

POLICY PRIORITIES





DRUGS AND MEDICAL DEVICES

Goal: Ensure that people with alpha-gal syndrome (AGS) have access to safe drugs and medical devices

- **Priority:** Label drugs and select medical devices that contain alpha-gal.
- **Priority:** Determine the risks associated with drugs and medical products that contain or potentially contain alpha-gal.
- **Priority:** Accelerate the development and approval of alpha-gal-friendly drug and medical device alternatives e.g. heparin and bioprosthetic heart valves made from alpha-gal knockout pigs.



FOOD

Goal: Ensure that people affected by alpha-gal syndrome (AGS) have equitable access to safe food options

- **Priority:** Formally recognize alpha-gal as a major food allergen.



EDUCATION

Goal: Advance awareness and understanding of alpha-gal syndrome (AGS) within key groups

- **Priority:** Raise awareness among decision-makers about the needs and policy priorities of the alpha-gal syndrome community.
- **Priority:** Educate healthcare providers (HCP) to improve timely diagnosis and management of alpha-gal syndrome (AGS).
- **Priority:** Include information about AGS in community outreach efforts regarding tick-borne disease prevention.
- **Priority:** Raise awareness about alpha-gal syndrome among disproportionately impacted, underserved, and underdiagnosed communities.



RESEARCH AND EPIDEMIOLOGY

Goal: Advance alpha-gal syndrome (AGS) research and surveillance

- **Priority:** Improve surveillance of alpha-gal syndrome to aid public health decision-making.
- **Priority:** Deepen our understanding of the immunological mechanisms and natural history of alpha-gal syndrome.
- **Priority:** Develop, improve, and evaluate tools and protocols for the diagnosis of alpha-gal syndrome.
- **Priority:** Evaluate and optimize existing treatment protocols and therapies and develop new protocols, therapies, and other tools for the management of AGS.
- **Priority:** Determine the economic burden of AGS in high-incidence areas.



PREVENTION

Goal: Reduce the incidence of alpha-gal syndrome

- **Priority:** Address white-tailed deer overpopulation.
- **Priority:** Accelerate the development, improvement, and evaluation of tick control and tick bite prevention tools and strategies effective against lone star ticks.
- **Priority:** Ensure that states, tribes, and territories disproportionately impacted by AGS have sufficient support and technical assistance to implement tick bite prevention programs.
- **Priority:** Understand and address the impact of climate change on lone star tick populations and alpha-gal syndrome.

GOAL: Ensure that people with alpha-gal syndrome (AGS) have access to safe drugs and medical devices



Priority: Label drugs and select medical devices that contain alpha-gal

- **Action:** Amend the Federal Food, Drug, and Cosmetic Act to require the label of a drug intended for human use to identify each ingredient in such drug that is derived, directly or indirectly, from a mammal (excluding non-catarrhine primates and mammals genetically modified not to express alpha-gal), red algae (Rhodophyta), or other known sources of alpha-gal.
- **Action:** Require the label of select medical devices intended for human use that have the potential to expose patients to alpha-gal to identify each ingredient in such drug that is derived, directly or indirectly, from a mammal (excluding non-catarrhine primates and mammals genetically modified not to express alpha-gal), red algae (Rhodophyta), or other known sources of alpha-gal. Examples of such devices include heparin flushes, extracellular matrix, bioprosthetic heart valves, bandages with mammal-derived adhesive, and collagen sutures.
- **Action:** Require that biologics, vaccines, and other medical drugs and devices made in non-catarrhine primate*, mammal-derived cell lines, including chimeric human/mammal cell lines, be tested for alpha-gal above a standardized, detectable level. Additionally, require that this information be disclosed publicly, including on the labels of these products.
- **Action:** Allow labeling of drugs and dietary supplements to include an accurate and truthful certification symbol denoting that the product(s) are free of animal-derived ingredients.
- **Action:** In the absence of the above legislation, as a stop-gap measure:
 - Mandate that the FDA create and maintain a publicly funded and accessible database with information about the alpha-gal content of drugs and other medical products or fund a private entity to do this.
 - Mandate that the FDA create a dedicated, drug information service to assist providers and patients with information about drug safety related to alpha-gal syndrome or fund a private entity to do this.



