Assessment Tools for Synthetic Biology Products RFA (STAR)
Informational Webinar
Thursday, May 28, 2020

Questions and Answers

Eligibility Questions:

Question: Are federal research entities eligible to apply? USGS/USFWS, even as a CO-PI?
Answer: Please see the funding notice (https://www.epa.gov/research-grants/assessment-tools-biotechnology-products), Section III.A. EXCERPT:

National laboratories funded by Federal Agencies (Federally-Funded Research and Development Centers, "FFRDCs") ***may not apply***. FFRDC employees may cooperate or collaborate with eligible applicants within the limits imposed by applicable legislation and regulations. They may participate in planning, conducting, and analyzing the research directed by the applicant, but may not direct projects on behalf of the applicant organization. The institution, organization, or governance receiving the award may provide funds through its assistance agreement from the EPA to an FFRDC for research personnel, supplies, equipment, and other expenses directly related to the research. However, salaries for permanent FFRDC employees may not be provided through this mechanism.

Federal Agencies may not apply. Federal employees are not eligible to serve in a principal leadership role on an assistance agreement. Federal employees may not receive salaries or augment their Agency's appropriations through awards made under this program unless authorized by law to receive such funding.

The applicant institution may enter into an agreement with a Federal Agency to purchase or utilize unique supplies or services unavailable in the private sector to the extent authorized by law. Examples are purchase of satellite data, chemical reference standards, analyses, or use of instrumentation or other facilities not available elsewhere. A written justification for federal involvement must be included in the application. In addition, an appropriate form of assurance that documents the commitment, such as a letter of intent from the Federal Agency involved, should be included.

Question: Are national lab scientists eligible for PI position?
Answer: No. Please see the answer to the question, above.

Question: Can an early career PI collaborate with a Lab at Oak ridge national Lab?
Answer:
It depends what you mean by collaborate. Applicants may procure equipment and services as specified in the RFA, Section III.A. If you have specific questions concerning your situation, please contact us directly.

Question: Can an individual from a company be Co-PIs?
Answer: PIs and co-PIs cannot be from private companies. However, private companies may provide **consulting services** and donate equipment or materials to the research. A proposal's budget and budget

justification should only address the use of EPA funds. Any donated or 'in kind' type of services or materials may be referred to in the proposal narrative, but not the budget tables or justification.

Question: Can a for profit company partner with a University and jointly obtain the grant.

Answer: Private firms may not directly receive assistance under this funding notice. However, private consultants may have a role in the research. Please see the RFA, Budget Justification, Section IV.C.7.b(6):

Contractual: List the proposed contractual activities along with a brief description of the scope of work or services to be provided, the proposed duration of the contract/procurement, the estimated cost and the proposed procurement method (competitive or non-competitive). Any procurement of services from individual consultants or commercial firms (including space for workshops) must comply with the competitive procurement requirements of 2 CFR Part 200.317-200.326. Please see https://www2.epa.gov/grants/epa-solicitation-clauses#Contracts and Subawards for more details. Examples of Contractual costs include:

i. Consultants – Consultants are individuals with specialized skills who are paid at a daily or hourly rate. EPA's participation in the salary rate (excluding overhead) paid to individual consultants retained by recipients or by a recipient's contractors or subcontractors is limited to the maximum daily rate for a Level IV of the Executive Schedule (formerly GS-18), to be adjusted annually.

ii. Speaker/Trainer Fees – Information on speakers should include the fee and a description of the services they are providing.

Please note that consultants are not to be considered Key Personnel, Principal Investigators, or co-PIs.

Question: Could a company provide materials or an in kind contribution of one of their products?

Answer:

Yes, this is permitted. Private companies may donate equipment or materials to the research. A proposal's budget and budget justification should only address the use of EPA funds. Any donated or 'in kind' type of materials may be referred to in the proposal narrative, but not the budget tables or justification.

Question: What is the equivalent of Assistant/Equivalent professor mean?

Answer:

For people in academia, we are looking for people who have not yet received tenure (as defined in the RFA). For non-academic tenure-track equivalent positions, it must meet all of the following requirements: (1) the employing department or organization does not offer tenure; (2) the appointment is a continuing appointment; (3) the appointment has substantial educational responsibilities; and (4) the proposed project relates to the employee's career goals and job responsibilities as well as to the goals of the department/organization.

