Institute on Science for Global Policy (ISGP)

Food Innovations:
Innovative Foods and Ingredients

A conference organized and convened by the ISGP and sponsored by the U.S. Food and Drug Administration, Minneapolis, Minnesota
June 23—27, 2019

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An ongoing series of dialogues and critical debates
examining the role of science and technology
in advancing effective domestic and international policy decisions

Institute on Science for Global Policy (ISGP)

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Introduction

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Preface

The content of this book was taken from material presented at a conference organized and convened by the Institute on Science for Global Policy (ISGP) on June 23-27, 2019, in Minneapolis, Minnesota. This specific topic of this ISGP conference, Innovative Foods and Ingredients, is part of the ISGP Food Innovation Program and was sponsored by the U.S. Food and Drug Administration (FDA). The focus of this ISGP conference reflects a common commitment among governmental agencies and departments, private sector entities, and public advocacy organizations to effectively and accurately inform the public writ large of evidence-based information and analysis concerning a broad range of innovative foods and ingredients. The debate/caucus format, pioneered by the ISGP, was used in this conference to foster candid discussions among communities that are known to disagree about some widely available information and policy decisions. In general, the ISGP debate/caucus format has been effective in significantly improving the communication of credible scientific and technological (S&T) understanding among stakeholders and the public facing major decisions.

The organization of this IFI conference was based on the recognition that the introduction of innovative foods and ingredients is becoming a focal point on their impact on human health, environmental sustainability, economic prosperity, and global food requirements. These relationships are affecting major societal decisions and need to consider the diverse cultural, ethical, and economic characteristics that often define large parts of 21st century societies. Societal decisions concerning how to appropriately incorporate the often-transformational S&T advances associated with innovative foods and ingredients into public and private sector policies are well served by critical debates and caucus discussions identify evidence-based options and

real-world opportunities. ISGP conferences offer rarely encountered environments in which such debates and caucuses assemble distinguished representatives from diverse stakeholders (government, private sector, public advocacy, and subject matter experts in science, technology, and economics) holding often contradictory views and priorities. These are stakeholders who routinely make or significantly influence major governmental and private sector decisions affecting the public *writ large*.

Current Realities

At the outset of the 21st century, most societies face difficult challenges concerning how to appropriately use, or reject, the dramatic new opportunities offered by modern S&T advances. Since scientific research programs, and commercially viable technologies, are now developed globally, societal challenges related to S&T necessarily involve domestic and international policy decisions, both in government and the private sector. The daunting challenges to simultaneously recognize immediate technological opportunities while identifying those emerging S&T achievements that foreshadow transformational advantages, and potential risks, are now critical governmental and private sector responsibilities. The complexity of these responsibilities reflects the multitude of societal demands, most having conflicting views, priorities, and goals. Policy decisions need to balance these differences with the cultural sensitivities that often determine if, and how, S&T is successfully integrated into any society.

ISGP Conference Format and Structure

Extensive interviews by ISGP staff (248 interviews for the IFI conference) were used to identify internationally recognized subject-matter experts who are invited to prepare eight, concise (three-page) position papers. Each position paper includes the authors views on the current realities, scientifically credible opportunities and associated risks to address the challenges, and policies and decisions concerning the introduction of innovative foods and ingredients into the food supply system.

The conference began with eight, moderated, 90-minute debates, each one of which addressed one of the position papers. At the outset, the author presented a 5-minute summary of his or her views while the remaining 85 minutes were opened to all participants, including other authors, for questions, comments, and debate. The audio recordings made of each debate were held in the custody of the ISGP and, together with their transcripts, were used by the ISGP staff to prepare not-for-attribution summaries of the debates. These summaries represent the ISGP's best effort to accurately capture the points made by all participants during each debate. These summaries do not necessarily represent the views of any specific participant,

including the author as evidenced by his or her respective position paper. Rather, the summaries are, and should be read as, an overview of the points of agreement and disagreement that emerged from all those participating in the debates.

Following the eight debates, small (10-12 people), moderated caucus groups representing a diverse cross section of all participants were convened to identify evidence-based options and real-world opportunities to be considered by stakeholders and policy makers. The results from all eight caucuses are reviewed by all participants in a moderated plenary session prior to the adjournment of the conference.

The eight position papers, together with their respective, not-for-attribution debate summaries, are published in this book. The evidence-based options and real-world opportunities emerging from the caucuses are presented at the front of this book in the section "Caucus Outcomes."

Concluding Remarks

The IFI conference was designed to provide an environment that facilitated candid debates and discussions among diverse stakeholders focused on obtaining an accurate understanding of diverse views and priorities concerning the emergence of a wide range of innovative foods and ingredients. As one of the most significant challenges facing 21st century societies, IFI impacts many aspects of essentially All societies. Obviously, the IFI conference builds on authoritative reports from and experiential expertise in many domestic and international organizations actively pursuing different priorities with respect to IFI topics. Since the not-for-profit 501(c)(3) ISGP has no opinions and does not lobby for any issue except rational thinking, this IFI conference offers opportunities to debate IFI issues without pursuing predetermined outcomes, but rather seeks to significantly improve the communication of credible options and opportunities.

Caucus Outcomes

Small-group caucus

The evidence-based options (EBO) and real-world opportunities (RWO) included in the proceeding section represent the views expressed by participants during the small-group caucus sessions held on the third day of the Institute on Science for Global Policy (ISGP) Innovative Foods and Ingredients (IFI) conference.

Small-group caucuses (with a maximum of 12 people in each) were comprised of a cross section of IFI conference participants representing the diverse views and priorities of the private sector, public advocacy, not-for-profit, subject-matter experts, and government regulatory communities attending. Each small-group caucus was tasked with answering six questions (presented below) previously identified by the ISGP staff. The same six questions were used in all eight caucuses, which were held over the course of a day with the assistance of ISGP moderators and scribes. The moderator's role in each caucus was to ensure participants had the opportunity to voice their views and perspectives in response to the six questions. Scribes recorded all comments, which were projected on a screen to facilitate viewing by all caucus members.

Small-group caucus members were asked to answer each question in terms of separate EBOs and RWOs.

An EBO described a scientifically credible approach to achieving the outcomes and goals framed by a given question (e.g., how to accurately assure the consumer that a promoted benefit for human health, environmental sustainability, economic prosperity, and/or expanding global food supply from a given innovative food or ingredient was realistic). Each caucus member was encouraged to provide his/her own EBO before being asked to find common ground with other suggested EBOs.

An RWO describes a real-world, practical opportunity that could be used to achieve a given EBO. Caucus members were encouraged to provide as many RWOs as they wished.

Taken together, the EBOs and RWOs are meant to articulate how evidence-based understanding can be used to develop and support specific activities and decisions that improve the potential for innovative foods and ingredients to improve human health, environmental sustainability, the global food supply, and economic prosperity.

Procedurally, ISGP moderators and scribes remained neutral except for

clarifying comments and recording and projecting all responses for viewing by the caucus members. While each caucus member was asked to identify RWOs he/she could support in achieving a specific EBO, the precise procedure for aligning EBOs and RWOs varied slightly in all eight caucuses.

Plenary Caucus

The resulting EBOs and RWOs from the small-group caucuses were presented to all participants at a plenary session prior to adjournment and are recorded here. All EBOs and RWOs are presented here together with the number of caucus members (e.g., 11/12) who supported the precise wording. As agreed in the plenary session, ISGP staff edited these results by combining equivalent EBO and RWO statements and included specific differences in wording in brackets. Where the general EBO and RWO wording was agreed upon except for a different phrase or word, those differences were presented (underlined and italicized) within brackets ([ ]) together with the number of supporting caucus members. EBOs and RWOs supported by only one caucus member (1/1) were presented separately.

Evidence-Based Options and Real-World Opportunities

Question One:

Demonstrable Benefits of Innovative Foods and Ingredients

How confident are you in the purported benefits associated with advances in innovative foods and ingredients as described in the position papers and debates (e.g., human health, environmental sustainability, humanitarian goals, economic advantages)? What actions could be taken to assess the validity of these claims of benefit, and what accountability options exist to ensure that the promoted benefits materialize?

GROUP ONE

EBO 1:

We are confident in the scientific approaches to achieve benefits (e.g., human health, environmental sustainability, humanitarian goals, and economic advantages) but are less confident in our ability to translate and deliver these benefits to the market. In realizing these benefits, we should account for consumer wants and needs, as well as environmental, social, economic, and health needs. (**10/12**)

RWOs:

a. Utilize existing evaluative procedures for functional or health benefit assessments. (**10/10**)
b. Utilize assessment tools for food system variables. (**10/10**)
c. Undergo regulatory review in relevant markets when necessary. (**8/10**)
d. Encourage a food systems approach which stimulates the use of innovative technologies to address real needs by supporting intersectoral and interdisciplinary communication and education. (**7/10**)
e. Develop public-private partnership to provide for these ends. (**7/10**)

EBO 2:

We are more confident in some possible benefits than others. Some benefits will be easier to realize than others. In dictating these benefits, we must account for consumer wants and needs: environmental, social, economic, and health. (**1/12**)

RWOs:

none

GROUP TWO

EBO 1:

We have medium-low confidence in whether products will deliver on economic benefits and social good. Historically, it takes much longer to determine whether

new technologies will deliver social good (e.g., environmental sustainability). Publicly accessible, third-party review and associated data, including peer reviews, are necessary for assessment and accountability to validate the delivery of promised traits. **(6/10)**

RWO:

a. Engage a trusted third party to examine a holistic view of the entire marketplace of stakeholders, not exclusive to the companies making such claims (e.g., health and sustainability). **(6/6)**

EBO 2:

Confidence levels vary across benefits and the short-term versus the long-term, but confidence levels remain medium-high that the traits promised will actually deliver social good (e.g., environmental sustainability). Publicly accessible, third-party reviews and associated data, including peer reviews, are necessary for assessment and accountability to validate the delivery of promised traits and benefits. **(4/10)**

RWOs:

a. Engage a trusted third party to examine a holistic view of the entire marketplace of stakeholders, not exclusive to the companies making such claims (e.g., health and sustainability). **(4/4)**
b. Develop a new/modified regulatory safety certification. **(2/4)**

GROUP THREE

EBO 1:

Innovative foods and ingredients will make it to market and fulfill important niches. Hopefully, they will be scalable enough to realize the net, purported benefits to society. **(7/7)**

RWOs:

a. Ensure that companies making claims transparently provide data (depending on the claim) so that claims can be verified by the government and the public, and in the marketplace. **(7/7)**

GROUP FOUR

EBO 1:

There is strong potential for benefits of innovative foods and ingredients. *[Long-term, downstream analyses for safety should be included to ensure readiness and confidence of society to accept these technologies **(3/12)**.] [A limited number of participants are concerned about safety and human health. A critical component to success is the readiness of society to accept specific innovations (which are different for different technologies) when supported by proper stewardship **(9/12).**]* **(12/12)**

RWOs:

a. Employ science-based risk oversight, transparency, and stewardship to ensure public trust. **(12/12)**
b. Encourage public education on food and technologies. **(12/12)**
c. Create a roadmap to support food companies to guide them, ensuring that they stay on the right path (i.e., ensuring safety, stewardship, and communicate benefits). **(12/12)**

GROUP FIVE

EBO 1:

Value exists in broad technology innovation versus individual applications, since there is a lack of knowledge concerning how to assess major benefits made by innovative food and ingredients associated with human health, environmental sustainability, humanitarian goals, and economic advantages (i.e., prosperity). Criteria for standard measurable benefits are still needed. Flexible, adaptable regulatory frameworks will be needed to enable innovation, ensure safety, and be enforceable. *[Confidence (**10/12**)] [Consumer confidence (**1/12**)] [Stakeholder confidence (**1/12**)]* will build over time as the industry develops, thus business innovation is needed along with technology innovation. Impact of these benefits will be determined largely by consumer adoption. **(12/12)**

RWOs:

a. Determine a role for international organizations. **(11/12)**
b. Encourage public-private partnerships. **(9/12)**
c. Create a transparent, standardized regulatory roadmap for seeking compliance (e.g., safety, labeling, *[and efficacy (1/12)]*). **(9/12)**
d. Require oversight by a third party to ensure the efficacy of the proposed benefit. **(6/12)**
e. Educate critical stakeholders (e.g., communication, media, NGOs). **(1/12)**
f. Create public-private partnerships that promote buy-in (product development, regulatory framework). **(1/12)**

GROUP SIX

EBO 1:

We are confident in the benefits associated with new technology, but we are concerned that some benefits will not be realized in the current environment of distrust of food technology. We have imposed an overly cautious view on assessment and food regulation that has slowed innovation in this area. We must realize how flexible the food system is in order to encourage innovation in this space. It needs to be balanced against public-private trust, bio-vigilance, and accountability inside an appropriate

(i.e., risk-reward) governance framework. Innovation will be worldwide, so any regulatory oversight must be rapid and agile in order to maintain leadership and to protect against misuse of these technologies. **(12/12)**

RWOs:

a. Encourage investment and open, transparent initiatives that promote responsible leadership in compliant government structures (e.g., fund, expand, and leverage resources that currently exist in land grant universities to perform risk-benefit analyses). **(12/12)**
b. Include advocates and on-the-ground voices in discussion of importance of new technologies (e.g., dietitians that advocate for consuming better food; physicians discussing vaccines and benefits and risk associated with not using vaccines; people discussing scarcity of resources and benefits of aquaculture; community dialogue). **(12/12)**
c. Create a discussion where people have confidence in health and wellness (e.g., find people to talk about new technologies in a positive way; address consumer distrust in meaningful ways; foster and implement thought leadership that is multi-disciplinary to address these situations). **(12/12)**
d. Create a regulatory structure that is risk-evidence-based, agile, and pro-innovation. We need the government and other influencers (e.g., dietitians, physicians, farmers, mainstream influencers) to support the technology and the proper regulatory structure to engender consumer confidence in these products. **(12/12)**
e. Define scope and framework of bio-vigilance. **(3/12)**
f. Start with consumers and not the technology. If the consumers do not accept new technology, we fail. Clearly communicate and deliver benefits to consumers. **(1/12)**

GROUP SEVEN

EBO 1:

Confidence in demonstrable benefits of IFI is tied to scale, consumer acceptance, and international alignment. *[Clear standardized regulations **(2/12)**] [Consistent regulatory framework **(1/12)**] [Consistent regulatory framework and clear standardization of the evaluation of benefits **(9/12)**]* and incentives are essential. Confidence is generally moderate in the technical ability to achieve the benefits of these innovations. We have a high degree of confidence in the need for, and power of, innovation. **(12/12)**

RWOs:

a. Develop a robust rubric for the evaluation of benefits and grading claims, as well as a timeline for doing so. **(5/12)**
b. Develop productive intergovernmental activities that enable market access

for innovations (e.g., establish a new multi-national WTO round). (**3/12**)

c. Develop a coordinated consumer communication and engagement plan to bolster benefit and safety confidence. (**2/12**)

GROUP EIGHT

EBO1:

Authoritative bodies (governmental and non-governmental) working with industry will establish standardized, data-driven mechanisms to develop, validate, and enforce product claims with the aim of boosting consumer need, confidence, and protection. (**11/11**)

RWOs:

a. Develop sector-based standards that reflect the sentiment and needs of stakeholders based on criteria (i.e., definitions) for establishing standards. (**10/11**)

Question Two:

Responsibilities for Accurate Public Communication and Advocacy

What responsibilities do all stakeholders (e.g., government, private sector, public interest, philanthropic, academic) have for providing accurate, evidence-based information to the public regarding innovative food and ingredient technologies and products?

GROUP ONE

EBO 1:

All stakeholders have a responsibility and/or mandate to communicate science-based and accurate descriptions of all current and relevant data concerning innovative foods and ingredients to the public. (**6/12**)

RWOs:

a. Enforce the legal responsibilities of government agencies and departments, as well as the responsibilities of private sector companies, for the timely and audience-appropriate communication of accurate, evidence-based information to the public. All stakeholders have responsibilities to communicate to varied communities in appropriate and diversified ways. (**6/6**)
b. Ensure that communication enhances consumer understanding and minimizes consumer confusion. (**6/6**)
c. Create a public-private partnership, sponsored by FDA, USDA, EPA, and other relevant governmental entities, to facilitate the development of well-defined standards for communication of accurate, evidence-based information to the public. (**3/6**)

EBO 2:

Certain stakeholders have a mandated responsibility, and others have a responsibility, to communicate science-based, accurate, and relevant data concerning innovative foods and ingredients. (**5/12**)

RWOs

a. Enforce the legal responsibilities of government agencies and departments, as well as the responsibilities of private sector companies, for the timely and audience-appropriate communication of accurate, evidence-based information to the public. All stakeholders have responsibilities to communicate to varied communities in appropriate and diversified ways. (**5/5**)
b. Ensure that communication enhances consumer understanding and minimizes consumer confusion. (**5/5**)

c. Create a public-private partnership, sponsored by FDA, USDA, EPA, and other relevant governmental entities, to facilitate the development of well-defined standards for communication of accurate, evidence-based information to the public. (**3/5**)

GROUP TWO

EBO 1:

When communicating to the public, all stakeholders have the responsibility to provide accurate, evidence-based information using publicly understandable, standardized language. Where regulatory expectations and standards exist, stakeholders have the obligation to disclose whether or not the information adheres to these standards. (**9/10**)

RWOs:

a. Create and/or support existing mechanisms that avoid misleading public understanding using peer review, comment by third parties, and accepted sets of criteria available to the public in the original context of the data. (**9/10**)
b. Require journal editors to disclose deviation from accepted research design standards (e.g., redbook). Funding sources and profits associated with the communicating entity should be disclosed. (**9/10**)
c. Establish an organization which vets and provides journal citations for food-related claims (e.g., Politifact). (**9/10**)

GROUP THREE

EBO 1:

When providing information to the public, stakeholders should provide accurate, current, evidence-based information *[within their areas of expertise (**3/7**)]*. (**7/7**)

RWOs:

none

EBO 2:

Academia, government, and consortia of non-governmental organizations need to help communicate scientifically credible information to the public. In our current situation, research documents are not sufficiently communicated to the general consumers, and thus, we need new organizations focused on this communication. (**3/7**)

RWOs:

none

EBO 3:

Science-based communication strategies are unlikely to be effective for consumer choices of food. In the current chaotic information age, there is not an obvious winning strategy and we should try a variety of strategies. **(2/7)**

RWOs:

none

GROUP FOUR

EBO 1:

While all stakeholders are responsible for communicating accurate, evidence-based information and data, each stakeholder has a distinct role. Scientific integrity, transparency, and verification builds trust, which is essential for public acceptance. *[It is necessary to listen to opposing views and understand the other perspective to allow for collaboration **(6/12)**]*. All stakeholders have a responsibility to call out misinformation (e.g., education, regulatory processes). **(8/12)**

RWOs:

a. Define and understand the audience (e.g., consumers, retailers) using different vehicles of communication (e.g., packaging, advertising). Identify and seek to understand the various communities that are impacted by the claims being made. **(3/8)**
b. Take advantage of social media to educate the public. Define and understand the audience (e.g., consumers, retailers) using different vehicles of communication (e.g., packaging, advertising). **(3/8)**
c. Create a verifiable, public source that allows people to understand their products and processes. **(3/8)**
d. Adopt and enhance mechanisms to support stakeholders to enable them to fulfill their responsibilities. **(1/8)**

GROUP FIVE

EBO 2:

All stakeholders are responsible for accuracy, scientific integrity, transparency, and verification in their communication to the public. **(4/12)**

RWOs:

a. Define and understand the audience (e.g., consumers, retailers) using different vehicles of communication (e.g., packaging, advertising). Identify and seek to understand the various communities that are impacted by the claims that are made. **(2/4)**
b. Define and create a verifiable database of food products, their ingredients, and processes used to develop them. **(2/4)**

c. Adopt and enhance mechanisms to support stakeholders to enable them to fulfill their responsibilities. (**2/4**)

GROUP SIX

EBO 1:

There must be shared responsibilities on different aspects of communication: academics on science; private sector on products and processes; governmental agencies on regulatory systems and standards. Government regulators need to defend the rigor of the regulatory processes and decisions and promote responsible application of technology. A regulatory and communications system structure is needed to respond to the most informed and evidence-based stakeholders, not just the loudest and best funded. (**11/12**)

RWOs:

a. Require government, philanthropic/not-for-profit, industry, and academic organizations to accurately communicate and advocate for evidence-based regulatory decisions and to actively correct mis/disinformation in order to encourage public trust. (**11/12**)
b. Build informed evidence-based knowledge systems (e.g., universities) and dynamic fact-finding databases that include bio-vigilance and return-on-investment information. There needs to be more accountability for return-on-investment by government, universities, and industry. (**5/12**)

GROUP SEVEN

EBO 1:

All stakeholders, relative to their role and expertise, share a responsibility for ensuring that communication uses accurate and *[science-based evidence (**7/12**)] [evidence-based information (**5/12**)]*. (**12/12**)

RWOs:

a. Create a single, regulated claim that says a product meets FDA standards for food safety. Regulate all other claims in the same manner so that the USDA regulates other product claims (e.g., "The FDA affirmatively approves the safety of this product"). (**5/12**)
b. Ensure the creation of rigorous, formative research in order to decide what the message should be and which trusted sources of information need to be the messengers (e.g., healthcare professionals, teachers). There is a need for a multi-pronged, sustained approach to reach a broad sector of consumers through different mechanisms. (**3/12**)
c. Ensure that the government and broader society recognizes and supports the balanced reporting of science in the media. (**2/12**)

d. Include agricultural and food science in primary and secondary education. **(2/12)**

GROUP EIGHT

EBO 1:

In the arena of providing information, all entities bear responsibility for providing accurate, non-misleading, validated, and defensible claims regarding benefits. *[Companies bear the most responsibility, and consumer groups need to be incentivized **(4/11)***]. Government has a role in ensuring that the claims are truthful and scientifically validated (by reasonable scientific agreement). Other stakeholders (e.g., academic, consumer, NGOs) have a role in providing input. **(11/11)**

RWOs:

a. Require government to ensure claims (either through government research, the funding of external research, or through audit), review data, and instate other mechanisms when certain criteria are met, such as consumer challenges, whistleblowers, etc. Any recommendations need to consider first amendment rights for commercial speech. **(8/11)**

Question Three

Labeling of Innovative Foods and Ingredients

If necessary, how can labeling and naming of foods and ingredients derived from innovative technologies more clearly and accurately convey the products' safety and benefits to consumers?

