



## **The BSC as a public-private partnership: HESI's involvement in the BSC**

**Connie Mitchell**  
*Scientific Program Manager*  
*Health and Environmental Sciences Institute (HESI)*



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# Outline

- Introductions
- Overview of the BSC
  - Mission
  - Objectives
  - Strategy
- HESI's role
- Organizational Structure
  - General Public
  - Stakeholder Council
  - Technical Working Groups
  - Steering Committee
- Timeline



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# Introductions – HESI Staff



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# The Botanical Safety Consortium

Applied In Vitro Toxicology, Vol. 5, No. 1 | Roundtable

 Full Access

## The Botanical Safety Consortium

Moderator: Amy L. Roe Participants: Joseph T. Dever, Stefan Gafner, Daniel S. Marsman, Cynthia V. Rider  and Sibyl Swift

Published Online: 13 Mar 2019 | <https://doi.org/10.1089/aivt.2018.29018.rtl>

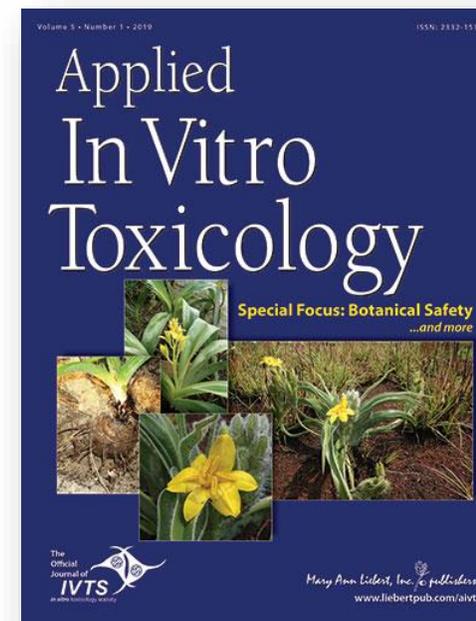
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 Tools  Share

FDA STATEMENT

### Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency's new efforts to strengthen regulation of dietary supplements by modernizing and reforming FDA's oversight

*"...as with other commodities that the agency regulates, it's critical that FDA continue to work closely with our partners in industry to achieve our primary goal of protecting public health and safety. As the dietary supplement industry develops new products and ingredients, advances new delivery systems and innovates in other ways, the FDA must do more to leverage its existing resources and authorities to evaluate these products. This requires collaborative research and a shared understanding. I'm pleased to announce that we've recently created the Botanical Safety Consortium, a public-private partnership that will gather leading scientific minds from industry, academia and government to promote scientific advances in evaluating the safety of botanical ingredients and mixtures in dietary supplements. This group will look at novel ways to use cutting-edge toxicology tools, including alternatives to animal testing, to promote the goals of safety and effectiveness we share with consumers and other stakeholders."*



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# The Botanical Safety Consortium

19 Nov 2019

## FDA Announces Convening of the Botanical Safety Consortium

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### Constituent Update

November 14, 2019

The U.S. Food and Drug Administration (FDA) announced today that the Botanical Safety Consortium (BSC) has formally been convened. This milestone is the result of a [Memorandum of Understanding \(MOU\)](#) that was recently signed between the FDA, the [National Institutes of Health's National Institute of Environmental Health Sciences](#), and the [Health and Environmental Sciences Institute \(HESI\)](#) [↗](#). This MOU establishes the framework for the BSC.

The BSC was originally announced in the FDA's [February 2019 statement](#) on the agency's new efforts to strengthen regulation of dietary supplements through modernization and reform. The Consortium's mission is to provide a forum for scientists from government, academia, consumer health groups, industry, and non-profit organizations to work collaboratively to generate a sound scientific basis for integrating existing safety data and the latest toxicology tools to evaluate botanical safety in dietary supplements. With the execution of the MOU, specific guidelines for membership and participation in the BSC will be established by early 2020.



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# History of the Botanical Safety Consortium

2018-2019

- Conceptualization of the BSC
- Formation of working groups
- Identification of mission & objectives

3Q 2019

- Discussions initiated between FDA, HESI, and NIEHS

4Q 2019

- MOU signed
- HESI named as convener
- Announcement made by FDA
- Scoping meeting held

2020

- Launch & official announcement of the BSC
- Website launched
- Adding new members