Question: Has EPA identified any Resource Centers/Labs/institutions for supplying such biotech products to the applicants?

Answer: Please see Section I.F. of the funding notice. EXCERPT:

Agency policy and ethical considerations prevent EPA technical staff and managers from providing applicants with information that may create an unfair competitive advantage. Consequently, EPA employees will not review, comment, advise and/or provide technical assistance to applicants preparing applications in response to EPA RFAs. EPA employees cannot endorse any particular application.

For Agency personnel to provide this information would be a violation of Agency ethics regulations.

Question: Given the interdisciplinary nature of the topic, could you provide any information on the expected scientific background of peer reviewers for this call?

Answer:

We expect reviewers to have significant expertise and/or experience in the field, usually (but not all the time), with a Ph.D. We welcome reviewers from academia, the private sector, non-profit organizations, government agencies, etc. Reviewers may not be affiliated with any application or be EPA employees.

Question: Can the Postdoc and student be added a key personal for the early career application?

Answer:

The applicant institution may add whatever personnel it deems appropriate, as long as those personnel are affiliated with the institution. However, please note that one of the evaluation criteria listed in Section V.A. of the RFA has to do with qualifications of the investigators, such as experience, publications, etc. Post-docs, graduate students, and undergraduates may receive support under this research without necessarily being PIs or co-PIs.

Question: The resume is limited to 2 pages, but the RFA also says that NIH biosketch format is acceptable; however, the NIH biosketch page limit is 5 pages. Can you clarify? Can you also can you confirm there is no page limit on the reference section?

Answer:

Please limit the resume to two pages. You may use the NIH format, but if your document is five pages you will have to edit out three of the pages.

Question: Are letters of support a required element of the proposal? If not, is there a significant benefit to the application of including letters of support?

Answer:

Letters of support or intent are not required. If you are planning to receive support, materials, or other kinds of research assistance from outside parties, then it is recommended to include letters of support or intent in your application. Each letter must be limited to one page, but there is no limit as to the number of letters that may be included in an application. No letters of support or intent from EPA employees are allowed.

Question: Is there any limit in the amount requested for the PI Summer Salary?

Answer: No, but costs in every category overall will be reviewed and are expected to be reasonable, allowable and allocable to the project.

Question: Has EPA identified any Resource Centers/Labs/institutions for supplying such biotech products to the applicants?

Answer: No

Question: Will the bar for preliminary data be lower for early career PIs?

Answer: No. Although early career PIs may have projects smaller in scope, the data quality demands would be the same.

Electronic Submissions Questions:

Question: Do you prefer to evaluate white pages?
Answer: Pre-submission or white papers cannot be accepted.

Technical Questions:

Question: In Slide 5, last bullet, there is a point of 'public trust'. Is there room for Stakeholder Engagement or Social Science research in the dimension of public trust?
Answer: Yes, it could be a component of the research, but since it is not specifically included as a Specific Area of Interest, it cannot be a major focus of the research.

Question: Would a grant where predictions of motifs were made by the group of the PI at an academic institution and tested in a federal lab be acceptable?
Answer: Yes, as noted in the eligibility questions.
Please see Section III.A. in the funding notice (https://www.epa.gov/research-grants/assessment-tools-biotechnology-products), excerpt: FFRDC employees may cooperate or collaborate with eligible applicants within the limits imposed by applicable legislation and regulations. They may participate in planning, conducting, and analyzing the research directed by the applicant, but may not direct projects on behalf of the applicant organization.

Question: It seems the RFA emphasizes modeling. How trusted is a modeling result in a regulatory submission.
Answer: Modeling will be more important for some areas where environmental release is problematic or requires a long regulatory review. These proposals are not intended to be used as a regulatory submission. The research work requested is to inform risk assessors and others.
Modeling can form part of a regulatory submission, particularly when it is not possible to conduct even small scale field tests or mesocosm studies. Gene drives are a good example of technology which will not likely be allowed for environmental release in the near future without significant assessment / discussion. Regulators recognize that all models have limitations and are based upon assumptions; it is up to the risk assessor to determine how much weight to place upon anyone modeling parameter / conclusion. Models may be the best tool we have with truly synthetic organisms as the literature and past experience may not adequately address the novelty of the product.

