APPENDIX VII

FINAL

Environmental Assessment for Food Additive Petition Naphthalate / Terephthalate Polymers

1. *Date:* December 28, 1994

2. *Name of petitioner:* Shell Chemical Company

3. *Address:* Correspondence on this Environmental Assessment should be sent to:
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   Shell Chemical Company
   Polyester Research & Development
   130 Johns Avenue
   Akron, Ohio 44305-4097

4. *Description of the Proposed Action:*

4.A. ***Requested approval.*** Shell Chemical Company (Shell) proposes that an amendment to the regulation at 21 *CFR* 177 be made to permit the safe use of poly(ethylene-2,6-naphthalate) polymers and poly(ethylene-2,6-naphthalate terephthalate) polymers for single and repeated use food contact applications, with the terephthalate content varying from 0 to 50 weight percent. Shell proposes that these naphthalate-containing polymers 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.

4.B. ***Intended Market for Food Packaging.*** Shell expects that naphthalate-containing polymers will compete with existing food-packaging applications, particularly in use as containers. Shell believes that these uses are primarily characterized as "single-use" although, in practice, some containers may be re-used by consumers. The properties of the subject polymers may make repeated-use applications feasible. Shell assumes, for the purposes of this environmental assessment, 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 market for all food-contact uses for naphthalate-containing polymers that Shell believes reasonable following FDA approval of this and related Shell petition(s). In other words, the cumulative impacts of approvals for several uses of naphthalate-containing polymers are evaluated in this assessment.

In order to develop this new polymer, Shell sought to define the market requirements and then to design a polymer to meet those performance and economic requirements.[1] Shell's market evaluation revealed that once fill temperatures are above 200°F, different needs and drivers emerge than had been previously recognized in the beverage packaging industry. At fill temperatures above 200°F, requirements for uses in food products and their attributes become more significant than requirements for beverage applications. For example, food's seasonality creates some absolute requirements. When a pea-picking season arrives, the whole year's production is harvested, processed and packaged for the next year's sales. Even with the best inventory management, required shelf-life must be at least one year for such products.

Shell's market segment evaluation also determined that there are basically two segments based on high temperature: those products that require a 212°F maximum fill temperature (termed hot-fill), and those that require a 245°F minimum retort temperature (termed retort). There is very little demand for containers to meet requirements between 212 and 245°F.

Barrier needs include gas permeability, water vapor transmission rate, and specific solvent resistance. Barrier needs are not well quantified or described. Glass and steel packaging have provided adequate properties without packagers having to determine barrier properties. Niche markets require specific solvent resistance and UV barrier properties, making broad generalizations about market potentials difficult.

Shell provides a market estimate in the Confidential Appendix IV 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 containers are suitable for

[1]Callander, D., and E. Sisson, 1994, "High Performance PEN & Naphthalate Based Packaging Resins," Presented at Bev-Pak Americas '94, April 11-12, 1994, Tarpon Springs, Florida.

making naphthalate-containing polymer containers, so many food packagers would probably not need to make significant process changes or investments. However, a shift from significantly different packaging materials, such as a shift from a glass container to a naphthalate-containing polymer container, may be affected by considerations other than technical compatibility. Market acceptability or dramatic economic shifts might alter market penetration in ways that Shell cannot reasonably anticipate.

The presence of the naphthalate component conveys a number of key properties on the naphthalate-containing polymers that are not available in polyethylene terephthalate (PET). These include better carbon dioxide, oxygen and water barrier properties, higher temperature resistance, greater strength and an intrinsic ultraviolet light barrier. There is a significantly higher cost for the raw material, so economics are expected to severely limit the use of naphthalate-containing polymers to those applications where the physical properties are sufficiently desirable.

The anticipated market consists primarily of rigid and semi-rigid food packaging containers, i.e., bottles and jars. The anticipated market would capitalize on the improved properties of the naphthalate-containing polymers. The major applications for naphthalate-containing polymers are currently packaged in glass. Other competitive materials existing in these applications include steel, multilayer plastics (such as polypropylene-EVOH, polypropylene-PET, or polyacrylonitrile constructions).

There are a number of products currently used in similar applications. These would include glass and plastic bottles and jars, some metal cans, and some plastic sheet. Table VII-1 shows EPA's estimates of these products in the municipal waste stream.[2] For 1990, EPA estimated that municipal solid waste (MSW) contained a total of about 12 million tons (23.8 x 10^9 pounds) of glass in similar packaging applications, about 2.6 million tons (5.2 x 10^9 pounds) of steel in food packaging applications, about 1.6 million tons (3.2 x 10^9 pounds) of aluminum in similar applications, 4.8 million tons of paper and paperboard in similar food packaging applications and 2.1 million tons of plastics in similar applications. Note that these EPA figures do not provide any better details about the actual applications, so Shell cannot further differentiate exactly what containers are included in theses categories. Consequently, the EPA figures are significant overestimates of the potential market for the specific applications of naphthalate-containing polymers.

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[2]U.S. Environmental Protection Agency (US-EPA), 1992. "Characterization of Municipal Solid Waste in the United States: 1992 Update." Office of Solid Waste and Emergency Response, Washington, DC. EPA/530-R-92-019. NTIS # PB92-207/166.

Table VII-1. Similar Products Generated in the Municipal Waste Stream
Values are in millions of tons. Source: US-EPA, 1992, Table 18.

Type of Product	1980	1985	1990
Glass Beer & Soft Drink Bottles	6.7	5.7	5.7
Glass Wine & Liquor Bottles	2.5	2.2	2.1
Glass Food/Other Bottles & Jars	4.8	4.2	4.1
Combined Glass	*14.0*	*12.1*	*11.9*
Steel Beer & Soft Drink Bottles	0.5	0.1	0.1
Steel Food & Other Cans	2.9	2.6	2.5
Combined Steel:	*3.4*	*2.7*	*2.6*
Aluminum Beer & Soft Drink Cans	0.9	1.3	1.6
Aluminum:	*0.9*	*1.3*	*1.6*
Paper/paperboard milk cartons	0.6	0.5	0.5
Paper/paperboard folding cartons	3.7	4.0	4.3
Combined Paper/paperboard	*4.3*	*4.5*	*4.8*
Plastics Soft Drink Bottles	0.3	0.4	0.4
Plastic Milk Bottles	0.2	0.3	0.4
Plastic other Containers	0.9	1.2	1.8
Plastic Wraps	0.8	1.0	1.5
Combined Plastics:	*2.2*	*2.9*	*2.1*

Market estimates of various plastic resins are published by *Modern Plastics*. Table VII-2 shows selected market applications for PET. Estimated sales of PET and its copolymers exceeded 2.7 billion pounds in 1993, including exports, according to *Modern Plastics* (January 1994). The 1997 US market is estimated to exceed 3 billion pounds, according to *Chem Data* (March 1994).

Shell estimates that the market for the naphthalate-containing polymers will be a small fraction of the current and future markets for PET (detailed in the Confidential Appendix IV of this petition). PET is manufactured by several companies in the U.S., including Eastman Chemical, Shell, Hoechst Celanese and ICI. U.S. production capacity of PET in 1994 exceeds 3.5 billion pounds. Table VII-3 shows major producers of PET and their capacities.

