

**Vela, Monet@OEHHA**

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**From:** Raymond Chan <ge00us@yahoo.com>  
**Sent:** Monday, September 26, 2016 12:04 AM  
**To:** P65Public Comments  
**Cc:** Vela, Monet@OEHHA; Kammerer, Fran@OEHHA  
**Subject:** BPA Warnings

BPA Warnings

Ms. Monet Vela  
Office of Environmental Health Hazard Assessment  
1001 I Street, 23rd Floor  
Sacramento, California 95814.

P65Public.Comments@oehha.ca.gov  
(sent via email)

Dear Ms. Vela,

As a Californian, I am writing to object the proposed amendment to Proposition 65 warning requirement for bisphenol A (BPA), and the emergency regulation (for the safe harbor warning method and content for exposures to BPA from canned foods and beverages sold at retail level). I propose 1. the emergency regulation be sunset in October; 2. amendments should be made to Proposition 65 and the DART IC review practices to make the law and the practices reasonable; and 3. BPA for oral exposure from food and beverages should be exempted from the warning requirement until a MADL for oral exposure can be established, or when there is sufficient evidence to support that food containers containing BPA is unsafe. In the meantime, OEHHA should issue a statement supporting the FDA position on BPA in food containers, thus exempting BPA warning to be required for food containers with BPA.

The following are my reasons:

**1. FDA stated that BPA is safe for the present use in containers**

FDA's position is that BPA is safe for the present use in food containers.

"Based on FDA's ongoing safety review of scientific evidence, the available information continues to support the safety of BPA for the currently approved uses in food containers and packaging. People are exposed to low levels of BPA because, like many packaging components, very small amounts of BPA may migrate from the food packaging into foods or beverages. Studies pursued by FDA's National Center for Toxicological Research (NCTR) have shown no effects of BPA from low-dose exposure.... In the fall of 2014, FDA experts from across the agency, specializing in toxicology, analytical chemistry, endocrinology, epidemiology, and other fields, completed a four-year review of more than 300 scientific studies. The FDA review has not found any information in the evaluated studies to prompt a revision of FDA's safety assessment of BPA in food packaging at this time. The

studies reviewed were published or available from November 1, 2009 to July 23, 2013.” See <http://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/ucm355155.htm>

“Uses of all substances that migrate from packaging into food, including BPA, are subject to premarket approval by FDA as indirect food additives or food contact substances. FDA can make regulatory changes based on new safety or usage information. The original approvals for BPA were issued under FDA’s food additive regulations and date from the 1960s.”... “FDA continues to review the available information and studies on BPA. FDA will update its assessment of BPA and will take additional action if warranted. Based on FDA’s ongoing safety review of scientific evidence, the available information continues to support the safety of BPA for the currently approved uses in food containers and packaging.” See <http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm064437.htm>

## **2. California is the only state that imposes a warning requirement on BPA**

Contradictory to the FDA position on BPA, California is the only state among the 50 states that imposes a warning requirement on BPA for the use in food containers. On May 11, 2015, BPA was added to the Proposition 65 list of chemicals known to cause reproductive toxicity. This addition was made as a result of the voting of the meeting of a committee of this State’s Qualified Experts (SQE), the Developmental and Reproductive Toxicant Identification Committee (DART IC), held on May 7, 2015. DART IC unanimously voted that BPA is a female reproductive toxicant. One must wonder why this panel of expert scientists took a totally inconsistent position, from that of the scientists at FDA.

