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Via E-Mail To: *kristin.stauffacher@calepa.ca.gov*

Dear Kristi:

In response to your request, the Grocery Manufacturers Association (GMA) has the following comments on the legislative proposals presented by the Governor's office in the course of the recent stakeholder discussions on possible reform of Proposition 65.

As we have noted, at this point in the process, it is difficult for GMA to evaluate the proposed legislative package apart from the regulatory changes that OEHHA proposes to undertake as well as other possible actions by the Administration. We therefore look forward to reviewing the Administration's next draft, which we understand will encompass all the areas discussed to date, and to understanding the Administration's plans for other actions.

Below we address each of the three major areas in which the Governor's office has circulated proposals. Our overall view is that the proposals under consideration to date do not fulfill the expectations set out by the Governor's initial press release on reform of Proposition 65 litigation, and we would encourage you to revisit the goals of this process as you prepare the next draft of legislative language for stakeholder review. Furthermore, we have also included several concepts for your consideration that more directly address the unique concerns and needs of the food industry.

Litigation Reform

In general, GMA believes the proposals under consideration for litigation reform are relatively modest and make common sense. But none of these will significantly deter the worst abuses of Proposition 65: cases that proceed to litigation without scientific merit, and/or are in conflict with, if not contravention of, carefully considered decisions by responsible policymakers that promote public health, nutrition, and confidence in the food supply. Proposition 65 was not intended to be used in this way, and we would like to work with the Administration to ensure a more substantial and formalized role for food policymakers in deterring these abuses and developing policy solutions. We understood that to be among the goals of the Governor's initiative, but it is not addressed by the current proposals.

Although we do not believe that any of the legislative proposals under consideration will reduce litigation against the food and beverage industry, we do think some will be beneficial on the margins, and particularly in enabling the Attorney General and the courts to better police the least scrupulous of the private enforcers and reduce the financial incentives for fomenting unnecessary litigation. The most important of these is the proposal to specifically authorize a court to approve the substantive portions of a settlement, and review the appropriateness of the proposed attorneys fee award for the lawyers who are supposedly acting in the public interest. This proposal would provide great benefit to the public. We note that this has long been the process for approval of class action settlements in both state and federal court, so this change is hardly groundbreaking and indeed brings Proposition 65 into line with procedures in other litigation with the ostensible goal of consumer protection.

Warnings

GMA has serious concerns with the initial proposal to increase the minimum requirements of a "clear and reasonable" warning under Proposition 65. For more than 25 years, those elements have been set forth in the lead agency's regulations and have provided businesses with flexibility to tailor their warnings -- both in message and method -- to the multitude of specific situations covered by Proposition 65. Many businesses and indeed entire industries have designed warning programs with these minimum elements in mind. This flexibility is particularly important in the food and beverage industry, where there are hundreds of thousands of points of purchase in California, from large grocery stores to hot dog stands, and from vending machines to internet shipments, and where there are regulatory and public health considerations involved in fashioning appropriate warnings.

Public and private enforcers already have remedies to address warnings they believe are not "clear and reasonable": they are entitled to sue, and many have done so. Decisions in these cases inform industry, as do settlements, particularly when approved by courts. Furthermore, guidance from the Attorney General's office in the context of settlement approval hearings also has been a useful reference point for businesses fashioning warnings. In short, the existing threat of litigation is a significant incentive for businesses either to use an approved safe harbor warning or to fashion a warning that satisfies the longstanding minimum requirements set forth in regulations. GMA does not believe the warning system is in need of reform where more elements are added to define "clear and reasonable." Especially with 25 years of experience and a variety of warnings and programs designed around it.

That said, we understand that some would like to see more information provided with warnings in some contexts, and we suggest that OEHHA look to revise and expand the current system of "safe harbor" warnings in order to address such concerns, rather than add a number of new elements for all warnings. As an example, providing information on how to avoid an exposure is not necessary and lacks common sense for a food product, since it is obvious that one will avoid the exposure by not eating the food product.

The safe harbor warnings were designed to provide businesses with greater certainty and a means to avoid costly litigation, while also providing consumers with uniform and recognizable information rather than multiple forms of warnings and differing information about the same types of exposures. In some cases, the safe harbor warning specified in

the regulations provides more information than a business would arguably need to provide, or in a manner that may be more onerous than a business may prefer or be required to use, but that is the tradeoff for the increased protection from litigation. So long as the lead agency promulgates safe harbors that are reasonable and practical, they can provide additional information, and more prominently, than the minimum standard, and businesses may well use the safe harbors. This has been the experience with the alcoholic beverage safe harbor warnings.

GMA endorses this framework, which has a long history, and GMA will continue to participate in efforts by the lead agency to update safe harbor warnings and expand their scope to other specific situations. As is well known, GMA and others in the food, beverage, and agricultural communities worked toward a safe harbor program for food warnings several years ago but were unable to come to agreement on a program that all segments of the industry found reasonable and practical. While we are hesitant to invest the substantial resources necessary to revive that process and see it to conclusion, we are open to doing so should there be other developments on Proposition 65 reform that increase the likelihood of success of such an effort. One such area can generally be described as "when you warn." By first addressing the unique issues of food in these areas (e.g., listing process, NSRLs, MADLs, naturally occurring, cooking exemptions), we believe the discussion of "how you warn" becomes substantially simplified because the number of potential products is greatly reduced. Most importantly, reform in this area would help avoid the regulatory contradiction where the very foods we encourage people to eat could be required to have warnings.

