



# Space Technology Mission Directorate Game Changing Development Program

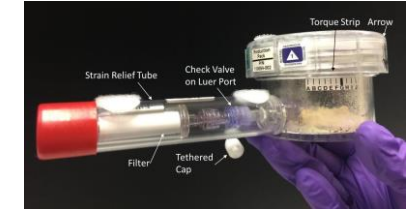
John A. Hogan, Synthetic Biology Project | FY21 Mid-Year Review Presentation | 03.03.21

# Technology Overview

## ➤ Technology Product Capability

Two Elements – BioNutrients and CO<sub>2</sub>-based Manufacturing

- **BioNutrients:** develop and demonstrate an on-demand nutrient production system for long-duration missions to mitigate demonstrated nutrient degradation in stored foods. Develop an evolvable platform for future surface missions – capable of producing other compounds (e.g., Medicines) requiring minimal resources. Perform an ISS time-course hydration, incubation, freezing and return for analysis over 5-year period.
- **CO<sub>2</sub>-based Manufacturing:** develop and demonstrate a prototype system that enables microbial manufacturing via abiotic CO<sub>2</sub> conversion to products that drive biomanufacturing for future long-duration missions.



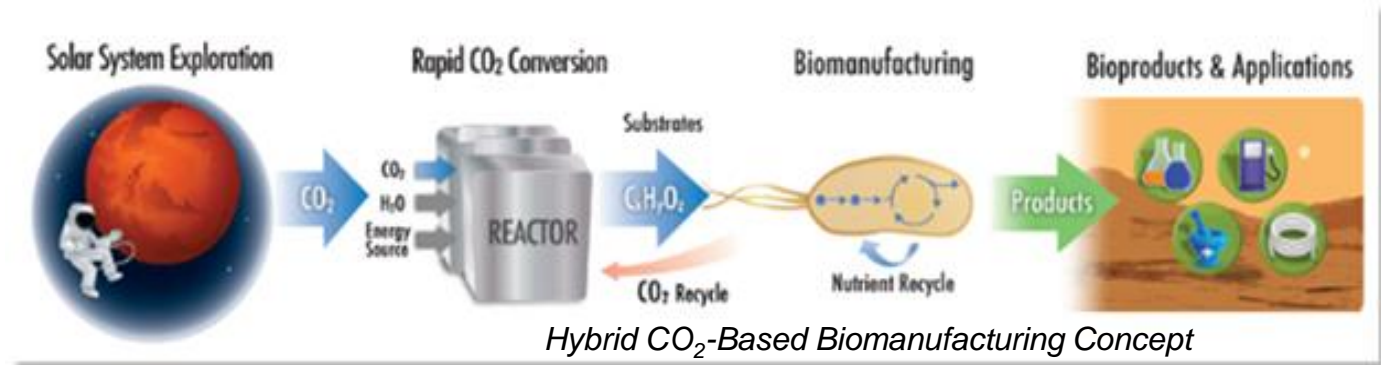
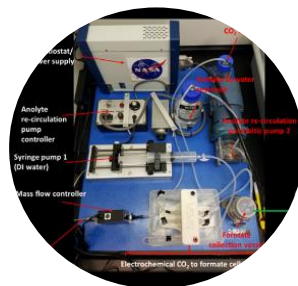
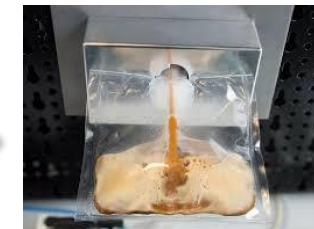
BioNutrients - 1 Flight Production Pack for on-orbit testing



## ➤ Technical Capabilities

- Reduced gravity compatible bioreactor development
- Long-duration ambient storage of microorganisms
- Methods for ensuring quality and safety of biomanufactured products
- Development of ISRU based growth media
- Space-relevant biomanufacturing system development
- Space qualified organisms for biomanufacturing

Future Implementation Concept





# Mission Impact



## Government Investments Supporting In-Space Biomanufacturing



**DARPA/DOD/Space Force**  
Biofoundries Program  
In-Space Biomanufacturing  
BRICS  
Living Structural Materials

**NASA Centennial Challenges**  
CO<sub>2</sub> Conversion Challenge



**NASA STTR**  
Nature's Fynd - Fungal Protein  
Mango Materials - Bioplastics



**NASA STMD GCD**  
Synthetic Biology project at ARC:  
BioNutrients & CO<sub>2</sub>-Based  
Manufacturing



**NASA STMD STRI**  
Center for the Utilization of  
Biological Engineering for  
Space (CUBES)

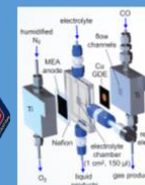


## Potential NASA Applications

### CO<sub>2</sub> ISRU for Biomanufacturing

MOXIE

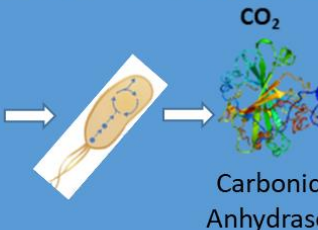
Stanford Univ.



