49 New Concord Road
East Chatham, NY 12060
www.alterecho.com

December 3, 2012

Kerri Malinowski
Maine Department of Environmental Protection
Bureau of Remediation and Waste Management
17 State House Station
Augusta, Maine 04333

Reference: Alternatives Analysis Report (AAR) for Bisphenol-A in Infant Formula Cans and Baby Food Jars

Dear Ms. Malinowski:

Please find enclosed the Alternatives Analysis Report for Bisphenol-A in Infant Formula and Baby Food Jar Lids (AAR). The AAR provides background on the State of the Science with respect to bisphenol-A (BPA) and its implementation as a food packaging liner and incorporates a discussion of the known and presumed human health and environmental hazards associated with this compound. In a review of the functionality and health considerations of alternatives, the AAR did not identify a readily available alternative to replace BPA under its current model of use. In light of this, the AAR does assess alternative packaging options currently available in the marketplace and considers alternative materials under development which may present viable options in the future.

Overall, TechLaw believes that polyethylene, in a number of different formulations, represents the clear preferred choice in packaging to replace containers which employ a BPA-based lining. Polyethylene is unreactive, stable and inexpensive. There are no health implications associated with polyethylene's use as a food packaging alternative and the compound's widespread use and recyclability tip the overall scales in favor of this compound as the (likely) preferred infant formula and baby food container-based packaging option.

Appendix A provides an assessment of End-of-Life/Recyclability considerations for the primary alternatives considered in the AAR.

Appendix B provides a GreenScreen Analysis for BPA.

Appendix C provides a tabulation of the Alternatives considered in the AAR.

Appendix D provides the Clean Production Action GreenScreen Version 1.2 Assessment Template.

TechLaw performed a cursory review of *Risk-Based Green Screen Assessment of Bisphenol A* (Gradient report) (Gradient, 2012), prepared for Crown Cork and Seal. TechLaw notes that this report is not a GreenScreen, performed consistent with the process as developed by Clean

Production Action (CPA). In point of fact, there is some misapplication of classic risk assessment terminology, wherein the Gradient report fails to clarify risk vs. risk of exposure in comparison to hazard. Also, Gradient defines "toxicity" as a function of hazard and exposure, which is awkward in a report titled as a GreenScreen. Overall, the Gradient report is more akin to an overview of the toxicological implications associated with a targeted exposure assessment. The Gradient report focuses on dose (especially as it pertains to low dose assessment of the target populations of infants and children), for the purposes of recommendations as to level-of-concern. This particular focus is not incorrect, and indeed, may be more valuable than a generic review (like the GreenScreen) in a more pragmatic assessment of human exposure, but it is misrepresented (or is perhaps the wrong paradigm) as a GreenScreen. In point of fact, the CPA GreenScreen process takes a much broader view of the implications associated with bisphenol-A contact, assessing all relevant exposures and effects from the primary literature, not limited to nursing infants, for example. There are no dose limitations that confine the GreenScreen, as the Gradient report limits perspective to the probabilities of exposure and the likelihood of low dose administered or absorbed. Overall, the Gradient report characterizes BPA exposures and toxicological hazard (in combination) in US society as low – a Category 3 constituent. Contrary to initial impression, this is not a direct conflict with the GreenScreen report appended to the AAR wherein TechLaw has characterized BPA as a Category 1 constituent. As noted above, the GreenScreen does not limit its scope to low dose exposures or allow the probability of exposure to influence judgment of a category assignment.

The Gradient report does tend to point out shortcomings in the GreenScreen process and the reliance in an AAR on the results of the GreenScreen process: The information which is most helpful to administrative authorities is whether the dose being delivered has the capacity to elicit an adverse health effect – and that is not (necessarily) the primary focus of a GreenScreen which does not entirely consider the actual dose (i.e., exposure) to a given human health receptor. As we discussed in Augusta on October 11, 2012, an exposure assessment, based on the USEPA Oral Reference Dose (RfD_o) can consider BPA concentrations in infant formula mixes (best if it also assesses BPA releases to foodstuffs based on period of time in the container) it may be possible to calculate a meaningful hazard quotient, specific to nursing infants. Although there are issues associated with interpretation of the seminal studies, and despite the fact that the two reports do not share a great deal in common, TechLaw does not consider the Gradient report to be in direct conflict with the GreenScreen category assigned to BPA by TechLaw.

The health implications associated with BPA exposure addressed in the attached AAR and in Appendix B (specifically, the GreenScreen for BPA) discuss any and all potentially adverse health effects associated with BPA via any investigated and documented route of exposure. The discussion of associated health effects is not limited to a particular dose range, constituent delivery mechanism, or receptor population. Because the focus of the AAR is on infant formula and baby foodstuffs, a targeted human health assessment, focused on dose and route of exposure, is the more appropriate metric to underpin administrative authority decisions regarding actual or expected health risk for the targeted populations. Utilization of USEPA's Integrated Risk Information System (IRIS)-promulgated oral reference dose (RfD_o), could underpin an exposure

assessment specific to nursing infants and babies predicated on ingestion of BPA-contaminated food – although it may require some adjustment (i.e., provisional RfD_o) to ensure hazards reflect the infant subpopulation and account for sensitive individuals. In its simplest form, this latter influence could be represented by an additional order-of-magnitude safety factor to account for sensitive populations (infants). Development of a Human Health Risk Assessment for BPA exposure to nursing infants and babies is beyond the scope of this assessment.