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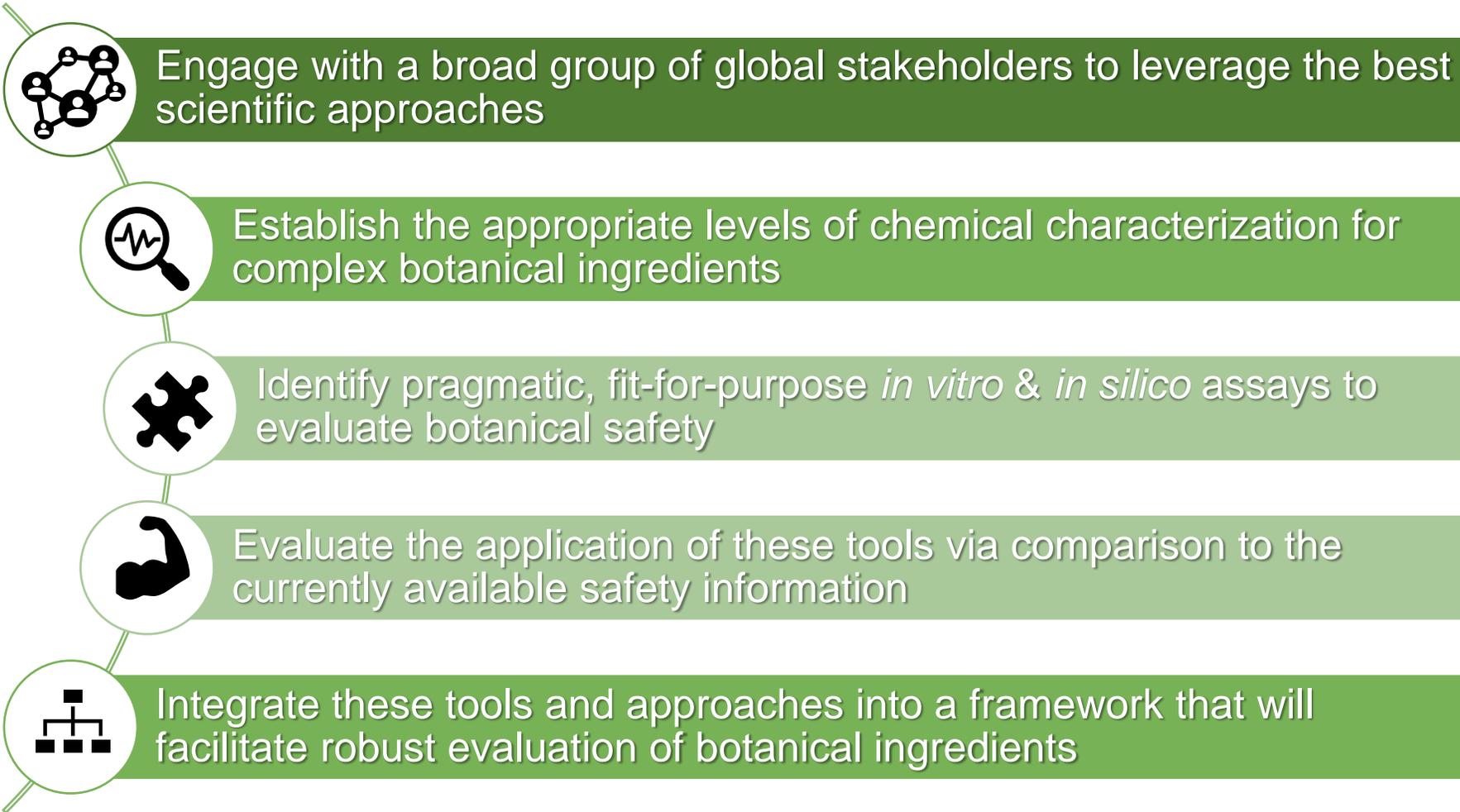
# Mission of the Botanical Safety Consortium

To enhance the botanical safety toolkit and bring clarity to botanical dietary ingredient assessments for manufacturers and regulators.

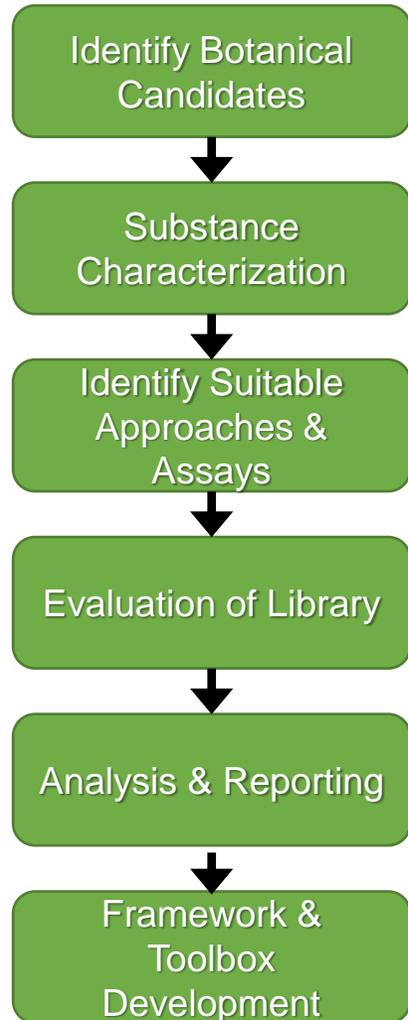


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# Botanical Safety Consortium Objectives



# Botanical Safety Consortium Strategy



- Develop a list of botanical ingredients that have available safety information
- Create a reference botanical ingredient library
- Utilize analytical approaches and chemometrics for adequate characterization
- Develop strategies to address variability between botanical ingredients for safety assessment
- Identify suitable *in vitro/in silico* assays that are within the identified domain of applicability for botanical ingredients
- Evaluate the reference botanical ingredients in a battery of selected *in vitro/in silico* assays
- Perform suitable data analysis
- Compare the results from the testing battery to existing animal and human safety data
- Make data publicly available
- Leverage learnings to determine suitable *in vitro & in silico* approaches for botanical ingredient evaluation
- Identify challenges for botanical application
- Prioritize research and evaluation needs