GROUP ONE

EBO 1:

Current food labeling authorities and regulations are adequate for current and new innovative foods. Labeling should not stigmatize innovation. (**10/11**)

RWOs:

a. Support consumer understanding of novel technology by providing FDA-led guidance and education. (**10/10**)
b. Ensure the FDA continues to evaluate the need for regulatory changes and/or guidance as new technology emerges. (**10/10**)
c. Enforce existing rules regarding false and misleading claims that undermine the FDA's credibility and confuse consumers. (**9/10**)

EBO 2:

Food labeling should change compared to how it is currently executed. Labeling should not stigmatize innovation. Things that don't communicate safety should not be labeled. (**1/11**)

RWOs:

a. Make voluntary labeling and marketing claims/information accessible via a QR code, website, or other means, rather than on the label. (**1/1**)
b. Make people accountable via the FDA for false and misleading claims. (**1/1**)

GROUP TWO

EBO 1:

Labels need to be evidence-based, accurate, and need to adopt understandable language developed with consumer input. While labels need to move away from specificity, a search option denoting the development process should be encouraged as an industry standard for consumers who desire additional information. (**8/10**)

RWOs:

a. Include a website or QR code on product labels (e.g., "for more information about processes and social benefits..."). Labels other than nutrition facts need to be carefully considered for unintended consequences (e.g., creating fear and misperception). (**8/8**)

EBO 2:

Labels need to be evidence-based, accurate, and need to adopt understandable language developed with consumer input. Specificity should be driven by consumer research. (**2/10**)

RWOs:

a. Include a website or QR code on product labels "for more information about processes and social benefits." Use consumer research to define how social benefits should be communicated. (**2/2**)

GROUP THREE

EBO 1:

The current labeling structure works. This includes government-mandated information, such as the nutrition facts panel, as well as other benefit claims voluntarily communicated on the package or via web resources. The FDA approves health claims, and the marketplace and the legal system police non-health claims. However, as innovative foods and ingredients do not fit into classical nomenclature categories, uniform rules and standards are needed. (**4/7**)

RWOs

none

EBO 2:

The current labeling system works, with the exception of "non-XXX" product claims (e.g., non-GMO, non-animal, no bugs), which imply that other products are unsafe. (**2/7**)

RWOs:

none

EBO 3:

Regulator approval is needed for any labeling claims that have the potential to mislead consumers. As innovative foods and ingredients do not fit into classical nomenclature categories, uniform rules and standards are needed. (**1/7**)

RWOs:

none

GROUP FOUR

EBO 1:

It is necessary to communicate clearly through labeling of food composition, sources, and processes. (**9/12**)

RWOs:

a. Facilitate further discussion with the stakeholder community to determine

the best way to communicate attributes of innovative foods to consumers so as to create truthful and consistent language. (**7/9**)

b. Make certain components of labeling mandatory (e.g., ingredients). Define other parts of labeling that can be voluntary but must be truthful and consistent. (**7/9**)
c. Develop mandatory standardized language for labeling. (**2/9**)

EBO 2:

Food sources should be labeled if they act as a replacement. (**3/12**)

RWOs:

a. Voluntarily develop industry-wide labeling guidelines that are certified by regulatory/industry. (**3/3**)
b. Support regulations that enforce honesty and consistency in the labeling system to prevent misinformation/misleading information. (**3/3**)

GROUP FIVE

EBO 1:

Truthful, credible, and non-misleading food labels are necessary for understanding innovative foods. Labeling includes what is on the packaging as well as externally linked information (e.g., websites). This requires consistent nomenclature for voluntary language that is based on consumer understanding. Marketing needs to be used to clarify perceived safety issues and promoted benefits, and ingredient names should be clear and non-misleading. (**11/11**)

RWOs:

a. Update processes for regulating health claims made on labels. (**11/11**)
b. Support a consumer education campaign in order to improve ingredient/label understanding. (**10/11**)
c. Provide funding for the enforcement of labeling regulations. (**9/11**)
d. Simplify labels by regulators and industry. (**7/11**)
e. Revise current standards of identity. (**6/11**)
f. Involve the health and medical community in allergenicity labeling. (**5/11**)
g. Reform standards of identity (i.e., remove them). (**3/11**)
h. Simplify ingredient names used by regulators and industry. (**3/11**)

GROUP SIX

EBO 1:

In order for a food to be marketed in the first place, it must be safe. This is a requirement that is separate from labeling. Clear and accurate labeling policy has three elements: mandatory, voluntary, and prohibitory. Mandatory elements of

labeling policy include ingredients, risks, and nutrition. Voluntary elements of labeling policy include processes, substantiated health claims, traceability, and QR codes/websites. Prohibitory elements of labeling policy include false or misleading claims. **(12/12)**

RWOs:

a. Regulate labeling of products, not processes, and apply such regulations evenly across foods. **(12/12)**
b. Enforce applicable statutes against false or misleading claims in food labeling. **(12/12)**
c. Encourage modifier, voluntary labeling where needed, under the presumption of safety. Provide statements such as "non-animal whey" or "flora-based whey" that may be helpful to the consumer. **(7/12)**

GROUP SEVEN

EBO 1:

Using common terms/definitions for food ingredients and claims, mandatory labeling should be limited to safety, nutrition, *[and ingredient **(11/12)**]* information, not information about benefits. *[Similar products should have similar labels, regardless of whether they contain innovative foods and ingredients.* **(11/12)***]* Safety labeling must be backed by the appropriate regulatory agency and be consumer-friendly (i.e., short and "smart"). There may be voluntary industry agreement on harmonizing industry claims. **(12/12)**

RWOs:

a. Work towards achieving agreement within industry on the harmonization of terms used in voluntary product claims, and create an optional FDA safety rating for ingredients. (4/12)
b. Work towards achieving agreement within industry on the harmonization of terms used in voluntary product claims. (3/12)
c. Actively affirm that current labeling for non-innovative foods and ingredients is working. (3/12)
d. Create an optional FDA safety rating for ingredients. (2/12)

GROUP EIGHT

EBO 1:

Safety of the process and all products is required. Product/ingredient names need to be subjected to standardized naming conventions, and claims of benefits need to be truthful and non-misleading. **(11/11)**

RWOs:

a. Establish and partner with food segment platforms to develop naming

conventions pre-market *[and provide additional guidance clearly differentiating between mandatory labeling (i.e., allergens and public health) and voluntary labels for consumers (**4/11**)]*. **(11/11)**

b. Develop an FDA mechanism for either pre-market approval of labels of new products and ingredients, or plan ahead for naming conventions of new product categories as needed. **(10/11)**
c. Additional information needs to be accessible in extension of the information (e.g., website, QR code) on product labels. **(10/11)**
d. Establish partnerships between the FDA and food segment platforms to develop these conditions. **(1/11)**

Question 4

Harmonizing Food and Ingredient Regulations

What is the importance of harmonizing regulatory standards for innovative foods and ingredients among different governmental entities (i.e., states and countries)? What are realistic goals for establishing and/or harmonizing such standards?

GROUP ONE

EBO 1:

To enable interstate trade and deliver benefits to society, it is important and advantageous to harmonize science- and risk-based food regulations nationally. It is more challenging, yet still advantageous, to harmonize science- and risk-based regulations internationally. Mechanisms are needed for addressing asynchronous approvals and asymmetric systems globally. (**12/12**)

RWOs:

a. Encourage government-to-government engagement in varied fora (i.e., bilateral and multilateral). (**12/12**)
b. Support development of food safety frameworks within partner countries to facilitate global market participation. (**12/12**)
c. Identify, strategize, and implement capacity building resources among cooperative partners. Some of these regulations may hamper the ability for poorer markets to enter trade agreements. (**10/12**)
d. Facilitate stakeholder participation. (**9/12**)
e. Promote inclusion in trade agreements. (**6/12**)
f. Adopt low-level presence policy. (**6/12**)

GROUP TWO

EBO 1:

Harmonization of regulatory standards has various benefits, including simplified supply chain logistics, reduced costs, and avoiding consumer confusion with multitudes of terms. There are more disincentives to harmonization than incentives because of trade and international competition. *[Due to the changing nature of innovative products, there are more opportunities in certain sectors than in others. **(3/10)**]* (**9/10**)

RWOs:

a. Identify where there are more realistic goals while recognizing that harmonization with some countries may be more unrealistic in the short- or medium-term than with others (e.g., Latin America). Also, while there are standards for preemption of state law, domestic harmonization may present more realistic opportunities than international. (**9/10**)

b. Develop a complete and evidence-based information-sharing structure to pursue partnerships with the aim of harmonizing regulations for economic benefit. (**3/10**)

GROUP THREE

EBO 1:

[While harmonizing regulatory procedures would be beneficial, (**3/7**)*]* it is critical, and likely achievable, to harmonize safety and environmental data and analysis. Increasing reciprocity among nations for food and ingredient approval is important and would help innovation reach scale. (**7/7**)

RWOs:

none

GROUP FOUR

EBO 1:

It is necessary to have a single statutory authority for regulations of food and ingredients, harmonize national inter-agencies (e.g., USDA, FDA) to a national standard, and mutually recognize safety on a global scale, all while allowing for labeling flexibility. Regulations need to be modernized to reflect new science and innovation. (**11/12**) *[The USDA should be abolished, and food regulations should be transferred entirely to the FDA.* ***(1/11)****]*

RWOs:

a. Change U.S. law to establish a single statutory authority. (**9/11**)
b. Align Congressional oversight with USDA and FDA authority. There is a need to establish new appropriately funded and staffed regulatory authority to harmonize oversight. There is also a need for further conversation with stakeholders. (**8/11**)
c. Change U.S. law to abolish the USDA and transfer authority for food regulations to a well funded and staffed FDA. There is a need for further conversation with stakeholders. Pursue mutual recognition with other nation-states. (**1/11**)

EBO 2:

Mutually recognize safety on a global scale while allowing for labeling flexibility at state and national levels. (**1/12**)

RWOs:

a. Change the laws to establish a single, well-funded and well-staffed statutory authority for food oversight and safety based on further conversations with stakeholders. (**1/1**)

GROUP FIVE

EBO 1:

It is of high importance that we work towards global harmonization so that regulations are compatible. Harmonization can more quickly help increase market access for innovative products to realize important societal benefits (e.g., human health, environment, humanitarian goals). *[Improved harmonization could have a positive impact on consumer perception. **(5/12)**]* *[The process of harmonization must consider cultural differences. **(1/12)**]* **(12/12)**

RWOs:

a. Use bilateral, regional, and international forums among governments to begin the harmonization process (with roles for non-governmental bodies to participate). **(12/12)**
b. Create guiding principles and policies that multiple governments will adopt after being developed by CODEX, the WTO, IPPC, WHO, and the FAO. **(12/12)**
c. Develop a core set of principles to help initiate and drive the harmonization process among governments (e.g., government industry). **(12/12)**
d. Leverage the Sustainable Development Goals framework to create momentum between countries. **(12/12)**
e. Set realistic goals that acknowledge the real-world limitations and challenges of regulatory harmonization. **(12/12)**
f. Identify and create a consortium of champion countries for internationally harmonized regulations. **(10/12)**
g. Promote awareness and dissemination of harmonized regulations in order to build understanding and consumer trust. **(5/12)**

GROUP SIX

EBO 1:

Harmonizing regulatory standards with reasonable trading partners across different geographies would facilitate global trade, facilitate innovation, and reduce regulatory burden on governments and industry. However, cultural differences alongside state, federal, and national regulations minimize the potential for realistic harmonization. Common end points could promote a consistent approach to the scope of regulations for food innovation and global trade. State-to-state issues are more likely to be resolved within a country. **(12/12)**

RWOs:

a. Establish agreement among reasonable trading partners on the criteria that would be used to determine the scope of regulatory oversight process (e.g., agreeing on definitions and timelines). There should be mutual recognition

of other countries' decisions and standards. (**12/12**)

b. Support federal preemption regarding regulatory oversight. (**12/12**)
c. Adopt a common lexicon among U.S. agencies while seeking to engage other countries. Different definitions for different regulatory authorities creates confusion. (**12/12**)
d. Build a coalition and alliance around a common vision and investment goals (e.g., adoption of novel bioeconomy) to facilitate harmonizing standards, best practices, and international guidelines. (**11/12**)
e. Support innovative approaches and solutions to create an environment that is more likely to foster harmonization. Increase state subsidies and programs to embrace more innovative practices. These programs need to be widespread and proactive, rather than reactive. (**3/12**)

GROUP SEVEN

EBO 1:

A reasonable level of regulatory coherence and equivalency could serve as a first step towards harmonization for innovative foods and ingredients regulations. This provides market access, economic benefits for consumers and producers, fosters innovation, and ensures safe and affordable food to the consumer. (**10/11**)

RWOs:

a. Take a leadership role in the U.S., as a global agricultural leader, in continuing to establish regulatory coherence with key and potential trading partners. The U.S. needs to demonstrate leadership within international standard-setting bodies, primarily CODEX, to reinvigorate a movement towards harmonization. (**5/10**)
b. Prioritize the harmonization of unclear regulation or uneven standards within the U.S., given the extremely influential position of the U.S. (**3/10**)
c. Invest (by the U.S. government) in biosafety frameworks and food safety systems in low-income countries. (**2/10**)

EBO 2:

Governments play a critical role in ensuring the harmonization and equivalency of regulation of innovative foods and ingredients and must focus on it. (**1/11**)

RWOs:

a. Take a leadership role in the U.S., as a global agricultural leader, in continuing to establish regulatory coherence with key and potential trading partners. The U.S. needs to demonstrate leadership within international standard-setting bodies, primarily CODEX, to reinvigorate a movement towards harmonization. (**1/1**)

GROUP EIGHT

EBO 1:

Globalized standards are an ideal outcome. While it is not necessarily achievable, it is an outcome we should still work towards by starting to focus on priority targets. (**12/12**)

RWOs:

a. Have traders and trade associations define appropriate priority targets for harmonization. (**3/12**)
b. Begin with bilateral government-to-government discussions. (**3/12**)
c. Establish a common application process for safety across international organizations. (**2/12**)
d. Establish a global database from which global authorities can obtain knowledge as a precursor to harmonization. (**2/12**)
e. Encourage stakeholders and coalitions to engage politically, and encourage the government to commit to assessing political agendas. (**1/12**)

Question 5

Risk Management

What are the appropriate mechanisms and who are the stakeholders responsible for evaluating the safety of innovative foods and ingredients to minimize, manage, and respond to risk? What criteria are needed to balance risks versus benefits?

