

Life Sciences Caucus Meeting
September 18, 2023
12:00noon
NCSU Plant Sciences Building

Co-chairs:
Senators Newton and Woodard
Representatives White and Reives

Meeting will begin shortly



NCBIO SCIENCE.NET



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Agenda

- Welcoming Remarks by Chairs
- North Carolina Biotechnology Center
 - **Doug Edgeton**, President and CEO
- Biotechnology Innovation Organization
 - **Beth Ellikidis**, Vice President, Agriculture & Environment
 - **Gene Harrington**, Senior Director, State Government Affairs, Agriculture & Environment
- Pairwise
 - **Dan Jenkins**, Vice President, Regulatory and Government Affairs
- Plant Sciences Initiative
 - **Celeste Brogdon**, Director of Strategic Engagement, N.C. Plant Sciences Initiative

North Carolina: A Global Life Sciences Leader

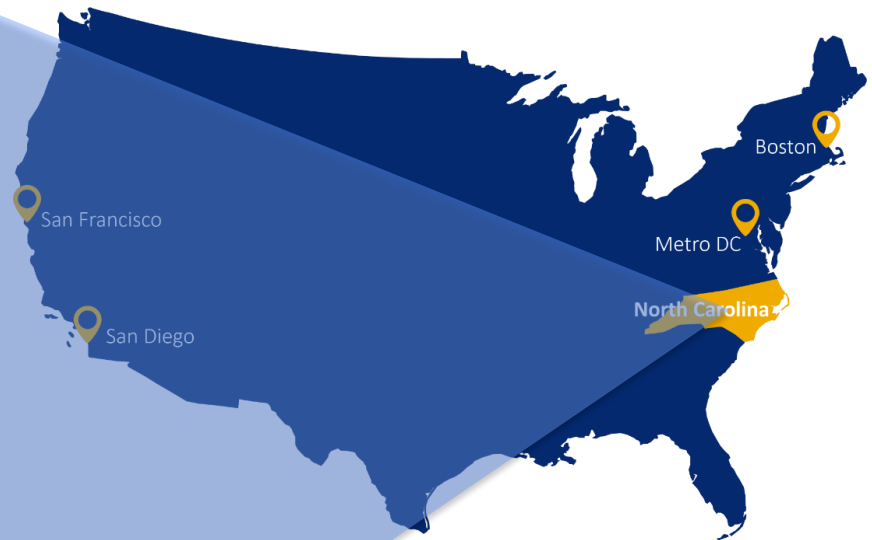
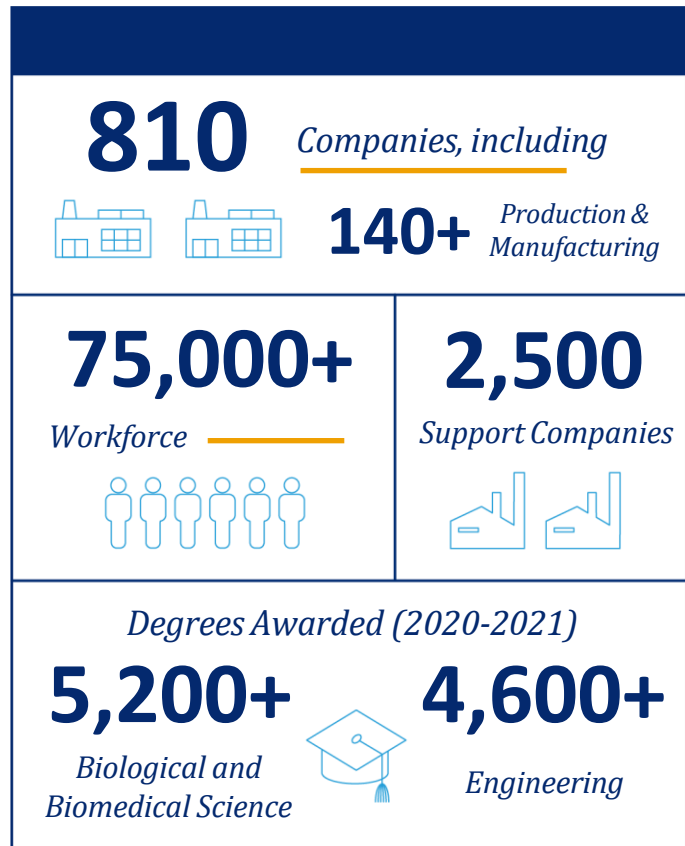


North Carolina Biotechnology Center

Doug Edgeton
President, NCBiotech
Sep. 18, 2023

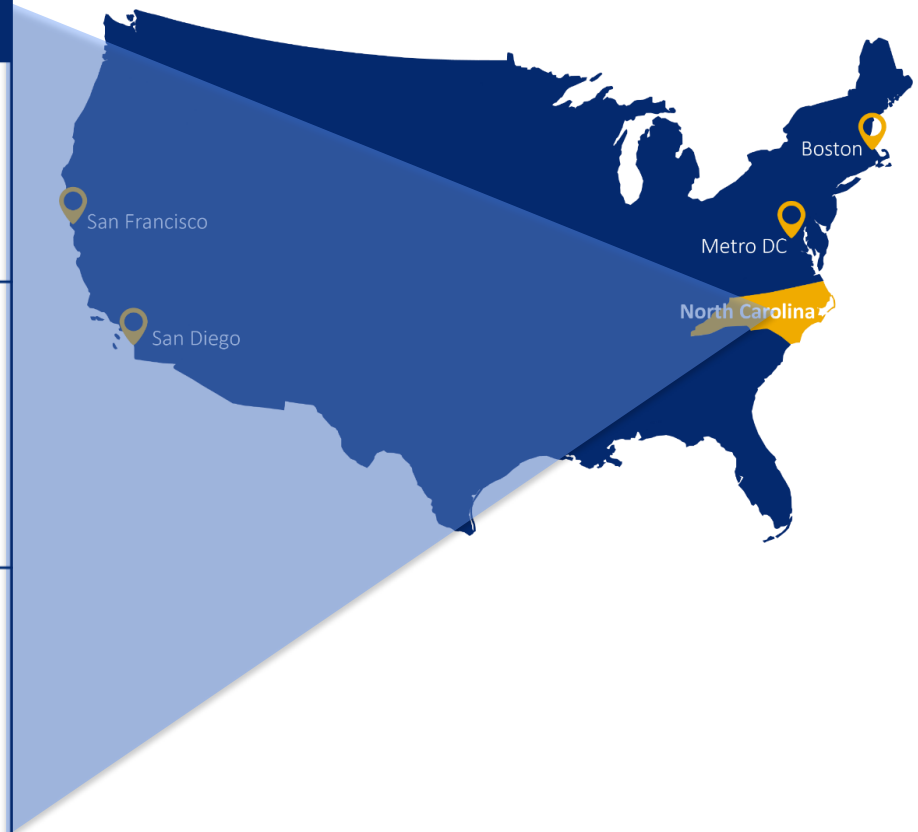
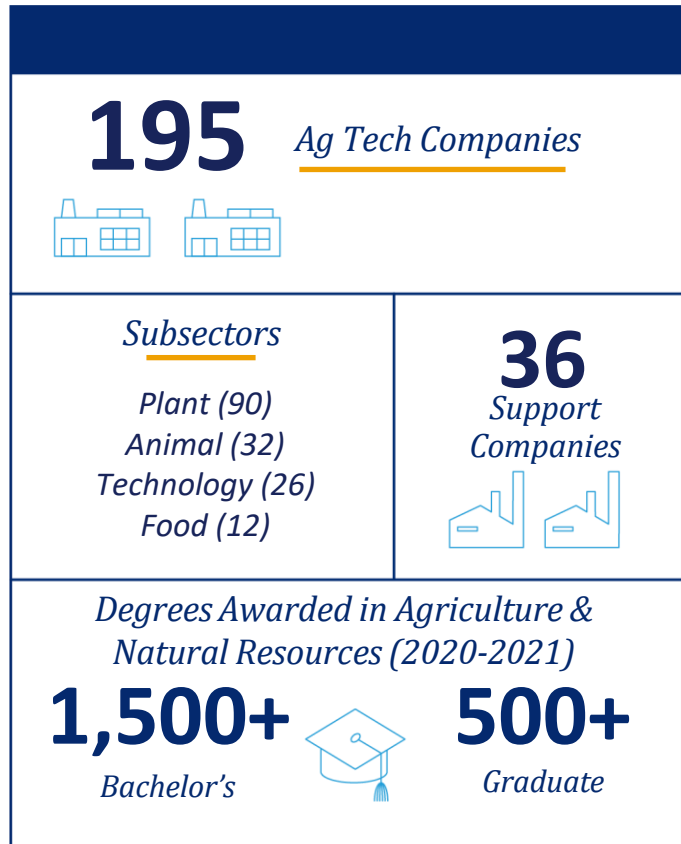
ncbiotech.org

