APPENDIX VII (Revised)

Environmental Assessment for Food Additive Petition Naphthalate - Terephthalate Polymers

1. ***Date:*** Dec. 20, 1994, Revised 4 Nov. 1998, 10 May 1999 (Editorial changes 4 August 1999)

2. ***Name of petitioner:*** Shell 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.*** Shell Chemical Company (Shell) proposes that an amendment to the regulation at 21 *CFR* 177.1630 be made to permit the safe use of copolymers and blends of ethylene terephthalate with 2,6-naphthalate for single and repeated use food contact applications, with the naphthalate 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.

In a related petition, Shell proposes that the regulation at 21 *CFR* 177.1637 be amended to permit the safe use of copolymers and blends of ethylene-2,6-naphthalate with terephthalate for single and repeated use food contact applications, with the naphthalate content varying from 50 to 100 weight percent. In an action taken after Shell's petitions were originally filed, FDA has cleared the use of poly(ethylene-2,6-naphthalate) homopolymer, i.e., having a naphthalate content of 100 weight percent in certain food contact applications.

Shell's original environmental assessment (EA) was submitted in January 1995. On August 7, 1996, FDA first commented on this EA in two "guidance documents", stating that additional information, clarifications and corrections were required. Shell provided supplementary cracking", an unexpected brittle failure of a polymer under stress. Factors which are believed to contribute to stress cracking include poor material distribution in bottle blowing, use of caustic lubricants in bottle filling lines, and harsh storage conditions.

Stress cracking problems have been confined to a limited number of bottle manufacturers. However, due to an industry shift from two-piece to one-piece bottles, associated changes in bottle design, and an industry trend toward lightweighting, stress cracking may become a more widespread problem.

Shell believes that a very low naphthalate content in PET could minimize or eliminate stress cracking problems. In laboratory tests, Shell has shown that low levels of naphthalate do improve the inherent stress cracking resistance of the polymer.[4] Although this work used laboratory measurements and did not specifically test bottles, Shell anticipates this would be a viable solution for the limited number of bottle manufacturers who have experienced problems. This use of naphthalate would be as a low-level modifier, e.g., at 1.5% by weight, such as isophthalate and CHDM are currently being used.

Approval of homopolymer PEN has led to trials or demonstration projects for beer. Recent interest in plastic beer bottles is reported from Bass Brewers and Anheuser-Busch.[5] Such applications appear targeted for outdoor and stadium events where a light, shatterproof package is highly valued. Another market analysis group anticipated the use of PET/N bottles for beer, although cost and consumer reluctance were seen likely to limit the market.[6] A low naphthalate-content material appears to be feasible for this type of market, so Shell has incorporated an estimate for this type of application into the revised market estimate. Because beer bottles would likely be colored (brown), they would be readily distinguishable from other polyester-based packaging. This market was not in the original EA but has been included in this revised EA.

There are a number of materials currently used in rigid and semi-rigid food packaging, e.g., glass and plastic bottles and jars, metal cans, and plastic sheet. Table VII-1 shows EPA's estimates of

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[4]Sisson, E.A., 1996, "HiPERTUF Resins: Redefining Packaging", Bev-Pak Asia '96, October 14, 1996 (Reference Tab 31).

[5]Reynolds, P., 1998, "Bass is bullish on beer in plastic " *Packaging World*, March, 1998, p. 54. (Reference Tab 4)
Reynolds, P., 1998, "Is Bud ready for plastics?" *Packaging World*, April 1998, p. 68. (Reference Tab 5)

[6]Anon., 1998, "Predicting world demand for beer packages " *Packaging World*, January 1998, p. 4. (Reference Tab 6)

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.248-260 °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 VII-2 above).

Copies of selected Shell Material Safety Data Sheets (MSDSs) for polymeric materials containing naphthalates are attached to this environmental assessment (Reference Tab 1).

A related polymer is 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 polymer is regulated for food-contact use in the U.S. and 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).

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

6.A. ***Introductions at Sites of Production.*** FDA revised its environmental regulations effective 29 July 1997 and now does not routinely ask that information about environmental introductions resulting from the production of an FDA-regulated article. No extraordinary circumstances (as defined in 21 *CFR* 25.21) apply to the manufacture of the proposed food additive.

