Attachment 2
Environmental Assessment

1. **Date** October 12, 2004

2. **Name of Applicant/Notifier** Cargill Dow LLC

3. **Address** All communications on this matter are to be sent in care of Counsel for Notifier, Ralph A. Simmons, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Telephone: (202) 434-4120.

4. **Description of the Proposed Action**

The action requested in this Notification is the establishment of a clearance to permit the use of High D polylactide (PLA) as a component of food-contact articles in contact with all types of food under Conditions of Use C through G as defined at 21 C.F.R. Section 176.170(c), Table 2. The polymers that are the subject of this notification are marketed under the trade name NatureWorks™.

High D PLA is an alternate grade of the polylactide polymers cleared by virtue of FCN No. 178. Similar to regular PLA, the subject polymers offer several technical properties that make them useful in a variety of food and pharmaceutical applications. In particular, the

moisture and oxygen barrier properties of the polymers make them useful in food and pharmaceutical flexible packaging and in certain rigid packaging applications. The polymers also offer good contact clarity.

The Notifier does not intend to produce finished food packaging materials from the subject High D PLA polymer, although the potential exists for the Notifier to manufacture film and sheet from High D PLA, which would be supplied as components to finished package converters. Primarily, the polymers will be sold to manufacturers engaged in the production of food-contact materials. Typical applications include multilayer articles such as biaxially oriented PLA film, in which High D PLA is used as a coextruded sealant layer. High D PLA is not expected to replace other materials such as polyethylene terephthalate (PET),[1] aluminum, or glass in the manufacture of food packaging applications. Food-contact materials produced with the use of the polymers 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 will occur nationwide, with about 79% of the materials being deposited in land disposal sites, and about 21% combusted.[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

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[1] While High D PLA may be used as an alternative to PET in some food packaging applications, it is not suitable for high heat applications or for PET carbonated soft drink bottles. Therefore, High D PLA is certainly not expected to fully replace the PET market.

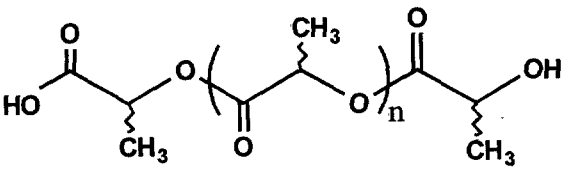
[2] *Characterization of Municipal Solid Waste in the United States: 2001 Update*, EPA 530-R-03-011, U.S. Environmental Protection Agency (5305W), Washington DC, 20460, October 2003.

[redacted]

are no special circumstances regarding the environment surrounding either the use or disposal of food-contact materials prepared from the PLA polymers.

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

The additive that is the subject of this Notification is High D polylactide (PLA), a polymer of lactide, which is the cyclic dimer of lactic acid. As dealt with by the Notifier, the polymers are marketed under the trade name NatureWorks™. PLA polymers are already permitted under FCN No. 178, which became effective on January 3, 2002. PLA has been assigned Chemical Abstract Service (CAS) Registry Number 9051-89-2. Its CAS Registry Name is (3R,6R)-3,6-dimethyl-1,4-dioxane-2,5-dione, polymer with rel-(3R,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione and (3S,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione. Its structure may be represented as follows:



A confidential description of the polymers appears in Section B of FCN No. 178. Information on the physical properties of High D PLA is included in the brochure on NatureWorks™ PLA that is provided as an attachment to the present environmental assessment.

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 High D PLA. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No environmental release is expected upon the use of the subject polymers to fabricate packaging materials. In these applications, the polymers 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.

In addition, the material can be introduced into commercial compost sites; the polymer degrades into lactic acid and smaller compounds, ultimately to carbon dioxide and water. The process takes 45 to 60 days in a controlled compost site operated at 140°F with the presence of moisture. Microorganisms in compost and soil consume the lactic acid and smaller compounds as nutrients; as lactic acid is widely found in naturally occurring materials, a large number of organisms metabolize lactic acid. Cargill Dow LLC has undertaken biodegradability testing on various grades of PLA in accordance with European Committee for Standardization (CEN),

DIN,[3] and American Society for Testing and Materials (ASTM) standards, as summarized below. A summary of the studies performed is provided in FCN No. 178, Appendix VIII. The certification by DIN CERTO Gesellschaft für Konformitätsbewerung mbH is included in FCN No. 178, Appendix IX.

a. Inherent Biodegradability

Organic Waste Systems N.V. (OWS) Belgium conducted this testing based on ASTM D-5338.92. The result after 45 days was 91% biodegradation relative to the cellulose control.

b. Disintegration

Disintegration testing, performed by OWS, indicated the test article exhibited complete disintegration at the end of 12 weeks. The validity of the testing was demonstrated, as the produced compost was similar in quality to the control compost.

c. Ecotoxicity

The compost generated in the disintegration test was subjected to ecotoxicity testing by OWS. No adverse ecotoxicity was observed in summer barley (plant growth) and water cress (seed germination).