# Health and Environmental Sciences Institute (HESI)



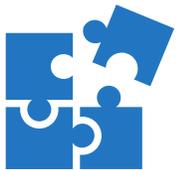
## OUR VISION

Science-based solutions for a sustainable, healthier world



## OUR MISSION

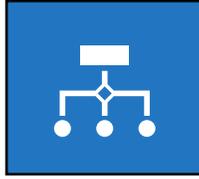
Engage scientists from academia, government, industry, and other scientific organizations to identify and resolve global health and environmental issues



## OUR CORE PRINCIPLES

- Create opportunities to collaborate
- Driven by solutions
- Transparent
- Independent
- Committed to excellence

# HESI Project Mechanisms



DECISION FRAMEWORKS



DATA SHARING & COLLECTIVE ANALYSIS



NOVEL EXPERIMENTAL STUDIES



MANUSCRIPTS



TOOL / ASSAY DEVELOPMENT



SCIENTIFIC MEETINGS & TRAININGS

# The HESI Model: Bridging Research to Application

IMPROVED

## SAFETY AND INNOVATION FOR HUMAN AND ENVIRONMENTAL HEALTH



Academic, Clinical,  
& Research Scientists  
& Organizations



Industry  
Research &  
Development



NGOs, Patient  
Advocacy Groups,  
& Foundations

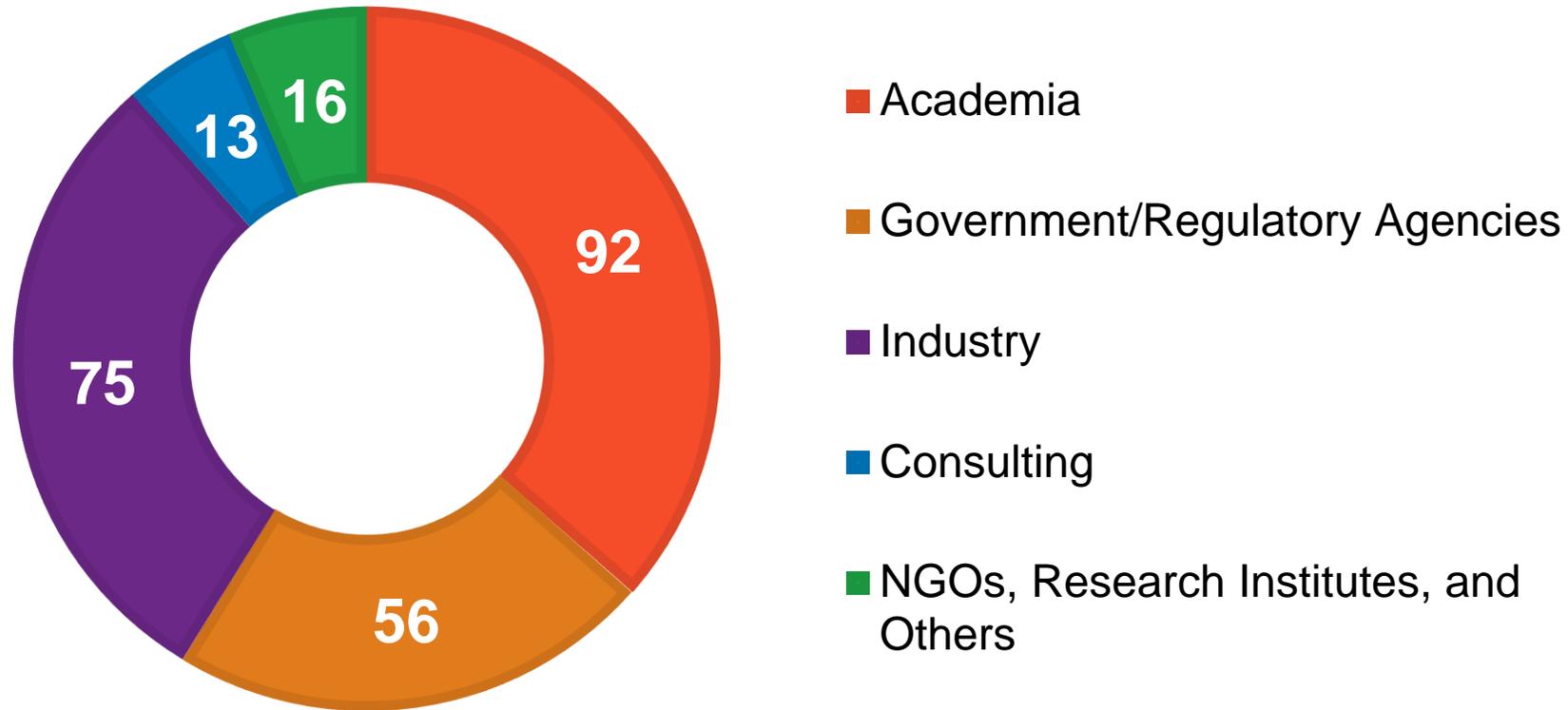


Government  
Research &  
Regulation



**30**  
THIRTY YEARS  
**HESI**

Science for a Safer,  
More Sustainable World



## **HESI Participation & Support**

- 65% Public Sector
- 35% Private Sector
- >250 Active Partner Organizations, >600 scientists
- Research Program Funding from Both Public & Private



# JRC SCIENCE FOR POLICY REPORT EURL ECVAM Status Report

on the Development, Validation and Regulatory Acceptance of Alternative Methods and Approaches (2018)

MOU 225-19-

Over 335 peer-reviewed publications from HESI scientific programs have been published over the last 30 years, with more than 100 publications in the last decade.