Question: Is risk analysis a topic that could be funded--e.g. meta-analysis of literature for survivability of syn bio microbe in environment and quantitative modeling? Or are you looking more for risk science biological research?
Answer: Yes, risk analysis is an acceptable research topic as long as the efforts address at least one of 3 research areas listed in the RFA

Question: Would Wolbachia bacteria-modified mosquitoes also qualify?
Answer: Not for this RFA. Wolbachia are naturally occuring, albeit oftentimes used in hosts which that strain may not normally infect. If the Wolbachia strain was modified with synthetic components, it could qualify for inclusion under this RFA.

Question: Would a New Mosquito + New Ecology + New tool (Super-infection) be a subject of Risk Assessment research?
Answer: No. Superinfection of a host arthropod with multiple Wolbachia strains is not considered for this RFA unless the Wolbachia genome is altered with synthetic components, as described in the RFA.

Question: Can you explain in more detail about (1) the types of synbio methods seen now in TSCA and FIFRA submissions (CRISPR, etc.)? This is relevant to focus on which methods should be looked at most closely in the near term.
Answer: We have not seen the types of components as envisioned in this RFA for submissions of pesticidal products (yet). We have seen codon optimization and modified amphipathic peptides, which are not truly natural or found in existing organisms. However, these are not the types of technology addressed by this RFA. We have not seen the types of components as envisioned in this RFA under TSCA yet either.

Question: Does the containment and restriction assessment of **naturally occurring biological contaminants** using synbio constructs fall into Specific Area 1?
Answer: Research that addresses the need for improved risk assessments of new biotechnology products, including those developed through synthetic biology, genome editing, and metabolic engineering would be of interest. Assessments of the long-term stability, persistence, efficacy, and reliability of synbio-based containment strategies in general meet this need and fall within Specific Area of Interest 1. This is especially true where the objective is to contain synbio constructs or engineered organisms. Assessments of synbio approaches to contain *naturally occurring biological contaminants* are marginally within Area 1.

Question: Would a genetically engineered mouse with gene drive be considered as a subject for risk assessment research?
Answer: Yes

Question: Would plant based extracts infused into nanobubbles for Aedes mosquito control be a subject for ecological risk assessment?
Answer: No

Question: Would classification systems/risk prediction methods for microbes meet topical requirements?
Answer: Yes

Question: Can you comment on the expectations for preliminary data for this program?
Will the bar for preliminary data be lower for early career PIs?
Answer:
No, the purpose of the early career award is to fund research projects smaller in scope and budget by early career PIs, but does not lower the bar on the research quality. It is expected that the majority of the research will be performed by early career investigators. Please see Section III of the Request for Applications (RFA) for details on the early career eligibility criteria.

Question: Which one is more interesting to EPA with this RFA: Development of microbial biocontainment strategies vs. development of tools to evaluate them? In terms of deciding where to focus innovation, would creation of new biocontainment methods be of greater or lesser interest to this program than new tools to characterize existing biocontainment methods?
Answer: Both are equally interesting.

Question: Would plant based extracts infused into nanobubbles for Aedes mosquito control be a subject for ecological risk assessment?
Answer: No, Plant extracts are not a subject of interest for ecological risk assessment

Question: Would developing “kill-switches” be acceptable under this RFA?
Answer: Yes, kill switches are 1 mechanism among many that would be appropriate.

Question: In terms of deciding where to focus innovation, would creation of new biocontainment methods be of greater or lesser interest to this program than new tools to characterize existing biocontainment methods?

Answer: Given the need for improved risk assessments of new biotechnology products, simply developing novel biocontainment methods would not be the highest priority. However, innovative development of biocontainment methods along with assessments of their long-term stability, persistence, efficacy, and reliability would meet the need and be of greater interest.

Question: Associated to this, I assume this also addresses physical containment, in addition to genetic containment methods.
Answer: Modeling will be more important for some areas where environmental release is problematic or requires a long regulatory review. These proposals are not intended to be used as a regulatory submission. The research work requested is to inform risk assessors and others.

Question: We are planning to use a biotechnology product (microbial fuel cells) to mitigate naturally occurring genetic contaminants (antibiotic resistance genes) and minimize the horizontal gene transfer within the biotechnology product. Experimental and modeling tools will be developed to assess the mitigation performance. Would this be in line with the topics of this RFA?
Answer: Yes