CO<sub>2</sub> → CO → Acetate

### CO<sub>2</sub> Removal – Life Support

Acetate



Enabling new liquid amine  
CO<sub>2</sub> removal technologies

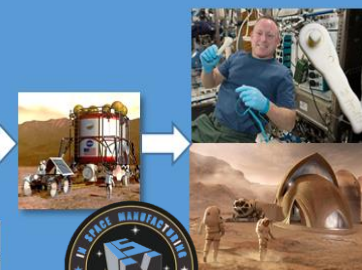
### On-Demand Nutrient, Medicine, and Food Production



### Future Scaled Biomanufacturing

CO<sub>2</sub>

Sugars



# SynBio BioNutrients Element Technology Goals & Project Objectives



## Technology Goals

<b>Goal #1</b>	Develop a platform technology for safe, on-demand microbial production of nutrients during missions.
<b>Goal #2</b>	Demonstrate hardware/microbes in space and use results to guide this technology development effort.
<b>Goal #3</b>	Develop in-space implementation requirements and methods for initial deployment.

## Project Objectives

<b>Objective #1</b>	Conduct 5-year test to verify concept and create space-adapted hosts for future tests.
<b>Objective #2</b>	Develop space-ready low mass/volume storage and growth system
<b>Objective #3</b>	Develop and verify a food safety plan to prepare for operational use

# SynBio CO<sub>2</sub>-Based Manufacturing Goals & Project Objectives



## Technology Goals

<b>Goal #1</b>	Develop microbiological techniques using ISRU to add enhanced capabilities for In Space Manufacturing.
<b>Goal #2</b>	Provide methods to enable novel liquid amine CO <sub>2</sub> removal systems for human life support.
<b>Goal #3</b>	Provide technology tests and trade studies demonstrating the technology's potential impact on lunar and Mars surface missions.

## Project Objectives

<b>Objective #1</b>	Design, build, and test a prototype CO <sub>2</sub> -to-relevant mission product system in ground based facilities.
<b>Objective #2</b>	Provide enabling physicochemical methods for producing organic microbial feedstock from CO <sub>2</sub> and water.



# Chief Engineer Status Slide

Enter your status of completion in the table below. This information is required for the MYR assessment.

**NOTE:** The official SPAR data call will be released in March; however, this information while contained in the SPAR tab, is necessary for the MYR assessment.

Assessment Information to be Completed in GCD SharePoint	Applicable (Yes/No)	Status (complete/incomplete)
KPP's entered into SharePoint SPAR tab <i>*only enter NO/Incomplete if KPPs are not yet approved by GCD CE</i>	yes	Complete
Updated Technology Providers – Academia, Industry	no	
Updated Potential Customers – OGA, Industry, Primary Partner	yes	Complete
Updated Contributing Partner – OGA, Industry, Academia, etc.	yes	Complete

# Syn Bio Mid-Year Assessment Summary

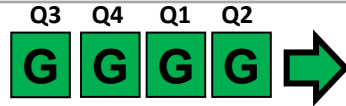


## ***Project description:***

Build organisms and bioreactor systems to demonstrate the value of emerging synthetic biology approaches to meet mission demands and support in situ resource utilization.

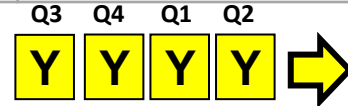
**Current TRL: 3**

## **Cost:**



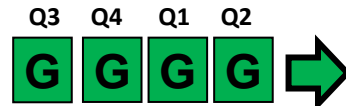
No cost issues at this point

## **Schedule:**



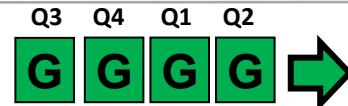
BioNutrients-2 production pack development and testing, and CO<sub>2</sub>-based manufacturing bioreactor and genetic engineering of organisms delayed due to mandatory telework. Lab access has been regained on a limited basis for BioNutrients activities only (Nov 30), and impacts to the schedule of both tasks are ongoing. Procurement delays are contributing to the delay and are expected to continue in FY21.

## **Technical:**



No known technical challenges at this point, but schedule delays are impacting our progress.

## **Programmatic:**



BioNutrients: The BN-2 ISS Kick-off meeting was completed in February and the draft Payload Integration Agreement (PIA) has been uploaded to the OZ Requirements Baseline and Integration Tool (ORBIT). A CEF to approve the PIA is currently open and review is expected to complete by the end of the March. We are in the process of updating the BN-1 flight experiment agreement with BioServe to extend use of the SABL incubator for on-orbit runs 4-6. A similar agreement covering use of SABL for BN-2 was approved on March 1



# BioNutrients Key Performance Parameters (KPP) Status



## Key Performance Parameters

Parameter	Units	State of the Art (SOA)	Threshold Value	Project Goal	Current Value To Date	Current Value: Technical Basis of Estimate	Expected Exit Value	Exit Value: Technical Basis of Estimate
KPP 1: ISS production pack viability lifespan <sup>(1)</sup>	years	N/A <sup>(2)</sup>	3	5	3 runs, results pending	Estimate	5 years	Verified based on measurement
KPP 2 : Microbial safety assessment <sup>(3)</sup>	cfu/100ml	<100	<50	<1	3 <sup>rd</sup> Run in process	Estimate	<1 CFU/100ml	Verified based on measurement
KPP 3: Biomanufacturing platform supplies multiple nutrients <sup>(4)</sup>	number of nutrients	1	2	4	1	Substantiated	4	Verified based on measurement

**Notes:** <sup>(1)</sup> A production pack is considered “viable” if it demonstrates the ability to make targeted nutrients at >50% when compared to initial ISS production packs. This KPP assesses effects of storage over time. Viable production packs that have been stored and tested on ISS for 3 years (Threshold Value) are assumed to be suitable for extended Lunar surface mission needs, and a 5-year lifespan (Project Goal) is needed for Mars surface missions as per the Human Research Program 5-year stored food shelf-life requirements.