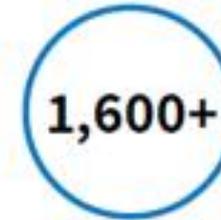
### HESI citations by the numbers:



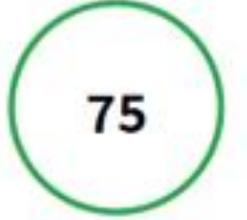
total citations



scientific journals citing HESI work



citing organizations



citing countries

## MEMORANDUM OF UNDERSTANDING Among The Food and Drug Administration (FDA) And The National Institutes of Health National Institute of Environmental Health Sciences (NIEHS), Division of the National Toxicology Program (NTP) And Health and Environmental Sciences Institute (HESI)

## MEMORANDUM OF UNDERSTANDING BETWEEN U.S. ENVIRONMENTAL PROTECTION AGENCY AND HEALTH AND ENVIRONMENTAL SCIENCES INSTITUTE

Environmental Protection Agency (EPA or the Agency) and the International Life Sciences Institute (ILSI) Health and Environmental Sciences Institute (HESI) (collectively, "Parties") are entering into this Memorandum of Understanding (MOU) to address existing and emerging scientific progress through the exchange of scientific capital to address the protection of human health and the environment.

### I. PURPOSE

Cardiovascular safety is a significant public health concern and challenge for those seeking to improve cardiovascular health and reduce the burden of cardiovascular disease.

improve cardiovascular health and reduce the burden of cardiovascular disease.



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> [Testing of chemicals](#)

## OECD Test Guidelines Programme

## CDER Biomarker Qualification Program

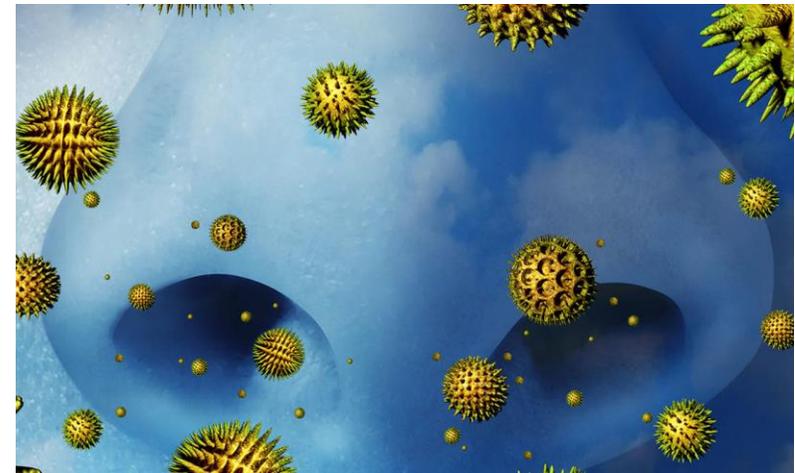
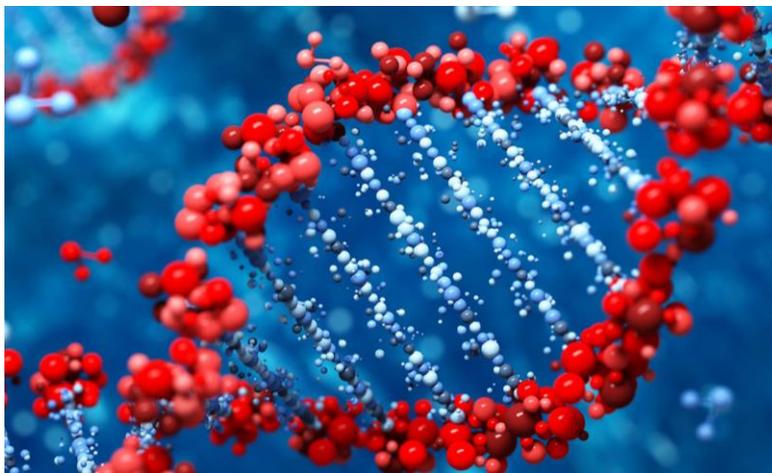
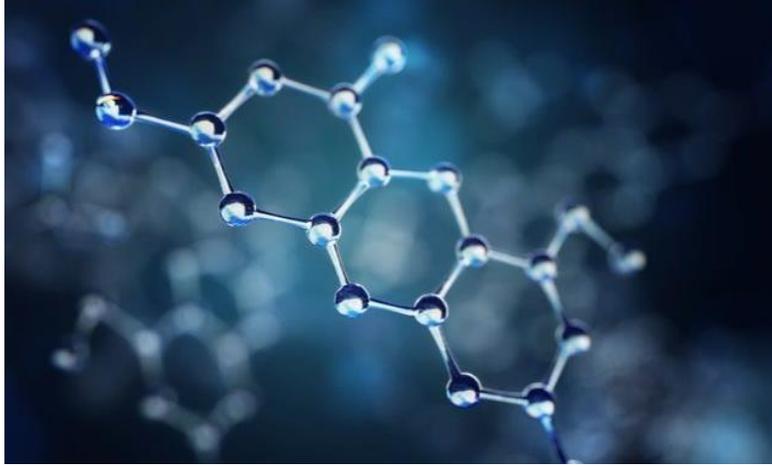
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**Biomarker Qualification Program**

