



Attachment 8 - Environmental Assessment

1. **Date** October 27, 2005
2. **Name of Applicant/Notifier** Futura Polymers,
a division of Futura Polyesters Limited
3. **Address** All communications on this matter are to be sent in
care of counsel for Notifier at the following address:
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4. **Description of the Proposed Action**

The action requested in this Notification is to establish a clearance for polyethylene terephthalate, diethylene glycol-isophthalic acid modified, for use as components of food-contact articles. The purpose of the Notification is to establish a regulatory clearance that permits the use of the subject polymer, containing up to 12 mole percent of total diethylene glycol and isophthalate units, as films or articles intended for contact with aqueous, acidic, alcoholic (up to 50% alcohol by volume), dry, and fatty foods under Conditions of Use A through H as described in 21 C.F.R. § 176.170(c), Table 2, and for use in contact with high-alcohol foods (greater than 50% alcohol by volume) under conditions of use E through G as described in 21 C.F.R. § 176.170(c), Table 2. The notification also establishes a regulatory clearance for the subject polymer, containing between 12 and 16 mole percent total diethylene glycol and isophthalate units, for use as films or articles intended for contact with aqueous, acidic, alcoholic (up to 50% alcohol by volume), dry, and fatty foods under Conditions of Use B through G as described in 21 C.F.R. § 176.170(c), Table 2.

The types of environments present at and adjacent to these disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact materials prepared from the subject polymer.

5. **Identification of Substance that Is the Subject of the Proposed Action**

The food-contact substance that is the subject of this Notification is polyethylene terephthalate, diethylene glycol-isophthalic acid modified. The polymer is produced from terephthalic acid and/or dimethyl terephthalate, isophthalic acid and/or dimethyl isophthalate, ethylene glycol, and diethylene glycol. The FCS is chemically identical to other PET copolyesters that are already cleared for the same uses covered by this notification.

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6. Introduction of Substances into the Environment

Under 21 C.F.R. § 25.40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of the food-contact substance. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No significant environmental release is expected upon the use of the subject polymer to fabricate packaging materials. In these applications, the polymer is expected to be used as a films or articles, and will be entirely incorporated into the finished food package. Any waste materials generated in this process, e.g., plant scraps, are expected to be disposed of as part of the packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Food packaging materials produced from the subject PET copolyesters will be used nationwide. Food-contact articles produced from the polymers are expected to be disposed of in patterns similar to the current disposal of containers made from PET copolyesters that is chemically identical to the polymers covered by this notification. Bottles fabricated from the subject PET copolyesters are expected to bear the resin identification code used for PET containers and are expected to be disposed of similarly to conventional PET.

Thus, in keeping with established disposal patterns for PET bottles, it is expected that about 36% of carbonated beverage containers and 12% of custom bottles prepared from PET copolyesters will be recycled.¹ The remaining containers are expected to be disposed of in accordance with usual solid waste disposal patterns; thus, about 79% of the containers not recycled will be disposed of by means of landfill and 21% will be incinerated.

When food packaging materials made from the subject copolyester resins are added to sanitary landfills, no significant amount of leaching of any substance from these materials into the environment is anticipated. This conclusion is based on the low levels of migration of resin components under exaggerated exposure conditions (from an environmental standpoint) as shown in the migration study conducted on comparable PET copolyesters submitted to FDA in support of Food Contact Notification No. 85. Based on the results of the extraction studies (which were conducted to simulate food-contact use conditions rather than landfill conditions), only very low levels of substances are expected to leach from these materials in landfills. Thus, the introduction of these substances into the environment will not threaten a violation of the Environmental Protection Agency's regulations in 40 C.F.R. part 258 that pertain to landfills.²

¹ The U.S. Environmental Protection Agency. *Characterization of Municipal Solid Waste in the United States: 2001 Update*. Report No. EPA 530-R-03-011, October 2003, Washington, DC.

² EPA's regulations require new municipal solid waste landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate

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The lack of any leaching is especially true considering that the food-contact substance is a high-molecular weight polymer that contains only low levels of extractable material even under conditions that exaggerate environmental exposure conditions.

The subject polymer consists of carbon, hydrogen, and oxygen. When incinerated, the combustion products are expected to be carbon dioxide and water. Thus, no toxic combustion products are expected as a result of the proper incineration of the copolymer.

7. Fate of Emitted Substances in the Environment

(a) Air

No significant effects on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the PET copolyesters. The polymer is of high molecular weight and does not volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with this polymer.

The products of complete combustion of the polymer would be carbon dioxide and water; the concentrations of these substances in the environment will not be significantly altered by the proper incineration of the polymer in the amounts utilized for food packaging applications.