North Carolina's Life Sciences Community



*Top State for Business
2023, 2022*

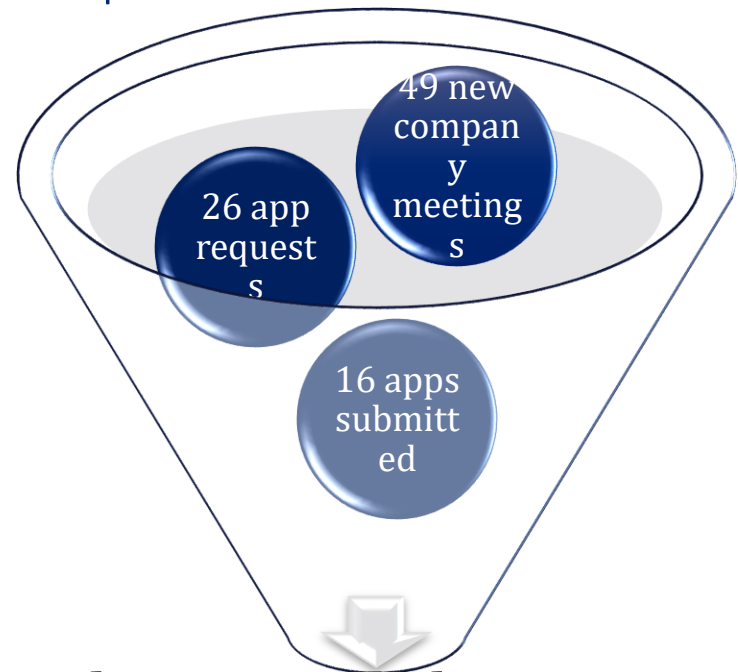
North Carolina's Ag Tech Ecosystem



NCBiotech Ag Tech Loans for Startups

Supporting companies that impact
NC agriculture or agribusiness with
\$500K in both 2022 and 2023

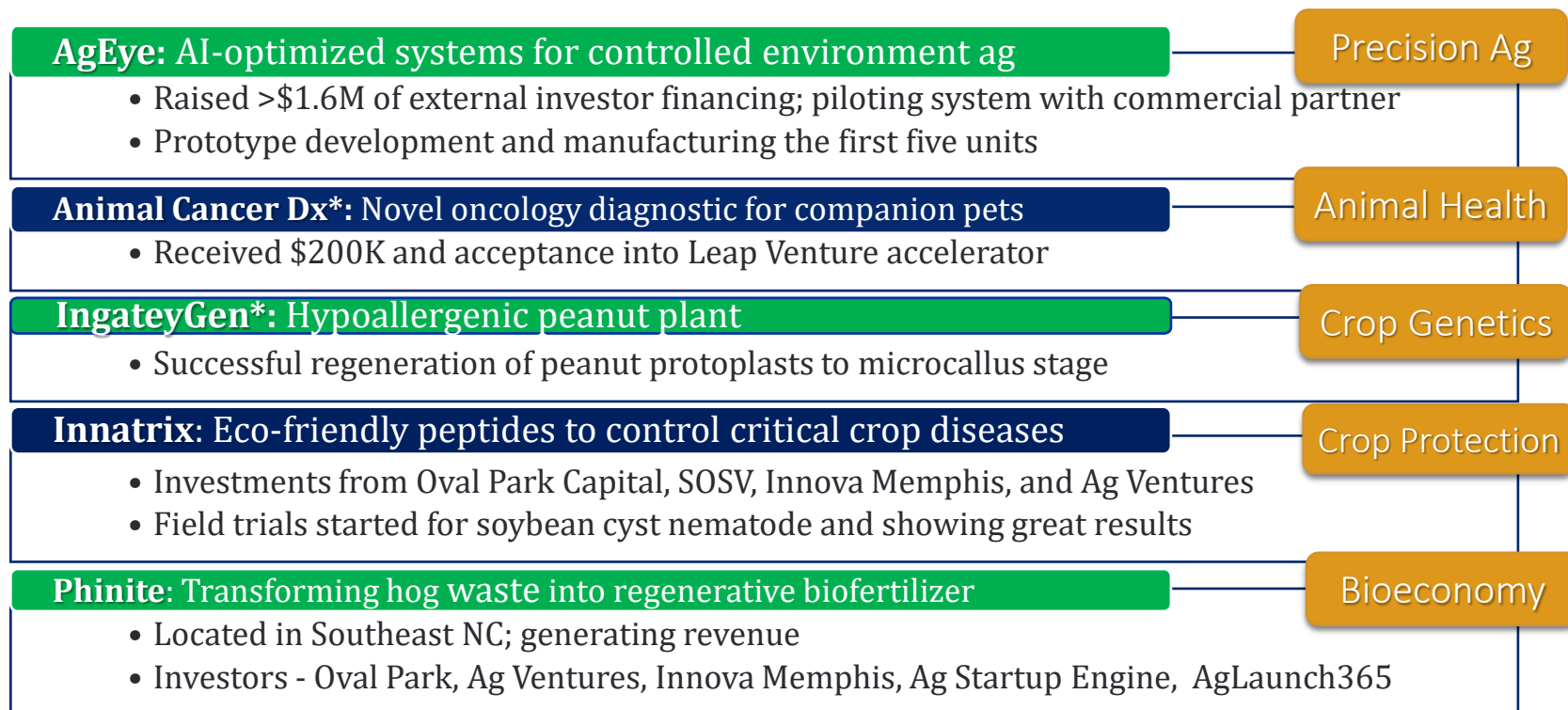
- Animal Health
- Bioeconomy
- Crop Genetics
- Crop Protection
- Data Science
- Food Tech
- Precision Ag



2 loans awarded in FY2022
3 loans awarded in FY2023

*2 Ag tech companies funded by conventional loan program funds to enable use of ag funds for companies that do not fit traditional requirements for IP and regulatory pathway

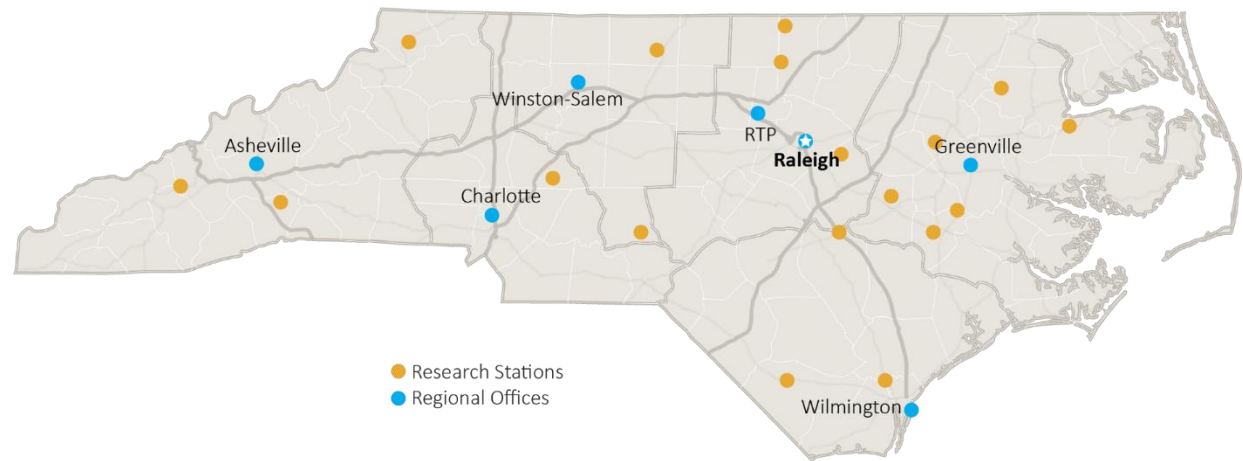
Funded Ag Tech Companies



* Funded by conventional loan program

Research Stations

- 18 stations for agricultural research
- Making farming more efficient, productive and profitable
- Maintaining a sound environment and providing consumers with safe, affordable products