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

Market	1991	1992	1993
Blow molding			
Soft-drink bottles	793	915	1015
Custom bottles (cosmetics, toiletries, pharmaceuticals, food, liquor)	403	478	560
Extrusion			
Film (excluding magnetic)	550	560	562
Magnetic recording film	90	92	94
Ovenable trays	50	54	57
Coating (for ovenable board)	13	13	15
Sheeting (blisters, cups, food trays, etc.)	87	100	112
Strapping	36	38	40
Exports	318	383	280
TOTAL	**2340**	**2630**	**2735**

Shell, ICI, and Eastman have announced that they are currently manufacturing naphthalate-containing polymers in the U.S. in commercial quantities. Marketed quantities are held as confidential information by the manufacturers, but combined totals are estimated to be far less than 1% of current PET markets. Besides its utility in food packaging, naphthalate-containing polymers are expected to be successful in other non-food packaging applications, and in non-packaging applications, including film applications such as video tape, and fibers, such as tire cords, hosing and belts. Markets are expected to be international, including Europe and Asia.

The basic naphthalate monomer, dimethyl-2,6-naphthalene dicarboxylate, will be manufactured by Amoco Chemical Company at its facility in Decatur, Alabama, with production scheduled to begin in 1995. The estimated Amoco production capacity is 60 million pounds when that facility attains its design capacity. A Dutch company, Skilpack, announced commercial production of naphthalate-containing hot-fillable wide-mouthed bottles and jars (*Packaging Week*, 11/3/94). Mitsubishi Gas Chemical also produces the naphthalate monomer.

Table VII-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.

Supplier	1990	1992	1994	1997
Hoechst Celanese	250	360	430	530
ICI Americas	125	130	140	360
Shell / Goodyear	490	560	715	730
Eastman	920	1240	1240	1280
E.I. DuPont	0	25	25	25
Wellman	0	5	80	80
Nan Ya Plastics	0	0	225	225
PET Processors	75	75	100	100
TOTAL	**1860**	**2395**	**2665**	**3330**

Consumption	1990	1992	1994	1997
Total	1508	2100	2280	3220

4.C. ***Location of Production.*** The locations of production of the proposed food-packaging material are likely to be facilities, such as Shell, that currently manufacture similar polymeric materials. Shell Chemical Company manufactures naphthalate-containing polymers, including food-grade polymers for export, at its existing PET plant in Apple Grove, West Virginia. Polymers complying with the proposed regulation will be made at this facility. Table VII-4 is a list of the substances expected to be emitted as a result of manufacture of these food-grade polymers and the controls exercised to minimize emissions.

Manufacture of these polymers will be in full compliance with all applicable local, State and Federal laws and regulations including those administered by the Occupational Safety and Health Administration. Any process volatile emissions will be controlled in full compliance with all federal, state and local requirements. All solid and liquid wastes produced in the manufacture will be disposed of in compliance with applicable laws and regulations. Compliance with such requirements will not be affected by approval of this food additive petition.

Shell manufactures food contact-grade naphthalate-containing polymers at its Apple Grove, WV facility. The address of the facility is:

Shell Chemical Company
Point Pleasant Polyester Plant
State Route 2
Apple Grove, West Virginia 25502

This site is located in a rural area. Environments that might be affected by production include the workplace and adjacent areas subject to air and water emissions. Solid production wastes are disposed in licensed landfills or incinerators.

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 PET container fabrication. There are a variety of such facilities and Shell is not able to identify that a specific facility will produce food packaging containing the proposed food additive. Consequently, Shell is not able to describe the environments where such production may take place in other than general terms.

Because of the similarity of the proposed food additive to existing food additives used in similar packaging applications, Shell 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.

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 recycled where PET recycling programs are in place. Shell believes that the types of food packaging that will use the proposed food additive are likely candidates for post-consumer recycling programs. Trends in U.S. solid waste management suggest that the proportion being landfilled will decrease, while the proportions being incinerated and recycled will increase. 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.

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

The proposed food additives are naphthalate-containing polymers not exceeding 50% ethylene terephthalate content by weight. Shell has described the chemical nature of the materials and the anticipated technical improvements due to the naphthalate-containing polymers in Section A of this petition. Shell 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 additives include the homopolymer, Poly(ethylene-2,6-naphthalate) (CAS 25853-85-4). The homopolymer is also known as 2,6-naphthalene-dicarboxylic acid, dimethyl ester, polymer with 1,2-ethanediol (9CI), abbreviated as PEN. PEN has the generic molecular formula $(C_{14}H_{10}O_4)_x$. PEN has a density of about 1.37 g/cm^3. PEN is chemically stable and resists moderate heat (melting point ca. 267°C). PEN polymers are not presently regulated for food-contact use in the U.S., although they do meet requirements for food contact uses in several other countries.

Other names for PEN include:

- 2,6-naphthalene dicarboxylic acid, dimethyl ester, polymer with 1,2-ethanediol (CAS 25853-85-4),

- 2,6-naphthalene dicarboxylic acid, polymer with 1,2-ethanediol (CAS 25230-87-9),

- Poly (oxyethylene oxycarbonyl-2,6-naphthalene-carbonyl) (CAS 24968-11-4).

The subject of this petition are also naphthalate-containing polymers consisting of poly (ethylene terephthalate-2,6-naphthalate) polymers (CAS 25915-92-8, 107845-66-9, 27289-84-5 and 26221-57-8) in which the finished polymer may contain from greater than zero to 50 weight percent of ethylene terephthalate.

Other names for the naphthalate-containing copolymer include:

- 2,6-naphthalene dicarboxylic acid, polymer with 1,4-benzenedicarboxylic acid and 1,2-ethanediol (CAS 25915-92-8),

- 2,6-naphthalene dicarboxylic acid, dimethyl ester, polymer with 1,4-benzenedicarboxylic acid and 1,2-ethanediol (CAS 27289-84-5),

- 2,6-naphthalene dicarboxylic acid, polymer with dimethyl-1,4-benzenedicarboxylate and 1,2-ethanediol (CAS 107845-66-9),

- 2,6-naphthalene dicarboxylic acid, dimethyl ester polymer with dimethyl-1,4-benzenedicarboxylate and 1,2-ethanediol (CAS 26221-57-8).

The weight percent of ethylene terephthalate units in the subject polymers may vary from greater than 0 to 50%.

The naphthalate/terephthalate polymer is formed by either trans-esterification or esterification followed by polycondensation of terephthalic acid (TPA) or dimethyl terephthalate (DMT) and dimethyl-2,6-naphthalene dicarboxylate (DMN) or 2,6-naphthalene dicarboxylic acid (NDA) with ethylene glycol during which water or methanol is removed from the reactor vessel. The relative composition of the copolymer is controlled by adjusting the ratio of DMN or NDA to DMT or

TPA. The homopolymer PEN is formed by either esterification or trans-esterification followed by polycondensation of DMN or NDA with ethylene glycol.

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-ethanediol, abbreviated as PET or PETE, and has the generic molecular formula $(C_8H_6O_4.C_2H_6O_2)_x$. PET is a medium-density (about 1.33 g/cm^3) resin with a relatively high melting point (ca.248-260oC), 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 VII-2).

