**RWP-BIO-24-01**

**Questions and Answers**

Proposal Topic:

1. If a company has a medical application that seems to fit the spirit of the Domestic Bioindustrial Manufacturing Investment, would the "Fitness" category be the best for this type of proposal?

As stated in the Problem Statement (see “5fs”), “Pharmacological/medical products, diesel replacement fuel, and enabling technologies such as software or advanced enzyme design are also not of interest.”

1. Our company produces critical pharmaceuticals and focuses on developing a training program to create individuals capable of working in the biomanufacturing industry. Would our project be worth submitting a proposal to the recent announcement?

As stated in the Problem Statement (see “5fs”), “Pharmacological/medical products, diesel replacement fuel, and enabling technologies such as software or advanced enzyme design are also not of interest.” Training programs are not a focus of this RWP.

1. Our company produces a cultured animal fat combined with plant protein creating a blended meat product, so arguably is a superior quality product rather than a simple substitution. Would our project be considered as addressing the problem statement for this white paper? Or is this not in scope?

As stated in the Problem Statement (see “5fs”), “Simple substitution of a biomanufactured product for material that is not in limited supply (e.g., “cultured” meat whole proteins) is not of interest.

1. "Cultured meat whole proteins" is excluded from the list of interested applications. Would you be open to considering cultured meat if it could be produced entirely in the US and cheaper than traditional meat?

As stated in the Problem Statement (see “5fs”), “Simple substitution of a biomanufactured product for material that is not in limited supply (e.g., “cultured” meat whole proteins) is not of interest.

1. The DIBC Problem Statement states that “Simple substitution of a biomanufactured product for material that is not in limited supply (e.g., “cultured” meat whole proteins) is not of interest.” Could you elaborate on this criterion?
   1. The assertion implies a focus on commodities currently facing scarcity. Could you provide examples of such food materials deemed to be in short supply?

The Government cannot provide a list of food materials in short supply as supply chain disruptions and scarcity may occur for many reasons. It is the Government’s intent and interest to collect and evaluate EWPs as to why the proposed prototype solution should be of interest.

* 1. Would technologies enabling the on-site production of food components under extreme conditions, such as in conflict zones—despite the primary products not being scarce domestically—align with the DIBC's objectives?

The objective is to produce products and not enabling technologies.

1. Our company has been developing and biomanufacturing an alternative to antibiotics in animals and animal protein. Does our proposed project respond well to what the DIBC program is looking for, or is having the military as a customer a necessary requirement for funding? In other words, do we have to market our product to military markets, or is marketing to commercial markets sufficient?

Proposed prototype solutions must have a direct military use for this problem statement. Additionally, as stated in the Problem Statement (see “5fs”), “Pharmacological/medical products, diesel replacement fuel, and enabling technologies such as software or advanced enzyme design are also not of interest.”

1. We have a novel biomanufacturing process that makes a critical food ingredient currently made by animals. While there is currently not a shortage, there are scenarios that could disrupt the supply chain. We would also be using this ingredient to make several ingredients related to nutrition and preservatives. Can you comment if novel processes like this are suitable for this proposal, especially considering other advantages such as energy and emissions reductions, lower water usage, producing a higher purity product, alternative supply chains, etc.?

The Problem Statement includes the 5F definitions, which extends to products with improved performance characteristics, as a basis for a prototype solution. Proposers may submit an EWP with reasonable and supportable risks for supply chain disruptions, and meets those requirements stated in the EWP.

1. Would biomanufcaturing of a byproduct - specifically platform materials for construction of defense products, be eligible for an award if the specific material is not supply constrained? In such a case, would providing a suitable supply chain by eliminating or decreasing reliance on petroleum-based manufacturing be sufficient for being eligible for an award or does the material need to be supply constrained as well?

The objective of the program is to resolve shortages and supply chain gaps. As stated in the Problem Statement, “Simple substitution of a biomanufactured product for material that is not in limited supply… is not of interest.”

1. Is expansion of manufacturing capabilities to improve supply chain reliability a strong proposal topic?

The Government will not comment on the strength or merit of individual proposal topics.