GROUP ONE

EBO 1:

[Allowing for exemptions ***(2/11)****]*, government regulatory decisions need to be informed by pre-market risk assessments, which should be based on problem formulation (including product and process), risk- and science-based evidence, *[necessary mitigation measures* ***(9/11)****]*, and need to have appropriate post-market authority to mitigate any harms that were not addressed. (**11/12**)

RWOs:

a. Create and share risk management guidance among governments, third party labs, companies, and public advocacy groups. (**9/11**)
b. Define criteria to balance risks versus benefits as hazard times exposure in demonstrated incidences. (**7/11**)
c. Perform life cycle assessments, conducted by regulatory bodies or third party labs. (**5/11**)

EBO 2:

Regulatory frameworks for product evaluation should be risk-based. (**1/12**)

RWOs:

none

GROUP TWO

EBO 1:

The primary responsibility to manage risk lies with developers/innovators and regulators while being supported by academics, advocacy groups, media, and consumers. The mechanisms used include, but are not limited to, pre- and post-market safety reviews and long-term data collection, regulatory review processes, academic research, investigative journalism, and consumer feedback. Risk-benefit evaluations should be dynamic and continuous, recognizing that there are multidimensional tradeoffs and priorities, starting with the assumption that human health is the highest. (**10/10**)

RWOs:

a. Reduce transaction costs for trust-engendering processes by incentivizing companies to engage in such processes through mechanisms, such as

underwriters offering discounts for those certified by federal or third party agencies. (**4/10**)

b. Provide legal protection to a product provider, manufacturer, or distributor for a specified amount of time following a competent authority's decision to remove the product from the market, so long as the product was approved by that authority in the first place. (**4/10**)
c. Provide consumer education via regulatory agencies for informed decision-making. (**1/10**)

GROUP THREE

EBO 1:

Safety should be re-evaluated in a broader sense to encompass health. *[A governmental authority with appropriate expertise needs to define, assess, and manage risks associated with innovative foods and ingredients. (**5/7**)] [There should be a new or improved mechanism to educate/communicate to consumers the health risks, or lack thereof, associated with the consumption, or levels of consumption, of innovative foods and ingredients. (**2/7**)]* The private sector that manufactures, markets, or sells food is also responsible for ensuring that their food is safe and managing potential risks. (**7/7**)

RWOs:

a. The current system is effective at this. (**2/7**)

GROUP FOUR

EBO 1:

Regulation should always go through regulatory authority - no self-certification. *[Ensure appropriate security to eliminate insider threat access to new technologies. (**2/9**)]* Ensure appropriate resources for FDA, as everything should be treated the same. (**9/12**)

RWOs:

a. Consolidate risk assessments to the FDA, and require new products to go through FDA oversight. (**9/9**)
b. Create a clear roadmap for FDA to use when assessing innovative foods and ingredients. Seek stakeholder consensus and Congressional appeal. (**9/9**)
c. Engage with appropriate stakeholders to assist in determining risk. (**2/9**)

EBO 2:

Revise/replace the GRAS process to ensure active oversight, as everything should be treated the same. (**1/12**)

RWOs:

a. Allocate resources to the FDA for risk assessments to be consolidated to them, and require new products to go through FDA oversight as coordinated with stakeholder consensus and Congressional appeal. (**1/1**)

EBO 3:

Ensure appropriate security to eliminate insider threat access to new technologies. (**1/12**)

RWOs:

a. Engage with appropriate stakeholders to assist in determining risk. (**1/1**)

EBO 4:

There should be no self-certification for GRAS because it violates U.S. law. (**1/12**)

RWOs:

a. Have FDA independently review GRAS, receive all notices of GRAS and their bases, and notify the public about GRAS notifications and their bases. (**1/1**)
b. Require manufacturers to maintain GRAS notifications and their bases, and the FDA to develop criteria for GRAS status for the FDCA. (**1/1**)
c. Mandate the FDA to correct legal deficiencies found by the court. (**1/1**)

GROUP FIVE

EBO 1:

Government authorities are responsible for developing a framework for the evaluation of product safety that could be assessed by product, ingredient, category, or self-determination, as appropriate. Transparency and predictability needs to be part of the government systems to minimize, manage, and respond to risk. Better awareness of innovative ingredients/foods in the market is needed. (**8/12**)

RWOs:

a. Streamline and adapt regulatory processes to encourage innovation. (**6/8**)
b. Develop a system, such as a federal registry of food ingredients, that includes the ingredient name, brief description, and company information. (**5/8**)
c. Establish a mechanism for reassessing safety on novel food ingredients. (**3/8**)
d. Create a system that informs healthcare and medical professionals of updates in innovative food ingredients. (**1/8**)

EBO 2:

Government authorities are responsible for developing a safety framework and for evaluating the safety of innovative foods. Transparency and predictability must be

part of the government systems to minimize, manage, and respond to risk. *[Better awareness of innovative ingredients/foods in the market is needed.* ***(1/4)****]* **(4/12)**

RWOs:

a. Establish a mechanism for re-assessing the safety of food ingredients. **(3/4)**
b. Develop a system such as a federal registry of food ingredients that includes the ingredient name, brief description, and company information. **(2/4)**
c. Create a system that informs healthcare and medical professionals of updates in innovative food ingredients. **(2/4)**
d. Streamline and adapt regulatory processes to encourage innovation. **(1/4)**

GROUP SIX

EBO 1:

Risk management needs to be evaluated in the context of accelerating innovation. Innovation should be the focus of policy and regulation at least as much as risk. The appropriate stakeholders are the government agencies currently tasked with this (e.g., FDA, EPA, USDA) and companies. The regulatory agencies have adequate authority to ensure the safety of innovative foods and ingredients. The Coordinated Framework should be modernized in order to harmonize risk management across agencies. Developers of innovative ingredients need to also be incentivized and supported to seek pre-submission guidance from regulatory agencies. **(11/12)**

RWOs:

a. Increase resources to accelerate regulatory reviews. Health and Human Services and the Centers for Disease Control and Prevention might be worth engaging. **(4/12)**
b. Monitor chronic and long-term health effects across the food supply. Once in the market, innovative foods should be subject to the same requirements as other foods. **(4/12)**
c. Increase proactive efforts for industry to address allergenicity and toxicology prior to launching new ingredients. **(3/12)**

GROUP SEVEN

EBO 1:

The current paradigm for risk assessment works. **(7/11)**

RWOs:

a. Establish expert advisory panels to advise regulatory bodies at regular intervals in improving risk management and oversight based on current science. **(4/7)**
b. Improve and coordinate risk communication within specialized agencies, NGOs, and private industry. **(2/7)**

c. Assess and declare safety of innovative foods and ingredients via the U.S. government to build consumer confidence. (**1/7**)

EBO 2:

The current paradigm does not work in terms of risk management. Mandatory risk assessment would improve risk outcomes, risk communication, and consumer confidence. There is a role for the U.S. government in assessing and declaring the safety of innovative foods and ingredients to build consumer confidence. (**4/11**)

RWOs:

a. Give authority to the FDA for mandatory notifications of innovative foods and ingredients and, when appropriate, implement a graduated risk assessment that does not impede innovation. (**2/4**)
b. Consult with risk experts to determine how we evaluate risk and benefit ratios. (**2/4**)

GROUP EIGHT

EBO 1:

Developers of new products *[and food technologies (e.g., food sterilization)* ***(9/11)****]* are ultimately responsible for evaluating and ensuring food safety and minimizing risk to the *de minimus* levels. Government agencies confirm these evaluations while market and legal forces are an additional mechanism to ensure safety. (**11/11**)

RWOs:

a. Focus safety evaluations only on human risk in order to limit the scope of what we are dealing with in the context of the conference's discussion. (**9/11**)
b. Focus safety evaluations on human risk in order to limit the scope of what we are dealing with in this effort, but there must be environmental evaluation, as well. (**2/11**)

Question 6

Transparency of Data Sharing for Proprietary Knowledge

What is the appropriate degree of confidentiality for the exchange of proprietary data and information among private sector entities, government regulators, and public advocacy groups? How can proprietary information be used to shape public views of the safety and benefits of innovative foods and ingredients?

GROUP ONE

EBO 1:

The government regulatory authorities should maintain maximum confidentiality for proprietary data, and no proprietary information sharing should occur. (**11/11**)

RWOs:

a. Pursue transparency by sharing information that is not considered proprietary or confidential (e.g., safety information, environmental impact, sustainability, humanitarian, labor value) to promote trust *[and knowledge **(6/11)**]*. (**11/11**)
b. Discourage sharing of proprietary information due to risk of espionage. (**6/11**)
c. Encourage owners of the proprietary information to share information (e.g., process, safety information, environmental impact, sustainability, humanitarian, labor value) with the public and advocacy groups to promote transparency and trust. (**5/11**)

GROUP TWO

EBO 1:

Greater transparency builds greater trust and consumer confidence that may contribute to support for the innovative food sector as a whole. Entities, companies, and organizations should be transparent except when it would compromise competitive advantage by disclosing proprietary information and/or private company-owned data. (**10/10**)

RWOs:

a. Encourage voluntary self-disclosure of data in the public sphere and develop an industry standard. If there is a desire for anonymity, create a mechanism whereby companies can submit data to authorities through third parties. (**10/10**)

GROUP THREE

EBO 1:

For better consumer protection and trust, some of the health and safety information

(i.e., data) should be made public. There is a need for an alternative process to protect the intellectual property of foods, especially innovative foods and ingredients, because it cannot and should not be protected in the current GRAS system. (**5/7**)

RWOs:

none

EBO 2:

For better consumer protection and trust, speed of resolution of regulatory approval is at a value in terms of sharing information. The disclosure of exact manufacturing processes to show safety is not necessary. There are enough trade secrets that no one can copy the entire process from GRAS public information. It is important to keep the GRAS self-affirmation step and to not wait to go to market, while mandating all parties undergo 180-day process. (**1/7**)

RWOs:

none

EBO 3:

FDA should annually publish a 25-page summary innovation report based on company filings to encourage public trust and discussion (e.g., looking at GRAS, new plants, additives). There is no summary of what is currently happening in innovative foods and how are they coming to market. (**1/7**)

RWOs:

none

GROUP FOUR

EBO 1:

Companies must share all information to make necessary safety determinations (e.g., environmental, human, animal) with FDA and the public. Other information companies wish to share with the private sector is determined by the company. Companies should also consider promoting the spirit of public acceptance. (**12/12**)

RWOs:

a. Publish in peer-reviewed literature to allow discussion amongst public, private, and scientific communities where possible. Explore possibilities to create a public repository for information. Create forms through which companies can submit the information, which FDA will review. (**12/12**)
b. Release information to the government for national security concerns. (**12/12**)

GROUP FIVE

EBO 1:

More transparency may build more consumer trust in innovative food and ingredients. Relevant proprietary data should be fully disclosed to relevant regulatory bodies to ensure safety. Companies should be encouraged to define proprietary information as narrowly as possible in order to disclose more *[safety and benefit information (7/12)]* information to the public. This will promote transparency and avoid the perception that businesses are hiding information. (**12/12**)

RWOs:

a. Maintain confidentiality regulations that are currently in place. (**12/12**)
b. Foster better communication between stakeholders on the need to balance business information and public disclosure. (**12/12**)

GROUP SIX

No comment due to absence of time

GROUP SEVEN

EBO 1:

A sufficient level of transparency between private sector actors in the food system is needed. Full transparency between the private sector and the United States government is expected with legally binding confidentiality between the parties, which may include international partners. (**6/9**)

RWOs:

a. Make publicly disclosed information available in real-time in multiple forms of media. Industry needs to develop unified standards for public disclosure of information to support popular confidence in the United States government's regulatory process, the companies themselves, and consumer acceptance of innovative foods and ingredients. (**4/6**)
b. Provide enough safety data and/or summaries prior to commercialization to enable food companies and their suppliers to have an assurance of safety for the product. (**5/6**)
c. Allow for sufficient information at commercialization to enable the global food system to provide customer choice and ensure compliance with national and key market requirements. (**5/6**)
d. Seek ways to allow NGOs access to appropriate amounts of information to keep them inside the tent, as opposed to throwing bricks outside of it. (**1/6**)

EBO 2:

Continued transparency between the private sector and the United States government needs to ensure legally binding confidentiality between the parties, which may include international partners. (**3/9**)

RWOs:

a. Seek ways to allow NGOs access to appropriate amounts of information to keep them inside the tent, as opposed to throwing bricks outside of it. (**3/3**)

GROUP EIGHT

EBO 1:

Companies cannot hide behind confidentiality for safety evaluations when sharing information with regulatory authorities and have a responsibility to make data as public as possible. (**8/11**)

RWOs:

a. Look towards previous data transparency commitments as models for data sharing/transparency in food technologies. (**8/8**)

EBO 2:

Mechanisms already exist that allow private sector and government to share sets of proprietary data. Companies cannot hide behind confidentiality for safety evaluations when sharing information with regulatory authorities. (**2/11**)

RWOs:

a. Look towards previous data transparency commitments as models for data sharing/transparency in food technologies. (**1/2**)
b. No action required. (**1/2**)

EBO 3:

It is the company's responsibility to be as transparent as possible without compromising intellectual property. Mechanisms already exist that allow private sector and government to share sets of proprietary data. (**1/11**)

RWOs:

a. Look towards previous data transparency commitments as models for data sharing/transparency in food technologies. (**1/1**)

Participant Landscape

Total participants: 78 entities and 98 representatives

(❖ indicates presenters)

Companies Focused on Innovation

3F BIO
❖ Algae Biomass Organization
❖ Amai Proteins
Benson Hill Biosystems
Beyond Meat
❖ Calyxt, Inc. (2)
Chobani**
MicroByre
Motif Ingredients
MycoTechnology
❖ Pairwise Plants (2)
❖ Parabel, Inc. (2)
Pebble Labs
❖ Perfect Day (2)
PlantBased Solutions
Stem Foods
Unovis/New Crop Capital
Spruce Capital Partners
The Herbivorous Butcher
ZBiotics Company
20 entities/ 24 representatives

Multinational Companies

ADM
American Seed Trade Association (2)
BASF
Bayer Crop Science (4)
Biotechnology Innovation Organization (2)
Cargill (2)
ConAgra Brands, Inc.
Corteva Agriscience
DSM Nutritional Products**
General Mills, Inc. (2)

Kerry Group
Mars. Inc.
Mondelez International
PepsiCo
The Hershey Co. (2)
Unilever
Young Living Essential Oils
17 entities/ 25 representatives

Public-Advocacy and Not-For-Profit Organizations
❖ Center for Science in the Public Interest
Center for Food Safety
❖ Environmental Defense Fund
Farm Foundation
Genetic Literacy Project
ILSI Research Foundation**
Institute of Food Technologists
The Algae Foundation
The Aspen Institute
The Chicago Council on Global Affairs
The Good Food Institute
The National Academies
12 entities/ 12 representatives

Government Entities
Federal Bureau of Investigation Department of Justice
Federal Bureau of Investigation Weapons of Mass Destruction (2)
U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition (4)
U.S. Food and Drug Administration Center for Veterinary Medicine
National Institutes of Health National Center for Complementary and Integrative Health
U.S. Department of State
U.S. Department of Agriculture Food Safety and Inspection Service
U.S. Department of Agriculture Foreign Agricultural Service
8 entities/ 12 representatives

European Groups
European Commission**
European Foods Safety Authority
European Seed Association
National Research Council of Italy
4 entities/ 4 representatives

Subject-Matter Experts
Expertise: Science (S), Legal (L), Communication (C), National Security (NS), Ethics (E), Economics (EC), and Policy (P)
California Center for Algae Biotechnology, University of California, San Diego (S)
Eckerd College (S)
German Marshall Fund of the U.S. (NS, EC)
Great Falls Development Authority (EC)
Harvard University Law School (2) (1)** (L, P)
Hills & Co (L, P, NS)
Institute for Food Safety & Health (2) (S, C)
Kansas State University (S)
Michigan State University (E)
North Carolina State University (EC)
Pennsylvania State University (2) (S,C)
Potomac Ridge Consulting (EC, NS)
Sidley Austin LLP (L)
Stanford University (P, NS)
U.S. Army War College (NS)
University of Florida (S)
Virginia Polytechnic Institute (S, NS)
17 entities, 21 representatives

**Confirmed to participate but did not attend

Innovation Foods and Ingredients (IFI)

Hilton Minneapolis/St. Paul Airport
Minneapolis, Minnesota
June 23–27, 2019

Conference Agenda

DAY ONE

Sunday, June 23

12:00 – 17:30 **Registration**
Registration Desk: Minnesota Valley Ballroom

13:00 – 14:30 **Panel Discussion**
"Recent Decisions on GMO and Gene-Edited Food Regulation"
Mallard Point Room
Introduction: **Dr. George Atkinson,**
Founder and Executive Director, ISGP
Moderator: **Daniela Baeza Breinbauer**, Senior Fellow, ISGP

Panelists:
Dr. Laura White, USDA Foreign Agricultural Service
Dr. Matthew Ramón, European Food Safety Authority
Dr. Bernice Slutsky, American Seed Trade Association
Dr. Petra Jorasch, European Seed Association

16:00 – 16:30 **Conference Meeting: Presenters**
Mallard Point Room
Moderator: **Dr. George Atkinson**

16:30 – 17:30 **Conference Meeting: All Participants**
Minnesota Valley Ballroom II-IV
Moderator: **Dr. George Atkinson**

17:45 – 18:45 ***Reception*** *(No Host)*
Foyer, Minnesota Valley Ballroom I

19:00 – 20:00 ***Dinner*** (Please refer to dinner place cards for seating)
Minnesota Valley Ballroom I

20:00 – 20:30 **Brief Evening Remarks and Questions**
Introduction: **Dr. George Atkinson**
Speaker: **Mr. Peter Hutt**, Senior Counsel in the Washington, D.C. law firm of Covington & Burling LLP, specializing in Food and Drug Law**
"The Essential Role of Food Regulation Throughout History"

DAY TWO

Monday, June 24

06:30 – 08:30 ***Breakfast*** *- on your own*

08:35 – 08:45 Minnesota Valley Ballroom II-IV
Please be seated behind your placard

08:45 – 09:00 **Introductory Remarks**
Dr. George Atkinson, Founder and Executive Director, ISGP

09:00 – 10:30 **Debate 1**
"Gene Editing Enters the Food Supply"
Dr. Daniel Voytas, Chief Science Officer, Calyxt, Inc., Minneapolis, Minnesota

10:30 – 11:00 ***Break***
Foyer, Minnesota Valley Ballroom

10:50 – 11:00 Minnesota Valley Ballroom II-IV
Please be seated behind your placard

11:00 – 12:30 **Debate 2**
"Using CRISPR Technology to Improve Health by Increasing the Consumption of Fresh Fruits and Vegetables"
Dr. Haven Baker, Chief Business Officer and Co-Founder, Pairwise, Research Triangle Park, North Carolina

12:30 – 14:00 ***Lunch***
Minnesota Valley Ballroom I

13:50 – 14:00 Minnesota Valley Ballroom II-IV
Please be seated behind your placard

14:00 – 15:30 **Debate 3**
"Aquatic Plants for Sustainable Food and Protein Production: Implications for Global Food Security"
Ms. Cecilia Wittbjer, Vice President of Marketing, Parabel Inc., Vero Beach, Florida

15:30 – 16:00 ***Break***
Foyer, Minnesota Valley Ballroom

15:50 – 16:00 Minnesota Valley Ballroom II-IV
Please be seated behind your placard

16:00 – 17:30 **Debate 4**
"Expanding Production and Consumption of Algae in Our Food System"
Ms. Jill Kauffman Johnson, Vice-Chair, Algae Biomass Organization, Preston, Minnesota

17:45 – 19:00 ***Reception*** *(No Host)*
Foyer, Minnesota Valley Ballroom

19:00 – 20:00 ***Dinner*** (Please refer to dinner place card for seating)
Minnesota Valley Ballroom I

DAY THREE
Tuesday, June 25

06:30 – 08:45 ***Breakfast*** *- on your own*

08:50 – 09:00 Minnesota Valley Ballroom II-IV
Please be seated behind your placard

09:00 – 10:30 **Debate 5**
"Curing the Language of the Food 2.0 Era"
Dr. Ilan Samish, CEO and Founder, Amai Proteins, Rehovot, Israel

10:30 – 11:00 ***Break***
Foyer, Minnesota Valley Ballroom I

11:00 – 12:30	**Debate 6** **"Toward a Diversified Protein Future"** **Mr. Ryan Pandya**, Co-Founder and CEO, Perfect Day, Berkeley, California
12:30 – 14:00	***Lunch*** Minnesota Valley Ballroom I
13:50 – 14:00	Minnesota Valley Ballroom II-IV *Please be seated behind your placard*
14:00 – 15:30	**Debate 7** **"Safety, Benefits, and Transparency Are Critical to Consumer Acceptance of Innovative Foods"** **Mr. Greg Jaffe,** Director, Project on Biotechnology, The Center for Science in the Public Interest, Washington, D.C.
15:30 – 16:00	***Break*** Minnesota Valley Ballroom II-IV
15:50 – 16:00	Minnesota Valley Ballroom II-IV *Please be seated behind your placard*
16:00 – 17:30	**Debate 8** **"Licensing Innovative Food Additives and Ingredients by FDA"** **Mr. Thomas Neltner,** Chemicals Policy Director, Environmental Defense Fund, Washington, D.C.
17:45 – 19:00	***Reception*** *(No Host)* Foyer, Minnesota Valley Ballroom I
19:00 – 20:00	***Dinner*** (Please refer to dinner place card for seating) Minnesota Valley Ballroom I
20:00 – 20:30	**Brief Evening Remarks and Questions** Introduction: **Dr. George Atkinson,** Founder and Executive Director, ISGP

Speaker: **Dr. Maria Velissariou**, Chief Science and Technology Officer, Institute of Food Technologists
"Connecting Food, Human Health, and the Environment: An Option or a Necessity?"