Copies of selected Shell Material Safety Data Sheets (MSDSs) for these types of products are attached to this environmental assessment.

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

6.A. ***Introductions at Sites of Production.*** Production of the proposed food additive is not expected to introduce significant quantities of chemicals into the environment. Shell Chemical Company will manufacture food-grade naphthalate-containing polymers at its existing polyester resin plant in Apple Grove, West Virginia.

Table VII-4 lists the substances expected to be emitted as a result of manufacture of these food-grade polymers and the controls exercised to minimize emissions. Substances that might be emitted from the production of naphthalate-containing polymers for food contact use include: ethylene glycol, dimethyl-2, 6-naphthalene dicarboxylate (DMN), dimethyl 2, 6-terephthalate (DMT), terephthalic acid (TPA), methanol, ethylene glycol, diethylene glycol, oligomers, and fines (small particles) of PEN polymers and copolymers, and fugitive emissions of volatile organic compounds (VOC).

The controls installed to limit emissions of these substances include fabric filters to control dust and particulate emissions. Air and water emissions are controlled by shell and tube condensers, recycling, biological treatment and incineration. Operational controls include appropriate use of protective clothing and equipment such as dust masks to limit employee exposure. Solid waste management procedures include recovery and reclaim of usable materials and off-site disposal of remaining solid wastes as non-hazardous wastes.

Manufacture of these polymers will be in full compliance with all applicable laws and regulations including those administered by the Occupational Safety and Health Administration. Any process volatile emissions will be controlled in full compliance with all federal, state, requirements which

Table VII-4. Substances Emitted

The substances expected to be emitted from the site of production of the food additive (naphthalate-containing polymers) are listed below. In addition, the controls exercised

Substance	Type of Emission	Type of Control
PEN	Particulate Solid Waste	Bag Filter Recycle or Non-hazardous solid waste
PEN Copolymers	Particulate Solid Waste	Bag Filter Recycle or Non-hazardous solid waste
2,6-Naphthalate dicarboxylate	Particulate Solid Waste	Bag Filter Recycle or Non-hazardous solid waste
Terephthalate Acid	Particulate Solid Waste	Bag Filter Recycle or Non-hazardous solid waste
Dimethyl terephthalate	Particulate Solid Waste	Bag Filter Recycle or Non-hazardous solid waste
Acetaldehyde	Volatile Organic Compounds (VOC) in air, water	Shell and Tube (S&T) Condenser, Recycle, Biotreatment
Ethylene Glycol	VOC in air, water	S&T Condenser, Recycle, Biotreatment
Diethylene Glycol	VOC in air, water	S&T Condenser, Recycle, Biotreatment
Methanol	VOC in air, water	S&T Condenser, Recycle, Incineration
Fugitive Air emission	VOC in air	None

will not be affected by approval of this food additive petition. Attached in item 14 is a citation of applicable emissions requirements, noting that FDA approval will not adversely affect compliance with current emissions requirements at Shell's production site.

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

Environmental releases at sites of use of the naphthalate-containing 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 Shell is not able to identify that a specific facility will produce food packaging using the proposed food additive. Consequently, Shell is not able to describe the environments where such production may take place, except in general terms.

Shell 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 extruding or molding process. The only measured volatile residual is acetaldehyde. Since the chemistry and manufacture of the subject food additive is essentially the same as that for PET, any such air emissions would be the same as presently emitted from processing 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.

Shell 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. These issues are discussed below as part of environmental releases at sites of disposal.

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 naphthalate-containing polymers are summarized below, but are discussed in the Confidential Appendix IV 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. Shell believes that incineration of subject polymers are not expected to release problematic air emissions. Combustion products of the incinerated naphthalate-containing polymers are summarized below, but are discussed in the Confidential Appendix IV 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.[3] 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 $(f_{landfilled}) = 80\% \times (1 - f_{recycled})$

FDA approval of new polymers could result in competitive replacement of the currently-used packaging materials in affected applications. If there is a major change in packaging materials in the waste stream, then the efficiencies and economics of current municipal sold waste (MSW) management practices might change. For example, if there is too little of a material, post-consumer recycling may become less efficient because of the increased transport costs to collect such material. However, the overall changes that might result from FDA approval of this current petition are so small that no significant impact can reasonably be foreseen.

To quantify the changes in MSW, the mass of packaging materials replaced by terephthalate/-naphthalate products was calculated. Each container predicted to be made of terephthalate/-naphthalate polymers was taken to replace one container made of the competing material. These numbers were multiplied by the anticipated container weight to estimate the mass of competing material not present in solid waste.

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

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: PET and laminate plastics, -10% per 5 years; glass, -5% per 5 years; metal, -3% per 5 years.[4] 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 IV).

6.B.ii. **Disposal by Recycling.** Shell expects that food-contact articles containing naphthalate/terephthalate polymers can be readily recycled. EPA has projected recycling rates for a variety of materials. However, PET recycling has specific characteristics which have been more carefully studied; where information pertinent to PET recycling is available, Shell's analysis uses the more detailed information rather than the general EPA analysis. A description of current and future recycling patterns is given below and further discussion of recycling of containers made from the proposed food additive is in item 9 of this environmental assessment. Figures for recycling rates of used food packaging ("recovered" in US-EPA's terminology), are shown in Table VII-5, as provided by US-EPA (1992).

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[4]The patterns were derived from data in EPA (1992) and 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. Prairie Village KS.

Table VII-5. Recycling of Similar Products Generated in the Municipal Waste Stream

Values are in percent recovery. Source: US-EPA, 1992, Tables 20 and 21, B-2. 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	1980	1985	1990	2000
Glass Beer & Soft Drink Bottles	11.9%	17.5%	33.2%	50.0%
Glass Wine & Liquor Bottles	--	4.5%	10.0%	29.8%
Glass Food/Other Bottles & Jars	--	--	12.7%	29.8%
Combined Glass	*5.7%*	*9.1%*	*22.0%*	*39.2%*
Steel Beer & Soft Drink Cans	10.0%	10.0%	24.7%	60.0%
Steel Food & Other Cans	3.4%	4.3%	23.4%	55.0%
Combined Steel	*4.2*	*3.8%*	*22.1%*	*51.7%*
Aluminum Beer & Soft Drink Cans	32.4%	46.2%	63.2%	70.0%
Combined Aluminum	*23.6%*	*37.5%*	*48.0%*	*59.8%*
Paper/paperboard milk cartons	--	--	--	25.0%
Paper/paperboard folding cartons	13.5%	5.0%	7.9%	25.0%
Combined Paper/paperboard	*27.3%*	*26.4%*	*36.9%*	*48.9%*
Plastic Soft Drink Bottles	0.0%	25.0%	31.5%	50.0%
Plastic Milk Bottles	0.0%	--	6.9%	35.0%
Plastic Other Containers	--	--	1.2%	35.0%
Plastic Wraps --	--	2.0%	11.2%	
Combined Plastics	--	*2.2%*	*3.7%*	*22.5%*

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. According to published reports, this rate has been increased rapidly, with targeted recycling rates set at 50-60% by various policy-making groups. One published projection predicted that collection of PET containers would almost double from 1991 to 1996 (*Modern Plastics*, October, 1993, p. 79). Market demand for recycled polyester feedstock has been increasing, which supports higher recycling rate projections.

