



June 18, 2008

Via E-Mail

Executive Director  
Existing Substances Division  
Environment Canada  
Gatineau, Quebec K1A 0H3

Re: Draft Screening Assessment Report on Bisphenol A (BPA); Proposal to Add BPA to Schedule 1; Proposed Risk Management Scope for BPA; Canada Gazette Part 1 (Apr. 19, 2008)

Dear Executive Director:

The North American Metal Packaging Alliance, Inc. (NAMPA)<sup>1</sup> submits these comments in response to the notice published in the *Canada Gazette*, Part 1, on April 19, 2008,<sup>2</sup> in which the Canadian Ministers of Health and Environment (Ministers) announced availability of and requested comment on a draft screening assessment report for phenol-4,4'-(1-methylethylidene)bis- (bisphenol A or BPA).<sup>3</sup> The Ministers also proposed to add BPA to the List of Toxic Substances in Schedule 1 to the Canadian Environmental Protection Act of 1999

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<sup>1</sup> NAMPA member companies are committed to the safe and efficient manufacture and distribution of sustainable, wholesome, and nutritious food and beverage products. NAMPA's members manufacture and/or use epoxy resins derived from bisphenol A (BPA) to produce protective polymer coatings for the inner surface of light metal food and beverage containers.

<sup>2</sup> Department of the Environment, Department of Health, Canadian Environmental Protection Act, 1999, *Publication after screening assessment of a substance – Phenol, 4,4'-(1-methylethylidene)bis- (bisphenol A), CAS No. 80-05-7 – Specified on the Domestic Substances List*, Vol. 142, No. 16 (Apr. 19, 2008), available at <http://canadagazette.gc.ca/partI/2008/20080419/pdf/g1-14216.pdf>.

<sup>3</sup> Health Canada, Draft Screening Assessment for Phenol- 4,4'-(methylethylidene)bis- (80-05-7) (Apr. 2008) (Screening Assessment), available at [http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2\\_80-05-7\\_en.pdf](http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_80-05-7_en.pdf).



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(CEPA), and requested comment on a proposed risk management strategy to be utilized by the Ministers if BPA is added to Schedule 1.<sup>4</sup> NAMPA is pleased to provide these comments.

NAMPA is vitally interested in the subjects addressed in the Screening Assessment and Risk Management Scope, and in the proposed listing. NAMPA members manufacture and/or use BPA-derived epoxy resins in protective coatings for the inner surface of light metal food and beverage packaging. This critical technology protects the contents of these containers from aggressive food products, thereby assuring a safe, wholesome, and nutritious food supply. Compared to other coating technologies, coatings derived from epoxy resins are unique in their ability to provide superior adhesion to the metal surface, greater durability, flexibility, a low taste and odor threshold, and higher resistance to the wide range of chemistries found in foods and beverages. These attributes are essential to protect the packed food from container corrosion, leakage, and microbiological contamination, which are significant food safety issues.

NAMPA offers the following comments on the Screening Assessment, the Risk Management Scope, and the proposal to add BPA to Schedule 1.

I. THE SCREENING ASSESSMENT FOR BPA PREPARED BY HEALTH CANADA INCORRECTLY CHARACTERIZES THE WEIGHT OF THE SCIENTIFIC EVIDENCE

NAMPA is concerned that the Screening Assessment mischaracterizes the weight of scientific evidence concerning BPA. CEPA Section 77 provides that, once a screening assessment has been completed, there are three regulatory outcomes that may follow: (1) a decision to take no further action; (2) a decision to add the substance to the Priority Substances List for further study; or (3) a proposal to add the substance to the list of toxic substances under Schedule 1. The basic criteria for listing as a toxic substance are set forth in CEPA Section 64, and a substance is deemed toxic:

[I]f it is entering or may enter the environment in a quantity or concentration or under conditions that

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<sup>4</sup> Environment Canada, Health Canada, Risk Management Scope for Phenol- 4,4'-(methylethylidene)bis- (Bisphenol A) (Apr. 19, 2008) (Risk Management Scope), available at [http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2\\_80-05-7\\_rms\\_en.pdf](http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_80-05-7_rms_en.pdf).