## **3. DART IC was advised not to consider the quantity of exposure when it voted to enlist BPA in the list of Proposition 65 chemicals**

DART IC was advised not to consider the quantity of exposure at the May 7 meeting. Ms. Carol Monahan Cummings, Chief Counsel of the Office of Environmental Health Hazard Assessment (OEHHA) stated, right after the presentation by the representative of the Can Manufacturers Institution, that “the question before the Committee is not about whether or not the current human exposures to BPA are sufficiently high to be of concern....But the – whether or not the current exposures, for example, Dr. Plopper, from migration from the epoxy to the food is, you know, at any level in particular, isn’t a question that would inform the Committee about whether or not the scientific evidence shows that the chemical causes a particular effect.... It’s not a legal standard, and you don’t have to determine today whether or not the listing will have any effect on any product or what kinds of exposures humans might have now or in the future.” <http://oehha.ca.gov/media/downloads/proposition-65/transcript/may72015transcript.pdf> at 138:24 – 139:10.

Ms. Cummings further stated, “what I’m saying is that the current exposures to human right now is not a concern for this Committee. It’s not something that’s part of your criteria, and it is something that would be addressed later in the Prop. 65 process when there’s determinations about levels of exposure that require warning for example. And that’s something that our Office does.” *Id.* at 140:25 – 141:7.

In another words, Ms. Cummings advised the Committee not to consider the quantity of exposure factor of BPA. This is definitely a non-scientific advice. Any scientist will logically position that the amount of exposure is critical in determining whether a chemical will cause reproductive

toxicity. Elimination of the exposure factor is an unacceptable imposed decision criteria. No wonder that the Committee made a voting that seemed to contradict with the FDA findings and position.

Ms. Cummings seemingly acknowledged that the Committee was asked to make an unscientific decision. “the Prop. 65 is kind of an unusual law”, *Id.* at 138:23; “this particular Committee it is – the charge is somewhat unusual, because of the way that the statute was drafted. We don’t have regulatory criteria, other than what the actual language out of the statute that says that it has to be clearly shown by scientific valid testing, according to generally accepted principles to cause reproductive toxicity. And that’s why the Committee in the past developed the criteria that you have as guidance.” *Id.* at 140:14 – 21.

OEHHA, being a government agency, has the responsibility to correct laws that are written unjustly, instead of pushing an unscientific decision restriction on the State’s Qualified Experts purely base on an existing law.

#### **4. OEHHA failed to establish a Maximum Allowable Dose Level except for dermal exposure from solid materials**

Although Ms. Cummings committed to DART IC that OEHHA will determine the level of exposure that require warning in the later enactment of the Prop, 65 process, *Id.* at 141:3-6, OEHHA failed to establish a Maximum Allowable Dose Level (MADL) for BPA (except for dermal exposure from solid materials) during the whole year after BPA was listed. Instead OEHHA enacted an emergency regulation for the safe harbor warning method, without providing any evidence of an exposure for which a warning plausibly is required.

OEHHA violated the premises where DART IC’s voting was based on. Hence the discrepancy should be reflected back to DART IC, and BPA for oral exposure from food and beverages should be exempted from the warning requirement until a MADL for oral exposure can be established, or that there is sufficient evidence to support that food containers containing BPA is unsafe.

#### **5. OEHHA cannot explain why it only targeted canned food in the warning**

Without a MADL, any environment that contain BPA, even a very minimal amount, should bear a warning sign according to Proposition 65. Besides being found in canned food, BPA is also found in other places such as refillable water bottles, water, dust, and even in air. Even if warnings were posted according to OEHHA’s enactment, this does not prevent unnecessary lawsuits to be filed or to be threatened in situations where minute amount of BPA can be detected. Hence OEHHA’s emergency enactment imposing warnings just on canned food is ineffective and insufficient to prevent people from abusing this loophole to initiate unnecessary threats to lawsuits attacking innocent businesses and enterprises in order to make money. It seems to me that the only solution is to exempt BPA warning for oral exposure from food and beverages until its MADL from oral exposure from food and beverages can be established.

#### **6. OEHHA cannot disprove FDA’s position that BPA is safe for the present use in containers, the proposed warning is absurd**

OEHHA offers no evidence to disprove FDA’s position that BPA is safe for the present use in food containers and packaging. OEHHA also cannot provide any evidence to disprove FDA’s cited studies showing there is no effects of BPA on health from low-dose exposure. This means that even the consumers are exposed to BPA through consumption of food or beverages packaged in cans with linings or coating containing BPA, there should not be any adverse health effect. There is no need for manufactures to switch to non-BPA coating or lining materials.