DAY FOUR
Wednesday, June 26

06:30 – 08:30 ***Breakfast*** *- on your own*

08:30 – 08:45 Proceed to assigned Caucus rooms with Moderators & Scribes

8:50 – 9:00 *Be seated in your caucus room behind your placard (remember to bring your placard)*

09:00 – 12:15 **Moderated Small-Group Caucus Session 1**

12:15 – 13:30 ***Lunch***
Minnesota Valley Ballroom I

13:20 – 13:30 *Be seated in your caucus room behind your placard*

13:30 – 16:30 **Moderated Small-Group Caucus Session 2**

16:30 - 18:00 ***Break*** *- Walk through Minnesota Valley National Wildlife Refuge*
(Please refer to area map and ISGP guides)

18:00 – 19:00 ***Reception*** *(No Host)*
Minnesota Valley Ballroom Foyer

19:00 – 20:00 ***Dinner*** (Please refer to dinner place card for seating)
Minnesota Valley Ballroom I

20:00 – 20:30 **Brief Evening Remarks and Questions**
Introduction: **Dr. George Atkinson,** Founder and Executive Director, ISGP
Speaker: **Ms. Pam Strifler**, Vice President, Global Stakeholder Engagement and Sustainability, Bayer Crop Science
"The Time for Discovery is Now: Harnessing the Power of Innovation, Collaboration, and Collective Voice"

DAY FIVE

Thursday, June 27

06:30 – 07:45 ***Breakfast*** *- on your own*

07:50 – 08:00 Minnesota Valley Ballroom II-IV
Please be seated in General Session Room

08:00 – 11:30 Please complete and return ISGP Conference Evaluation Form

08:00 – 11:20 **Plenary Caucus Session**
Minnesota Valley Ballroom III-IV
Moderator: **Dr. George Atkinson** and **ISGP staff**

11:20 – 11:30 **Closing Remarks**
Dr. George Atkinson, Founder and Executive Director, ISGP

11:30 ***Adjournment***

**Due to a family illness, Mr. Hutt was unable to attend.

Gene Editing Enters the Food Supply**

Daniel F. Voytas, Ph.D., Professor, Genetics, Development and Cell Biology,
and Director, Center for Precision Plant Genomics,
University of Minnesota, St. Paul, Minnesota
Chief Science Officer, Calyxt, Inc., Roseville, Minnesota

Summary

Plant agriculture is poised at a technological inflection point. Recent advances in gene editing make it possible to precisely alter DNA sequences in living cells, providing unprecedented control over a plant's genetic material. Crops derived through gene editing are already beginning to enter the food supply. Because gene editing technologies are advancing at such a rapid pace, traditional crops will soon serve as genetic chassis that are precisely engineered to produce an array of novel food products—fruit with enhanced nutritional value, flour with increased fiber, protein with a balanced amino acid composition, to name a few. Such crops will also be designed to withstand the many stresses created by a changing environment and to grow with fewer inputs, such as water and fertilizer. Appropriate regulatory structures need to be put in place to ensure that the food products developed through gene editing are safe for use as food and feed and for the environment. Public perception will also impact the extent to which gene editing enters the food supply and whether this powerful technology will contribute toward food security.

Current Realities

Over the past 100 years, technological advances have resulted in remarkable increases in agricultural productivity. Such advances include the production of hybrid plants and the use of the genes of the Green Revolution (i.e., genes that alter plant stature and thereby increase productivity). More recently, transgenesis, or the introduction of foreign DNA into plant genomes, has been a focus of crop improvement efforts. In the U.S., more than 90% of cultivated soybeans and corn contain one or more transgenes that provide traits such as resistance to insects or herbicides.

Transgenesis, however, is limited since it is fundamentally a process of gene addition and does not harness a plant's native genetic repertoire to produce traits of value. Furthermore, public concerns over the cultivation of crops with foreign DNA, particularly those generated by the introduction of genes from distantly related organisms, have impeded their widespread use. The regulatory frameworks

created to protect the environment and to address public safety concerns have added considerably to the cost and timelines for transgenic crop production. These costs have limited the use of transgenesis to a few high-profit crops (e.g., cotton, soybean, corn) and to traits that benefit the farmer (e.g., herbicide tolerance, pest resistance).

The advent of gene editing allows DNA in living cells to be precisely altered. Although gene editing can be used to add transgenes to specific locations in genomes, thereby offering an improvement over existing methods of transgenesis, modifying a plant's native genetic information offers many additional opportunities to produce traits of value. Traditionally, new traits are introduced into cultivated varieties through breeding regimes that take advantage of natural genetic variation. Alternatively, new genetic variation is produced through mutagenesis, which includes the use of chemical mutagens as well as ionizing radiation. With gene editing, it is possible to first determine the DNA sequence modifications that are desired in the cultivated variety and then introduce this genetic variation precisely and rapidly. The ability to control the type of genetic variation introduced into crop plants is a transformative advance in breeding technologies and is rapidly being adopted by the agricultural biotechnology industry.

This year, the first gene-edited crop entered the food supply. Calyxt, Inc., a company that uses gene editing to produce healthier food ingredients, developed a soybean variety that produces oil with an improved fatty acid profile. Specifically, oil from this soybean variety is higher in monounsaturated fats (i.e., oleic acid) and lower in polyunsaturated fats when compared to conventional soybean oil. The editing approach involved inactivating two genes in the fatty acid biosynthetic pathway by removing a few nucleotides in the genes' coding sequences. These genes normally produce polyunsaturated fats, and consequently, oil from this soybean variety is higher in monounsaturated fats and therefore healthier for consumers (monounsaturated fats have been linked to reducing low-density lipoproteins, cholesterol, and triglycerides and raising HDL cholesterol). Further, the high levels of monounsaturated fats increase the oil's shelf-life and fry-life. Because the oil does not need to be hydrogenated to lower the polyunsaturated fat content, the oil also has no trans fatty acids (zero grams trans fat per serving).

The USDA concluded that the soybean variety is not a regulated article under the Plant Protection Act. The soybean variety was also evaluated by the Food and Drug Administration (FDA) through the voluntary consultation process, and it meets all applicable FDA requirements. In February 2019, Calyxt sold its first improved soybean oil to the foodservice industry for frying and salad dressing as well as sauce applications. This sale marks the first time a gene-edited ingredient has entered the food supply.

Scientifically Credible Approaches and Challenges

Gene inactivation, as carried out by Calyxt to produce its high oleic soybean variety, is one of the easiest types of gene edits to execute. In this particular case, loss of gene function disrupted a metabolic pathway (i.e., fatty acid biosynthesis) and changed the relative levels of fatty acids produced in the soybean seed. Other editing approaches allow for a greater diversity of changes to the genetic code (e.g., specific nucleotide substitutions can be introduced that alter protein function or change levels of gene expression). This control over genetic circuitry makes it possible to dial up or down the activity of certain genes and more precisely control metabolic pathways to produce specific types and quantities of carbohydrates, proteins, or fatty acids. In the technology's current form, typically one to a few genes are edited in a genome to produce one or a few traits at a time. Rapid advances in the technology, however, will soon make it possible to introduce hundreds to thousands of edits simultaneously, allowing a redesign of the genetic code on a much larger scale and the introduction of many traits simultaneously.

While the ability to produce designer organisms may seem revolutionary, gene editing is only an extension of what has occurred in plant genomes for centuries. For example, compare modern maize to its wild ancestor, teosinte. The latter is a tall, highly branched grass that produces a handful of seeds, in stark contrast to its modern descendent, which produces a single stalk with ears full of carbohydrate-rich grains. The genetic blueprint of modern maize began as teosinte and was edited by humans over centuries through selection. Every year, seed for the next crop was selected from the plants that produced the most grain. Underlying these subtle increases in productivity were DNA sequence changes that occurred naturally. Year after year, by selecting increasingly more productive plants, the teosinte genome was rewritten, resulting in a new species, *Zea mays*. In the past century, new tools have made it possible to induce genetic variation through mutagenesis and more recently, through transgenesis. The advent of gene editing makes it feasible to decide in advance the exact types of genetic changes that one wants to produce in a crop plant.

The advent of gene editing also requires a new lexicon to describe applications of biotechnology to food. What does the term "genetically modified organism (GMO)" mean? Many consider a GMO to be a plant that has foreign DNA added to its genome, typically DNA from a distantly related, non-sexually compatible species. But is not *Zea mays* a GMO when compared to its ancestor, teosinte? Are plants that have been mutagenized using chemicals or ionizing radiation not GMOs? Gene editing can already produce diverse DNA sequence alterations, from DNA deletions to insertions to base substitutions. Currently, an easy path is to place new plant varieties into one of two classes: GMO or non-GMO. This approach, however, is

an unfair depiction of the matter since it does not provide the consumer with the desired clarity about how the food they purchase was developed. It also invokes a sense of fear that might harm the overall use of a truly transformative technology—a technology that could help produce healthier, more abundant food to meet the demands of a burgeoning global population and a rapidly changing climate.

Evidence-Based Options and Real-World Opportunities

- Foster collaboration between the agriculture and food industries to demonstrate that biotechnology can benefit consumers and improve sustainability. Initially, biotech products were focused on benefiting the farmer and therefore the consumer found little value in traits such as herbicide tolerance or pest and pathogen resistance. The initial gene-edited products need to focus on traits of value to the consumer (e.g., healthier food with increased nutrients, fibers, proteins and reduced saturated fats or allergens). If consumers see a benefit, they are less likely to dismiss the underlying technology outright.
- The USDA, FDA, and EPA need to create and enforce a vocabulary that clearly defines how biotechnology is applied to food. While the public wants to know how their food is produced, the scientific complexity and nuances of how biotechnology is used in food makes it difficult to provide clear, understandable explanations for the consumer (i.e., terms such as GMO, organic, or bioengineered).
- Develop the evidence-based regulatory frameworks the USDA, FDA, and EPA need to evaluate the products developed using new technologies and that are less concerned with the technology itself (i.e., the process used in food production need not trigger regulation).
- Governmental regulatory agencies need to exercise their regulatory authority to avoid confusion concerning the role of non-governmental groups (e.g., the Non-GMO Project) that attempt to usurp the role and credibility of regulators.
- Harmonize international regulatory frameworks to avoid confusion in global agricultural markets, especially with respect to the distinctions between GMO and gene-edited foods and ingredients.

** ***A position paper prepared for presentation at the conference on Innovative Foods and Ingredients convened by the Institute on Science for Global Policy (ISGP), with support from the U.S. Food and Drug Administration, on June 23-27, 2019, in Minneapolis, Minnesota, United States.***

Debate Summary

This not-for-attribution Debate Summary was prepared by the ISGP staff from the audio recording, and its transcription, of the debate of the position paper prepared by Dr. Voytas (see above). Dr. Voytas initiated the debate with a 5-minute statement of his views and then actively engaged the conference participants, including other authors, throughout the remainder of the 90-minute period. This Debate Summary represents the ISGP's best effort to accurately capture the comments offered and questions posed by all participants, as well as those responses made by Dr. Voytas and other participants. Given the not-for-attribution format of the debate, the views comprising this summary do not necessarily represent the views of Dr. Voytas, as evidenced by his position paper. Rather, it is, and should be read as, an overview of the areas of agreement and disagreement that emerged from all those participating in the debate.

Current Realities

It was generally recognized that genetic approaches to crop improvement are rapidly advancing. Specifically, the development of gene editing techniques (i.e., CRISPR, TALENs) was widely credited with dramatic increases in the power, speed, and precision of plant breeding. It was repeatedly mentioned that, while past generations of genetically engineered food products focused on farmer-oriented traits (e.g., herbicide resistance, pest control, yield), a new generation of gene-edited products is shifting focus from farmer to consumer benefits. In addition to technological advancement and a changing approach to trait development, it was emphasized that a more diverse set of developers is emerging, notably from the academic, public sector, and non-profit communities, as compared with the first generation of genetically modified organism (GMO) production.

While breeding technologies continue to rapidly advance, it was generally agreed that an existing gap in public understanding may continue to grow. As was the case for transgenic approaches, many expressed the opinion that the success of gene editing will be significantly impacted by the degree to which public trust and acceptance is achieved. It was repeatedly mentioned that consumers do not understand the differences between diverse technologies, nor the labels currently used to describe them (e.g., non-GMO, organic). There was doubt that (i) there is significant public interest in understanding the processes underlying gene editing approaches and (ii) the public is appropriately appreciative of the importance of these differences. By contrast, there was concern related to underestimating the

degree of interest consumers have in their food, as well as their ability to follow such explanations.

Despite some public concerns specifically related to the process by which genetic engineering occurs and the direct consequences of its use, it was widely acknowledged that consumer trust depends more on who delivers the message rather than the message itself. Specifically, it was suggested that large, private companies are less likely to gain consumer trust, and small companies, the public advocacy sector, and academic institutions were noted as having greater potential in gaining consumer acceptance.

When considering public communication strategies, many saw an opportunity to engage trusted members in society (e.g., farmers, chefs, health influencers, plant-based food proponents, urban agriculture/allergen communities). It was also noted that, while these groups have not historically seen value in past generations of genetically engineered foods, there is potential alignment with a renewed focus on consumer-oriented traits (e.g., health, flavor, texture). However, it was recognized that not all advertised benefits of the previous generation of genetically engineered crops were realized. Given the impact this disconnect had on public trust regarding the benefits of genetic engineering, it was suggested that fidelity to promoted benefits will be important for gaining public trust in gene editing. While discussing advertised benefits to consumers, it was noted that there is no standard for proving such claims and, currently, little infrastructure exists to ensure that information is accurately communicated at the point of purchase, particularly as this information relates to environmental benefits.

In addition to maintaining accountability with regard to the benefits of gene editing, transparency was widely acknowledged as another key element in gaining public trust. To most, it was unclear as to what degree and in what form transparency would be most effective in responding to consumer demand for information about food. It was noted that the first developers to enter the food supply will play an important role in setting the standard for both communication and transparency, ultimately influencing how gene-edited products are received by the public.

While it was suggested that gene editing techniques have the potential to provide solutions for a multitude of global challenges, concern was expressed that technology is not always developed and applied in direct connection with societal needs (e.g., human health, biodiversity). There was also some concern that with any new and powerful technology, alternative and potentially more effective approaches to addressing global challenges are often undervalued and/or ignored (e.g., encouraging birth control in developing countries, reducing resource demands for food and feed).

Regarding risk, it was suggested that there is a need to invest in further research on secondary, unintended consequences of gene editing. There was also broad concern related to the traceability of gene-edited foods and the potential contamination of supply chains, particularly as it relates to commodity crops. These concerns were recognized as important from a consumer perspective and as especially significant for global trade.

It was generally agreed that concerns related to traceability are particularly important considering inconsistencies in the current global regulatory environment. For many, harmonization and clear regulatory pathways are high priorities in the context of the rapidly advancing pace of gene editing technologies and the diverse array of applications (i.e., both emerging and anticipated). It was noted that regulatory asymmetry has already begun to impact (i) where gene editing technologies are developed and (ii) the markets from which food developed via these technologies are excluded (e.g., Europe). There was also concern expressed that a fractured global regulatory environment could present global security issues by undermining the goal of interlinking economies established after World War II. However, it was generally agreed that global harmonization, while desirable, is unlikely to occur, given national governments' resistance to change.

Scientifically Credible Approaches and Challenges

There was broad agreement regarding the growing interest by consumers in understanding more about their food choices. However, significant disagreement arose regarding the type and amount of information consumers demand, as well as the extent to which the public is capable of comprehending the nuances of various approaches.

A pervading theme within the discussion on informing an increasingly concerned public focused on process- versus product-based communication. It was repeatedly emphasized that public demand for process-based communication is significant, as is the consumer's "right to know" from the standpoints of choice and safety (e.g., allergenicity). It was noted that, although many applications of gene editing will not fall under the purview of the National Bioengineered Food Disclosure Standard, it appears that the Non-GMO Project will not include gene editing under its label. Thus, the opinion was expressed that without voluntary positive labeling, consumers can only rely on negative (i.e., exclusionary) labeling to make decisions regarding their food choices. Along similar lines, there were several suggestions focused on informing consumers and building trust by voluntarily and proactively communicating on the process used to create gene-edited crops. Contrary opinions held that developing products with direct, tangible benefits to

the consumer and a focus on advertising those benefits needs to be prioritized over process-based communication and will have a greater impact on public perception and acceptance.

Another area of contention regarding public communication centered on whether proponents need to try to distinguish gene editing from transgenics. While some support was expressed for re-branding gene editing as a distinct approach, there also was concern that denying any similarities between the technologies would be perceived by consumers as misleading. Instead, it was suggested that proponents can build trust by acknowledging the similarities, while also taking steps to distinguish the finer details of the technology.

Despite disagreement regarding specific public messaging, it was generally agreed that public acceptance could be improved by creating products that align with the values of groups and individuals trusted by the average person (e.g., farmers, doctors, small companies, health influencers, non-profit entities) and engaging those messengers in communication efforts. However, it was repeatedly mentioned that reaching the loudest and most influential voices (e.g., social media influencers) remains a key challenge.

Consistent with aligning products to the values of key messengers, it was broadly agreed that changes introduced by gene editing approaches must provide clear and tangible value to society. It was also suggested that, to provide impact (e.g., environmental, human health, economic), gene editing must be developed in direct connection with specific local, national, and/or global challenges, and the link must be clearly communicated to the public. The importance of considering gene editing applications from a larger food system perspective was also emphasized. As an example, it was noted that crop developers must not only consider which traits and crops are desirable now, but those that will be needed 10 to 20 years from now in light of current and anticipated global issues (e.g., climate change, diet-linked health challenges). While gene editing has the potential to help solve global challenges, it was repeatedly noted that promoters of the technology must be cautious of over-promising potential benefits, especially considering the impact on public perception in the event that purported benefits do not materialize. Specifically, it was noted that the benefits of gene-editing applications must emerge from niche markets to create wide-scale impact where most needed.

It was also mentioned that a key challenge to creating meaningful impact on human health is ensuring that product development and implementation is consistent with consumer demands that are rapidly evolving (e.g., from high fiber to high protein, low fat to ketogenic) and do not always reflect the best science in terms of dietary nutrition guidelines. It was noted that consumer expectations

are not the only aspect driving product development, and successful applications also will need to respond to the needs of farmers, processors, and food companies. In response, it was suggested that the speed of gene editing, from a scientific and regulatory perspective, will aid in responding to multiple demands on a more rapid time scale (i.e., from 10-plus years for a traditional biotech crop to about 3 years for gene-edited products), as compared with previous genetic engineering approaches.

Another prevailing theme focused on issues related to corporate responsibility. While it was generally recognized that global harmonization driven by government leadership is unlikely to occur, it was suggested that there is a role for the private sector to harmonize trade and encourage multilateral trade negotiations. There was also a general recognition that, given the fragmentation of the global marketplace and the subsequent development of products for regional application, it is especially important that the private sector take steps to ensure responsible supply chain management, including traceability. Risk (i.e., perceived and actual) management was likewise described as a key responsibility of the private sector, with particular attention to actions private companies are willing to take on a voluntary basis to improve transparency (e.g., labeling), build trust, and mitigate actual risk (e.g., FDA voluntary consultation process). Finally, it was noted that the private sector is largely responsible for public communication given that there is a lack of trust in the federal government.

Evidence-Based Options and Real-World Opportunities

It was generally agreed that improving consumer confidence in the safety and benefits of food technology is essential for food innovation to address global economic, environmental, and human health challenges. Given the widely recognized gap in scientific literacy among the public, it was suggested that the best mechanism for addressing public concern is a coordinated, carefully crafted, and well-executed public communication campaign. Alternatively, support was expressed for a government and/or industry effort to identify scientifically feasible consumer benefits associated with specific food and ingredient innovations, engaging consumers in prioritizing the public views of these benefits, and developing innovative products based on the results. A different approach to public education and communication could involve curriculum development for public education to prepare the next generation to make informed decisions regarding food choices.

While it was acknowledged that scientific literacy among the public is lacking, there is a need to target consumers who have varying levels of sophistication and interest in their food. As an example, the Biotechnology Innovation Organization is currently developing a consumer-oriented website targeting more sophisticated

consumers. However, point-of-purchase communication was emphasized as essential with regard to reaching the general population. Regardless of the level of sophistication or communication medium, it was also suggested that communication needs to be consistent across the industry. Thus, it was noted that establishing a regulatory-supported vocabulary for products of biotechnology could help address confusion by creating a clear, meaningful, and consistent lexicon.