Qualified biomarkers can make drug development more efficient.

# HESI Committees

- Cardiac Safety
- Developmental & Reproductive Toxicology (DART)
- Genetic Toxicology
- Immuno-Safety
- Multi-Component Substances (MCS) & UVCBs
- PBPK Models



### HESI Project Mechanisms



DECISION FRAMEWORKS



DATA SHARING & COLLECTIVE ANALYSIS



NOVEL EXPERIMENTAL STUDIES



MANUSCRIPTS



TOOL / ASSAY DEVELOPMENT



SCIENTIFIC MEETINGS & TRAININGS



### HESI's Role as Convener

- Scientific program design and strategy
- Managing project teams and convening partners
- Leveraging expertise from other HESI projects
- Pooling data and resources
- Ensuring public benefit and communication

# Structure of the BSC

## STAKEHOLDER COUNCIL

- Interested parties with justification statement; private sector must provide financial contribution

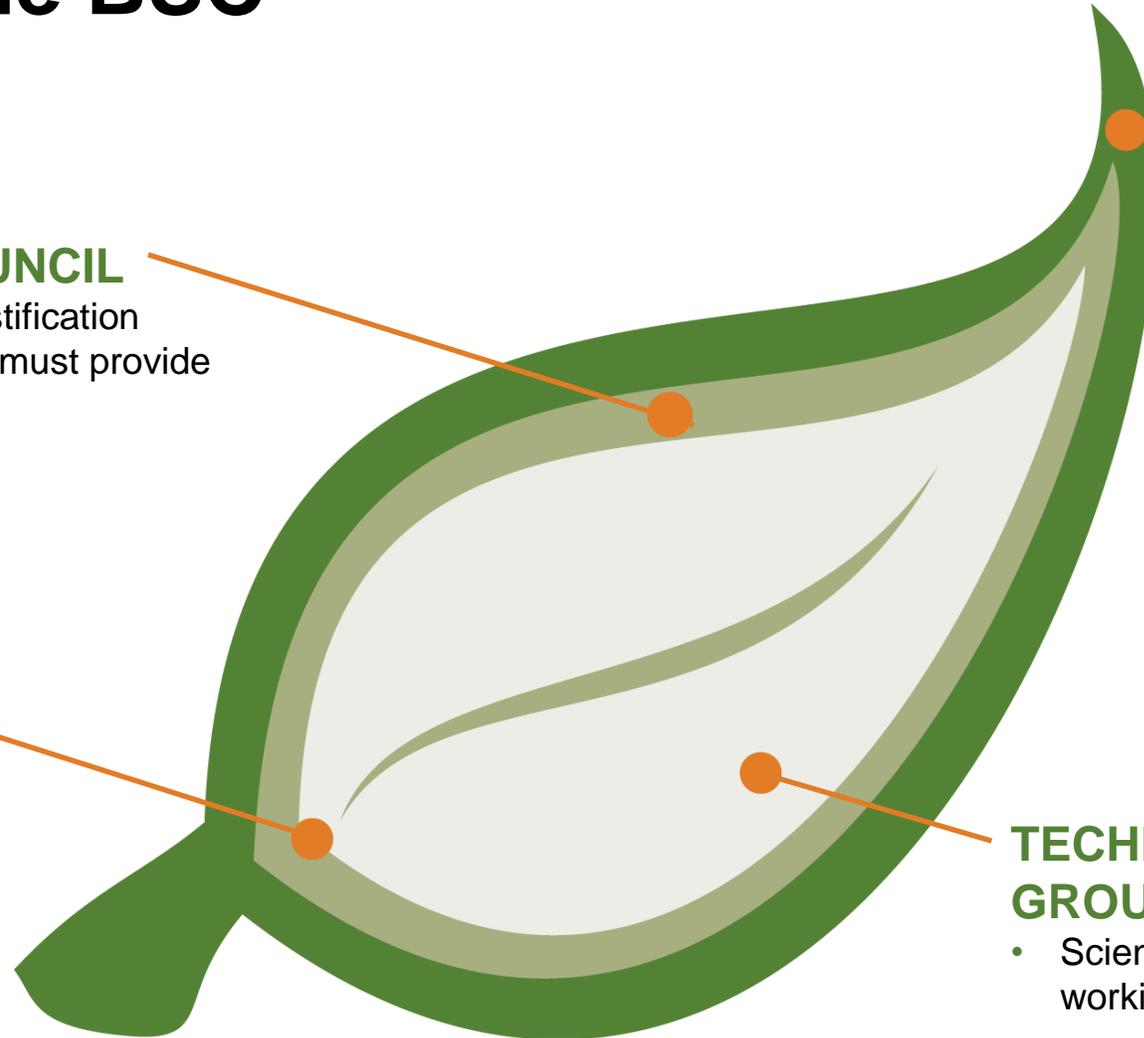
## GENERAL PUBLIC

- Open to all

## STEERING COMMITTEE

## TECHNICAL WORKING GROUPS

- Scientific/technical experts on working group topics



# Resourcing for the BSC

## Foundational Multi-Year Funding from NIEHS + FDA

- Private sector funding to support additional activities + research
- In-kind support from all participants (time, expertise, etc.)
