



VITAKEY

Precision Delivery of Nutrition®

Precision Delivery of Nutrients to Enhance Nutrition

Aaron. C. Anselmo
Chief Scientific Officer

World-Class R&D Team Built by VitaKey

Co-Founder Dr. Robert Langer, A Founding Father of Controlled-Release Technology

- Institute Professor at MIT, the highest honor awarded to a faculty member
- Authored over 1,500 articles and 1,400 issued and pending patents
- Most cited engineer in history
- Patents have been licensed or sublicensed to more than 400 pharmaceutical, chemical, biotechnology, and medical device companies
- Co-founder of more than 40 biotechnology companies with an estimated market value of \$250 billion
- Co-founder of Moderna and VitaKey  
- Improved more than two billion lives worldwide through innovations and inventions created in his lab, and with the recent development of Moderna's Covid vaccine, billions more have been touched by his disease treatments
- Received over 220 major awards for science and innovation
 - One of three individuals to have received both the United States National Medal of Science and the United States National Medal of Technology and Innovation
 - Received the Charles Stark Draper Prize, the equivalent of the Nobel Prize for engineers, and the Queen Elizabeth Prize for Engineering for his global impact on human health
- Requested by NASA to deliver probiotics to astronauts on their journey to Mars



Experienced, Proven Team



Robert S. Langer, ScD
Founder and Board Member

Institute Professor at MIT. National Medal of Science winner and holder of +1,400 patents licensed by +400 companies worldwide. Co-founded +40 companies including Moderna.



Catherine B. Reynolds
Founder and Board Member

More than 30 years experience in the finance industry. Currently serves on the boards of General Dynamics and Lindblad Expeditions. Board Chairman of Lyndra Therapeutics.



Roger W. Ferguson, Jr., PhD, Board Member

Board member of General Mills, Alphabet, and IFF. Former President and Chief Executive Officer of TIAA and former Vice Chairman of the Board of Governors of the U.S. Federal Reserve System.



Ana Jaklenec, PhD
Founder and Board Member

Co-Principal Investigator at Koch Institute MIT. AIMBE and CRS Fellow. Co-inventor of the initial VitaKey delivery technology with +30 papers and +20 patents. Founder of multiple companies.



Hon. Elaine Chao
Board Member

Former U. S. Secretary of Transportation and U. S. Secretary of Labor. Serves on the boards of Kroger and a number of new economy technology companies in the mobility sector.



Giovanni Traverso, MB, BChir, PhD, Board Member

Assistant professor at MIT and a gastroenterologist at Brigham and Women's Hospital, Harvard Medical School with a focus on the development of drug delivery platforms to the intestines.



Abigail Blunt
Board Member

Former Vice President of Government Affairs at Kraft Foods, Former Strategic Advisor on Government Affairs + ESG, Advisor to the Board, Member Kraft Heinz Foundation at Kraft Heinz.



Peter Hutt, JD
Board Advisor

Senior Counsel at Covington & Burling, specializing in Food and Drug Law. Former Chief Counsel at the FDA. Since 1994, has taught a full course on Food and Drug Law at Harvard Law School.



Aaron Anselmo, PhD *Chief Scientific Officer*

Co-inventor of delivery technologies with experience in drug and probiotic precision delivery techniques. Authored over 50 nutraceutical, pharma & probiotic articles.



Andrea Stamp
Chief Strategy Officer

20+ years experience managing companies, business development, regulatory, clinical trials, IP, finance, & technical teams.



Hamid Nasir, JD
Head of Global Affairs

Distinguished military career paired with extensive international business experience. Graduate of West Point and Georgetown Law.



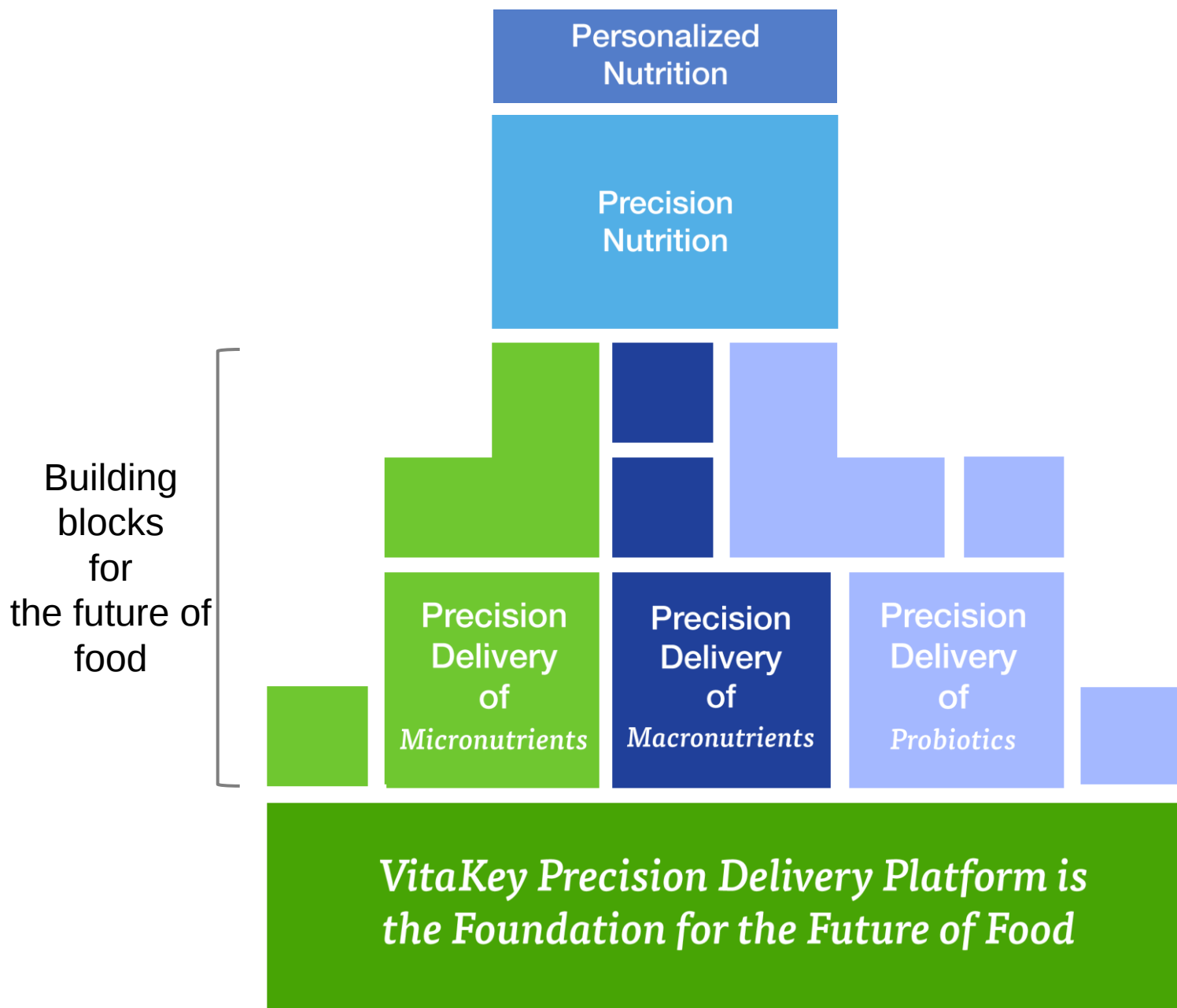
Our Story

VitaKey's precision delivery technology was born in the Langer Lab at MIT by engineer, inventor, scientist and entrepreneur **Dr. Robert Langer** – a pioneer for 48 years of drug delivery, including targeted and time-controlled release technology.

With VitaKey's targeted and time-controlled release and bioavailability enhancement **precision delivery technology for nutrients**, customers can enjoy the benefits of vital nutrients without making drastic changes to their eating habits or following a complicated schedule of vitamin pills and dietary supplements. Adding potent and durable micronutrients, macronutrients, probiotics, amino acids, proteins, antioxidants, lipids, and flavors to food and beverage manufacturing can dramatically improve the quality of the foods we eat and enhance the health and wellness while boosting the immunity of men, women and children at every stage of life.