OEHHA recently published a MADL for dermal exposure from solid materials of BPA, and did inform the DART IC about this enlistment.

However, without any showing of any scientific justification and/or evidence of damage caused by BPA contained in canned food products; and apparently OEHHA did not even table this issue for DART IC discussion, OEHHA initiated an emergency regulation requiring retailers to display warnings at its checkout points and also requiring manufacturers and distributors to perform certain tasks. Out of the hundreds of chemicals on OEHHA's chemical list, BPA is the only chemical that requires an emergency regulation, and is the only chemical that is proposed to be mentioned inside the body of the law, but OEHHA did not highlight why BPA is special.

The fact that OEHHA published a MADL for dermal exposure from solid materials of BPA basically closed the case for BPA enlistment, and the present Proposition 65 law could satisfactorily address the Warning issue. This also mean that warning would only be required when consumers are exposed to BPA in dermal exposure from solid material cases.

The facts that OEHHA cannot find evidence to support that BPA contained in canned food can cause health problem and cannot establish a BPA MADL for oral consumption, together with the fact that FDA positioned that BPA is safe for the present use in food containers, strongly support that no Warning is required for food products in containers containing BPA.

The OEHHA argued that there are current researches underway, the safe harbor level for oral exposure to BPA may be available in the next one to two years[<sup>i</sup>], in the interim, a warning would be required. This argument is illogical. There are always researches in progress, and every day new discoveries are found. We cannot enact laws and regulations anticipating future scientific findings. (What if the future finding proves that BPA is perfectly safe?) When there are new findings that justifies the enactment of new laws and regulations, we shall enact the laws then, we cannot make laws and regulations based on unfound and anticipated evidence.

The Warning as suggested by OEHHA does not protect and enhance public health but only adds to the confusion and promotes unnecessary fear and doubt among consumers. It is unnecessary to issue such a warning because it does not offer any benefit for consumers. Actually the warning is absurd and destructive because it unreasonably attacks a product deemed safe by FDA and other government agencies.

#### **7. OEHHA understated the impact of the proposed regulation and the evaluation of the impact was incomplete**

The proposed warning causes unnecessary alarm to the consumers and discourages consumers to purchase canned food products and food products with jar lids and bottle caps, irrespective of whether such containers contain BPA or not. The loss in sales of food or beverages because of the warning and fear was not estimated. Such losses could be in the millions and the losses are difficult to estimate until they are materialized.

Food products are not just manufactured for California. Out-of-state and overseas food manufactures might avoid shipping products to California because of the unnecessary proposed regulations and warnings required. This will also result in the loss of sales of California retail outlets and will deprive Californians from the availability of products which otherwise can be available. OEHHA failed to substantiate such losses.

Foods are manufactured and packed in containers containing BPA in California. California also manufactures containers containing BPA. The new rule will require warning to be displayed on containers or that manufacturers would have to switch to BPA-free materials, seemingly even those shipped to locations accept containers containing BPA. The cost of posting warnings or switching to BPA-free materials would be substantial. These California manufacturers would also lost competitive edge and competitive ability as compared with manufactures in other states that does not have this regulation. OEHHA failed to evaluate and disclose such impact.

Costs would be incurred for retailers and distributors to enquire whether BPA was contained in the container of the manufacturers of food products. These enquires are unnecessary if not for the proposed regulation. Even if a few hours were spent in each retailer and distributor for these inquires for each product carried, the total labor cost for the total number of retailers and distributors would be substantial. OEHHA did not evaluate nor disclose such labor costs.

