

## Innovative Solutions Canada Program

### Challenge EN578-170003/33: Identification of Microbial Mixtures

#### Attachment 1

#### Questions and Answers #1 to #7

This document contains questions and answers related to this challenge.

##### Question #1:

Are there specific applications (health, environmental) you are most interested in?

##### Response #1:

Health Canada works jointly with Environment and Climate Change Canada to conduct risk assessment of new microbial mixtures or consortium used in consumer and industrial applications.

Some examples that are of interest to Health Canada include: use of microbial mixtures or consortia in contamination site remediation, production of biofuels and biogas, microbial based cleaning products (such as household drain cleaners and degreasers, surface cleaners) and general cleaning and odour control products. Additional examples can be found in the following [review article published in 2018](#).

##### Question #2:

We need clarity on 2 of the 3 “essential outcomes”. What is meant by “characterize their stability and population dynamics, and predict possible interactions between individual micro-organisms of the mixture (e.g. using OMIC approaches such as genomics, transcriptomics, proteomics, etc.) that may mask or enhance adverse effects (pathogenicity, toxicity, allergenicity, hypersensitivity, etc.) in humans”? We would appreciate specific examples you may provide.

##### Response #2:

Innovative Solutions Canada is designed to seek truly novel solutions from Canadian small business. Challenges posted through ISC may appear to provide few details or specifications on what the desired solutions should look like. This is intentional. Challenge statements will contain some guidance on desired outcomes, but will not prescribe how a solution should work or function. We leave that to the creativity and ingenuity of Canada’s innovators.

##### Question #3:

What is the scope of Phase 1 and Phase 2? It looks like Phase 1 is up to 6 months and should bring us to (or close to) technology readiness level (TRL) 4, which is “Basic technological products and/or processes are tested to establish that they will work” (i.e., feasibility). We assume Phase 2 is for validation, prototype demonstration, etc. to reach TRL 9, but we would be grateful if you provided further details about this.

**Response #3:**

Phase 1 is for the development a Proof of Concept to determine the scientific and technical feasibility of the proposed solution. Proposed solutions must enter Phase 1 between TRLs 1-4 and cannot exceed TRL 4 upon completion of Phase 1. If the proposed solution has achieved minimum TRL 3 at the completion of Phase 1, the company will be invited to submit a Phase 2 proposal to develop a Prototype based on the Proof of Concept developed in Phase 1. Phase 2 is meant to push the R&D as far as possible with a goal of completing the R&D (TRL 9) and preparing for commercialization. If TRL 9 is not achieved upon completion of Phase 2, the sponsoring department may have options to continue funding the R&D depending on various factors including what TRL the solution is at upon completion of Phase 2, and if the solution continues to meet the needs of the sponsoring department.

**Question #4:**

Do you have any experts who were consulted for this call for bids, and can we ask them questions? And will these experts evaluate the proposals?

**Response #4:**

Subject matter experts at Health Canada prepared this challenge. In order to maintain the integrity of this procurement, all questions regarding this challenge must be submitted to the contact listed below. Communication directly with subject matter experts at Health Canada during the solicitation period is not permitted. An evaluation team composed of the National Research Council – Industrial Research Assistance Program (NRC-IRAP), and/or subject matter experts from Health Canada and/or other government departments will evaluate proposals. If required, Canada may use an external Subject Matter Expert to evaluate any proposal.

**Question #5:**

Do other sources of funding need to be secured, or can the entire amount be requested under the ISC program?

**Response #5:**

Up to \$150K can be requested under the ISC program. It is not a requirement, but permissible, to secure additional funding

**Question #6:**

We would be grateful for some background on how the current cost estimate for accurate identification and characterization (about \$150K per micro-organism) was calculated. Knowing this will also help us determine how our solution will advance the state-of-the-art over existing technologies.

**Response #6:**

Based on stakeholder's feedback and our experiences with notifications under the NSNR (Organisms), the cost estimate in generating the necessary data and information to fulfill the following NSNR (Organisms) regulatory requirements is suggested to be about \$150K. This cost includes:

- Identification and the information substantiating the identification, paragraph 1(a) of Schedule 1 of the Regulations
- Data from tests conducted to determine the effects of the micro-organism on aquatic plant, invertebrate and vertebrate species likely to be exposed, subparagraph 5(a)(i) of Schedule 1 of the Regulations
- Data from tests conducted to determine the effects of the micro-organism on terrestrial plant, invertebrate and vertebrate species likely to be exposed, subparagraph 5(a)(ii) of Schedule 1 of the Regulations
- Data from tests of antibiotic susceptibility, paragraph 6(b) of Schedule 1 of the Regulations
- The data from tests of pathogenicity that are valid for related micro-organisms that are pathogenic to humans, paragraph 6(c) of Schedule 1 of the Regulations

**Question #7:**

Can more than one bidder be selected for the call?

**Response #7:**

Multiple contracts could result from this Challenge.