Finally, GMA wholeheartedly endorses the Governor's proposal to grandfather warning messages and methods that have been approved by the Attorney General, the lead agency, or a court. As the Governor's office must recognize, it will serve no one to require wholesale changes in warnings that have been officially approved and in use. We also believe that these warnings should be grandfathered not only as to the companies who obtained the official approval, but also as to companies providing the warnings voluntarily for similar types of alleged exposures.

Uncertainty Factor

GMA has long criticized the 1000-fold uncertainty factor for reproductive toxicants set by Proposition 65, which we believe is plainly contrary to sound science and results in unnecessary and indeed misleading warnings. We understand that this factor was rationalized by Proposition 65's original proponents as being necessary in light of the early stage of development of the field of reproductive toxicity assessment. But there is widespread agreement among scientists that such a prescribed factor, and at 1,000 times, for all chemicals, is not justified today. Indeed, this Proposition 65 standard is out of step with almost every other risk-based standard.

The Governor's proposal would allow the lead agency to reduce this uncertainty factor to 100 times if there are human studies on the chemical that support such a reduction. We support providing the agency with greater discretion in this area since it will, by law, have to be based on evidence and standards of comparable scientific validity. In fact, we cannot see why the lead agency's ability to consider more recent, relevant, and comprehensive science should be limited to human studies as opposed to, for example, science concerning the ways in which chemicals create the reproductive effect. Nor do we see why the uncertainty factor should be arbitrarily constrained at 100 times.

The Proposition 65 regulations do not constrain litigants or courts from considering better science -- and they should not -- so there is no reason why the lead agency should itself be constrained to set standards that ignore better science and can lead to unnecessary warnings or product reformulations, with concomitant monetary and non-monetary costs.

We understand that we must be mindful of making amendments that "further the purposes" of Proposition 65, but we believe that providing the lead agency with this additional discretion will do so for the following reasons:

- Proposition 65 clearly endorses the concept of using the best science available to the state's experts.
- Proposition 65 recognizes that it burdens businesses, and so it is not outside its purposes to lessen those burdens when the goal of informing consumers is maintained.
- The government is constrained by the First Amendment from forcing false or misleading speech by regulated entities, and the combination of the 1000-fold uncertainty factor and the warning requirement can lead to warnings that are misleading.
- California case law has recognized, in the context of upholding the naturally occurring regulation, that reducing overwarning is consistent with the purposes of Proposition 65, and allowing the lead agency to apply a lower uncertainty factor, when indeed there is lower uncertainty, would reduce overwarning.
- It surely furthers the purposes of Proposition 65 to bring it into line with other, more modern risk-based laws and scientific consensus.

GMA also understands the current proposal as being intended to eliminate the ability of an alleged violator to prove a higher warning limit (i.e., Maximum Allowable Dose Level or MADL) where the lead agency has set a safe harbor level for a reproductive toxicant using a 100-fold uncertainty factor. We do not see any reason to deviate from the historical structure of Proposition 65 in the statute and the regulations, in which the lead agency sets default levels. Those safe harbor levels provide businesses with certainty, to the extent they are able to or choose to comply with them. But they also allow courts to consider higher levels that are supported by sound science.

The reason is that the lead agency lacks the resources to adopt a safe harbor level for every chemical and often lacks the resources to update safe harbor levels as new science becomes known. Furthermore, because the law is exclusively enforced through litigation, the courts should not be constrained from reviewing all available evidence at the time the dispute arises. And if the lead agency is setting determiniative levels, rather than default levels, there is a far greater likelihood that regulated businesses will challenge OEHHA's determinations in court rather than simply prepare their scientific evidence in the event they are sued in an enforcement action (where the lead agency will not be a party).

GMA therefore supports the Governor's proposal to allow the lead agency to use a lower uncertainty factor in setting the safe harbor level for a chemical when warranted by the current science, and does not believe that it is appropriate to limit either the types of data or the uncertainty factor that the agency may apply below the current 1000-fold factor.

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In closing, we again want to emphasize that there is little, if anything, in the current proposals that addresses the major challenges that Proposition 65, in its current form, presents to the food and beverage industry. It would not affect the wholesale listing of chemicals, the setting of warning trigger levels that are much lower than any other regulatory standard, the conflicts presented by warning of insignificant risks for safe and nutritious foods and beverages, and the difficulty inherent in using the current naturally occurring and cooking provisions of the Proposition 65 regulations. Furthermore, the current proposals threaten to disrupt long-settled approaches to the implementation of Proposition 65 -- through the use of safe-harbor warnings and safe-harbor levels -- that have proved workable in practice and provided at least a modicum of certainty to those trying to do business in California.

We hope you can therefore understand our reluctance with respect to the current package under consideration. Nevertheless, GMA and its members will continue to be active participants in this process of developing a package of administrative, regulatory, and legislative proposals that is balanced and furthers the purposes of Proposition 65, lessens the burdens on the food and beverage industry, and promotes the interests of our consumers.

Sincerely,

John Hewitt
Western Region Director, State Affairs