1. Will technologies that utilize biogenic CO2 as a feedstock be eligible, or must all processes be chassis?

The Government’s interest is feedstock-agnostic so long as the other project parameters are observed.

1. Our company produces an edible bioproduct through a synthetic route rather than traditional bioengineering methods. Does the DIBC acknowledge and support technologies like ours that yield bioproducts through synthetic processes?

Novel bioproducts produced through novel synthetic processes may be submitted through an EWP for consideration.

1. Would you consider the production of high-value proteins and minor proteins such colostrum, currently too expensive to purify, eligible for this funding?

Proposed prototype solutions must have a direct military use for this problem statement. The objective of the program is for the expansion of biomanufacturing production, not just processing of biological products. Also, please reference 6.3 Cost Evaluation, “The Government is responsible for final review and acceptance of the cost and/or price to determine if it is fair and reasonable.”

1. Are bio-enabled or plant-based precursor compounds acceptable, or are fermentation sources a requirement? If so, is bio-fermentation additives that enable defense technologies sufficient?

Fermentation is not a requirement. Extraction of bio-based products may be considered for DoD needs.

1. In the Problem Statement, it states "Proposers should focus on the bioproduction of material(s) that fit within the categories as described below". Does the EWP need to focus on specific molecule(s) of interest, or is a process for exploring a bro[a]der class acceptable, (e.g. all terpenes in general as fuel replacements/additives, or multiple polymer precursors for textiles) and down selecting during the prototype phase?

Submissions to this RWP should meet the criteria identified in the RWP and will be evaluated by Government evaluators based on Section 4.1 Evaluation. A class or family of molecules, in whole or in part, that align with the objectives and evaluation criteria may be considered.

1. If a chemical is currently made internationally (ie China), potentially at a lower cost than it could be domestically, would the DoD pay a premium for said chemical(s) to be produced domestically under the context of this program, especially if involved with defense applications?

As stated in the Problem Statement, “…to build the long term capability and viability of sources of high-quality critical material. The DoD seeks to engage in prototype projects that will develop and demonstrate technical and business processes to produce pure, stable, high-quality biomanufactured product(s).” Proposers should consider their ability to build an economically viable business.

Proposal Categories:

1. If we wish to be considered for more than one category, should we submit just one EWP or a separate EWP for each category we wish to be considered for? Is the review process capable of evaluating proposals that strongly address multiple application areas across these sectors?  Is it advisable to present a single strong proposal in one area, or to present a strong proposal that addresses multiple areas?

EWP’s will be evaluated on the basis of the merit of the proposed prototype solution in addressing the problem statement for a specific critical sector detailed in the Problem Statement. An EWP(s) should be submitted for each critical sector to be evaluated on the basis of merit for each proposed prototype solution.

1. We received a lot of outreach to partner on our materials and renewable oils platform. Our team is looking for guidance on how we should structure our white paper submission in light of the range of application development opportunities which fit solidly within the five "Fs".

The Government will not provide guidance. Each company will need to make teaming and submission decisions that align with their internal strategies.

1. We plan to submit under both the Fuel/Firepower and Food topic areas as our production facility is product agnostic. Should these be multiple submittals, or contained in one application understanding that they would have different partners?

See the answer to Question # 16.

1. Is it necessary for a company with a facility that could be upgraded/retrofitted to support bioproduction of critical products to partner with a product company for a submission, or can the map and measure period be used to work with product companies with which we have relationships to determine the best product company to fit the existing infrastructure and DoD needs?

EWPs should fit within the 5fs. A company with existing facilities should be able to demonstrate that they have the capability to produce the proposed prototype solution, or what modifications would be needed in order to do so. The Government will consider Letters of Interest or Letters of Commitment included with the EWP. These will not be counted against the page count limitations.

Technology:

1. Our technology and business is currently operating at a TRL7+ level.  Does this advanced level of readiness align with the goals of the RWP?

As stated in the Problem Statement, “…must be at least technology readiness level (TRL) 4, but preferably, TRL6.” Higher TRLs are acceptable.