Although there was disagreement on the relative importance of process-based communication, it was repeatedly mentioned that building trust will improve receptivity to messaging regarding science communication. As central elements in building trust, it was suggested that developers create products that align with consumer values and engage trusted figures as messengers for the technology. Examples of such messengers include individuals from the farming, culinary, health, plant-based, indoor/urban agriculture, and allergen communities. In particular, it was noted that these messengers need to focus on demonstrating the public good provided by diverse developers (i.e., both small and large) and the crop varieties they produce. It was also suggested that developers communicate how ownership of crop traits can be useful to society, given that this was a major source of tension among the public with the first generation of GMO production.

Several comments emphasized the importance of systematic approaches to global challenges, specifically when it comes to the ways in which gene editing is applied. Within these discussions, it was emphasized that problems must be evaluated to identify which tools and approaches are appropriate to specific situations (e.g., how will a specific application affect biodiversity?; does the application fit within the framework of local conditions?). It was also suggested that the products of gene editing must be developed, where appropriate, in tandem with systematic approaches (e.g., improving access to birth control) to global challenges (e.g., population growth). Consistent with this view, it was noted that crop development must focus not only on specific desired traits, but also on how the final product interacts with the environment.

While there was a general agreement that government-led regulatory harmonization is unlikely to occur, it was suggested that there is a role for the private sector to harmonize regulation and encourage multilateral trade negotiations. However, in the current regulatory framework, which was generally seen as resulting in fragmented or isolated markets, it was emphasized that supply chains must be managed diligently to ensure regulatory compliance and supply chain integrity, and to prevent potential public backlash in the event that a gene-edited product enters a market where it is prohibited or restricted.

Taking a wider view, the opinion was expressed that companies are responsible

for stewardship of the technologies they introduce. Specifically, it was emphasized that public perception must be collectively managed by private sector stakeholders, a responsibility that includes mitigating risk for all stakeholders (e.g., farmers, consumers). In particular, it was noted that as the first wave of gene-edited products enters the food supply, those stakeholders that are first-to-market bear the burden of pioneering new product introductions to the public and also have an opportunity to set the stage for the technology, as well as for companies in the industry. While a significant number of comments focused on what steps companies were willing to take to improve transparency and public trust, a question arose, but was not answered, regarding the responsibility of companies to either be individually proactive or coordinate industry-wide practices.

Using CRISPR Technology to Improve Health by Increasing the Consumption of Fresh Fruits and Vegetables**

Haven Baker, M.B.A., Ph.D., and Tom Adams, Ph.D.,
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Summary

Dietary factors are the number one disease risk globally. In the U.S., on average, Americans consume approximately 50% of the daily recommended intake for fruit and 65% for vegetables. While there are myriad factors that influence diet and food choices, both individual experiences and consumer data demonstrate that many fruits and vegetables are not always available, are unpalatable, and/or have limited shelf-life—all factors that contribute to low consumption of fruits and vegetables and high food waste. While the underlying genetics for addressing many of these problems already exist in wild and domesticated species of fruits and vegetables, it could take decades or even centuries to use traditional plant breeding to achieve the needed improvements. Although molecular breeding and genetic modification are viable tools in addressing this major health challenge, the use of these technologies has focused primarily on increasing yields in a few large acreage row crops. Whereas the emerging CRISPR technology can increase productivity for crops such as corn and soy, broader technology uses can more quickly improve public health by increasing the quality, convenience, and availability of fruits and vegetables at lower costs.

Current Realities

Globally, while humans cultivate and consume about 200 different plant species, only three crops (i.e., corn, wheat, rice) provide over 50% of the world's calories. In the U.S., about 88% of cropland is planted with corn, soy, and wheat. Thus, attention given to addressing the global food challenges via plants is disproportionately focused on row crop agriculture with two major outcomes: (i) the economics of row crops are almost exclusively focused on maximizing and protecting yield and (ii) crop improvements using molecular breeding and other technologies are narrowly focused on just a few plant species.

Globally and nationally, diet is the number one cause of poor health. A

2012 Lancet study identified the most significant global health risks, and, with the exception of tobacco use, diet was the main contributing factor to several major health challenges, including high blood pressure, obesity, childhood malnutrition, high fasting plasma glucose, iron deficiency, high cholesterol, etc. Although a subset of these problems can be partially addressed by transforming row crops, many of these disease factors can only be addressed by increasing fruit and vegetable consumption. In the U.S., only about 20% of people's diets meet the USDA recommendation for fruit and vegetables and the average person eats only about 50% of fruit and about 65% of vegetables. Unfortunately, this problem is not a new challenge. Total produce consumption has only improved by about 10% in vegetables and 5% in fruit since 1970 (Figure 1). Despite education campaigns, improvements in school lunches, and better nutritional information, relatively little significant progress has been made.

Scientifically Credible Approaches and Challenges

Outside of cost, enticing consumers to eat more fruits and vegetables needs to focus on three factors: (i) consistent flavor and quality, (ii) year-round availability, and (iii) convenience. Although there is no one solution for all produce, modern plant breeding tools (e.g., CRISPR) in individual crops could improve the consumer experience and increase produce consumption. Since many produce crops are genetically underdeveloped, and in some cases barely domesticated, CRISPR could significantly improve produce relative to more advanced row crops.

Research has shown that consumers make their first purchase of berries based on appearance, but repeat purchases are based on flavor. Thus, a negative consumer experience can delay a second purchase for months. Delivering consistent flavor is a complex challenge because flavor derives from a combination of environmental and genetic factors in addition to seasonality and ripeness components. In many cases, the underlying genetics are generally understood; therefore, an opportunity exists for CRISPR to increase the yield, shelf-life, and ripeness of the more flavorful varieties to meet consumer priorities.

Year-round availability is another important factor for increasing consumption. More than 40 years of conventional breeding enabled blueberry production in warmer climates, and this enabled southern U.S. production and imports, which led to year-round availability in 2008. As a result, consumption of blueberries increased four times in the last 10 years (Figure 2). Similar increases in consumption are likely if other fruits (e.g., cherries, peaches, plums) were available year-round. CRISPR technology can be used to rapidly adapt the growing regions for many plants, thereby making popular fruits more available.

The impact of convenience on escalating consumption reflects the general trend of consumer eating habits for increased snacking (10% of 1970s U.S. consumers snacked once a day, versus the current 94% snacking at least once a day and 50% snacking more than twice daily). While nut consumption has increased, fruit and vegetable consumption has not, with notable exceptions such as ready-to-eat salads and baby carrots. One recent example demonstrates that consumption can increase with convenience: easy-to-peel, seedless mandarin oranges became widely available this decade, and in the last five years consumption of them doubled, increasing the overall consumption of the fresh orange category by 30%. While traditional breeding efforts cannot keep up with consumer demands for ready-to-eat food, breeding innovation such as CRISPR technology could be used to make the same popular fruits and vegetables more consistently flavorful, available, and snackable. In turn, this could lead to healthier snacks improving societal diet and health.

One challenge with traditional plant breeding in produce is that consumer palates have evolved with a specific taste profile for specific produce. The predominant sweet cherry variety, Bing, was introduced in 1875 and still has significant market share even though its yields are 3 times lower than more recent, slightly different cherries varieties. Thus, plant breeders are always challenged with reproducing exact flavor profiles that consumers expect, while also trying to add agronomic benefits to increase yields for farmers. Since both goals cannot always be achieved with traditional breeding, growers are cultivating the same avocado, peach, and potato varieties used for generations to maintain taste without taking advantage of the opportunities offered by biotechnology (e.g., CRISPR) for more sustainable production.

Although there are numerous technical and marketplace challenges for the use of CRISPRs in plants, in many cases the largest barrier is technical and involves introducing the CRISPR enzymes into the plants. This transformation process has largely been developed in private industry. Collectively, it is estimated that billions of dollars have been invested in developing efficient transformation systems for row crops. There are a few vegetables for which transformation systems have been developed, but in most cases, commercial ready systems are not available. While both university labs and companies can build off the existing row crop transformation lessons for fruit and vegetables, each distinct plant species and sometimes each distinct variety needs its own unique transformation protocol. This takes time and a considerable investment of private capital to achieve the performance required for specialty crop-breeding innovation using CRISPR.

The availability and patience of private capital largely depend on the perception of public acceptance and the belief in a reasonable and predictable regulatory

system. Despite the business opportunities and broad potential public benefit of improved produce, specialty crops would be too expensive to develop if a regulatory environment similar to that of genetically modified organisms (GMOs) were implemented. If gene-edited products were regulated as GMOs, many companies otherwise interested in developing improved produce through CRISPR would focus their priorities on row crops instead, thus limiting the impact of CRISPR technology for public health benefits. Public acceptance is paramount, but for too long, the dialogue has focused on the technology itself. What is needed is a public dialogue about how better fruits and vegetables can create benefits for everybody.

Evidence-Based Options and Real-World Opportunities

The supermarket of the 20th century has focused mainly on the availability of produce, often at the sacrifice of product flavor and quality. With CRISPR technology, the supermarket of the 21st century can have great tasting produce year-round by progressively taking a more informed and sophisticated approach to genetic variation. These improvements are derived from the inherent potential of a plant's biology to create better tasting, healthier, better yielding, and safer food. Most applications of gene editing are a more precise method of doing what breeders have already been doing for a very long time in plants and, therefore, do not need to be regarded as a GMO. The following options are scientifically justified and would be highly supportive of our shared goals of increasing consumption of fresh fruits and vegetables.

- Update governmental regulations based on the following principles: (i) it is the product and not the process that should be considered when reviewing safety concerns (i.e., "like products must be regulated in like ways") and (ii) gene-editing that does not introduce foreign DNA is a more precise method of traditional breeding and should not be treated like a GMO.
- Create a strong record, defining and supporting the "Gold Standard" for science-based updates to regulatory policies for gene-editing.
- Promote healthy food choices through informative nutritional labeling and recommended daily allowances.
- Ensure consumer trust in the integrity of safe fruits and vegetables by emphasizing the significant post-market oversight authorities, responsibilities, and actions taken by federal and state regulatory agencies and departments to ensure the safety of the American food supply.

- Emphasize to the public the significant oversight responsibilities fulfilled and actions taken by governmental (federal and state) regulatory agencies and departments to ensure the safety of the American food supply.

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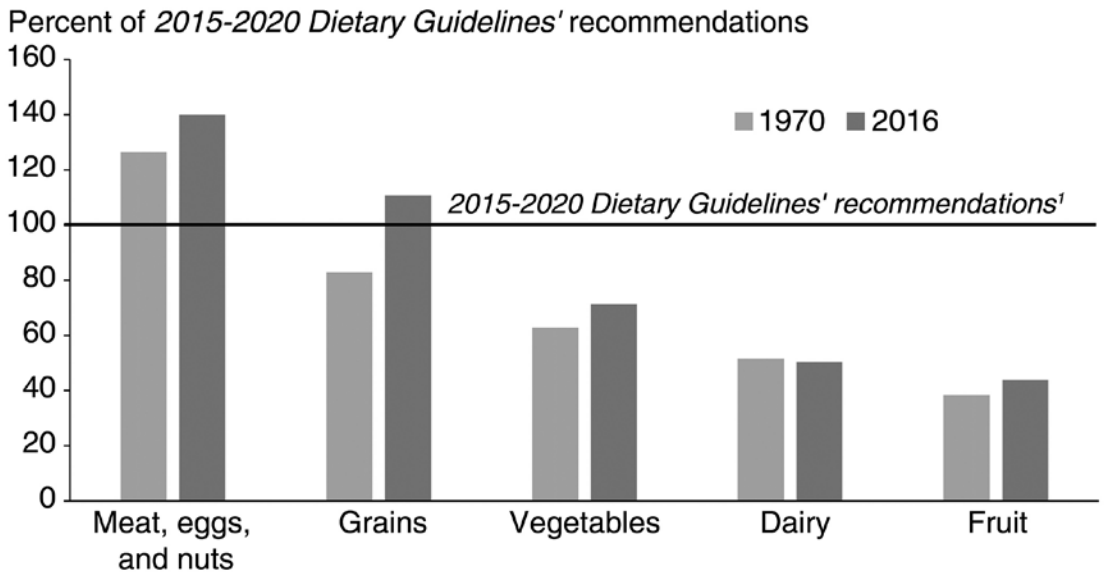
**** A position paper prepared for presentation at the conference on Innovative Foods and Ingredients convened by the Institute on Science for Global Policy (ISGP), with support from the U.S. Food and Drug Administration, on June 23-27, 2019, in Minneapolis, Minnesota, United States.***

Figure 1.

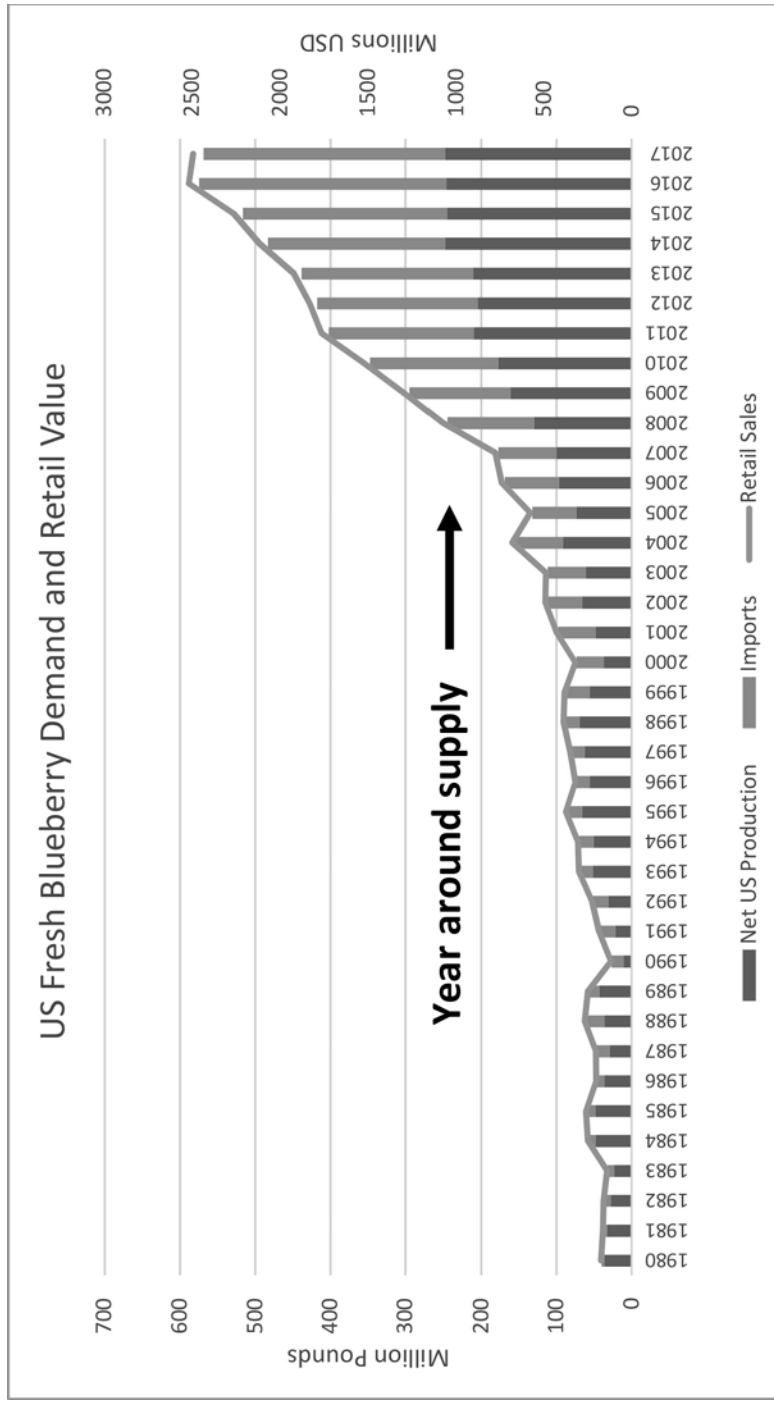
Estimated average U.S. consumption compared to recommendations, 1970 and 2016



[1]Based on a 2,000-calorie-per-day diet.
Loss-adjusted food availability data are proxies for consumption. Rice availability data were discontinued and thus are not included in the grains group.
Source: USDA, Economic Research Service, Loss-Adjusted Food Availability Data and *2015-2020 Dietary Guidelines*.

https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=58334

Figure 2.
Year around blueberry supply increases consumption



Source: USDA ERS Fruit and Tree Nut Yearbook Tables

Debate Summary

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Current Realities

Because U.S. consumers are, in general, not eating the recommended daily allowance for fruits and vegetables, thereby creating nutritional deficits, increasing consumption of fruits and vegetables was generally considered to be advantageous for human health. At the center of the debate was the challenge of how to increase consumption of fruits and vegetables to improve nutritional health, and it was generally agreed that CRISPR technologies hold promise in lengthening shelf-life, improving nutritional quality and flavor, and, potentially, creating year-round availability of many fruits and vegetables. These qualities, it was generally agreed, have the potential to increase consumption of produce and, therefore, provide people with more nutrients from fruits and vegetables.

It was suggested that CRISPR technologies could be applied to improve flavor quality of fruits and vegetables, which generally contain a beneficial balance of macro- and micronutrients and fiber for human health. Improved flavor, it was further suggested, likely would promote increased consumption of fruits and vegetables, thereby improving consumer health. Some countered that it is more important to focus on improving the nutritional quality of produce rather than improving flavor alone. It was also mentioned that neither flavor nor nutritional quality has been extensively pursued by producers, as their focus has largely been on increasing yields.

It was generally agreed that lengthening shelf-life could improve food security, especially for those residing in food deserts, which are impoverished areas nearly devoid of fresh fruit, vegetables, and other healthy, whole foods. CRISPR

technologies were presented as a solution to increase the shelf-life of fruits and vegetables. Because between 30% and 50% of produce is lost to waste on farms, in retail and wholesale outlets, and in homes, it was proposed that improved produce longevity could reduce food waste, decrease prices, and improve productivity.

Year-round availability was suggested as vital to improving consumption of fruits and vegetables. As an example, blueberry consumption increased by four times with the advent of year-round availability. It was noted that CRISPR could be used to bring some of the 750 species of fruits and vegetables worldwide to market year-round and therefore generate results analogous to those found in blueberries. However, some noted that seasonal spikes in demand and subsequent sales have resulted primarily from consumer understanding that availability is temporally limited. While year-round access to products may lead to a decrease in the rate of seasonal consumption, it was proposed that total annual consumption rates would increase. However, it was noted that consumers in Europe prefer seasonal access because of a perceived increase in quality.

There was general agreement that it is crucial to gain consumer trust in rapidly developing technologies such as CRISPR before products derived from those technologies appear in the marketplace. Debaters generally concurred that consumer trust and messaging transparency must be established soon after the development of these technologies if consumers are expected to accept the subsequent innovative or novel foods. It was also recognized that consumers are more likely to accept the use of a technology when the benefits are clear and direct (e.g., improving health). It was broadly agreed that gaining consumer trust in gene editing is a central challenge, particularly as it relates to technology applications used in grain development. It was further agreed that the lack of transparency observed in previous messaging for technologies used in grain improvement must be avoided moving forward.

Scientifically Credible Approaches and Challenges

There was general agreement that increasing the consumption of healthy foods (e.g., fruits, vegetables) within socioeconomic communities that would benefit from increased access to nutritious foods is a challenge that demands multiple solutions. One approach mentioned repeatedly was increasing the shelf-life of nutritious foods, such as fruits and vegetables. This point was considered to be especially important for individuals residing in food deserts with limited access to nutritious food. However, it was pointed out that creating a product with a longer shelf-life also could increase supplier and consumer costs, which could lead to an unintended consequence of limiting access for those with lower incomes who might have a greater need for the nutritional value of the produce.