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(a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;

(b) constitute or may constitute a danger to the environment on which life depends; or

(c) constitute or may constitute a danger in Canada to human life or health.

The Ministers cannot make a proper determination whether a substance is “toxic” under these criteria unless the weight of the scientific evidence has been correctly characterized.

The Screening Assessment evaluates the weight of evidence for neurological and behavioral effects that have been reported at BPA doses well below those that have caused developmental effects in standard reproductive studies based on four criteria: “rigour, power, corroboration/consistency, and biological plausibility/coherence.” The Screening Assessment states that the dataset for neurobehavioral effects is “limited” under each of these individual criteria and that the overall weight of the evidence is thus “limited” as well.<sup>5</sup> NAMPA believes that the available data on the developmental neurotoxicity of low level BPA exposure should not be classified as “limited” under these four criteria. The studies in which these effects have purportedly been observed suffer from poor design and limited statistical power. Most critically, these so-called “low dose” studies are woefully deficient under the criteria for “corroboration/consistency” or “biological plausibility/coherence,” because other investigators have been unable to replicate key studies and a non-monotonic dose-response curve for developmental effects that involves no adverse effects at all at higher doses is biologically implausible.

The reported “low dose” developmental effects of BPA are contradicted by multiple high-quality studies,<sup>6</sup> including one study that attempted exactly to replicate the results

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<sup>5</sup> Screening Assessment at 67-69.

<sup>6</sup> Cagen, S.Z., Waechter, J.M., Dimond, S.S., Breslin, W.J., Butala, J.H., Jekat, F.W., Joiner, R.L., Shiotsuka, R.N., Veenstra, G.E., and Harris, L.R. (1999). Normal reproductive organ development in CF-1 mice following prenatal exposure to bisphenol A. *Toxicol. Sciences* 50:36-44; Ashby, J., Tinwell, H., and Haseman, J. (1999). Lack of effects for low dose levels of bisphenol A and diethylstilbestrol on the prostate gland of

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in a previous low dose study.<sup>7</sup> BPA has been extensively tested across a wide range of possible exposure levels, and exhibits developmental effects only at very high levels of exposure. The “low dose” hypothesis for BPA is just that, a hypothesis that has not been accepted by scientific reviewers at any regulatory agency.

The evidence underlying the “low dose” hypothesis for BPA has been evaluated numerous times by expert panels and regulatory agencies that are responsible for protecting food supplies around the world. The low dose hypothesis is not supported by comprehensive reviews of the science that have been conducted by the National Institute of Environmental Health Sciences Center for the Evaluation of Risks to Human Reproduction (CERHR),<sup>8</sup> the European Food Safety Authority (EFSA),<sup>9</sup> and the U.S. Food and Drug Administration (FDA).<sup>10</sup>

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CF1 mice exposed in utero. *Reg. Toxicol. Pharmacol.* 30:156-166; Tinwell, H., Haseman, J., Lefevre, P.A., Wallis, N., and Ashby, J. (2002). Normal sexual development of two strains of rat exposed in utero to low doses of bisphenol A. *Toxicol. Sciences* 68:339-348; Ashby, J., Tinwell, H., Lefevre, P.A., Joiner, R., and Haseman, J. (2003). The effect on sperm production in adult Sprague-Dawley rats exposed by gavage to bisphenol A between postnatal days 91-97. *Toxicol. Sciences* 74:129-138.

<sup>7</sup> Eichenlaub-Ritter, U., Vogt, E., Cukurcam, S., Sun, F., Pacchierotti, F., and Parry, J. (2008). Exposure of mouse oocytes to bisphenol A causes meiotic arrest but not aneuploidy. *Mutation Research/Genetic Toxicol. Environ. Mutagenesis* 651(1-2):82-92.

