

BUSINESS GROUPS LIKE IDEA OF NATURALLY OCCURRING DEFAULT LEVELS BUT SEE NEED FOR CHANGES IN OEHHA PROPOSAL

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In September, the Office of Environmental Health Hazard Assessment released a [proposal](#) that would establish default levels for calculating the amount of "naturally occurring" lead and arsenic in some "unprocessed" food products [see [OEHHA Proposes Default Levels for Determining Lead and Arsenic in Certain Foods](#), September 15, 2015]. The proposal was the subject of an October 14 workshop and written comments by the November 12 comment deadline.

Business groups generally favored the proposal, although they suggested a number of changes to make it more palatable. The only two private plaintiff groups commenting either opposed it outright or attached conditions that would make it unworkable.

The existing naturally-occurring defense is set forth in [Title 27, section 25501](#) of the OEHHA Proposition 65 regulations. It allows a defendant in quantifying the amount of a listed Prop. 65 contaminant in a food product to deduct that portion of the amount that is naturally-occurring as a result of absorption or uptake from the soil in which it is grown. In order to come up with the deductible amount the defendant must demonstrate the background level of the contaminant in the area in which it is grown eliminating any portion of the chemical that was deposited in the soil as a result of anthropogenic activity, such as the use of fertilizer, pesticides, or drift of pollutants emitted from gasoline vehicles. The defendant also has to show that the levels are not "avoidable by "good agricultural or good manufacturing practices" and that the "producer, manufacturer, or distributor" of the food product utilized "quality control measures" to reduce chemical content the lowest feasible level. This type of demonstration has proved extremely difficult to apply in practice and results in what OEHHA contends is the possibility that different parties will come up with different calculations for the same chemical-food combination in the same growing area.

The OEHHA proposal is one of four "pre-regulatory" proposals the agency released in September that are designed to improve the determination of safe harbor levels for exposure to Prop. 65 listed chemicals. The other three would establish new safe harbor levels for lead exposure [see [OEHHA Suggests Radically Different Approach for Calculating Lead Safe Harbor Levels](#), September 15, 2015], change how the "level in question" is determined for a reproductive toxicant safe harbor, and would clarify the calculation of the "rate of intake" of a chemical for calculating exposure to that chemical [see [OEHHA Proposes Two Changes to Regulations for Calculating Exposure to Reproductive Toxicants for Safe Harbor Purposes](#), September 15, 2015].

OEHHA's naturally-occurring pre-regulatory proposal establishes default levels for the following food stuffs:

- Inorganic arsenic in white rice grain-60 parts per billion (ppb)
- Inorganic arsenic in brown rice grain-130 ppb
- Lead in raw leafy vegetables-8.8 ppb
- Lead in raw non-leafy vegetables, fruit, meat, seafood, eggs, and fresh milk-6.2 ppb

The above levels are based on various surveys of food consumption for different types of foods undertaken by the federal government, state agencies, foreign government agencies, and other researchers.

In addition to [comments at the October 14 workshop](#), OEHHA received nine written comments. Seven of these were submitted by business interests, while two were submitted by organizations that undertake private enforcement actions under Prop. 65.

BUSINESS COMMENTS

All of the business groups commenting heartily agreed with OEHHA's concerns that the existing naturally occurring regulation is impossible to apply in practice and that OEHHA was doing a good thing in attempting to come up with these default levels. However, only one of those commenting actually agreed with the current proposal in its entirety. That comment was received by the [California Rice Commission](#), which concluded that the proposed default levels for arsenic in white and brown rice grain would bring consumer exposure levels in rice below the safe harbor levels for arsenic thereby ending what the Commission describes as "meritless litigation."

One of the commenters, the [Natural Products Association](#), is opposed to the current effort, raising several complaints about the methodology that OEHHA used in calculating the default levels.

The remainder of the business groups, while praising OEHHA's effort, suggest a number of changes in the proposal:

- The [Farm Bureau Federation](#) and other commenters believe that OEHHA should strike the word "raw" from the described foods and the word "unprocessed" in the proposal's title, because it creates confusion about how the default levels will apply to processed foods. The Bureau points out that most naturally-occurring chemicals continue to exist after the raw products are processed.
- The [California Chamber of Commerce](#), which provided comments on behalf of a large coalition of business interests, points out that the lead and arsenic levels in the proposal are based on levels in soils in California. However, notes the Chamber, much of the food products are grown in areas outside of the state where the soils have greater natural background levels of lead or arsenic or where various factors cause a greater amount of the chemicals to be taken up by the plant. The Chamber suggests that OEHHA come up with some mechanism to reflect this differential. Given that California soil levels are generally lower than elsewhere the Chamber suggests that OEHHA might use the highest detection level of the chemical found in the FDA's Total Diet Survey (TDS), upon which the OEHHA proposal is based.

- The Chamber also asks OEHHA to make it clear that use of the suggested default levels frees the defendant from the other parts of the demonstration in the current regulation, requiring it to show the food was grown with best practices and reduced to the lowest feasible level. The Chamber suggests that this could be done by making it clear that meeting the default levels means that there has been no "exposure" to the listed chemical for purposes of Proposition 65.
- The [Chamber, the National Confectioners Association](#)(NCA), and others suggest that OEHHA consider incorporating into the regulation default levels for lead established pursuant to various consent decrees. The Chamber has included in its comment a list of such decrees and asks OEHHA to review it and adopt the default levels set by these decrees so that they apply to all conveyors of the product and not just to the individual litigants.
- [Sedgwick attorney Carol Brophy](#), who represents a coalition of organizations, argues that the use of default levels tied to foods grown in California is inconsistent with the international market in foodstuffs and may be held to be an undue burden on interstate commerce. She also suggests that OEHHA consider adopting adopt the FDA standard tolerances for lead and other contaminants in foods.

PRIVATE ENFORCERS

The two private enforcer groups commenting on the proposal were the [Environmental Health Foundation](#)(ELF) and [Center for Environmental Health](#)(CEH). ELF is unqualifiedly opposed to the effort suggesting that it is illegal, the methodology is unproven, and that OEHHA, at a minimum, should retain the best practices and lowest feasible level requirements. ELF believes OEHHA should stick with the current regulation.

CEH does not necessarily oppose the OEHHA effort. However, it insists that the best practices and lowest feasible level requirements be maintained, that any numerical level for a single food product be based on data from the region in which the product was grown, and that only "trace" amounts of any listed chemical be allowed.