

NORTH CAROLINA STATE UNIVERSITY

MEMORANDUM

RE: REGULATING AGAINST FOOD ADDITIVES IN SCHOOLS INDEPENDENT OF FDA
GUIDANCE (OR LACK THEREOF) MODELED OFF THE CALIFORNIA SCHOOL FOOD
SAFETY ACT OF 2024

FROM: KAYLA MALONEY

TO: THE NORTH CAROLINA GENERAL ASSEMBLY

DATE: 25 NOVEMBER 2024

INTRODUCTION

This memorandum will demonstrate that the level of federal oversight on regulation of food additives is insufficient considering their recently-discovered relation to neurobehavioral issues in children, and as such states like North Carolina should model California by passing regulations against food additives without waiting for direction from the FDA. California has mandated through their California School Food Safety Act (AB-2316) that all school districts, county superintendents, or K-12 charter schools provide “nutritionally adequate”¹ breakfast and lunch entirely devoid of Blue 1, Blue 2, Green 3, Red 40, Yellow 5, and Yellow 6.² The North Carolina state legislature can and should pass a similar mandate, requiring that all school districts prohibit these additives in foods provided at school.

The nature of regulation as it applies to food and its ingredients has been disaggregated in the United States. As it currently stands, the Food and Drug Administration (FDA)’s policy allows the food industry to regulate itself when adding ingredients to products.³

THE 1958 FOOD ADDITIVES AMENDMENT’S GRAS PROVISION

In 1958, the Food Additives Amendment was added to the Federal Food, Drug, and Cosmetic Act of 1938. While this 1958 amendment has been updated a few times to include and amend a list of ingredients “generally safe” for consumption, the FDA still operates to this day under its relaxed structure and language, which is exactly what allows the food industry to essentially regulate itself. Under this Amendment, “any substance intentionally added to food is a food additive and is subject to pre-market approval by FDA unless the use of the substance is generally recognized as safe (GRAS).” This is known as the GRAS provision.⁴

Under the GRAS provision, food industries can determine an ingredient or additive to be “generally safe” and add it to their foods without the approval of the FDA. Since few to no studies have been conducted on the thousands of ingredients added to American foods since the provision was put in place,⁵ they have been consumed for decades without data on their potential for harm. In recent years, as neurobehavioral problems proliferate in children, groups independent of the FDA have been conducting studies on various food additives, and finding links between them.

Due to the lack of guidance from the FDA and the amount of time it takes to update the GRAS list, it is up to states to act on the most up-to-date research on food additives and regulate them as they are connected to physical and mental health issues.

FDA’S NEO-MANAGERIALIST APPROACH TO REGULATION HINDERS FOOD SAFETY

In Public Administration, it has become increasingly common for governments to follow a less rigid structure, trading command and control in favor of an independently guided

¹ AB 2316: California School Food Safety Act (§1-6)

² AB 2316: California School Food Safety Act, Legislative Council’s Digest

³ Harrison, *How a Legal Loophole Allows Unsafe Ingredients in U.S. Foods*

⁴ FDA: *FDA’s Approach to the GRAS Provision: A History of Processes*

⁵ Harrison, *How a Legal Loophole Allows Unsafe Ingredients in U.S. Foods*

approach. This is true in Western Europe, according to Taylor and Millar, and also for many areas of Public Administration in the United States: “Disaggregation, interdependence and interaction between policy networks are now to the fore. In essence, it represents a shift away from rigid bureaucratic structures of the interventionist state where the emphasis was upon rules and regulations, to new forms of service delivery.”⁶

When it comes to food regulation in the United States, this disaggregation has led to a neo-managerialist approach⁷ which has allowed harmful additives to be sold in foods for too many decades. Neo-managerialism here is explained as removing regulatory responsibilities from the public sector in favor of allowing the private market to dictate what is necessary in policy.⁸ In the case of food safety regulation, one can imagine how market forces might motivate the food industry to prioritize making food appealing over the health and safety of American consumers. That is why a neo-managerialist approach to public administration is not feasible in the world of food safety,⁹ and yet, neo-managerialism explains the FDA’s approach to food regulation (and its current relationship with the food industry, which is dominated by market forces).¹⁰

