



BOTANICAL SAFETY CONSORTIUM

Organizational Framework

March 2021

The **mission** of the Botanical Safety Consortium (BSC) is to enhance the botanical safety toolkit and bring clarity to botanical dietary ingredient assessments for manufacturers and regulators.

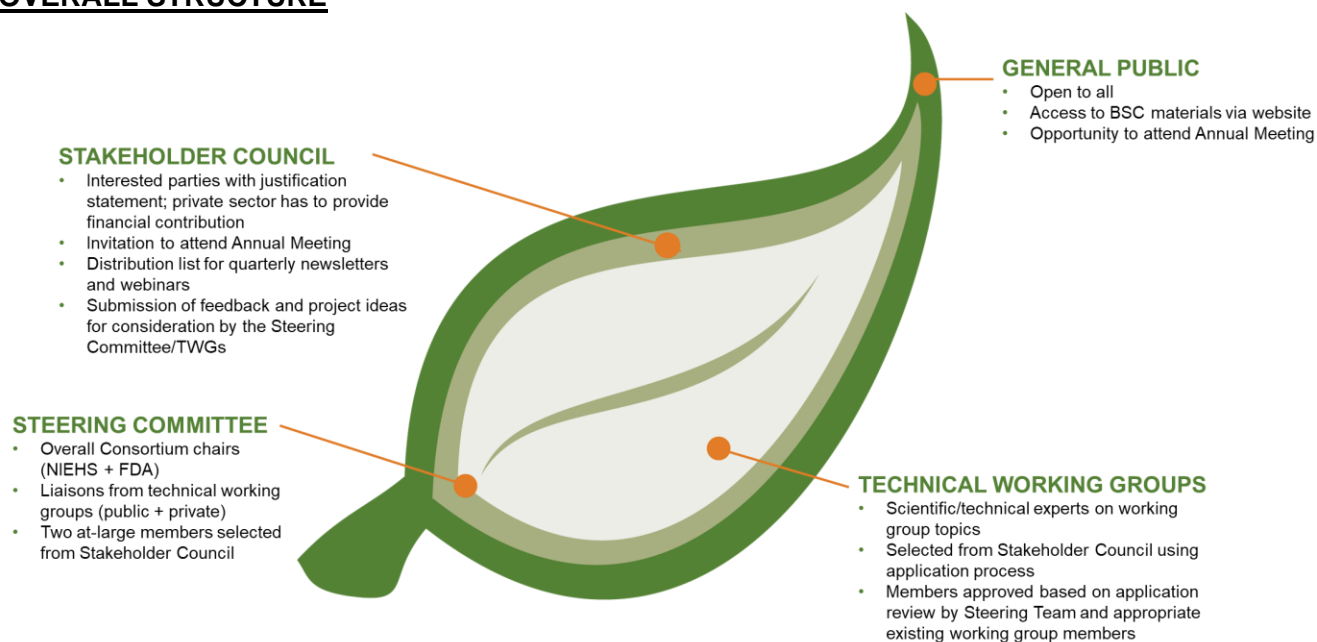
The BSC will fulfill this mission via the following **objectives**:

- Engage with a broad group of global stakeholders to leverage the best scientific approaches
- Establish the appropriate levels of chemical characterization for complex botanical substances
- Identify pragmatic, fit-for-purpose, in vitro & in silico assays to evaluate botanical safety
- Evaluate the application of these tools via comparison to the currently available safety information
- Integrate these tools and approaches into a framework that can facilitate robust evaluation of botanical substances

The following are draft guidelines for the organization, leadership, and overall governance of the Botanical Safety Consortium (BSC). It should be noted that the BSC already has an existing structure and some identified working groups with leadership and members identified. This document is intended to provide an overview of the future structure and organization of the BSC, recognizing that there will be several interim steps before full implementation.

STRUCTURE & GROUPS

OVERALL STRUCTURE



STEERING COMMITTEE

Roles & responsibilities

The role of the BSC Steering Committee (SC) is to serve as a collaborative leadership group that helps to achieve the following goals of the BSC:

- Evaluate overall progress towards the BSC mission;
- Align available resources within the BSC against current projects and evaluate future projects;
- Provide feedback on new TWGs or major scope changes within working groups;
- Provide feedback on additional participants and organizations to the SHC and the TWGs.
- Ensure communication and promote synergy across the TWGs;
- Promote cohesive and broad communication of the BSC's impact.