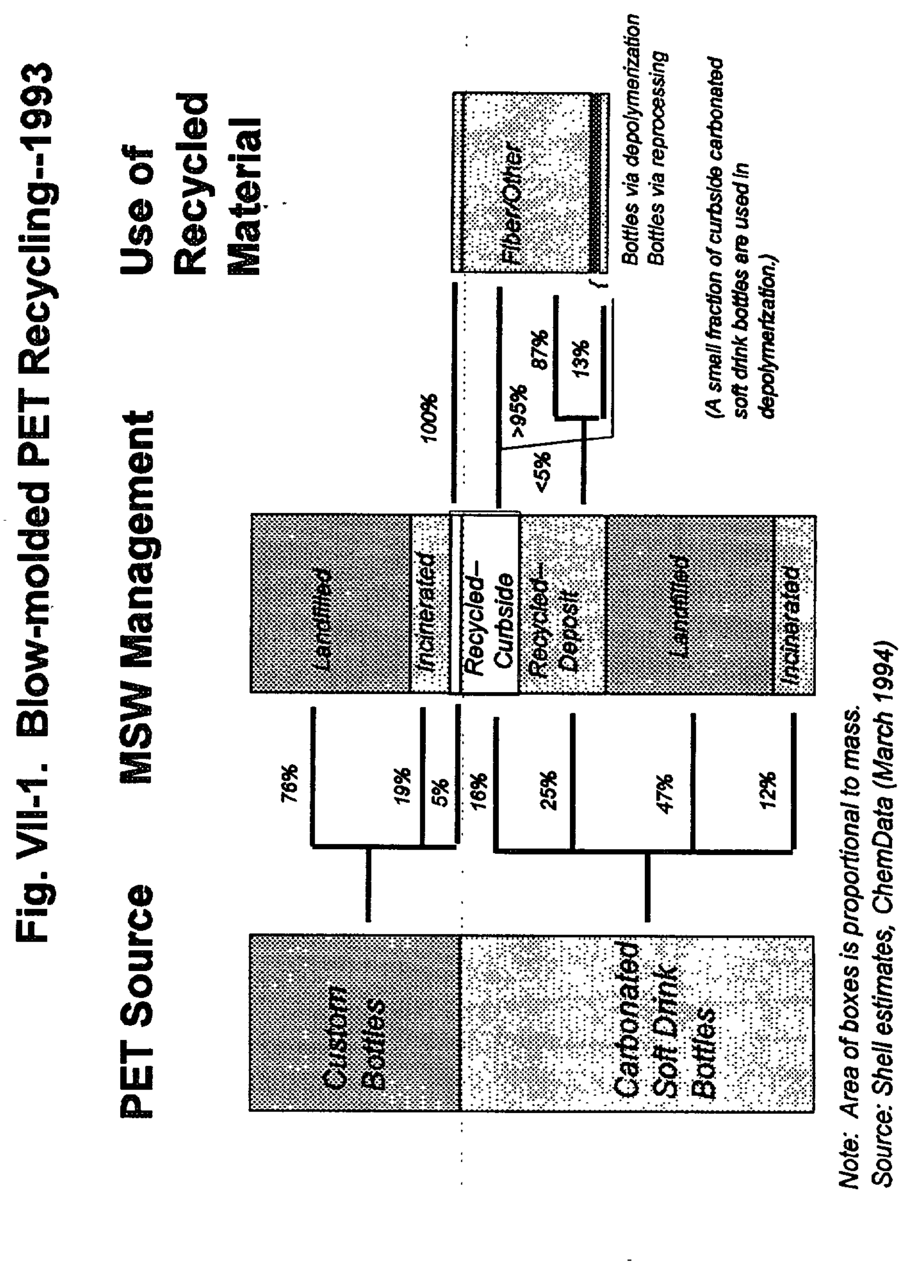

Fig. VII-1. Blow-molded PET Recycling--1993

Note: Area of boxes is proportional to mass.
Source: Shell estimates, ChemData (March 1994)

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 municipal recycling facilities (MRFs) sort and bale the collected materials, usually segregating glass, aluminum, steel and some plastics from the collected post-consumer materials.

Figure VII-1 graphically illustrates the disposition of blow-molded PET in 1993 including the primary markets for naphthalate-containing polymers. The sources (or applications) of the recycled PET are carbonated soft drink bottles and custom bottles. For each application, the figure shows how the discarded packaging is handled by current municipal solid waste (MSW) management. The use of recycled material is also shown. As shown, virtually no custom bottle material is handled via bottle deposit collection. These patterns have direct impacts on the quality of recovered material and their eventual disposition.

The overall PET recycling rate in 1993 was 28%.[5] 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%. These patterns are reflected in Figure VII-1.

The level of contamination in curbside collection is significantly greater than in bottle-state materials, so there is a significant difference in prices paid by recyclers. These price differences can be up to $0.05/lb, a 50% discount from the typical price for post-consumer deposit-state PET of about $0.10 to $0.13/lb.[6] This is because of the poorer quality of any resulting final end product. PVC contamination in such materials represents one critical factor.

EPA (1992) has projected recycling rates that would achieve overall recycling of 25%, 30% and 35%. For the 30% overall recycling rate, 50% recycling of soft drink bottles was projected, along with rates of 35% for other containers (i.e., custom bottles), and 11.2% for other plastics packaging (e.g., sheet). The applications most likely to use naphthalate-containing polymers are best described as "custom bottles" so the 35% recycling rate appears applicable. However, Shell has used the more conservative rates derived from the available detailed information on PET recycling. Recycling for custom bottles is expected to be 16%, which represents Shell's best estimate of the recycling rate for containers subject to the proposed food additive petition.

Approval of the subject petition is not expected to adversely impact current recycling programs. Recycling is feasible because naphthalate-containing polymers are compatible with current PET recycling at the naphthalate concentrations that could occur under present or foreseeable recycling

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

[6]Schut, J.H., 1993. "Working with Recycle." Plastics Technology (August 1993). pp. 40-45.

patterns. (The compatibility of materials containing naphthalate with current PET recycling processes is discussed in more detail in item 9 of this environmental assessment). Significant uses of recycled PET include spinning into fiber and making containers. Potential uses of recycled PET exceeded 500 million pounds in 1993 and is projected to grow at about 3% per year.[7] Recycling demand is expected to exceed supply for the next several years[8] so that interest in expanding PET recycling is likely to continue.

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 naphthalate-containing products that would be landfilled is estimated in Confidential Appendix IV because it directly reflects market volumes.

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. Shell notes that PET has been used in a variety of applications 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 PET complying with current FDA approvals. The presence of naphthalate in the polymers might change the leachable fraction to include oligomers containing the naphthalate structure, replacing some of the terephthalate component.

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)*. Shell provides a confidential market volume in the Confidential Appendix IV of this petition.

6.B.iii.b. *Fraction to be landfilled ($f_{landfilled}$)*. The net percent of naphthalate-containing polymers subject to this petition expected to enter landfills is 67%, i.e., 80% of the materials not recycled.