***VitaKey helps to unleash the power of food
as the first and best medicine.***





Precision 2030™

*Convergence
of Big Tech,
Health & Nutrition*



The Problem

Nutrients are added to **food**, feed, and agricultural products but not stabilized or delivered



Micronutrients (vitamins and minerals), macronutrients (proteins, amino acids, carbohydrates, lipids), probiotics, prebiotics, nutraceuticals, antioxidants and flavors are sensitive to:

- Heat
- Moisture
- Oxygen
- Light



Loss occurs during:

- Processing
- Storage
- Cooking
- Environmental Exposure
- Ingestion and digestion



Delivery is not controlled:

- When
- Where
- How much



Lesson 1: Food is the First and Best Medicine



Government Mandates

Changes in the way nutrition are delivered to the population



Consumers are demanding healthy options with improved bioavailability

Top Down

Bottoms Up

The US federal government is forming focused nutrition efforts currently distributed across ten agencies including:

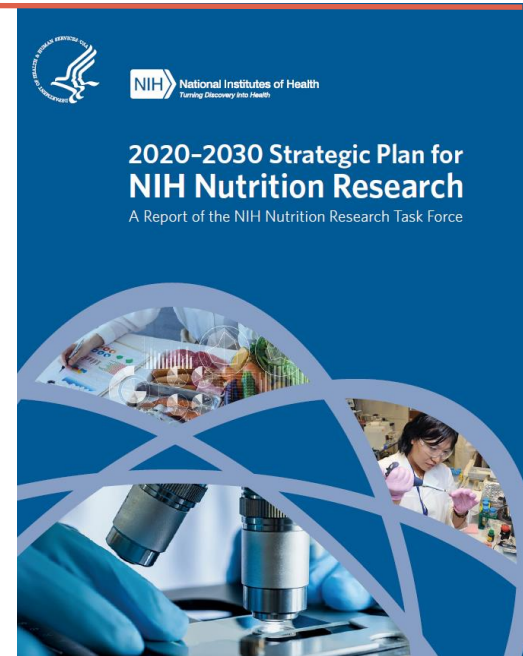
- New proposed office of the National Director of Food and Nutrition
- New NIH National Institute of Nutrition

EU's 2020 Farm to Fork Strategy

- Focus on food security, waste reduction, and sustainability

Healthy China 2030

- The National Nutrition Plan (2017-2030) promotes healthy food options and the development of technologies to prevent nutrition-related diseases



Bold vision of the 2020–2030 Strategic Plan for NIH Nutrition Research:¹

What if each of us had individualized, actionable dietary recommendations that helped us decide what, when, why, and how to eat to optimize our health and quality of life?

1. National Institutes of Health. 2020-2030 Strategic Plan for NIH Nutrition Research: A report of the NIH nutrition research task force. 2020



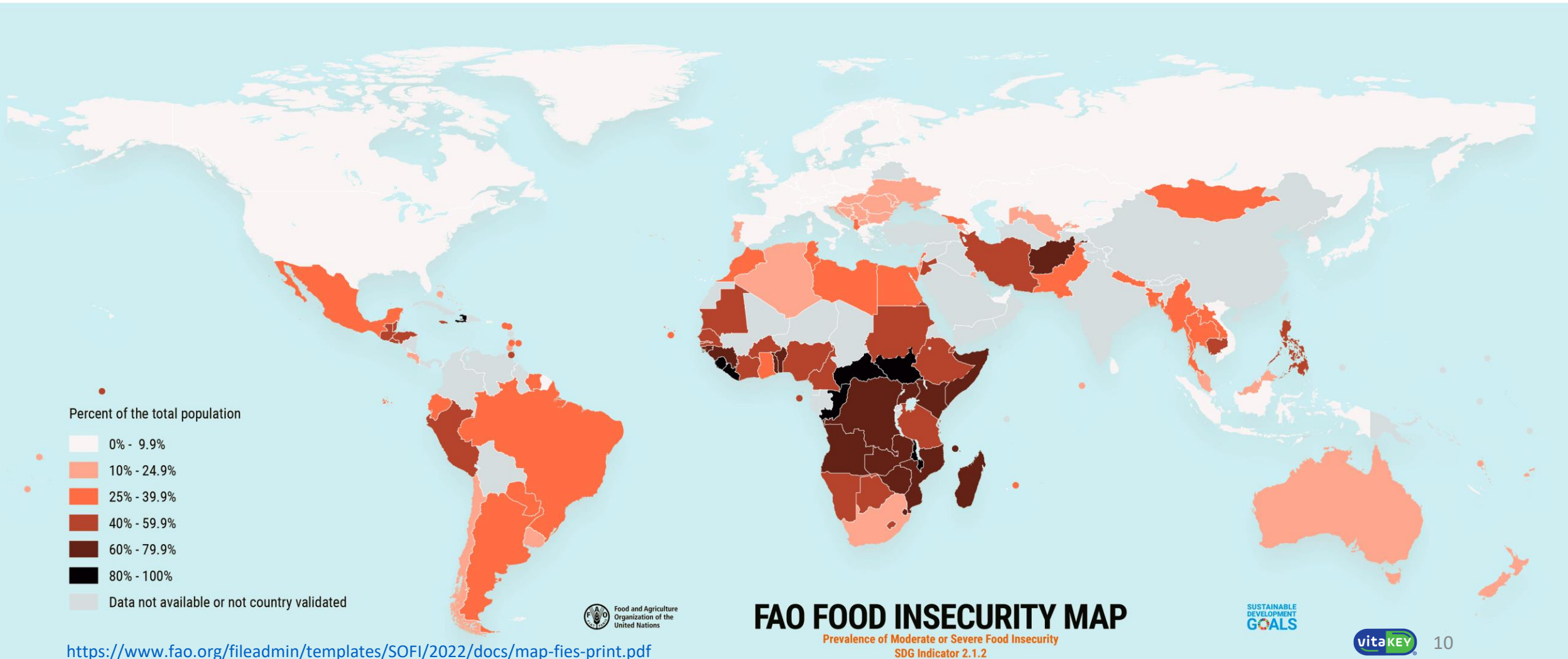
We are Running Out of Food...

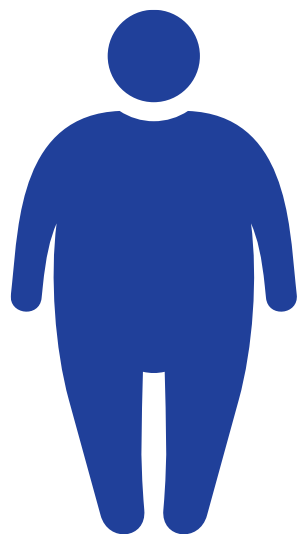
- In 2050, we will need to produce 60% more food to feed over 9B people worldwide¹
- We will need to produce more food in the next 30 years to feed the population in 2050 than we've produced in the last 10,000 years

1. <https://www.un.org/en/chronicle/article/feeding-world-sustainably>



...Food Insecurity is High Today and Will Be Worse Tomorrow....





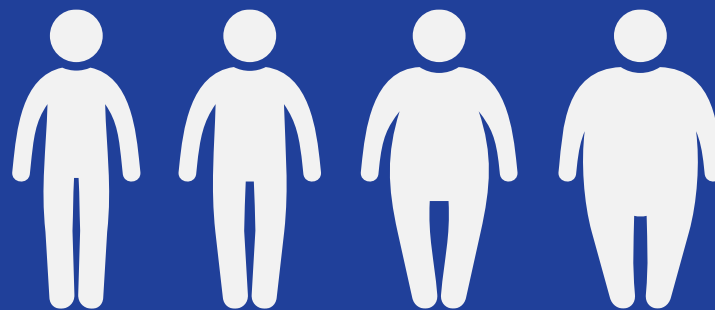
51%

of the worldwide population over 5 years old will be overweight or obese by 2035¹

3X

Worldwide obesity has tripled since 1975²

But while we've made headway on feeding the population with cheap processed food, the unintended consequence is a global epidemic in diet related diseases such as diabetes, obesity and cardiovascular.



We've never had a more overweight yet under nourished global population.



