate content polymers could be processed into fiber and bottles. Based on industry feedback, bottle manufacture is recognized as the most critical and demanding application in which rPET is used. Demonstration of compatibility in bottle manufacture would reasonably assure compatibility in less demanding general extrusion applications such as sheeting and strapping. BP Amoco has sponsored the following studies to assess the compatibility of increased levels of isophthalates in the rPET stream.

Bottle-to-bottle recycling. A highly demanding use of post-consumer PET is for recycling into bottles, for both food- and non-food contact applications. BP Amoco has investigated whether an increased level of isophthalate is compatible with bottle-to-bottle recycling.

There are two bottle making processes in use: "one-step" in which the resin is melted and injected into its final shape, and "two-step" in which the resin is extruded into an intermediate preform that is then reheated and blown into its final shape. BP Amoco sponsored a study of the more demanding, two-step process, conducted at PTI. The study was designed to evaluate the effects of introducing higher level isophthalate containing materials into the rPET stream under commercial bottle-making conditions. Potential effects evaluated included injection molding, blow molding, and physical performance of bottles made from blends of resins containing a higher level of isophthalate material. [42]

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[41] "Non-incremental PET" occurs when PETI replaces PET in a blend or copolymer application. Non-incremental PET refers to the amount of terephthalate-based polymer that is not changed. For example, suppose a certain application has a 100,000 lb/yr market and currently was made from PET. Assume that use of a 10% isophthalate content would improve the performance of this application. After competitive replacement of the PET product with the PETI product, there still would be 90,000 lb/yr of PET in this market, with the balance being 10,000 lbs of isophthalate. If one were considering the change in the PET market, there would be a net decrease of 10,000 lbs terephthalate polymer, with 90,000 lbs of non-incremental PET use.

[42] Plastic Technologies, Inc. (PTI), January 20, 1999. "Final Report for the PETI-10 Bottle-to-Bottle Recycling Study." (Reference Tab 16)

Test bottles were constructed using recycled-content, carbonated soft drink (CSD) bottles produced under simulated commercial conditions. The bottle flake used for this study was obtained by grinding production-grade manufactured bottles containing 10 mol% isophthalate and blending 25 wt% of this material with virgin PET resin. Control and comparator bottles were fabricated for comparative purposes. The comparator contained 100% virgin PET resin, and the control was made by mixing 25% rPET with 75% virgin PET. The isophthalate increment was about 2.5 mol%, i.e., the PETI/PET blend bottles had about 2.5 mol% more isophthalate than the control. The isophthalate increment tested exceeds the estimated change in isophthalate level in the recycling stream associated with FDA approval of this petition as determined in Confidential Appendix V (Table V-5.B).

Sample resins were molded into 20 oz. and 2 liter preforms and then blown into bottles without difficulty. Slight modifications to machine settings, comparable to those necessary when changing rPET source or grade, were necessary for the test resin. No impact on measured bottle properties was observed. An important property of preforms in the two-stage process is lack of color and opacity. The presence of higher isophthalate levels had no impact on preform color or opacity. Also, physical performance testing of the bottles made in this study showed that there was no significant difference between bottles made containing standard rPET (the control) and the PETI-10 recyclate. Based on this study, the incorporation of PETI copolymers into the rPET stream, would have no apparent negative effect on the use of rPET materials for commercial bottle production., given the anticipated isophthalate increment associated with FDA approval of this petitions.

Bottle-to-fiber recycling. As shown in Table H-5, most recycled PET is used in fibers. Virgin polyester fibers are produced either as filament, as staple (short fibers similar to cotton and wool), or as a spun-bonded product. Filament is manufactured by extrusion of molten polymer into long unbroken filaments. Mechanical properties of the filament, such as strength, are the most critical for acceptability in weaving clothing fabric or in industrial applications. Because of the variations in recycled PET, it has not been widely used in the manufacture of filament.[43] Extrusion into staple fiber for use in spun yarns, fiberfill and non-woven fabrics provide a more probable outlet for rPET recycling into fibers. Non-woven fabric can also be produced by spun-bond or melt-down polyester fiber production.

