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8 **BEFORE THE OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT**
9 **CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY**

10 In the Matter of)
11 PROPOSED NEW SECTIONS 25506 AND) **COMMENTS ON PROPOSED**
12 25507: EXPOSURES TO HUMAN AND) **REGULATION**
13 PLANT NUTRIENTS IN HUMAN FOOD)
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Introduction

These comments respond on behalf of various GT clients to OEHHA’s public notices dated November 3 and 20, 2008. OEHHA’s desire to avoid requiring Proposition 65 warnings on healthy foods is commendable. Unfortunately, the proposed regulation would not accomplish OEHHA’s goals. The proposed regulation would not protect the public health or California’s food producers. The proposed regulation provides an affirmative defense, which will still require food producers to use warnings to avoid expensive, high-risk litigation. Worse, it proposes an affirmative defense that is likely to be challenged because it exceeds OEHHA’s statutory authority.

Instead of creating an affirmative defense that will not protect consumers or agriculture, OEHHA should acknowledge that boron and manganese do not belong on the Proposition 65 list because they are not dangerous.

The public notice dated November 3, 2008, notes that boron and manganese may in future be considered for listing. That would be a mistake. Both boron and manganese are nutrients required for both human and plant health –indeed, strong evidence indicates that the *absence* of sufficient boron or manganese in pre-natal diets impairs fetal development. For human beings, the primary source of boron and manganese is from a healthy diet high in fresh fruits and vegetables. OEHHA has ample authority to exempt nutrients from listing to accomplish the purposes of Proposition 65. In contrast, the proposed regulation appears to contradict the statutory thousand-fold-factor for “exposures” to listed reproductive toxins under Health and Safety Code section 25249.10(c).

Factual Background

Boron occurs naturally in soil, forming about 0.0008% of the earth’s crust and 0.0005% of surface- and seawater.

Boron is essential for plant growth, and crops deplete boron from soil as they grow. Boron must be replenished to prevent boron deficiency in crops. It is usually added as a soil amendment or by foliar application. Perennial crops such as grapes, olives, and tree fruits commonly need added boron for proper growth. Annual crops also require boron. Cotton, sugar

1 beets, alfalfa and canola can be destroyed by boron deficiency if they are grown without boron
2 amendments in Central Valley soil.

3 In humans at all stages of life, including development in utero, boron promotes bone
4 growth, regulates metabolic function and insulin production, and allows for proper brain
5 function. It may also play a role in gene expression and in blood coagulation. It does not
6 accumulate in tissues, is rapidly excreted in urine, and in healthy people its blood
7 concentrations fall within a very narrow range.

8 Foods account for more than 90% of human exposure to boron. Fruits, vegetables, nuts
9 and legumes are particularly high in boron. Thus the highest exposure to boron comes in the
10 foods that are most nutritionally valuable and least abundant in the American diet. And boron
11 itself appears to play an important part in the nutritional value of those foods. That is why it
12 would be harmful to place warnings on foods high in boron. Boron warnings would undermine
13 public health.

14 **Affirmative Defenses Cannot Prevent Warnings On Healthy Foods.**

15 Unfortunately the proposed regulation would not prevent warnings on healthy foods.
16 The proposed warning exemption would apply only when the defendant "can show" that the
17 substance is naturally occurring or that the "anticipated level of exposure from consumption of
18 a food" is less than some number OEHHA has not yet determined. For plant nutrients, the
19 defendant must also show that the nutrient was added to soil "in an amount necessary for
20 healthy plant development." The defendant bears the burden of proving these highly technical,
21 disputed facts in court, at trial. That is, the proposed regulation creates an affirmative defense
22 for food producers.

23 When the outcome of litigation depends on an affirmative defense, the cost of litigation
24 becomes prohibitive. To state a cause of action, bounty-hunters need only allege that a listed
25 substance is present in food. Defendants must marshal the team of scientific experts --plant
26 pathologists, chemists, nutritionists, agronomists, soil scientists-- to defend the decisions made
27 by the farmers who grew the food. This may be impossible to do, since most fruits and
28 vegetables are sold as commodities, not traceable to a particular grower. Where a bounty-

1 hunter chooses to sue based on allegations of boron in a bottle of prune juice, the defendant
2 cannot trace the prunes back to a particular field, or even to a particular county. Without
3 knowing where the prunes were grown, the defendant cannot present evidence about the
4 amount of boron added to the soil. Even where the location of the crop is known --for example,
5 should a bounty hunter choose to sue one of the Capay Valley's many organic family farms--
6 the defendant's burden is unbearable because plants take up micronutrients based upon delicate
7 and sometimes unknown balances between their needs and the availability of the nutrient in the
8 particular soil. Soil amendments are expensive, and farmers have no incentive to add more
9 than is necessary to the soil. But that doesn't stop a plaintiff from debating whether the
10 farmer's choices were really "necessary" for health plant growth. This factual dispute prevents
11 summary adjudication of the defense and requires a lengthy and expensive trial--throughout
12 which the plaintiff wages a press war accusing the defendant of "poisoning" consumers.