As a courtesy to the State of Maine, TechLaw has considered infant exposure based on a set of non-specific calculations. In a cursory review of Geens, et al. (2012), the 95th percentile exposure estimates for infants (based on urinary excretion) in the US general population may be as high as 1.61 ug/kg-day. Comparison to the USEPA RfDo, 5e-02 mg/kg-day, yields a hazard quotient of 3.22E-02. This HQ is greater than an order-of-magnitude below unity and would not be associated with an unacceptable level of exposure.

Also, consider Table 1: Example Infant Ingestion Rates of Bisphenol-A, below. Values are excerpted from FDA's 2008 document entitled, "Draft Assessment of Bisphenol-A for Use in Food Applications", and indicate daily infant ingestion rates/body weight based on a diet of liquid formula.

Table 1: Example Infant Ingestion Rates of Bisphenol-A

Age (mos.)	0-1	1-2	2-3	3-4	4-5	5-6	6-7	7-8	8-9	9-10	10-11	11-12	Mean Rate	Overall Mean Rate
♂BPA exposure (µg/kg bw/day)	2.2	2.25	0.56	0.5	0.43	0.38	0.32	0.31	0.31	0.26	0.2	0.15	0.65583333	0.681666667
♀ BPA exposure (µg/kg bw/day)	2.32	2.42	0.61	0.55	0.47	0.42	0.35	0.34	0.34	0.29	0.22	0.16	0.7075	

With a mean overall daily exposure (ingestion) rate of 0.682 ug/kg-day (0.000682 mg/kg-day), the hazard quotient is approximately 0.0136 – again, over an order of magnitude below unity and the standard for concern. This review is very basic and should not be the basis for any decision-making. The RfD_o is a value which assumes no adverse impact if the subject is exposed for an entire lifetime. The BPA ingestion rates for infants are significantly higher (in consideration of body weight) than older children or adults. Thus, the assessment of this sensitive subpopulation may include conservative bias. These types of back-of-the-envelope calculations do, however, provide some small understanding of the relative hazards associated with BPA ingestion – based on the current USEPA RfD_o.

Having provided these gross calculations, there is a significant need to perform a more defensible review of infant intake rates, in consideration of residual BPA in infant formula, infant ingestion rates, and time periods over which this sensitive subpopulation is exposed. In addition, a detailed review of the USEPA RfD_o should also be conducted to determine its specific applicability in an assessment of infant exposures.

TechLaw has not included these data in the current Alternatives Assessment Report, given their sensitive nature and the fact they are beyond the scope of the current investigation. If the State of Maine wishes to include these data, TechLaw will be pleased to amend the report at the direction of the State.

TechLaw wishes to note that, overall, we were unsuccessful in gathering demonstrative pricing information. Manufacturing companies and distributors were less than forthcoming with package/packaging costing information, wholesale or retail, and TechLaw was not able to develop a definitive economic review – or even a very detailed relative relationship between costing for the various alternatives. A cursory assessment of retail products in the marketplace (i.e., cost-to-consumer), presented below, represents mixed results and cannot account for intangible-included costs such as brand name influence.

Consider the following tables. Table 2, Infant Formula Retail Pricing, is a cursory assessment of infant formula costs in the on-line marketplace. As an aside, please note that Enfamil and Similac continue to be available in metal cans, either for ready-to-feed or formula concentrate, though company assertions indicate they do not include BPA as a component in the packaging manufacturing process. Costs were reduced to cost/ounce for comparative purposes. For concentrate options, similar costs were seen between products utilizing metal cans and aseptic cartons. A significantly higher cost is associated with the Similac concentrate product packaged in an HDPE bottle, but the formula is for sensitive infants and the product itself may be associated with a higher cost. It is not clear why the basic Similac infant formula (Advance) is not available in a resealable HDPE-based container/bottle. The trend associated with a significantly higher cost/plastic container does not continue for the single use, ready-to-feed products. An approximately 10% higher cost was associated with polypropylene-packaged single containers over metal can packaging. In multiple container packages, costs were varied, with the highest costs associated with glass bottles, followed by metal cans and the lowest cost/packaging is as associated with polypropylene containers. These cost differentials cannot be related to packaging influence solely. Other intangibles, such as buying power and competitive pricing of the retail outlet and brand name costs, are more likely to be significant influences.

Table 3, Baby Food Retail Pricing, is a similarly cursory assessment of baby food costs in the on-line retail marketplace. In this case, there may be associated cost influence with respect to packaging. Based on this cursory review, it does appear that baby food packaged in PE plastics are less expensive than baby food packaged in glass jars and significantly less expensive than baby food packaged in aseptic containers, such as Cheer Pack.

This assessment of packaging costs is beyond the scope of the current investigation and should not be considered complete or exhaustive, and in all likelihood does not provide the means to assess relative packaging costs. This cursory assessment is provided to the State of Maine as a courtesy and should be considered preliminary findings.