A study was conducted by Amoco Chemicals to evaluate the effect of increased isophthalate on PET bottle-to-fiber recyclability.[44] Fibers were spun and tested using commercially available rPET resin and various levels of PETI-10 copolymer resin (isophthalate at 10%). Blends of these two resins could be melt-spun and drawn into multifilament fiber without problem, under processing conditions identical to the control. The properties tested were tensiles (tenacity, modulus, elongation), thermal shrinkage, crystallinity, and melting behavior. Addition of an incremental 4 mol% isophthalate had no significant impact on either the fiber spinning process or on the properties of the resulting fiber.

An additional evaluation of bottle-to-fiber for automotive carpet applications was conducted by a European

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[43] PCI (Xylenes & Polyesters) Ltd., "North America PET Recycling Supply/Demand Report 1993/94." Devonshire House, 66 Church Street, Leatherhead, Surrey, KT22 8DJ, England. (Confidential report)

[44] Sakellarides, S. L. (Amoco), July 23, 1998. "Melt Spinning/Drawing Study on Blends of PET with PETI-10 in Order to Evaluate the Impact of PETI-1 Presence on PET Bottle-to-Fiber Recyclability." (Reference Tab 17)

manufacturer[45]

> "Montefibre, the only supplier of recycled low denier PET textile fibers in Europe, was requested to carry out an evaluation to determine whether high pressure dyeing techniques used in Europe lead to results similar to those reported when employing low pressure dyeing. Montefibre prepared 6.7 dtex staple fibre from 0.8 IV PET containing 0-100% flake from 10 wt% isophthalate bottle scraps (up to 10 wt% isophthalate content).
>
> "Textile characteristics, including tenacity, elongation, TA5, TA10, and modulus of the fibres produced were maintained at acceptable levels in all cases. Dye uptake (Beck's dyeing of fibre at 125 C for 1 hour) was judged to be acceptable by Montefibre at an incremental isophthalate level 1.0 wt% higher than that which currently exists in rPET Montefibre uses to make textile fibers."

Tests have thus demonstrated that incremental changes in isophthalate content do not have adverse impacts on representative processes and products using current rPET. The incremental isophthalate increases that were tested (about 2 wt% for bottles, 1 wt% for fiber) exceeded the increments anticipated based on he market analysis presented in Confidential Appendix V. This supports the conclusion that FDA approval of this petition will have no significant impact on PET recycling.

9.A.i.d. *Potential uses of Recycled Material.* As noted in Table H-5, uses of recycled PET include fibers, food and non-food bottles, strapping, and non-packaging films. Since FDA approval would not introduce new modifier into the recycled PET stream, and the potential isophthalate concentrations would not be significantly altered, no change in the potential uses of the recycled material would be expected.

The amber PETI beer bottle application may potentially increase the amber recycling stream with the clearance of this FAP, although, this segment of the rPET recycling infrastructure has been increasing rapidly over the past few years. A potential use for this recycled material could be as the middle (non-food contact) layer in a new beer bottle. The use of laminate technology for beer bottles has been mentioned by Bass Brewers.[46] Also, the new Miller beer bottle is a laminate.[47] Other uses of amber rPETI would be for fiber and strapping applications that currently use rPET, where color is not a concern.

Recent developments by Seydel Research, Inc. suggest that amber PETI beer bottles can be recycled and utilized in coating applications where amber PETI flake is processed and used to coat paper or paperboard. The use of isophthalate in this application is well noted by Seydel in many of the formulation examples.[48] Because these resins contain a high concentration of hydrophobic groups, the coated surface of paper or paperboard show an increased water repelling effect. Also, most of these uses would not be color sensitive and would provide an additional recycling path for the amber PETI bottles. The advantages for using these resins in the food industry where paper and paperboard packages need high hydrophobic properties of the

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[45] Personal communication, Franco Francalanci (Montefibre SPA) to G. E. Schmidt (Amoco Chemical), December 1998.

[46] Reynolds, P., 1998. "Bass is bullish on beer in plastic" *Packaging World*. March 1998, p. 54.

[47] *USA Today*, October 30, 1998, "Miller taps plastic for beer anywhere" Money Section, p. 1.