Land Grant Universities



- **16 colleges with interdisciplinary ag-focus, including:**
 - College of Agriculture and Life Science
 - College of Sciences
 - College of Veterinary Medicine
- **NC State Agricultural Institute**
 - Two-year training program
 - Summer Internship Program



- **College of Agriculture and Environmental Sciences**
 - Agribusiness
 - Applied Economics
 - Family and Consumer Sciences
 - Center for Environmental Farming Systems
 - Natural Resources and Environmental Design
- **#1 in graduation of Black agricultural science undergraduates**

NSCU CALS and Plant Science Initiative

- Global hub for plant science innovation
- Engaged with 175 partners worldwide
- Interdisciplinary approach to building tomorrow's workforce



Farming with Artificial Intelligence



Big Data for Better Crops



Impact of NC A&T to the State

- \$2.4B total economic impact
- Equivalent to 17,337 jobs
- \$1.42B added state income

N.C. A&T RECEIVES \$18.1M TO LEAD MAJOR PART OF USDA NEXTGEN AGRICULTURE PROGRAM

By Lydian Bernhardt / 06/21/2023 [College of Agriculture and Environmental Sciences](#)



<https://www.ncat.edu/about/facts/ncat-economic-impact-study-2023-final.pdf>

USDA AWARDS \$1.8M TO N.C. A&T AGRICULTURE, NUTRITION, CONSUMER SCIENCES PROJECTS

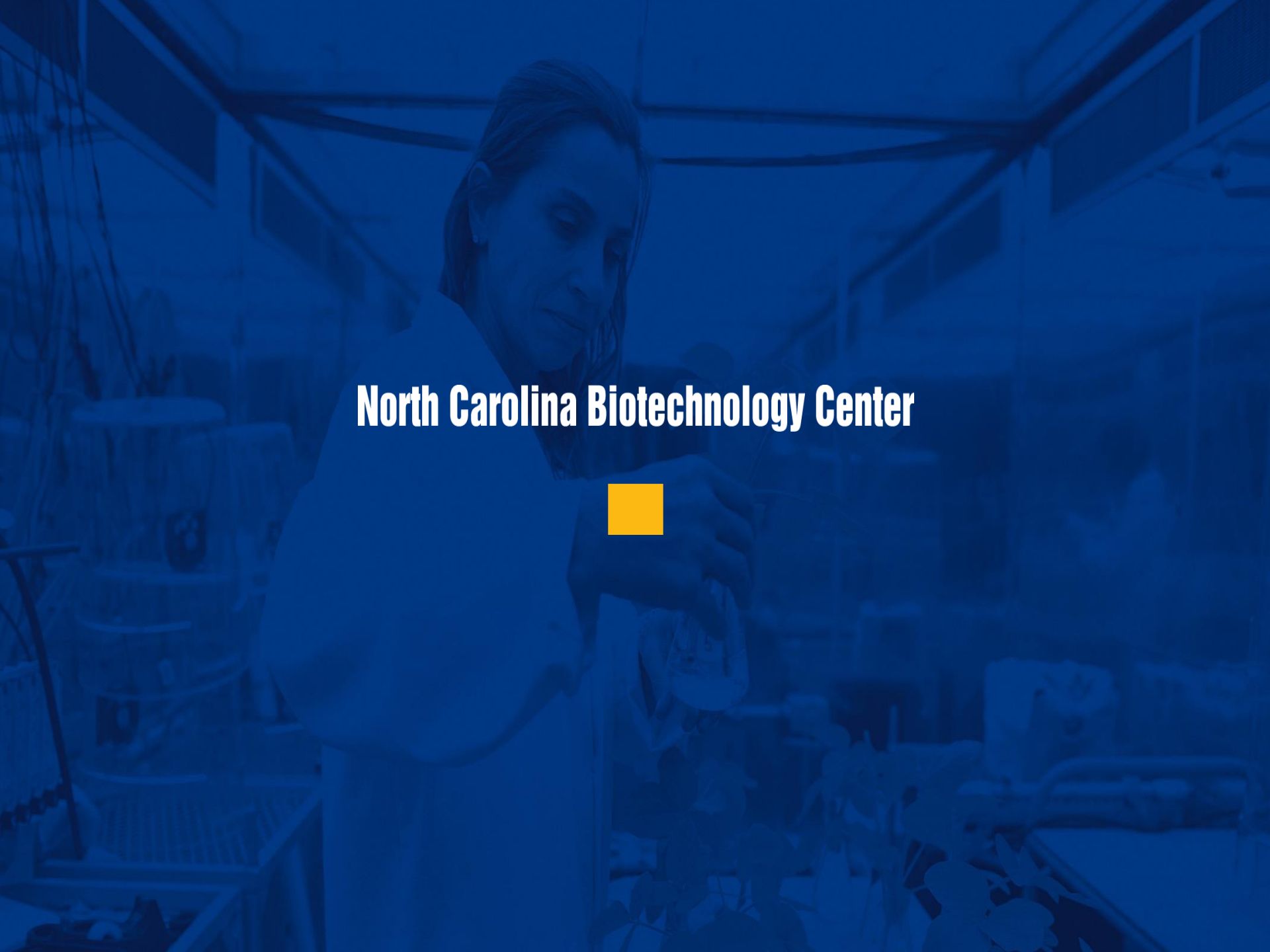
By Lydian Bernhardt / 08/02/2023 [College of Agriculture and Environmental Sciences](#)



CAES RESEARCH PORTFOLIO SETS RECORD, REACHES NEARLY \$40M

By Lydian Bernhardt / 09/08/2023 [Research and Economic Development](#), [College of Agriculture and Environmental Sciences](#)



A photograph of a female scientist in a white lab coat working in a laboratory. She is holding a small vial and a pipette. The image is overlaid with a solid blue color. A small yellow square is positioned below the text.

North Carolina Biotechnology Center



State and Federal Issues Impacting Ag Biotech

Presentation to NC General Assembly's Life Sciences
Caucus & Agricultural/Rural Caucus

Beth Ellikidis | Vice President, Ag & Environment

Gene Harrington | Senior Director, State
Government Affairs, Ag & Environment

Raleigh NC | September 18, 2023

Presentation Overview

ABOUT BIO

FEDERAL ISSUES

- U.S.-Mexico Trade Dispute
- Recent U.S. EPA Plant Incorporated Protectants Rule
- Farm Bill and Plant Biostimulants Act

STATE ISSUES

- Legislation Banning or Restricting Vaccination of Livestock
- Incentivizing Sustainable Aviation Fuel Production or Use
- Bills Banning or Restricting Foreign Ownership of Agricultural Land and Adversely Impacting R&D Work

BIO and the Ag & Environment Section



Who is BIO?

- BIO is the world's largest advocacy association representing biotechnology companies, state biotechnology groups, academic and research institutions, and related organizations across the United States and in 30+ countries.
- Corporate members range from entrepreneurial companies developing a first product to Fortune 500 multinationals.
- BIO members are involved in the research and development of innovative healthcare, agricultural, and environmental biotechnology products.



MISSION - What we do

Drive a bio-revolution through Education, Collaboration, and Advocacy



PURPOSE - Why we do it

Cure patients, protect our climate, and nourish humanity

Making the impossible
possible.