2B

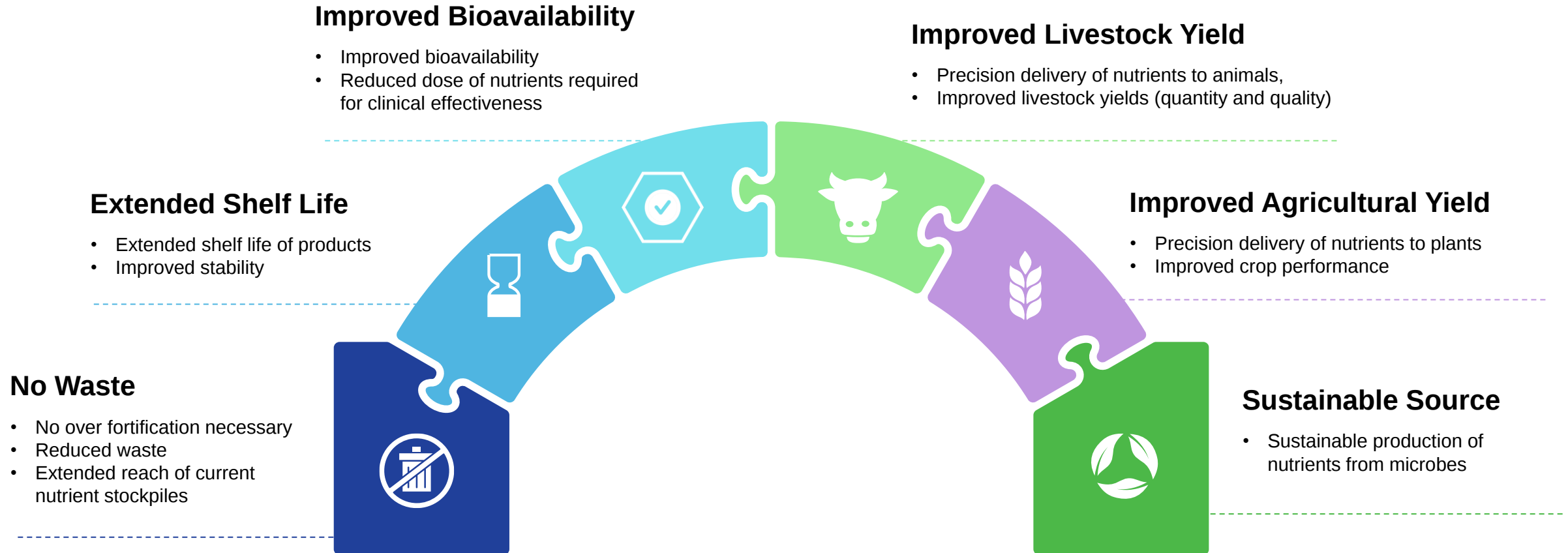
Over 2 Billion of the world's population is affected by malnutrition³

1. https://www.worldobesityday.org/assets/downloads/World_Obesity_Atlas_2023_Report.pdf
2. <https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight>
3. http://www.fao.org/3/x0245e/x0245e01.htm#P38_2721



...VitaKey is the Answer

Improving nutrition while advancing food security and sustainability



Precision Delivery

Importance of spatio-temporal delivery

Mouth:

6.5-7.5 pH
up to 1 min
Taste, digestion

Stomach:

1.5-3.5 pH
1-3 hrs
Digestion, regulate food transit
into intestines

Small Intestine:

5.5-7.4 pH
0.5-5 hrs
Digestion, absorption

Large Intestine:

6.0-7.0 pH
10 hrs-days
Excretion, main microbiome site

Vitamins

Vitamins

Probiotic

Satiety Protein

Probiotic

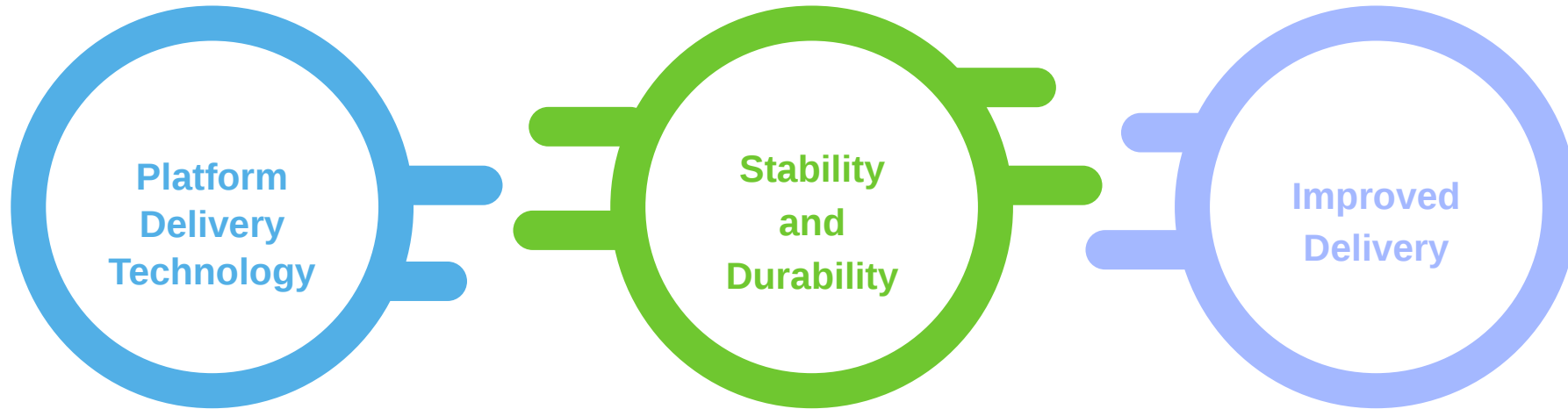
Topical Skin Delivery

Satiety Protein



One Platform Across the Entire Portfolio

Plug-and-Play Solution



Delivery technology can be used in a plug and play fashion for exchanging not only protective materials but also exchanging the following types of payloads:

- Micronutrients
 - Vitamins/minerals
- Macronutrients
 - Proteins, amino acids, carbs, lipids
- Probiotics
- Prebiotics
- Nutraceuticals
- Antioxidants
- Flavors
- Electrolytes
- Fertilizers

- Protects against degradation in austere environments
 - Boiling water
 - High temperature
 - Baking in an oven
 - High humidity
 - Direct sunlight
 - Moisture
 - Rainfall
- Prevents interactions between nutrients, ingredients, and environmental factors
- Mitigates waste and optimizes value of each payload

- Delivery enhancement through spatiotemporal payload delivery in any environment for humans, animals, and plants
- Enables dispersion in variety of foods, beverages, animal feed, or fertilizers
- Customized solutions for targeted and time-controlled release



Application Areas

VitaKey technology can be customized to delivery probiotics across the entire food supply chain into human supplements/food, baby formula, agriculture products (e.g., fertilizers), animal feed...