- Trade Associations can join – \$10,000 sponsorship plus 2 member companies must join the BSC

Yearly sales (US Dollars)	BSC Annual Sponsorship Fee	HESI Annual Affiliate Sponsorship Fee**
Sales ≤ \$49.99 million	\$2,000	\$500
Sales \$50 million – 499.99 million	\$8,000	\$2,000
Sales > \$500 million	\$16,000	\$4,000



*\*\*Organizations that are already HESI Sponsors pay NO Affiliate Sponsorship Fees*



## General Public



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- Open to all
- Access to BSC materials via website
- All scientific publications will be available open access
- Opportunity to attend Annual Meeting

# Stakeholder Council (SHC)

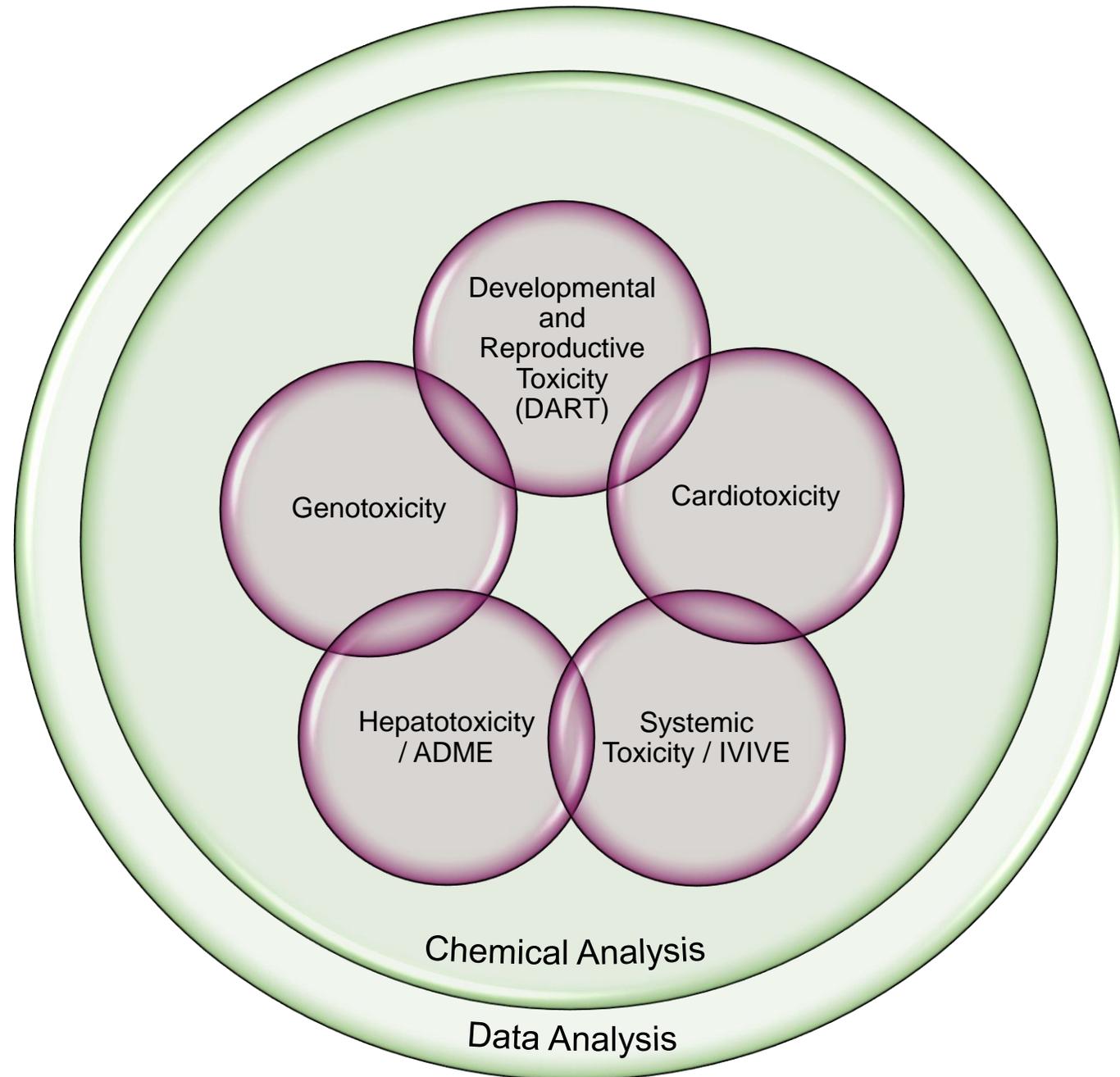


**NOTE: All TWG and Steering Committee members are, by definition, part of the SHC**

**Individuals & organizations that provide input & mission support to the BSC via:**

- Voting on the Steering Committee composition
- Nominating self or other scientists for participation in the TWGs
- Participation in quarterly BSC update webinars
- Providing direct financial or in-kind resources
- Submitting proposal for new areas of scientific work by the BSC
- Responding to specific requests for input from the SC or TWGs

