



November 14, 2014

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Dear Ms. Vela:

Thank you for the opportunity to provide input about possible regulatory actions that OEHHA may pursue. As a non-profit organization that works to reduce exposures to toxic chemicals the Center for Environmental Health has found Proposition 65 to be an effective law, and we look forward to working with OEHHA to make it even more effective.

I. Alternative Risk Levels for Chemicals in Foods (25703(b)(1))

Consumers expect that the food they purchase is safe and healthy for themselves and their families. They also expect that government agencies are actively working to make the food supply even safer and healthier. The alternative risk levels described in 25703(b)(1) seem contradictory to the purposes of Proposition 65, as well as consumer expectations, in that they allow businesses to avoid providing consumers with information about toxic chemicals if those chemicals are formed as a result of "cooking necessary to render the food palatable or to avoid microbiological contamination." Yet those chemicals are no less toxic than chemicals in food for other reasons.

We suggest that OEHHA update 25703(b)(1) by eliminating it altogether such that to warnings will be required for toxic chemicals in food no matter how they are formed. Alternatively, to the extent OEHHA insists on maintaining an exemption for chemicals in food produced by cooking under certain circumstances, OEHHA should limit the exemption to chemicals produced by cooking necessary to avoid microbiological contamination and should eliminate the exemption for chemicals produced by cooking necessary to render the food palatable. Simply put, if a type of food cannot be rendered palatable without the presence of toxic chemicals, there is no sound public policy reason not to warn consumers about the presence of those toxic chemicals.

In addition, regardless of the scope of the exemption, OEHHA should specify what alternative risk level is appropriate if the chemical is formed by cooking. Otherwise, those determinations will be made on an ad hoc basis by courts.

2. Update the Naturally Occurring Regulation (25501)

Our perspective about this is similar to our perspective about 25703(b)(1). A chemical is no less toxic if it is naturally occurring than if it occurs in food through some other process. Therefore, the exemption for naturally occurring chemicals in food should be narrowly tailored.

We suggest accomplishing this in two ways. First, OEHHA should issue regulations to clarify the meaning behind the terms used in the existing regulation. For instance, more clarity is required on issues like what constitutes good agricultural and manufacturing practices, and what quality control measures are required to reduce the level of a chemical to the “lowest level currently feasible.”

Second, even where the criteria of the regulation are satisfied, there should be a cap on the levels of naturally occurring chemicals that are allowed in food without a warning. Simply put, it is neither sound public policy nor consistent with the purposes of Proposition 65 to allow businesses to expose consumers to potentially limitless levels of toxic chemicals in food without a warning. The cap could be tied to the existing safe harbor levels. For instance, for reproductive toxicants, OEHHA could specify that, regardless of whether a chemical is naturally occurring, a warning will be required if the level of the chemical is more than 10 times the MADL (i.e., OEHHA could apply a 100-fold safety factor instead of a 1000-fold safety factor for naturally occurring chemicals in food). We believe that this is more consistent with the purposes of the statute than the current approach, under which substantial quantities of toxic chemicals could be found in foods without a warning.

3. Clarify regulatory provisions on averaging exposures (25701, 25721, 25801, 25821)

In our Proposition 65 work, we see the establishment of a safe harbor level for a chemical that causes reproductive harm as incorporating the duration over which an exposure is averaged. This concept is recognized by OEHHA’s existing regulations, which provide that the “rate of exposure” is to be based on “the pattern and duration of exposure that is relevant to the reproductive effect which provided the basis for the determination that a chemical is known to the state to cause reproductive toxicity.” 27 Cal. Code Regs. § 25821(b). In the case of lead, for instance, which was listed based on its teratogenic effects, this should mean that a warning is required if the 0.5 ug/day safe harbor level will be exceeded by a single day of exposure.

Nevertheless, as OEHHA is aware, the trial court in *ELF v. Beechnut* ruled that the defendants could average the exposures over a 14-day period. The net effect of the trial court’s ruling in *Beechnut* is that the companies named as defendants in that lawsuit can expose pregnant woman, children and other consumers with up to 7 ug of lead in a single day (0.5 ug x 14) without providing any warning whatsoever.

While the *Beechnut* decision is an isolated trial court opinion that is pending appellate review, the opinion highlights the need for OEHHA to take regulatory action. The duration of any potential averaging is a technical scientific issue, and should be determined by an agency with scientific expertise like OEHHA. Dr. James Donald of OEHHA testified at the *Beechnut* trial that OEHHA views the MADLs listed in 25805 as daily exposure levels, regardless of frequency of consumption.

OEHHA should formalize its informal policy by revising its regulations to clarify that the default rule is that exposures should not be averaged over time for reproductive toxicants. For any exceptions to the default rule, OEHHA specify the proper duration of exposure for any particular chemicals for which averaging may be appropriate.

4. Chemicals to give priority in the development or update of Safe Harbor levels

There is a high priority need for updated safe harbor levels for the reproductive effects of lead. Given the huge amount of additional science that has been generated since this level was established, an update is crucial.

There is also a high priority need for a safe harbor level for arsenic's reproductive effects. This is particularly true because the accumulating body of scientific studies indicates that reproductive harm can occur at low exposure levels.

5. Where Interpretive Guidance is needed

We believe that any necessary clarifications should be made by regulation and not interpretive guidance to ensure a full vetting with appropriate input from all affected stakeholders.

6. Use of data on postnatal developmental exposures

In regulation of toxic chemicals, the term development toxicity commonly includes exposures during childhood (<http://www.epa.gov/raf/publications/pdfs/DEVTOX.PDF>). Lead is a well-known example of a toxic chemical that causes serious developmental harm (brain development) following childhood exposure. Thus we support the use of postnatal exposure data.

7. Other

In our decades of work with Proposition 65, one of the most significant problems we have seen is what we call "overwarning," warnings that are provided for products even if they don't cause a Proposition 65 exposure. We support OEHHA's efforts to address this issue.

Sincerely,

A handwritten signature in cursive script that reads "Caroline Cox".

Caroline Cox