The cost of the warning display was not estimated by OEHHA. The proposed 5\*x5\* warning occupies valuable rental space at the retail outlets. The rental cost should be estimated for the warning sign and the surrounding area which cannot be productively used. The rental cost should be multiplied by the number of checkout points for each retail outlet and then this rental cost per outlet should be multiplied by the estimated number of retail outlets throughout the state. The total number of lost retail space for the whole state per year should be very substantial. Also, checkout points were not constructed nor designed to display warning signs, the amount of re-design and re-construction cost would be substantial.

OEHHA did not estimate the policing, lab testing and prosecution costs associated with the implementation. I wonder whether OEHHA has the manpower or the budget to properly police this law, to conduct investigation, to do lab tests and experiments, and to prosecute offenders. The money loss to defend the lawsuit arising from state and private initiated lawsuits should also be included as part of the economic and productivity losses.

OEHHA did not include the cost to enact the proposed emergency regulations and the cost to write those regulations to law upon sunset. No evaluation was made on the manpower and cost to evaluate and to respond to public comments. No evaluation was made on the manpower required to address the contradicting position on BPA.

#### **8. The emergency warning requirement for BPA began on May 11, 2016 was not generally implemented**

The emergency warning requirement for BPA began four months ago on May 11, 2016. However it was not observed to be generally followed. In Oakland and in the surrounding San Francisco Bay area, there are only a few retailers posting the suggested warning signs at each checkout points. Some post only one warning in inconspicuous place for the whole store. It is not reasonable to assume that all the containers containing BPA sold in retail outlets disappeared overnight (estimated by OEHHA to be 66 to 90% of all canned goods<sup>[iii]</sup>), nor there is no violation to the emergency regulation. I believe the reaction of the retailers are the same statewide. This statewide resistance to the new emergency warning requirement as a silent protest indicated that the emergency regulation is unpopular, costly and difficult to implement.

#### **9. OEHHA should amend its DART IC practices to review and approve the exposure quantity at the same time a chemical is tabled for review**

This whole argument and OEHHA's emergency warning regulation was initiated because DART IC did not consider whether the human exposures to BPA were sufficiently high to be of concern when it voted to list BPA in the chemical list back in May 7, 2015. OEHHA then spent one year trying to establish the MADL for BPA oral consumption and finally determined that such MADL could not be established. OEHHA seemingly did not further table this issue to DART IC for review, ignored the FDA position on the safety of BPA in food containers, and unilaterally enacted the current emergency regulation, giving rise to numerous objections. The sudden emergency regulation also defeated the purpose of the one year implementation window period of Proposition 65, giving no time for the manufacturers, distributors and retailers to react to the new chemical added to the list because the MADL was unknown and not published.

If the unreasonable and unscientific practice (of ignoring the quantity) were not changed, more and more chemicals to be reviewed by DART IC would fall into this trap and more and more emergency regulations would be required by OEHHA in the future.

There seems to be only one simple and reasonable solution – the DART IC should consider the human exposure to any chemical that is tabled for review in the future.

### **Summary**

In sum, for the reasons above, I object to the proposed amendment to the Proposition 65 warning requirement for BPA, and the emergency regulation (for the safe harbor warning method and content for exposures to BPA from canned foods and beverages sold at retail level). I propose 1. the emergency regulation be sunset in October; 2. amendments should be made to Proposition 65 and the DART IC review practices to make the law and the practices reasonable; and 3. BPA for oral exposure from food and beverages should be exempted from the warning requirement until a MADL for oral exposure can be established, or when there is sufficient evidence to support that food containers containing BPA is unsafe. In the meantime, OEHHA should issue a statement supporting the FDA position on BPA in food containers, thus exempting BPA warning to be required for food containers with BPA.

Yours Sincerely,

Raymond Chan  
Oakland, California

[i] <http://oehha.ca.gov/media/downloads/cnr/responsecommentsbpaemerg041916.pdf> p.3

[ii] <http://oehha.ca.gov/media/downloads/cnr/bpawarningsregisor072916.pdf> p.5

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