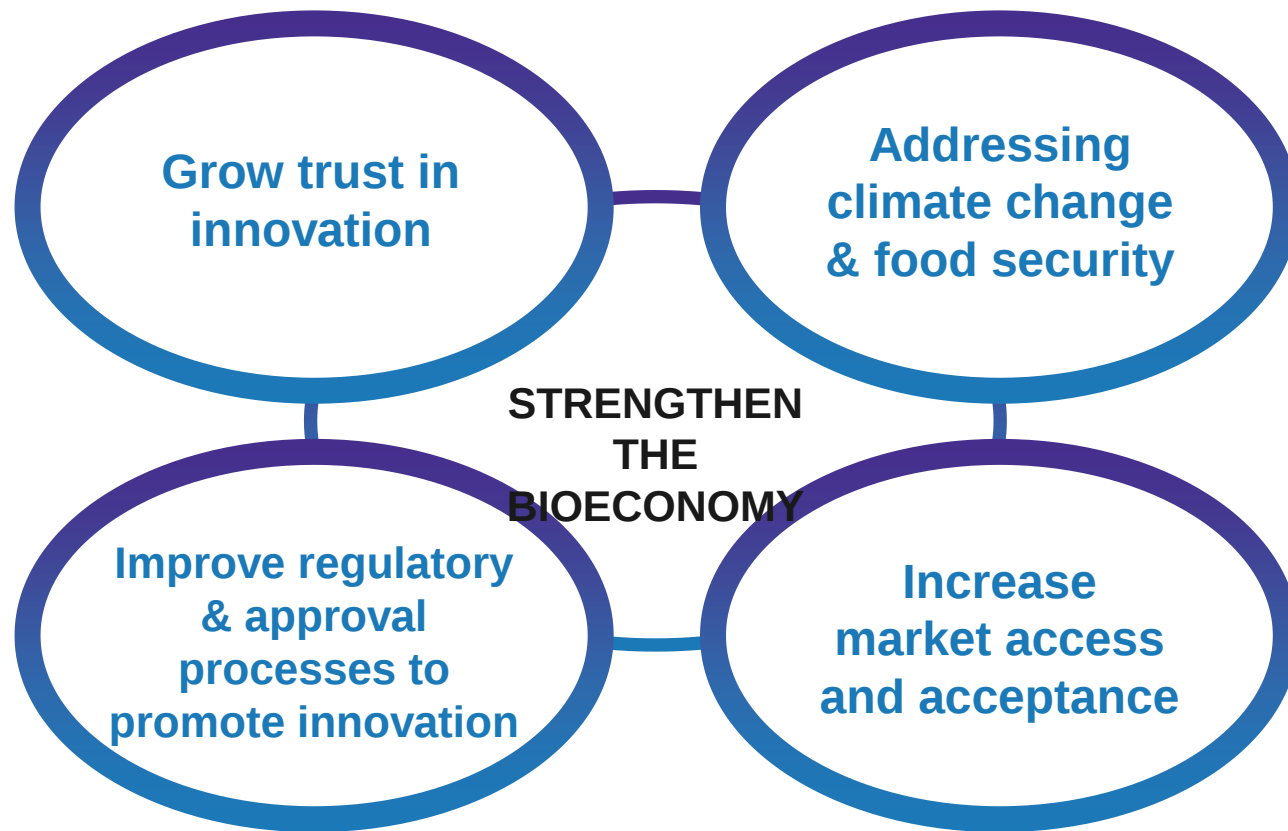
Ag & Environment Section Value Proposition

We champion agriculture and environmental biotechnology innovations focused on resiliency and sustainability by:

- 1 Highlighting the need for functional, risk-proportionate regulations
- 2 Ensuring regulatory alignment across key agencies
- 3 Supporting global One Health conversations
- 4 Advocating for trade objectives to be a part of U.S. trade policies

Ag & Environment Section Priorities

Growing the bioeconomy is critical to meeting societal challenges.



Proprietary and Confidential



BIO Agriculture and Environment Section Member Companies



Federal (and International) Policy Issues



U.S-Mexico Trade Dispute and Upcoming Import Ban on GE Corn

- In December 2020, the Mexican Government issued a decree phasing out the use of glyphosate & GE corn imports in early 2024.
- More than 90% of corn grown in the U.S. is genetically modified to resist pests and drought and to tolerate herbicides. Mexico is the second-highest importer of that corn, behind China, bringing in 15.4 million metric tons of 2022.
- Last year, BIO & stakeholders released a study assessing the economic impact of the decree. The study showed that banning all biotech corn could impact Mexico by:
 - GDP would fall by \$11.72 billion over 10 years
 - Economic output reduced by \$19.39 billion
 - Annual loss of 56,958 jobs
 - Reduction in labor income by \$2.99 billion
- In August 2023, the U.S. Trade Representative announced that the U.S. will exercise its rights under the United States-Mexico-Canada Agreement to establish a third-party dispute settlement panel

U.S. EPA Plant Incorporated Protectant (PIPs) Rulemaking

- In late May, the U.S. EPA finalized a rulemaking related to PIPs; The rule went into effect in late July (but not yet enforceable)
- BIO & other industry groups submitted comments seeking exemptions to make it easier to bring gene edited products to market; however, the new rule will actually increase regulatory burdens, bureaucracy, and costs for companies seeking to bring gene edited PIPs products to market

Farm Bill & Plant Biostimulants

Plant biostimulants are new agricultural inputs that:

- Enhance plant growth and development
 - Improve efficiency of plant nutrients (increased nutrient uptake or reduced nutrient losses)
 - Act as soil amendments that help improve soil structure, health, function, or performance
 - Reduce nutrient runoff and improve water quality
 - Derived from natural or biological sources such as bacterial or microbial inoculants, biochemical materials, amino acids, humic acids, fulvic acid, seaweed extract and similar materials
- There is federal legislation (Plant Biostimulants Act) with of goal inclusion in the Farm Bill
 - BIO's has joined with The Fertilizer Institute and industry groups to develop model state plant biostimulants legislation seeking to establish a consistent definition and labeling requirement
 - The model bill was developed in response to state plant biostimulants legislative activity in 2020 and 2021 including in Utah, Vermont, New Hampshire & Delaware
 - We are still determining our course of action for 2024 for the model state legislation
 - Industry's goal is to have a standard definition and uniform label

State Policy Issues



Legislation Banning or Restricting Vaccination of Livestock

- Bills banning, criminalizing or otherwise disincentivizing the vaccination of livestock introduced during 2023 legislative session in Arizona, Idaho, Missouri, South Carolina, Tennessee & Texas; None of the bills came close to passing
- Measures aimed largely at mRNA animal vaccines – none of yet have been commercialized or are in the marketplace yet
- Anticipate such legislation could also be put forward in Iowa, Kansas, Oklahoma in 2024

Incentivizing Production/Use of Sustainable Aviation Fuel

- Last year's federal Inflation Reduction Act established a new set of tax credits incentivizing the production of sustainable aviation fuel
- The goal is to boost SAF production to at least 3 billion gallons/year by 2030 and wean the sector off petroleum-based jet fuel completely by producing 35 billion gallons/year of SAF by 2050.
- Transportation is the largest source of greenhouse gas emissions in the US, with 11% of those emissions coming from non-military flights within and departing from the US.
- Piggybacking off the federal law, several state legislatures took up legislation incentivizing SAF production/use in their states, with bills being enacted in Colorado, Illinois, Minnesota, Montana, North Dakota, Washington State

Bills Banning/Restricting Foreign Ownership of Ag Land/Adversely Impacts R&D Work

- During 2023 state legislative sessions, almost 40 states considered legislation banning or restricting the foreign ownership of agricultural land
- Bills were aimed primarily at China and other “foreign adversaries”
- Fifteen states enacted said legislation including AL, AR, FL, ID, OH, MS, MT, LA, ND, OK, SD, TN, UT, VA, WV
- Industry is concerned that these bills could restrict R&D work and undermine seed companies’ ability to work with U.S. farmers to bring new, innovative products to the marketplace
- Bills enacted in North Dakota (2023) and Indiana (2022) include express exemptions for R&D work; Also, most bills don’t prohibit leasing of land

Thank you!

Beth Ellikidis
bellikidis@bio.org
202-360-2725

Gene Harrington
gharrington@bio.org
202-962-9513



A woman with dark skin and braided hair, wearing a white lab coat over a blue shirt, is holding a small green plant with both hands. She is looking at the plant with a focused expression. The background shows a laboratory or greenhouse environment with shelves and other plants.

Pairwise

Dan Jenkins

Vice President, Regulatory and Government Affairs



PAIRWISE WAS FOUNDED AND IS LED BY FOOD, AGRICULTURE, AND GENOMICS EXPERTS

ABOUT PAIRWISE

Powered by its best-in-class technology, Pairwise is creating a new consumer-centric category of novel, nutritious foods under its Conscious™ Foods brand.

An early innovator in applying CRISPR and gene editing to plants and plant-based systems, Pairwise holds exclusive licenses from Harvard and Massachusetts General Hospital to base editing and high-fidelity enzymes.