[48] World Intellectual Property Organization, International Publication Number: WO 98/33646, August 6, 1998, "Water Dispersible/Redispersible Hydrophobic Polyester Resins and their Application in Coatings" (Reference Tab 18)

box surface to ensure package shelf-life under high moisture conditions are threefold. One advantage is the use of lesser amount of materials to achieve a waterproof or water repellent surface; a second advantage is the recycling of waste PET (bottle sources) back into packaging materials, and the third advantage is that all materials coated in this manner can be easily repulped and therefor recycled.

9.A.i.e. *Steps taken to encourage recycling.* FDA approval of this FAP will broaden the number of plastic packaging items that can be recycled with PET (especially easily identified and collected beverage containers). This makes collection of such materials easier and reduces the number of items that are discarded outside of recycling streams. Through trade associations, BP Amoco is involved with plastics-recycling programs, thus encouraging recycling of these products.

9.A.ii. **Landfill Volume.** The approval of the proposed food additive is not expected to cause any significant changes in the landfill volume required to dispose of food-packaging articles. Since packaging made from the proposed food additive would replace packages made from competing materials, net changes would be minimal.

BP Amoco estimated the landfill volume required for disposal of the isophthalate-containing resin containers in the Confidential Appendix V of this petition. Assuming that each container made from the proposed food additive replaces one container of a competing material (glass, aluminum, other plastic), fewer containers of these competing materials would be landfilled. Because incineration of glass and aluminum results in eventual landfilling of these materials (as incinerator ash), replacement of the proposed food additive reduces landfill requirements for municipal incinerator ash.

Table H-6. Density Factors for Materials in Landfills

Tabled values are the estimated density of packaging or related products in pounds per cubic yard. Values are from Table 39, US-EPA 1992.

Material	Density (lbs/cu yd)
Glass containers	2,800
Steel containers	560
Aluminum containers	250
Paper/Paperboard Packaging	740
Plastic rigid containers	355
Plastic film	670
Other plastic packaging	185

Landfill capacity is determined by volume requirements, which is derived from the density of the materials being landfilled. Table H-6 shows relative density factors for landfilled materials. The proposed food additive will compete mostly with applications that use glass and plastic. In general, a plastic container weighs less than a glass container of the same capacity but occupies more volume per container in a landfill. Table H-6 shows that about 7.8 times as much glass (by weight) occupies a cubic yard of landfill than plastic rigid containers. Also, plastic containers are typically 1/7 the weight of an equivalent glass container. In addition, glass in incinerator ash will require additional volume. When all of these factors are considered (as done in section 6.B.iii and in the Confidential Appendix V) the net change (a slight decrease) is predicted to be less than 0.1% of the current total landfill volume of 319 MM cu yd (a value derived from Table 48 of US-EPA, 1997 and Table 42, US-EPA, 1994). These changes are within the limits of variability of the numbers used to make the estimates.. BP Amoco concludes that this evaluation shows that there would be no significant change in landfill volume requirements as a result of FDA approval of this petition.

9.B. ***Energy Consumption.*** The approval of the proposed food additive is not expected to cause any significant changes of energy consumption for the production, transport, use or disposal of food packaging affected by the action.

9.B.i. *Qualitative energy consumption analysis.* BP Amoco has not quantified the energy requirements to produce, transport, use and dispose of the food packaging material or the energy requirements of existing packaging materials because of the similarity between the proposed food additive and the existing materials. FDA has previously referred petitioners to work done by Franklin Associates for information about resource and energy usage.[49] However, published studies from Franklin Associates have focused on milk and carbonated soft drink containers, not on the types of sheet products anticipated by this present petition. Further, Franklin Associates projects have been used most often to compare alternative packaging systems, for example, 1000 gallons of a soft drink packaged in glass or aluminum or PET containers.

For the applications envisioned for the proposed food additives, comparisons of competing products are likely to find that there is no significant difference between the proposed food packaging material and the currently used food packaging materials. This logical conclusion comes from looking at the steps in preparing, using and disposing of the food packaging. The similarity of these steps, described below, suggests that any energy changes from replacing a small fraction of a PET polymer with isophthalate will be small relative to the entire energy requirement of the food packaging life-cycle.