The American method of regulating the food industry in general is far behind the European Union’s. In terms of regulating food safety, Hyde et. al. explains, “Central to the EU regime is the requirement that a food safety management system based on Hazard Analysis and Critical Control Points (HACCP) be implemented at most stages of farm-to-fork food production, and it is strongly encouraged in all other areas, including primary production. To date, in the United States, there has not been a formal requirement to implement a food safety management system akin to the EU mandate, but such systems are encouraged, particularly by trade associations.”¹¹

In terms of ingredients, once an additive is GRAS according to the food industry or the FDA, it is allowed in food with little to no further testing or regulation. It is also important to note that most of the additives in American foods today have either been tested by actors in the food industry itself (who do not have a vested interest in prioritizing customer health over market efficiency), or by the FDA decades ago before any of the neurobehavioral problems seen in children today were prominent.¹² Now that studies are coming out linking certain additives with hyperactivity and other neurobehavioral problems, the urgency to review them has been rapidly growing. But, the FDA is far behind other countries, and now states.

⁶ Taylor and Millar, *The Politics of Food Regulation and Reform in Ireland*, (588)

⁷ Durant and Legge, “*Wicked Problems*” (313)

⁸ Durant and Legge, “*Wicked Problems*” (313)

⁹ While food safety is distinct from food additives and food ingredients, they are each discussed as one for the purposes of this memorandum. The latter two are a subset of the former, making them relevant to the discussion of the regulatory arena’s current shortcomings. Moreover, in light of numerous studies demonstrating a link between certain food ingredients and neurobehavioral problems in children, this is now a question of food safety as far as public administration is concerned.

¹⁰ Harrison, *How a Legal Loophole Allows Unsafe Ingredients in U.S. Foods*

¹¹ Hyde, et. al., *One HACCP, Two Approaches* (963)

¹² OEHA, *Report Links Synthetic Food Dyes to Hyperactivity and Other Neurobehavioral Effects in Children*

In March, the FDA announced that it plans to review 21 food additives, several of which are already banned overseas and one of which appears in California's School Food Safety Act.¹³ Jennifer Pomeranz, first author of *Regulation of Added Substances in the Food Supply by the Food and Drug Administration Human Foods Program*,¹⁴ said "This is a stark example of the FDA's regulatory gap. We're seeing states starting to act to fill the regulatory void left by the FDA's inaction over substances increasingly associated with harm."¹⁵ In other words, the delay on the part of the FDA shows the importance of states acting on their own merit to implement policy that, it is already widely agreed-upon, will benefit children's health.

CALIFORNIA HAS TAKEN RESEARCH AND POLICY INTO ITS OWN HANDS

According to Melanie Benesh, Environmental Working Group's vice president of Government Affairs, "The FDA continues to fail to keep us safe from harmful chemicals in our food. In the absence of federal leadership, states like California are stepping up to ensure our safety from toxic chemicals in snacks and other food we and our families enjoy."¹⁶

Due to the lack of urgency on the part of the FDA, the California Assembly has taken research and responsive policy into its own hands. In the wake of increasing amounts of data suggesting that synthetic food dyes (many of which are still recognized by the FDA and the food industry as generally safe) are linked to neurobehavioral problems (like Attention Deficit/Hyperactivity Disorder, or ADHD) in children, the California legislature requested a health effects assessment from the Office of Environmental Health Hazard Assessment (OEHHA) in 2019.¹⁷

OEHHA first opened their data collection to the people of California, allowing them to provide scientific information on the negative impacts of synthetic food dyes. A symposium was then held in September of that year where researchers and experts held formal discussions on the matter. A draft report subject to peer review was released the following year, and the final report was released in April of 2021. It demonstrated a clear link between the six food additives and ADHD (and other neurobehavioral issues in children).¹⁸ So, in August 2024, the California Assembly passed the California School Food Safety Act (AB 2316). This legislation occurred mere months after the FDA announced that they would be reviewing their list of additives (let it be emphasized that this process began years before the FDA decided to review their list of additives, and that process has not yet begun). This shows how far ahead of the FDA California's government is.