Sustainable growth across the entire food supply chain

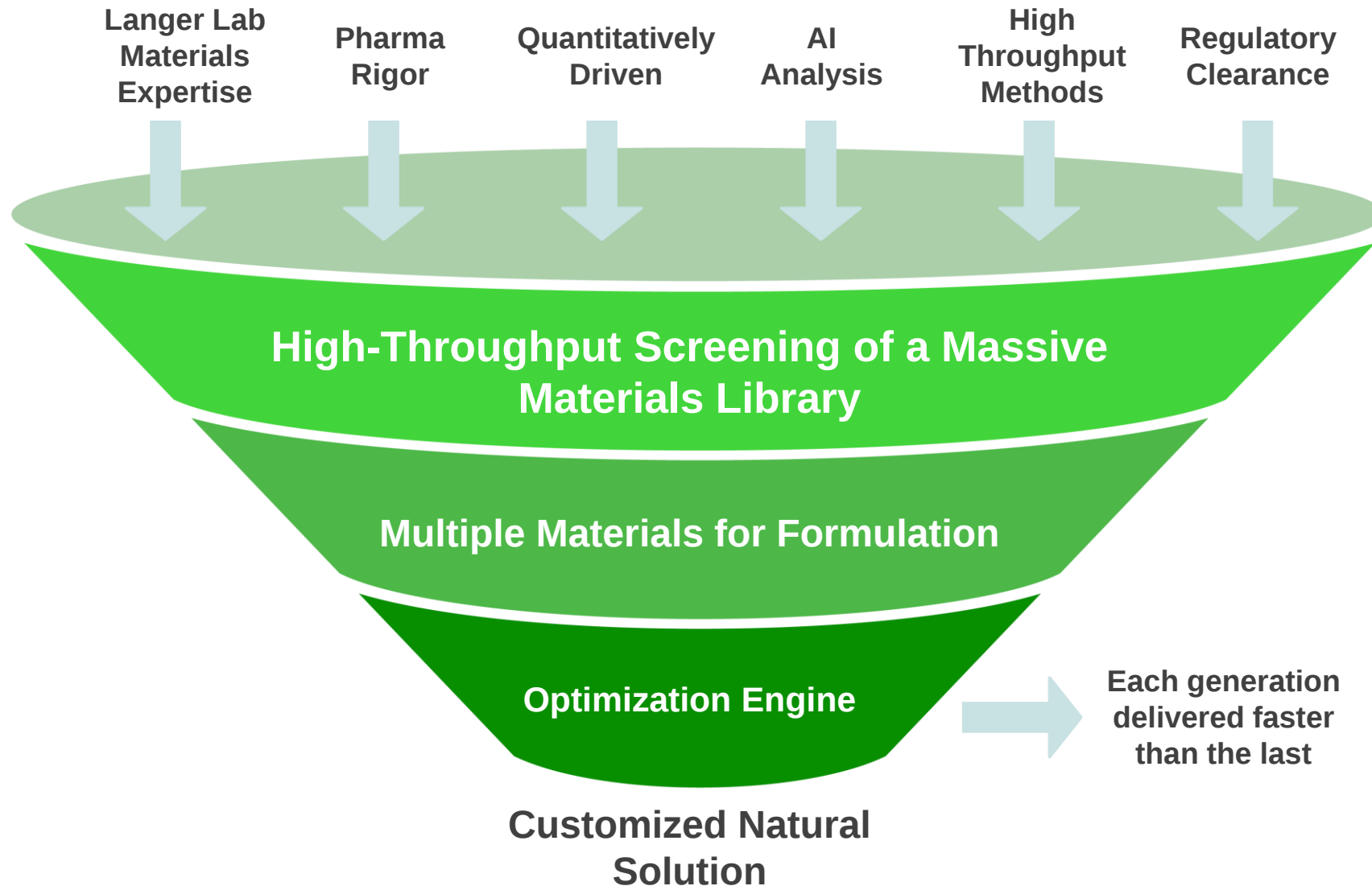


Lesson 2: There is No Substitute for Rigorous Science



VitaKey Approach

Innovation at the speed of light



Food and Agriculture Organization
of the United Nations



World Health
Organization



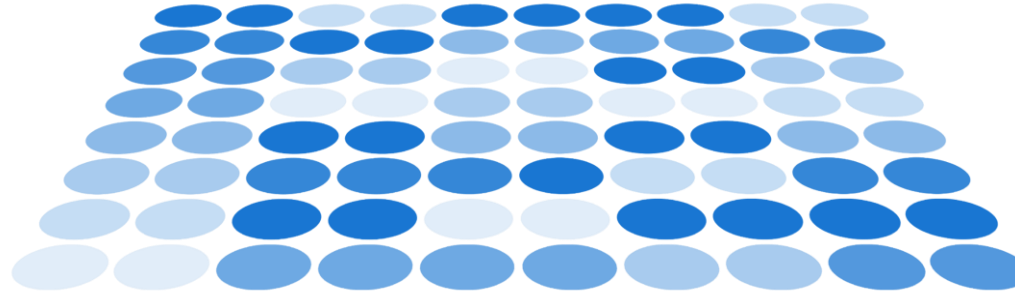
European Food Safety Authority



U.S. FOOD & DRUG
ADMINISTRATION



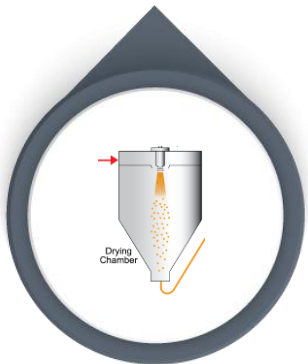
Formulate Nano/Microparticles



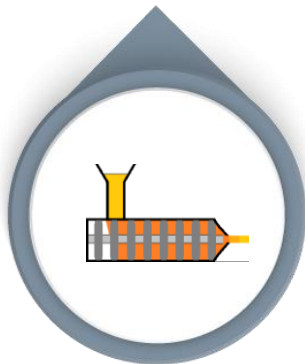
Screening hits and combinations of hits will be formulated together with the payloads using various scalable manufacturing equipment.



Manufacturing Options:



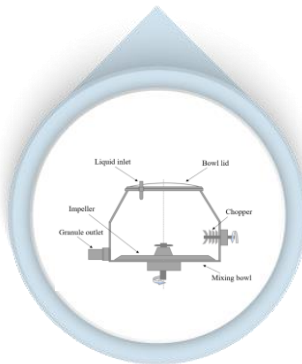
- Spray drying
- Spray congealing



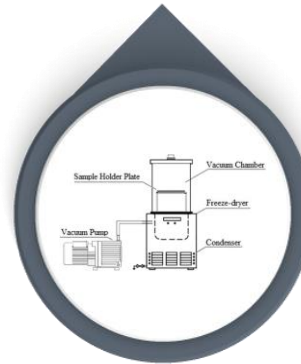
- Extrusion



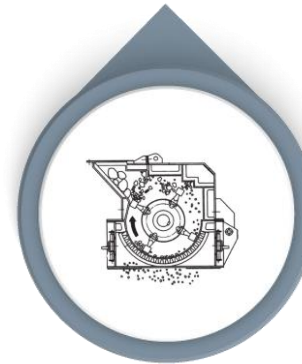
- Fluid bed coating



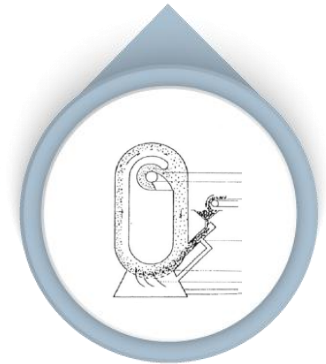
- Granulation



- Lyophilization



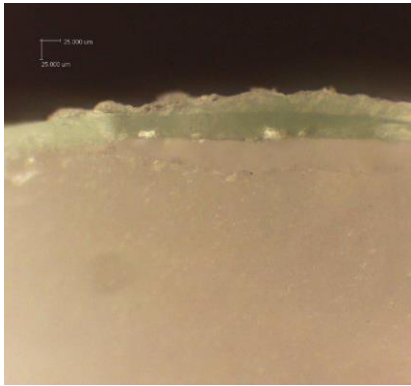
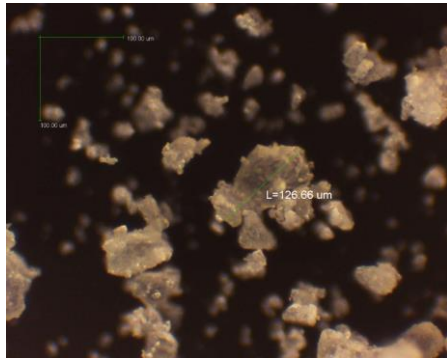
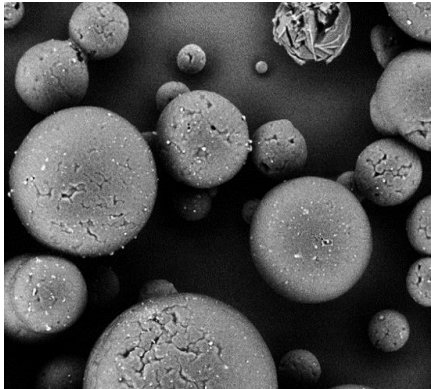
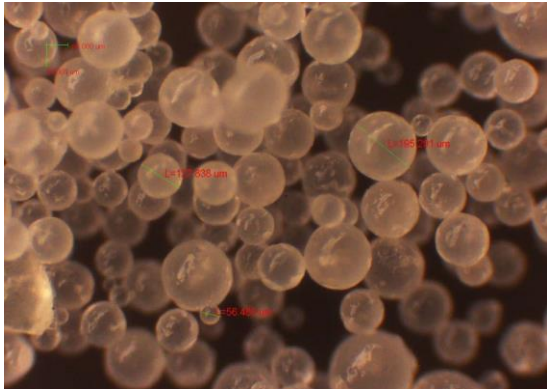
- Hammer milling



- Jet milling



Formulation Approaches



Transformative Technology Published in Three Highly-Acclaimed Journals

PNAS

RESEARCH ARTICLE

APPLIED BIOLOGICAL SCIENCES

OPEN ACCESS

Enhanced stability and clinical absorption of a form of encapsulated vitamin A for food fortification

Wen Tang^{a,b}, Jia Zhuang^a, Aaron C. Anselmo^c, Xian Xu^a, Aranda Duan^a, Ruojie Zhang^a, James L. Sugarman^a, Yingying Zeng^a, Evan Rosenberg^a, Tyler Graf^a, Kevin J. McHugh^{a,d}, Stephany Y. Tzeng^{a,e}, Adam M. Behrens^a, Lisa E. Freed^a, Lihong Jing^{a,f}, Surangi Jayawardena^a, Shelley B. Weinstock^a, Xiao Le^a, Christopher Sears^g, James Oxley^h, John L. Daristotle^a, Joe Collinsⁱ, Robert Langer^{a,1}, and Ana Jaklenec^{a,1}

SCIENCE TRANSLATIONAL MEDICINE | RESEARCH ARTICLE

DRUG DELIVERY

A heat-stable microparticle platform for oral micronutrient delivery

Aaron C. Anselmo^{1,*†}, Xian Xu^{1*}, Simone Buerkli^{2*}, Yingying Zeng¹, Wen Tang¹, Kevin J. McHugh^{1†}, Adam M. Behrens¹, Evan Rosenberg¹, Aranda R. Duan¹, James L. Sugarman¹, Jia Zhuang¹, Joe Collins¹, Xueguang Lu¹, Tyler Graf¹, Stephany Y. Tzeng¹, Sviatlana Rose¹, Sarah Acolatse¹, Thanh D. Nguyen^{1§}, Xiao Le¹, Ana Sofia Guerra³, Lisa E. Freed^{1||}, Shelley B. Weinstock⁴, Christopher B. Sears⁵, Boris Nikolic⁶, Lowell Wood⁷, Philip A. Welkhoff^{7¶}, James D. Oxley⁸, Diego Moretti^{2#}, Michael B. Zimmermann², Robert Langer^{1,**}, Ana Jaklenec^{1,**}

