STATEMENT BY Bryan Witherbee, President and CEO of Agragene, Inc.

Past Breakthroughs and Future Innovations in Crop Production

Tuesday, July 22, 2025

Chairman Thompson Ranking Member Craig and Members of the Committee:

Thank you for the opportunity to testify at today's hearing. My name is Bryan Witherbee and I am President and CEO for Agragene, Inc.

Agragene is an innovative agricultural biotechnology company working to transform how we manage pest species—sustainably, precisely, and without reliance on chemical pesticides. Agragene was fostered in the vibrant St. Louis biotech ecosystem, with early support from BioSTL and BioGenerator, two nationally recognized organizations dedicated to advancing science-driven startups and building next-generation technologies in agriculture, health, and the environment. Agragene is advancing a groundbreaking approach to insect pest control, precision-guided Sterile Insect Technique (pgSIT)**,** to meet the urgent challenges facing growers and regulatory systems today.

Modern agriculture is under increasing stress. Invasive pests, climate-related migration, resistance to pesticides, and environmental concerns are driving the need for safer, more targeted pest control tools. At the same time, outdated U.S. regulatory systems—based on legislation and guidance written decades ago—struggle to accommodate modern biological innovations**.** Our regulators are often constrained by these outdated frameworks, lacking the authority and tools to flexibly evaluate 21st-century technologies, even when they offer far safer and more sustainable alternatives to legacy chemical or genetic products.

Agragene's pgSIT technology represents a modern evolution of the Sterile Insect Technique (SIT)**,** a method used for decades to suppress pest populations like the Mediterranean fruit fly and New World Screwworm. Traditional SIT uses radiation to sterilize insects, but this process often causes broad, unpredictable DNA damage, reducing male fitness and performance in the field.

pgSIT, by contrast, uses modern gene editing tools like CRISPR, to precisely and reliably edit the genes responsible for fertility and female viability, producing sterile males, and only sterile males. These males are healthy, competitive, and self-limiting. When released into the environment, they mate with wild females, leading to population suppression without harming non-target species or leaving behind any residues. pgSIT is species-specific, scalable, and aligned with modern agricultural and ecological priorities.

Agragene's lead application is targeting Spotted Wing Drosophila (SWD), one of the most economically damaging invasive pests in soft fruit crops across North America and Europe. The annual economic impact from SWD in North America alone is around one billion dollars. Existing control options for SWD rely heavily on chemical pesticides, the average age of the most widely

used insecticides by berry growers is 42 years. These insecticides must be applied repeatedly and as a result SWD populations have developed resistance, not to mention that these insecticides can cause collateral harm to beneficial insects. pgSIT offers a breakthrough alternative.

To validate pgSIT SWD technology, university researchers at land-grant institutions in Washington, California, Oregon, Michigan, and Minnesota are currently conducting performance evaluations under controlled conditions. These trials, in partnership with leading entomologists and public-sector scientists, demonstrate strong institutional support for pgSIT's real-world potential as a safe, effective, and sustainable pest control method.

Despite this progress, regulatory uncertainty continues to limit deployment**.** Technologies like pgSIT don't fit neatly within categories defined by outdated laws like FIFRA or the Plant Protection Act. Current agency guidance does not provide regulators with the flexibility they need to evaluate modern gene-edited tools based on their precision, safety profile, or ecological behavior. As a result, innovators face costly delays, inconsistent treatment, and significant barriers to commercialization - even for technologies that outperform conventional methods in every key measure of safety and effectiveness.

Modernizing our regulatory system is not only necessary to bring better tools to growers, but also essential to national preparedness and biosecurity. The U.S. has faced costly, disruptive outbreaks of invasive pests such as *New World Screwworm*, *Mexican Fruit Fly*, and *Mediterranean Fruit Fly*. The next outbreak is inevitable. Without a modern regulatory framework that enables pre-approval and proactive validation of precision biocontrol tools, like pgSIT, we risk being caught unprepared.

To fix this, we must:

- Update federal legislation and agency authority to reflect the realities of 21st-century biology.
- Create science-based, risk-proportionate pathways that recognize the unique properties of biological and gene-edited pest control tools.
- Enhance interagency coordination is absolutely critical to streamline reviews and eliminate duplication.
- Support field validation programs in advance of emergency needs, so safe and effective tools are ready for rapid deployment when threats arise.

Agragene is proud to be part of the U.S. innovation ecosystem working at the intersection of agriculture, public health, and biotechnology. With support from organizations like BioSTL and BioGenerator, and in partnership with leading public researchers, we are demonstrating that sustainable, scalable, and precise pest control is possible. But for these solutions to reach growers and respond to emerging threats, our regulatory system must evolve with the science**.**

Cost and speed to market is absolutely critical to startup and emerging companies. This is truly a matter of survival. Therefore, an efficient, transparent, risk-based system is essential. The USDA, specifically, has made great strides in reforming regulations for certain new technologies. Now is the time and opportunity to expand both scope and applicability of these

changes for other technologies, and for other agencies. A system readily adaptable to new innovative technologies, such as gene-editing and other gene modifications systems, and importantly, not only limited to plants.

The U.S. has the opportunity to lead the world in agricultural innovation—but we must equip our regulatory agencies with the modern tools, guidance, and authorities they need to support that future.