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 small fraction (less than 10 percent) of current PET production and changes are within the projected growth rate of these polymers (Confidential Appendix IV).

As noted for Section 6.A., information about environmental introductions through production of the FDA-regulated article, i.e., the food-packaging material, is not required because no extraordinary circumstances apply to manufacture.

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 is 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.[9] 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 about 80% landfilling and 20% incinerated, as the following indicate:

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

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[9]FDA, Environmental Impact Staff, Center for Food Safety and Applied Nutrition, 1993. "New Polymeric Food-Packaging Materials: Key Environmental Issues." Draft.(Reference Tab 32)

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 solid 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.

Shell is not aware of any examples where a municipal MSW recycling program has in fact stopped collection and recycling of a material because of a competitive replacement associated with FDA action. (Changes have occurred because of altered market conditions for a particular material such as a changed price paid by reclaimers.) 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 (PET/N) products was calculated. Each container predicted to be made of PET/N 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.

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.[10] 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 PET/N 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-4, as provided by US-EPA (1997).

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[10]The patterns were derived from data in confidential industry sources and 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-97-015 (NTIS#PB92-207166).

Table VII-4. Recycling of Selected Products Generated in the Municipal Waste Stream

Values are in percent recovery. 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	1990	2000
Glass Beer & Soft Drink Bottles	10.8%	33.5%	50.0%*
Glass Wine & Liquor Bottles	--	10.3%	29.8%*
Glass Food/Other Bottles & Jars	--	12.5%	29.8%*
Combined Glass	*5.4%*	*22.1%*	*30.0%*
Steel Beer & Soft Drink Cans	9.6%	26.7%	60.0%*
Steel Food & Other Cans	5.3%	23.2%	55.0%*
Combined Steel	*5.5%*	*23.9%*	*61.5%*
Aluminum Beer & Soft Drink Cans	36.5%	63.9%	70.0%*
Combined Aluminum	*24.4%*	*53.2%*	*69.0%*
Paper/paperboard milk cartons	--	--	25.0%*
Paper/paperboard folding cartons	--	--	25.0%*
Combined Paper/paperboard	*27.4%*	*36.9%*	*57.8%*
Plastic Soft Drink Bottles	3.8%	32.6%	55.0%
Plastic Milk Bottles	0.0%	3.8%	35.0%
Plastic Other Containers	--	1.4%	15.0%
Plastic Wraps	--	2.0%	NA
Other Plastic Packaging	--	0.9%	6.0%
Combined Plastics	--	*3.8%*	*14.0%*

Source: USEPA, 1997, Tables 21, B-1
*USEPA, 1992, Table B-2 (Detail not provided in USEPA, 1997)
NA - Value not available

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 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 feedstock 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.

Figure VII-2 graphically illustrates the disposition of blow-molded PET in 1993 including what will be 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 1997 was 27%[11], about the same as in 1993.[12] Recent recycling rates have declined from rates of about 44% in 1995 and 40% 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 20 oz. 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 lower recovery rates. These patterns are reflected in Figure VII-2.

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[11]NAPCOR, 1998. "1997 PET Recycling Rate Information Released." Article viewed 9/28/98 at http://www.napcor.com.

[12]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)

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.[13] This is because of the poorer quality of any resulting final end product. PVC contamination in such materials represents one critical factor.

EPA (1997) projected recycling rates 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 6.0% for other plastics packaging (e.g., sheet). Based on industry analyses and Shell's experience with REPETE, Shell projects that plastic CSD bottles are likely to achieve a 46% recovery rate (vs. EPA's projected 55%) and that custom food bottles will achieve a 16% recovery rate (vs. EPA's projected 15%). Using this projection and the market estimates for each type of PET/N application, Shell estimates that the overall recovery rate from containers within the scope of FAP 5B4450 would be about 40% (Confidential Appendix IV, Table IV-7.D). This rate reflects the large number of 2-liter CSD and beer PET/N bottles within the scope of this petition.

Approval of the subject petition is not expected to adversely impact current recycling programs for two principal reasons: compatibility and sortation.

-- Recycled PET (rPET) processes and applications have been demonstrated to be compatible with rPET streams having a low naphthalate content, and the anticipated uses are likely to be diluted to low naphthalate levels in the large rPET stream.