Priority: Accelerate the development and approval of alpha-gal-friendly drug and medical device alternatives e.g. heparin and bioprosthetic heart valves made from alpha-gal knockout pigs

- **Action:** Secure federal funding for research to characterize and measure the presence of alpha-gal in drugs, select medical devices that have the potential to expose patients to alpha-gal, and mammal-derived ingredients commonly used in their production.
- **Action:** Secure federal funding to quantify risks associated with the use of products that contain or potentially contain alpha-gal.
- **Action:** Secure federal funding for the development of tools and protocols for use in the characterization and measurement of the presence of alpha-gal in drugs, select medical devices that have the potential to expose patients to alpha-gal, and mammal-derived ingredients commonly used in their production.



Priority: Determine the risks associated with drugs and medical products that contain or potentially contain alpha-gal

- **Action:** Secure federal funding to support the development of drugs and medical devices made from GalSafe or other alpha-gal knockout mammals, such as heparin, collagen, gelatin, dermis, heart valves and other implants.
- **Action:** Expedite the approval process of GalSafe medical products.

FOCUS AREA: FOOD

GOAL: Ensure that people affected by alpha-gal syndrome (AGS) have equitable access to safe food options



Priority: Formally recognize alpha-gal as a major food allergen

- **Action:** Amend Section 201(qq)(1) of the FD&C Act (21 U.S.C. 321(qq)(1)) to add galactose- α -1,3-galactose (alpha-gal) to the definition of “major food allergen.” For the purposes of this amendment, “alpha-gal” should include ingredients derived from non-catarrhine primate mammals, red algae in the Gigartinales order, and other known sources of alpha-gal. Mammal-derived ingredients for which there is compelling data documenting no alpha-gal above an established, detectable limit shall be exempt, e.g. ingredients made from GalSafe pigs.

FOCUS AREA: EDUCATION

GOAL: Advance awareness and understanding of alpha-gal syndrome (AGS) within key groups



Priority: Raise awareness among decision-makers about the needs and policy priorities of the alpha-gal syndrome community

- **Action:** Educate elected officials and representatives of key government agencies about AGS and the policy changes needed to support the AGS patient community.



Priority: Educate healthcare providers (HCP) to improve timely diagnosis and management of alpha-gal syndrome (AGS)

- **Action:** Secure federal funding for the design, implementation, and dissemination of educational strategies and tools for training healthcare providers about AGS, with a focus on the most impacted states and localities.
- **Action:** Secure federal funding for the design, implementation, and dissemination of educational strategies and tools for first responders about AGS, with a focus on the most impacted states and localities.



Priority: Include information about AGS in community outreach efforts regarding tick-borne disease prevention

- **Action:** Include AGS in both federally and state-produced, funded, and supported tick-borne disease prevention community outreach strategies, programs, and tools.



Priority: Raise awareness about alpha-gal syndrome among disproportionately impacted, underserved, and underdiagnosed populations

- **Action:** Secure federal funding for the design, implementation, and dissemination of educational strategies and tools for raising awareness about both AGS and tick bite prevention among disproportionately impacted, underserved, and underdiagnosed populations.

GOAL: Advance alpha-gal syndrome (AGS) research and surveillance



Priority: Improve surveillance of alpha-gal syndrome to aid public health decision-making

- **Action:** Work with the CDC, CSTE, and federal, state, and local governments to make AGS a mandatory reportable tick-borne condition.
- **Action:** Secure federal funding for states and localities to expand AGS surveillance capacity, including funding to modernize data collection.
- **Action:** Secure federal funding for additional surveillance work, including a patient registry and studies of the prevalence of a-Gal IgE sensitization in the general population.