THE DETAILS:

- Headquartered in Durham, North Carolina, USA, In the vibrant innovation community of the Research Triangle Park
- Employs 140+ people across the nation

CO-FOUNDERS



Tom Adams, PhD
Chief Executive Officer



Haven Baker, PhD
Chief Business Officer



Feng Zhang, PhD
MIT, Broad Institute



David Liu, PhD
Harvard



J. Keith Joung, PhD
Mass General Hospital



PAIRWISE IS A PURPOSE-DRIVEN COMPANY

MISSION

To build a healthier world through better fruits and vegetables

VISION

To build a food company that uses technology to break down the barriers keeping us from eating fruits and vegetables



WHY OUR MISSION MATTERS

Shifting diets to increased fruit and vegetable consumption creates healthier people and a healthier planet



HEALTHIER PEOPLE

A broad sweeping Harvard School of Public health study published in 2021 found that those who ate **5 servings of fruits and vegetables a day** had the lowest risk of death, even after adjusting for other factors



HEALTHIER PLANET

If American diets shifted just 10% to a plant-forward model defined by the USDA by 2030, **we could avoid ~30M MT of CO₂e emissions per year**; that's the amount of CO₂e sequestered by ~35M acres of forest – more than all the forest in California¹ – in a year

Sources: <https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.120.048996#d1e2796>, https://ucanr.edu/sites/forestry/California_forests/



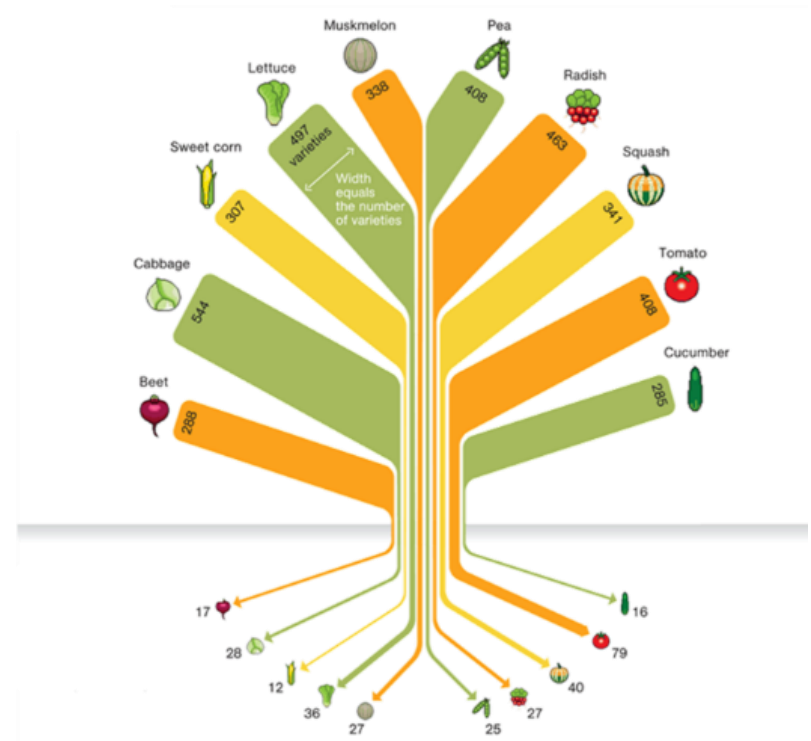
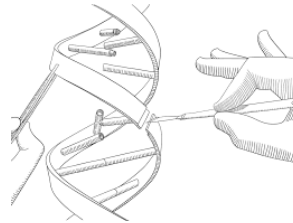
CRISPR and Genome Editing

American Invention

Nobel Prize Winning

No foreign DNA

Can do the same things as conventional plant breeding, only faster



OUR 5 YEAR ROW CROP COLLABORATION WITH BAYER YIELDED RESULTS

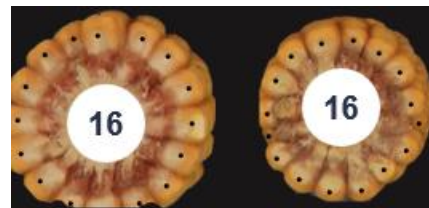
“With our collaborator Pairwise, we’ve now identified nearly 200 unique gene sequences that can improve productivity or disease resistance”

– *Bob Reiter*

Head of Crop Science R&D, Bayer

- ✓ A new type of corn with **up to 20% more** Kernel Row Numbers
- ✓ This innovation is a powerful example of Pairwise’s **solving intractable environmental and commercial problems**
- ✓ Increased ear size dramatically **improves the yield / acre of corn**

Original



Edited



New, consumer focused produce have expanded markets and consumption

BLUEBERRY

available year-round



- Blueberries grew the market by 4x



BABY CARROT

snack size, convenient

- Today: **80% of retail carrot sales are baby carrots**
- Increased U.S. fresh carrot consumption by:
 - 30% after 1 year
 - 100% within 10 years



HALOS MANDARIN

seedless, easy peel

- Captured **50%+** of U.S. mandarin market in **5 years**
- Increased total citrus consumption by 30%
- Ranked #1 healthy snack brand by parents and kids



National Policies are being formed

Like products should be treated in like ways



EPA Gene Editing Rule Went into effect July 31

Pesticides; Exemptions of Certain Plant-Incorporated Protectants (PIPs) Derived from Newer Technologies



EPA Regulates Substances that Mitigate a Pest, as well as affect Growth, as Pesticides

Process triggered: Traits EPA has authority over + use of biotechnology

- EPA's definition of "Conventional Breeding" explicitly excludes biotechnology
- Plant Growth Regulator: [substance(s)] intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or the produce thereof.
- Regulated biotechnology traits are called "Plant Incorporated Protectants"

Exemptions: LOF and genes from sexually compatible plants (exemptions do not apply to transgenics)

EPA has Pesticide authority (FIFRA) and Food Tolerance authority (FFDCA)

37



Like Products Being Treated in Unlike Ways



Dwarf Citrus Trees Are Commonly Sold Today

EPA standards:

- No unreasonable adverse affects on human health or the environment
- Reasonable certainty of no harm

Technique	Method	Potential to Create Something Plant Breeders Haven't seen Before?	Potential to Create an Increase or Decrease in a Substance that Affects Growth?	Potential EPA Capture?
Plant breeding	Crosses, wide crosses, embryo rescue	Yes	Yes	No
Mutagenesis	Chemical, radiation	Yes	Yes	No
Epigenetic	Methylation	Yes	Yes	No
Gene editing	CRISPR, TALENs	Yes	Yes	Yes



EPA's Rule is in Contrast with the Rest of the World

EPA would classify many traits as Pesticides



Treated as a
biotech
pesticidal plant

Submission
required

Ongoing
permitting,
record keeping
and reporting



Treated As
Conventional

No submission
strictly required

Argentina
Australia
Brazil
Canada
Chile
Colombia
England
European Union (Proposed)
Guatemala
Honduras
India
Nigeria
Japan
Philippines
United Kingdom