3 DIN CERTO Gesellschaft für Konformitätsbewerung mbH is the certification organization of DIN, the German Institutes for Standardization.

[redacted]

Disposal by the ultimate consumer of food-contact materials produced by the subject copolymers will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The subject copolymers consist of carbon, oxygen, and hydrogen. No toxic combustion products are expected as a result of the proper incineration of the polymers.

Only extremely small amounts, if any, of High D PLA constituents are expected to enter the environment as a result of the landfill disposal of food-contact articles, in light of the Environmental Protection Agency's (EPA) regulations governing municipal solid waste landfills. 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 ground-water 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. As noted above, under aerobic composting conditions, PLA decomposes to lactic acid and smaller compounds, ultimately to carbon dioxide and water. Under anaerobic conditions, PLA will decompose to lactic acid *per se*, provided there is an aqueous medium. Included in Appendix VI of FCN No. 178 is a report that describes the kinetics of the hydrolysis of lactide; this report summarizes data acquired by the Notifier as well as published data.[4] This report indicates that the half-life of hydrolysis of lactide in neutral aqueous media is 3.3 hours at 25°C. Consequently, the concentration of lactide *per se* in leachate is expected to be essentially

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[4] Holten, C.H. "Lactic Acid: Properties and Chemistry of Lactic Acid and Derivatives," Verlag Chemie, 1971.

entirely converted to lactic acid under the multi-year timeframes for land-filled material; lactic acid is a common food component with a long, safe history of use both as an intentionally added and naturally occurring substance. For example, lactic acid has been affirmed as generally recognized as safe (GRAS) under 21 C.F.R. § 184.1061 ("Lactic acid").

7. Fate of Emitted Substances in the Environment

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of High D PLA. 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 these polymers.

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 polymers in the amounts utilized for food packaging applications.

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 their disposal in landfills due to the extremely low levels of aqueous migration of polymer components.

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As noted above in Section 6 of this Environmental Assessment, PLA exhibited complete disintegration at the end of 12 weeks under controlled commercial composting conditions. The compost generated in the disintegration test was subjected to ecotoxicity testing; no adverse ecotoxicity was observed in summer barley (plant growth) and water cress (seed germination).

Considering the factors discussed above, because High D PLA is an alternate grade of PLA permitted under FCN No. 178 that is compositionally similar to regular PLA, no significant effect on the concentrations of and exposures to any substances in terrestrial ecosystems are anticipated due to the proposed use of High D PLA. In particular, the low production of High D PLA for use in food-contact applications, as indicated in Attachment 3 to this Notification, is not expected to result in significant introductions of landfill leachate. Finally, the presence of High D PLA in controlled commercial composting sites is not anticipated to result in introductions of adverse substances into terrestrial ecosystems. 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 High D PLA 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 polymers consist of extremely small quantities of combustion products, extractables, and the products of commercial composting. As discussed in Section F ("Comprehensive Toxicology Profile") of FCN No. 178 for polylactide polymers and PNC No. 274, none of the potential migrating components of the polymers present any toxicological concern at the minute levels at which they could be extracted upon use and disposal. Based on these considerations, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the copolymers. In addition, the use and disposal of the copolymers are not expected to threaten a violation of applicable laws and regulations, *e.g.*, the Environmental Protection Agency's regulations in 40 C.F.R. part 60 that pertain to municipal solid waste combustors and part 258 that pertain to landfills. Finally, PLA exhibited complete disintegration under controlled commercial composting conditions and the compost generated indicated no adverse ecotoxicity.

9. Use of Resources and Energy

As is the case with other food packaging materials, the production, use, and disposal of High D PLA involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject copolymers in the fabrication of food-contact materials is not expected to result in a net increase in the use of energy and resources, since the copolymers are

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intended to be used in place of similar polymers now on the market for use in food packaging applications (including regular PLA, which is the subject of FCN No. 178).[5] For example PLA compares favorably with petrochemical-based polymers with regard to fossil energy use. Specifically, data collected from the European plastic industry suggest that the initial production of PLA used 25 to 55% less fossil energy than petroleum based polymers. More importantly, Cargill Dow is pursuing various process improvements to reduce the use of fossil energy for the production of PLA by as much as 90% and more compared to any of the petroleum based polymers being replaced.[6]

The use of PLA as an alternative to these types of materials is not expected to have any adverse impact on the use of energy and resources. Manufacture of the copolymers and conversion to finished food packaging materials will consume energy and resources in amounts comparable to the manufacture and use of PET, cellophane, and polystyrene. Moreover, although High D PLA may be used to manufacture bottles, High D PLA is not anticipated for use in the manufacture of bottles used for packaging carbonated soft drinks. As the carbon dioxide transmission rate for High D PLA is significantly greater than that for PET,[7] as is the case for regular PLA, High D PLA will not be used to fabricate bottles for carbonated soft drinks, as they would not be technically suited for such use. Consequently, the use of High D PLA will not have an impact on the recycling of containers used to package carbonated soft drinks.