For the proposed and currently used materials, the ultimate sources of materials are the same: crude oil, natural gas and coal. Each material is made from chemical intermediates (e.g., terephthalic acid, isophthalic acid, styrene, propylene, ethylene) produced from derivatives of the raw materials (e.g., benzene, xylenes, naphtha). The polymeric material or resin is then formed into sheet via the same process (e.g., injection molding and extrusion). Finally, the materials are thermoformed into the finished food packaging. The technical benefit of the isophthalate-modified PET is expected to improve performance during processing. By increasing through-put and allowing lower temperature operation, energy costs per article might be reduced. Mass per article is roughly equivalent, so energy costs of transporting materials would not be significantly changed. Eventually, used packaging enters the solid waste stream.

In other words, every step in the production, use and disposal process is virtually identical between the proposed food packaging material and currently used food packaging material. BP Amoco concludes that a non-quantitative comparison is sufficient to support a conclusion that there will be no significant change in energy consumption as a result of FDA approval of this petition.

9.B.ii. *FDA additional request.* FDA (in a letter dated January 18, 1996 reviewing Amoco's EA dated 27 February 1995) provided no data to refute Amoco's qualitative evaluation but instructed Amoco to make

[49]Supplemental Information dated May 16, 1985, submitted by American Enka Co. in support of FAP 5B3871.

quantitative comparisons using two references. FDA instructed Amoco to compare the value cited from Boustead (1986) with values for LDPE, aluminum, paperboard, and PP film and with values from Kirk-Othmer (1982) for paper, PVC, HDPE and PS film.[50] FDA wished to have Amoco conduct a "cradle-to-pellet" energy comparison, but wanted Amoco to normalize the comparisons based on the unit weights of packaging material required to hold a selected volume of food product. FDA did not provide the values from the Kirk-Othmer reference, nor did FDA provide unit weights of packaging materials.

Based on the product survey described in Section 4.B of this revised EA, BP Amoco concludes that the competitive materials are more limited than FDA suggests, and do not include LDPE, aluminum, paperboard, paper, or PVC. Nor do PP film or PS film represent competitive applications for the thermoformed PET/PEI sheet applications identified in this petition.

BP Amoco also concludes that making comparisons of energy analyses done by different authors at different times is not a credible or reliable procedure without paying attention to the system boundaries and numerous intermediate values used in developing energy estimates. To illustrate, FDA's Final Environmental Impact Statement on Plastic Bottles for Carbonated Beverages and Beer reported a value of 68,101 Btu/lb for creation of a 10 oz "polyester" bottle.[51] Another report stated that typical gross energy required to produce one kilogram of PET resin to be used in packaging was 183 MJ/kg, or about 79,000 Btu/lb.[52] A more recent estimate by the same author (Boustead, 1995) suggests an energy requirement of 83.81 MJ/kg (36,000 Btu/lb) for bottle grade PET resin and 81.69 MJ/kg (35,000 Btu/lb) for amorphous PET resin.[53]

Rather than make a comparison that would be complicated by using varied data sources, Amoco sponsored a comparison of PET/PEI, PET, PS, HDPE and PS sheet to be done by Ecobalance, Inc., of Rockville MD. A non-confidential version of that report is attached to this EA as Reference Tab 20.

In order to "normalize" the use of several materials in equivalent applications, a typical approach has been to divide the weight of material in the application by the food capacity of the application. Thus, beverages have often been compared on the basis of material needed to deliver 1000 gallons.

To address the issue of normalization, Amoco investigated the mass and capacity of selected plastic food packages (report attached) currently marketed. The report provided mass/capacity ratios for selected PP, HDPE, PET and PS products. However, several cautions were noted in Amoco's report: (1) No single pattern of relative weights/capacity for different plastics emerged, (2) grouping containers into "similar"

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[50]Kirk-Othmer, 1982, Encyclopedia of Chemical Technology, 3rd Ed., Vol. 23. John Wiley & Sons, New York, p. 921, Table 11. "1970-1980 U.S. Energy Data of Nine Industries producing 16 Products."

[51]FDA, "Final Environmental Impact Statement on Plastic Bottles for Carbonated Beverages and Beer" (September 1976). Table 5 reports that 4510 Btu are needed for creation of a 30 gram container with 10 oz capacity, equivalent to a requirement of 68101 Btu/lb.