<sup>8</sup> CERHR, NTP-CERHR Expert Panel Report on the Reproductive and Developmental Toxicity of Bisphenol A (Nov. 26, 2007) (CERHR Panel Report), available at <http://cerhr.niehs.nih.gov/chemicals/bisphenol/BPAFinalEPVF112607.pdf>.

<sup>9</sup> EFSA, Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to 2,2-BIS(4-HYDROXYPHENYL) PROPANE (Bisphenol A), Question number EFSA-Q-2005-100 (adopted on 29 November 2006) (EFSA Panel Report), available at [http://www.efsa.europa.eu/EFSA/Scientific Opinion/afc\\_op\\_ej428\\_bpa\\_op\\_en.1.pdf](http://www.efsa.europa.eu/EFSA/Scientific%20Opinion/afc_op_ej428_bpa_op_en.1.pdf).

<sup>10</sup> FDA, Letter to Honorable John D. Dingell, Chairman, Committee on Energy and Commerce, U.S. House of Representatives (Feb. 25, 2008) (FDA Statement), available at <http://energycommerce.house.gov/Investigations/Bisphenol.022508.respto011708.HHS.Ltr.pdf>.

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The CERHR Panel Report, issued in 2007 by a scientific panel composed of independent experts, concluded that studies reporting “low dose” effects of BPA have not been replicated nor corroborated. They are both scientifically inferior to and materially inconsistent with studies employing internationally approved test protocols, significant sample size, a wide range of doses, appropriate experimental design and route of exposure, and conducted under Good Laboratory Practices (GLP). The CERHR Panel declined to assign any substantial credibility to the developmental effects of BPA reported in the “low dose” studies because it correctly found that those studies are not biologically plausible and that the results have not been successfully replicated. The CERHR Panel stated:

Hence, the failure of BPA to produce reproducible adverse effects via a relevant route of exposure, coupled with the lack of robustness of many of the low dose studies (sample size, dose range, statistical analyses and experimental design, GLP) and the inability to reproduce many of these effects of any adverse effect strains the credibility of some of these study results. They need to be replicated using appropriate routes of exposure, adequate experimental designs and statistical analyses and linked to higher dose adverse effects if they are to elevate our concerns about the effects of BPA on human health.<sup>11</sup>

Similarly, the EFSA Panel decided that it should base its risk assessment for BPA on a No Observed Adverse Effect Level (NOAEL) derived from well-conducted multi-generation reproduction studies in mice and in rats, rather than on the “low dose” studies. Like the CERHR Panel, the EFSA Panel was reluctant to assign any credibility to the developmental effects reported in the “low dose” studies. The EFSA Panel stated:

The Panel considered that low-dose effects of BPA in rodents have not been demonstrated in a robust and reproducible way, such that they could be used as pivotal studies for risk assessment. Moreover, the species differences in toxicokinetics, whereby BPA as parent compound is less bioavailable in humans than in rodents, raise considerable doubts about the relevance of any low-dose observations in rodents for humans.<sup>12</sup>

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<sup>11</sup> CERHR Panel Report at 352.

<sup>12</sup> EFSA Panel Report at 4.

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FDA also based its risk assessment for BPA on the same multi-generation reproduction studies utilized by the EFSA Panel. FDA made it clear that it is well aware of and has reviewed the “low dose” studies, but still concluded that “an adequate margin of exposure exists for the conclusion of reasonable certainty of no harm under the intended conditions of use.”<sup>13</sup>

With respect to the developmental effects reported in the “low dose” BPA studies, the Screening Assessment prepared by Health Canada appears to afford a significantly greater degree of credibility to these studies than the recent CERHR, EFSA, and FDA reviews.<sup>14</sup> NAMPA believes it is not scientifically defensible to give so much credibility to the “low dose” studies in the absence of a plausible explanation of the claimed non-monotonic dose-response relationship between the effects reported at low doses and the effects observed in numerous well-conducted studies at higher BPA exposure levels.