1. What CMMC/NIST level is required and at what stage?

As stated in the RWP, Section 1.0 BACKGROUND awardees must implement NIST-SP 800-171 Rev. 2 prior to handling any CUI. Reference the [Chief Information Officer > CMMC (defense.gov)](https://dodcio.defense.gov/CMMC/) for different levels applicable to the Cybersecurity Maturity Model Certification 2.0 (CMMC 2.0).

1. Fabrication / Fitness / Fuels second phase awards are expected in Q2 2027. Since this is 3 years away, there is a significant time available to improve the technology TRL level through R&D. Do proposals that have a lower TRL level (TRL 4 or lower) be encouraged for an award - given the opportunity to further develop the technology for another 3 years.

See the answer to Question # 20.

Eligibility:

1. Can foreign entities with a US-subsidiary apply to this opportunity as the lead applicant?  Can foreign entities with a US-subsidiary apply to this opportunity as a sub-applicant or contractor? What is the process for a foreign entity gaining membership into the DIBC on a case-by-case basis?

Consortium membership requires an active DD2345, which is limited to U.S.-/Canadian-based companies. Consortium membership is required prior to award. See also the answer to Question # 24.

1. Are there are any eligibility constraints for this grant? Does the company have to be owned by majority US citizens / green card holders? In addition, does DIBC have a list of biomanufactured products that are of high priority?

This is not a grant opportunity. This is being awarded under 10 U.S.C. 4022 with DPA Title III funds. Awardees must be a DIBC member at the time of award. Additionally, to be eligible for award of Defense Production Act Title III funds, U.S. based companies that are not U.S.-owned must have substantially all of the research and development, engineering, manufacturing, and production activities related to the proposed material in the U.S., Canada, UK, or Australia.

Reference the Desired Objectives in the Problem Statement. During the Virtual Industry Day, it was mentioned the current emphasis is on firepower; however, The DoD intends to award multiple prototype projects in each of the 5Fs.

1. Can an Australian-owned company with a U.S. subsidiary with at least one employee in the U.S. that holds lawful citizenship be eligible to hold an active DD2345 as part of its effort to gain eventual DIBC membership for the U.S. subsidiary?

The Defense Logistics Agency (DLA) reviews DD 2345 applications and determines eligibility. Pre-submittal requirements are outlined on the DLA site. The DLA DD2345 site is found here: <https://www.dla.mil/Logistics-Operations/Services/JCP/>.

1. We are a nontraditional defense contractor having never worked with the DoD before, but one of our proposed partners has worked with the DoD. Would we still qualify as a non-traditional in the White Paper Submission?

The definition for a nontraditional defense contractor (NTDC) can be found at 10 U.S.C. 3014. Also reference 10 U.S.C. 4022 - Appropriate Use of Authority, specifically (d). NTDCs may team/partner with traditional companies.

1. We are a manufacturer who will be partnering with a second company who provides the organism. Should this be contained within one application or do both companies need to submit?

If you are teaming with another company, only the prime should submit an EWP. Concerning the Prime Proposer: See also the Answers in Questions # 23 & 24 concerning Consortium Membership specifically.

1. Our firm is being approached by multiple interested parties seeking to partner on a submission.  Is there a limit to the number of submissions that we can appear in?  Will our submissions be penalized if we are on more than 1?

No, there is not a limit, nor is there a penalty.

Definitions:

1. Can you please define “capability advancement”?

A “capability advancement” is the maturation of the domestic supply chain’s ability toward meeting the desired objective.

1. Can you please define “technology advancement”?

A “technology advancement” being evaluated is the evolution of business and technical plans in support of achieving the capability of interest.

1. Can you please define “prototype solutions”?

Reference 10 U.S.C. 4022 (e) 5

1. For the purposes of the EWP, how is Project defined? Is it defined as the planning agreement phase or the entire MEMBR program lifecycle (Planning agreement phase along with the Build phase?)

See the Answer to Question # 31.

1. What is the accepted or common definition of what counts as biomanufacturing? Following on that, would a process that uses biomanufactured feedstocks fall under this RWP?

