BISPHENOL A (BPA) RISK MANAGEMENT APPROACH:

PERFORMANCE EVALUATION FOR BPA-HEALTH COMPONENT

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HEALTH CANADA

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1 Background

1.1 Purpose

The intent of this document is to evaluate the bisphenol A Risk Management Approach from a human health perspective, specifically, to evaluate the progress made towards meeting the human health objective of minimizing infant exposure to the greatest extent practicable [1].

1.2 Summary of Risk Assessment Report and Risk Management Approach

A Screening Risk Assessment Report for bisphenol A was published in October 2008 (Canada 2008a). The conclusions of the report indicated that bisphenol A may be entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health and that have or may have an immediate or long-term harmful effect on the environment or its biological diversity. Bisphenol A was subsequently added to the List of Toxic Substances in Schedule 1 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999).

At the time of the assessment, Bisphenol A (CAS RN 80-05-7, BPA) was a high-volume chemical used primarily to make polycarbonate - a hard, clear plastic with wide application in consumer products (e.g. repeat-use polycarbonate containers), in medical devices, glazing applications, film and in the electronics industry. Bisphenol A was also a major building block of most epoxy resins, which were used in coatings on the inside of metal-based food and beverage cans and were also used in protective coatings, structural composites, adhesives, sealants and electrical laminates. Bisphenol A was also used as an ingredient in certain polyvinyl chloride (PVC) plastics, thermal paper coating, lubricants and industrial-use waxes.

The basis of the health conclusion was that the neurodevelopmental and behavioural dataset in rodents, though highly uncertain, was suggestive of potential effects at doses ranging from the same order of magnitude to 1–2 orders of magnitude higher than levels of human exposure at that time. Given that toxicokinetic and metabolism data at that time indicated potential sensitivity of pregnant women/fetuses and infants; and that animal studies suggested a trend towards heightened susceptibility during stages of development in rodents, it was considered appropriate to apply a precautionary approach when characterizing risk.

In addition to being susceptible to the hazard identified, infants were identified as the most highly exposed subpopulation. A common source of exposure, across all age categories, was dietary due to migration of bisphenol A from food packaging and polycarbonate repeat-use containers, particularly under conditions in which boiling water was in contact with the container.

Risk Management documents published at the same time outlined actions to be taken by Health Canada and Environment Canada (now Environment and Climate Change Canada) to reduce risks associated with bisphenol A. The proposed human health objective for bisphenol A, as

[1] The ecological concerns identified in the BPA Risk Management approach document will be addressed in a subsequent report.

stated in the Risk Management Approach document (Canada 2008b), was to minimize infant exposure to the greatest extent practicable. In order to help reduce exposure to infants from polycarbonate baby bottles and canned infant formula, the proposed health risk management objective for bisphenol A was to achieve the lowest level of release to infant formula and from polycarbonate baby bottles that was technically and economically feasible.

2 Performance Evaluation

Evaluating the performance of the health component of the risk management approach means evaluating progress towards meeting both the risk management objective for health, (i.e. to achieve the lowest level of release to infant formula and from polycarbonate baby bottles that is technically and economically feasible) and the overall human health objective (i.e. to minimize the exposure of infants to bisphenol A to the greatest extent practicable). To determine whether these health objectives are being met, various forms of measurement and monitoring were used.

Biomonitoring in the age group of concern (i.e. 0-2 years), ideally measured before and after the risk management was put in place, would be one way to measure the progress made towards the objective. While Canadian BPA biomonitoring is available (e.g. Canadian Health Measures Study, Maternal Infant Research on Environmental Chemicals), it either does not include the age group of concern or is not repeated over time. While much useful information is being generated from these studies, they cannot help with this particular exercise.

In 2010, polycarbonate baby bottles that contain BPA were prohibited. Recent enforcement activities of this prohibition found only 1 non-compliant sample in 2011 and no non-compliant samples in 2013. Exposure to infants from bisphenol A from polycarbonate baby bottles is no longer expected (reduction 100%).

As of December 2014, Canadian consumers are not expected to find any liquid infant formula products packaged in BPA-containing packaging on the Canadian marketplace as consultations with the major manufacturers of infant formula confirmed that industry has abandoned or phased out the use of BPA-containing packaging for liquid infant formula. This was confirmed by a survey targeting 10 liquid infant formula products available in Canada where BPA was not detectable (Health Canada 2014). BPA was also not detected in 38 samples of powdered infant formula in an earlier survey (Health Canada, 2009). Exposure to infants from BPA from infant formula is no longer expected (reduction 100%). A follow-up survey of BPA in liquid infant formula products is planned to start in 2019.

An updated exposure estimate for infants to reflect these changes was calculated using recent data which indicated a **96%** decrease in exposures of infants who were bottle-fed formula when compared to the highest exposure estimate in the 2008 final assessment report (Canada, 2008a). See Appendix for detailed calculations. The remaining low exposure to BPA for this age group is from environmental media, mainly house dust (Canada, 2008a).

3 Conclusion

Significant progress (96% decrease in exposures of infants) has been made towards meeting the human health objective for BPA.

4 References

Canada. 2008a. Screening Assessment for the Challenge, Phenol, 4,4' -(1-methylethylidene)bis- (Bisphenol A) Chemical Abstracts Service Registry Number 80-05-7

Canada. 2008b. Proposed Risk Management Approach for Phenol, 4,4' -(1-methylethylidene)bis- (Bisphenol A) Chemical Abstracts Service Registry Number 80-05-7

Health Canada. 2009. Survey of Bisphenol A in canned powdered infant formula products.

Health Canada. 2012. Health Canada's Updated Assessment of Bisphenol A (BPA) Exposure from Food Sources

Health Canada. 2014. Bisphenol A: Update on the Food Directorate's Risk Management Commitments for Infant Formula

5 Appendix

The detailed calculations for the updated estimates of exposures are presented below.

The 2008 final screening assessment (Canada, 2008a) estimated the highest potential exposures to be 4.3 micrograms per kilogram body weight per day (µg/kg bw/day), adding together the estimated exposures from BPA in polycarbonate baby bottles (2.77 µg/kg bw/day), liquid infant formula (1.35 µg/kg bw/day) and environmental media (0.18 µg/kg bw/day).

Calculation: 2.77+1.35+0.18 = 4.3 µg/kg bw/day total highest estimated exposure

Revising the estimates to reflect the risk management that has taken place, with exposures from polycarbonate baby bottles and liquid infant formula no longer expected, the remaining exposure would be from environmental media (0.18 µg/kg bw/day)

Calculation: 0+0+0.18= 0.18 µg/kg bw/day revised total highest estimated exposure

The decrease from 4.3 µg/kg bw/day to 0.18 µg/kg bw/day represents a 96% decrease.

Calculation: ((0.18-4.3)/4.3)x100 = 96% decrease