<sup>(2)</sup> There is no SOA for this KPP because there are currently no means of making nutrients during spaceflight.

<sup>(3)</sup> Microbial safety is assessed using NASA food safety Petri-film testing procedures (NASA-STD-3001 Vol. 2, Rev. A) for the coliform, *Staphylococcus* and *Salmonella* tests expressed as Colony Formation Units (CFU)/100ml. Includes microscopic inspection for dead cells.

<sup>(4)</sup> Intent is to build a biomanufacturing platform that provides on-demand, simultaneous availability of multiple nutrients with minimal mass, power, and volume requirements .



# CO<sub>2</sub>-Based Manufacturing Key Performance Parameters (KPP) Status



## Key Performance Parameters

Parameter	Units	State of the Art (SOA)	Threshold Value	Project Goal	Current Value To Date	Current Value: Technical Basis of Estimate	Expected Exit Value	Exit Value: Technical Basis of Estimate
<b>KPP 4: Biomass harvest efficiency</b> <sup>(1)</sup>	percentage	- <sup>(2)</sup>	85	97	tbd	Estimated by stoichiometry	97%	Verified by measurement
<b>KPP 5: KPP 5: % of media components sourced from CO<sub>2</sub>, H<sub>2</sub>, and recycled mission wastes</b> <sup>(3)</sup>	percentage	0 <sup>(4)</sup>	50%	80%	21%	Substantiated	80%	Verified by measurement

**Notes:** <sup>(1)</sup> This represents the amount of biomass that is able to be processed in relation to the total amount produced within the system (total amount produced will be assessed as amount from nominal operation plus amount recovered following enhanced manual recovery and inspection of system). Biomass loss due to biofilm formation or inaccessible due to geometry and flow design of the reactor can significantly reduce performance of the overall system. Maximizing biomass recovery greatly improves overall system efficiency, and drives organism selection and efficient reactor design/operation. Our current product is carbonic anhydrase, a non-secreted product for which biomass is an acceptable proxy. Note: Biomass containing carbonic anhydrase can potentially be utilized in a liquid amine system without further purification.

<sup>(2)</sup> There are no space-based biomanufacturing systems to serve as a SOA. Harvest efficiencies in commercial terrestrial systems can vary based on specific organisms and procedures used. Commercial bioreactor harvesting efficiencies are often quoted as ~97% and we will use this as a comparative value.

# Technical Assessment



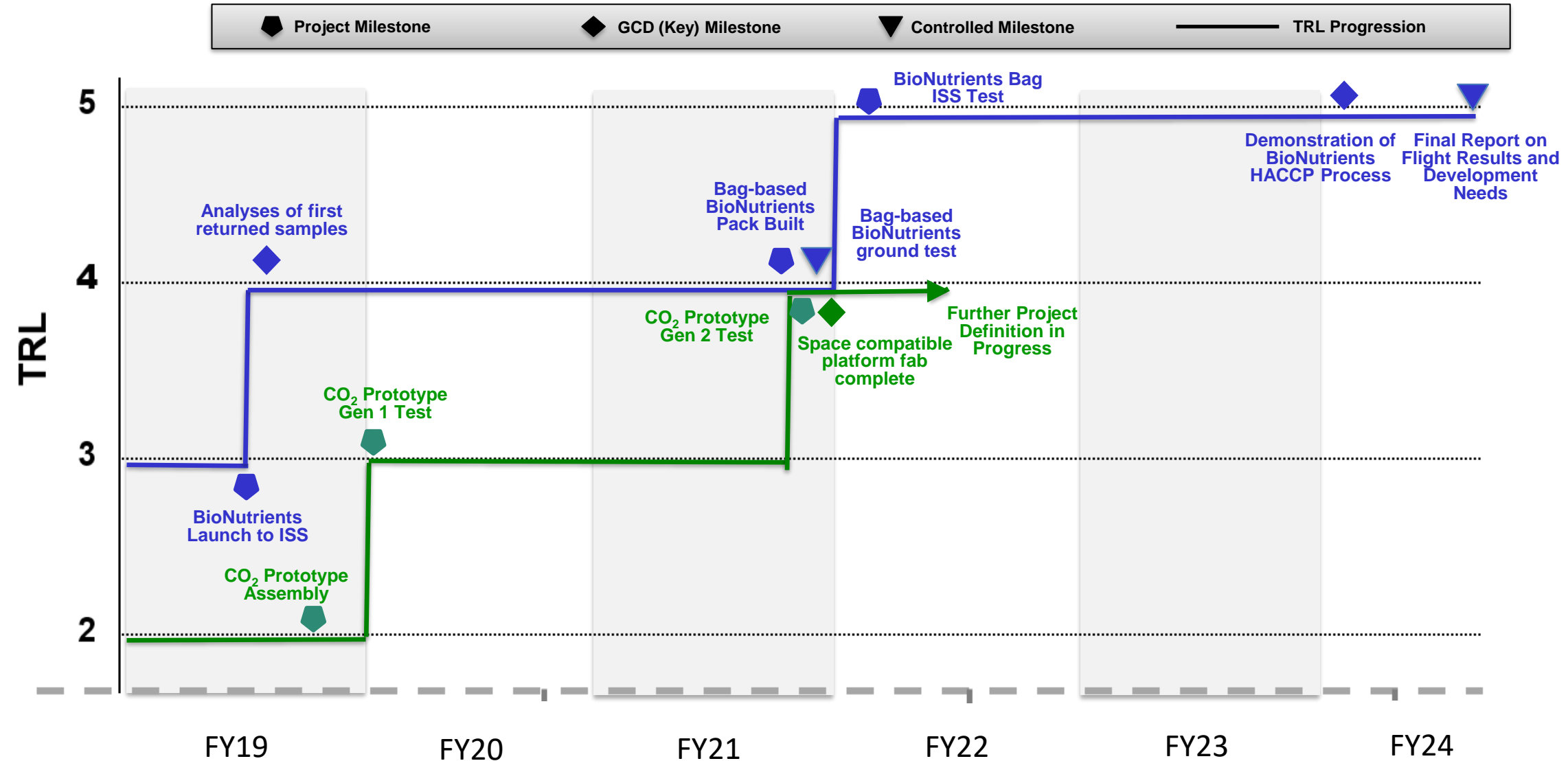
Technical Capability Elements	TRL			TRL Verification
	Entry	Exit	Current <sup>1</sup>	
Space qualified bioreactor development	3	5 <sup>(1)</sup>	4	Fight tests with prototype bioreactors will demonstrate performance
Long Duration storage of microorganisms	3	≥5	4	5 year flight and ground tests will demonstrate survivability and stability of test organisms
Methods for ensuring quality and safety of biomanufactured nutrients	2	4 <sup>(1)</sup>	2	Test and review of HACCP Plan for safe preparation of biomanufactured nutrients, post growth processing, safety assurance, and product quality verification.
Development of ISRU based growth media	<2	4	2	Demonstrated organism growth on prototype media in laboratory setting complete
Space relevant biomanufacturing system development	<2 <sup>(2)</sup>	4	3	Integrated prototype platform laboratory testing complete
CO <sub>2</sub> -Based Manufacturing space qualified organisms for biomanufacturing	3	4	3	Demonstrated product manufacture from organism grown on prototype media in laboratory setting.
CO <sub>2</sub> -Based Manufacturing CO <sub>2</sub> conversion reactor <sup>(3)</sup>	4	5	4	SOA formate commercial unit laboratory testing and verification and with integrated prototype
<sup>1</sup> Date of last TA was: <b>N/A - All TRL assessments are pre-review estimates. Dates for TAPR-ToR and TAPR are being worked.</b>				

