The California Office of Environmental Health Hazard Assessment (OEHHA) recently proposed levels of inorganic arsenic in rice that would be deemed “naturally occurring” and thus exempt from the Proposition 65 warning requirement. This is the first time in twenty-five years that OEHHA has taken action to give life to the naturally occurring exemption.

**Arsenic**

Inorganic arsenic is found in the environment from both natural and anthropogenic sources, including geologic processes, pesticides, and arsenic-contaminated irrigation water. Examples of anthropogenic arsenic contamination include arsenic-contaminated soil near and around arsenic smelters and the use of arsenical pesticides and herbicides in old orchards and cotton-growing regions. And while arsenic in rice is also (and likely mostly) the result of plant uptake of arsenic from the soil, the amount and form of arsenic (organic vs. inorganic) in the soil depends on various factors, including soil chemistry and the amount of water in the soil.

**The Naturally Occurring Exemption**

Under California's Proposition 65 (Prop 65) regulations, amounts of chemicals that are naturally occurring in food are excluded when determining whether an exposure from the food would require a Prop 65 warning. The regulations indicate that the naturally occurring level of a chemical may, among other things, be established by determining the natural background level of the chemical in the area in which the food is raised, grown, or obtained, based on reliable local or regional data. [1]

The naturally occurring exemption has been applied in a number of Proposition 65 settlements, [2] but it has rarely been litigated. In the few cases where the issue has been the subject of a trial, courts have adopted varying approaches to the naturally occurring exemption. Some courts have accepted general evidence indicating that most of a particular chemical in food is naturally occurring (e.g., levels of mercury in tuna), [3] while others have rejected companies' efforts to apply the exemption absent detailed data to support the proposed naturally occurring level at every location where the food is grown and proof that any existing methods to reduce levels of the chemical are not “currently feasible” (e.g., levels of lead in certain baby foods and fruit juices). [4]

**OEHHA's Prior Attempts to Address the Issues**

The naturally occurring exemption regulation has always been the subject of controversy. The regulation was challenged as being inconsistent with Proposition 65’s purposes when it was originally promulgated, but it was upheld by a court of appeal on the basis that the voters did not intend to require businesses to warn consumers about naturally occurring chemicals in foods they had safely eaten for many years. [5] Because the original regulation was proven difficult to apply in enforcement litigation, in 2015 OEHHA held a workshop to consider adopting a supplement to the original regulation that
would establish default background levels for certain ubiquitous chemicals, such as arsenic and lead, that are naturally present in unprocessed foods. [6] The pre-regulatory levels for naturally occurring inorganic arsenic in rice suggested by OEHHA appear to be based on the same data the agency is using in the current rulemaking.

The New OEHHA Proposal

The new supplemental regulation would only establish two specific default naturally occurring concentrations for inorganic arsenic in rice. While the current regulation does not propose default concentrations for other foods or other chemicals, OEHHA intends to propose allowances for other foods and chemicals in the future. In addition, for those willing to make the necessary showing, the new regulation does not preclude a person from using other evidence, assumptions, principles, or procedures consistent with the longstanding regulation to establish that a chemical in a food is naturally occurring.

To identify a default level of naturally occurring inorganic arsenic in rice, OEHHA staff reviewed 38 studies and reports and used three databases and two datasets. From this, OEHHA determined that “it is reasonable to assume that the majority of arsenic in California soil in rice-growing areas is naturally occurring.” As a result, OEHHA proposes the following naturally occurring levels of inorganic arsenic in rice:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Food</th>
<th>Concentration parts per billion (ppb)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inorganic arsenic</td>
<td>White rice grain</td>
<td>80</td>
</tr>
<tr>
<td></td>
<td>Brown rice grain</td>
<td>170</td>
</tr>
</tbody>
</table>

In deriving these concentrations, OEHHA determined the mean value of inorganic arsenic in California white rice to be 0.06 ppm, or 60 ppb, with 80 ppb as one standard deviation above this value. The mean value for brown rice is 0.13 ppm, or 130 ppb, with 170 ppb as one standard deviation above this value.

OEHHA reasoned that:

Since there is natural variation in the levels of arsenic in rice, these values that are one standard deviation from the mean are selected as the safe harbor naturally occurring levels of inorganic arsenic for these types of rice. Values toward the extreme of the distribution are not selected because of potential arsenic contribution from historical anthropogenic sources.

OEHHA explained that it also considered estimating levels of arsenic in rice from soil levels using uptake transfer factors. The agency concluded, however, that these factors vary across studies and do not provide reliable estimates and that the proposed safe harbor for naturally occurring levels of inorganic arsenic apply to all rice, regardless of location of production, since naturally occurring levels of arsenic in California soil appear similar to soils located elsewhere in the United States.

Implications of OEHHA’s Proposal

As to rice, OEHHA’s proposal would assist a company even if the concentration of inorganic arsenic in its rice exceeds the proposed default naturally occurring levels. In evaluating the exposure for which the business is responsible, the naturally occurring concentration of inorganic arsenic would first be subtracted from the measured concentration in the rice to determine if the rice is exempt from the Proposition 65 warning requirements pursuant to Health and Safety Code section 25249.10(c). If the concentration of inorganic arsenic in the rice were less than the default level, the company would not be required to make a further showing. However, even if the inorganic arsenic level in the rice exceeds the default level, a company would still be entitled to prove that the amount of inorganic arsenic in excess of the default level
presented an exposure to an average consumer below the statutory warning threshold. (For example, a company whose white rice contains 90 ppb could still defend against a Proposition 65 claim by proving that the 10 ppb not considered naturally occurring is exempt because an exposure of only 10 ppb from rice as consumed by a typical person is still below the statutory warning threshold.)

While OEHHA’s current proposal has no direct application beyond unprocessed rice, it may affect how the exemption is applied to processed foods that contain rice as an ingredient. Perhaps more importantly, the methodology OEHHA used in establishing the default naturally occurring levels for inorganic arsenic in rice may play a role in the agency or courts establishing other naturally occurring levels for other chemicals in other foods, such as for lead or cadmium.

Next Steps

OEHHA is accepting public comments on its proposed regulation for arsenic in rice until September 7, 2017, and it will schedule a public hearing if a request is made by August 23, 2017. It may begin developing naturally occurring levels for other chemicals and other foods as soon as next year.

Morrison & Foerster LLP is the leading law firm representing businesses in matters concerning Prop 65 and has played an active role in rulemaking proceedings and litigated cases involving Prop 65’s naturally occurring exemption. For more information on this proposed Prop 65 regulatory change and what it means for your business, contact: prop65@mofo.com.

Lois Miyashiro, an environmental analyst, in the San Francisco office assisted in the preparation of this client alert.