twitter.com/pairwisepl



facebook.com/pairwisePL



instagram.com/pairwiseproduction



linkedin.com/company/pairwise-plants



*THANK
YOU*

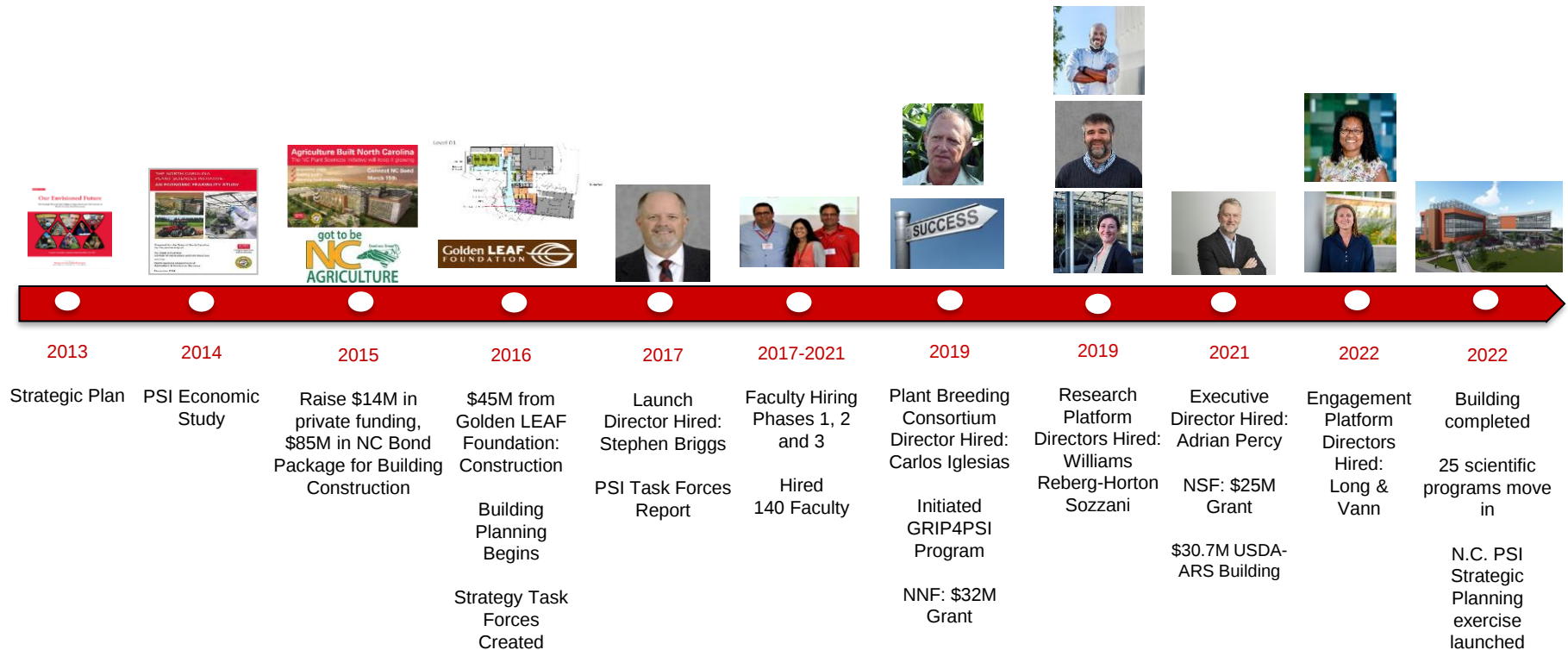


N.C. Plant Sciences Initiative

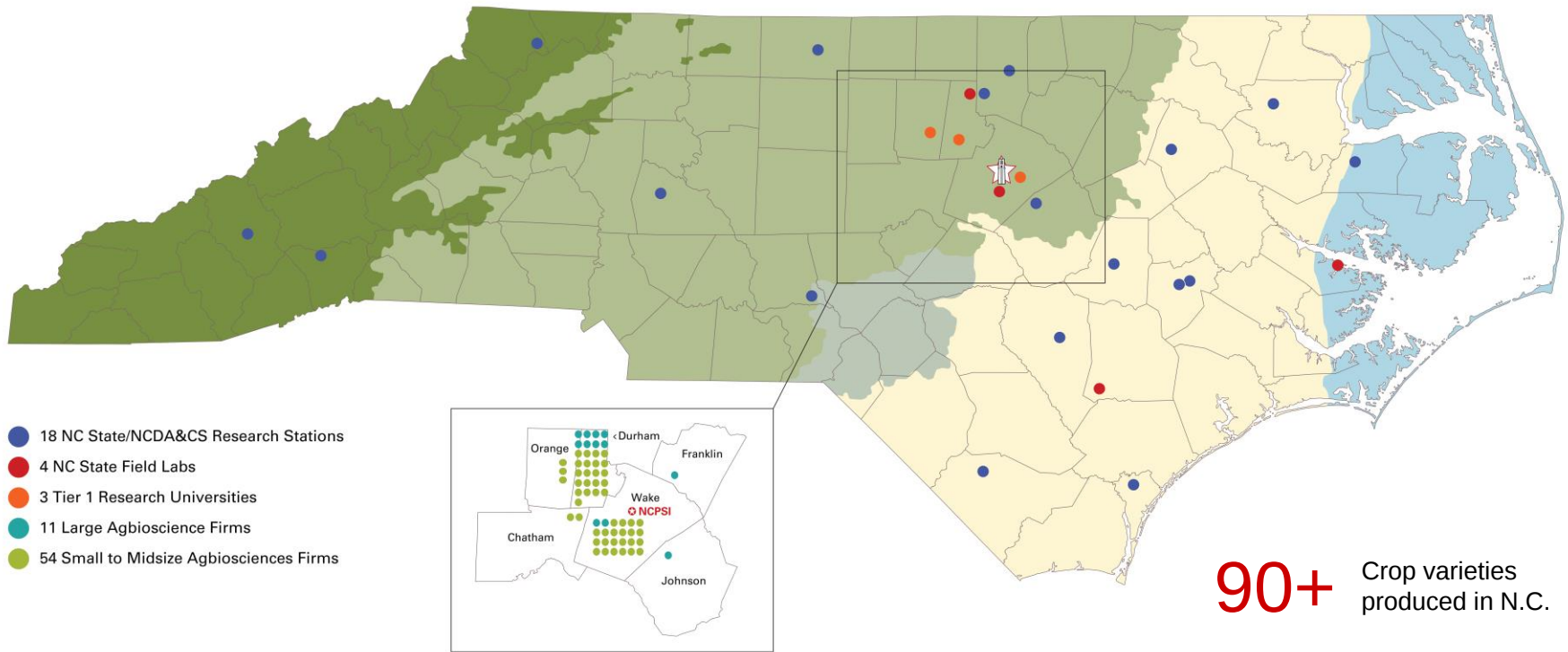
“Harnessing Interdisciplinary Science to Tackle Grand Challenges in Agriculture”

**Celeste Brogdon, Director of Strategic Engagement
N.C. PSI**

Our N.C. PSI Journey



N.C. PSI: Part of a Unique Ag Research Ecosystem



90+ Crop varieties produced in N.C.

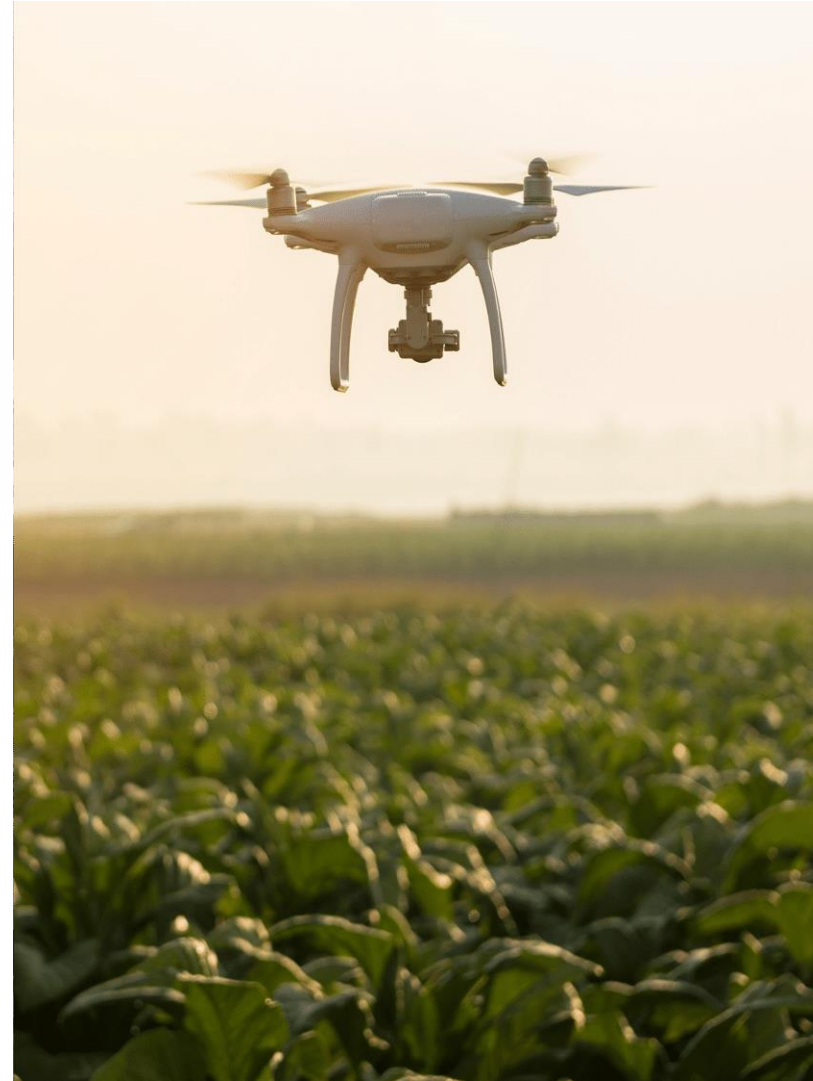
#1 Agribusiness is N.C.'s top economic sector

5 Geographic Regions: Mountains Piedmont Sandhills Coastal Plain Tidewater

N.C. Plant Sciences Initiative

Vision – Create a healthier, sustainable and more prosperous future through **plant science innovation**.