<sup>(1)</sup> Flight demonstration will indicate concept feasibility/performance, but does not render it flight-ready for actual use.

<sup>(2)</sup> Prototype subsystems demonstrate feasibility but require further optimization. Expect successful use to raise it to TRL 4 via integrated laboratory testing.

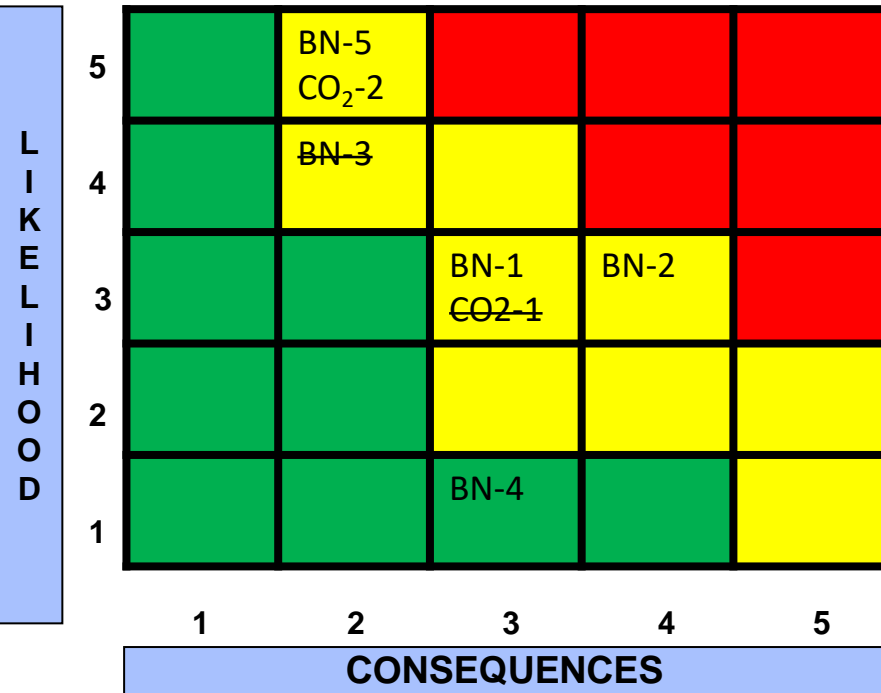
<sup>(3)</sup> Prototype conversion reactor being developed at Stanford University, Kannon Lab, as part of cooperative agreement.