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[7]R. A. Bennett (University of Toledo, College of Engineering), 1994. "PET Recycling Research: 1993 Activity and Markets" Prepared for The National Association for Plastic Container Recovery (NAPCOR), Charlotte, NC.

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

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 and would be expected to be minimal for two reasons: first, the polymers consist of large molecular weight polymers and second, the water solubility of the polymers is negligible (less than 0.1%; see attached MSDSs).

Landfill leachate has been described as "a very strong wastewater."[9] 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 is reasonably considered an aqueous solvent rather than an organic solvent. Because naphthalate-containing 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.
The extraction studies submitted elsewhere in this petition (Appendix VI) provide a very conservative estimate of the material potentially available for leaching. 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 materials 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 naphthalate-containing polymers were tested with different solvents. The highest value obtained under any condition leads 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 (0.3175 cm) thick. 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 17.7 micrograms per in^2, obtained in 100% corn oil, 250°F, at 240 hours, from a 85% terephthalate/ 15% naphthalate polymer (reported in Appendix VI of this petition). Converting 17.7 micrograms per in^2 to grams per in^2 gives 17.7×10^{-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 0.0000065, or less than 0.01%.

6.B.iii.d. *Estimated Landfill Leachate Concentration Maximum.* To estimate the potential concentrations in landfill leachate, Shell developed an upper-bound estimate obtained using estimates and 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.[10] The estimate is an upper-bound estimate

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

[10]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).

because it assumes that: all water-soluble materials are extracted from landfilled food packaging within the first year after deposition, all leachate in a landfill escapes without containment or treatment, and 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, the fraction estimated to be disposed in landfills and an upper-bound, conservative estimate of the fraction that may migrate into leachate (<0.01%), Shell has estimated that the concentration of extractable material that might migrate into landfill leachate is well below 50 parts per billion (see Confidential Appendix IV). Although the estimate varies slightly with assumptions about how much recycling will occur, the leachate concentration is much less than 50 parts per billion under all scenarios.

Shell 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 17% of the food-packaging materials resulting from FDA approval of this petition would 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 (1992) figures.

The proposed food additive would compete with and possibly replace glass, steel, and multilayer plastic containers. To the extent this occurs, there would be a reduction in total incinerator ash because of the non-combustible nature of glass and steel. The products of incineration of the proposed food additive (water, carbon dioxide) are the same as the products of incineration of the multilayer plastics (multilayer polypropylene, multilayer PET) that may be replaced.

The proposed food additive may replace some food packaging containing chlorine, such as polyvinyl chloride or polyvinylidene chloride. To the extent this occurs, approval of the petition might reduce the amount of chlorine-combustion products. However, Shell does not believe that this would constitute a measurable or significant change in the amount of chlorine-combustion products. Consequently, Shell expects no significant change in the environmental concentrations of airborne substances as a result of FDA approval of the proposed food additive.

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 significant introduction of substances into the air, with the possible exception of products of incineration, which are carbon dioxide and water. These would be immediately available as part of the normal hydrogeological cycles. However, no significant quantitative change is expected to result from FDA approval of this petition, so no significant impact on these cycles would be anticipated.

7.B. ***Freshwater, estuarine, and marine ecosystems.*** Using the confidential market and other information, Shell estimates that aquatic exposures to water soluble extractables from naphthalate-containing polymers would not exceed 50 parts per billion. Because the extractives are not chemically identified, it is not possible to quantify environmental concentrations of specific chemicals, nor to identify what environmental fate processes would be operative.

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, Shell 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 PET polymers are manufactured from products derived from crude oil, so land use and mineral use are those associated with the production of hydrocarbon materials. No effects are anticipated on any endangered or threatened species nor 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[11] on solid waste management strategies, including recycling programs.

9.A.i. ***Recycling.*** The proposed food additive is expected to be recycled after consumer use in the applications that would be affected by FDA approval. Successful recycling requires a reasonable market for products made from the recycled material. Successful recycling also usually requires some type of source separation, so the material can be economically separated from incompatible materials that interfere with downstream processes such as extrusion or injection. These points are discussed below.

Shell believes that naphthalate-containing polymers will be compatible with the existing PET recycling stream and that it is appropriate to include food packaging made with the naphthalate-containing polymers with recycled PET. Consequently, no separate recycling stream or infrastructure is necessary.

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[11]"Significant changes" in this context is taken to mean a change that is probably measurable, that 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 postconsumer 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.)

Table VII-6. Post-Consumer PET Recycling

The amount of post-consumer PET is given in 1000 tonnes. Percents are of the total PET. Source: *Modern Plastics*, Jan. 1994

Sources of Post-consumer PET material

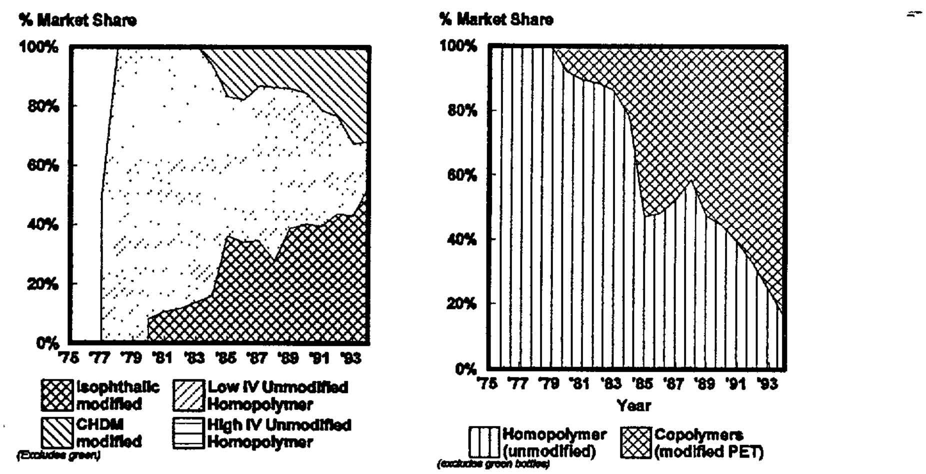
Material	1992		1993	
Soft drink bottles	141	(79.6%)	164	(80%)
Custom bottles	9	(5.1%)	14	(6.8%)
Non-packaging (mostly X-ray film)	27	(15.3%)	27	(13.1%)
TOTAL	177		205	
Grand Total for all Plastics	415		519	

Uses of Post-consumer PET

Material	1992		1993	
Fiberfill	86	(48.6%)	96	(47.1%)
Food bottles (via depolymerization)	16	(9.0%)	11	(5.4%)
Non-food bottles	9	(5.1%)	14	(6.9%)
Strapping	9	(5.1%)	11	(5.4%)
Export	14	(7.9%)	11	(5.4%)
All Other	43	(24.3%)	61	(29.9%)
TOTAL	177		204	
Grand Total for all Plastics	416		517	

Recycled PET is a dynamic, changing market reflecting the polymers that comply with 21 *CFR* 177.1630 and 177.1315, rather than a static market with totally homogenous material. Since about 1980, the proportion of homopolymer PET has decreased to be only about 20% of the PET market. Figure VII-2 shows how the abundance of PET copolymers and modified PET has increased. 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 isophthalic-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. Recycling processes have also been modified to improve processing of these changed materials.

