Bisphenol A: HUMAN SAFETY: AN OVERVIEW

Bisphenol A (BPA) is a key industrial chemical used to make polycarbonate plastic, epoxy resins and other products. Following the four-step procedure recommended by the United States National Academy of Sciences (NRC, 1983), a safety assessment of BPA concludes that the potential human exposure to BPA from polycarbonate plastic and epoxy resin food contact applications is **minimal and poses no known risk to human health**. This conclusion is based on the following key points:

1) BPA is not carcinogenic and does not selectively affect reproduction or development. The No-Observed-Adverse-Effect-Level (NOAEL) for BPA, confirmed in multiple laboratory animal tests, is 50 mg/kg body weight/day;
2) The estimated dietary intake of BPA from polycarbonate plastic and epoxy resin food contact applications, based on the results of multiple migration studies with consistent results, is less than 0.000118 mg/kg body weight/day;
3) This potential human exposure to BPA is more than 400 times lower than the maximum acceptable or “reference” dose for BPA of 0.05 mg/kg body weight/day established by the U.S. Environmental Protection Agency, which is derived from the NOAEL.

An independent analysis by the European Commission’s Scientific Committee on Food (SCF), using a similar methodology, has confirmed the safety of polycarbonate plastic and epoxy resin food contact applications. The SCF estimated total dietary intake of BPA from all food contact sources to be in the range of 0.00048 to 0.0016 mg/kg body weight/day, which is below the Tolerable Daily Intake set by the SCF of 0.01 mg/kg body weight/day. The use of polycarbonate plastic and epoxy resins for food contact applications has been and continues to be recognized as safe by the U.S. Food and Drug Administration, the European Commission’s Scientific Committee on Food, the United Kingdom Food Standards Agency, the Japanese Ministry for Health, Labor and Welfare, and other regulatory authorities worldwide.

The Safety Assessment Procedure
Hazard Identification
The objective of the hazard identification step is to qualitatively identify the health effects that may be associated with exposure to BPA.

Carcinogenicity
The weight of scientific evidence from numerous studies, including two long-term studies, indicates that BPA is not carcinogenic (Haighton *et al.*, 2002). Among these studies are lifetime exposure cancer bioassays conducted in rats and mice by the U.S. National Toxicology Program (NTP, 1982). There was no convincing evidence in either of the bioassays that BPA was carcinogenic. In addition, BPA is without mutagenic or genotoxic activity *in vivo*. These conclusions were also reached by the European Union in their comprehensive risk assessment on BPA (EU RAR, 2002).

Exposure Assessment
Oral exposure to the human population (including sensitive subgroups) that is likely to be
without an appreciable risk of deleterious effects during a lifetime (EPA, 1993).
Based on the results of the lifetime exposure cancer bioassays conducted by the U.S.
National Toxicology Program, the U.S. Environmental Protection Agency selected 50
mg/kg body weight/day as the basis for the reference dose. The reference dose is
calculated by dividing the selected dose of 50 mg/kg body weight/day by a safety factor
of 1000, which results in a reference dose of 0.05 mg/kg body weight/day (EPA, 1993).
The results of the two multi-generation studies designed to look for low-dose effects of
BPA (Ema et al, 2001; Tyl et al, 2002) support the use of the 50 mg/kg body weight/day
dose for calculating a reference dose. No low-dose effects were observed in either study.
As part of a comprehensive risk assessment on BPA, the European Union reviewed all
available toxicity data, including evidence for low-dose effects, and also concluded that
the NOAEL is 50 mg/kg body weight/day (EU RAR, 2002).
Likewise, the Bisphenol A Toxicology Task Force estimated the No-Observed-Adverse-
Effect-Level (NOAEL) for BPA to be 50 mg/kg body weight/day based on the dose
response results observed in the seven reproduction and development tests and the
lifetime exposure cancer bioassays (BATTF, 1995).

**Polycarbonate Food and Beverage Containers**

Many researchers have studied the potential for trace levels of BPA to migrate from
polycarbonate into food and beverages under conditions typical for uses of polycarbonate
products. These studies include ones conducted by government agencies in the US,
Europe and Japan, as well as studies conducted by academic researchers and by industry.
These studies generally show that, under typical use conditions, the potential migration of
BPA into food is extremely low. Migration testing under conditions that are typical of
how polycarbonate products are actually used indicates that migration of BPA, when it is
detected, is generally less than 5 parts per billion. The results of these studies are briefly
summarized below in reference to the type of polycarbonate product or article that was
tested.

**Baby Bottles**

Each of the studies conducted by the government agencies included or
focused entirely on baby bottles. In most cases, new baby bottles were studied under
well-characterized laboratory conditions. Migration was measured into infant formula,
fruit juice or a range of solvents to simulate food. In each case, migration of BPA from
new baby bottles, when detected, was less than 5 parts per billion.

**Water Bottles:**

In the US FDA study, water from several 5-gallon polycarbonate bottles
from a bottled water supplier was analyzed with a detection limit of 0.05 parts per billion.
In water that had been stored in the bottles for up to 39 weeks, BPA was found at
extremely low levels ranging from 0.1 to 4.7 parts per billion.

**Tableware:**

The Japanese NIHS study evaluated several mugs and rice bowls along with a measuring
cup. No BPA was detected above the 0.5 part per billion limit of detection
when 3 of 5 articles were exposed to either water (95°C for 30 minutes) or 20% ethanol
(60°C for 30 minutes). Migration of BPA was observed from the other 2 articles, but only at levels below 5 parts per billion.

Risk Characterization
The objective of the risk characterization step is to determine if the potential exposure to BPA, as estimated in the exposure assessment step, will result in any risk to human health. Based on the results of migration studies and procedures recommended by the U.S. Food and Drug Administration, the estimated total dietary intake of BPA from polycarbonate food and beverage containers and from epoxy can coatings totals less than 0.118 micrograms (0.000118 milligrams) per kilogram of body weight per day. The total estimated dietary exposure to BPA from polycarbonate food and beverage containers and from epoxy can coatings is more than 400 times lower than the reference dose of 0.05 milligrams per kilogram body weight per day.

The use of polycarbonate plastic and epoxy resins for food contact applications has been and continues to be recognized as safe by the U.S. Food and Drug Administration, the European Commission Scientific Committee on Food, the United Kingdom Food Standards Agency, the Japanese Ministry for Health, Labor and Welfare, and other regulatory authorities worldwide.

References
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