**ADVANCED
MATERIALS**

www.advmat.de

Materials
Views

www.MaterialsViews.com

Layer-by-Layer Encapsulation of Probiotics for Delivery to the Microbiome

Aaron C. Anselmo, Kevin J. McHugh, Jamie Webster, Robert Langer,^{*} and Ana Jaklenec^{*}

Science Translational Medicine

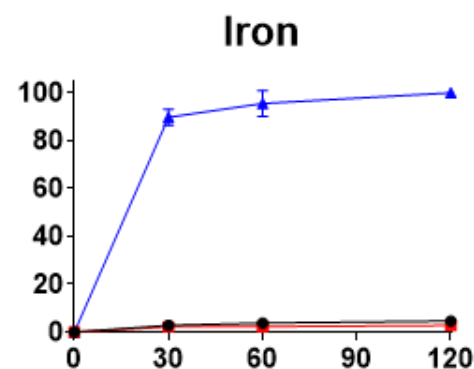
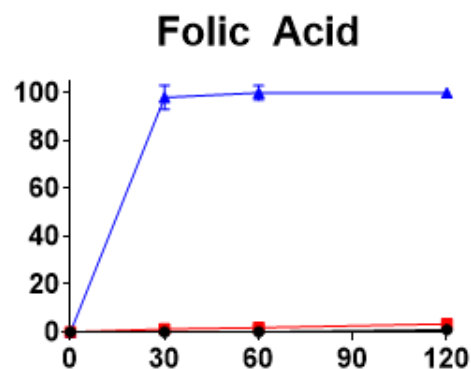
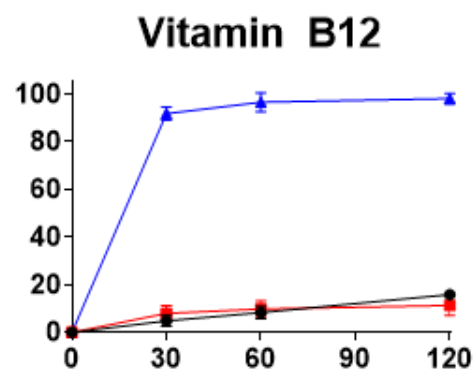
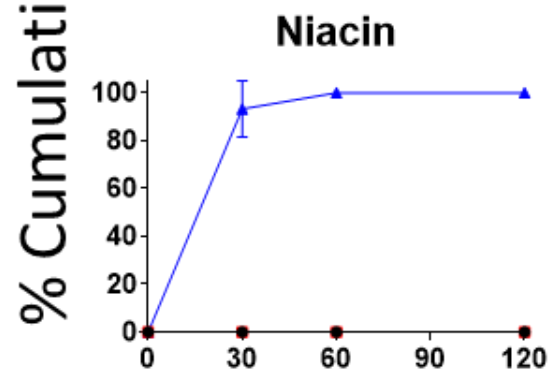
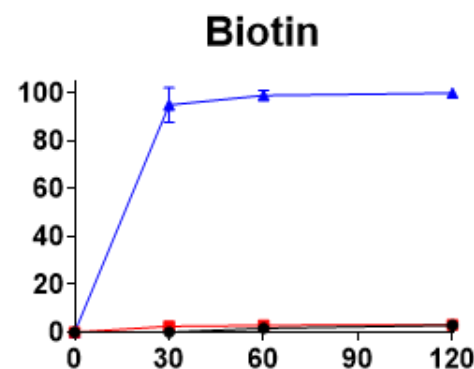
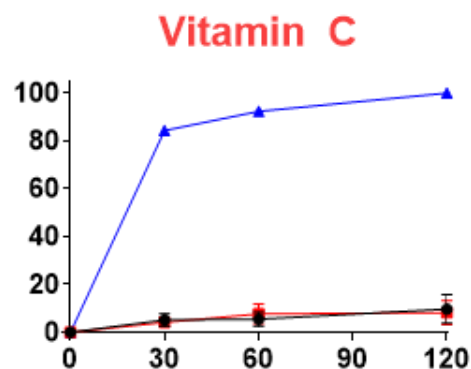
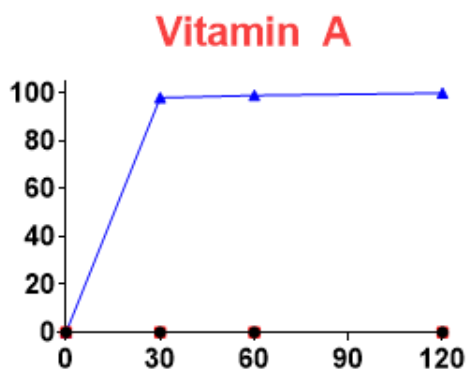
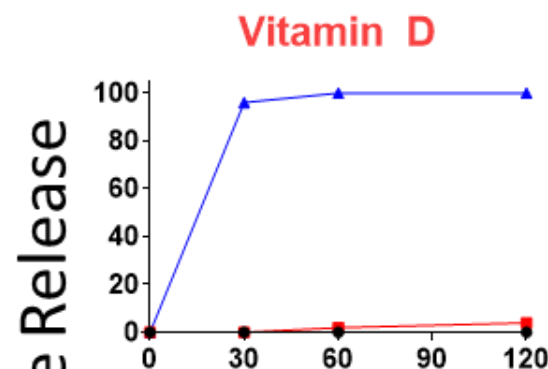
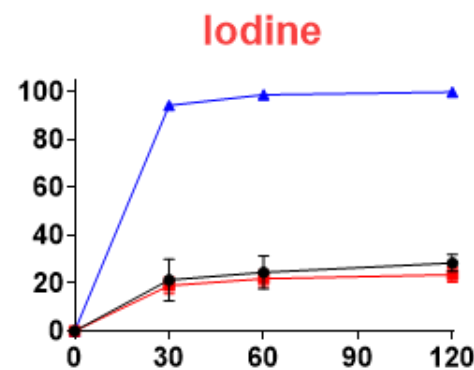
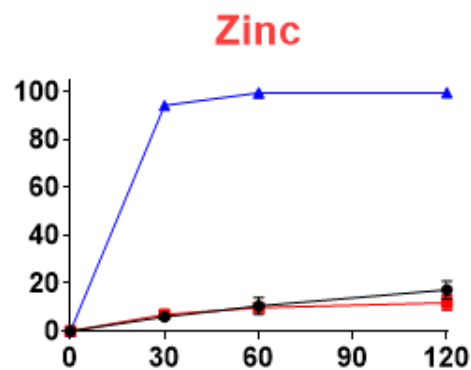
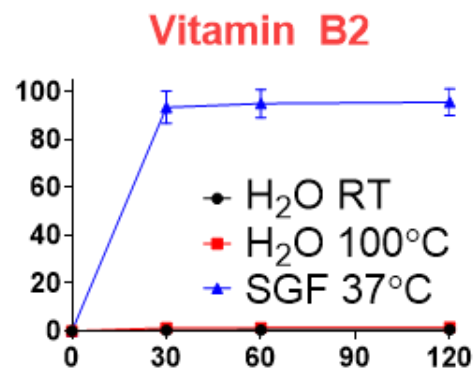
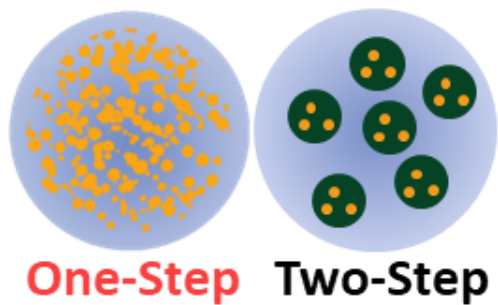
13 NOVEMBER 2019



Lesson 3:

Versatile Platforms Enable Plug-and-Play Functionality





Time [min]