Composition

The BSC SC will be comprised of the following 'seats':

- USFDA representative (public sector; funding agency)
- NIEHS representative (public sector; funding agency)
- Liaisons from technical working groups (½ private sector; ½ public sector)
- 2 at-large members elected from the Stakeholder Council (one public sector; one private sector) who are not members of any TWGs
- HESI staff

Process

- Liaisons from the technical working groups (TWG) will be nominated by TWG members, Steering Committee members, Stakeholder Council, themselves, or staff. Elections will be held via electronic ballot of the TWGs.
- A technical working group co-chair may serve as the liaison.
- Half of the TWG liaisons will be from the public sector, and half from the private sector. This public-private representation will switch every 2 years to ensure public-private balance to the extent possible.
- The 1 public sector and 1 private sector Stakeholder Council representatives will be elected by the broader Stakeholder Council membership. Candidates may be nominated by members of the Stakeholder Council, BSC SC, TWG members, themselves, or staff. Elections will be held via electronic ballot of the Stakeholder Council.
- BSC SC members will serve 2-year staggered terms

TECHNICAL WORKING GROUP (TWG) MEMBERS

Roles & responsibilities

The BSC TWGs are the core technical entities responsible for designing and executing the BSC's scientific mission.

- BSC TWGs will focus on specific scientific questions related to evaluation of botanical ingredient safety, as defined by each TWG's mission and objectives.
- Active participation on a TWG is defined as regular engagement in TWG teleconferences and/or meetings and providing technical and strategic input and perspectives during the TWG's ongoing scientific discussions. It may also include contributing directly to experimental research, data analysis, writing, and/or communicating on behalf of the TWG. These contributions may include direct experimental or analytical work but can also take the form of providing scientific leadership, contributing actively to technical and strategic discussions, and/or actively conducting outreach on behalf of the team. The TWG Members are responsible for maintaining the TWG action plan and timelines.
- Sub-teams within a TWG may be formed as needed on key topics related to the overall TWG mission / objectives.

- Progress reports/updates and all other products, including manuscripts, discussion papers, etc. will be available for all BSC TWG and Steering Committee members via a shared internet workspace (password-protected SharePoint site).
- The TWG will forward major technical recommendations on scope and sequence of work, Steering Committee for final approval, pending resource allocations.

Composition & Process

- TWG members may be nominated by BSC Steering Committee, Stakeholder Council members, TWG members, themselves, or staff.
- Eligibility for TWG participation will be evaluated by the BSC Steering Committee and TWG co-chairs based on scientific and technical expertise via submission of an application and Curriculum Vitae (*Attachment 2*).
- As is feasible, all TWGs will strive for balance across sectors (public / private), areas of expertise, and geography.
- Members of the TWG will review membership on a yearly basis and re-balance as necessary based on the specific objectives, needs, and most feasible operation of the TWG.

TECHNICAL WORKING GROUP CHAIRS

Roles & responsibilities

TWG chairs work with the BSC Steering Committee, staff, and TWG membership to provide scientific, strategic, fiscal, and organizational coordination and leadership for the TWG activities. TWG chairs may be asked to serve as spokespersons for the Committee at scientific meetings/workshops and/or in the context of BSC organizational activities.

Composition

Each TWG will be led by volunteer Co-Chairs. At least one chair will be from the public sector (academia, government, NGO, research institute) and one from the private sector (two public sector chairs is acceptable but not preferable). The overall goal is to achieve diversity across sectors and organizations. It is intended that experts from the same organization will not be eligible to chair multiple TWGs.

Process

- TWG co-chairs will serve 2-year staggered terms with potential for renewal.
- Incoming TWG co-chairs will serve a one year 'vice chair' role to gain experience in the position. After that one year, one of the two sitting chairs will rotate out of leadership and the vice-chair will serve with the existing co-chair.
- Chairs and chair elects may be nominated by BSC Steering Committee, TWG members, Stakeholder Council, themselves, or staff. Elections will be held via electronic ballot of the TWG.

TECHNICAL WORKING GROUP LIAISONS

Roles & responsibilities

The TWG Liaison will be expected to report progress to the Steering Committee during all scheduled Steering Committee calls and meetings and reconnect with the TWG chairs to report back on progress and input from the BSC Steering Committee. If the liaison cannot attend a scheduled Steering Committee meeting or call, one of the TWG chairs will be asked to serve in their place. TWG liaisons may be asked to serve as spokespersons for the Committee at scientific meetings/workshops and/or in the context of BSC organizational activities.

Process

- TWG Liaison will serve 2-year staggered terms

- TWG Liaisons can be from the public sector or private sector; sector representation will rotate every 2 years (e.g., public → private)
- TWG chairs may serve as the liaison if the sector balance is maintained and they have sufficient time to serve in this capacity.
- TWG Liaisons may be nominated by TWG members, Steering Committee Members, Stakeholder Council, themselves, or staff. Elections will be held via electronic ballot of the TWGs.

STAKEHOLDER COUNCIL

Roles & responsibilities

The BSC Stakeholder Council (SHC) is a circumscribed body of individuals and organizations that is the entry point to the BSC. The SHC has direct opportunity to provide input on and support for BSC activities and priorities as described.

