Hello Larry,

When we gave the IRP an overview of the Safer Consumer Products program, the panel requested that we notify them of the disposition on the petition from the Center for Environmental Health to list BPA in can linings as a Priority Product. We recently made our final decision to deny the petition. The merit standard for petitions in our regulations is quite rigorous and essentially requires that the petitioner compile data and information equivalent to the peer reviewed technical documentation we prepare to support rulemaking. We determined that CEH had not met that standard. For instance CEH did not provide a thorough discussion of existing conflicting regulatory findings regarding BPA (e.g., the Federal Food and Drug Administration and other authoritative bodies have determined that BPA in food can linings does not pose a health risk). Attached is a copy of the letter to CEH outlining the basis for the denial. We have since talked to the petitioner to answer any remaining questions.

Please share this with the panel and let us know if you have any questions regarding our determination.

Regards,
Meredith

Did you know... there are open positions in Safer Consumer Products? Apply now!

Meredith Williams
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June 29, 2017

Ms. Caroline Cox, Research Director
Center for Environmental Health
2201 Broadway Suite 302
Oakland, California

Dear Ms. Cox:

On August 10, 2016, the Center for Environmental Health (CEH) submitted a petition to the Department of Toxic Substances Control (DTSC), requesting that DTSC designate “Food cans with BPA resin linings” as a Priority Product under the Safer Consumer Product (SCP) Regulations. In our initial merits review, DTSC determined that the petition lacked adequate supporting documentation for us to grant it as submitted. On November 22, 2016 DTSC sent a letter to CEH describing these findings and offered CEH the opportunity to revise the petition. On March 14, 2017, CEH submitted additional materials to DTSC in support of the petition. DTSC has completed its review of these supplemental materials. I am writing to inform CEH of our decision.

After careful review, we have determined that, even with the supplemental information provided, the petition is still inadequate. Listing any product as a Priority Product requires rulemaking, pursuant to the California Administrative Procedure Act. DTSC must compile a body of reliable information demonstrating that 1) there is potential for exposure (either to people or non-human organisms) to a Candidate Chemical in the product and 2) such exposures have the potential to contribute to or cause significant or widespread adverse impacts. When a person petitions DTSC to add a product-chemical combination to the Priority Products List, the onus is on the petitioner to provide this body of information. As we noted in our earlier letter, in order “to make effective use of DTSC resources,” the Final Statement of Reasons for the SCP Regulation¹ requires that a petitioner provide “a significant body of high quality information wherever possible to facilitate DTSC’s scientific review.”

In our previous communications, DTSC explained that in order to support rulemaking, a more rigorous analysis of the proposed Priority Product would be required than was included in the original petition. DTSC referred CEH to three previously published Profiles documenting the basis for listing proposed Priority Products (http://www.dtsc.ca.gov/SCP/PriorityProducts.cfm). While the type and amount of reliable information discussed in these Profiles may vary from product to product, the Profiles still may serve as a general model for the level of detail that DTSC would deem adequate to support designating a product as a Priority Product.

Further, DTSC suggested that specific supplemental information CEH provided needed to include the following:

- Identification of data gaps pertaining to the prioritization criteria listed in Article 3 of the SCP Regulations
- A more rigorous description and analysis of the data relied upon in determining how the product-chemical combination meets the prioritization criteria set forth in Article 3 of the SCP Regulations
- A more rigorous analysis of hazard and exposure information for BPA
- A more thorough discussion of existing conflicting views surrounding BPA and why the evidence presented in the petition is sufficient to counter those conflicting views (e.g., the Federal Food and Drug Administration (FDA) and other authoritative bodies have determined that BPA in food can linings does not pose a health risk)
- A discussion of existing regulatory requirements pertaining to food cans and food can linings, and whether listing such products as a Priority Product would conflict with any existing regulations
- An expanded discussion of alternatives to the use of can linings containing BPA. The original petition mentioned some alternatives, and noted that some may be regrettable substitutes.

While the additional information submitted on March 14, 2017 did partially address some of the gaps in the initial petition, it did not sufficiently expand the discussion and analysis of the items listed above. For example, there was no additional discussion of data gaps and uncertainty related to the potential hazard traits and exposure data. It is the current opinion of the U.S. Food and Drug Administration and the European Food Safety Authority that BPA in food can linings does not present a threat to human health and safety. Before DTSC can consider taking an action contradictory to the findings of those authoritative bodies it is essential that DTSC be provided with sufficient information to fully understand and evaluate existing data gaps and potentially conflicting positions.
In addition, DTSC asked that CEH expand the discussion of existing regulatory requirements pertaining to food can linings. The additional information provided by CEH did not include any further discussion of any such regulatory requirements. Therefore, DTSC cannot evaluate if or how listing food can linings containing BPA as a Priority Product might conflict with the ability of manufacturers to comply with existing requirements. DTSC also asked that CEH expand the information contained in the original petition relating to potential alternatives to the use of BPA in can linings. The original petition suggested that there are many potential alternatives and that some possible alternatives may be of concern with respect to their potential hazard traits. The additional information provided by CEH did not contain any additional information on these alternatives.

We have concluded that the original petition and the supplemental information submitted on March 14, 2017 did not provide sufficient detail to enable DTSC to rigorously evaluate BPA in food can linings.

Thank you for your petition and for your engagement with us during the review process. Please be aware that DTSC’s decision to deny your petition does not preclude you from developing and submitting a new petition for food can linings containing BPA in the future. Further, the information you’ve provided has value and provides a strong basis for DTSC to include food packaging products as a consumer product category for the 2018-2020 Priority Products Work Plan. If you have any questions or concerns please do not hesitate to contact Andre Algazi, Chemical Product Evaluation Team Leader at (916) 324-2659 or Andre.Algazi@dtsc.ca.gov.

Sincerely,

[Signature]

Karl Palmer, Chief
Safer Consumer Products Branch

Cc: Barbara A. Lee
Director
Department of Toxic Substances Control

Meredith Williams
Deputy Director
Safer Products and Workplaces Program