[52]Boustead, I., 1986. "Energy Utilization" in Bakker, M. (Ed.) The Wiley Encyclopedia of Packaging Technology, John Wiley & Sons, New York, Table 3. pp. 266-270. (Reference Tab 4)

[53]Boustead, I. 1995. "Eco-profiles of the European plastics industry. Report 8: Polyethylene Terephthalate (PET)." Association of Plastics Manufacturers in Europe, Technical and Environmental Centre, Brussels. (Reference Tab 18)

applications is not a simple task and has major impacts on the variability of any resulting estimates, (3) the Coefficient of Variation (CV) was found to be a useful tool to evaluate the grouping and normalization strategies with a baseline CV=15% emerging as the lowest amount of variability in a grouping of similar applications, and (4) generalizations about the mass of plastic material per unit capacity of non-beverage packages should be used only with caution because variabilities are likely to exceed 50-60%. The Ecobalance report used the mass/capacity ratios found in this report.

The Ecobalance report concluded that "there is very little difference in the energy needed to produce PET, PETI (even in the worst-case scenario of 17% isophthalate content), HDPE and PP" (p. 12). On a MJ per-kg polymer basis, PETI was within 3% of the lowest value for any of the resins. On a MJ per ounce-capacity basis, PET and PETI ranked the lowest of the applications evaluated. Asked about the procedures used, Mr. Remi Coulon of Ecobalance reported that the precision of energy analyses was expected to be within 20%.[54]

The energy included in the "cradle-to-pellet" analysis does not include that needed to make the finished food packaging, nor to transport the material or packaging to the next location in filling or marketing the food package. BP Amoco believes that using the PETI copolymer can improve energy use during sheet formation and thermoforming of the sheet into package shapes relative to unmodified PET. However, such information is not generalizable and is developed by final users of the material.[55]

The quantitative procedure reported by Ecobalance led to the same conclusion as reached by Amoco's qualitative analysis, namely that approval of the petition will not result in a significant change in energy requirements.

9.B.iii. *New market qualitative energy consumption analysis.* The new markets discussed in this revision indicate that the proposed food additive will now also compete with standard PET, glass, aluminum and paper in some food-packaging applications.

The replacement of standard PET with the proposed food additive will use very similar resources as those used in existing packaging. Processes to produce the resin are the same, so the processes would be expected to have similar energy requirements (as concluded in the Ecobalance study). As described previously, the technical benefits of the proposed food additive materials during bottle fabrication, such as lower processing temperatures and reduced cycle time (increased through-put), reduce power requirements during processing for the proposed food additive.

In addition, comparisons of energy consumption for dissimilar materials are difficult because, among other factors, differences in weight (affecting the energy required to transport materials) may be offset by different energy requirements to create the material itself. Because the relative change in amounts of packaging materials that would result from FDA approval of this petition is so slight, BP Amoco believes that the overall impact on energy consumption cannot be considered significant. As stated above, the precision of energy analyses are expected to be within 20%. The projected markets for PETI applications show a fractional change in material used in glass, aluminum, and paper food packaging applications to be less than 1%. Therefore, Amoco concludes that any quantitative difference would be very small and within

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[54]Personal Communication with Ms. M.L. Michaels (Amoco), 9 October 1996.

[55]While Amoco has worked with potential users, the results of such work remains the confidential property of the users and so is not available.

the expected precision of the techniques.

Amoco concludes that there will be no significant change in energy consumption as a result of FDA approval of this petition.

10. ***Mitigation measures:***

No significant adverse environmental impacts have been identified, so no mitigation measures are appropriate.

11. ***Alternatives to the proposed action:***

No significant adverse environmental impacts have been identified, so no detailed discussion of all reasonable alternatives to the proposed action is appropriate.