The CERHR Panel stated that it could not afford greater credibility to the developmental effects reported in some low dose studies because of the failure of other researchers to detect “some manifestation of toxicity (e.g., altered weight, histopathology)” at higher BPA doses. As the CERHR Panel observed:

Every chemical that produces low dose cellular and molecular alterations of endocrine function also produces a cascade of effects increasing in severity resulting in clearly adverse alterations at higher doses, albeit the effects can be different from those seen at low doses.<sup>15</sup>

The EFSA Panel also questioned the plausibility of the claimed non-monotonic dose-response relationship. The EFSA Panel stated:

[T]he Panel notes that toxicologists are familiar with U-shaped and inverted U-shaped dose-response curves for hormonal activities, but the presence of a response at one dose level does not

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<sup>13</sup> FDA Statement at 3.

<sup>14</sup> Screening Assessment at 62-63.

<sup>15</sup> CERHR Panel Report at 352.

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necessarily indicate a causal relationship between the administration of a substance and an observed change. To demonstrate U-shaped dose responses in a robust way, it is necessary to have reasonably spaced dose intervals, usually of less than 10-fold, and not steps of 1000-fold as in some recent studies.

Health Canada classifies the available data on the claimed neurological and behavioral effects at BPA doses below the established NOAEL for developmental and reproductive toxicity developmental effects as “limited” based on “corroboration/consistency.”<sup>16</sup> Given the lack of consistency between the “low dose” BPA studies and well-conducted studies with BPA at higher doses, and the inability of independent investigators to replicate the effects reported in the “low dose” studies, the classification under this criterion substantially overstates the quality and consistency of the data.

Similarly, Health Canada classifies the data on low dose developmental effects as “limited” based on “biological plausibility/coherence.”<sup>17</sup> Given the absence of a plausible explanation for the absence of any adverse effects at much higher levels, assigning so much scientific credibility to a non-monotonic dose-response relationship based on the current data for BPA is scientifically unprecedented. Overall, the classification of “limited” for the data on the claimed “low dose” developmental effects of BPA substantially exaggerates both the scientific value and the coherence of the available data.<sup>18</sup>

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<sup>16</sup> Screening Assessment at 68-69.

<sup>17</sup> Screening Assessment at 69.

<sup>18</sup> Although NAMPA is focused primarily on the potential risks associated with use of BPA-derived polymers in food packaging, NAMPA also questions whether the current weight of the evidence is sufficient to support a determination that BPA is entering the environment in a quantity or concentration that may have a harmful effect on the environment or its biological diversity. The current data do not substantiate any concern regarding potential ecologic effects, since BPA is removed with greater than 99% efficiency by modern wastewater treatment plants, degrades rapidly under aerobic conditions, and has limited bioaccumulation potential. A recent comprehensive updated risk assessment prepared for the European Community confirms that BPA is readily degraded and has low bioaccumulation potential, and finds no basis for concern regarding risk to freshwater or marine organisms, risk to terrestrial species, or secondary poisoning of avian or marine predators. European Union, Updated European Risk Assessment



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On balance, the Screening Assessment implies that the scientific evidence upon which the proposed listing of BPA as “toxic” is based exhibits a far greater degree of scientific rigor and reliability than it really has. The conclusions concerning the weight of the evidence in the Screening Assessment should be revisited and revised to reflect the consensus of expert scientific opinion based upon reproducible studies employing internationally approved test protocols conducted under GLP.