According to the Press Release accompanying the publishing of OEHHA's 2021 Report, "OEHHA's mission is to protect and enhance the health of Californians and our state's environment through scientific evaluations that inform, support, and guide regulatory and other

¹³ Harrison, *How a Legal Loophole Allows Unsafe Ingredients in U.S. Foods*

¹⁴ Pomeranz, et. al., *Regulation of Added Substances in the Food Supply by the FDA Human Foods Program*

¹⁵ Harrison, *How a Legal Loophole Allows Unsafe Ingredients in U.S. Foods*

¹⁶ Myers, *California Leads the Nation with First Ban on Six Harmful Food Dyes in School Food*

¹⁷ OEHHA, *Report Links Synthetic Food Dyes to Hyperactivity and Other Neurobehavioral Effects in Children*

¹⁸ OEHHA, *Report Links Synthetic Food Dyes to Hyperactivity and Other Neurobehavioral Effects in Children*

actions.”¹⁹ California is setting a new trend to “fill the regulatory void”²⁰ left by the FDA’s hands-off approach to regulating food safety and food ingredients, and North Carolina ought to follow suit.

NORTH CAROLINA SHOULD IMPLEMENT POLICY THAT MODELS CALIFORNIA’S

North Carolina currently has no additional policies in place regulating food additives beyond the 1940 North Carolina Food, Drug, and Cosmetic Act.²¹ Now that California has broken the class ceiling, it is time for other states to follow their example. Since North Carolina’s rate of hyperactivity diagnoses in children is in the top 25 percent of states nationwide,²² it is of utmost importance and urgency for North Carolina to implement policies of its own.

The rate of children diagnosed with ADHD in California (about six percent) is not only half of the rate in North Carolina (over 12 percent), but it is also the lowest rate in the nation (as of 2019) according to Statista.²³ The national average is about 11.4 percent according to the CDC (as of 2022).²⁴ To put this in perspective, the state with the lowest ADHD diagnosis rate in the country happens to be the one taking action.

Like California, North Carolina can use preexisting (and increasing) data and studies linking these additives to hyperactivity to proactively regulate them without waiting for the results of the FDA’s pending review. While it would take time to draft policy which expands beyond the school district, North Carolina can capitalize on the example set by California to at least regulate food safety in schools.

The North Carolina state legislature would simply need to mandate that school districts provide meals devoid of at least the six additives that California acknowledges relate to neurobehavioral problems in students. As demonstrated in North Carolina’s 2023 state budget,²⁵ Education is a big priority in North Carolina. If the state legislature passes a bill like AB 2316 prior to the release of the 2025 state budget, the state can allocate the necessary funds to cover any costs incurred by school districts to implement the policy.

CONCLUSION

North Carolina ought to implement a food safety bill like California’s, mandating school districts to provide food devoid of the aforementioned food additives, in order to start combatting the already-too-high (and still growing) rate of hyperactivity in its children. The data that shows a link between food dyes and neurobehavioral issues exists independent of FDA guidance, and waiting for its pending review would be unnecessary and, at this point, harmful. It is time to encourage transferring the responsibility of food safety regulation from the private market to the states.

¹⁹ OEHHA, *Report Links Synthetic Food Dyes to Hyperactivity and Other Neurobehavioral Effects in Children*

²⁰ Harrison, *How a Legal Loophole Allows Unsafe Ingredients in U.S. Foods*

²¹ North Carolina State Legislature, *Food, Drug, and Cosmetic Act* (Article 12)

²² Statista, *Percentage of Children in the United States Diagnosed with (ADHD) as of 2016-2019, by State*

²³ Statista, *Percentage of Children in the United States Diagnosed with (ADHD) as of 2016-2019, by State*

²⁴ CDC, *Data and Statistics on ADHD*

²⁵ North Carolina 2023 State Budget

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