A generally acceptable definition, but is not limited to the following: Bioindustrial manufacturing uses living organisms, cells, tissues, enzymes, or cell-free systems to produce materials and products for non-pharmaceutical applications. The objective of the RWP is inclusive of the biomanufacturing of goods; projects centered on processes that simply consume biomanufactured goods are not objectives.

1. Does DIBC have a specific definition of a biomanufactured additive?  Likewise, is there a definition of what qualifies (or does not qualify) as biomanufacturing process?

A biomanufactured additive is a product produced through bioindustrial manufacturing process that is combined with a primary product to achieve performance requirements for the combined product. For example, an additive may be a fuel stabilizer or a dopant for polymer composites. Bioindustrial manufacturing uses living organisms, cells, tissues, enzymes, or cell-free systems to produce materials and products for non-pharmaceutical applications.

Submissions:

1. I see that we are required to submit plans to obtain/employ *resources*to develop strategic business and marketing plans but are any parts of the business and marketing plans themselves required in the first phase or only once downselected (like a summary for example)?

This RWP is for the Prototype Assessment and Planning phase. Consider the sequence in this way: 1) The EWP should inform the USG as to how you will execute the Planning phase, including the resources you would apply; 2) during the Planning phase you will apply the resources to complete the 6 deliverables. Upon successful completion of the Prototype Assessment and Planning phase, The Government may select some companies to proceed to the Prototype Build phase.

1. Attachment 2 – Enhanced White Paper Template, Section 1.6: Implementation and Transition (est. 1 page) --- asks us for the following, “Provide details of how the business and manufacturing solution proposed will be implemented and product brought to market in military and commercial supply chains and applications.”

Our understanding is that the purpose of this entire EWP is to deliver [**plans**] surrounding (i) how we will taking our TRL4 to TRL6 technologies to BioMRL10 and FRL; (ii) the development of plans to ensure business operations are sufficient to become a supplier to the DoD and the federal government at large; (iii) defining both the product specifications and volumes required from the government; (iv) developing marketing and business development plans so that, once scaled, our technologies can be commercialized in the broadest way possible.  First, is our understanding correct?  Meaning, the purpose of this first phase is to assess and plan, not to execute?

If this is the case, can you please help clarify exactly what Section 1.6 is asking of to outline?  The red text seems to be asking us how we will implement plans that we will develop as part of these initial grants.

This is not a grant opportunity. Reference Answer to Question # 24 concerning Type and Funding. As stated in the Problem Statement, this RWP is to make awards first for the Prototype Assessment and Planning phase. Proposers should detail how the assessing and planning for business and manufacturing solutions will be implemented, and how the proposed prototype solution could be brought to the DoD and commercial supply chains and applications.

1. Do[es] resources mean a preliminary TEM / facility size, unit ops/equip, workforce, systems, go-to-market strategy, etc? In other words, should this be the “vision” to get to BioMRL10 and full production?

Yes; “plans to obtain/employ resources” is inclusive of all types of resources applicable to meeting the desired objective as stated in the Problem Statement.

1. How much of the business/market plan should be addressed in the EWP? This is not mentioned in the template.

See the RWP Section 4.1 Evaluation. The EWP has a 15 page limit excluding the cover page. If a business/market plan is already established by a proposer, that information should be included. The EWP template is a guide with recommendations, subject to the proposer’s specific capabilities, status, and interests.

1. Should the EWP focus mostly on the plan, milestones, deliverables for the planning phase or the build phase? Section 1.2 - Milestones: Are these milestones for the planning phase or for the build phase?

The RWP is for the Prototype Assessment and Planning phase and is to focus on the foundation and execution of this phase. The “Capacity Instantiation and Qualification” task will be addressed in a Build Phase proposal and SOW, upon successful completion of the Planning Phase and to be negotiated at a later date, and is not intended to be addressed in the EWP.

1. Section 2.2 - I assume these are the existing facilities that we will leverage for both planning, and design/build of new facility?

Yes. The goal is to identify the proposer’s existing physical resources.