## II. THE EXPOSURE ASSESSMENT IN THE SCREENING ASSESSMENT OVERSTATES THE LIKELY CONTRIBUTION TO DIETARY BPA EXPOSURE ASSOCIATED WITH MIGRATION FROM FOOD PACKAGING

NAMPA questions the reliability of much of the residue data reporting BPA in foods upon which the exposure estimates in the Screening Assessment are predicated.<sup>19</sup> NAMPA believes that the levels of BPA reported in food, and attributed to migration of residual monomer from the epoxy coating on metal food and beverage containers, are often significantly overstated. Unless an analytical methodology suitable for measuring very low BPA levels in complex matrices is utilized, the reported results can be influenced by interferences from other food constituents. As the CERHR Panel Report documents,<sup>20</sup> much of the sampling to date has been done utilizing Gas Chromatography with Mass Spectrometry (GC/MS), an approach prone to interferences from other substances that are naturally present in food products. High Performance Liquid Chromatography with tandem MS (HPLC/MS/MS) is a more reliable approach, but has seldom been used for monitoring BPA levels in food because of the high cost of equipment and operation.

Questions concerning the accuracy of BPA residue levels in food that have been attributed to excess monomer from the epoxy lining of containers are underscored by one GC/MS study that found levels in raw agricultural produce “equal to or higher than those found in canned foods.”<sup>21</sup> While it is possible that these reported BPA residues were attributable to

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Report, 4,4'-Isopropylidenediphenol (Bisphenol-A), CAS Number: 80-05-7, EINECS Number: 201-245-8 (Environment Addendum of Feb. 2008) at 130-138.

<sup>19</sup> Screening Assessment at 35-37.

<sup>20</sup> CERHR Panel Report at 14.

<sup>21</sup> *Id.*



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BPA from another source, it is highly probable that the researchers incorrectly reported other phenolic substances naturally present in the commodities as BPA. In any case, these data call into question the general presumption utilized in most BPA studies of metal packaged foods that all of the reported BPA is from excess monomer migrating from the epoxy lining. NAMPA believes that BPA exposure estimates would be more reliable if the residue data utilized to develop such estimates are collected with more robust and defensible analytical technologies and protocols.

### III. BPA SHOULD BE ADDED TO THE PRIORITY SUBSTANCES LIST RATHER THAN THE SCHEDULE 1 LIST

CEPA Section 76.1 requires the Ministers to use “a weight of the evidence approach and the precautionary principle” when conducting and interpreting a screening assessment under CEPA Section 74. The “precautionary principle” is defined by CEPA Section 2(1) as follows:

[W]here there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

This general principle is reasonable and was adapted from Principle 15 of the *Rio Declaration on Environment and Development*.

In the current proposed listing, the Ministers appear to conclude that the criterion that BPA “may constitute a danger in Canada to human life or health” is met based on a juxtaposition of the finding that the “low dose” developmental effects data for BPA should be afforded “limited” weight with the general “precautionary” approach to risk characterization required by CEPA Section 76.1. This interpretation of the meaning of the available scientific data places far too much reliance on a limited subset of the data that most recognized experts consider to be scientifically insufficient on its face. The problem in this instance is not a “lack of full scientific certainty.” Rather, it is the lack of the degree of scientific rigor and plausibility required to establish a credible basis for concern. Thus, the manner in which “precaution” has been interpreted and applied in this instance is excessive and unwarranted. Based on a more balanced characterization of the current weight of the scientific evidence, the application of the “precautionary” principle would not lead to a conclusion that the criteria for a “toxic” substance established by CEPA Section 64 have been satisfied.

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When existing data are not adequate to support even a tentative determination whether or not the criteria for a “toxic” substance are met, CEPA Section 77 establishes a reasonable and prudent middle course. Rather than adding BPA to Schedule 1, the Ministers can add it to the Priority Substances List for further scientific study.

The Screening Assessment identifies a number of specific studies that would assist in resolving current uncertainties regarding the potential developmental toxicity of BPA.<sup>22</sup> Indeed, it is NAMPA’s understanding that significant studies directed at the unresolved issues identified in the Screening Assessment are already underway.