# Technical Working Groups



# Technical Working Group: Topic Selection

- Severity of associated disease
  - (e.g., genotoxicity and cancer, cardiotoxicity and heart disease)
- Adverse event reporting and research on botanicals
  - (e.g., hepatotoxicity, cardiotoxicity)
- Building bridges with current gold standard - animal safety data
  - (e.g., *in vitro* systemic toxicity vs repeat dose *in vivo*)
- Availability of alternative assays to measure effects in that system
  - *In vitro*
  - *In silico*

# Current Steering Committee

## Government



Cynthia Rider  
NTP/NIEHS

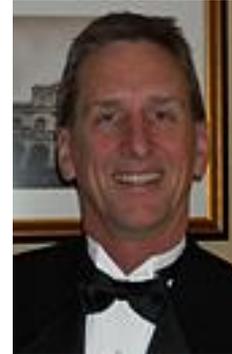


Cara Welch  
USFDA

## Industry



Joe Dever  
Amway  
(Liaison: Systemic Tox)



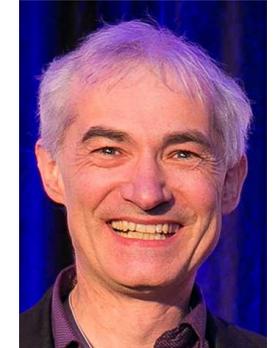
Dan Marsman  
P&G  
(At-large)

## Trade Association



Jim Griffiths  
CRN  
(At-large)

## Non-Profit



Stefan Gafner  
American  
Botanical Council  
(Liaison:  
Chemical  
Analysis)