# BioNutrients/CO<sub>2</sub>-Based Manufacturing Lifecycle Milestone/Maturity Schedule





# Technical Risk Summary



Risk ID	Description/Status	Trend
BN-1	Microbial growth negatively affected by microgravity with subsequent unacceptable decrease in target products. Initial flight tests will yield results and guide mitigation if needed.	↓
BN-2	Shelf-life of stored microbes will not adequately allow for feasible use of this system for longer duration missions. Approaches for increasing stasis are incorporated into testing. Will require years to determine effects on all test strains.	→
BN-3	Delays in sample analysis and potential flight operations delays due to Covid-19 impacts may result in lower fidelity sampling time points and lower sample quality, ultimately impacting overall understanding of system performance.	Closed
BN-4	Launch and crew time schedule misalignment may result in lower fidelity sampling time points, potentially impacting overall understanding of system performance.	→
BN-5	Covid safety requires social distancing which in turn requires minimal staff access to facilities. Combined with procurement delays due to Covid-19 supply chain issues and new P-card purchasing limitations, this may result in lower overall optimization of BioNutrients element.	→
CO <sub>2</sub> -1	Formic acid suitability as microbial substrate. Additional methods under development to obtain more efficient substrates.	Closed with acetate
CO <sub>2</sub> -2	Delay in CO <sub>2</sub> -based manufacturing progress due to Covid 19 access limitations and procurement delays may result in lower optimization of CO <sub>2</sub> -based manufacturing element.	→

Criticality	L x C Trend	Approach
High	↓ Decreasing (Improving)	M - Mitigate
Med	↑ Increasing (Worsening)	W - Watch
Low	→ Unchanged	A - Accept
	□ New Since Last Period	R - Research

# Education/Public Outreach

## EPO Involvement

- Article on BioNutrients third on-orbit run is being coordinated with GCD and center communications and is pending sample analysis completion.
- BioNutrients element will hold a Design Review of the generation-1 bioreactor. The new design will test out new products, new organisms and a new flexible soft-shell reactor designed for lower mass and volume. We are actively working dates for this review but expect in to be no earlier than **May 1**.
- VIRTUAL 50th International Conference on Environmental Systems - ICES 2021. Pending analysis, team may present new results. Lab access and procurement issues may impact this, but team will attend this conference.
- SLSTP 2020 intern Benjamin Alva won 1st place in the Physical and Liberal Sciences category at the 2020 Wernher von Braun Memorial Symposium for work in the CO<sub>2</sub>-Based Manufacturing Project
- SLSTP 2020 intern Benjamin Alva presented his work on the CO<sub>2</sub>-Based Manufacturing project at the 3rd Annual StarTech Conference (virtual)

## EPO Calendar Outlook (High Priorities):

### FY21 Activities to Date

Star Tech Conference	11/20
NASA virtual Tech Day on the Hill – we submitted a short video of on orbit hydration and growth of BioNutrients production packs to GCD for their consideration	12/20
BioNutrients on orbit operations	1/21

### 6 Month Look-Ahead

BioNutrients gen-1 bioreactor Design review	Net 5/1
ICES 2021, virtual event	7/11 -7/14

# Project Summary



## BioNutrients

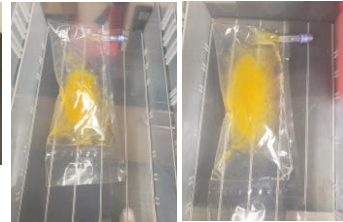
- BN-1: ~2 years of 5-year ISS test of system viability complete, third run completed January 2021. On-orbit/ground operations performed with no anomalies. Organism growth visually confirmed, full analysis of nutrient production is pending.
- BN-2: gen-1 bioreactor design testing is underway. Growth of yeast test strain confirmed. New commercial strain-based products yogurt and kefir identified, purchased and preliminary testing completed. pH indicator dye for yogurt/kefir maturation identified and tested post sterilization of media.
- BN-3: nutrient production system safety and quality standards under development. HACCP training complete.
- Human Research Program Advanced Food Systems interaction continues with incorporation of BioNutrients effort into Food Roadmap.

## CO<sub>2</sub>-Based Manufacturing

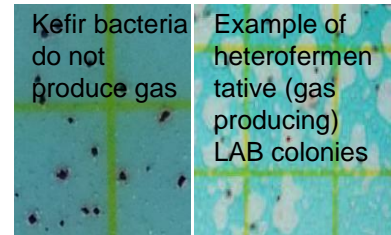
- Covid-19 restrictions have prevented any laboratory access limiting physical testing of sub-systems but progress has been made on modeling of the production pathways, identifying commercial off-the-shelf subsystems that can be modified to allow for more rapid testing once lab access is restored, and working with commercial vendors for genetic engineering of the product so that secretion from the organism may become an option, thus expanding the capabilities of the system and simplifying purification steps for products that can be secreted.
- Improved Strain design report “Roadmap for improved in-space biomanufacturing strains” – deliverable submitted to GCD.
- Preliminary Use Case review and report – Synthetic Biology team review held 9/28, deliverable submitted to GCD.
- Advancements continue for the CO<sub>2</sub> conversion reactor at the Kanan Lab, Stanford University.