13 Unsurprisingly, therefore, Proposition 65 trials are rare. Most defendants settle rather
14 than risk the prohibitive fees and uncertainty of a Proposition 65 trial. Where a listed chemical
15 is present, a growing number of businesses decide to place warnings on their products even
16 where they have valid affirmative defenses --just to avoid litigation. Just as grocery-store fish
17 counters now carry Proposition 65 warnings despite the naturally-occurring regulation, fruits
18 and vegetables are unprotected by this draft regulation.

19 **The Draft Regulation Does Not Protect Agriculture**

20 Proposition 65's warning requirement is not the only threat to the public health if boron
21 or manganese is listed. It is important to the public health, not only to avoid warnings on
22 nutritious fruits, vegetables and legumes, but also to grow those food crops in California so that
23 they can be eaten by local consumers. Those crops cannot grow unless they can take up
24 adequate boron from the soil. When boron is depleted from the soil, farmers must replenish it.
25 The draft regulation attempts to protect nutrients in food from the warning requirement, but it
26 does not address the need to add nutrients to soil.

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1 Proposition 65 prohibits discharges and releases of listed chemicals “onto or into land”
2 where they may contact drinking water. If plant nutrients are listed under Proposition 65,
3 Californian farmers would be vulnerable to litigation under the discharge prohibition for using
4 fertilizers and soil amendments that contain those nutrients. The use of listed nutrients in soil
5 amendments should not be subjected to litigation under the discharge prohibition. The draft
6 regulation makes no attempt to prevent such attacks on California agriculture.

7 **The Draft Regulation Exceeds OEHHA’s Authority.**

8 Where an exemption is invalid, of course, it is no exemption at all. The draft regulation
9 would set specific levels for listed chemicals, below which no warning is required. Where the
10 listing is based on reproductive effects, those regulatory levels will be higher than one-one-
11 thousandth of the no-observable-effect limit set by the statute. There is no reason to believe
12 that any court will uphold OEHHA’s authority to create a warning exemption for levels greater
13 than those specifically determined by statute. The proposed regulation directly contradicts the
14 thousand-fold safety factor for reproductive toxicants.

15 At the public workshop presented by OEHHA on December 12, 2008, staff referred to
16 the court decision upholding the naturally-occurring exemption as a source of authority for
17 defining the term “exposure.” In that case, *Nicolle-Wagner v. Deukmejian* (1991) 230
18 Cal.App.3d 652, the Court of Appeal for the Second District upheld the regulation based on its
19 interpretation of the ballot arguments for Proposition 65. The court noted “strong language” in
20 the arguments for and against “indicating that naturally occurring substances are not intended
21 to be controlled” by Proposition 65. Rather, the ballot arguments “indicated that only man-
22 made substances would be regulated,” and that the “activity to be controlled” by Proposition 65
23 was “human conduct which results in toxins being *added* to the environment.”

24 The court did not address the thousand-fold safety factor. No court has considered
25 whether OEHHA may contradict the thousand-fold exemption by setting a different numerical
26 limit on warnings for a listed chemical. Regulations inconsistent with the enabling statute are
27 void.

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1 **OEHHA Has Better Alternatives.**

2 Rather than adopting an invalid regulation that contradicts the statutory thousand-fold
3 factor, OEHHA can determine that boron and manganese cannot be “known to cause cancer or
4 birth defects” because our chief exposure to them is in healthy foods that *prevent* cancer and
5 reproductive harm. Such a determination is well within OEHHA’s statutory authority as the
6 lead agency for maintaining the Proposition 65 list, and is more congruent with the
7 considerations of public health that motivate this regulatory proposal. It is also supported by
8 the ballot arguments and public policies that underly Proposition 65.

9 The ballot arguments in favor of Proposition 65 proposed to list “dangerous” chemicals
10 that are “extremely toxic.” Human and plant nutrients are not “dangerous chemicals;” they are
11 the same chemicals that occur naturally in the soil, and must be replenished when depleted
12 from the soil by normal plant growth. Just as cancer and birth defect warnings do not belong
13 on fresh fruits and vegetables, boron and manganese do not belong on a list of “dangerous
14 chemicals” that are “extremely toxic.” OEHHA has the authority to acknowledge that.

15 OEHHA also has the authority to prioritize listing decisions and allocate its resources
16 sensibly. As California’s budget crisis deepens, it is more appropriate than ever for OEHHA to
17 focus on listing decisions for chemicals that may be causing harm. No epidemiological data
18 suggest that anyone, anywhere, has ever been harmed by eating foods high in boron. In
19 contrast, abundant evidence establishes that cancer, birth defects, obesity, diabetes and heart
20 disease would be reduced if more people ate more fruits, vegetables, and legumes --which
21 provide more than 90% of the average person’s exposure to boron. The public-health risks of
22 listing boron are significant: reduced availability of fresh local fruits and vegetables, and
23 paradoxical warnings on the most nutritious and healthy foods. The benefits of listing boron
24 are nil. The most candid and defensible way for OEHHA to respond to these facts is to
25 determine that boron should not be listed. That determination can be an informal determination
26 based on OEHHA’s workload and the public good. Or, it could be adopted as a regulation
27 specific to boron or manganese.

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