FDA Food Chemicals Transition Memo

*Actions Requested for First 100 Days:*

- Restore direct line-authority to a Deputy Commissioner over the Center for Food Safety and Nutrition and include food responsibilities of the Office of Regulatory Affairs.
- Close the "generally recognized as safe" or "GRAS" loophole that industry uses to self-certify safety of new additives in secret.
- Begin the process of modernizing the FDA's scientific approach to assess safety of chemicals in food.
- Direct staff to make a decision on pending petitions addressing cumulative effects of chemicals added to food, banning *ortho*-phthalates in food contact articles, and banning lead as an additive to food handling equipment.
- Resolve two lawsuits regarding perchlorate in food contact articles and a flawed rule that allows industry to make safety decisions for "generally recognized as safe" or GRAS substances in secret without notifying the FDA.
- Revoke existing approvals for per- and poly-fluoroalkyl substances (PFAS) in food packaging and food service ware.
- Create an office to reassess the safety of existing chemical additives to food to complement the Office of Food Additive Safety which is focused on new chemical safety reviews. Seek funding to support the office.

*Introduction*

There are thousands of chemicals added to the foods we eat every day. Some of these chemicals are directly added. Others are used in packaging materials and processing equipment and migrate into our food. Still others are contaminants coming in from the environment.

Many of these chemicals were reviewed for safety by the FDA decades ago but have not been re-assessed, even when scientists have identified new health concerns. Others have never been assessed by the FDA for safety because of legal loopholes. The FDA and industry have failed to consider the cumulative effect of these chemicals in the diet.

Many chemicals commonly found in food are linked to serious health concerns but remain legal to use, putting consumers at risk. For example:

- The synthetic food dye FD&C Red No. 3 was determined to cause cancer by the FDA itself in 1990 yet it is still allowed in food. The synthetic food dyes known

as FD&C Red 40, Yellow 5, and Yellow 6 can cause or worsen attention deficit hyperactivity disorder and other behavioral problems.[1]

- Per- and polyfluoroalkyl substances, or PFAS, are chemicals used in food service ware and packaging, and are linked to reproductive and developmental harms, reduced effectiveness of vaccines, and increased risk of cancer.[2]
- *Ortho*-phthalates are another group of chemicals used in food processing equipment and packaging that migrate into food and that are linked with reproductive, neurodevelopmental and hormone disruption.[3]
- Perchlorate is used in food packaging and processing equipment as an anti-static agent. It disrupts the thyroid gland's normal function and reduces production of thyroid hormone needed for healthy fetal and child brain development.[4]
- Potassium bromate is used as a flour improver in some bread and is linked to cancer.[5]
- Butylated hydroxyanisole (BHA) is a preservative used in cereals, chewing gum, potato chips and vegetable oil that is linked to cancer.[6]

The law prohibits the use of food additives found to induce cancer "in man or animals." However, as seen in many of the examples above, the FDA has allowed many of these substances to remain in food.

In order to protect public health, the FDA must act to re-assess existing food chemicals, strengthen its approach to evaluating new food chemicals, close loopholes that companies exploit to use new additives without FDA review, and modernize its scientific approach to evaluating safety.

The undersigned organizations have developed top-line recommendations we urge the FDA to take without delay. Taking these initial steps would go a long way toward addressing the dangerous gaps in food safety connected to toxic chemicals in food and food packaging. We would welcome the opportunity to discuss any of the below items in greater detail and offer more specific, detailed next steps. We appreciate the opportunity to provide this input.

*Restore direct line-authority to a Deputy Commissioner over CFSAN and include food responsibilities of the Office of Regulatory Affairs.*

Under the Obama Administration, the FDA had a Deputy Commissioner for Foods who was responsible for the Center for Food Safety and Nutrition (CFSAN) and Center for Veterinary Medicine (CVM). He provided essential policy leadership on an issue that can take a secondary

[1] https://oehha.ca.gov/media/downloads/risk-assessment/report/fooddyesassessmentdraft082820.pdf
[2] https://www.atsdr.cdc.gov/toxprofiles/tp.asp?id=1117&tid=237
[3] https://www.regulations.gov/document?D=FDA-2016-F-1253-0001
[4] https://www.regulations.gov/document?D=EPA-HQ-OW-2016-0438-0019
[5] https://oehha.ca.gov/proposition-65/chemicals/potassium-bromate
[6] https://ntp.niehs.nih.gov/ntp/roc/content/profiles//butylatedhydroxyanisole.pdf

role to drugs, biologics and medical devices at the agency. Especially with the pandemic demanding attention on vaccines and drugs, the FDA needs to restore that responsibility to the Deputy Commissioner and include food-related compliance responsibilities in the Office of Regulatory Affairs.