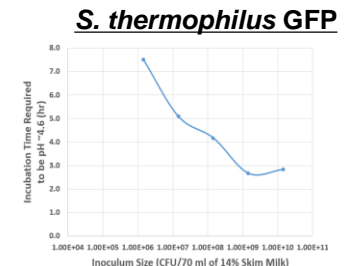
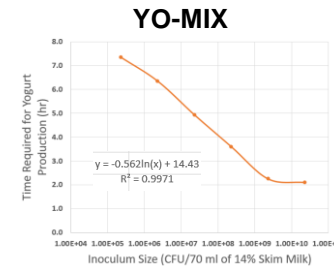
BN-1 run 3 performed by Astronaut Shannon Walker, nutrient yeast growing in gen-0 bioreactor in SABL



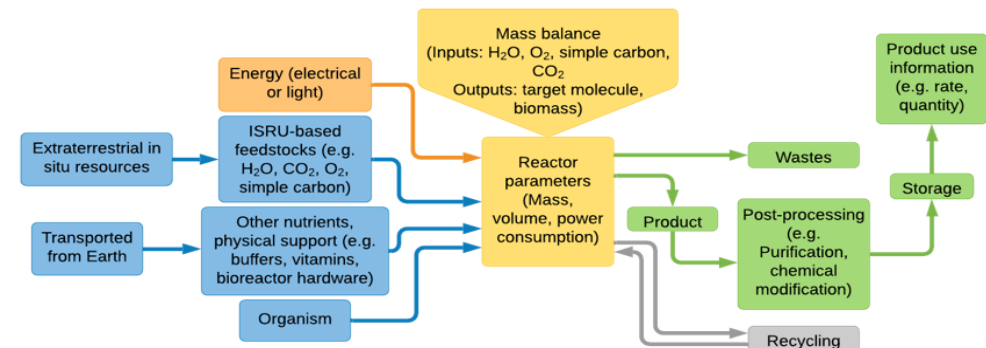
Gen-1 preliminary test with yeast demonstrates successful operations and growth in bag format



Kefir strain analysis reveals minimal unwanted gas production



Yogurt strain inoculum size and incubation timeline testing results



CO<sub>2</sub> Preliminary Use Case Review-Analysis overview



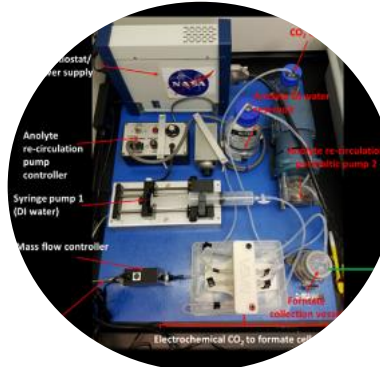


**BACKUP**

# Space Synthetic Biology



View of BioNutrients-1 production packs during ISS crew operations. Packs were removed from incubator for mid-course agitation.



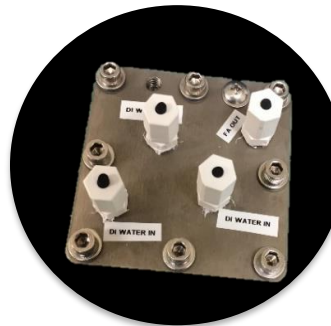
CO<sub>2</sub>-Based Manufacturing project prototype that demonstrated the production of formic acid from CO<sub>2</sub> and water, while also producing oxygen.



Ground testing of BioNutrients-1 production packs in SABL flight incubator (ground unit) to verify temperature, fit and no leakage.



View of open BioNutrients-1 production pack during loading. Dried edible media (powder) and yeast pellets (red) are visible.



State-of-the-Art CO<sub>2</sub> electrochemical system that converts CO<sub>2</sub> and water to formic acid without electrolytes. The formic acid serves as an media for microbial production systems.



Loading BioNutrients-1 production packs with media and organisms under sterile conditions. The pack lid and sterile water filter are attached during this assembly.



# SynBio - BioNutrients

## Adverse impact of microgravity on microorganism – John Hogan

**Risk ID #**  
BN-1.

**Trend**  
Decreasing

**Criticality**  
**medium**  
**Current L/C**  
3x3

**Affinity Group**  
Technical,

**Planned Closure**  
09/31/2024

**Open Date**  
09/31/2019

**Risk Statement :**

Given that microgravity can have unpredictable or adverse effects on microbial growth, there is a possibility that the expected growth of the microorganisms will not occur resulting in an unacceptable decrease in target products.

**Approach:** Watch

**Context**

Microgravity causes an absence of convective forces which in turn can limit gas exchange, mixing and consequently limit resources and negatively impact microbial growth. Conditions on orbit may also limit degree of full mixing and dissolving of the microbial pellet during hydration due to impacts on wetting actions under microgravity. As the crew is manually shaking the bioreactor to create mixing, and checks to see if mixing and dissolving has occurred, this is relatively unlikely but not predictable from ground testing. These two factors together represent a risk unique to the microgravity environment that can only be assessed via on orbit testing.

**Status**

03/2021. We have conducted 3 runs on the ISS and are awaiting sample analysis to determine if there has been any unexpected and unfavorable impacts to the expected microbial growth. We have seen bubble formation and strong color creation inside the bioreactors run on orbit, and both are signs of microbial respiration (growth) and of manufacture of carotenoid products. Analysis of the returned samples will more strongly inform this and will be used to guide mitigation as needed.

Mitigation Steps	Dollars to implement	Trigger/ Start date	Schedule UID	Completion Date	Resulting L/C

(Note: The Schedule UID is the unique id no of the mitigation step in your schedule if appropriate.

Dollars to implement are not extra approved \$ from the Program Office but \$ set aside as part of project budget to mitigate.)