-- rPET streams with higher naphthalate content can be sorted to levels compatible with rPET streams, using a commercially available process in an economically justifiable way.

The compatibility of rPET with naphthalate content is discussed further in section 9 of this environmental assessment. In brief, the level of naphthalate in the rPET stream would be so small that no significant changes in processing rPET or in uses of rPET would be necessary. Conventional techniques to sort colored (amber or brown) from clear containers will produce (1) a clear rPET stream containing less than 1% naphthalate and (2) an amber rPET/N stream composed virtually entirely of beer bottles. Significant uses of rPET include spinning into fiber and making containers. Potential uses of rPET exceeded 500 million pounds in 1993 and is projected to grow at about 3% per year.[14] Recycling demand is expected to exceed supply for the next several years[15] so that interest in expanding PET recycling is likely to continue. Studies noted

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[13]Schut, J.H., 1993. "Working with Recycle." Plastics Technology (August 1993). pp. 40-45. (Reference Tab 7)

[14]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.(Report available from NAPCOR)

[15]Powell, J., 1993. "The ever-changing PET recycling market." *Resource Recycling*, (Oct) pp. 26-31.

9.A.i.b. ***Encouraging recycling of PET/N***

As stated elsewhere, Shell and other companies have an active vested interest in maintaining a healthy PET recycling industry. Shell believes, as stated in Section 6.B.ii, that food-contact articles containing PET/N can be readily recycled. Shell and BP Amoco believe that the actions reported in this EA and elsewhere constitute the most comprehensive effort to encourage recycling of a new plastic material ever undertaken before introduction of the material into food packaging in the U.S. These actions include:

(1) Identifying how PET/N is expected to enter the existing PET recycling stream. Shell and BP Amoco have described the flow of post-consumer PET food packaging for recycling and how PET/N packaging would enter that flow (see Figures VII-4 and VII-5, and Section 9.A.i.c). A quantitative analysis was prepared (Confidential Appendix IV) that estimated the quantity of PET/N materials in various phases of the rPET stream. This provided a basis for discussions with recyclers and users of recycled PET about whether and how naphthalate might appear in their materials.

(2) Identifying what uses the recycled materials will have and testing the compatibility of rPET/N with surrogate applications. Shell and BP Amoco have demonstrated, through tests of applications that use rPET, that introduction of rPET/N packaging materials will not cause significant problems (see Section 9.A.i.d). The results of these tests have led to an industry consensus by the National Association for PET Container Resources (NAPCOR).[28] NAPCOR stated that "the presence of naphthalate copolymers and blends below specific levels has been demonstrated to have no effect on several critical recycled PET end uses."[29] The end uses tested represent the significant majority of current end uses for rPET.

(3) Developing the capability to sort and remove rPET/N from the stream, should that be necessary or desirable. Shell and BP Amoco have subsidized the development of special sortation equipment to provide market flexibility in the naphthalate content in recycled PET (see Section 9.A.i.e). This equipment is ready for commercial application. Regarding this work, the industry consensus, again as stated by NAPCOR, is that "Means have been technically shown that can remove naphthalate-containing bottles from the stream of recycled

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[28]NAPCOR's mission is to facilitate the development of PET recycling programs and to promote the usage of PET containers. NAPCOR's 28 member companies represent the PET resin manufacturing, the PET bottle and container manufacturing, and supplier industries. These companies have a vested interest in maintaining the long-term success of PET recycling. NAPCOR has a long history of providing information and advice concerning issues related to PET recycling to industry officials, local solid waste and recycling officials, state officials, users, and others.

[29]Luke Schmidt, President, National Association for PET Container Resources, October 30, 1998. Letter to Hortense Macon, FDA, page 3. (Reference Tab 33)

any need or benefit from a differentiating mark on containers made from PET/N copolymers and blends. Shell believes that maximum recycling of naphthalate-containing polymers associated with this petition would occur by inclusion in the rPET stream. Consequently, Shell believes that any labeling of these products should (a) comply with existing applicable laws and regulations, including those established by states,[34] and (b) encourage recycling with PET materials. FDA-mandated labeling would ensure neither of these goals.