(b) Water

No significant effects on the concentrations of and exposures to any substances in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the subject polymer. No significant quantities of any substance will be added to these water systems upon the proper incineration of the polymer, nor upon its disposal in landfills due to the extremely low levels of aqueous migration of polymer components.

(c) Land

Considering the factors discussed above, no significant effects on the concentrations of and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the PET copolyesters. In particular, the extremely low levels of migration of polymer components demonstrated by the extraction studies discussed above indicate that virtually no leaching of these substances may be expected to occur under normal environmental conditions when finished food-contact materials are disposed. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the polymer.

from entering ground and surface water, and to have groundwater monitoring systems. 40 C.F.R. Part 258. Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collections systems, they are required to monitor groundwater and to take corrective action as appropriate.

Considering the foregoing, we respectfully submit that there is no reasonable expectation of a significant impact on the concentration of any substance in the environment due to the proposed use of the PET copolyesters in the manufacture of articles intended for use in contact with food.

8. Environmental Effects of Released Substances

As discussed previously, the only substances that may be expected to be released to the environment upon the use and disposal of food packaging materials fabricated with the use of the subject polymer consist of extremely small quantities of combustion products and extractables. No adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the polymers. In addition, the use and disposal of the polymer are not expected to threaten a violation of applicable laws and regulations, *e.g.*, EPA's regulations in 40 C.F.R. Part 60 that pertain to municipal solid waste combustors and Part 258 that pertain to landfills.

9. Use of Resources and Energy

As is the case with other food packaging materials, the production, use, and disposal of the PET copolyesters involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject polymer is not expected to result in a net increase in the use of energy and resources, since the copolymer is intended to be used in place of similar materials now on the market for use in food-contact articles. Polymers currently used in such applications include, but are not limited to, PET copolyesters covered by FCN No. 85, which also provides for the use of PET copolymerized with isophthalic acid (IPA) and diethylene glycol (DEG), as well as other PET homopolymers and copolymers cleared under 21 C.F.R. § 177.1630.

The partial replacement of these types of materials by the subject PET copolyesters is not expected to have any adverse impact on the use of energy and resources. Manufacture of the polymer, and its conversion to finished food packaging materials, will consume energy and resources in amounts comparable to the manufacture and use of other polymers that it is intended to replace.

Food-contact articles prepared from the subject PET copolyesters are expected to be recycled along with other PET containers. The subject PET copolyesters are intended as replacements for polymers that are already cleared under an applicable food additive regulation (*i.e.*, 21 C.F.R. §§ 177.1315 and 177.1630) or effective food contact notification (*e.g.*, FCN Nos. 4, 85, 280, 376). Because the polymers that are the subject of this notification do not differ chemically from other regulated PET copolyesters,³ the presence of the subject copolyesters in post-consumer PET recycle streams will have no adverse impact on the recycling of these

³ The maximum individual comonomer content of the subject FCS permitted under this notification has been previously cleared by FDA under FCN 4 (establishing clearance for isophthalic acid up to 17 mole percent) and under FCN 280 (establishing clearance for diethylene glycol up to 12 mole percent).

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materials. This being the case, the containers are expected to bear the PET resin identification code to facilitate post-consumer collection, as do PET containers currently produced. PET copolyester containers will be included in the same post-consumer stream as other ethylene terephthalate-based bottles and will be processed and sent into appropriate recycle markets with the related polymers. Thus, the use of the subject PET copolyesters will not adversely affect existing collection programs from recycled PET since the notified resins will be indistinguishable from the currently recycled PET resins.

For the foregoing reasons, the Notifiers respectfully submit that the proposed use of PET copolyesters containing a total of up to 16 mole-% of DEG and IP units will have no significant adverse impact on current or future recycling programs for post-consumer PET.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials fabricated from the subject polymer. This is primarily due to the minute levels of leaching of potential migrants from the finished article; the insignificant impact on environmental concentrations of combustion products of the polymer; and the close similarity of the subject polymer to the materials they are intended to replace. Thus, the use of the polymer as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein which would necessitate alternative actions to that proposed in this Notification. The alternative of not approving the action proposed herein would simply result in the continued use of the materials which the subject polymer would otherwise replace; such action would have no environmental impact. In view of the excellent qualities of PET copolyesters for use in food-contact applications, the fact that the polymer constituents are not expected to enter the environment in more than minute quantities upon the use and disposal of finished food-contact articles, and the absence of any significant environmental impact which would result from its use, the establishment of an effective Food Contact Notification to permit the use of the PET copolyesters as described herein is environmentally safe in every respect.

12. List of Preparers

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The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of his knowledge.

Date: October 27, 2005



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