Table 2: Infant Formula Retail Pricing

Product	Description	Container	Retailer	oz	Cost	$/oz
Concentrate Options						
Enfamil 13 oz. Concentrate	Enfamil Premium Lipil Infant Formula Concentrated Liquid 13 oz Concentrate makes 26 Fluid Ounces	Metal Can	Walgreens.com	13	$5.29	$0.41
Similac Advance 13 oz. Concentrate	Similac Infant Formula Concentrated Liquid 13 oz Concentrate makes 26 Fluid Ounces	Metal Can*	Walgreens.com	13	$4.99	$0.38
Gerber Good Start Gentle Formula Concentrate Pack	Gerber - Good Start Gentle Milk-Based Formula with Iron, 12.1 oz, 12-Pack	Aseptic Carton*	Walmart.com	145.2	$58.56	$0.40
Similac Sensitive Infant Formula with Iron, Concentrated Liquid	32 oz. Bottle	HDPE w. O2 Barrier	Amazon.com	32	$20.95	$0.66
Single Container - Ready to Feed						
Enfamil 32 oz Ready to Use	Enfamil Premium Infant Formula - Ready to Use	Metal Can	Walgreens.com	32	$7.49	$0.23
Enfamil 32 oz Ready to Use	Enfamil Premium Infant Formula - Ready to Use	Metal Can	Meijer.com	32	$7.00	$0.22
Similac Advance Infant Formula - Ready to Feed - 32 oz	Similac Advance Infant Formula - Ready to Feed	PP Container	Walgreens.com	32	$7.99	$0.25
Multiple Containers - Ready to Feed						
Enfamil 4 pack 8 oz (32 oz total)	Enfamil Premium Ready to Feed Formula	Metal Cans	Toysrus.com - Babies R' Us	32	$9.49	$0.30
Enfamil 4 pack 8 oz (32 oz total)	Enfamil Premium Ready to Feed Formula	Metal Cans	Walgreens.com	32	$9.99	$0.31
Similac Advance Infant Formula 6 pack 8 oz (48 oz total)	Similac Advance Infant Formula On-the-go Read to Feed Bottles 6 Pack - 8oz each (nipple ready)	PP Containers	Walgreens.com	48	$11.49	$0.24
Similac Advance Infant Formula 6 pack 8 oz (48 oz total)	Similac Advance Infant Formula On-the-go Read to Feed Bottles 6 Pack - 8oz each (nipple ready)	PP Containers	Toysrus.com - Babies R' Us	48	$11.99	$0.25
Gerber Good Start Gentle Formula	Gerber Foods Good Start Gentle Baby Formula - 3 oz - 8-Pack	Glass Bottles*	Toysrus.com - Babies R' Us	24	$8.99	$0.37

Table 3: Baby Food Retail Pricing

Product	Description	Container	Retailer	oz	Cost	$/oz
Baby Food						
Hain Earth's Best 3rd Baby Food Puree	Hain Earth's Best 3rd Food Puree - 9 months and older; single Cheer Pack	Cheer Pack	Toysrus.com - Babies R' Us	4.2	$1.49	$0.35
Sprout Starter Organic Baby Food	Sprout Starter Organic Baby Food, 2.5 oz	Cheer Pack	Toysrus.com - Babies R' Us	2.5	$1.19	$0.48
Hain Earth's Best 2nd Baby Food, 4 oz. jars,12 Pack	Baby Food Gourmet Meal Variety Pack, 12 pack, 48 oz total	Glass Jar, coated lid	Toysrus.com - Babies R' Us	48	$10.99	$0.23
Gerber 2nd Foods Baby Food	Gerber 2nd Foods Baby Food -1 Jar - 4 oz	Glass Jar, coated lid	Meijer.com	4	$1.00	$0.25
Gerber Organic 2nd Baby Food, 2 pack	Gerber Organic 2nd Baby Food, 2 pack 3.5 oz each	PE and PS Layered Plastic	Toysrus.com - Babies R' Us	7	$1.49	$0.21
Range of Values for All Containers ($/oz)			**$0.21-$0.48**			
Geometric Mean ($/oz)			**$0.29**			
Lowest cost container			**$0.21/oz - PE and PS Layered Plastic (Gerber)**			
Highest cost container			**$0.48/oz - Cheer Pak (Sprout)**			
% increase - glass (based on max price)			**17.45%**			
% increase - Cheer Pack (based on max price)			**123.62%**			
Cheapest Choice for Consumer			**PE and PS Layered Plastic (Gerber)**			

In response to requirements stipulated in the current contract (20120626*6204) and outlined in *Regulation of Chemical Use in Children's Products*, 06-096 CMR 880(3)(B)(3)(f), TechLaw is providing a set of hardcopy references (and search terms) under separate cover.

TechLaw wishes to thank the State of Maine for this opportunity to assist the State with this very interesting and timely review. If you have any comments or questions, please feel free to contact me at (703) 818-3226.

Sincerely,

Travis R. Kline, MEM
Vice President

Attachments:
Alternative Assessment Report (AAR)