



April 9, 2013

Ms. Monet Vela
Office of Environmental Health Hazard Assessment
P. O. Box 4010
1001 I Street
Sacramento, California 95812-4010

Via email: P65Public.Comments@oehha.ca.gov; monet.vela@oehha.ca.gov

Re: MADL-Bisphenol A

Dear Ms. Vela:

The Can Manufacturers Institute (CMI) appreciates the opportunity to submit these comments on the California Environmental Protection Agency Office of Environmental Health Hazard Assessment (OEHHA) proposal to adopt a Maximum Allowable Dose Level (MADL) of 290 micrograms per day for exposures to bisphenol A (BPA) by amending Section 25805(b) of Title 27 of the California Code of Regulations, pursuant to Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986. CMI is the national trade association of the metal can manufacturing industry and its suppliers in the United States. The can industry accounts for the annual domestic production of approximately 124 billion food, beverage and other metal cans; together they employ some 28,000 people with plants in 36 states. CMI member companies have more plants, 21, and more employees, 2621, in the state of California than in any other state in the nation.

As noted in our earlier comments dated March 21, 2013, CMI opposes OEHHA's Notice of Intent (NOI) listing proposal for BPA as inappropriate and scientifically unsound. As recently as September 2012, international and government organizations concluded that the weight of scientific evidence indicates that BPA does not pose a reproductive or developmental health risk to consumers. Nevertheless, in the event that OEHHA persists in moving ahead with adopting an MADL for BPA, as discussed further below, the MADL as calculated should be an order of magnitude higher, or 2.9 milligrams/day.

OEHHA (2013a) relies on eight studies to reach its conclusion that BPA "had clear evidence for developmental toxicity at high levels of exposure." These studies vary in their quality. For example, the studies by Tinwell *et al.* (2002) and Tan *et al.* (2003) had only seven and 12 animals per dose group, respectively, and animals were dosed for a shorter period of time than animals in the multigeneration studies. Despite this, OEHHA (2013b) states that "The most sensitive of these seven studies were by Tinwall [*sic*] *et al.* (2002), Tyl *et al.* (2002b) and Tyl *et al.* (2008). These studies are of sufficient quality to serve as the basis for the MADL [Maximum Allowable Dose Level]." Although we do not agree that the Tinwell *et al.* (2002) study is of sufficient quality, OEHHA appears to rely solely on the Tyl *et al.* studies for its calculations. Specifically, OEHHA (2013b) states:

The following calculations were performed in accordance with Section 25803 to derive the (MADL) for BPA:

- The studies by Tyl et al. (2002b; 2008) in rats and mice provided a NOEL [no-observed-effect-level] of 5 mg/kg-day.
- Calculation of the NOEL for a 58 kg woman:
 $5 \text{ mg/kg-day} \times 58 \text{ kg} = 290 \text{ mg/day}$.
- The MADL is derived by dividing the NOEL by one thousand (Section 25801(b)(1)). Thus, the adjusted NOEL was divided by 1,000 to obtain the MADL.

$$\text{MADL} = 290 \text{ mg/day} \div 1,000 = \mathbf{290 \text{ micrograms/day}}$$
 [emphasis in original]

One issue with this calculation is the NOEL is not based on reproductive or developmental effects. Although the scientific evidence indicates that reproductive and developmental effects are actually a result of maternal toxicity and not indicative of reproductive or developmental effects *per se*, if OEHHA concludes otherwise, then it must acknowledge the NOEL for reproductive/developmental effects is at 50 mg/kg-day (10-fold higher). This would result in a MADL of 2.9 mg/day.

If OEHHA lists BPA under Proposition 65, despite all the evidence indicating it is not appropriate to do so, the MADL should be 2.9 mg/d.

The MADL is based on a BPA exposure of 5 mg/kg-d. OEHHA (2011) states:

The NOEL shall be converted to a milligram per day dose level by multiplying the assumed human body weight by the NOEL. When the applicable reproductive effect is upon the male, human body weight of 70 kilograms shall be assumed. When the applicable reproductive effect is upon the female or conceptus, human body weight of 58 kilograms shall be assumed.

When data indicate that exposure of the neonate, infant, child or adolescent results in the applicable reproductive effect, the bodyweights specified below shall be assumed:

Adolescent (age 11 - 18 years) 40 kg
Child (age 2 - 10 years) 20 kg
Infant (age 29 days - 1 year) 10 kg
Neonate (age 0 - 28 days) 3.5 kg

Based on these numbers, an MADL of 290 µg/day is equivalent to an exposure of 7.25 µg/kg-d for an adolescent, 14.5 µg/kg-d for a child, 29 µg/kg-d for an infant, and 83 µg/kg-d for a neonate. It is worth noting that all of these far exceed even the maximum estimated exposures, and include sources other than metal cans.

Another way to consider this is to calculate the MADL based on a neonate's weight of 3.5 kg. Based on this calculation, the MADL would be $5 \text{ mg/kg-day} \times 3.5 \text{ kg} \div 1,000 = 17.5 \text{ µg/day}$, which still exceeds maximum estimated exposures by almost 10-fold.

In one of the most recent comprehensive studies of dietary BPA intake estimates based on measurements of food composite samples, researchers from Health Canada found that BPA intakes ranged from 1.5-5.8 µg/day, corresponding to 0.052-0.33 µg/kg-d, with neonates 0-1 month of age at the high end of the range (Cao *et al.*, 2011). These estimates are consistent with the high-end values reported in recent biomonitoring studies (Carwile *et al.*, 2011, Teeguarden *et al.*, 2011). Although Health Canada reported that most exposure was associated with food in cans or jars, the high end of this range is almost 10-fold less than the maximum exposure estimates discussed above, providing further evidence that exposure from canned foods is far below the MADL.

In sum, considering all of the arguments discussed in these comments, it is evident that listing BPA under Proposition 65 will not result in a public health benefit. Please contact me at 202-232-4677 or gcullen@cancentral.com with any questions.

Sincerely,

A handwritten signature in black ink that reads "Geoffrey Cullen". The signature is written in a cursive style with a long horizontal flourish at the end.

Geoffrey Cullen
Vice President of Government Relations
CMI