The Deputy Commissioner would be charged with: 1) renovating the process of reassessing the safety of ingredients in food; 2) developing an assessment framework for innovative technologies and ingredients; 3) closing the loophole for generally recognized as safe substances in foods and supplements; 4) installing and overseeing a process to update the science used to assess substances in food; 5) articulating clear, public priorities for CFSAN work regarding the safety of food ingredients; and 6) recommending to Congress budgetary and statutory changes as needed.

*Close the GRAS loophole that industry uses to self-certify safety of new additives in secret.*

For decades, food chemical manufacturers have taken advantage of a loophole in the Food Additives Amendment of 1958 for substances that are generally recognized as safe, or "GRAS." The law required that new food chemicals go through a rigorous premarket safety review process but allowed chemical substances to circumvent safety review if they are "GRAS." The exemption was designed for common ingredients with established safety records like vinegar and flour. However, the GRAS loophole is now utilized far more frequently than the FDA's premarket safety review process. The GRAS loophole is even being used for novel substances, based on industry's own safety reviews, in secret without notice to the agency or the public.

Although some companies opt to notify the FDA about their GRAS determinations and seek a "no questions" response letter, this notification is voluntary. If the FDA expresses concern about a notified chemical, companies can withdraw their notifications and proceed in secret. This process leaves consumers in the dark about what is in their food and undermines the FDA's role in protecting the safety of our food supply and public health.

For nearly twenty years, the voluntary GRAS notification program was operating under a proposed rule the FDA issued in 1997. The FDA finalized the rule in 2016 after the Center for Food Safety filed a lawsuit for unreasonable delay. The Environmental Defense Fund and the Center for Food Safety are currently in active litigation against the FDA over the weak rule. The FDA should immediately amend the GRAS rule to prohibit secret GRAS determinations, prohibit novel ingredients from being marketed as "GRAS," clarify that chemicals that cause cancer are not GRAS, and create rules prohibiting conflicts of interest.

At a minimum, the FDA should require agency notice and opportunity to review GRAS determinations. This should apply to all new ingredients as well as ingredients that have already

been secretly self-determined to be GRAS. The FDA should consider any ingredients that have not been the subject of a GRAS notice to be adulterated.

*Update FDA science.*

The FDA's approach to the science of evaluating the safety of food chemicals is greatly outdated and fails to meet the statutory requirements of the 1958 Food Additives Amendment. The law requires FDA to determine whether food additives are safe, which implementing regulations define to mean "a reasonable certainty of no harm." The law requires the FDA to look at three factors when making a safety determination, including 1) probable consumption of the additive, 2) the cumulative effect of the additive, taking into account any chemically and pharmacologically related substances; and 3) additional safety factors. Although this is a statutory requirement, an Environmental Defense Fund review of public records found that the FDA routinely fails to take into consideration cumulative effects when assessing an additive's safety. In September 2020, several health and environmental groups filed a citizen petition to request that the FDA define key terms and consider these cumulative effects in safety reviews. The FDA's science has also not kept up with best scientific practices for chemical risk assessment. Its outdated toxicology guidelines largely ignore health effects like developmental and reproductive harms and immune system effects, except at very high exposure levels, and other low dose effects, like hormone disruption. The FDA must take steps to immediately update and modernize the science it uses to authorize and review chemicals.

While the FDA is updating its scientific approach to food chemicals, the FDA should take into consideration the findings from a forthcoming GAO report on indirect food additives. The FDA should also seek outside expertise and validation from the National Academy of Sciences. These external reviews should be used to strengthen and revise the FDA's scientific approach as needed, but the FDA should not wait until external review is complete to begin assessing chemicals, updating regulations, or modernizing its methodologies.