The listing and regulation of BPA as a “toxic” substance will have significant economic impacts and entail substantial disruption. As a prudential matter, the wiser course for the Ministers would be to wait for additional research that will clearly establish whether there is any scientifically plausible reason to assign credibility to the “low dose” studies on BPA. As the “precautionary principle” recognizes, “full scientific certainty” is an elusive goal. In contrast, clarification of the nature of the “low dose” effects of BPA (if any) is a reasonable and attainable scientific goal, and regulatory determinations with substantial concrete impacts should be based on more than mere supposition.

If the Ministers rush to judgment now on BPA and subsequent scientific research confirms the current consensus view that the “low dose” studies are not credible, there will be no way to reverse the adverse impacts of precipitous action. Although CEPA Section 90(2) allows the Ministers to delete a substance from the Schedule 1 List and to repeal all associated regulations if it is determined that listing is no longer necessary, such action would be unprecedented and would not be a meaningful remedy for the disruption that would follow a premature listing decision.

Based on a correct characterization of the current weight of the scientific evidence, the “precautionary principle” does not require an immediate determination by the Ministers that BPA is “toxic” and listing on Schedule 1. Rather, the correct response at this time is to add BPA to the Priority Substances List for further scientific study.

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<sup>22</sup> Screening Assessment at 73-74.

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**IV. IF BPA IS ADDED TO SCHEDULE 1 RATHER THAN THE PRIORITY SUBSTANCES LIST, ANY REGULATIONS THAT FOLLOW MUST BE DEVELOPED USING THE “LIFECYCLE APPROACH”**

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If the Ministers decide to add BPA to Schedule 1, there are two basic policy approaches that may follow. Under CEPA Section 77(4), if a substance is deemed to be “persistent and bioaccumulative,” is present in the environment primarily from human activity, and is not naturally occurring, the Ministers are directed to propose a regulation that will lead to the “virtual elimination” of the substance. On the other hand, if the substance meets one of the criteria for classification as a toxic substance, but does not meet the criteria in CEPA Section 77(4), the Ministers then use a “lifecycle approach” intended to prevent or minimize releases into the environment.

Under the applicable criteria, the Screening Assessment correctly concludes that BPA does not meet the criteria for a “persistent and bioaccumulative” substance applicable under CEPA Section 77(4).<sup>23</sup> Thus, the Ministers have correctly determined that regulations requiring “virtual elimination” would not be legally warranted. Accordingly, any regulations the Ministers may adopt following any listing of BPA under Schedule 1 must be based on the “lifecycle” approach, and directed at minimizing rather than eliminating environmental releases of BPA.<sup>24</sup>

**V. ANY PROPOSED RISK MANAGEMENT REGULATIONS FOR BPA MUST ACKNOWLEDGE THE VALUE OF BPA-DERIVED EPOXY COATINGS IN PROTECTING FOOD FROM CONTAMINATION, AND FULLY CONSIDER THE LACK OF ANY EFFICACIOUS AND PROVEN ALTERNATIVE TECHNOLOGIES**

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If the Ministers decide to add BPA to Schedule 1, any risk management regulations that are adopted for food packaging must be practicable. NAMPA does not believe that the current weight of the scientific evidence warrants a determination that BPA meets any of the criteria for a “toxic” substance in CEPA Section 64. Even if the Ministers disagree, the “precautionary principle” in CEPA Section 2(1) only requires that the Ministers adopt measures to address uncertain risks when such measures are “cost-effective.” Thus, any risk mitigation measures directed at minimizing BPA exposure from food packaging must consider the

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<sup>23</sup> Screening Assessment at 14-17.

<sup>24</sup> Risk Management Scope at 6.

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practicality of available alternatives and the potential economic impacts and adverse impacts on public health of any required changes in packaging.