Mission – To solve grand challenges in agriculture and the environment in North Carolina and beyond through **interdisciplinary team-based science, partnerships and talent development**.



Areas of Expertise

A word cloud of expertise areas. The words are arranged in a non-uniform, overlapping manner. The colors of the text include red, blue, green, and orange. The background is white, and the top of the image features a solid red horizontal band.

Data management

Molecular biology

Robotics

Agricultural Economics

Proteomics & metabolomics

Imaging systems

Regulatory science

Machine learning & deep learning

Crop production

Biotechnology

Multi-scale modeling

Genome sequencing

Genome editing

High throughput phenotyping

Climate change mitigation & carbon sequestration

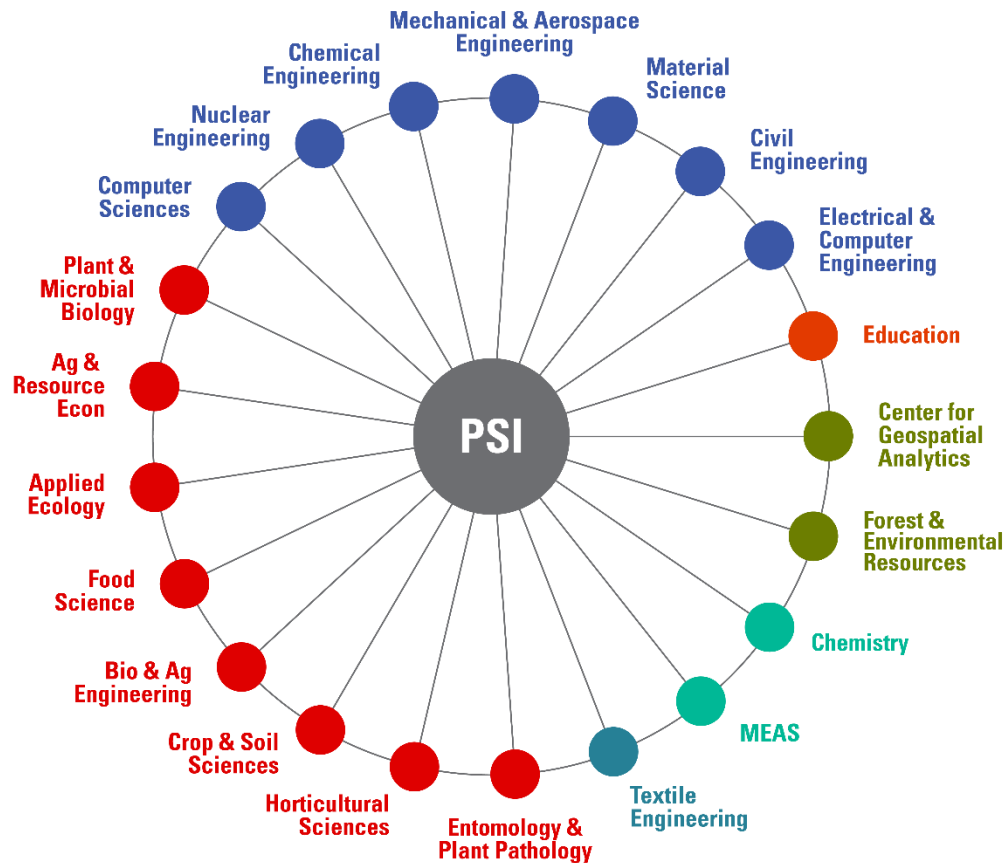
Computer vision

Bioinformatics

Sensor development

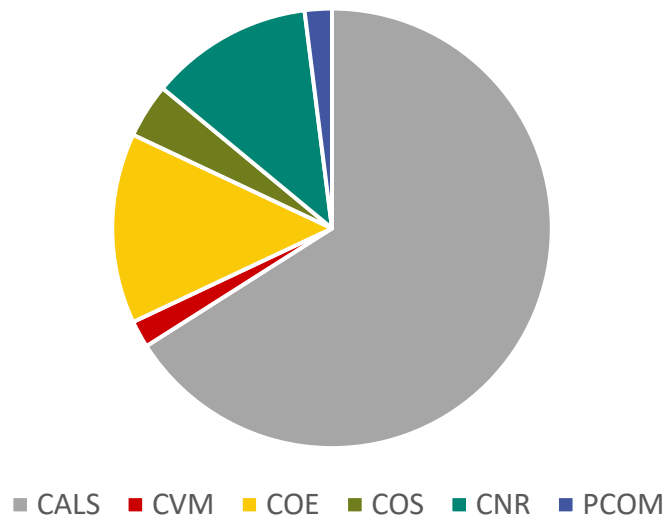
Pest resilience & management

N.C. PSI Draws From Talent Across NC State

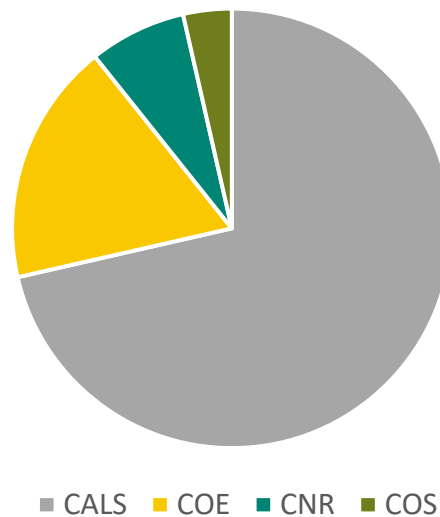


N.C. PSI Draws From Talent Across NC State

N.C. PSI Affiliated Faculty (50)

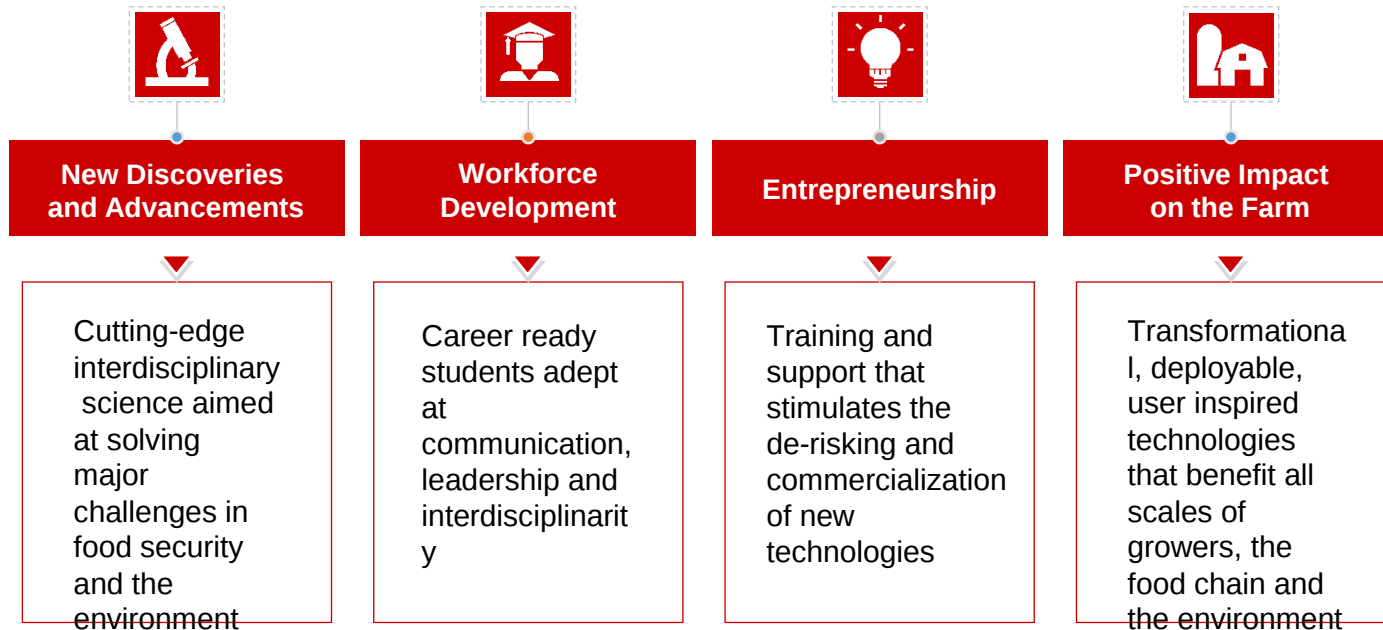


PSB Resident Faculty (28)