# SynBio - BioNutrients

## Adverse impact of ambient long duration storage on microorganism – John Hogan



**Risk ID #**  
BN-2.

**Trend**  
Unchanged

**Criticality**  
**med**  
**Current L/C**  
3x4

**Affinity Group**  
Technical

**Planned Closure**  
09/31/2024

**Open Date**  
09/31/2019

### **Risk Statement :**

Given that microbial viability is impacted by oxidative stress and temperature over time, the long duration ambient storage (shelf-life) of stored microbes may cause microbial viability decreases that ultimately do not allow for feasible use of this system for longer duration missions.

### **Context**

Approaches for increasing stasis are incorporated into testing. This risk will require years to determine effects on all test strains. Ground based testing indicates over 3 years of storage can be tolerated for the primary strain used in the production pack study, with little to no impact on viability.

### **Status**

03/2021 Results from terrestrial testing indicate more than 3 years of ambient storage can be tolerated by at least the primary yeast strain. Approaches for increasing stasis are incorporated into testing. Will require years to determine effects on all test strains.

**Approach:** Watch

Mitigation Steps	Dollars to implement	Trigger/ Start date	Schedule UID	Completion Date	Resulting L/C
Approaches for increasing stasis are incorporated into testing. Results from this 5 year experiment will be incorporated in future efforts.					

(Note: The Schedule UID is the unique id no of the mitigation step in your schedule if appropriate.  
Dollars to implement are not extra approved \$ from the Program Office but \$ set aside as part of project budget to mitigate.)

# SynBio - BioNutrients



## Delay in sample analysis due to Covid 19 -John Hogan

**Risk ID #**  
BN-3.

**Trend**  
Closed

**Criticality**  
**med**  
**Current L/C**  
4x2

**Affinity Group**  
Technical

**Planned Closure**  
03/03/2021

**Open Date**  
09/11/2020

### **Risk Statement :**

Given that the project has lacked laboratory access since March 9 due to Covid-19 safety precautions, delays in sample analysis and potential delays in flight operations may result in lower fidelity sampling time points and lower sample quality, ultimately impacting overall understanding of system performance.

### **Context**

This project relies upon collection of data during a 5 year mission. There are periodic crew operations to run the stored production packs on orbit, and analysis of the products is conducted in our ground based facilities at NASA Ames. We have samples returned from the ISS from our first two production pack runs but have been unable to perform the analysis due to Covid-19 facilities restrictions. We also need access to support upcoming on orbit operations and ground control operations for the next production pack run. We can delay the next run but this creates a greater period within our planned sampling schedule, and we may miss data that impacts our understanding of how the system is impacted over time. Furthermore, delays in analysis of the samples already produced and returned from the ISS while frozen, are undergoing some degree of degradation over time. Some aspects such as carotenoid production may be relatively unaffected, but nucleic acid analysis may be impacted.

### **Status**

03/2021 **Closed**. We have been given approval for facilities access for no more than 4 team members on site at a given time and not past 6 PM. We conducted the production pack run as planned. We are beginning to process the backlog of samples. Some aspect of the risk was realized as one of the stasis packs used to monitor shelf life could not be processed before on-earth storage limits were exceeded. This loss is minimal due to the other time points that can still provide data on shelf life. The risk due to ongoing Covid impacts is captured in BN-5.

Mitigation Steps	Dollars to implement	Trigger/ Start date	Schedule UID	Completion Date	Resulting L/C
We have submitted a request to return to work to get analysis of the samples back on track and to continue operations.	0				
We have examined potential new dates and considered re-planning to move on orbit operations out to meet new restricted ground operations - less than idea but still viable.	0				

(Note: The Schedule UID is the unique id no of the mitigation step in your schedule if appropriate.

Dollars to implement are not extra approved \$ from the Program Office but \$ set aside as part of project budget to mitigate.)

# SynBio - BioNutrients



## Launch and crew schedule misalignment – John Hogan

**Risk ID #**  
BN-4.

**Trend**

Unchanged

**Criticality**  
**low**  
**Current L/C**  
1x3

**Affinity Group**  
Technical  
**Planned Closure**  
09/30/2014

**Open Date**  
09/31/2019

**Risk Statement :**

**Approach:** Accept

Given that launch and crew time schedules are subject to unpredictable changes, a launch and crew time schedule misalignment may occur that impacts our planned on orbit production runs and sample returns and result in lower fidelity sampling time points, potentially impacting overall understanding of system performance.

**Context**

Launch schedules are prone to alterations due to weather, mechanical issues/delays, and other unpredictable events. Crew time can also be subject to changes based on crew availability, prioritization and other factors.

**Status**

03/2021 We have had no significant misalignments to date and do not have any specific concerns at this time. We have regular communication with the payload integration management and our expectation is that we can meet our planned timeline. We did have some trouble obtaining conditioned stowage for return of samples from the ISS but we were accommodated and are currently on track for this.

Mitigation Steps	Dollars to implement	Trigger/ Start date	Schedule UID	Completion Date	Resulting L/C

(Note: The Schedule UID is the unique id no of the mitigation step in your schedule if appropriate.  
Dollars to implement are not extra approved \$ from the Program Office but \$ set aside as part of project budget to mitigate.)



# SynBio - BioNutrients



## Delay in BioNutrients progress due to Covid 19 access limitations and Procurement delays -John Hogan

**Risk ID #**  
BN-5.

**Trend**  
Unchanged

**Criticality**  
**med**  
**Current L/C**  
5x2

**Affinity Group**  
Schedule >>Technical

**Planned Closure**  
09/31/2021

**Open Date**  
03/11/2020

### **Risk Statement :**

Given that the project lacked laboratory access from March to December 2020 and currently has constrained access due to Covid-19 safety precautions, and given that there are procurement delays due to supply chain and p-card issues, there is a possibility of ongoing delays in obtaining analysis needed to optimize BioNutrients bioreactor designs, and new product development, resulting in overall decrease in optimization of BioNutrients element.