The best strategy to increase recycling is to include PET/N materials in the current rPET infrastructure. 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, according to an R.W. Beck study,[35] approximately 80% of the U.S. population has access to some kind of plastics recycling program, and 97% of the communities that provide plastics collection programs accept PET. In contrast, about 12% of these communities accept all plastic bottles. Encouraging inclusion of PET/N with PET will enhance the percent of materials recovered and presents a better opportunity than trying to differentiate PET/N from other plastics and create a separate collection infrastructure.

Because bottle labeling requirements are imposed by states, it is unclear what benefits would result from FDA imposition of special requirements for PET/N containers. PET/N containers will be subject to state laws, just as any other container would be. States differ in how they define appropriate labels; what may be labeled as "PET" in one state may not be acceptable as "PET" in another state. This means that a Federal mandate of a seemingly appropriate code may lead to significant conflicts with state law.

Available information suggests that the majority of states with coding laws would permit coding by predominant resin based upon a demonstration of compatibility in recycling.[36] Thus coding of a PET/N copolymer or blend as polyester would be consistent with existing laws. In such circumstances, no further action is needed to encourage recycling beyond the existing programs, e.g., via NAPCOR and APC, to communicate with the recycling industry that PET/N should be included with rPET.

A small number of states have responded to past inquiries (not involving PET/N containers) that their state laws do not allow the leeway for a container to be coded according to its

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[34] Laws in most states impose specific requirements about codes or logos on containers. Eleven states (Alabama, Idaho, Montana, New Hampshire, New Mexico, New York, Pennsylvania, Utah, Vermont, West Virginia, and Wyoming) and the District of Columbia have published no resin identification coding laws.

[35] R.W. Beck & Associates, "1997 National Post-Consumer Plastics Collections Study," September 1997. (excerpt from http://news.foodonline.com/feature-articles/19971117-29.html, viewed October 1998)

[36] Personal communication, Ralph A. Simmons, Keller and Heckman, LLP, with Sheila D'Cruz, BP Amoco Law Department, April 1, 1999. (Privileged attorney-client communication)

predominant resin, even where that container has been shown to be recycleable with other containers made from the predominant resin. We are aware of no enforcement actions being taken in this area. Consequently it is premature to conclude that any state would foreclose the possibility of specific codes for naphthalate-containing packaging.

It is possible that PET/N containers would have to be coded as something besides polyester (SPI code "1"). However, the absence of a polyester label in the resin code does not inevitably mean that a container would not be recycled. Of the states that might not accept a polyester resin code for PET/N, several have bottle deposit or redemption programs which would provide a significant incentive to recycle containers. Deposit and redemption programs do not rely on a resin code so the issue of container labeling is not relevant. PET/N containers subject to such programs would be returned just as are other containers.

The SPI resin code provides a means of identifying the resin content of bottles and containers commonly found in the residential waste stream but must be inconspicuous so as to avoid constituting an environmental claim.[37] Shell, and the industry, believes that in practice, collection and sorting do not rely primarily on container labels. Rather, consumers and recyclers rely on the product profile: does the bottle look like a brand or product that is recycled? Consequently, consumers include clear beverage containers of any plastic in recycling bins because they look like the soda and milk bottles that are currently recycled. Consumers are likely to include PET/N containers because of their similarity to currently recycled plastic containers. Thus, while there are curbside collection programs which state that only containers coded with a "1" or "2"are acceptable, many consumers identify packaging using other criteria.

The resin identification code has been a convenient shorthand for collection programs to communicate to consumers about which containers are acceptable, but it may be too limited as new types of packaging are introduced. For example, APC and Mesa (Arizona) officials will study whether instructions to "recycle all plastic bottles" can help increase recycling rates.[38]

For new products, such as non-beverage PET/N containers (custom bottles), information and education efforts are the appropriate tools to expand the profile of acceptable containers in a recycling stream. As noted above, NAPCOR presentations now have included information about the work done with naphthalates and their acceptability in rPET streams. Identifying specific products as rPET-compatible can be done, but only when such products are being introduced, i.e., following FDA regulation. We understand that a resin code may be used occasionally by recyclers to classify a new container when no other information is available.

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[37]Society of the Plastics Industry, Inc. Resin Identification Code Information . Viewed on 4 August 1999 at http://www.socplas.org/About/Resin/index.html.

[38]*Plastics News*, March 15, 1999, p. 16.