Priority: Deepen our understanding of the immunological mechanisms and natural history of alpha-gal syndrome

- **Action:** Secure federal funding for basic and clinical research on alpha-gal syndrome's molecular and cellular mechanisms and natural history.
- **Action:** Secure federal funding for research on atypical presentations of AGS, including GI and rheumatological phenotypes, AGS complicated by mast cell syndromes, and the relationship between sensitization to alpha-gal and cardiovascular and other non-allergic disease.
- **Action:** Secure federal funding for additional as-of-yet unfulfilled, basic research priorities outlined by AGS experts in the report from the National Institute of Allergy and Infectious Diseases Workshop on Understanding IgE-Mediated Mammalian Meat Allergy.



Priority: Develop, improve, and evaluate tools and protocols for the diagnosis of alpha-gal syndrome

- **Action:** Secure federal funding to:
 - Develop and refine low-cost, low-tech, diagnostic alternatives (including tools and protocols) to the alpha-gal IgE blood test.
 - Develop international, evidence-based guidelines for the diagnosis and management of AGS.
 - Evaluate the efficacy of existing diagnostic tools and protocols, especially those appropriate for use in underserved populations where the alpha-gal IgE is not available.
 - Compare the efficacy of new, lab-developed alpha-gal IgE blood tests to that of the pre-existing Viracor test.



Priority: Evaluate and optimize existing treatment protocols and therapies and develop new protocols, therapies, and other tools for the management of AGS

- **Action:** Secure federal funding for evaluating and optimizing existing therapies and protocols; developing new therapies; and exploring the repurposing of existing therapies for the management of AGS.
- **Action:** Secure federal funding for evaluating the risks and benefits of continued dairy consumption in people with alpha-gal syndrome.



Priority: Determine the economic burden of AGS in high-incidence areas

- **Action:** Secure federal funding to determine the annual economic burden of AGS in high-incidence areas of the United States and its territories.

FOCUS AREA: PREVENTION

GOAL: Reduce the incidence of alpha-gal syndrome



Priority: Address white-tailed deer overpopulation

- **Action:** Require that disease risk, in addition to carrying capacity, be incorporated into federal and state analyses of optimal deer density.
- **Action:** Revise wildlife management strategies to address deer overpopulation in areas with a high prevalence of AGS.



Priority: Accelerate the development, improvement, and evaluation of tick control and tick bite prevention tools and strategies effective against lone star ticks

- **Action:** Secure federal funding for the development, improvement, and evaluation of tick bite prevention tools and strategies effective specifically against lone star ticks, including lone star tick larvae.
- **Action:** Secure federal funding for the development, improvement, and evaluation tools and strategies for the removal of lone star ticks (including larvae), with an emphasis on minimizing the subsequent development of AGS.
- **Action:** Increase flexibility and coordination in the regulatory processes to expedite novel tick control specifically targeting lone star ticks.



Priority: Ensure that states, tribes, and territories disproportionately impacted by AGS have sufficient support and technical assistance to implement tick bite prevention programs

- **Action:** Ensure an equity-centered approach to federal funding and technical assistance for tick bite prevention and control, inclusive of lower-income jurisdictions that are disproportionately affected by AGS.



Priority: Understand and address the impact of climate change on lone star tick populations and alpha-gal syndrome

- **Action:** Secure federal funding to study and address the impacts of changing climate on lone star tick populations and AGS.



ALPHA-GAL ALLIANCE
ACTION FUND

Alpha-gal Alliance Action Fund is a nonprofit that advances policy solutions to improve the lives of people affected by alpha-gal syndrome. Alpha-gal Alliance Action Fund is the advocacy partner of Alpha-gal Alliance.

**5614 Connecticut Ave., NW #114
Washington, DC 20015-2604
U.S.A**

**www.alphagalaction.org
info@alphagalaction.org**