1. Section 1.5 asks for the following:  “Provide the capability improvement metrics that will be developed for the project and how they will be measured. May include items such as: business/financial assessment and planning metrics; marketing assessment metrics; technical design completion metrics; product and/or process capability metrics (for optional tasks).” I assumed this was just really what are the deliverables from the tasks we would undertake as part of Section 1.2.  But section 1.2 is really asking for both tasks and deliverables.  Can you please help us understand what is meant by “metrics” in the context of these efforts?  Most of this is not quantitative and is developing planning documents, so I am [un]sure what metrics / KPIs would be in this section.

Responses to Section 1.2 Proposed Milestones should define and identify dates for deliverables 1-6 (as applicable). If awarded, those milestones could include drafts or other substantive incremental advancements that indicate that the project efforts are on track.

Responses to Section 1.5 Success Metrics should identify the measurable (qualitative and quantitative) goals that will either result from the activity or be critical standards around which plans are built. For example: deliverable 1 - business plan metric may be to identify the market-competitive product price, while a deliverable 6 - chassis improvement goal may be to demonstrate a titer increase of 15%.

Award:

1. Is the $1.5M award solely for the Prototype Assessment and Planning phase? Or is it for the two phases? If the award targets phase 1, then, is there further funding planned for the Build Phase? And, if so, what will be the eligibility criteria?

See the Answer to the Question # 39. As stated in the Problem Statement, “To proceed to the Build phase, the Government will negotiate a revised SOW with the consortium member and request an updated cost proposal.” And the following section Anticipated Funding **“**The Government estimate is approximately $1.5M per award. Deliverables 1, 2, and 3 must be completed, and are expected to consume approximately 60% of the proposer’s budget. One or more of Deliverables 4, 5, and 6 may be completed and are expected to consume approximately 40% of the proposer’s budget. This estimate is provided as guidance…”

1. Is there a target amount of award funding required to be allocated to the biomanufacturing component of a proposed project? Does this amount have an impact on a project’s evaluation for award?

See the Answer to the Questions #39 & 42. Actual splits may vary according to the proposer’s existing capabilities, business and technical maturity, and is subject to negotiation, if selected. Also, see the RWP section 6.0 Pricing Proposal Process, “The price proposal shall provide sufficient detail to substantiate that the overall proposed price is realistic, reasonable, complete for the work proposed, and reflects the best price for the proposed solution.”

1. Are the 5F focus areas equally important, or are there specific focus areas more likely to receive awarded projects?

See the Answer to Questions #16 & 24. The number of awards for each of focus area may vary depending on the evaluations and recommendations for award in each focus area.

1. Assume that the awards are not loan guarantees nor offtake guarantees?

Correct. See the Answer to Question # 24.

1. If we have offtake agreements for the same chemicals with companies, combined with signed agreements for said chemicals, will that improve the chances of success?

The government assumes ‘improve the chances of success’ to mean evaluation, selection, and award rather than improve the chances of success of the prototype project; EWPs will be evaluated according to the RWP section 4.0 Enhanced Whitepaper Evaluation Process. Offtake agreements may be discussed in the EWP.

Deliverables:

1. In the problem statement on Page 2, There is a sentence that states: "The Government **may** select companies to enter prototype agreements at the Prototype Assessment and Planning phase that **may** result in the following deliverables for biomanufacturing technologies." Then, later in the Problem Statement on page 4, there is a statement that reads: "The resulting prototype agreements for biomanufacturing technologies, **may also** result in the following deliverables." Finally, on Page 7, the Problem Statement reads: "The Government estimate is approximately $1.5M per award. Deliverables 1, 2, and 3 **must be** completed, and are expected to consume approximately 60% of the proposer’s budget. One or more of Deliverables 4, 5, and 6 may be completed and are expected to consume approximately 40% of the proposer’s budget." Are Deliverables 1-3 Required or Optional? Are Deliverables 4-6 Required or Optional?

The Government has provided possible deliverables. Deliverables 1 – 6 will be determined during negotiations. If a proposer has already implemented any deliverables prior to award, then the Government will consider them completed and that deliverable will not become a part of the resulting agreement.