12. ***List of preparers:***

Environmental Assessment prepared by:

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- Expertise in Environmental Assessment of direct and indirect food additives, environmental fate evaluation, aquatic toxicology, and ecological risk assessment.
- Experience in FDA in review of environmental impact of food additives, evaluation of solid waste issues of food packaging, statistical analysis of environmental data, use of multispecies test systems for evaluation of aquatic toxicity, whole effluent aquatic toxicity testing, and product stewardship.
- Professional discipline: Environmental Science and Environmental Toxicology

Ms. Paula J. Ignat
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- Expertise in Product Stewardship, Product Regulatory issues such as TSCA, OSHA Hazard Communication and Assessment, Analytical Chemistry techniques and analysis.
- Experience in Environmental Assessment of direct and indirect food additives, Life cycle Assessment , statistical analysis of analytical chemistry data.
- Professional discipline: Zoology/Biology:Education and Analytical Chemistry

Persons consulted:

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13. ***Certification:***
The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Amoco Corporation.

September 15, 1999
(Date)

(Signature)

Specialty Intermediates - Business Unit Leader
(Title)

14. ***Attachments:***

A number of references were supplied to FDA and are attached as the following Reference Tabs:

1. Amoco Chemicals, "Bottle Enhancements: Extending the Performance of PET with Amoco® PIA", Bulletin PK-1, Chicago, Illinois. September, 1998. (Reference Tab 1)

2. M.C. Harrass, September 1996. "Market Survey Report" and "Food Packaging: Mass and capacity of selected non-beverage plastic items."

3. Bauer, C.W. 1999. "SIBU - PET-X Thermal Properties." BP Amoco Chemical Company.

4. Bakker, M. (Editor), 1986 "Thermoplastic Polyesters" in The Wiley Encyclopedia of Packaging Technology, John Wiley & Sons, New York. pp. 512-514.

   Boustead, I. "Energy Utilization" in Bakker, M. (Editor), 1986 "Thermoplastic Polyesters" in The Wiley Encyclopedia of Packaging Technology, John Wiley & Sons, New York. pp. 266-270.

5. Radian Corp., 1986, Polymer Manufacturing. Noyes Data Corporation, Park Ridge, NJ. pp. 325-332.

6. Selected Material Safety Data Sheets (MSDS).
   Amoco Chemical Co., TA-33 (Terephthalic Acid)
   Amoco Chemical Co., P.I.A. (Isophthalic Acid).
   Shell Chemical Co., Cleartuf® EB 1000 (Poly(ethylene terephthalate))
   Shell Chemical Co., Cleartuf® 7207 (Poly(ethylene terephthalate))
   Shell Chemical Co., REPETE 80310 (Terephthalate, isophthalate polymer with ethylene glycol)
   Canada Colors and Chemicals Limited, KODAR PETG Copolyester 6763
   DuPont Canada, Inc., Post-consumer Recycled PET, Types Clear, Green

7. Food and Drug Administration, Environmental Impact Staff, Center for Food Safety and Applied Nutrition, 1993. "New Polymeric Food-Packaging Materials: Key Environmental Issues." Draft. (Reference Tab 7)

8. R. A. Bennett, R.W. Beck, and Associated Services Group (ASG), August, 19, 1998. "1997 PET Recycling Rate Information Released" Prepared for The National Association for Plastic Container Recovery (NAPCOR), Charlotte, NC.

9. R. A. Bennett (University of Toledo, College of Engineering), 1994. "Research to determine the 1995 amount of post consumer PET bottles recycled, PET recycling rate and end use markets." Prepared for The National Association for Plastic Container Recovery (NAPCOR), Charlotte, NC.

10. Mitchell, A.K., "Polyethylene Terephthalate: Traditional container outlets thrive while new uses come to the fore," , *Modern Plastics*, Mid-November 1994. pp. B-48-B50.

11. T. Moore, 1998. Wellman, Inc. USA, "Improved Bottle Processing with PIA. Increased reheat capacity opens process window", Presentation to Bev-Pak America's '98 meeting, April 6&7.

12. *Chemical Market Reporter,* October 6, 1997, "Isophthalic Market Facing Oversupply: String of new plants and expansions are expected to kick product out of balance.", p. 5.

13. BP Amoco, "Recycling Polyethylene Terephthalate/Naphthalate (rPET/N) Food Packaging: A Flow Chart and Analysis (Non-confidential Version)", March 1997. (Edited for use with FAP 5B4455, November 1998)

14. P. Dinger, 1996. American Plastics Council (APC) Packaging Technical Committee, Presentation to SPI/PEN Committee meeting, August 6.

