Bisphenol A (CAS RN 80-05-7): Comments & Recommendations on the Draft Screening Assessment and Risk Management Scope Documents

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Bisphenol A (BPA), CAS RN 80-05-7, a high volume production substance worldwide, is utilized in epoxy and epoxy-modified resins, electrical encapsulations, internal lining of food and drink cans, polycarbonate (PC) and items from PC, dental materials, automotive components, medical devices, tin plating additives and cosmetics, among other products. This diversity of its usage makes its presence pervasive.

There is agreement with the Canadian Federal Government as to its proposal for BPA to be classified as toxic under the *Canadian Environmental Protection Act*. There is also agreement with banning the use of bisphenol A in baby bottles and the intended collaboration with industry on the reduction of BPA content in infant formula packaging. The latter is viewed only as an intermediate step; it is not a long term solution to protect the health of babies, infants and pregnant women.

Based on the draft assessment and the accompanying risk management scope documents for BPA, released on April 19, 2008, the Canadian Government has deemed it safe for other uses. There are no immediate plans to address the presence of BPA in other consumer products including polycarbonate water bottles, optical lenses, dental materials, automotive parts and epoxy adhesives.

Worldwide, BPA has been detected in almost all tested individuals with children having the highest levels. It has also been detected in human breast milk, house dust, waste water, in the ground and industrial waste water. The draft screening assessment report indicates that BPA does not meet the criteria for bioaccumulation as defined by the *Persistence and Bioaccumulation Regulations* made under CEPA 1999; human activity is responsible for the presence of BPA in the environment.

The above evidence implies that our exposure is chronic. The draft assessment noted that human levels of BPA were significantly higher than those reported to have health effects in animal studies. It was concluded that the health risks would be more relevant to the fetus and the developing child. However, it may be premature to come to this conclusion considering the lack of human and animal data relating to the health effects of chronic, low-level exposure to BPA.

The draft assessment noted the possible association between BPA and human health effects such as polycystic ovaries, obesity, endometrial hyperplasmia, recurrent miscarriages. The assessors were of the opinion that these studies

were not robust enough and concluded, as mentioned above, there will be continued use of BPA apart from the noted exceptions. Some scientific literature suggests that BPA also could play a role in human reproductive cancers of the breast, prostate, ovaries and the uterus.

Recognizing that a major exposure source for BPA is through our dietary intake, other sources of exposure such as transdermal and inhalation also require adequate evaluation. There is concern that some vulnerable populations as well as the population at large were not adequately evaluated in the draft screening. This submission will comment on some aspects of the draft screening and the risk management scope documents and make recommendations.

Occupational exposure to bisphenol A (BPA)

The government documents indicated that in 2006, BPA was not manufactured in Canada in quantities greater than 100kg. However, BPA is an integral substance in the manufacture of many products as mentioned above but it has seen reduced utilization in the manufacture of PVC and thermal paper. While industrial uses for BPA were detailed in the government documents, occupational exposure was not evaluated.

BPA is a solid and is available in flakes, pellets or granules. Some manufacturing processes using BPA take place in a closed system or loop but there can be BPA exposure during the sampling process. In less automated systems where reaction vessels have to be manually charged with BPA, inhalation of BPA dust particles can occur.

The residual monomer (BPA) content in polycarbonate (PC) can be as high as 100 p.p.m. and supposedly, is it held within the matrix of the molecule, therefore making it less available for reaction at room temperature. But there is concern with the inhalation of PC dust at the end of the manufacturing process and when the PC is utilized in the manufacturing of PC products.

Some epoxy powder paints can have residual BPA as high as 300 p.p.m. Their unique processing increases the exposure to BPA through the entire manufacturing process. Potential exposure to BPA during the application of the paint will depend on the type and efficiency of the ventilation system as well as the appropriateness of the personal protective equipment being used.

There is very little scientific literature on the human health effects to the occupational exposure of BPA. Noteworthy is a study by Hanaoka T. et al. (2002), where 42 men applying epoxy resins containing BPA diglycidyl resin measured higher levels of urinary BPA as compared to non-occupationally exposed men. Of concern should be sperm count and quality for the male workers in industries using BPA.

As of January 2008, The American Conference of Governmental Industrial Hygienists (ACGIH) has listed BPA as a chemical under study. Its exposure guideline for particulates, including BPA dust, is 10 milligrams per cubic meter and 3 milligrams per cubic meter for the respirable fraction. In Canada, many provinces recognize and use exposure levels assigned by the ACGIH. For comparison purposes, Germany and the Netherlands both use a workplace exposure level for BPA dust at 5 milligrams per cubic meter. Comparing these allowable occupational exposure levels to that of the ACGIH and given the current level of scientific knowledge and uncertainties about BPA, one can question the adequacy of protection offered by the ACGIH exposure level.

Recommendations:

- Considering the widespread and diverse use of BPA in industry, more detailed information on occupational exposure and occupational risk management for BPA could have been included in the documents.
- Because of the potential of BPA to be a reproductive toxicant, even at low concentrations, under Canada's Workplace Hazardous Materials Information System (WHMIS), material safety data sheets (MSDSs) should disclose the presence of BPA, regardless of concentration. Potential health risks should also be identified – including the potential to be a reproductive toxicant.
- Establishment of a workplace exposure level for BPA dust or particulate matter under the Canadian Occupational Health and Safety Regulations.
- To work with industry so that sectors with high occupational exposure in the BPA industry could be identified and risk management reviewed and revised, if necessary. This would also require provincial governments to be involved.
- To consult with industries that use BPA in determining the feasibility of reducing the levels of residual BPA in products.
- To consult with industry in the consideration of safe BPA substitutes particularly in situations where there is greater potential for BPA to do harm to human health.