1. Deliverable 4: Can you clarify the distinction between "plan" and "prepare" in subsections of this objective?  Specifically, can any of the funds can be used for *implementation* of CMMC compliance measures at existing locations, or if it is only for *assessment* of what needs to be implemented at new, commercial scale facilities?

A plan details the requirements and steps to be taken to execute toward and meet a deliverable. To prepare means to position resources to execute a plan. Proposers should provide information if the company is at a point of implementation instead of plan or prepare.

1. Deliverable 5: Similarly, while Objective 1 clearly states that it is for paper-based studies only, Objective 5 appears to leave room for applications testing when it says "demonstrate...product characteristics." Should that be interpreted as including applications testing in our company or contract labs, or only quality testing?

Deliverable 5 may include physical scientific testing [to include examples provided in original question]. The Proposers should propose the need/plan for execution of the type(s) or level(s) of testing that is in alignment with the status (maturity) of their product and/or process.

1. Objective 6 allows for strain improvement and/or material delivery. Is this intended to be done in the 6-month prototype and planning phase, or is initiation and partial completion of such work sufficient in this phase? Said differently, can support for Material Sampling/material prototyping be part of the future Building Agreement award?

All proposed milestones and deliverables are negotiated between the Proposer and the Government and are expected to be completed according to schedule and within the period of performance. Proposers should provide adequate detail within the EWP for the deliverables in each phase.

General Questions:

1. In regards to the Distributed Bioindustrial Manufacturing Investment Program, are you able to tell me what the authorizing language for this program is?  Was it originally authorized by the National Defense Authorization Act?

This program is in response to Public Law 117 - 263 - James M. Inhofe National Defense Authorization Act for Fiscal Year 2023, Section 215. The program is funded under the Defense Production Act Title III (50 U.S.C. 4531).

1. To what extent does the DoD evaluate supply chain risk in the future?  For example, drought, extreme weather, human or animal-based pandemic would further weaken defense readiness for traditional supply chains.  Does the agency recommend emphasizing current supply chain challenges, or both current and potential future supply chain challenges?

Current or future supply chain risk is not considered. It may, however, be relevant to certain stated evaluation criteria. The Government will not make recommendations about the content of particular EWPs. Proposers should use their best judgment based on the RWP and the Problem Statement regarding what to include and emphasize.

1. There is an emphasis on Firepower investments. Does this mean that Building Agreement awards in non-Firepower-focused areas might not come until the Summer of 2025?

This RWP is for the Prototype Assessment and Planning phase. Upon successful completion of the Prototype Assessment and Planning phase, The Government may select some companies to proceed to the Prototype Build phase. The Build phase and all future awards will be based, in part, on Congressional funding for FY24 and future years.

1. If direct cash, it is unclear what obligations to the agency are likely to be incorporated – i.e., will these facilities be a “warm facilities” in that the DOD has FROR for the capacity?

See the Answer to Questions # 24 & 36 and reference information located within 10 U.S.C. 4022.

1. Is DoD going to facilitate matchmaking after the EWPs are submitted, particularly for entities looking for partners with cheap renewable feedstocks for their processes?

See the RWP section 4.3 Feedback, “The Government anticipates evaluating white papers without further communication with the Proposer’s, though, in rare occasions, additional communication may occur, at the Government’s discretion through the CMO. Upon completion of the evaluation process.” Matchmaking is conducted by the CMO for consortium members.

1. How should we think about the total volume of production for specific chemicals at a green field site when the chemicals have multiple markets, many of which the DoD is interested in?

See the Answer to Question # 54 reminder to Proposers. This RWP is for the Prototype Assessment and Planning phase and should be responded to accordingly. Proposers should consider production volumes and process streams that address total market needs in economically viable operations, inclusive of the demand for product(s) that meet DoD needs.

1. Is there preference between one site for a specific chemical, or a flexible manufacturing site for multiple chemicals utilizing the same infrastructure for flexible on demand manufacturing for the DoD and others?

The comparison of scenarios as suggested will not be a consideration.