BHT, ADA, and food chemicals: When 'safe' isn't forever

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> For decades, the regulatory framework for food chemicals has largely operated on a pre-market approval basis, with less emphasis on systematic post-market re-evaluation. This approach left many substances, approved years ago, without modern scrutiny. The FDA has now formalized a program to address this gap, initiating a long-awaited reassessment of two widely used food chemicals: butylated hydroxytoluene (BHT) and adenosine deaminase (ADA).

KEY TAKEAWAYS

- The Pivot: The FDA established a formal post-market assessment program for food chemicals, moving beyond initial pre-market approvals.
- The Data: BHT and ADA are the first two substances targeted for re-evaluation under the new framework, based on current scientific understanding.
- The Action: Clinicians should be aware of the FDA's renewed focus on food chemical safety, as future reassessments may impact dietary recommendations and patient counseling.

The U.S. Food and Drug Administration (FDA) announced the finalization of its post-market assessment program for food chemicals, a significant policy shift designed to ensure the ongoing safety of substances added to the food supply. This program establishes a structured approach for the agency to systematically re-evaluate chemicals based on the latest scientific data and consumption patterns, moving beyond the initial approval process. The agency has immediately put this program into action, targeting butylated hydroxytoluene (BHT) and adenosine deaminase (ADA) for comprehensive re-evaluation.

BHT, a synthetic antioxidant, has been used for decades as a food additive to prevent rancidity in fats and oils, extending the shelf life of various processed foods, including cereals, chewing gum, and snack foods. ADA, an enzyme, finds application in food processing, particularly in the production of bread and other baked goods, where it improves dough elasticity and volume. Both substances have generally recognized as safe (GRAS) status or prior sanction, meaning they entered the food supply under older regulatory pathways without the extensive pre-market review now required for new additives. The FDA's decision to prioritize these two chemicals reflects evolving scientific understanding and public interest in their long-term effects.

The New Framework for Food Chemical Safety

The newly finalized program outlines a multi-step process for post-market assessment. First, the FDA will identify food chemicals for re-evaluation based on several criteria, including new scientific information, changes in consumption

levels, or emerging public health concerns. This initial screening will involve a review of published literature, adverse event reports, and data from other regulatory bodies worldwide. The agency will then conduct a comprehensive safety assessment, which may include soliciting data from manufacturers, commissioning new research, and convening expert panels. This systematic review aims to provide a current risk profile for each substance, considering both potential benefits and harms.

The program also includes provisions for public engagement, allowing stakeholders, including industry, consumer groups, and scientific experts, to submit data and comments throughout the review process. This transparency is intended to foster confidence in the FDA's decisions and ensure a broad range of perspectives are considered. The agency emphasized that this is not a punitive measure but a proactive step to maintain the highest standards of food safety. The FDA's authority to conduct these reassessments stems from its mandate under the Federal Food, Drug, and Cosmetic Act, which requires food additives to be safe under their intended conditions of use.

Reassessing BHT and ADA

The reassessment of BHT will focus on its potential endocrine-disrupting properties and its metabolism within the human body. Early studies, some dating back decades, raised questions about BHT's effects on liver function and its potential as a carcinogen in high doses in animal models. But other research has suggested antioxidant benefits. The FDA will now weigh this conflicting evidence with modern toxicological methods and current exposure estimates. This re-evaluation is critical because dietary exposure to BHT has been widespread for many years, making even subtle effects on human health a significant public health concern. The agency will consider both direct consumption and indirect exposure through food packaging materials.

For ADA, the re-evaluation will primarily examine its enzymatic activity and any potential for immunogenicity or allergenicity, particularly given its protein nature. While ADA is generally considered safe for its intended use in dough conditioning, the FDA will explore whether its widespread application could lead to unforeseen sensitivities or interactions in susceptible populations. The agency will also review the purity specifications for commercially available ADA preparations and assess whether any impurities could pose a risk. This reassessment aligns with a broader trend in food safety to scrutinize enzymes and processing aids with the same rigor applied to direct food additives. Clinicians should note that the Oxford Handbook of Gastroenterology & Hepatology provides essential guidance on dietary components and their impact on gut health, which may become increasingly relevant as these reassessments unfold.

The open-ended nature of the initial GRAS designations for many food chemicals is an obvious caveat. Many substances received this status based on scientific consensus or common use before the advent of sophisticated analytical techniques and a deeper understanding of molecular toxicology. The current program aims to bring these older designations up to modern scientific standards. The FDA has not set a definitive timeline for the completion of the BHT and ADA reassessments, indicating that the process will be thorough and data-driven rather than rushed. The outcomes could range from reaffirmation of current use, to revised usage limits, or even removal from the GRAS list if significant safety concerns emerge. This program represents a proactive regulatory stance, acknowledging that scientific understanding evolves and that food safety is an ongoing responsibility.

CLINICAL IMPLICATIONS

The FDA's new post-market assessment program for food chemicals signals a necessary evolution in regulatory oversight. For too long, substances grandfathered into the food supply have escaped the rigorous scrutiny applied to newer additives. This formalization means clinicians may soon have clearer, evidence-based guidance on the long-term safety of common dietary components.

The immediate reassessment of BHT and ADA highlights the agency's intent to address chemicals with a long history of use but with emerging scientific questions. While neither substance currently carries widespread clinical warnings, a revised safety profile could influence dietary advice, particularly for patients with chronic conditions or those with heightened sensitivities. GPs and specialists will need to stay informed as these evaluations progress.

This initiative also puts the onus on food manufacturers to provide comprehensive, up-to-date safety data for their ingredients. The era of relying solely on decades-old assessments is ending. Expect to see industry respond with more robust toxicological studies and potentially reformulations, which could ultimately benefit patient health by reducing exposure to substances with uncertain long-term effects.