However, Shell and others in the PET/N and PET industry have been very active in communicating information about the recycleability of PET/N, as noted earlier in section 9.A.i.b. We note that NAPCOR reports making 7 presentations in the past year specifically about PET/N recycling.[39] The message communicated was the same as shared with FDA in October, 1998, regarding the industry consensus position and the supporting data.

Based on its experience in the plastics recycling industry, Shell believes that MRFs primarily sort materials without differentiating between plastics, except for HDPE and PET. We also believe that MRFs' manual sortation relies solely upon recognition of package and brand name product profiles and NOT on the recycle logo or other marking. John Matthews, Recycling Director for the Garten Foundation, a plastics recycling facility in Salem, Oregon, addressed this while discussing the use of a separate label ("quill") to comply with the FDA requirement for PEN homopolymer:

> "If we had to do a manual sort, as we sometimes do, the sorting personnel doesn't *[sic]* have the time to look for the '1' or a quill. They just get to know what containers are what resin...." (*Plastic News*, June 24, 1996).

This statement from someone with experience in the field supports Shell's position expressed in the subject petition and in documents that Shell previously provided to the Agency in its request for a letter of no objection for its REPETE® resins (which are manufactured by Shell's depolymerization process). Based on descriptions of the sortation and recycling infrastructure and on discussions with numerous reclaimers, manual sortation is based upon package and brand name product profiles, not on mold marks on containers. In numerous discussions with recycling industry representatives, the unanimous opinion is that labeling will do nothing to facilitate sortation.

As justification for its labeling requirement, FDA asserted that PEN homopolymers must be distinguished from other plastic containers, stating ". . . for PEN containers to be recycled at all, it will be necessary for them to be identified as recyclable, and for them to be recycled separately from other plastic, would require a distinctive identification".[40] Shell observes that FDA's explicit rationale for this requirement is a supposition that PEN recycling would be separate from other plastic recycling streams, in accord with the confidential recycling plan submitted by Eastman Chemical Co. in that petition.

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[39]Personal communication from Michael Schedler, Director of Technology for NAPCOR, to Greg Schmidt, BP Amoco Chemical, April 12, 1999. Event sponsors include: Northeast Resource Recovery Association, Chelsea Center for Economic Development, Northeast Recycling Council, National Recycling Coalition, Association for Post Consumer Plastic Recyclers, Connecticut Recyclers Coalition, and Carolina Recycling Association.

[40]FDA, 1995 FONSI for FAP 8B4110., p. 3.

As the data developed since FDA approval of PEN homopolymer amply demonstrate, PET/N containers can be included in the rPET stream without disrupting the rPET recycling process. Consequently, FDA's rationale for requiring a distinguishing mark on PEN homopolymer containers does not apply to containers complying with this current petition, i.e., copolymers and blends. An FDA mandate to develop and maintain a separate recycling infrastructure for PET/N would shut off access to the simplest way to encourage recycling.

An additional factor in considering the probable future of PET/N recycling is the real and growing public pressure for new packaging to be accepted as recyclable. This pressure is exerted from consumers onto consumer product companies and then onto their packaging suppliers. Shell, BP Amoco and NAPCOR have already established a significant track record of developing and publishing information about the recycling of PET/N to the packaging industry, consumer product companies, and the recycling industry. Because commercial acceptance of PET/N packaging will depend in part on further communication with the operators of recycling programs and the consumers they serve, Shell anticipates continued aggressive communication once FDA clearance is obtained. As amply illustrated in Sections 9.A.i.d and 9.A.i.e, Shell has worked extensively to resolve questions posed by many stakeholders; should new issues emerge after PET/N packaging is approved, Shell and others will similarly work to resolve new issues.

Separate recycling of PET/N containers is neither necessary nor sensible. Industry consensus, as stated by NPC and NAPCOR, is that recycling PET/N with PET is an appropriate goal. NPC has stated that it believes that ". . . the goal of recycling containers with 25% or less naphthalate content with the PET stream is appropriate and desirable."[41] NAPCOR has concurred with this position and notes that sortation techniques are available as well.[42] Shell concludes that these efforts are a comprehensive demonstration of its work to encourage recycling of PET/N.