### **Context**

This project relies upon collection of data during a 5 year mission. The data will be used to improve the Gen-1 and 2 designs, to direct the engineering of products and choice of organism, and allow for safety and quality improvements to be implemented. We need facilities access, outside vendor support and consumables for testing and analysis.

### **Status**

03/2021 We have been given approval for facilities access for no more than 4 team members on site at a given time and not past 6 PM. We are beginning to process the backlog of samples. We are experiencing delays in procurement and have had to order from new vendors in some instances, requiring new testing and adding to delays. We can expect improvement with time, but its not certain if we can make up for the current delays.

### **Approach:** Mitigate

Mitigation Steps	Dollars to implement	Trigger/ Start date	Schedule UID	Completion Date	Resulting L/C
We have an approved request to return to work to get analysis of the samples back on track and to continue operations and we will continue to request extensions to that plan.	0				
We are identifying additional vendors and purchasing options to mitigate risk due to lapses in equipment and supplies	0				

(Note: The Schedule UID is the unique id no of the mitigation step in your schedule if appropriate.  
Dollars to implement are not extra approved \$ from the Program Office but \$ set aside as part of project budget to mitigate.)

# SynBio - BioNutrients



## Delay in CO<sub>2</sub>-based manufacturing progress due to Covid 19 access limitations and Procurement delays -John Hogan

### Risk ID #

CO<sub>2</sub>-2.

### Trend

Unchanged

### Criticality

med

### Current L/C

5x2

### Affinity Group

Schedule >>Technical

### Planned Closure

09/31/2021

### Open Date

03/11/2020

### Risk Statement :

Given that the CO<sub>2</sub> element has no access to lab facilities due to Covid-19 safety precautions, and given that there are procurement delays due to supply chain and p-card issues, there is a possibility of ongoing delays in obtaining analysis needed to optimize the CO<sub>2</sub>-based manufacturing bioreactor design, integrated platform testing, new product development, resulting in decreases in overall optimization of CO<sub>2</sub>-based manufacturing element.

### Context

This project relies upon Ames facilities for in-house testing of the bioreactor and platform systems, microbial organism engineering, and integrated experiments to drive decision making on optimization of the CO<sub>2</sub>-based manufacturing platform.

### Status

03/2021 The team has had no access to lab facilities since March 9, 2020 and we expect to remain without access until Covid restrictions are released. In lieu of access, the team is focused on modeling production pathways, identifying commercial off-the-shelf subsystems for laboratory testing, strain engineering via commercial vendors to test secretion of product, and formalizing a systems engineering approach for selecting design options. These activities should expand the capabilities of the system, simplify purification steps, and enable rapid design option testing when we have laboratory access. We have some concern that the procurement delays our other element has experienced will also impact this effort and we are attempting to mitigate by pre-ordering as much as is reasonable.

Mitigation Steps	Dollars to implement	Trigger/Start date	Schedule UID	Completion Date	Resulting L/C
We are identifying additional vendors and purchasing options to mitigate risk due to lapses in equipment and supplies, and to fast-track testing once lab access is available.	0				
We will work with GCD management to determine if additional schedule and budget can be approved to implement the effort as planned.	tbd				

(Note: The Schedule UID is the unique id no of the mitigation step in your schedule if appropriate.

Dollars to implement are not extra approved \$ from the Program Office but \$ set aside as part of project budget to mitigate.)



# GCD Project Performance Evaluation Criteria

	Technical/Performance
Green	Project is demonstrably making progress on the Learning Trajectory (e.g., milestones met, knowledge advanced) or advancing TRL. Project is on track to meet L1 requirements.
Yellow	Project is making progress on the Learning Trajectory or advancing TRL with issues. Project is on track to meet L1 requirements, but issues exist that may threaten achievement.
Red	Project has ceased to make progress on the Learning Trajectory or advance TRL. Project is unable to meet one or more L1 requirements.
	Cost
Green	Project can meet its commitments with its planned/allocated budget.
Yellow	Project cannot meet its commitments within its planned/allocated budget but will not be requesting additional budget from Program. Mitigation plans have been developed.
Red	Project cannot meet its commitments within its planned/allocated budget and will be requesting additional budget from Program.
	Schedule
Green	Project can meet its commitments within its planned/allocated schedule baseline for critical milestones.
Yellow	Project cannot meet its commitments within its planned/allocated schedule baseline, but mitigation plans have been developed to pull it back in.
Red	Project cannot meet its commitments within its planned/allocated schedule baseline.
	Programmatic (Institutional, Internal/External Dependencies **)
Green	Relevance of technology to stakeholders and/or technology infusion path is maintained. Mission sponsor still actively interested. No issues exist with workforce, test facilities, etc.
Yellow	Relevance of technology to stakeholders and/or technology infusion path are threatened. Mission sponsor backing off. Issues exist with workforce, test facilities, etc. but plans to mitigate are available.
Red	Relevance of technology to stakeholders and/or technology infusion path are not projected to be met or has lost relevance to stakeholders. Mission sponsor cancelled interest. Issues pertaining to workforce, test facilities, etc. are preventing progress along the Learning Trajectory.