Epoxy-based linings are the most efficacious and cost effective way to protect metal food packaging from aggressive food chemistries and potential microbiological contamination. Coatings on the inside of food and beverage metal packaging play a critical role in food safety. Coatings prevent interaction between the food and metal packaging and greatly reduce the risk of contamination resulting from corrosion.

Given this critical safety function, interior coatings need to exhibit:

- Flexibility to survive manufacturing, canning, and transport operations;
- High resistance to chemical attack by package contents; and
- Minimal ability to migrate into package contents.

Epoxy-coated steel has become the predominant metal packaging technology globally since it was introduced in the 1960s because it meets these fundamental food safety requirements exceedingly well. This critical epoxy technology protects the metal food containers from aggressive food products, thereby assuring a safe, wholesome, and nutritious food supply. Compared to other coating technologies, coatings derived from epoxy resins provide superior adhesion to the metal surface, greater durability, flexibility, a low taste and odor threshold, and higher resistance to the wide range of chemistries found in foods and beverages. These attributes are essential to protect the packed food from leakage and microbiological contamination, which are significant food safety issues.

Epoxy coatings are an enabling technology that protects public health by assuring food safety, reduces material usage, saves energy in production, saves petroleum in transportation (less weight), reduces GHG emissions, reduces food spoilage, increases shelf life, and saves the consumer money while providing safe and nutritious food. BPA is not the coating material itself. Rather, BPA is a building block for creating the epoxy resin components that are used in creating metal food packaging coatings. Today's epoxy coatings are high molecular weight, heat cured epoxy formulations. BPA may remain in trace quantities after the polymerization and thermal curing that converts it into an epoxy coating. The very small residual concentrations of BPA that may exist in the thermally cured metal packaging coating

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will not increase with time after thermal processing, storage, hydrolysis, or even damage to the polymer, *i.e.*, scratching or denting.

***There are no currently or readily available and cost effective alternatives to the use of epoxy linings for metal food packaging.*** No substitute coating material is currently ready for commercial scale use to replace epoxy linings. Of the potential alternative coatings being considered, none has been found that has all the important performance characteristics of BPA-based epoxy resins. None has been found that works for the full range of canned food products. Most critical of all, no alternative coating has had the same degree of toxicity testing as epoxy linings, nor has any received the regulatory scrutiny that would be mandatory before approval for commercial use.

Although NAMPA believes that there is no scientifically credible basis for concern regarding use of BPA-derived epoxy coatings in any food packaging, it is apparent that the health concerns of the Ministers are primarily focused on potential exposure of infants from reusable polycarbonate baby bottles and from infant formula packaged in metal containers.<sup>25</sup> These are discrete concerns where there may be practicable alternatives. In contrast, the suggestion in the Risk Management Scope that the Ministers may also explore “stringent migration targets” for “canned foods in general”<sup>26</sup> implies the possibility of broader regulation that is not specifically directed at mitigating any risk to infants. Given the essential role that metal packaging plays in assuring an economical, nutritious, and wholesome food supply, and the current lack of any viable alternative to epoxy linings derived from BPA, any “stringent migration targets” that would limit or preclude use of epoxy linings would have profound economic and public health consequences.

Nevertheless, although NAMPA opposes any mandatory limits for metal packaging in general, NAMPA has already advised Health Canada that it would be interested in working collaboratively with the Ministers and other stakeholders to develop a voluntary code of practice addressing BPA exposure concerns.<sup>27</sup>

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<sup>25</sup> Risk Management Scope at 7.

<sup>26</sup> *Id.*

<sup>27</sup> Letter from Dr. John M. Rost, Chair of NAMPA, to Dr. Samuel Godefroy, Director, Bureau of Chemical Safety, Health Canada (Apr. 30, 2008).



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NAMPA appreciates this opportunity to comment on the draft Screening Assessment for BPA, the proposed listing of BPA on Schedule 1, and the proposed Risk Management Scope.

Respectfully submitted,

John M. Rost, Ph.D.  
Chair, NAMPA