Fig. VII-2.
Changes in Composition of PET



The expected market includes several applications, particularly in use as jars and bottles, that are among applications currently targeted for post-consumer recycling programs, including curbside recycling. However, as addressed in the Confidential Appendix IV, introduction of naphthalate-containing food-packaging is not expected to have a large enough competitive displacement of packaging that is currently recycled that any significant negative impact would be expected on those recycling streams.

9.A.i.a. *Source separation.* Naphthalate-containing polymers would be incorporated into products that can be identified by consumers and placed in curbside collections or in bottle-deposit returns. This is currently the most successful approach for obtaining post-consumer material. Should automated separation be desired, the inherent fluorescence of the naphthalate structure provides a straightforward marker. Appended to item 14 is a photograph demonstrating how a naphthalate-containing polymer fluoresces under UV light.

Several grades of post-consumer PET are produced by recyclers. Carbonated soft drink (CSD) bottles from states with bottle deposits are the most desired grade because these baled materials have the least contamination. CSD bales from curbside collections are the next most valued grade. Custom bottles from curbside collections are more likely to have undesired contaminants, particularly polyvinyl chloride (PVC) bottles. PVC contamination at low levels can adversely affect the physical, chemical and visual properties of molded parts produced from recycled PET.[12]

[12]PET tech, Summer 1993. "New study explores acceptable levels of PVC in Post-consumer PET." National Association for Plastic Container Recovery, Charlotte NC.

Naphthalate-containing polymers subject to this petition would be included in the curbside custom stream, so could have no effect on the highest grade post-consumer PET materials. Further, their chemical compatibility with PET processing would mean they would not be considered contaminants, such as PVC.

Figure VII-1 showed current (1993) recycling for blow-molded PET. Fig. VII-3 shows this recycling stream as projected for the year 2000, to reflect anticipated changes in overall recovery rates. Custom bottles are projected to still be collected via curbside collection, not bottle deposit collections, so their recycled use will still be primarily in the fiber market.

9A.i.b. *Recycling Codes.* One tool developed by the plastics industry to aid consumer identification of packaging plastics is the SPI recycling code. The purpose of this code is to identify the resin content as a means to encourage and facilitate plastics recycling.[13] As originally developed, plastic bottles were distinguished by an insignia that identified one of seven resin types. Although conceived as a voluntary program, resin-type labelling was eventually required in some states.

Given the purposes of the SPI code, Shell believes that the naphthalate-containing polymers that are the subject of this petition can be identified with the code number "1" and "PETE" label. As discussed below in the context of reprocessing feasibility, the presence of a small percent of naphthalate would likely be accomodated within the continuously changing flow of post-consumer PET materials. However, the responsibility for determining that a code number "1" is appropriate for a specific product remains with the fabricator of the finished food packaging, i.e., the maker of the bottle or jar. Consequently, Shell cannot determine with certainty that all fabricators will choose to label naphthalate-containing polymers with the PET code. As part of its efforts to encourage recycling, Shell intends to work with trade associations and others as appropriate to develop the most broadly useful coding system.

Although the SPI code provides one tool to encourage recycling, it is Shell's understanding that actual sorting of PET products does not rely on the presence of a "1" code, but relies on recognition of specific products in the recycling stream. For example, soft drink bottles are not identified by inspecting a code on the bottle, but by their distinct appearance. This also explains why custom bottles have a lower recovery rate than soft drink bottles in curbside programs. Custom bottles are much more varied than soft drinks and the markets for specific packages are much smaller.

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[13]The Society of the Plastics Industry, Inc. (SPI). "Resolution on the Resin Identification Code" (adopted by SPI Board of Directors September 23, 1994). 1275 K Street NW, Suite 400, Washington DC 20005-4006.

9.A.i.c. *Automated or Municipal Recycling Facility Sorting.* Naphthalate provides a fluorescence that permits automated separation of items, should that be desired. In practice, visual separations at municipal recycling facilities (MRFs) rely on recognizing products, e.g., milk bottles vs. soft drink bottles. Should recyclers want to separate naphthalate-containing polymers from PET materials, visual recognition of specific products containing naphthalate polymers can be made. In other words, the custom bottles that contain naphthalate polymers would be distinct from other PET bottles and hence could be readily separated. The specific applications are identified in the Confidential Appendix IV.

9.A.i.d. *Reprocessing feasibility.* Shell has considered the potential compatibility of naphthalate-containing polymers with existing recycled PET applications. Post-consumer plastic processors report that the source and composition of the plastic feed stock is continuously changing, so they are continually adapting and adjusting processes.[14] The influx of a small percent of naphthalate-containing resins would likely be accommodated by this ongoing process of adjustment

[14]Schut, J.H., 1993. op. cit.