It was agreed that increasing the convenience of food works in conjunction with improved shelf-life. By offering modified fruits and vegetables in smaller sizes, with fewer seeds, and with better flavor, it was suggested that more fruits and vegetables could be included in the snacking value chain, offering higher nutritional options for consumers. It was noted, however, that pre-packaging comes with the challenge of a higher incidence of pathogen contamination. In general, given the tenets of the Food Safety Modernization Act (FSMA), it was noted that fruits and vegetables will likely be on the list of "high-risk foods," which could lead to a reduction in consumption. Food safety, debaters generally concurred, must be addressed at harvest, handling and management, and in all points comprising the supply system to prevent risk and consumer fear.

By giving consumers higher-quality, better-tasting produce, it was proposed that the result would be greater nutritional intake, even if nutritional values may be lower per-unit. However, it was noted that if the flavor of produce is prioritized in breeding without attention to micronutrient content, the nutritional value of certain foods could be significantly reduced. For example, when salt or sugar is added to boost flavor, neither of these ingredients contributes favorably to the nutritional properties of the final product and an excess of either ingredient could diminish the nutritional value.

Gaining consumer trust will become increasingly challenging when CRISPR techniques are used to generate innovative fruits and vegetables. It was suggested that emphasizing the genetic diversity created using these new tools could be utilized to encourage public acceptance of CRISPR technologies and resultant foods. There was general agreement that acceptance of a new product likely will be predicated on public discussions on gene editing itself and accurately communicating benefits to consumers.

The idea of a public repository of the genetic diversity that is created with these new technologies was proposed to emphasize a commitment to public good and consumer trust. However, the lack of protection of intellectual property (IP) was considered by some to be a downside to the creation of a public repository. While it was generally agreed that many of the novel and innovative foods would not need such protection, it was noted that money often cannot be raised without IP protections, making it necessary to stimulate innovation while simultaneously maintaining the product's original property. It was generally acknowledged that the U.S. has a relatively secure IP system.

Although it was recognized that the regulatory efforts of the FDA are well-regarded by companies, the need for a transparent regulatory system based on sound science was deemed essential. While it was generally agreed that like-products need

to be regulated in a similar fashion, it was noted that regulatory oversight can often reduce profitability and weaken competitive advantages. A concern was expressed that if new regulations are modeled on those used for grain crops, consumer concerns about fruits and vegetables may not be adequately anticipated or addressed.

It was generally agreed that the U.S., along with other developed countries, has the responsibility to advance these new technologies to address extended shelf-life and food availability to increase worldwide food security. However, it was mentioned that concern for global food security may not resonate with consumers in the U.S. and Europe, who have greater access to the food on supermarket shelves.

Evidence-Based Options and Real-World Opportunities

There was general agreement that to improve human health, increased consumption of more fruits and vegetables is advantageous. It was also generally agreed that diverse solutions, including CRISPR, could contribute to making fruits and vegetables more accessible, as well as address various food safety and security challenges around the world.

CRISPR technology, it was noted, offers an opportunity to increase nutritional value in food, as well as to improve flavor, potentially leading to increased fruit and vegetable consumption associated with improved human health. It was also repeatedly noted that CRISPR technology introduces a real possibility of producing fruits and vegetables year-round, eliminating seasonality by growing products in locations where it is currently impossible to do so. For example, if CRISPR technology could be used to make cherries available in the U.S. year-round instead of for 11 weeks out of the year, it would be expected that U.S. consumers would spread cherry purchases throughout the year, eliminating the current in-season spike. However, there were divergent opinions about yearlong access to fruits and vegetables since it could lead to increased waste or consumer disinterest. Questions were raised regarding unintended consequences of eliminating produce seasonality, which could have an adverse impact on wildlife (e.g., by lengthening the season of pesticide application).

CRISPR applications, it was proposed, could also make produce available in snack forms, thereby motivating consumers to eat more produce. To achieve produce "snackability," it was considered necessary to develop produce to fit within the snacking value chain (e.g., smaller product size, fewer seeds, better flavor, longer shelf-life). It was emphasized that there are genetic solutions that can be used to achieve many of these snack-like qualities. The potential to decrease obesity through increased consumption of fruits and vegetables was noted as an added benefit to creating more snackable fruits and vegetables.

Based on the observation that three types of grains account for the majority of calorie consumption in the world, a concern was raised as to whether producers may create a similar situation in which fruit and vegetable production gravitates to a few varieties of vegetables and fruits. Clarity on regulatory timelines was noted as critical for the investment community. The FDA was viewed as the "gold standard" in this regard. Encouraging new products that reduce the incidence of food pathogens during harvesting, handling, and management was noted as a needed step. Finally, it was emphasized that a conversation regarding federal versus state regulatory systems must occur because of the variety of state requirements for labeling. Customized labeling by state, it was generally agreed, is confusing for consumers and expensive for producers.

To avoid pushback from consumers, it was acknowledged by some that concise and persuasive communication needs to target the differences between gene-deactivated foods and transgenic modified foods. However, others adamantly expressed that communication must be about the product, not necessarily about the technology used to create it. Although diverging views on communication strategies were voiced, the collective view was that communication must be simplified so that consumers can understand the benefits of these innovative foods. Therefore, it was stated that the product needs to be presented to the public in understandable terms that make it desirable and demonstrate its benefits.

Aquatic Plants for Sustainable Food and Protein Production: Implications for Global Food Security**

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Summary

As the 21st century global population expands toward 9 billion people and the demand for higher quality, protein-rich diets increases, a revolution in agriculture is needed to meet food requirements in an environmentally sustainable manner.

Crop diversification efforts that deliver increased biomass and/or protein yields with reduced environmental costs are slow to evolve. Promising, non-conventional crops and protein sources (e.g., algae and aquatic plants) occupy niche markets in nutritional supplements and animal feed but have yet to materialize as disruptive players in the protein sector. Recently, water lentils (i.e., aquatic plants in the duckweed family) have become a focus of commercial farming operations for protein-rich foods. Scientifically credible opportunities exist with water lentils, including: (i) "sustainable intensification"; (ii) obtaining high-quality, plant-derived proteins; (iii) expanding use of non-arable land; and (iv) crop production intrinsically resistant to disease and natural and/or man-made disasters.

Evidence from early-stage commercial water lentil farms indicates large-scale production of a sustainable, aquatic, plant-based protein is a real-world option. Challenges to widespread adoption of this alternative crop include customer acceptance and a lack of clarity and synchrony in the regulatory environment. Promoting novel protein crops such as water lentils can be part of a broader strategy to address the intersection of exploding global food and protein demand and environmental sustainability.

Current Realities

The world's food needs are projected to nearly double by 2050, as global demand for environmentally costly high-protein diets (e.g., animal proteins) continues to increase. These negative externalities increase the probability of catastrophic food crises due to crop failures from natural disasters and/or diseases as well as man-made disruptions, including geopolitical tensions and agroterrorism.

Scientific strategies exist to increase traditional crop yields and reduce environmental footprints. Innovation in traditional crops, particularly in areas such as genetic modification and advanced breeding programs, has produced gains in crop yield per unit area and improved resistance to pests and pathogens. While such improvements in traditional crops form a critical component of addressing 21st century food requirements, the current reality suggests an urgent need for agricultural diversification with novel crops and protein sources to meet the world's food demands without increasing global environmental degradation. Not surprisingly, this diversification is consistent with the United Nations' Food and Agriculture Organisation conclusion that increasing biodiversity in the food and agriculture sector is a key element in global food security and sustainable development.

Key requirements of a sustainable, novel crop include: (i) providing balanced, high-quality nutrition; (ii) increasing crop productivity and yields so more crop/protein can be obtained per unit area; (iii) more effectively utilizing marginal or traditionally non-arable lands; (iv) reducing the environmental costs associated with crop production (e.g., soil erosion, nutrient runoff, land usage); and (v) ensuring improved resistance to disasters and disease.

There are diversification approaches using novel terrestrial crops that show promise for meeting these requirements. These include *de novo* domestication of perennial crops to enable superior crop productivity and increased environmental sustainability. A promising complement to diversifying terrestrial crops involves the farming of aquatic plants, such as water lentils, which represent some of the most productive and ubiquitous plants on the planet. Indeed, the potential of water lentils to produce vitamin-rich, high-protein foods has been recognized and studied in academic and government circles for decades. More recently, commercial-scale farming of water lentils has become a focus of private sector start-up companies.

Scientifically Credible Approaches and Challenges

Can aquatic plants, such as water lentils, contribute to solving the challenges of 21st century food security by producing nutritious, protein-rich foods, while mitigating collateral environmental degradation associated with traditional crops?

Farming of water lentils represents a true paradigm shift in crop and protein production since it involves the growth of an aquatic plant that primarily reproduces clonally (i.e., a "mother" plant buds off "daughter" plants). This mechanism of reproduction results in near-logarithmic growth rates and a doubling of crop mass in as little as 24 to 48 hours, thereby allowing the daily harvest of a significant

proportion of the floating crop (i.e., about 25%). These explosive growth rates, coupled with the nutritional profile of the plant, are at the core of water lentils' potential as a transformative and sustainable crop.

Water lentils are currently the focus of several private sector enterprises, including a commercial-scale duckweed farm in Florida (Figure 1, more than 50 acres) which provides real-world validation of the opportunities and risks associated with commercial production. Attributes of water lentils that make it an attractive novel crop, as it pertains to human nutrition, environmental sustainability, food security, and reduced environmental impacts, include:

- Nutritious and rich in protein, vitamins, minerals, and omega-3 oils;
- Highly digestible protein, containing a high percentage of essential and branched-chain amino acids (Protein digestibility-corrected amino acid score ≥ 0.90) with the capacity to exceed 40% of the plant mass;
- High areal protein productivities that are an order of magnitude (i.e., 10-fold) or greater than traditional plant protein crops (e.g., soy);
- Expanded availability for food production on marginal and/or non-arable lands, obviating competition with prime farmlands and/or biodiverse habitats;
- Amenable to "lined" growth systems that retain nutrients and prevent runoff pollution;
- Enables "sustainable intensification" (i.e., the production of more food per unit area while decreasing negative environmental impacts);
- Resilient to shock, as crop can recover from natural or man-made disasters on a time scale of weeks (i.e., restarting and repopulating ponds in several weeks);
- Intrinsic resistance to pests, greatly minimizing the use of pesticides and herbicides.

Real-world experience with water lentil farming confirms the rapid recoverability of these crops from natural disasters (e.g., water lentil crops recovered within two weeks to full protein productivity from the approximate 90% crop-loss caused by Hurricane Irma in Florida). In addition, water lentil crops nearly eliminated run-off and pesticide use.

As with other more traditional crops, we expect challenges associated with expanding and optimizing production of novel crops, such as water lentils, that will require continued research, development, innovation, and investment. Perhaps as challenging as the technical risks are the difficulties presented by the lack of clarity and synchrony in the global regulatory environment as it relates to novel foods, as well as a subsidy environment that favors traditional crops and large producers.

In addition, customer perception and public acceptance of novel foods presents a barrier to their widespread market penetration.

Evidence-Based Options and Real-World Opportunities:

Recognition of the remarkable value of water lentils as a food source, in addition to a wide range of additional environmental and economic advantages, strongly suggests the need to:

- Encourage stakeholders to harmonize the regulatory requirements for novel foods, such as aquatic plant-based products (e.g., water lentils), to ensure an accurate public understanding of their benefits while ensuring a productive commercial environment.
- Implement programs to inform the public about the nutritional benefits of novel foods/proteins that is consistent with similar efforts concerning other food products (e.g., Dairy Promotion Program, "Got Milk?").
- Promote government policies that decentralize crops by altering the subsidy landscape, thereby promoting crop diversification and supporting infrastructure.
- Encourage government agencies to favor healthier options and more environmentally sustainable producers in food procurement programs (e.g., military, schools).
- Expand industry and government engagement with environmental advocacy groups to promote a standardized system for ranking foods and ingredients based on sustainability to inform customer choices.
- Broaden existing nutritional education programs to include healthy novel ingredients and foods.

In conclusion, environmentally sustainable food production throughout the 21st century will require a revolution in agricultural practices and innovation in the novel food sector to balance the production of highly nutritious and protein-rich diets while minimizing the collateral environmental degradation associated with traditional agricultural practices; aquatic plants such as water lentils can play a significant role in addressing this challenge.

** ***A position paper prepared for presentation at the conference on Innovative Foods and Ingredients convened by the Institute on Science for Global Policy (ISGP), with support from the U.S. Food and Drug Administration, on June 23-27, 2019, in Minneapolis, Minnesota, United States.***

Figure 1.
Commercial "Water Lentils" (duckweed) farm located in Central Florida (Parabel, Inc, USA).

Debate Summary

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Current Realities

A recurring theme throughout the debate was the universal desire for food self-sufficiency and global food security while maintaining sustainable food systems and improving human health. It was noted that the current production of food is inadequate to feed the current world population, according to the World Health Organization (WHO). Discussions of creative solutions to help achieve food security included the adoption of alternative food sources. It was recognized that specific concerns to consider when exploring novel food sources include the effects of climate change, crop failure, and water depletion, as well as the growing global population.

It was suggested that duckweed, a water lentil that is sustainably grown and readily harvested on top of water, could become an important alternative food source for attaining global food security. It was noted that the threat of disease and extreme weather conditions (e.g., hurricanes) in Florida bring a large risk of citrus crop failure, which could eliminate as much as 90% of the economically vital citrus export industry. Recovery from such citrus losses would take years. By comparison, recovery of duckweed production has proven to be significantly more rapid (i.e., within weeks of a catastrophic devastation). It was acknowledged that although duckweed is rich in vitamins and high in protein, a challenge in achieving widespread consumer adoption would be the negative perceptions concerning its oxalic acid content, which compares to that of spinach. Oxalic acid binds minerals and has been linked to kidney stones and other health problems. In addition, the geopolitical climate concerning water control could have an adverse effect on growing this novel water-borne food.

There was general agreement that plant-based protein sources within the food supply are not necessarily intended to replace animal protein. Instead, the goal is to supplement animal protein and to provide diversity in protein sources. It was understood that the production of animal agriculture needs to continue, with the caveat that people be encouraged to make healthier and more environmentally sustainable choices. It was suggested that supporting ideas like "Meatless Mondays" or promoting the consumption of plant-based meat substitutes adds diversity to human diets, as opposed to solely consuming animal products and row crops. According to the Institute for Health Metrics and Evaluation, the production of grain and fish is 50% higher and the production of red meat is 568% higher than needed for global health. It was emphasized that, in comparison, far too few vegetables, nuts, and fruits are produced.

Debaters expressed divergent opinions regarding how to avoid and/or recover from bioterrorism affecting the agricultural system and the related food supply. While it was generally agreed that duckweed has the potential to recover quickly after a bioterrorism attack, some noted that duckweed does not necessarily have a place in alleviating the challenges that come with potential massive-scale agro-terrorism attacks.

Concerning the environmental sustainability of duckweed production, it was noted that much of the production occurs in Florida, a state with an abundance of well water (i.e., the primary water source for duckweed growing ponds). Duckweed requires a minimal production process since there is no need to use arable land. Once the ponds are filled with well water, refilling is not necessary since rainwater generally replenishes and recycles the water system. However, since duckweed is produced in open hydroponic ponds, there was concern that nutrients might leech into the surrounding water.

It was emphasized that food ethics concerns result in consumers purchasing food products that align with their beliefs. Additionally, debaters noted that consumers rely on labels to make purchasing decisions, especially when buying green proteins. Since "green protein" is marketed mostly based on nutrition, labels eschewing particular health claims that support consumer beliefs could encourage consumers to continue buying these foods on the basis of such health claims (e.g., allergen-free, high in protein, high in dietary fiber, high in antioxidants, certain calcium levels).

The importance of integrating duckweed usage into culinary traditions was noted on several occasions. In Vietnam and northern Thailand, sun-dried duckweed has been consumed by humans for centuries and is commonly used as a topping for soups and salads, providing a mild, slightly sweet taste. In other countries,

such as Uganda, duckweed is commonly used as feed for animals and is not part of the human diet. The question of how this green protein is labeled and recognized internationally was not definitively answered. In the United States, duckweed currently is labeled as a water lentil protein.

Debaters briefly discussed the idea of land or infrastructure subsidies when comparing the cost of producing an existing green protein, such as soybeans, to the cost of producing a novel green protein. It was stated that in Florida, the producer is responsible for funding surrounding roads and infrastructure. Without subsidies, the cost of novel green protein sources is consequently higher than those green protein sources that are subsidized.

Scientifically Credible Approaches and Challenges

Discussion focused on food safety and the need to ensure safe human consumption. It was pointed out that since duckweed is grown on surface water, it is possible that reptiles, amphibians, and waterfowl carrying *Salmonella* and other bacteria could be present during production. As such, it was emphasized that open-pond systems risk contamination with bacteria such as *Escherichia coli*, *Salmonella*, or *Listeria*. To reduce risk and create a safe food system, it was emphasized that monitoring contaminant levels in the growing ponds throughout the day is needed. It was also noted that exposing harvested duckweed to heat has been proven to remove contaminants.

Questions were raised regarding the challenge of dealing with human health risks that pertain to growing duckweed. For instance, there was concern regarding regions with standing water that have a higher prevalence of malaria (e.g., Uganda) where duckweed production is also taking place. Because the first stage of the mosquito life cycle occurs in water, where larvae feed and develop, there was concern that duckweed ponds would be vulnerable locations for mosquito development, which can impact the health and safety of duckweed pond workers and people nearby. However, it was countered that the Parabel duckweed ponds in Uganda have been closely monitored for mosquitos and none have been detected during crop production. Another health concern associated with waterborne disease was typhoid fever. It was acknowledged that training workers on basic sanitation is vital, as typhoid fever can be introduced by workers coming from villages to the worksite.

Concern was raised regarding the protection of the genetics of duckweed, which has a small genome with a high mutation rate. One of Parabel's systems has a duckweed population of about 9 billion individual plants of which 20% to 30% is harvested daily, depending on the season. This mass-harvesting and quick plant regeneration contributes to an accelerated evolutionary process of these duckweed

strains. The acceleration of harvesting is one way to greatly increase the base protein percentage and nutritional levels of these plants.

There were some questions concerning the current agricultural subsidy system and the assertion that the system needs to significantly change to adequately support novel foods. While the productivity of duckweed is 10 times higher than genetically modified soybeans, resulting in low production costs with higher volumes of product, duckweed is at a competitive disadvantage due to the crop subsidies for soy. It was noted that while water lentils have been recognized as a vitamin-rich protein source, they have not been previously commercialized. Such subsidies and commercialization issues contribute to the challenges associated with producing and bringing new products, such as duckweed, to market.

Communication was also noted as a significant challenge. Confusion was stated regarding the label of "water lentil" on a food product. The Parabel approach to communicating and educating consumers about water lentils did not resonate well with the general public, mainly because an actual product was not yet available for purchase. While a new communication approach will take time and money to establish, there was general interest in developing such a system to overcome communication challenges. It was also generally agreed that the time required to research, test, and produce a new food product was another hurdle, along with shareholder acceptance and the ability to raise capital.

It was noted that many plant proteins have a distinct flavor that would be difficult to change, although several different applications (e.g., pasta, smoothies, bars) have been developed. It was noted that, historically, plant-based, protein-rich foods have been nutritionally sound, despite their rather bland taste. Furthermore, Parabel is introducing soluble white plant milk with a more neutral flavor.

A concern was also briefly raised concerning duckweed as an invasive weed in certain locations (e.g., in the Amazon). In response, it was indicated that water lentils must be grown wherever water is available, and care must be taken to utilize only native species.