15. Clean Washington Center, 1998 "Best Practices in PET Recycling" 999 Third Avenue, Suite 1060, Seattle, WA 98104.

16. Plastic Technologies, Inc. (PTI), January 20, 1999. "Final Report for the PETI-10 Bottle-to-Bottle Recycling Study."

17. Sakellarides, S. L. (Amoco), July 23, 1998. "Melt Spinning/Drawing Study on Blends of PET with PETI-10 in Order to Evaluate the Impact of PETI-1 Presence on PET Bottle-to-Fiber Recyclability."

18. World Intellectual Property Organization, International Publication Number: WO 98/33646, August 6, 1998, "Water Dispersible/Redispersible Hydrophobic Polyester Resins and their Application in Coatings"

19. Boustead, I. 1995. "Eco-profiles of the European plastics industry. Report 8: Polyethylene Terephthalate (PET)." Association of Plastics Manufacturers in Europe, Technical and Environmental Centre, Brussels.

20. Ecobalance, Inc. "Life Cycle Assessment of Energy Requirements of Isophthalic acid-modified PET and other competing plastic materials for packaging applications." October 10, 1996. (Non-confidential version)

Reference Tab 13.

Amoco, "Recycling Polyethylene Terephthalate/Naphthalate (rPET/N) Food Packaging: A Flow Chart and Analysis (Non-confidential Version)", March 1997. (Edited for use with FAP 5B4455, November 1998)

Previously provided to FDA

Reference Tab 10.
Mitchell, A.K., "Polyethylene Terephthalate: Traditional container outlets thrive while new uses come to the fore," , *Modern Plastics*, Mid-November 1994. pp. B-48-B50.

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Reference Tab 8.

R. A. Bennett, R.W. Beck, and Associated Services Group (ASG), August, 19, 1998. "1997 PET Recycling Rate Information Released" Prepared for The National Association for Plastic Container Recovery (NAPCOR), Charlotte, NC.

Reference Tab 6.
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- Amoco Chemical Co., P.I.A. (Isophthalic Acid)
- Shell Chemical Co., Cleartuf® EB 1000 (Poly(ethylene terephthalate))
- Shell Chemical Co., Cleartuf® 7207 (Poly(ethylene terephthalate))
- Shell Chemical Co., REPETE 80310 (Terephthalate, isophthalate polymer with ethylene glycol)
- Canada Colors and Chemicals Limited, KODAR PETG Copolyester 6763
- DuPont Canada, Inc., Post-consumer Recycled PET, Types Clear, Green

Previously provided to FDA

Reference Tab 7.
Food and Drug Administration, Environmental Impact Staff, Center for Food Safety and Applied Nutrition, 1993. "New Polymeric Food-Packaging Materials: Key Environmental Issues." Draft

Provided by FDA to Amoco, currently BPAmoco has no copy.

Reference Tab 4.
Bakker, M. (Editor), 1986 "Thermoplastic Polyesters" in The Wiley Encyclopedia of Packaging Technology, John Wiley & Sons, New York. pp. 512-514.

Boustead, I. "Energy Utilization" in Bakker, M. (Editor), 1986 "Thermoplastic Polyesters" in The Wiley Encyclopedia of Packaging Technology, John Wiley & Sons, New York. pp. 266-270.

Previously provided to FDA

Reference Tab 2.
Harrass, M.C., September 1996. "Market Survey Report" and "Food Packaging: Mass and capacity of selected non-beverage plastic items."

Previously provided to FDA

These are non-confidential

Reference Tab 16.
Plastic Technologies, Inc. (PTI), January 20, 1999. "Final Report for the PETI-10 Bottle-to-Bottle Recycling Study."

Previously provided to FDA

Reference Tab 17.
Sakellarides, S. L. (Amoco), July 23, 1998. "Melt Spinning/Drawing Study on Blends of PET with PETI-10 in Order to Evaluate the Impact of PETI-10 Presence on PET Bottle-to-Fiber Recyclability."

Previously provided to FDA

Reference Tab 18.
World Intellectual Property Organization, International Publication Number: WO 98/33646, August 6, 1998, "Water Dispersible/Redispersible Hydrophobic Polyester Resins and their Application in Coatings"

Previously provided to FDA