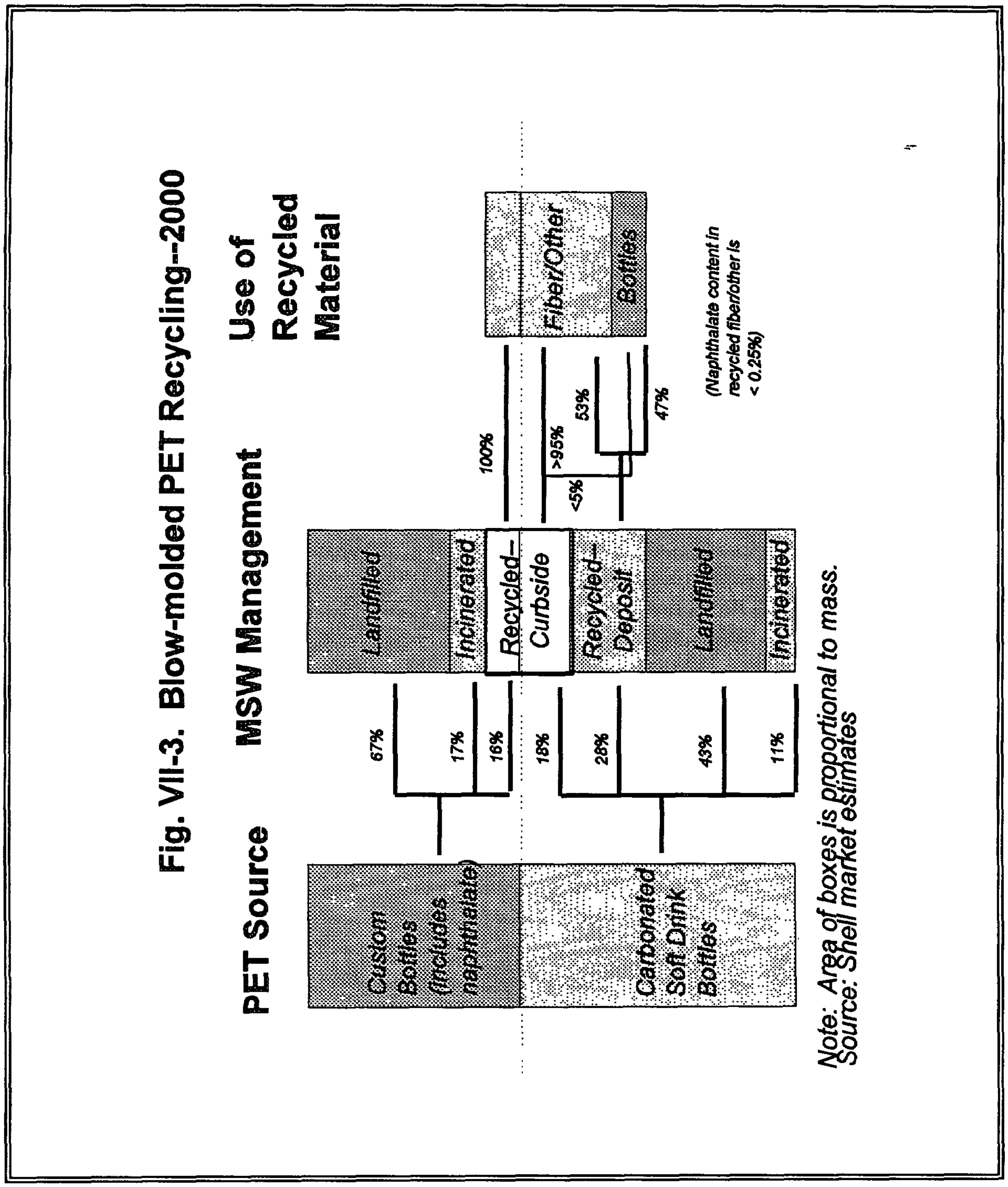

Fig. VII-3. Blow-molded PET Recycling--2000

As noted in Table VII-6, most recycled PET is used in fibers. Figure VII-3 shows that, because naphthalate-containing polymers will be used primarily in custom bottles, recycling of these materials will be into 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. These may be drawn (stretched) to obtain orientation and fiber strength. 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.[15]

Improved purity resulting from the shift from two-piece (PET bottle with HDPE base cup) to one-piece bottles, using deposit state materials and general technological improvements have allowed the recycled PET industry to produce thinner and thinner (finer denier) fibers.[16] Partially oriented yarn (POY) has been produced from recycled PET and used in fine denier applications. For example, the recreational clothing manufacturer Patagonia advertises clothing items that are made from recycled PET.

The second type of polyester fiber, staple fiber, is produced by extrusion of molten polyester, but the filaments are chopped into pieces, often about 1.25 to 2 inches in length. Fibers of this length are suitable for processing on machines that also handle cotton or wool, which have a similar fiber length. Staple fibers can be spun into yarns, used as fiberfill, and used to form non-woven products. These fibers are used in carpet yarns and in such products as insulation in coats, sleeping bags, and upholstery.

Staple fibers are also used to produce non-woven fabrics. To produce a non-woven fabric, staple fibers can be: (1) combed on a screen, then heated or glued to form a web (drylaid process) or (2) deposited as a slurry on a screen, dried, then calendaring to form a web (wetlaid process) or (3) bound to a base fabric with multiple needles (needle punched staple fiber). Uses for non-woven fabrics include backings, interlinings, filters and geotextiles. Geotextiles are used in engineering applications, such as linings or underlays, reinforcing slopes and landfill caps.

Recycled polyester has adequate performance to be used in these applications. In fact, this is the current major market for recycled PET. Uses in carpet face yarns and fiberfill constitute almost three-quarters of the fiber uses for recycled PET.[17] Non-wovens constitute the remainder.

The third type of polyester fiber production is described as spun-bond or melt-blown and is used to produce non-woven fabric. Extruded filaments can be fed onto a moving belt to form a web (spun bonded fiber). Geotextiles appear to be the major market for these materials.

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

[16]*Bottle Making Technology News*, 1994, Vol. 6, p. 9.

[17]PCI (Xylenes & Polyesters) Ltd.

Because Partially Oriented Yarn (POY) represents a very demanding set of requirements for porducing recycled polyester fiber, Amoco (a manufacturer of dimethyl-2,6-naphthalene dicarboxylate) investigated the potential impact of adding 6% by weight of naphthalate in recycled PET on the (POY) process. POY was chosen for this study as it represents a very demanding set of requirements for producing recycled polyester fiber. In addition, the 6% naphthalate-content significantly exceeded that which would be expected in the actual recycle stream. This study focused on the processibility of flake into fiber and the mechanical properties of the fiber.

The naphthalate content was obtained from three polymer sources: a high terephthalate/low naphthalate copolymer, PEN homopolymer, and a blend of copolymer and PET. These cases represented different types of napthalate-containing material that might reasonably be expected in containers.

The study focused on whether the high speed melt spinning process for producing POY, carried out using technology similar to that practiced commercially, is significantly impacted by the presence of naphthalate-containing polyesters in recycled PET. No significant impact upon processibility was found. The study also looked at the physical mechanical properties of the resulting fibers. Naphthalate content did not adversely impact the resulting fiber's physical properties, even though the naphthalate levels tested were well above projected future naphthalate content of the recycled PET stream. Differences were observed in dye uptake in this study between fibers derived from recycled PET containing 6% naphthalate and fibers derived from standard recycled PET.[18]

Dyeability of currently recycled PET is variable and dependent on the composition and purity of the recycled stream. In a discussion of quality and performance requirements of the fiberfill and non-wovens industry, PCI noted that:

> "It is difficult to achieve an adequate standard of dyeing with reclaimed polyester because the wide variety of sources of waste will tend to give a stream of recycled material which varies in colour. Even minor variations will cause an uneven final shading when the fabric is dyed."[19]

Techniques are available to improve the consistency in dyeing recycled polyester. For example, about one-third of polyester carpet produced in the U.S. contains recycled PET, illustrating that dye consistency can be managed successfully.[20] This is often handled by blending the recycled

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[18]Personal Communication, Dr. Gregory E. Schmidt, Amoco Chemical Company, 200 E. Randolph Dr., Chicago, IL 60601, November 16, 1994.

[19]PCI (Xylenes & Polyesters) Ltd.

[20]Ibid.

post-consumer PET with cleaner, more consistent post-industrial polyester waste to reduce variability.[21]

The scope of this Amoco study was thorough in its execution, but did not include a detailed evaluation on the potential impact of these materials on specific end-use applications which utilize POY fiber prepared from recycled PET. Consequently, it is seen as too limited to provide broad, definitive evidence to either endorse or disapprove of naphthalate-containing recycle feedstocks.[22]

Because of the multitude of specific end-use fiber applications, such as garments, geotextiles, auto trunk liners, carpets and fiberfill for pillows, jackets, sleeping bags, and insulation, it is impractical to conduct a definitive "endorsement" study because todo so one would have to definitively evaluate the impact of naphthalate on each and every property for each specific end-use application.

Another use of post-consumer PET is for recycling into bottles, for both food- and non-food-contact bottles. This requires a relatively uncontaminated source of post-consumer PET that, in practice, is obtained from states with bottle deposits. Post-consumer materials received from the curbside stream has a substantially higher contaminant level due to factors such as sorting mistakes or glass dust. Because little or no custom curbside material is used to manufacture recycled-content bottles (see Fig. VII-3), approval of terephthalate/naphthalate polymers will not be likely to affect this recycling stream. However, technology may advance to the point where curbside material can be made suitable for bottle manufacture, so Shell is investigating whether naphthalate-containing polymers are compatible with this process.