Evidence-Based Options and Real-World Opportunities

It was widely agreed that food security requires increased production, reduced waste, and redesigned food distribution to reach the billions of people suffering from malnutrition. Duckweed is an example of a scalable food source that is currently available as an ingredient and can be used to increase protein consumption. It was asserted that places such as Florida, Uganda, and Brazil have the amount of water, type of space, and environmental requirements for large-scale duckweed production, as well as distribution opportunities.

While harmonizing regulatory requirements is important for bringing a novel food, such as duckweed, to market, it was not clear in the debate how harmonizing regulatory requirements and ensuring a productive commercial environment fit together. It was noted that some countries use duckweed as food and regulated it as such, while others use it for animal feed, which is regulated differently from food. For example, Canada already recognizes two strains of duckweed, *Lemna minor* and *Wolffia*, as food. In China, however, only the *Wolffia* strain is approved for human consumption and extra degrees of safety regulations are required for other strains. Europe regulates duckweed only for feed material, while in the United States it is regulated as food. Since countries have very different lists of requirements for regulatory approval, it was emphasized that global harmonization of regulations could be beneficial to food security, because foods could more easily enter the supply chain.

General agreement was reached that increased food sustainability is essential and that duckweed can make some contributions, especially for reducing emissions from food production throughout the food system. It was also expressed that opportunity exists in promoting a standardized system for ranking foods and ingredients based on sustainability, which would improve how consumers make food choices. It was thought to be unfair to compare foods that strain the environment to foods that have a near-neutral effect on the environment. Due to the absence of a standardized system to incorporate sustainability into the food system, it was considered important to explore communication strategies designed to promote sustainability. While there were divergent opinions regarding the ranking of food products in terms of sustainability, it was noted that a standardized system could categorize duckweed as a sustainable crop that helps address global food security.

Accelerating Algae Into Our Food System**

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Summary

Algae have tremendous potential to deliver nutrient-dense food to address global challenges in food production and health. Algae produce high-quality proteins, carbohydrates, and oils in an efficient and scalable manner. Production systems for algae often have low environmental impact reducing the use of potable water, arable land, and fossil-based energy. Algae have been in our food system for centuries with a few varieties popularized in the last few decades including seaweed, spirulina, chlorella, astaxanthin, and omega 3 fatty acids (DHA & EPA). Although algae offer enormous potential for food production, additional development and infrastructure buildout is required to scale and enable economic production of algae-based food products. Governments around the world acknowledge the potential of algae and are actively investing in further development of algae for food and feed. For example, as part of the 2018 Farm Bill, the U.S. Department of Agriculture (USDA) was directed to classify algae as a crop for the first time. Now is the time to invest in a new Green Revolution that can deliver nutritious and sustainable food solutions.

Current Realities

According to the United Nations Food and Agriculture Organization, the world's population is expected to grow by 2 billion people to reach 9.3 billion people in 2050. This population increase and the expected dietary changes associated with global income growth indicate that by 2050, about 60 percent more food will be needed globally to meet demand. An underlying principle in addressing this challenge is "improving the efficiency in the use of resources." In other words, how can we produce more nutritious food using fewer resources, while maintaining the health of our soils, conserving potable water, and protecting the biodiversity and resilience of our ecosystems?

Both macroalgae and microalgae have the potential to deliver global, game-changing food solutions, and provide an expansion of food resources. Algae are

the most efficient organism on the planet for turning sunlight, carbon dioxide, and/or carbohydrates into nutritious biomass. Algae are naturally high in protein and healthy oils, offering an opportunity to bring new food and ingredients into the marketplace.

Globally, macroalgae (seaweeds) represent one of the world's largest crops by volume. They are typically grown in coastal areas using two production systems: (i) open pond; and (ii) offshore longline. Open pond systems are located on land and pipe seawater into containment structures that are several feet deep. Depending on location and species, ponds can be harvested continuously throughout the year. Production in ponds requires a small amount of fertilizer, plus electricity for pumps, filters, and aeration. Offshore longline cultivation involves an extensive cultivation model featuring moored longline arrays deployed within maritime concessions. The lines are seeded with strings saturated with seaweed spore, maintained through the grow-out period and then harvested. Offshore production tends to be a seasonal cycle, but multicropping different species can help improve yields.

Microalgae are naturally photosynthetic organisms but can be grown with or without light, and with systems that vary in complexity—from open ponds to highly controlled fermentation systems.

There are three basic productions systems for microalgae: (i) open pond, (ii) photobioreactors, and (iii) fermentation. Open ponds are primarily circular "river-like" systems driven by paddle wheels, often less than 2 feet deep, and can be several acres per pond. These systems have successfully produced numerous marketable commercial products. Photobioreactors are mainly clear plastic or glass tubular enclosed systems where algae are pumped through the tubes for gas exchange and light exposure. This system produces higher biomass yields than ponds. Fermentation systems involve growing algae "in the dark" using a reduced carbon source, such a sugar or acetate, usually in stainless steel tanks under highly controlled and sterile conditions. These systems have the highest yields (i.e., up to 50 to 100 times that of open ponds) and are already operating at scale in several locations with numerous products on the market.

Thousands of varieties of microalgae exist and can be improved in several ways to make them more productive and/or change the nutrient quality or density. Natural algae are collected in the wild, or from an algae collection, and may be adapted by classical mutagenesis and/or breeding. For some algae varieties, genetic engineering techniques are applied to natural algae to achieve targeted improvements. Gene-edited algae are potentially on the horizon, but no products using this technology are currently on the market.

Scientifically Credible Approaches and Challenges

Algae have a demonstrated ability to produce high-quality proteins, minerals, vitamins, and fats in an efficient and scalable manner, with the potential to reduce the use of potable water, arable land, and fossil-based energy. Algae are at the base of the food chain and often require fewer resources than other organisms to produce proteins and other food ingredients. In many cases, algae food production is climate resilient, and not subject to seasonality or geography. In the case of growing seaweed, it requires no fresh water or arable land and absorbs carbon dioxide helping to reduce acidification in the oceans.

In addition to providing high-quality nutrition, the health benefits of numerous algae varieties have been well-documented. A number of algae-based products can contribute to anti-inflammatory, cardiovascular, brain, and eye health benefits. Unique bioactive compounds are also found in seaweeds that may have broad-spectrum health benefits, including prevention of various cancers, metabolic, cardiovascular, digestive, and neurological diseases. Many varieties of algae have the potential to reduce consumer sodium and saturated fat intake and serve as a natural food preservative. The potential of algae to provide a significant food resource now and in the future, is significant.

There are a number of challenges for the algae sector as companies seek to scale up production and introduce algae products into the U.S. market:

- *Cost:* Continuous improvement in production costs are needed to enable broader incorporation of algae in food products.
- *Functionality and Taste:* Cooperative development with food manufacturers is needed to continuously improve the functionality and taste for food formulation.
- *Market Acceptance*: Consumer education and marketing investment is needed to familiarize and inspire consumers regarding algae-based foods.
- *Innovative Technology:* New technologies are needed to scale production, as well as to make improvements in algae varieties.
- *Regulatory Engagement:* More funding is needed for the Food and Drug Administration (FDA) to increase new food-ingredient reviews and speed to market, verify nutritional and health claims, and improve consumer confidence in the processes for ensuring food safety.
- *Investment:* Diverse funding is needed to scale-up operations; for R&D support for cultivation, processing, and product development; and to improve market penetration of new food products

Evidence-Based Options and Real-World Opportunities

The policy as well as public and private sector recommendations outlined here focus on developing products that are nutritious, cost competitive, and delicious. There are several key elements required for the global development of algae-based food and much of this effort needs to be implemented with the support and guidance from the U.S. Algae Interagency Working Group, which includes members from the FDA, USDA, Department of Commerce, Environmental Protection Agency, Department of Energy, and National Science Foundation:

- Accelerate development of algae production at scale. As part of the 2018 Farm Bill, the USDA was directed to classify algae as a crop for the first time. This decision opens the way for algae to be regulated and supported alongside other crops such as wheat, corn, and soy. For example, the USDA can provide Crop Assistance and Crop Insurance programs to help decrease the risk of investments in algae production and other significant infrastructure investments needed to produce algae at scale. The USDA also needs to contribute its unique federal role to develop an Algae Agriculture Research Program to help fund technology research and development needed to scale production as well as establish standard reference strains and genome sequencing for algae. These types of efforts are similar to the support provided for crops.
- Accelerate adoption of algae ingredients and products by food manufacturers. Through a public-private effort (i.e., USDA, National Institutes of Health, State Department, philanthropic foundations and companies), the USDA needs to establish a Center of Excellence that will support the development of commercial algae products that meet consumer needs for flavor, texture, nutrition, color, consistency, functionality, and safety. This Center could provide a platform to facilitate collaborations for product testing, regulatory guidance, development of analytical standards and methods, and resources to accelerate adoption of algae into foods. In addition, these efforts could also expand publicly available data and information on algae for food applications. This public-private effort could provide the support and a framework to accelerate incorporation of algae in commercial food applications as well as emergency food rations.
- Create greater demand by consumers. Like the efforts of the National Dairy Council and other government-supported commodity marketing efforts, a clear and compelling communications effort needs to be launched about the benefits of algae ingredients and products. This effort should address the demand side to educate about the nutritious, delicious, and sustainable

attributes of algae. Accelerating adoption by consumers is critical for the growth of the industry and to address some of the largest health crises we face (i.e., obesity and cardiovascular disease).

The development and production of algae food products are rapidly expanding and can meet many of the health and environmental challenges associated with food consumption and production today. Algae will play an important role in addressing food security and health challenges globally.

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*** A position paper prepared for presentation at the conference on Innovative Foods and Ingredients convened by the Institute on Science for Global Policy (ISGP), with support from the U.S. Food and Drug Administration, on June 23-27, 2019, in Minneapolis, Minnesota, United States.*

Debate Summary

This not-for-attribution Debate Summary was prepared by the ISGP staff from the audio recording, and its transcription, of the debate of the position paper prepared by Ms. Kauffman Johnson (see above). Ms. Kauffman Johnson initiated the debate with a 5-minute statement of her views and then actively engaged the conference participants, including other authors, throughout the remainder of the 90-minute period. This Debate Summary represents the ISGP's best effort to accurately capture the comments offered and questions posed by all participants, as well as those responses made by Ms. Kauffman Johnson and other participants. Given the not-for-attribution format of the debate, the views comprising this summary do not necessarily represent the views of Ms. Kauffman Johnson, as evidenced by her position paper. Rather, it is, and should be read as, an overview of the areas of agreement and disagreement that emerged from all those participating in the critical debate.

Current Realities

During the debate, it was generally recognized that climate change presents both current and future challenges to ensuring the availability of nutritious and sustainable food for a growing population. As an example, it was noted that the

increasing demand for protein in developing countries will require finding efficient and, in some cases, novel foods and production methods, such as algae, to address some of these concerns. While the market opportunities and potential human and environmental benefits of algae were widely recognized, there were varying degrees of confidence in algae becoming a viable option for food and feed, as well as the likelihood of widespread, positive impact. The degree to which participants had confidence in the benefits of algae was largely dependent on factors such as marketing and public communication, scalability, quantification of positive outcomes, and potential environmental and human health risks, all of which emerged as recurring themes.

There was significant contextual discussion centered on understanding the current and anticipated applications of algae in the food system. While the conversation mainly focused on algae for direct human consumption, there were several questions regarding the potential for other applications, including carbon dioxide sequestration, wastewater treatment, and soil amendment. It was widely acknowledged that algae-based products are already on the market as both food (e.g., candies, smoothies, infant formula, pasta, mayonnaise, granola bars) and feed (e.g., for salmon, cattle, and chickens).

Despite its use in numerous common food products, concern was expressed that the average consumer is not familiar with algae as a food source. It was repeatedly mentioned that lack of consumer education is one of the greatest challenges hindering the success of algae in the food system, especially in places where it is associated with environmental damage and/or health risks (e.g., eutrophication and red tide in Florida). In response, it was noted that coordinated, industry-wide communication efforts have effectively begun shifting the public's frame of reference from perceiving algae as an environmental nuisance to a product with health-promoting benefits.

In addition to public communication successes, several promising developments within the algae industry were discussed. First, it was noted that the landscape for algae product labeling had recently shifted. For macroalgae, the Marine Stewardship Council developed a Seaweed Standard recognizing the minimal negative social and environmental impacts of farming seaweed. This was noted as a step forward in highlighting the benefits of algae. For microalgae, it was mentioned that foods containing high-oleic oils may now use the recently established, qualified health claim for reducing risk of coronary heart disease. Second, algae were classified as a crop for the first time in the 2018 Farm Bill, a development which was noted as key in creating new opportunities for risk reduction among producers (i.e., Crop Assistance and Crop Insurance programs) and increased support for marketing,

research, and education through the USDA Commodity Checkoff program.

Another key theme of the debate centered on the scalability of algae production, with specific attention given to microalgae fermentation. Specifically, there was a keen interest in understanding why algae products were ultimately unsuccessful in fulfilling their promised benefits in the biofuel industry. Given these previous outcomes, concern was expressed that food-based applications would also not be able to deliver on their promised benefits. Within this discussion, it was suggested that scientific and commercial understanding of algae has advanced significantly as a result of public and private investment in research and infrastructure development for biofuel applications. As an example, it was noted that the most efficient microalgae fermentation methods currently use the same bioreactor systems (and, in some cases, hardware) as biofuel production. Furthermore, while biofuel applications were unable to meet the efficiencies required to compete with fossil-based fuels, algae have reached higher productivity levels for lipids and proteins than most other crops (i.e., excluding palm oil).

Despite their widely recognized productivity rates, it was repeatedly noted that the high monetary cost of algae production compared with alternative sources of lipids and proteins (e.g., canola and soy) needs to be addressed for algae to have a widespread impact on economics, human health, and the environment. Nonetheless, it was acknowledged that microalgae production is approaching cost-competitiveness with staple food sources as a result of advancements in research and development. It was suggested that further improvements in strain development and productivity rates will help reduce this remaining cost gap. However, further price drops were simultaneously thought to be constrained by the cost of energy required to run an algae production facility and the cost of feedstock used in the fermentation process (i.e., sugar).

Scientifically Credible Approaches and Challenges

A significant amount of the debate centered on consumer education and marketing of algae products. Specifically, engaging the nutrition and environmental communities was viewed as central to gaining buy-in and trust from influential voices. While there was some endorsement of engaging with these communities to understand their priorities and perspectives, divergent opinions were expressed regarding the ethics of engaging influencers in advertising and marketing. Specifically, the concern was raised that engaging influencers has failed historically and may have unintended effects on public perception (e.g., previous experience in the pharmaceutical industry).

There was general agreement that algae have numerous substantiated health

benefits (e.g., cardiovascular and eye health). A discussion of how such benefits are best communicated to consumers ensued. Concern was expressed regarding unregulated terms often found on packaging for "health" products (e.g., clean, whole, real, complete), many of which were noted as lacking scientific credibility and viewed as misleading to consumers. It was noted that several lawsuits have been filed against the food industry as a result of using such language in marketing. Thus, it was asserted that defining how such health claims can be effectively regulated to reflect scientific agreement and understanding is important to ensure consumer confidence in labeling in general. The Food and Drug Administration's (FDA) qualified health claims were acknowledged as a model for such regulation and noted as important in empowering consumers to make informed choices based on accurate and scientifically credible labeling.

The productivity and cost viability of algae production compared to alternative food sources was presented as another significant theme of the debate. While there was general support for the potential of algae, not all were convinced that algae offer enhanced capabilities compared to what can be achieved using established commodity crops (e.g., corn, soy, wheat, cotton), especially considering the current difference in price per kilogram (i.e., approximately four-fold). However, it was repeatedly noted that microalgae fermentation is more productive than most crops when considering both protein and lipid content (i.e., excluding palm oil). As such, it was generally agreed that achieving economies of scale is key to establishing viability in algae production and realizing the potential benefits of algae consumption.

While it was broadly recognized that sugar is currently the most developed and widely used feedstock for fermentation, most agreed that converting waste products (e.g., baby carrot shavings, grass clippings, crop residue) into cellulosic sugars is a promising approach to lowering cost and scaling algae production. However, it was widely acknowledged that the success of cellulosic sugar will depend on (i) continued research into optimizing the enzymes used in processing biomass and (ii) developing efficient ways to collect waste inputs. In conclusion, it was suggested that alternative feedstocks, such as carbon dioxide and/or methane, should be explored.

In addition to optimizing feedstocks for algae fermentation, it was repeatedly mentioned that the slow speed of the regulatory approval process is another limiting factor in scaling algae production and achieving cost-competitiveness with alternative food sources. Specifically, while acknowledging the FDA's Generally Recognized as Safe (GRAS) program is effective and straightforward, it was suggested that understaffing at the FDA significantly delays the approval process, often for longer than the 90-day period. Thus, increasing funding and staffing at the FDA was proposed as essential to achieving lower costs by decreasing time to market.

Apart from scalability, risk was identified as another pervading theme, with discussion focused on issues of potential contamination. Specifically, there was concern expressed that gene-edited algae could escape commercial systems and outcompete native varieties in the environment. However, it was noted that gene-edited algae varieties do not behave differently than wild algae strains, and so the former are not expected to outcompete the latter. In addition to apprehension regarding contamination of wild environments, some questioned whether open-pond systems could be at risk of microbial contamination, which could result in toxicity and subsequent human health impacts if consumed. In response, it was noted that monitoring contamination has proven effective at ensuring safety, though chemical controls may be needed in the future to treat and/or prevent such contamination events.

Evidence-Based Options and Real-World Opportunities

Conversations on algae marketing and communication into the future focused on five key areas. First, it was suggested that the algae community join the USDA Commodity Checkoff Program to increase awareness of algae and expand its market. Second, it was suggested that the Algae Biomass Organization continue to play a strong role in the industry, perhaps serving as a model for other biotechnology sectors to work together with a clear communication objective to shift public perception. Third, to maintain public trust, it was advised that the algae industry establish a code of conduct for engaging influencers. Fourth, innovators in the algae community were encouraged to continue pursuing FDA-qualified health claims. Fifth, it was suggested that a system be developed to regulate false or misleading claims (e.g., whole, clean).

Within the discussion on scalability, production costs and speed to market were noted as the most significant factors. To lower production costs, it was generally agreed that more research and development into improving the overall efficiency of using cellulosic sugars as feedstocks needs to be pursued. Conversely, the opinion was expressed that alternative feedstocks (e.g., methane, carbon dioxide) need to be explored as a means of diversifying algae production systems. To increase speed to market, it was widely agreed that decreasing the length of the regulatory process is particularly important. In response, it was suggested that additional staff and funding resources are needed for the FDA, which could be sourced through user fees paid by applicants to the regulatory process. It was also noted, however, that as the FDA becomes more familiar with algae products, the speed of approval will increase as a result of enhanced understanding.

The debate also included a minor focus on how algae production can be most responsibly applied within the food system. Specifically, given current and anticipated resource constraints, stakeholders were encouraged to work collectively to improve efficiency across multiple industries (e.g., by exchanging waste products as inputs). As an example, it was suggested that algae could be used to process agricultural waste (e.g., wastewater runoff, crop residues). Further, there was support expressed for strategically applying algae systems in ways that build resilience within the food system. As a specific example, it was suggested that algae fermentation systems need to be developed in Brazil given this nation's position as the world's largest sugar producer and its capacity for year-round production.