Members of the Technical Working Groups (TWG) and Steering Committee are, by default, Members of the BSC Stakeholder Council. The BSC Stakeholder Council Members can provide input and mission support to the BSC in the following ways:

- Voting on Steering Committee composition via electronic ballot
- If nominated and elected, serving on the BSC Steering Committee
- Nominating self or other scientists for participation in the TWGs and/or Steering Committee
- Participating in quarterly BSC Stakeholder Council technical update webinars; materials for the calls will be distributed 1 week prior to allow for active participation and input on the calls
- Providing direct financial or in-kind resources towards various BSC activities
- Attending the BSC Annual Meeting
- Submitting proposals for new areas of scientific work by the BSC (see section on “process for launching new projects” for details)
- Responding to specific requests for input from the Steering Committee and/or TWGs related to the ongoing BSC work
- Recruiting additional public or private participants to the efforts and mission of the BSC.
- May be contacted to assist in providing feedback and review on research, communications, etc. based on expertise categories.

Composition & Process

Participation in the Stakeholder Council will be subject to approval by the Steering Committee and is open to both individuals and organizations. Eligibility for membership will be determined by submission of a brief justification statement that demonstrates the Stakeholders specific interest in the topic of botanical safety (*Attachment 1*) as well as fulfillment of other membership criteria (for private sector entities and trade associations) as specified in the Membership section below. Approval of new members to the Stakeholder Council will occur on a quarterly basis via Steering Committee evaluation.

HESI SCIENTIFIC PROJECT MANAGEMENT STAFF

- HESI’s scientific management staff are critical contributors to the BSC coordination, stewardship, outreach and communications, resourcing, strategic and scientific design.
- Scientific management staff participate and support all official Steering Committee, TWG, and Stakeholder Council, calls and meetings.

MEMBERSHIP

JOINING FROM THE PUBLIC SECTOR

Individual public-sector scientists (e.g., from academia, research hospitals, foundations, research institutes, NGOs, governmental organizations, etc.) may join the BSC Stakeholder Council upon submission of their application form and approval by the Steering Committee. There are no direct costs required for public participation, although in-kind contributions as described above are encouraged. Public sector entities who would like to provide financial support to the BSC should contact staff directly for additional information.

JOINING FROM THE PRIVATE SECTOR

For private-sector organizations (i.e., for-profit businesses not owned or operated by a government entity that are eligible per HESI bylaws), participation in the BSC Stakeholder Council requires an annual assessment fee to help support the planned activities of the BSC. For private-sector organizations who are not currently HESI Sponsors, an additional fee is required to support HESI staffing and coordination (HESI Affiliate Sponsorship fee). Fees are based on a company's worldwide sales using the most recently available year-end figures (all in US Dollars).

Yearly sales	BSC Annual Assessment Fee <i>(For companies that are already HESI Sponsors)</i>	BSC Annual Assessment Fee <i>(All other eligible companies)</i>
Sales ≤ \$49.99 million	\$2,000	\$2,500
Sales \$50 million – 499.99 million	\$8,000	\$10,000
Sales >\$500 million	\$16,000	\$20,000

Eligibility

The Health and Environmental Sciences Institute (HESI), and the HESI Botanical Safety Consortium (BSC) by extension, is committed to upholding high [ethical, scientific, and legal standards](#). This includes a commitment to preserving the integrity of the [Memorandum of Understanding](#) between the U.S. Food and Drug Administration (FDA), National Institute of Environmental Health (NIEHS), and HESI that serves as the founding basis for the Consortium. In support of these guidelines and principles, the BSC will not knowingly admit any private company that manufactures or distributes a botanical dietary product for which the FDA has:

- affirmatively determined the product cannot be sold as a dietary supplement (e.g., [CBD or THC products](#))
- warned consumers not to use the product in any form for safety reasons (e.g., [Kratom](#)); or
- banned the product as a dietary supplement (e.g., [ephedrine alkaloids](#))

JOINING FROM TRADE OR BUSINESS ASSOCIATIONS

Trade associations or other business associations classified as tax-exempt under Section 501(c)(6) of the U.S. Internal Revenue Code who are not eligible to be HESI Sponsors or Affiliate Sponsors, as set forth in the HESI bylaws can be Members of the BSC. Although not eligible to be HESI Sponsors, these individuals and entities agree to be bound by the HESI bylaws “as if” they were HESI Sponsors. An association with ≥25 member companies must have at least 2 association members who independently support the BSC from the private sector to be eligible for Membership in the BSC. Smaller trade associations (with <25 members) will be evaluated on a case-by-case basis. The yearly assessment fee for a trade association to join the BSC is **\$10,000.00**. Participation in BSC events is open to staff of BSC Member Associations but not to representatives of their member companies unless those companies are themselves BSC Members.