Depolymerization of PET, i.e., reducing the polymer to constituent monomers or low molecular weight oligomers, has been done. Shell has been a leader in the development of this process and markets products containing recycled PET under the REPETE® trademark. REPETE®, produced by glycolysis, is the only ongoing depolymerized product on the market. Shell believes that the presence of naphthalate will not affect the process of producing REPETE®.

While not a widespread practice, depolymerization to constituent monomers is not expected to be a problem. These processes currently separate DMT from dimethyl isophthalate (a commonly

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[21]Recycled content usually distinguishes between "post-consumer waste" (PCW) which has been discarded after having fulfilled its intended application, and "post-industrial waste" (PIW) which is generated as a by-product in a given process. Certified content claims provided by third-party organizations such as Scientific Certification Systems, (1 Kaiser Plaza, Suite 901, Oakland, CA) document the composition of specific products, showing how recycled content includes both PCW and PIW. For example, polyester fiber marketed as Fortrel EcoSpun™ by Wellman Inc. of New Jersey for geotextile, carpet, and fiberfill, is certified to be made of 100% recycled PET plastics with 35% PCW and 65% PIW.

[22]Ibid.

used modifier of PET) and technology exists to separate DMN from DMT. Patent number 4,876,378 has been issued for this process (Oct. 24, 1989, held by Eastman Kodak Company). Because of the higher cost of the naphthalate structure, recapture of this material might be economically reasonable.

9.A.i.e. *Naphthalate Content.* The properties of recycled PET reflect the makeup of the combination of materials present and have been found to vary from batch to batch.[23] If post-consumer materials were to vary greatly or be changed significantly in composition, then the potential uses of the recycled materials might be affected. This is not expected to happen, however, as a foreseeable result of any FDA approval of naphthalate-containing polymers.

The overall naphthalate content of a recycled PET waste stream would be very low. In the Confidential Appendix IV, Shell has estimated potential compositions of the recycled PET waste stream under different assumptions about PET market growth and recycling of naphthalate-containing polymers. Although the exact percent of naphthalate varies with the combinations of assumptions, the percent naphthalate in a recycled PET waste stream never exceeds 1% under the market conditions considered for this petition.

9.A.i.f. *Potential uses of Recycled Material.* As noted in Table VII-6, uses of recycled PET includes fibers, food and non-food bottles, strapping, and non-packaging films. Recycling of naphthalate-containing polymers in applications subject to FDA approval, i.e., custom food bottles, is expected to be primarily into fibers, a large potential market.

9.A.i.g. *Steps taken to encourage recycling.* The most effective encouragement would be to ensure that polymers subject to this petition are compatible with existing PET recycling processes. Shell and Amoco are continuing studies to demonstrate recycling compatibility and to identify issues associated with commercial-scale reprocessing. The results of one study were discussed above. Such studies and demonstrations will encourage development of products with recycled naphthalate-containing polymers. Shell's commercial interest in recycled PET, i.e., its REPETE® products, will also encourage continued interest and involvement in the market success of recycled PET. By helping the market for recycled products to thrive, the entire recycling chain is encouraged.

Broadening the number of plastic bottles that can be recycled with PET makes collection of such materials more sensible and reduces the number of items that are discarded outside of recycling streams. For example, many curbside collection programs identify acceptable materials using the recycling codes; items with codes "1" are already collected. If the polymers that are the subject of this petition competitively replace plastic laminate containers coded with the recycling code "7" (other), that are not collected by curbside programs, then the overall amount of recycled post-

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[23]Schut, J.H., 1993. "Working with recycle." *Plastics Technology*, (Aug.), pp. 40-44.
Culp, E., 1994 "Additives can give reclaim a second life." *Modern Plastics*, (Sept). pp. 61-65.

consumer material will increase. Through trade associations, Shell and Amoco are both 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.

Shell estimated the landfill volume required for disposal of all the naphthalate-containing resin food-contact applications in the Confidential Appendix IV of this petition. Assuming that each container made from the proposed food additive replaces one container of a competing material (glass, steel, other plastics), fewer containers of these competing materials would be landfilled. Because incineration of glass and steel results in eventual landfilling of these materials (as incinerator ash), replacement by the proposed food additive reduces landfill requirements for municipal incinerator ash.

Table VII-7. Density Factors for Packaging 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	2800
Steel containers	560
Paper/Paperboard Packaging	740
Plastic rigid containers	355
Plastic film	670

Landfill capacity is determined by volume requirements, which in turn reflect the density of the materials being landfilled. Table VII-7 shows relative density factors for landfilled materials. The proposed food additive will compete mostly with applications that use glass. In general, a plastic container weighs less than a glass container of the same capacity but occupies more volume per container in a landfill. This difference is very slight, however. Table VII-7 shows that about 7.8 times as much glass (by weight) occupies a cubic yard of landfill than plastic rigid containers. But plastic containers typically are 1/7 the weight of an equivalent glass container. Plus, glass is not reduced in volume by incineration, so glass in incinerator ash will require additional volume. When these factors are considered together (as done in Confidential Appendix IV), the net change is predicted to be less than 0.1% of the current total landfill volume of 412 million cubic yards per year (a value taken from Table 40 of US-EPA, 1992). These changes are within the limits of variability of the numbers used to make the estimates. Shell 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.

The proposed food additive will compete with glass and steel in some food-packaging applications. 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, Shell believes that the overall impact on energy consumption cannot be considered significant. Franklin Associates, a longtime practitioner of techniques to quantify and compare energy requirements and author of the US-EPA (1992) report, states that differences of less than 10% in energy requirements are insignificant (see earlier footnote). The fractional change in material used in glass and steel food packaging applications is less than 10%. Shell concludes that any quantitative difference would be very small and probably within the errors associated with the techniques.

The proposed food additive will compete with some polymers in food-packaging applications. The raw materials are hydrocarbon-based polymers that use very similar resources as the polymers used in existing plastic packaging, e.g., laminated structures. Processes to produce the food-packaging are the same, e.g., injection molding and extrusion, so the processes would be expected to have equivalent energy requirements. Technical benefits of the proposed food additive materials, such as improved melt flow, might marginally reduce power requirements during processing, but these would probably not be measurable or significant.

Shell 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. Shell 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.

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.
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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 Shell Chemical Company.

Jan 5, 1995
(Date)

(Signature)

Mgr PS:C
(Title)

14. ***Attachments:***
    Material Safety Data Sheets (MSDSs)
    Letter from I.W. Love (Point Pleasant Polyester Plant) regarding Compliance
    Photograph: Fluorescence of Naphthalate-containing Polymer under UV light
        Four bottles are shown, illuminated by UV light at wavelength of 250 nm. The PET bottle does not fluoresce, while bottles made from naphthalate-containing copolymer, naphthalate homopolymer (PEN), and a blend of naphthalate-containing polymer with PET all demonstrate detectable fluorescence. Should it be desired, this difference could facilitate automated sortation of naphthalate-containing bottles from PET.