

American Herbal Products Association

Statement of Critical Issues for Herbal and Other Dietary Supplements Prepared and submitted by Michael McGuffin, July 3, 2008

1. Dietary supplements are classified under federal law as foods. Thus, the working group should make sure that its focus extends beyond conventional foods to include dietary supplements.
2. Several dietary supplement marketers have been the subjects of at least forty Proposition 65 complaints since 2000. These complaints have been based on purported failure to provide clear and reasonable warnings related to alleged presence of heavy metals. While some of these complaints have identified alleged presence of arsenic, cadmium, or mercury, all have claimed that the identified products contained lead in excess of 0.5 micrograms per day (the Maximum Allowable Dose Level, or MADL, for this chemical), with failure to warn of reproductive toxicity as a basis for the complaints.
3. Several of the companies that were named in the above-cited complaints have settled on terms that include agreements to provide label warnings related to the presence of one or more heavy metal above OEHHA's MADLs. These warning statements warn of "birth defects or other reproductive harm." It should be noted that a primary concern about lead consumption at levels just above the MADL may be on developmental harm in very young children, and that birth defects and other reproductive harm may not, in fact, be associated with very consumption of very low levels of lead.
4. The above-described experiences of several herbal dietary supplement marketers may be useful in the discussions and decisions of the working group. Heavy metals are ubiquitous in the environment, both as naturally occurring chemicals and due to human activities. Many plants, including those used in dietary supplements and also those used in conventional foods, absorb heavy metals from the soil in which they are grown. The lead content of the daily serving size of some conventional foods exceeds 0.5 micrograms, the MADL for this chemical, and such foods could therefore be subject to the Proposition 65 requirement to provide clear and reasonable warnings.