## HESI



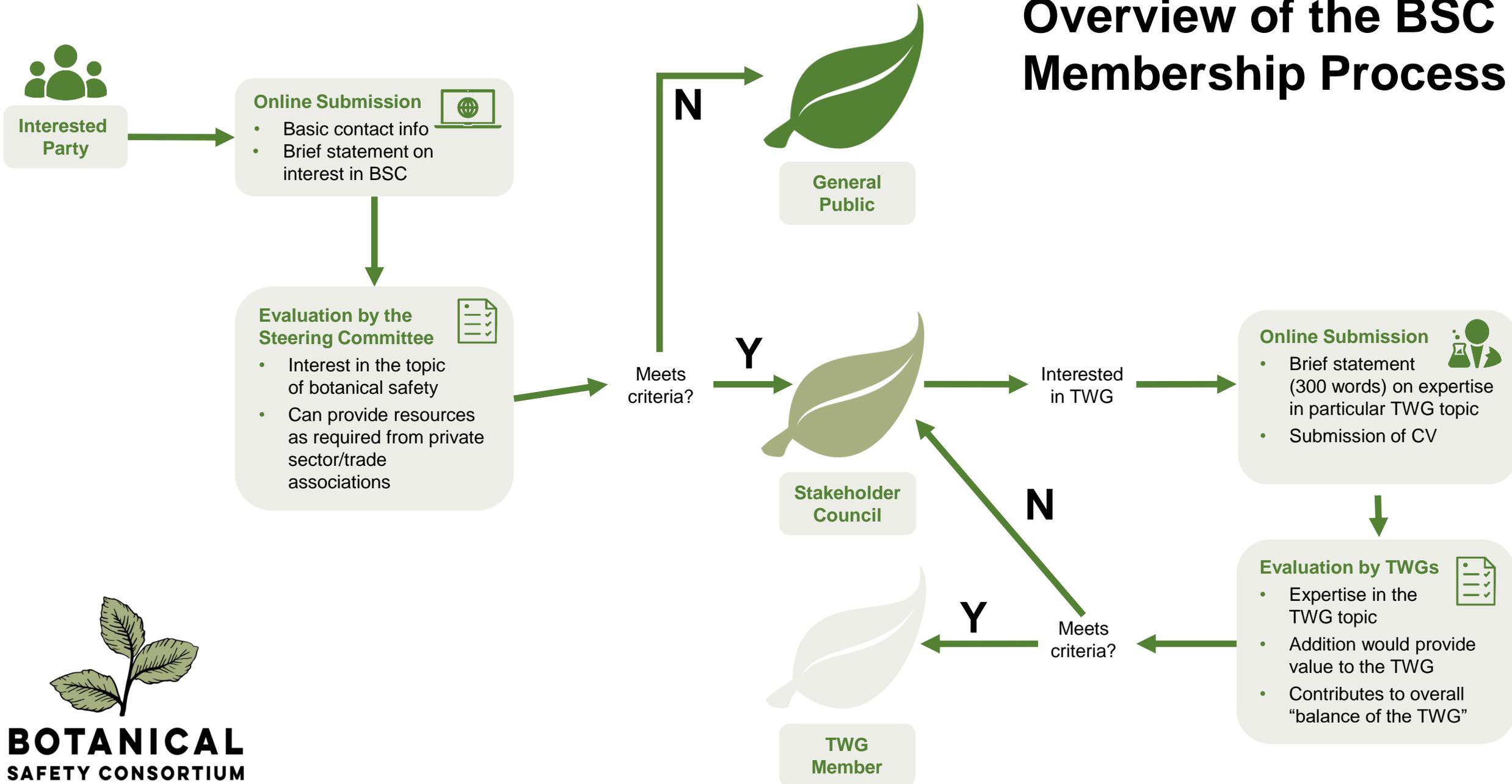
Michelle Embry



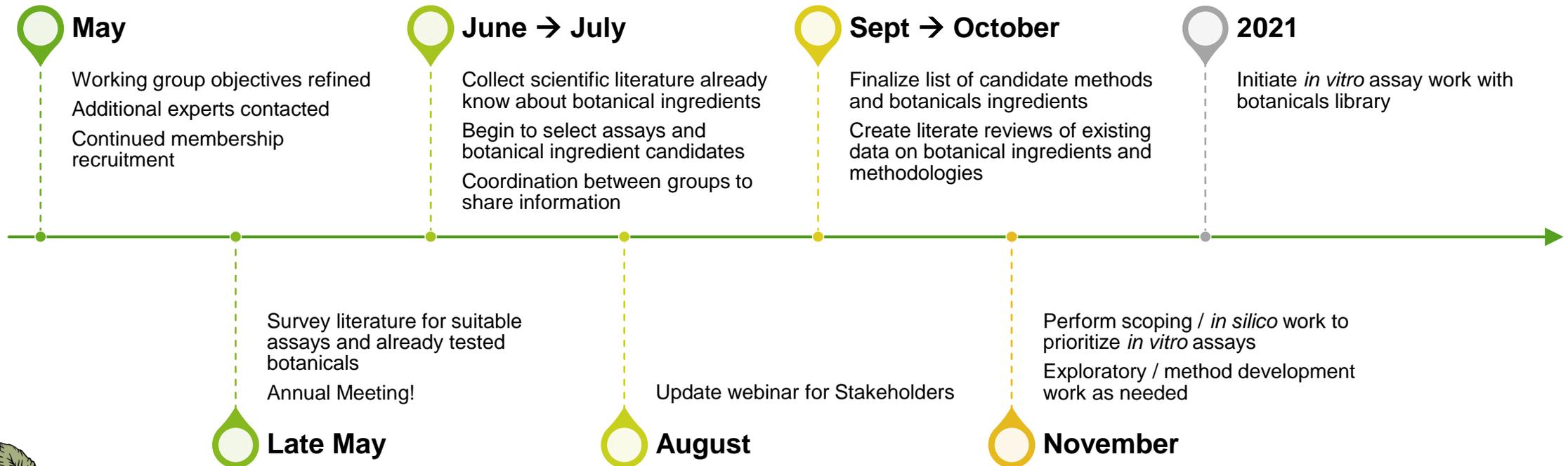
Connie Mitchell



# Overview of the BSC Membership Process



# BSC Timeline



[www.botanicalsafetyconsortium.org](http://www.botanicalsafetyconsortium.org)



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*A public-private partnership to improve botanical safety*

# BOTANICAL SAFETY CONSORTIUM

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The Botanical Safety Consortium (BSC) was officially convened in November 2019, as the result of a Memorandum of Understanding between the *US Food and Drug Administration (FDA)*, the *National Institutes of Health's National Institute of Environmental Health Sciences (NIEHS)*, and the non-profit *Health and Environmental Sciences Institute (HESI)*.



## Application Form

Name

Affiliation

Address

Phone

Email

Optional 2nd Email

Sector

\*Private sector and trade association applicants must pay an annual BSC sponsorship fee.

Please provide a brief statement regarding you or your organization's specific interest in the BSC (150 words or less):

## Sign up for our general distribution list!

\* Email

\* First Name

\* Last Name

\* Company

By submitting this form, you are consenting to receive marketing emails from: HESI, 740 Fifteenth Street, NW, Suite 600, Washington, DC, 20005, US, <http://www.hesiglobal.org>. You can revoke your consent to receive emails at any time by using the [SafeUnsubscribe®](#) link, found at the bottom of every email. [Emails are serviced by Constant Contact.](#)

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- Website: [www.botanicalsafetyconsortium.org](http://www.botanicalsafetyconsortium.org)
- Email: [botanicalsafety@hesiglobal.org](mailto:botanicalsafety@hesiglobal.org)
- [cmitchell@hesiglobal.org](mailto:cmitchell@hesiglobal.org)
- [membry@hesigloal.org](mailto:membry@hesigloal.org)



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