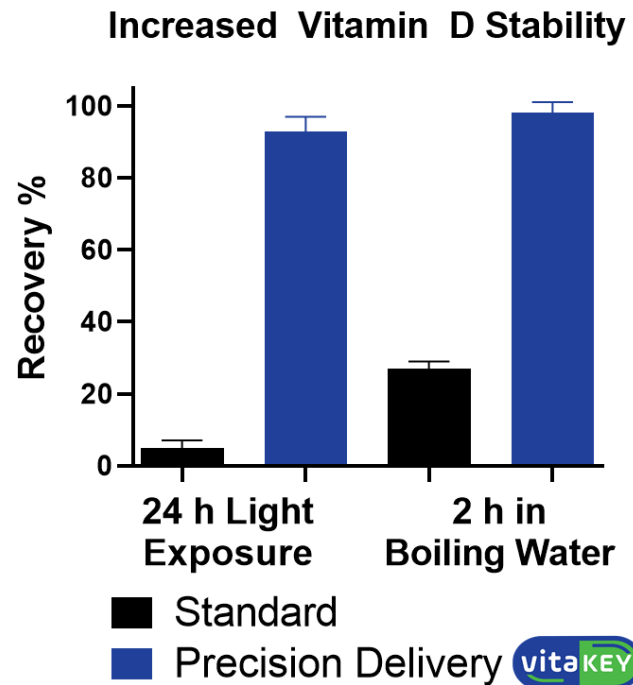


VitaKey's Micronutrient Plug and Play Platform

A highly differentiated vitamin D

VitaKey Outperforms Leading Competition:

- Compared to BASF vitamin D, VitaKey provides
 - ✓ >7x stability against light
 - ✓ Stability in liquids
 - ✓ >298x stability in boiling water
- Compared to DSM vitamin D, VitaKey provides
 - ✓ Similar performance against light
 - ✓ Stability in liquids
 - ✓ ~3x increased stability in boiling water



87%
of urban Chinese
Vitamin D deficient

Beijing population at risk of 'severe' vitamin D deficiency (nutraingredients-asia.com)

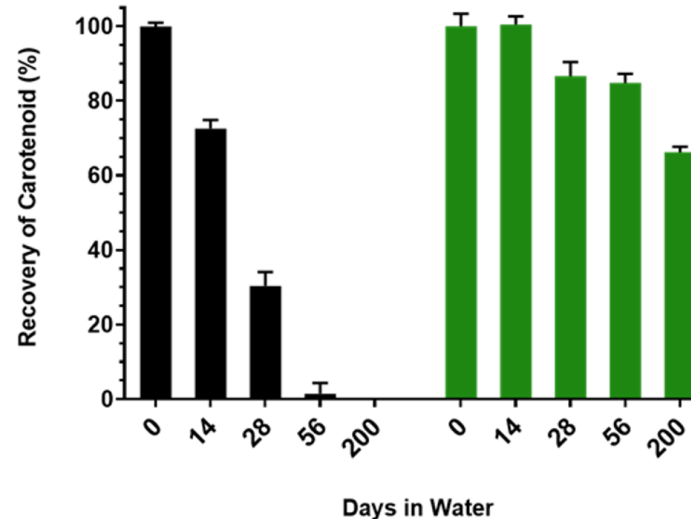
VitaKey's Lutein and Zeaxanthin

Differentiated liquid-stable platform for beverages

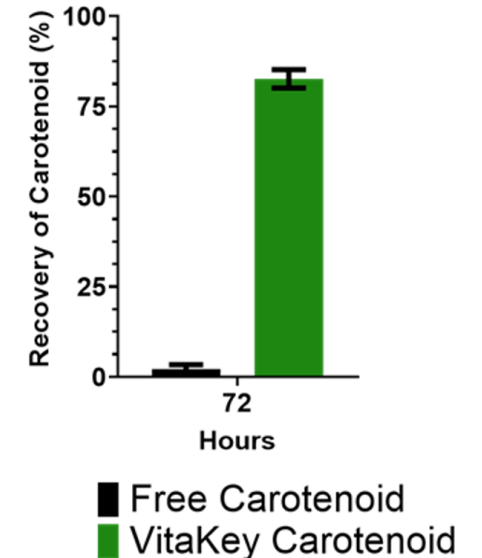
VitaKey's L&Z is highly stable in any environment:

- ✓ Outperforms leading competition
- ✓ Increased stability against oxidation and moisture
 - >35x more stable
- ✓ Increased storage stability
 - 100% payload remains after 4 months storage
- ✓ **World's first liquid stable L&Z formulation**
 - >1000x more stable in water (25°C)
- ✓ Increased stability against light
 - >100x more stable (80k Lux, 1 week, 37°C)
- ✓ Increased stability against heat (2 hours in boiling water)
- ✓ Incorporates widely utilized scalable production methods
 - >100kg manufactured in 2022 under food grade quality
 - Cost competitive
- ✓ Platform proven in 3 human clinical studies, multiple sensory studies and animal studies

Carotenoid Water Stability
(Ambient Temperature; in Dark)



Light Stability
(80,000 Lux; 37°C; 72 Hours)



VitaKey technology improves carotenoid:

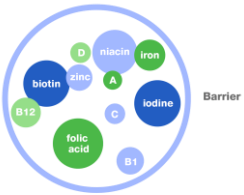
- **Liquid stability**
 - >1000x more stable with VitaKey technology
- **Light stability**
 - >38x more stable with VitaKey technology



Micronutrient Technology

Micronutrient Platform

- Proven to protect 15 nutrients (out of 15 tried)
 - **Highly unstable payloads (e.g., Vitamin A, Vitamin C, etc.)**
- Controlled release in the stomach
 - **Customizable for tailored release profiles**
- Compatible with and improved stability in complex (e.g., nutrient-rich, salt-rich, ion-rich, etc.) powders and liquids
 - **Ability to better-control product uniformity**
- Flexibility with payload choices and concentrations creates
 - Nutrients can be encapsulated individually and combined in a single product
 - **Nutrients separately encapsulated but in the same product have been shown to mitigate negative nutrient-nutrient interactions**
 - Nutrients can be co-encapsulated (e.g. water soluble AND fat soluble together) in a single formulation
 - **Nutrients co-encapsulated have been shown to mitigate negative nutrient-nutrient interactions**
- Tunable size, loading
- Enhanced stability compared to non-VitaKey nutrients and competition when exposed to heat, light, moisture, oxidation
 - **Stability proven highly austere environments (boiling water, 80% + RH, liquids, etc.)**
- Incorporates widely utilized scalable production methods
 - **> 2 Million doses manufactured in the last 5 months for commercial products**



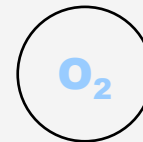
Heat stable



Light protective



Moisture resistant



Oxidation preventative



Scaled production



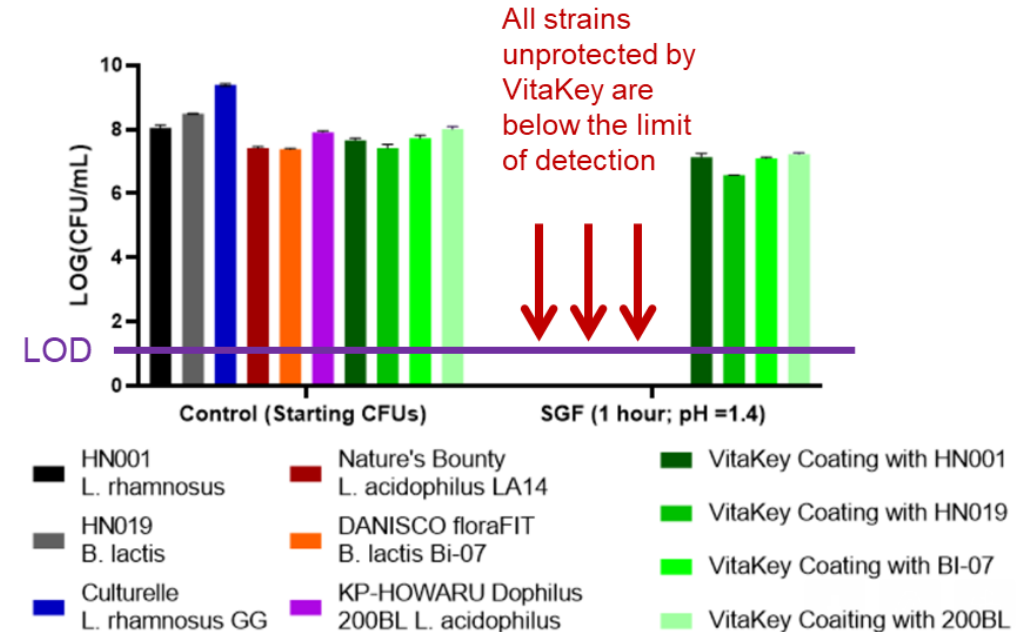
Lesson 4: Probiotics are **EXTREMELY** Sensitive