Cosmetics

The draft assessment noted that BPA-based polymers may be used in the production of cosmetics, such as lipsticks, face and eye makeup and nail lacquers and it was expected that BPA exposure through this type of dermal contact to be minimal. This is direct skin exposure and depending on the type of cosmetic, there can be frequent exposure. There were no scientific references to qualify this assumption of minimal harm and neither were there any explanations as to the rationale for the presence of BPA-based polymers in cosmetics. Also not known or mentioned in the assessment is the packing composition of some cosmetics – are they BPA-based or not.

Recommendations:

- Assumptions cannot be made as to the safety of BPA-containing cosmetics since the government has not provided any evidence as to the effects of these

products on human health. Dialogue between the government and the cosmetics industry could clarify the following:

- the level of free monomer (BPA) in the cosmetics mentioned above,
- bioavailability of the free BPA when the product is used as intended,
- safe alternatives to BPA-based polymers,
- cosmetic packaging that may be based on BPA polymers.

▪ Cosmetics containing BPA-based polymers should indicate this on the label with an appropriate warning that BPA is a potential reproductive toxicant.

Human exposure – interior epoxy coatings for food and drinks

While there is agreement with the ban of polycarbonate baby bottles and consulting with industry on the reduction of BPA in the epoxy coating lining of infant formula, there are still some areas of concern.

The draft screening recognized the vulnerability of babies, infants and pregnant but in reality, the government's current proposal for adequate protection from BPA exposure requires further action. Despite the promise by the government to advise pregnant women and mothers with infants or babies about BPA exposure, particularly when using hot liquids in BPA containers and the repeat usage of polycarbonate containers, there have been no formal announcements in this regard. The risk management scope document did not elaborate on the details for this initiative.

While we are exposed to BPA through air, water and dust, a significant percentage of our exposure comes from the release of BPA from epoxy lined food and drink cans and the use of polycarbonate bottles. In the case of food or drink cans, labeling does not indicate the presence of free BPA in the can lining nor its potential health effects. What is not clearly defined is why BPA migrates from the matrix of the molecule when some documents suggest that it is tightly held within the matrix of the molecule. Apart from temperature and possibly pH, other contributing factors to BPA migration were not identified.

Data from the draft assessment document indicated that some foods have significantly higher residual BPA levels than others. Very noticeable is the wide range of measured BPA for some foods. Without further statistical details for these commonly used foods, the geometric mean while meaningful, may not be fully understood.

One food manufacturer has been using BPA-free cans except for tomato sauce. It was noted that these non-BPA cans cost slightly more than an epoxy lined can.

Several studies have indicated that the human metabolic elimination pathways for BPA are more rapid than those for rodents. This could possibly indicate that

actual human exposure is greater than what many studies have indicated. Also, a few studies are indicating that different routes of exposure can result in different health outcomes and the metabolism of acute BPA exposure as compared to low dosage BPA differ in laboratory animals. Data from laboratory animals with chronic low level exposure to BPA would be more pertinent to real life BPA exposures for humans.

Recommendations:

- Initiation of public health documents and information sessions aimed at pregnant mothers and mothers with babies and infants as to the ways in which they can reduce their BPA exposure in everyday life. Timelines should also be established.
- The government could consult with the food industry about BPA-free can linings since they are already in existence. Manufacturers should be obligated to prove that these linings are safe before they go on the market.
- With some timelines, the government can work with industry on the reduction and eventual phase out of BPA in the internal lining of food and drink cans. As already planned, initial emphasis should be on infant food.
- All food and drink cans that have internal epoxy linings should be appropriately labeled indicating the presence of BPA and its potential to be a reproductive toxicant. Similarly, all other consumer products with free BPA should be appropriately labeled.
- For the tested foods that have a wide range of BPA concentrations, if the ranges were subdivided into smaller ranges and the number of cans indicated for each subcategory, the geometric mean value would be more meaningful, particularly for vulnerable populations.

Resources:

- ACGIH – American Conference of Governmental Industrial Hygienists http://www.acgih.org/tlv/CSTLVStdy.htm Viewed May 30, 2008.
- Draft Risk Assessment of Bisphenol A, February 2002. Member state rapporteur: United Kingdom.
- Eden Organic. http://www.edenfoods.com/about/environment.php Viewed June 6, 2008.
- Hanaoka T, Nawamura N, Hara K, Tsugane S. Urinary bisphenol A and plasma hormone concentrations in male workers exposed to bisphenol A diglycidyl ether and mixed organic solvents. Occup Environ Med. 2002;59:625-8.
- Health Canada, Chemical Substances http://www.chemicalsubstanceschimiques.gc.ca/en/
- National Toxicology Program, National Institute of Environmental Health Sciences, National Institutes of Health, U.S. Department of Health and Human Services. Draft NTP Brief on Bisphenol A. April 14, 2008.
- Vandenberg, LN, MV Maffini, BS Rubin and AM Soto. 2007. Comments on Bisphenol A expert panel interim draft report.
- vom Saal, FS, SM Belcher, LJ Guillette, R Hauser, JP Myers, GS Prins, WV Welshons, JJ Heindel et al. 2007. Chapel Hill Bisphenol A Expert Panel

Consensus Statement: Integration of mechanisms, effects in animals and potential impact to human health at current exposure levels**.** Reproductive Toxicology 24:131-138.