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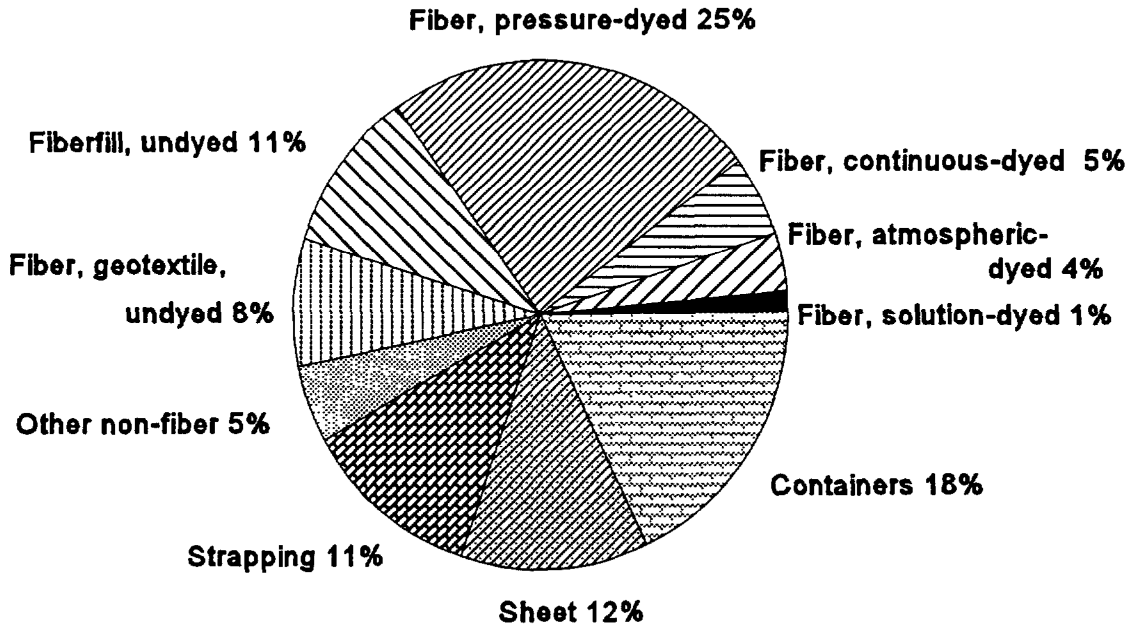
[41]Naphthalate Polymer Council, "Position Statements" May, 1997, revised September 1998. NPC was formerly a business unit within the Society of the Plastics Industry (SPI). In May, 1998, NPC transferred its operations under the administrative organization of the National Association for PET Container Resources (NAPCOR).

[42]FDA, during a telephone conversation on 18 March 1999, asked Shell to clarify the NAPCOR statement. The industry consensus is based on three components: (1) Data demonstrate that low levels of naphthalate are compatible with current PET recycling for a variety of applications, (2) blending and mixing of PET and naphthalate-containing materials, as currently occur in the PET recycling process, will result in low levels of naphthalate within rPET streams so that naphthalate content is unlikely to be a significant issue, and (3) sortation and removal of naphthalate-containing materials is feasible and provides an option to control excess levels of naphthalate.

Fig. VII-6. Consumption of rPET in U.S.



Sources: *Modern Plastics*, Jan.'98; RBI, Mar.'97; PCI, '95. Excludes exports.

In all three studies, 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 naphthalate had no impact on preform color or opacity. In the study sponsored by Coca-Cola, the bottles met or exceeded Coca-Cola's commercial performance standards.

In the two Shell studies of the one step process, no changes in machine parameters were necessary to blow commercially acceptable bottles. In the PTI study of the two step process, minimal modifications to machine settings were necessary for feed containing up to 3% naphthalate. Between 3% and 6% naphthalate, slight modifications in machine settings, comparable to those necessary when changing rPET source or grade, were necessary. The nominal level of naphthalate in curbside bales would only reach 6% if 3.6 billion pounds of 15 wt% naphthalate custom containers entered the marketplace. This would require nine times the current capacity of BP Amoco's nameplate capacity for naphthalate production.

Initially, the recycle industry's biggest concern was over the possible impact on bottle manufacture. After evaluating the data from these studies, no bottle manufacturer has voiced any further concern.