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5 Polymers currently used in the applications in which PLA is anticipated to be used include polyethylene terephthalate (PET), cellophane, and polystyrene.

6 *See* Erwin T.H. Vink, Karl R. Rábago, David A. Glassner, and Patrick R. Gruber, *Applications of life cycle assessment to NatureWorks™ polylactide (PLA) production*, Polymer Degradation and Stability 80 (2003) 403-419. A copy of the article is provided as an attachment to the present environmental assessment.

7 Data on the oxygen and carbon dioxide transmission rates of High D PLA are provided in the attached brochure, entitled "NatureWorks™ PLA Polymer 4060D for Heat Seal Layer in Coextruded Oriented Films." Data on the oxygen and carbon dioxide transmission rates of regular PLA and PET are contained in confidential Appendix VIII to FCN No. 178.

[redacted]

While High D PLA may conceivably be used to package milk, the potential impact on the recycling of plastic milk bottles is unknown because the potential market penetration of High D PLA into the milk packaging market is not known. However, if High D PLA becomes used to a significant extent, it is likely that collection and recycling infrastructures will be designed and become available to take advantage of the relative ease of de-polymerization and re-polymerization of PLA into useful recovered High D PLA articles. As described in confidential material located in FCN No. 178, Appendix VIII, the manufacture of PLA readily lends itself to de-polymerization and re-polymerization. In fact, recovered PLA could readily be used as a feedstock in the existing and planned manufacturing processes for regular and High D PLA. With regard to packaging for those types of food other than carbonated soft drinks and milk, these are not recovered for recycling to a significant extent but more typically are disposed of by means of sanitary landfill and incineration. Such packaging materials produced from High D PLA are expected to be disposed of according to the same patterns when they are used in place of the current materials. For all of the above reasons, there will be no impact on current or future recycling programs. For additional information on the impact of PLA in the HDPE and PET recycling stream, see attached Cargill Dow brochure, entitled "PLA in the Recycling Stream."

One important facet of the manufacture of High D PLA that is similar to regular PLA, and different than most other polymers, is that High D PLA is not manufactured from petroleum derived substances as the basic raw material. Rather, the lactic acid from which High D PLA is manufactured is derived solely from grain derived sugars that are fermented and distilled; currently, the lactic acid is derived from corn, although future alternative sources may be other

grains, such as wheat, sugar beets, and rice. Thus, High D PLA is manufactured from a renewable resource. According to Section 101(b)(6) of the National Environmental Policy Act (NEPA) (42 U.S.C. Section 4331(b)(6)),

> (b) In order to carry out the policy set forth in [NEPA], it is the continuing responsibility of the Federal Government to use all practicable means, consistent with other essential considerations of national policy, to improve and coordinate Federal plans, functions, programs, and resources to the end that the Nation may...(6) *enhance the quality of renewable resources* and approach the maximum attainable recycling of depletable resources. [emphasis added]

Thus, as High D PLA is manufactured from a renewable resource, the potential replacement of other polymers by High D PLA will have a net effect of reduction of the use of depletable resources.

Therefore, for all of the foregoing reasons, the use of High D PLA as described in this Notification will not have an adverse impact on energy and resources.

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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 polymers. 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 polymers; and the use of renewable resources for the manufacture of High D PLA. Thus, the use of High D PLA 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 copolymers would otherwise replace; such action would have no environmental impact. In view of the excellent qualities of High D PLA 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 their use, the clearance of the use of High D PLA as described herein by allowing this Notification to become effective is environmentally safe in every respect.

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12. List of Preparers

Ralph A. Simmons, Partner, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001.

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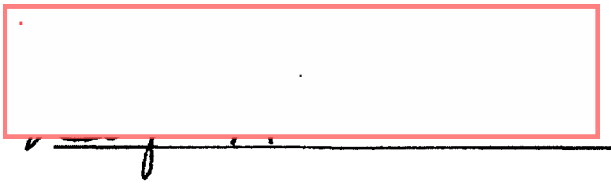
The undersigned certifies that the information provided herein is true, accurate, and complete to the best of his knowledge.

Date: Oct. 12, 2004



Ralph A. Simmons

Counsel for Cargill Dow LLC

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