Probiotic Platform

Gastric stability

- ✓ Improved survival in stomach acids
 - **>10,000,000x** more survive
 - For up to 24 hours
- ✓ Improved stability in high humidity (50% RH) conditions
 - **>50x** more stable
- ✓ Improved stability in both nutrient-rich and nutrient-devoid liquids
 - **>1,000x** more stable
- ✓ Maintains key functions of probiotics
 - Metabolite secretion
 - Growth
- ✓ Tunable size, loading, probiotic choice, number of probiotics
- ✓ Compatible with aerobic and anaerobic probiotics
- ✓ Incorporates widely utilized scalable production methods
- ✓ Cost competitive



All strains without VitaKey technology showed complete die-off in stomach acids



400+

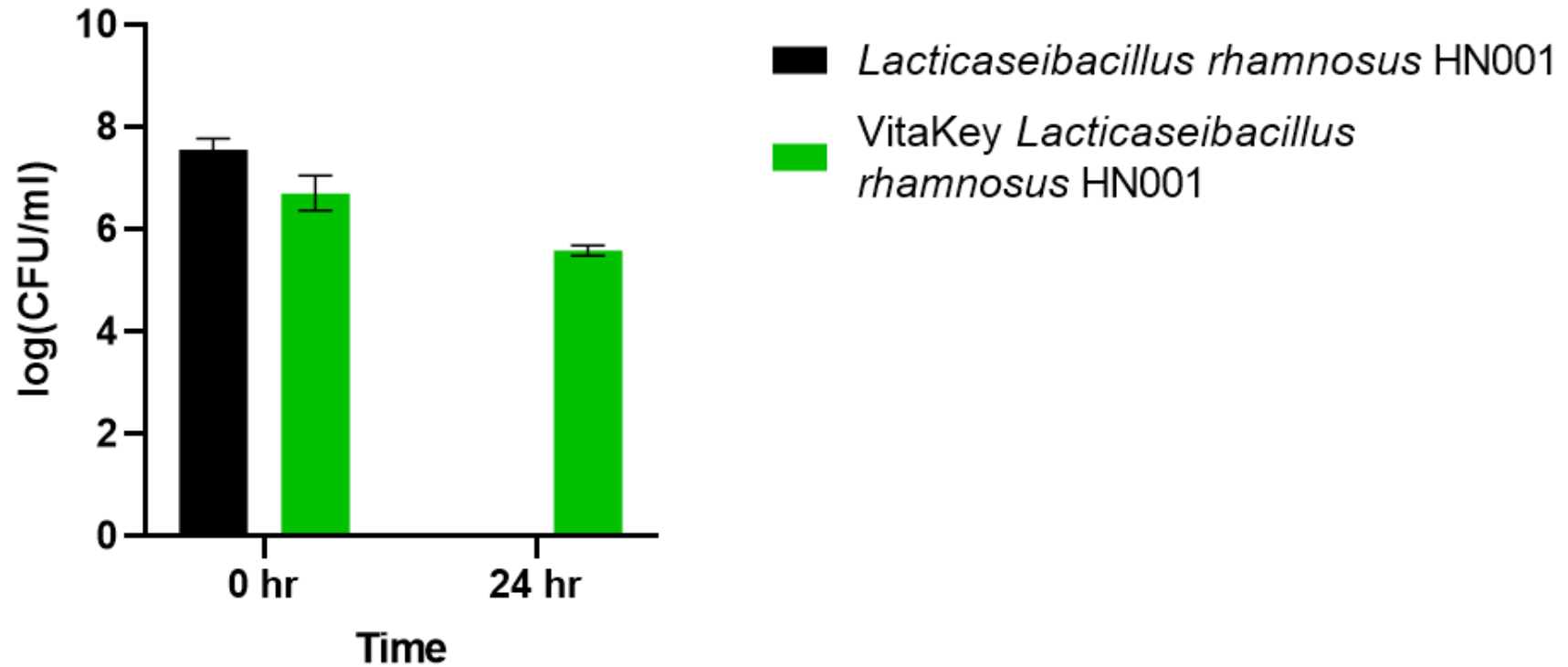
Probiotic products on the market
carry viability claims¹



24 Hour Acid Stability

Extended Simulated Gastric Fluid (SGF) study

24 Hour SGF exposure (pH= 1.5)

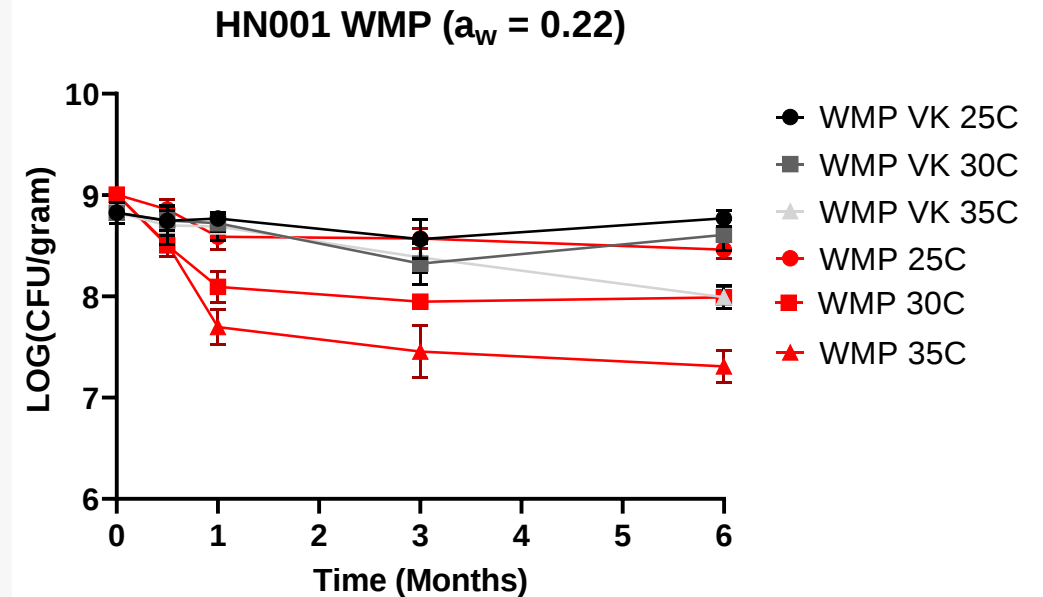


Probiotic Platform

World's first and only probiotic that is compatible with high water-activity products

VitaKey probiotics solve shelf-storage problems, creating novel food formats to improve consumer convenience:

- ✓ Improved stability in high water activity powders at 6 months:
 - VK-HN001 has >3X (25°C) more viability (survival) than control
 - VK-HN001 has >6.4X (30°C) more viability (survival) than control
 - VK-HN001 has >7X (35°C) more viability (survival) than control
 - **VitaKey technology mitigates blending loss**
- ✓ Maintains key functions of probiotics
 - Metabolite secretion & growth
- ✓ Compatible with dry powders and high water activity products
 - Milk and protein powders, ingredients (e.g. L&Z), infant formula, medical nutrition, and cosmetic actives
- ✓ Screened hundreds of materials, constructed dozens of formulations, manufactured millions of doses under food grade conditions.
- ✓ Newer formulations available to test in powders with significantly improved performance



> 7X

More survivability of VitaKey probiotics in high water activity powders



Innovative Formulation Technologies To Unlock Next-Generation Gummy Payloads and Markets



High Water Activity Environment

- Gummies have high water activity so they remain chewy
- Nutrients (especially probiotics) are unstable in high water activity foods/high humidity conditions
- Gummies ~0.6 aW
 - Water = 1.0 aW
 - Probiotics unstable ≥ 0.2 aW



Acidic Matrix

- Preservatives (e.g., citric acid) create acidic environment (gelatin and pectin gummies)
- Acidic environment is required for pectin gummies to properly gel
- Acidic (low pH) environments decrease viability of probiotics
 - Gummies ~pH 3.0 - 3.5



Heat during Manufacturing

- High temperatures required to solubilize gummy constituents and facilitate molding of final gummy
- Elevated temperatures decrease viability of probiotics
- Gummy manufacturing temperatures can reach ~ 175F and above