Bottle-to-Fiber Compatibility. As noted in Figure VII-6, 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. 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.[49]

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, has allowed the recycled PET industry to produce thinner and thinner (finer denier) fibers.[50] 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 made into spun yarns, fiberfill, or 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.

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[49]PCI (Xylenes & Polyesters) Ltd., "North America PET Recycling Supply/Demand Report 1993/94." Devonshire House, 66 Church Street, Leatherhead, Surrey, KT22 8DJ, England. (Confidential)
[50]*Bottle Making Technology News*, 1994, Vol. 6, p. 9.

Table VII-7. 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	

9.A.ii. ***Potential Uses of Recycled Material.*** As noted in Table VII-7, uses of recycled PET include fibers, food and non-food bottles, strapping, and non-packaging films. Recycling of naphthalate-containing polymers in applications subject to FDA approval, i.e., food or drink bottles, is expected to be primarily into fibers, a large potential market. Such recycling would be labeled "secondary" recycling, i.e., making new products through physical manipulations such as extruding or blow molding, without chemically destroying the resin.

One relatively new recycled material stream is the amber beer bottle rPET/N supply. A potential use for this would 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.[77] Such a use would be permissible without any FDA regulation if the food contact layer of the bottle were

[77] Reynolds, P., 1998. "Bass is bullish on beer in plastic." *Packaging World*, March 1998, p. 54. (Reference Tab 4)

an approved material such as virgin PET. Other uses of amber rPET/N would be for fiber and strapping applications currently using rPET where color is not a concern.

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 has marketed products containing recycled PET under the REPETE® trademark produced using a glycolysis process. Shell believes that the presence of naphthalate would 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 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. Depolymerization would constitute tertiary recycling, i.e., a regeneration of materials that are the same as the raw materials originally used.

A new and potentially large volume market for rPET/N, including amber-colored material, is suggested by a patent held by Seydel Research, Inc. for a coating with water-repellent properties.[78] According to the patent description, polyesters suitable for use in this application include polyethylene naphthalate. One application for such a coating is in paper and paperboard where polyethylene vinyl acetate copolymers combined with paraffin wax might currently be used. Other uses might be in printing or magazine papers, or in paper bags for carrying consumer purchases. The new coating is stronger, but also is redispersible during repulping, making simpler the recycling of the paper/paperboard.

9.A.iii. ***Steps taken to encourage recycling.*** Eastman Chemical Co.'s public documents in its petition to FDA for approval of PEN homopolymer referred to a recycling plan, although details of any such plan have not made public. The plan appear to expect that a separate recycling and collection system would be developed. At this time, Shell is not aware of any current US recycling program for PEN homopolymer food packaging that is operational nor that is planned. The high cost and current very limited marketing of these containers is one likely reason there is no program.

Shell believes that a separate collection and recycling system for naphthalate blends and copolymers is not desirable. The most effective encouragement of recycling would be to ensure that PET/N containers subject to this petition are part of the existing PET recycling processes. Shell, BP Amoco and others have clearly demonstrated that reasonably foreseeable

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[78]World Intellectual Property Organization, International Publication Number WO 98/33646, 6 August 1998. "Water dispersible/redispersible hydrophobic polyester resins and their application in coatings."

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

July 22 1999

(Signature)

J.C. Willett
(Printed Name)

MGR Product Stewardship
(Title)

Tab 27. RBI, "RBI Carpet Education Manual" (Copyright: Reg Burnett, Inc.), "Yarn Manufacturing" pp. 1-2.

Tab 28. Process Adjustments which may be necessary to blow commercially acceptable bottles from a feed stream containing up to 6.25% naphthalate. (Table)

Tab 29. J. Bickman (Magnetic Sortation Systems, Inc.). April 29, 1999. Letter to G.E. Schmidt, BP Amoco Chemical Company.

Tab 30. 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, FL

Tab 31. Sisson, E.A., 1996, "HiPERTUF Resins: Redefining Packaging", Bev-Pak Asia '96, October 14, 1996.

Tab 32. FDA, Environmental Impact Staff, Center for Food Safety and Applied Nutrition, 1993. "New Polymeric Food-Packaging Materials: Key Environmental Issues." Draft

Tab 33. Luke Schmidt, President, National Association for PET Container Resources, October 30, 1998. Letter to Hortense Macon, FDA.