

Prop. 65 Clearinghouse – Freshmen Orientation: Key Legal Decisions that Shape Prop. 65

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Monsanto Company v. Office of Environmental Health Hazard Assessment (2018) (1)



- ◆ Monsanto challenged state's listing of glyphosate as a substance known to cause cancer based on IARC monograph
- ◆ IARC found glyphosate - Group 2A (probable human carcinogen)
- ◆ Chemicals listed under Prop 65 if:
 - ◆ Labor Code Mechanism – Labor Code § 6382, **or**
 - ◆ Opinion of state's qualified experts, **or**
 - ◆ Authoritative body identifies as causing cancer, **or**
 - ◆ Agency of the state or federal government requires it to be labeled or identified as causing cancer

(Health & Safety Code § 25249.8)

Monsanto Company v. Office of Environmental Health Hazard Assessment (2018) (2)



- ◆ Monsanto - improper for a foreign entity to determine what chemicals are “known to the state of California to cause cancer” when they are not accountable to Californians
- ◆ OEHHA - Californians had already decided the state should not be the sole entity to identify potential carcinogens
- ◆ Trial court and Court of Appeal agreed with OEHHA:
 - ◇ Listing mechanisms ensure list always includes, “at minimum”, substances identified by Labor Code mechanism
 - ◇ Broad listing mechanisms that can effectively exclude state review of the decision. Listed even if there are conflicts

People ex rel. v. Tri-Union Seafoods, LLC (2009)(1)



- ◆ Case dealt with trace levels of methylmercury in canned tuna that was not labeled with Prop 65 warnings
- ◆ Trial court found:
 - ◇ Prop 65 was preempted in this case by federal law
 - ◇ The amount of methylmercury did not rise to label triggering level
 - ◇ Virtually all methylmercury is naturally occurring and does not count toward threshold exposure
- ◆ Human consumption of food is not an “exposure” “to the extent the person responsible for the exposure can show that the chemical is naturally occurring in the food.” (27 CCR § 25501).

People ex rel. v. Tri-Union Seafoods, LLC (2009)(2)



- ◆ “Naturally occurring” if: natural constituent or present solely as a result of absorption or accumulation which is naturally present in the environment; not due to any known human activity; manufacturer uses GMP to reduce to lowest level feasible.
- ◆ Appeals court upheld the trial court ruling based only on substantial evidence that methylmercury is naturally occurring in canned tuna
 - ◇ Not a product of human activity (i.e., pollution)
- ◆ Deep sea hydrothermal vents are the source of methylmercury in tuna
- ◆ Increase in atmospheric mercury since the industrial revolution - but no change in methylmercury levels in fish

Environmental Law Foundation v. Beech-Nut Nutrition Corp. (2015) (1)



- ◆ Case concerned lead in baby food
- ◆ Trial court ruled that Beech-Nut (and others) had no duty to warn because average consumer's anticipated rate of exposure fell below regulatory threshold
- ◆ Safe harbor for reproductive toxin ("Maximum Allowable Dose Level"):
 - ◆ No Observable Effect Level ("NOEL") - max dose level at which chemical has no observable repro effect
 - ◆ MADL = NOEL divided by 1000
 - ◆ OEHHA has determined for lead – 0.5 µg/day
 - ◆ Burden on defendant

(Health & Safety Code § 25249.10(c)).

Environmental Law Foundation v. Beech-Nut Nutrition Corp. (2015) (2)



- ◆ Appeals Court affirmed:
 - ◇ Averaging lead concentration across lots was appropriate
 - ◇ Ruled that averaging exposure over time was acceptable to determine exposure relative to MADL
 - ◇ Level of exposure = level in question X reasonably anticipated rate of exposure
 - ◇ Level of exposure based in part on the “pattern and duration of exposure relevant to the reproductive effect...” (27 CCR § 25821(b))
 - Averaging single-day lead exposure over several days when there was an 8-week “window of susceptibility” to lead effects and the products in question were eaten no more than four times per month
 - $0.5 \mu\text{g}/\text{day} \times 14 \text{ days} = 7 \mu\text{g}$ max over two weeks

Thank You

Any questions?

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