Students: 70 undergraduate · 197 graduate · 59 postdocs

N.C. PSI - Principal Areas of Impact



N.C. PSI's Five Platform Directors



Ross Sozzani

**PLANT
IMPROVEMENT**

Professor of
Synthetic and
Systems Biology

Department of
Plant and
Microbial Biology



Chris Reberg-Horton

**RESILIENT
AGRICULTURE
SYSTEMS**

BCBS Kellogg
Distinguished
Professor in
Sustainable
Community-Based
Food Systems

Department of
Crop and Soil
Sciences



Cranos Williams

**DATA-DRIVEN
PLANT
SCIENCES**

Goodnight
Distinguished
Professor of Ag
Analytics

Dept. of Electrical
& Computer
Engineering

Dept. of Plant &
Microbial Biology



Terri Long

**EDUCATION &
WORKFORCE
DEVELOPMENT**

Professor of Plant
Molecular Biology

Department of
Plant and
Microbial Biology



Rachel Vann

**EXTENSION
OUTREACH &
ENGAGEMENT**

Assistant
Professor and
Soybean
Extension
Specialist

Department of
Crop and Soil
Sciences

Grower Advisory Council & Extension Agent Network

To execute our mission and achieve our vision, it is critical that applied expertise is incorporated from interdisciplinary project conception through execution in the field.

Grower Advisory Council

- Provide guidance on the relevance of scientific research to production systems in the field
- Isaac Boerema, Reggie Baker, Kenny Barnwell, Sue Leggett, Bert Lemkes, Danny Pierce, and Bo Stone

Extension Agent Network

- Beta-test PSI-developed technologies in the field to accelerate seamless adoption on North Carolina farms
- Host PSI-developed technology outreach events within counties



Welcoming Future Plant Scientists



First Annual Plant Sciences Day

N.C. PSI hosted **75 high school students** from **nine counties** in North Carolina for our first annual Plant Sciences Day. The students rotated through **four sessions** to gain information and inspiration about what a career in plant sciences could be. They took part in an industry panel, a research lab tour, a demo lab exercise, and a meet and greet with current NC State students.



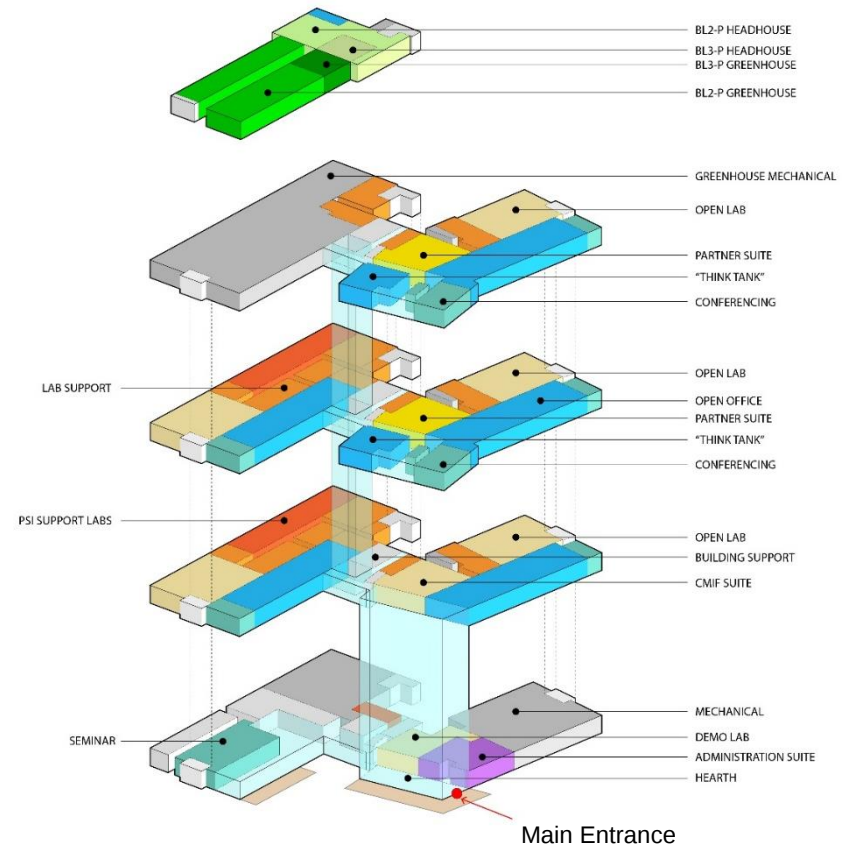
High school students from the **Horticultural Science Summer Institute** learn how to make soil sensors in the Demo Lab.

The Premier Plant Sciences Infrastructure in the World

- 5 stories, including a rooftop greenhouse space (BSL2&3)
- First floor is the public floor with 135-person capacity seminar room
- Floors 2 – 4 are research floors
 - State-of-the-art facilities in imaging, spectrometry, genotyping, tissue culture/transformation, engineering, and a makerspace facility
 - **Designed for maximum flexibility:** Can evolve as research needs change (e.g., mobile benches)
- Partnerships with academia, industry & government
 - USDA-ARS scientists
 - Innovation Hub for collaboration with PSI corporate members
 - AgTech Incubator Suite for PSI affiliated startups

Key Stats:

- 185,000 square-foot building
- 72,000 square feet of research labs
- 300+ occupants
- 25 NC State faculty research programs
- 10,000 square feet of greenhouses
- 3 University core lab facilities



Plant Sciences Building – Core Facilities



The Cellular and Molecular Imaging Facility (CMIF)

- Confocal microscopes with FLIM/FRET, laser microdissection system, and slide scanner



Molecular Education, Technology and Research Innovation Center (METRIC)

- Magnetic resonance and X-ray crystallography
- Assists proteomics, metabolomics and VOC analysis



Genomic Sciences Laboratory (GSL)

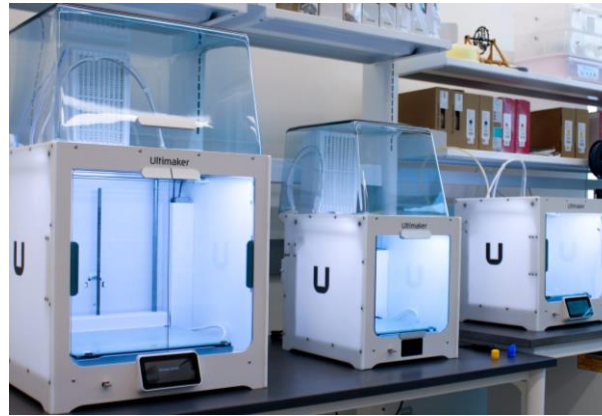
- Advanced genomics research
- High-throughput DNA sequencing, traditional Sanger sequencing and genotyping, functional genomic assays

Plant Sciences Building – Other Facilities



Demo Lab

- Showcases ongoing N.C. PSI research projects to the public
- Hands-on educational lab for students, teachers, extension agents, etc.
- Facilitates training and enables technology transfer from lab to field



Makerspace

- Rapid prototyping of low-cost custom hardware and software solutions
- 3D printers/scanners, imaging systems, IoT platforms, drones, sensors
- Only Makerspace at NC State dedicated to interdisciplinary ag research



Rooftop Greenhouses

- 11 adaptable greenhouses bays
- More efficient and successful experimentation by minimizing outside variables
- 1 bay officially designated Biosafety Level 3 (BSL-3) area



Thank You