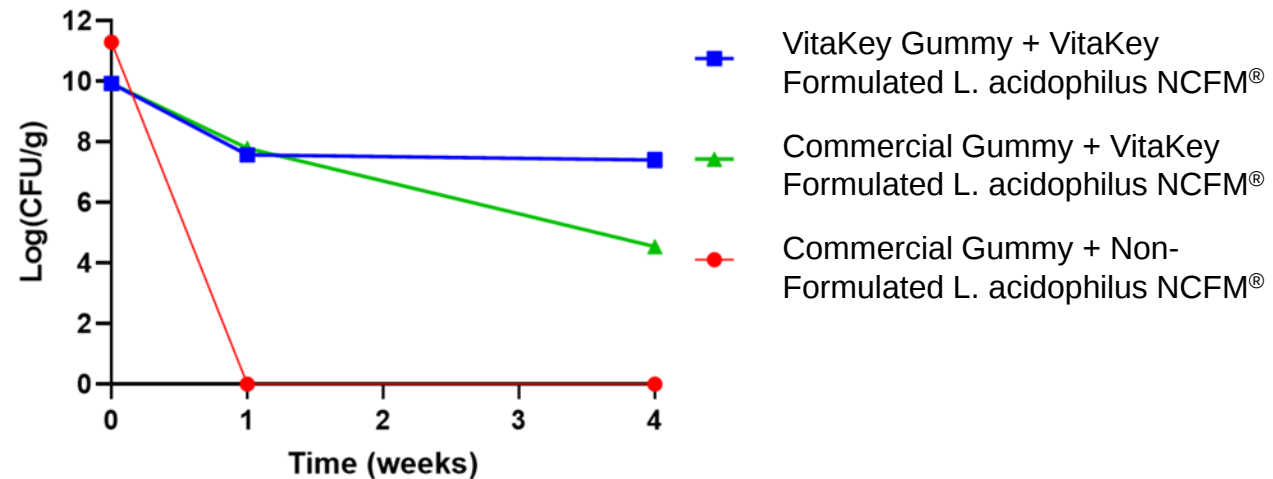


Creating the World's First Lactic Acid Probiotic Gummy



VitaKey probiotics demonstrate survival advantages when stored with gummies (water activity of ~ 0.65)

- ✓ Existing VitaKey probiotics tested **without optimization/customization** for gummies
- ✓ HOWARU Dophilus (L. acidophilus NCFM[®]) is undetectable after 1 week storage with gummies at 25°C
- ✓ VitaKey technology provides **>50 million** times survival advantage
- ✓ Less manufacturing complications
- ✓ Lower cost



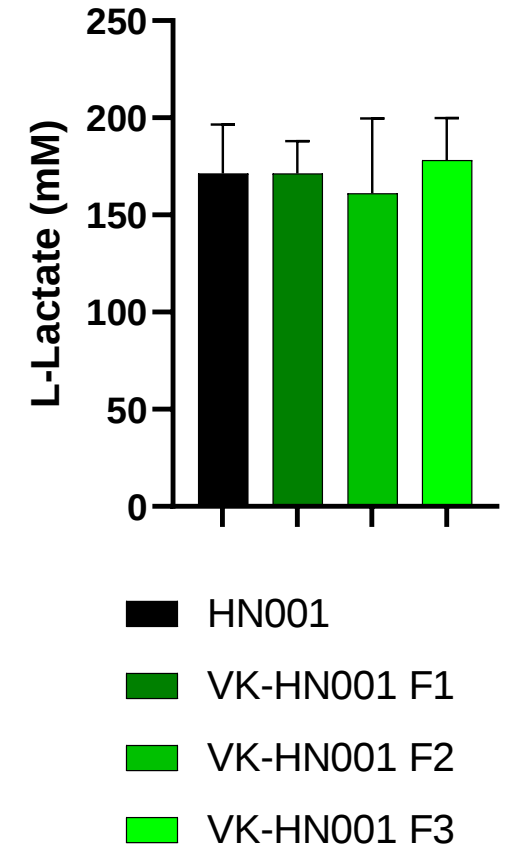
Probiotic Platform



Probiotic Platform

- Proven to protect probiotics with survival in the stomach
 - 10 Million times more than competitors**
 - Delivery of living probiotics to the intestines**
- Improved stability in high water activity powders
 - >7 survival at 35C and 0.22 aW**
- Improved stability in high humidity (50% RH) conditions
 - >50x more survival**
- Maintains key functions of probiotics
 - Metabolite secretion, growth**
- Tunable size, loading, probiotic choice, number of probiotics
 - Given payload size (microns), formulations can be tuned between 10-300+ microns**
- Compatible with and stable in complex (e.g., nutrient-rich, salt-rich, ion-rich, etc.) capsules, powders, and liquids
- Compatible with aerobic and anaerobic probiotics
 - Highly sensitive (oxygen-sensitive) anaerobic payloads**
- Incorporates widely utilized scalable production methods
 - > 1 Million food-grade doses manufactured in last 4 months**

Lactic Acid Secretion



Probiotics grow, proliferate,
and secrete metabolites



Enhanced survival
In high moisture
environments



Protects from
physiological challenges
(stomach acid, bile)



Viable delivery
to intestines



scaled production



Lesson 5:

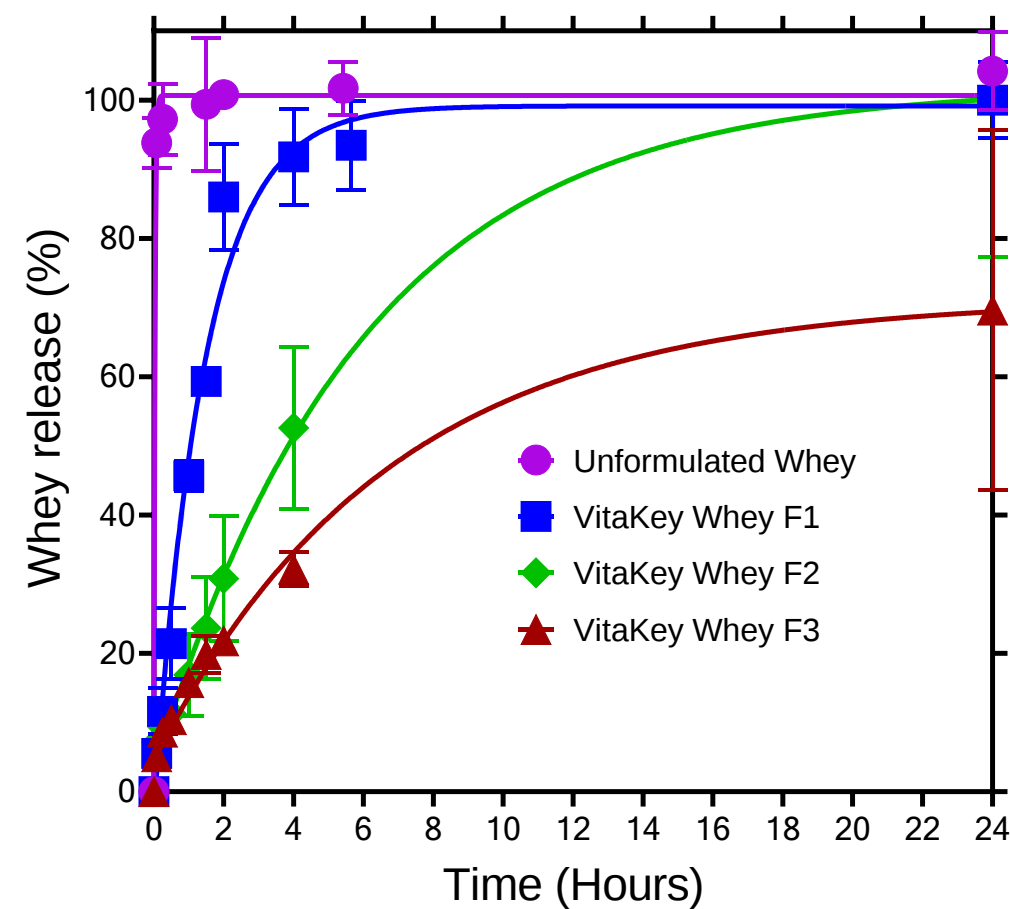
Dietary Proteins DO NOT Behave like Biologics



Protein Extended Release

Extended release

Whey protein: time release over 24 hours



Macronutrient Technology



Macronutrient Platform

- Precision delivery of payloads
 - **Proteins, peptides, amino acids**
 - **Sugars, prebiotics**
 - **Fats, lipids, fatty acids**
 - **Ketones**
 - **Satiety modulators**
- Controlled bioavailability
 - **Increased absorption of proteins (e.g., better muscle building/recovery/maintenance from protein shakes)**
 - **Decreased absorption of sugars with the same taste (e.g., sweets with the same taste but fewer calories)**
- Sustained release of payloads
 - **Longer duration of benefits from food (e.g., 12-hour protein shakes)**
- Programmed satiety
 - **Extended duration of satiety**
- Tunable size, loading, payload choice, number of payloads
- Compatible with and stable in complex (e.g., nutrient-rich, salt-rich, ion-rich, etc.) capsules, powders, and liquids
- Incorporates widely utilized scalable production methods



Natural materials



Stable against oxygen,
heat, light, moisture



Controlled
Satiety



Controlled
absorption



Scaled production



Our Mission Statement

***“Do something that can really change the world
rather than something incremental.”***

— Robert S. Langer, Sc.D.

