March 8, 2024

The Honorable Joseline A. Pena-Melnyk
Chair, Health and Government Operations Committee
Maryland General Assembly
Room 241
House Office Building
Annapolis, Maryland 21401

Dear Chair Pena-Melnyk:

I write to thank you and the entire Committee for your courtesy and kindness in accepting my testimony in opposition to HB 1098, a bill to ban four food additives in Maryland.

The National Confectioners Association's primary objection to the bill exists because, as heavily regulated food manufacturers with national distribution networks, we must follow one unified federal standard operated by the FDA. Different laws in all 50 states would severely disrupt the economy and increase the cost of food, and it would do nothing to improve food safety or consumer confidence.

The Committee noted California's new law and its impact on the food and beverage economy due to that state's size and scale. We too acknowledge that reality. However, states (California, Maryland, or others) making food safety determinations by political acclimation, rather than by a rigorous, science-based approach will severely undermine the entire reason for existence of the FDA. California has banned four additives; Maryland is considering the same. Other states around the country are debating bills to ban more than a dozen food additives, and if HB 1098 passes, year after year your Committee will almost certainly be asked to expand Maryland's list.

The FDA, at the direction of President Biden, is doubling down on the intensity of its food additive reviews and is shifting resources internally to make that reality possible. NCA is fully supportive of this initiative, but HB 1098 is a direct signal to the Biden Administration that they are not up to the task, which as noted above, would be severely detrimental to the unified, federal food safety system that is the envy of the rest of the world.

Just last week, the FDA updated its list of additives currently under the agency's review to include propylparaben and potassium bromate, joining Red No. 3 and other additives under scientific review. The FDA is now actively reviewing all the additives in HB 1098 and has already taken steps to remove one of those additives (brominated vegetable oil) from the food supply. This timely, responsive review of these additives is direct evidence of the FDA's system working. Rather than pass HB 1098, a more lasting and impactful solution would be for Maryland to support the Biden Administration's efforts, rather than undermining them.

I did also want to take this opportunity to provide more information on past studies of Red No. 3, which you and other delegates raised during the hearing. No regulatory and scientific authoritative body in the world has identified safety concerns with the use of Red No. 3 in food, including FDA, the European Food Safety Authority (EFSA), and the United Nations Food and Agriculture Organization and World Health Organization Joint Expert Committee on Food Additives (JECFA). Although there are broader uses permitted in the U.S., the EU has determined that Red No. 3 is safe in food.

You noted that FDA found Red No. 3 to be carcinogenic in 1990 and denied listing it as a color in cosmetics ("FDA 1990 Denial"), but it is critical to note that the science and research on carcinogenesis has evolved over the last 34 years providing a clear basis that Red No. 3 is not genotoxic. As set forth below, studies and expert evaluations show that Red No. 3 is non-genotoxic, operates as a secondary mechanism of carcinogenesis, and the findings on Red No. 3 in only one species of male rats is not relevant to humans.

FDA's 1990 Denial and finding that Red No. 3 is an animal carcinogen was based upon the Agency's inability to determine genotoxicity and industry's inability to show Red No. 3 operates as a secondary mechanism. At that time, FDA concluded that "unresolved issues concerning the genotoxicity of Red No. 3 remain", and the agency had insufficient evidence to show that Red No. 3 operates through a secondary mechanism of carcinogenesis. In cancer risk assessments, as FDA recognizes today, non-genotoxic substances are "not directly DNA reactive but operating through a secondary mechanism," and are "assumed to have a threshold of exposure level below which tumor development is not anticipated and the risk of cancer is negligible." As set forth below, Red No. 3 is well-established to be non-genotoxic, and this inherent property is justification for further consideration of the science of Red No. 3's secondary mechanism of carcinogenesis.

Mechanistic studies examining rat thyroid carcinogenesis have been published on a wide range of chemical compounds, including Red No. 3 prior to and since the 1990 FDA delisting of Red No. 3. For example, in a 1987 Color Additives Review Panel, convened by FDA to consider evidence of Red No. 3 as a secondary carcinogen, concluded "there is no reason to suspect that this toxicity [from results of an International Research and Development Corporation study] results from direct interaction [Red No. 3] with the DNA" and that there is "no evidence for a direct mechanism for [Red No. 3]." In other words, in 1987, expert evaluations concluded that Red No. 3 was non-genotoxic.

Between 1988 and 1998, more than 600 papers on thyroid function, regulation, carcinogenesis, and epidemiology appeared in the literature. Additional support that Red No. 3 is non genotoxic developed during this time as the fields of toxicology and carcinogenesis advanced to better interpret the results on secondary mechanism of carcinogenesis in animals including rodents and to adequately determine the applicability of these findings to humans. A variety of recent expert evaluations by the Joint FAO/WHO Expert Committee on Food Additives ("JECFA"), European Food Safety Authority ("EFSA"), and other scientific bodies concluded that Red No. 3 did not show any genotoxic activity and is a non-genotoxic compound based on in vivo and in vitro mutagenicity studies.

Expert evaluations by the International Agency for Research on Cancer ("IARC") and several studies demonstrating chemically induced thyroid carcinogenesis through secondary mechanism which is also applicable to Red No. 3 lead to the following conclusions:

- the male rat is not considered a suitable model for potential effects on the thyroid in humans; and;
- thyroid follicular tumors in male rats are secondary to hormonal effects and have species-specific sensitivity.

Studies and expert scientific evaluations have concluded that chemically induced tumors in rodent test animals via a secondary mechanism of carcinogenesis allows the observed tumors to be considered of limited or no relevance to humans.

On a personal note, I want to acknowledge the grace with which you conducted the portion of the hearing on opioid addiction and treatment initiatives. As a staff member in the U.S. Senate staff member earlier in my career I worked intimately on the opioid crisis, and I commend you for allowing your committee room to be a safe space for Marylanders to share their personal stories and discuss lasting solutions to this epidemic.

Sincerely,

Brian M. McKeon

CC: Vice Chair Cullison; Delegate Alston