PROCESS FOR LAUNCHING NEW BSC PROJECTS

GENERAL

- TWGs allow the BSC to fulfill its mission via the conduct of scientific project work in the form of focused research teams. These teams may conduct *de novo* experimental work, build databases, perform data analyses, develop decision-frameworks and methodology, and/or conduct training and outreach. TWGs cover a range of topics of interest to committee participants across sectors.
- Tripartite sector participation is an integral and mandatory component of all BSC projects. All BSC project work is supported and coordinated by HESI management staff.
- The adoption of new initiatives requires strong interest by the BSC Stakeholder Council, Steering Committee, and TWG membership, commitment of in-kind and/or financial resources by BSC members to support the proposed study, and sufficient management and coordination resources at HESI. New projects may fall under the auspices of an existing TWG or may merit the formation of a new TWG.
- **All new proposals should be considered by the BSC Steering Committee (and/or TWGs and Stakeholder Council when feasible) as the resources of the BSC are finite and the adoption of new work streams should be evaluated strategically.**

CRITERIA FOR EVALUATION

New projects and/or TWGs will be evaluated on the following criteria:

- *Scope*. Projects will be assessed for clear alignment with the BSC's mission.
- *Anticipated impact of the topic on practice*. Desired areas of impact include:
 - Enhancing the knowledge of botanical ingredient safety
 - Developing new in vitro and in silico tools to improve safety testing
- *Novelty of the topic*. If other scientific groups, workgroups or institutes are working in the same area then the proposal must demonstrate that the proposed efforts will be synergistic, novel, or address an unmet need.
- *Clarity of the proposal*. The proposal should adequately specify the design, resourcing, and anticipated outcome of the project.
- *Potential for success*. The project should have a high likelihood that it will achieve its stated objectives given available time and resources.
- *Resource availability*. Project feasibility will be evaluated in relation to the anticipated direct and indirect resource contributions from the committee members (or other partners), impact on the completion of other ongoing or planned projects within the committee, and overall budget and resourcing for project management.

PROCESS FOR LAUNCHING NEW PROJECTS

- To propose a new project within an existing TWG
 - Informal brainstorming/discussion around new project themes and emerging science frequently occurs in the context of working group teleconferences and other interactions among working group members.
 - If Stakeholder Council members wish to more formally propose a new project that fits within the scope of an existing TWG, they are encouraged to complete a new project template.
 - The new project proposal template is a brief two-page (maximum) document that captures key objectives, stakeholders, resources, and impact of the proposed topic. Once completed, this document can be shared with the TWG for consideration – proposed leadership and core membership should be identified in the proposal but may be modified as the project progresses;

- If the TWG is supportive of the new proposal, the HESI staff will assist in distributing the proposal to the Stakeholder Council with a request for input/comment on the content and approach. The proposal, and any critical input elicited from the Stakeholder Council outreach, should then be submitted to the Steering Committee for consideration. The Steering Committee may
 - Offer their support for adoption of the proposal within the TWG and thus the proposal will be enacted; or
 - Recommend that the topic moves for more extensive discussion by the full Stakeholder Council to assess whether the topic is impactful for the BSC's portfolio and merits the use of BSC resources; and/or
 - Recommend additional topic/proposal development and refinement for future consideration; or
 - Recommend that the project not be adopted.

- To propose a new TWG
 - If a new project concept does not align with an existing TWG, Stakeholder Council Members may propose the formation of a new TWG.
 - If members wish to more formally propose a new project, they are encouraged to complete a new project template.
 - The new project proposal template is a brief two-page (maximum) document that captures key objectives, stakeholders, resources, and impact of the proposed topic.
 - Proposed new TWGs must clearly define their scientific aim and a 1-2 year and 3 – 5 year action plan with proposed milestones and deliverables that supports initiation of the TWG.
 - Once the proposal is drafted, the HESI staff will assist in the distribution of the proposal to the Stakeholder Council.
 - In parallel with submission of the proposal, HESI staff will assist in scheduling a presentation of the proposal by the authors to the Stakeholder Council by webinar or at the face to face meeting.
 - Following presentation and review of proposal, Stakeholder Council members will provide general input/comment on the content and approach.
 - The proposal, and any critical input elicited from the BSC outreach, should then be brought to the Steering Committee for consideration.
 - Upon review, the Steering Committee may:
 - Offer support of the proposal and disseminate to the full committee membership to request engagement in the proposed TWG and to assess level of interest in participation; and/or
 - Recommend more extensive discussion to determine whether the topic is sufficiently impactful for the BSC's portfolio, and to assess whether there is sufficient interest and resources within the BSC; or
 - Recommend additional that the proposal needs further development and refinement, and should be reconsidered in the future; or
 - Recommend that the project not be adopted.