

**ENVIRONMENTAL ASSESSMENT
DAK AMERICAS FOOD CONTACT NOTIFICATION**

1. **Date:** April 28, 2006
2. **Name of Applicant/Notifier:** DAK Americas, LLC
3. **Address:** 5925 Carnegie Boulevard
Suite 500
Charlotte, North Carolina 28209

All communications on this matter are to be sent in care of Counsel for Notifier:
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4. **Description of the Proposed Action**

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS), polyethylene terephthalate (PET) copolyesters that are diethylene glycol- and isophthalate-modified. The polymers will contain a total of not more than 10 mole-percent of diethylene glycol (DEG) and isophthalate (IP) units with the DEG content expressed as mole-percent of total glycol units and the IP content expressed as mole-percent of total (tere/iso)phthalate units. The clearance established by this Notification would permit the use of the FCS (hereinafter referred to as "PET copolyesters") in contact with aqueous, acidic, low-alcohol, 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 under Conditions of Use E through G as described in 21 C.F.R. § 176.170(c), Table 2.

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The Notifier does not intend to produce finished food packaging from the subject copolymers. Rather, the copolymers will be sold to manufacturers engaged in the production of food-contact articles. Food-contact articles produced with the copolymers will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal of the modified PET will occur nationwide, with the material being land disposed, combusted, or recycled. According to the U.S. Environmental Protection Agency's 2005 update regarding municipal solid waste in the United States, 59.6% of municipal solid waste generally was land disposed, 15.1% was combusted, and 25.3% was recovered for recycling.¹

5. Identification of Substance that is the Subject of the Proposed Action

The FCSs that are the subject of this Notification are certain PET copolyesters, specifically, copolymers manufactured by the condensation of dimethyl terephthalate or terephthalic acid with ethylene glycol and with one or more of the following: dimethyl isophthalate, isophthalic acid, and diethylene glycol. The finished polymer shall contain a total of not more than 10 mole-percent of diethylene glycol and isophthalate units, with the diethylene glycol content expressed as mole-percent of total glycol units and the isophthalate content expressed as mole-percent of total (tere/iso) phthalate units. For purposes of the notification

¹ U.S. Environmental Protection Agency. Municipal Solid Waste Generation, Recycling, and Disposal in the United States: Facts and Figures for 2003. EPA 530-F-05-003, April 2005, Washington DC. The percents noted above are based on municipal solid waste, excluding waste recovered for composting.

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language proposed for the polymers, they are identified as polyethylene terephthalate copolyesters (diethylene glycol-isophthalate modified). They are generally referred to herein as PET copolyesters. The FCS is chemically identical to other PET copolyesters that are already cleared for the same uses covered by this notification.

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 copolymers. 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 copolymers to fabricate packaging materials. In these applications, the copolymers are expected to be used as the basic polymer to fabricate all forms of food-contact articles, and will be entirely incorporated into the finished food-contact article. 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 are

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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.² The remaining containers are expected to be disposed of in accordance with usual solid waste disposal patterns; thus, about 80% of the solid waste not recycled or composted will be disposed of by means of landfill and 20% will be incinerated.³

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 FCN No. 85. Based on the results of 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.⁴ The lack of any leaching is especially true considering that the food-contact substance is a high-molecular weight polymer

² 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.

³ See Footnote 1.

⁴ 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 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.

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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 effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the copolymers produced from the FCS.

The polymers are of high molecular weight and do not volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with the copolymers.

The products of complete combustion of the copolymer 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 polymers in the amounts utilized for food packaging applications.

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(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 copolymers. No significant quantities of any substance will be added to these water systems upon the proper incineration of the polymers, 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 subject copolymers. In particular, the extremely low levels of maximum migration of components of the copolymers, demonstrated by the extraction studies, indicate that virtually no leaching of these substances may be expected to occur under normal environmental conditions when finished food-contact materials are disposed of. Furthermore, the very low production of the copolymers for use in food-contact applications precludes any substantial release to the environment of their components. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the copolymers.

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 copolymers in the manufacture of articles intended for use in contact with food.

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8. Environmental Effects of Released Substances

No information need be provided on the environmental effects of substances released into the environment as a result of the use and disposal of the subject copolymers in landfills and by combustion, because, as discussed under Item 6 above, only very small quantities of substances, if any, are expected to be introduced into the environment. Therefore, the use and disposal of the subject copolymers in landfills or by combustion are not expected to threaten a violation of applicable laws and regulation, *e.g.*, the Environmental Protection Agency's regulations in 40 C.F.R. Parts 60 and 258.

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 polymers is not expected to result in a net increase in the use of energy and resources, since the copolymers are 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 and diethylene glycol, 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

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polymers, and their 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, 376, and 547). Because the polymers that are the subject of this notification do not differ chemically from other regulated PET copolyesters, the presence of the subject copolyesters in post-consumer PET recycle streams will have no adverse impact on the recycling of these 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 existing collection programs from recycled PET since the notified resins will be indistinguishable from the currently recycled PET resins.

As discussed in the EA for FCN No. 85, the inclusion of increased levels of DEG and IP units in PET is not expected to adversely affect recycling. The basis for this conclusion is set forth in Section 9 of the Environmental Assessment that was submitted in support of FCN No. 85.

For the foregoing reasons, the Notifier respectfully submits that the proposed use of PET copolyesters containing a total of up to 10 mole-% of DEG and IP units will have no significant adverse impact on current or future recycling programs for post-consumer PET.

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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 copolymers. 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 copolymers, and the close similarity of the subject polymers to the materials they are intended to replace. Thus, the use of the copolymers 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 that would necessitate alternative actions to those proposed in this Notification. The alternative of not approving the action proposed herein would simply result in the continued use of the materials that the subject copolymers would otherwise replace; such action would have no environmental impact. In view of the fact that the copolymer 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 their use, the establishment of an effective Food Contact Notification to permit the use of the subject copolymers as described herein is environmentally safe in every respect.

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12. List of Preparers

Lester Borodinsky, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite
500 West, Washington, D.C. 20001.

13. Certification

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

Date: 4/28/06



Catherine R. Nielsen
Counsel for DAK Americas

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