*Grant pending petitions and resolve pending lawsuits.*

There are several food additive petitions and citizen petitions pending before the FDA related to food chemical safety concerns. These petitions include a food additive petition to ban ortho-phthalates for food contact use (FDA-2016-F-1253-0002), and a citizen petition addressing cumulative effects from food chemicals (FDA-2020-P-2003-0001). A petition banning lead from food handling equipment was also recently filed. The FDA should prioritize responding to these petitions. There is also an ongoing lawsuit related to the FDA's denial of a food additive petition to ban perchlorate as a food contact substance. The FDA should resolve the lawsuit by agreeing to reconsider the petition in light of the issues and data raised and do so by a specific date.

*Revoke existing approvals for per- and poly-fluorinated alkyl substances (PFAS) in food packaging and food service ware.*

The EPA estimates that for most people outside of highly contaminated communities, the predominant source of exposure to the toxic fluorinated chemicals known as PFAS is from food. Food is contaminated with PFAS through several pathways. Crops can be contaminated when grown in contaminated soils, fertilized with contaminated sewage sludge, or irrigated with PFAS-contaminated water. Meat and milk can also become contaminated with PFAS when animals consume contaminated feed and water. PFAS chemicals can also migrate from food packaging and service ware into food, particularly hot and greasy foods like popcorn, pizza and hamburgers.

Grease-resistant food packaging and service ware is a major but non-essential use of PFAS chemicals. The FDA should revoke approval of granted food additive petitions for PFAS in food contact materials and rescind authorized food contact notifications for PFAS in food contact materials. The FDA should also clarify that use of PFAS in food contact materials is not "generally recognized as safe."

The FDA should also expand its analytical method for PFAS in food, which was created in October 2019. The validated method covers 16 kinds of PFAS in four products: bread, fish, lettuce, and milk. Most of the 16 PFAS measured are PFAS that are environmental contaminants, not PFAS intentionally used in food packaging. The FDA should expand its method or develop new methods that can test for more PFAS, including those PFAS used in food packaging and service ware. The FDA should also consider a method that can test for PFAS in additional kinds of food.

*Create an office to reassess the safety of existing chemical additives to food to complement the Office of Food Additive Safety which is focused on new chemical safety reviews. Seek funding to support the office.*

Food chemicals are currently authorized in three ways: through food and color additive petitions, through the GRAS loophole, or through the food contact notification system (for chemicals used in food packaging and food processing and handling equipment). None of these processes requires periodic post-market safety reviews of these substances and the FDA rarely revisits a chemical's safety, even after it has been on the market for decades. When it does, the Office of Food Additive Safety is typically responding to public demands or legal action that all-too-easily take a backseat to review of new chemicals notices filed by industry. As a result, unsafe additives remain in use.

Given the enormous advances in environmental health sciences regarding chemicals over the last two decades, the FDA should systematically re-review chemicals for safety. The FDA can expedite this review process by reviewing classes of chemicals like PFAS and phthalates. To make this work possible, the FDA should create a new office dedicated to food chemical reassessment and seek Congressional appropriations to support that office's work.

Modernizing the FDA's approach to the science of food safety reviews and science will take funding. Unlike many of FDA's regulatory programs, food chemical companies do not pay user fees. As such, the FDA relies on Congressional appropriations to fund this work. The FDA must seek additional financing from Congress so that it is able to quickly update its science, rigorously assess risks from new substances, and re-review chemicals used in food—those that were approved as food additives and through food contact notifications, as well as any GRAS substances—including based on considerations of cumulative effects.

Signed,

Breast Cancer Prevention Partners
Center for Environmental Health
Center for Food Safety
Consumer Reports
Defend Our Health
Earthjustice
Endocrine Society
Environmental Defense Fund
Environmental Working Group
Green Science Policy Institute
Healthy Babies Bright Futures
National Women's Health Network
Natural Resources Defense Council
Safer Chemicals Healthy Families
Sierra Club
Union of Concerned Scientists