Curing the Language of the Food 2.0 Era**

Ilan Samish, Ph.D., Founder and CEO, Amai Proteins, Rehovot, Israel

Summary

The global food system is undergoing tectonic changes involving health, economics, sustainability, and scientific advancement. Emerging innovations target major environmental and global health challenges. Following Kuhn's *Structure of Scientific Revolutions*, such innovative solutions are held back by lack of consumer trust and acceptance including: (i) the intrinsic friction between conservative traditional food choices and the disruptive nature of food innovation and (ii) the confusion caused by competitor ads, less successful past innovation attempts, primordial fear of synthetic biology, and consumer groups that oppose innovation. Ensuring that food innovations improve food systems requires an integrated effort of all stakeholders. First, a new lexicon that accurately describes food choices must be agreed upon. Second, following Popper's *Paradox of Tolerance,* a U.S. interagency regulatory framework must provide crystal-clear prescriptive (rather than responsive and narrative-based) national safety guidelines on new food innovation as to the regulatory clearance path and labeling. Third, a non-partisan organization should focus on consumer research and education at all levels so as to not leave the stage to 'fake-news' on the one hand, and to commercial and potentially less consumer-trusted entities on the other. The focus should be translating the language of technological and consumer-beneficial innovation into Rousseau's emotional language rather than solely to the Chomsky's logical 'internal' language lacking the 'external' language aspect. Hence, an array of practically applicable policy adaptations can improve the language in the Food 2.0 Era to help both consumers and the planet enjoy a healthy future through cost-effective food innovation made available via a safe, sustainable, healthy, and trusted process.

Current Realities

The world's leading health challenge of sugar overconsumption is an example of a current reality that did not exist a century ago and must be targeted by disruptive food technology innovation. In 1928, penicillin was discovered by Alexander Fleming, marking a century of curing disease. In parallel with increased longevity attributed to improved treatment of disease, the last century is characterized by

a sharp rise of non-communicable diet- and lifestyle-linked diseases with sugar overconsumption defined by large epidemiological studies as the leading global cause of compromised health. Consequently, an emerging reality formed by consumers, health organizations, and governments consists of pressure to cure the food we eat, rather than the diseases caused by it. For the example of sugar overconsumption, this materializes into sugar-tax and anti-sugar consumer education. In addition to looming health challenges, the lack of sustainable methods to support the food and animal feed of the growing population emphasizes the need for disruptive solutions. Thus, the current reality presents an evolving pressure for sustainable and healthy food with consumer trust as a precondition.

Along with the declining consumer trust toward processed food, these factors result in a market-share decline for the large food and beverage multinationals. Moreover, consumers are often confused by what is perceived as contradicting demands for healthy, cost-effective, sustainable, and disruptive solutions. The evolving paradigm shift in our food system exemplifies a classic scientific revolution defined by Kuhn as "a change that is not a normal development-by-accumulation, but a game-changing earthquake that leads to new paradigms." Intrinsic to such disruption, as observed for genetically modified organisms (GMOs) and other synthetic biology food and beverage solutions, communities often refute these disruptive innovations by poorly reasoned rationalizations; ranging from unsystematic data-driven scientific evidence to pseudo-science and "fake news." The public perception of GMOs, anti-vaccination subgroups, and numerous other examples teach us that language and regulation emerging from academic ("ivory tower") sources need to be articulated carefully for dissemination to less scientifically literate consumers. Such examples illustrate how revolutionary advances can be hampered by a failure to translate scientific understanding and jargon into narratives that consider the perceived emotional perspectives and primordial fears of the public.

Scientifically Credible Approaches and Challenges

Amai Proteins applies Agile-Integrative Computational Protein Design (AI-CPD) and biotechnological production by fermentation to produce proteins that are compatible with the mass food and beverage market. Amai's first product is the sweetest protein in the world. Healthy sweet proteins are found in fruits along the equatorial belt. Yet, their usage is compromised by cost and supply, hampered stability (temperature, acidity, fat milieu), and a lingering taste. AI-CPD enables Amai to circumvent the stability and sensory challenges by designing a protein that is similar to proteins that grow in harsh conditions. These proteins are then produced via fermentation

biotechnology, thereby enabling sustainable and cost-effective production. This is an example of beneficial production by new synthetic biology and biotechnology methods. While fermentation is an old preparatory method underlying wine, bread, and yogurts, there are successful examples of regulatory-authorized fermentation-based protein products, one of the challenges of materializing the health and sustainable potential is consumer acceptance. This includes obtaining regulatory clearance and positive, accurate labeling, both of which are essential components driving the essential consumer trust. Amai is an example of an emerging synthetic biology category of a novel protein sequence produced by heterologous expression fermentation. To the non-scientific consumer, such innovation may elicit primordial fears related to DNA modification using microorganisms as the biotechnology factory. The fear tends to level off once consumers understand that the product is 100% protein produced by yeast fermentation, namely, it is brewed like beer. An additional fear is caused by past safety incidents, mainly associated with small molecules (not protein macromolecules) and substances that enter the body not by eating them. Hence, while Amai's product can help solve the world's leading health concern, it must overcome challenging consumer education due to reasons which are mainly not scientific.

Consumer acceptance is a multidimensional challenge that has been bruised over the years by lack of a common language, natural fear from the unknown, glitches of unsuccessful innovation (or specific batches thereof), negative public relations, biased lobbying, and fake news. In 1754, Jean-Jacques Rousseau claimed that "one does not begin by reasoning, but by feeling…that is why the first languages were singable and passionate before they became simple and methodical." Reflecting this understanding, Noam Chomsky split language into the categories of *internal* (*I*) and *external* (*E*). While I-language is a mentally represented linguistic knowledge of a native speaker, E-language encompasses other notions of what a language is from a body of knowledge to behavioral habits shared by a community. In the era of new media and fake news, consumer education cannot be abandoned to the private commercial media and conspiracy groups. Rather, there is a need to embrace an accurate language that is tailored to a wary consumer audience who follow Kuhn's *Structure of Scientific Revolutions*.

The challenge of successfully translating scientific jargon into language that resonates with the logical and emotional reasoning of the public has been partially addressed in the medical field through the adaptation of hospital-oriented jargon (e.g., from *sickness* and *patient* to *health* and *customer*). In food innovation, language designed to reassure consumers of the safety and benefits (e.g., health and sustainability) of innovative foods and ingredients is needed. With a consumer-

focused mindset, Amai attempts to use jargon that is not associated with fear. For example, Amai's proteins are *designed* rather than *engineered* and contain *substitutions* rather than *mutations.* Further, these are not *recombinant* proteins, but proteins produced by heterologous expression. Despite the fact that they are 100% protein, one of the first questions of consumer brands is whether they are *natural* since AI-CPD was used to alter the protein sequence. Such consumer-education barriers actually slow down the process of embracing consumer-beneficial innovations.

A condition for achieving public trust is the availability of credible, unbiased, clear, and consistent guidelines as to the regulatory process and safety evaluation of innovative foods and ingredients. Answering the clash between disruptive innovation and conservative tradition is not via embracing full tolerance. Rather, Popper's *Paradox of Tolerance* shows that unlimited tolerance leads to the disappearance of tolerance calling for prescriptive credible regulation. The U.S. Food and Drug Administration (FDA) traditionally uses a case-dependent, narrative-based approach to ensure regulatory requirements meet specific food safety needs. The rapidly changing technological developments and shifting cultural priorities that now characterize the public environment make the traditional approach challenging at best. To encompass emerging innovation and maintain consumer trust, a prescriptive, regulatory approach would be more effective. Since the basis for Food 2.0 is increasingly multidisciplinary, regulatory responsibilities can be anticipated to be influenced by a larger number of different stakeholders having distinct perspectives and priorities. Thus, interagency prescriptive guidance may act to stabilize new fields and enhance consumer trust. This may also facilitate better coordination between regulatory agencies with overlapping responsibilities, thus further reducing consumer confusion in understanding safety guidelines.

Evidence-Based Options and Real-World Opportunities:

- Form a consortium comprised of regulators and non-governmental organizations tasked with presenting a dictionary of consumer-accepted language that considers consumers views and psychology, positive and negative. The Academy of Hebrew Language is an example of such an entity used to centrally guide a rejuvenating language.
- Form an interagency group including the FDA, U.S. Department of Agriculture, National Institute of Health, and Environmental Protection Agency aimed at (i) coordinating innovative foods and ingredient regulation, (ii) strengthening consumer trust in the resultant products, and (iii) providing clear prescriptive regulatory-clearance roadmaps.
- Form a nonpartisan organization targeting consumer (regulatory) education

in the following areas: (i) research into consumer trust and perception and the effectivity of consumer education methods, (ii) dissemination of evolving language and regulation, (iii) education of past and present case studies, and (iv) communication on the specific benefits food innovation can present to humanity and to the planet (e.g., The Davidson Institute of Science Education provides a model approach).

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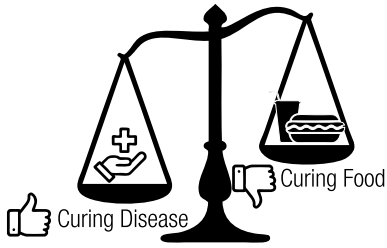
***** A position paper prepared for presentation at the conference on Innovative Foods and Ingredients convened by the Institute on Science for Global Policy (ISGP), with support from the U.S. Food and Drug Administration, on June 23-27, 2019, in Minneapolis, Minnesota, United States.***

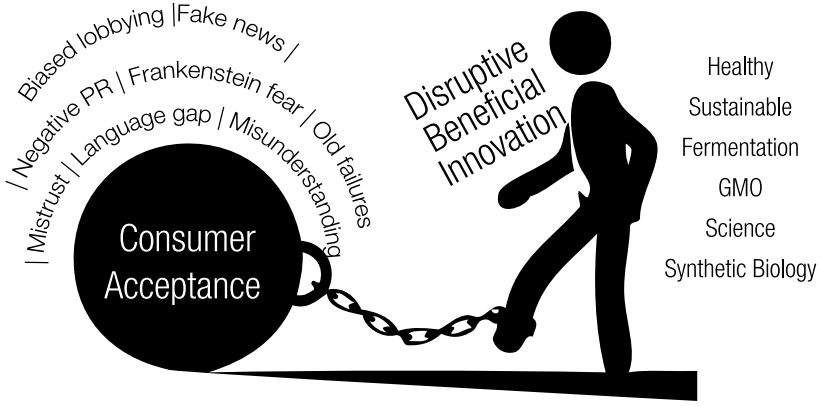
Current state:

Success in curing diseases but not in curing food



The challenge:

Beneficial solutions are held back by lack of consumer acceptance



The solution:

Earning back consumer acceptance via regulation, language and education

Jean-Jacques Rousseau 1754	Why (Philosopher)?	Why (reason)?	By whom?	How to solve?
 Augmenting rational language with lost perception of feeling and emotion	 Noam Chomsky 1986	Focus on internal- and not external language	Regulatory & NGO consortium	External-language rejuvenation
	 Karl Popper 1945	Tolerance paradox	Inter-agency regulatory group	Prescriptive regulatory track to innovation
	 Thomas Kuhn 1962	The structure of scientific revolutions	Non-partisan organization	Consumer perception research & education

Debate Summary

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Current Realities

Throughout the debate, there was general agreement that the procedures by which novel foods are named and described, as well as how consumers are educated regarding the often-unfamiliar products, are critical to building trust in innovative foods and ingredients. It was noted that the use of scientific lexicon or jargon in consumer communication often has led to confusion and fear of novel foods. One example offered was that consumers tend to have a different connotation of the term genetically modified organism (GMO) than the scientific community. Because terms such as GMO may provoke fear or distrust within some consumer circles, it was noted that understanding these fears is critical to improving the terminology for novel foods.

While consumers today are exposed to often-untrustworthy sources (e.g., social media), it was asserted that consumers still prefer to receive information regarding their food choices from reliable and unbiased sources, such as non-partisan organizations. While insights gained from the advertising industry could improve and simplify the technical terminology used to communicate scientific terms to consumers, some noted that instead of developing new research on food terminology, it would be more efficient to tap the existing, robust body of qualitative, empirical research collected over the last 50 years. This research, it was further noted, provides insight for facilitating transformational change regarding how new food products are named and labeled.

While U.S. agencies have differing definitions for terms such as GMO and genetic engineering, it was noted that such inconsistencies in language have the

potential to impact regulatory approaches and communication strategies. Further, there were diverging views regarding the role of regulators in specifying authoritative terminology. Accordingly, some argued that consumer terminology is out of the jurisdiction or purview of regulatory agencies.

When establishing a vocabulary to describe new fermented foods specifically, it was considered useful to understand that decisions concerning the selection of foods for consumption often are based on emotional or personal perspectives. These perspectives reflect the consumers' beliefs or values, which are often influenced or reinforced by advertising. It was noted that marketing and advertising professionals often use storytelling as a strategy to enhance consumer acceptance of novel foods. As an example, a story may be crafted to explain how a particular food product is "natural," which appeals to consumers' beliefs that only natural ingredients are used or that the animal was free-roaming in a natural environment.

Providing information about the qualities of an innovative food or ingredient, it was suggested, may appeal to consumers more than information regarding the technology used to produce it. Amai Proteins, for example, is working to gain consumer acceptance of its fermentation processes. Although *Escherichia coli*-based fermentation could produce products more quickly and consequently cheaper, yeast-based fermentation has been chosen because of the recognition that consumers are more likely to reject foods fermented using *E. coli.*

It was emphasized that governments generally use two strategies for influencing behavior: (i) targeting harmful behaviors and products through prevention efforts and (ii) subsidizing beneficial practices and products. For example, a growing number of countries have instituted policies that place a tax on sugar to reduce overconsumption (e.g., United Kingdom, Chile). While the United States has not implemented a sugar tax, it was noted that some individual states have instituted sugar policies. It was also noted that more discussions regarding methods of influencing behavior are taking place in academia, large and small companies, and non-governmental organizations.

Scientifically Credible Approaches and Challenges

During the debate, it was generally understood that the processes of choosing terminology for food labels and educating consumers are interdependent. Finding the words, phrases, and descriptions that facilitate consumer understanding and acceptance is a key challenge. While it was noted that education is critical for both the scientific community and the consumer population, it was asserted that the messenger is often as important as the message. It was agreed that cultural awareness is essential when developing new food terms and that descriptive labeling needs to

be truthful, avoiding words that may deceive the consumer. Changing a descriptive term to one the consumer does not recognize, solely for the purpose of removing fear, was also considered deceptive. While it was generally agreed that an accurate lexicon is important, properly labeling a food becomes increasingly difficult when certain words, though scientifically correct, may be tethered to past misrepresentations or misunderstandings of those words or phrases (e.g., GMO). It was emphasized that creating a new lexicon to replace well-established terms would not directly address the current misunderstandings, but would merely circumvent the problem. Additionally, it was noted that there is always risk involved with devising new terms since they can have the opposite effect than what was intended (i.e., creating, rather than alleviating, distrust or confusion).

When assessing the creation of a new lexicon for novel foods, it was emphasized that the information deficit model needs to be taken into consideration. The deficit model is premised on the idea that public skepticism towards modern science and technology is caused primarily by a lack of information and can be ameliorated by providing more information. Conversely, it was noted that empirical evidence indicates the information deficit model does not necessarily lead consumers to learn more about a food or product, but instead results in consumer confusion, mistrust, or apathy. For effective communication, it was suggested that academic and business organizations need to work together to disseminate credible information in a format that is understandable for the consumer.

It was generally agreed that in developing a lexicon, focus needs to be placed on changing the consumer's frame of reference, rather than altering language. A suggested approach included conducting consumer research to learn what consumers want and using this information to inform terminology choice. It was mentioned that scientists and regulators are not experts in communication and marketing, and therefore engaging consumers directly regarding a new lexicon could provide insights regarding best practices. To disseminate scientific information most efficiently to bridge the communication gap, it was considered necessary to identify or establish an organization to lead this initiative.

Some noted that building a relevant, tailored body of vocabulary based on consumer research is an effective communication strategy. For example, it was mentioned that consumer research has revealed that substituting descriptors of food products, such as "alternative" or "replacement," with a word such as "option" has been successful in changing consumer perspectives. Benefit-centric terminology can also be successful in creating a message that consumers will accept. However, when used by the scientific community or industry, it was noted that benefit-centric

lexicon can also appear to be hiding the reality of a product, and thus be considered deceptive by consumers. While the public needs information to make informed decisions, it was noted that the challenge lies in providing this information with an emphasis on either the product itself or the product's benefits. This approach provides a transparent message to the consumer.

It was noted that young consumers can be successfully targeted by marketing for new products since this demographic tends to adopt change more easily. Lessons learned from such targeted marketing can inform efforts to engage broad demographics. It was suggested that the food industry could also benefit by including sociologists and psychologists when determining how to better listen to and communicate with consumers.

While reaching consumers in rural areas with new, healthy foods (e.g., products developed through fermentation) was understood to be difficult, it was suggested that a combination of education and regulation is needed to effectively address this challenge. It was agreed that current fermentation technology can be revolutionary with respect to food production, but before the fermentation processes can be scaled up, consumers need to be prepared to accept fermented food products.

Evidence-Based Options and Real-World Opportunities

It was widely acknowledged that when developing a new lexicon for novel foods and ingredients, it is imperative that confusion regarding the meaning of terms be avoided. It was further agreed that to increase consumer acceptance, word choices must invoke a high level of trust and be meaningful to the consumer. It was suggested that regulatory agencies need to take a more prescriptive approach to regulating novel foods and ingredients to help companies garner consumer trust. Research involving focus groups and public polling needs to determine the terminology required to accurately inform consumers about the benefits of novel foods and ingredients. Since regulatory and scientific communities have well-established lexicons, it was suggested that structuring terminology in a way that reflects consumer understanding be undertaken by separate groups focused on public communication. The harmonization of vocabularies and lexicons among regulatory communities, both domestic and international, also needs to be given priority. This effort needs to address the connotations implied by the existing lexicons.

It was strongly suggested that a non-partisan institute undertake the task of researching consumer acceptance, trust, and education regarding the terminology used to describe novel foods and ingredients, primarily with respect to synthetic biology, foods adapted with technology, and genetic engineering. It was noted that not enough is understood regarding effective outreach and information

dissemination strategies describing novel foods and ingredients.

In support of these views, it was generally agreed that more effective consumer education based on transparent information is required to establish public trust in novel foods and ingredients if they are to be successfully introduced into the market. However, there was disagreement regarding the use of social media as a platform for educating consumers. While social media platforms facilitate the sharing of information, ensuring the accuracy of the information remains a matter of great concern. The use of university-based programs on social media could make positive contributions to disseminating accurate information on novel foods and ingredients. Increased government and private sector funding for such university programs is also needed.

Toward a Diversified Protein Future**

Ryan Pandya, Chief Executive Officer, Perfect Day, Berkeley, California

Summary

Global demand for high-quality, animal-sourced protein is expected to rise substantially in the coming decades as population grows and household incomes rise. Simultaneously, climate experts are calling for a rapid transition away from animal-derived foods in an effort to curb greenhouse gas emissions from animal agriculture. There is a global need for innovative solutions to produce quality protein without contributing to the negative environmental impacts associated with industrial animal agriculture.

Current Realities

Currently, the world's highest-quality proteins come from animal products and have been shown to provide important defense against malnutrition and stunting, especially in the developing world. Among animal-sourced proteins, dairy is the most bioavailable in the human diet. Global demand for dairy protein is projected to increase 60% by 2050 as global incomes rise and the population grows to over 9 billion. Unfortunately, many people cannot afford to buy food that contains dairy protein, are unable to consume it because of milk protein allergies or lactose intolerance, or choose to restrict their consumption of dairy products. Additionally, dairy's reliance on animal agriculture poses a serious challenge to sustainability by burdening land and water resources already in high demand.

In light of these realities, many consumers are choosing dairy alternatives derived from plants. However, these products are of a much lower nutritional quality than animal proteins, as indicated by the Protein Digestibility Corrected Amino Acid Score and the Digestible Indispensable Amino Acid Score. In addition, plant-based products do not have the same taste, texture, and functional properties of dairy products. As a result, plant proteins alone are ill-equipped to address the global challenge. There is no obvious solution for consumers who want the nutritional value and sensory experience of dairy without the animal welfare concerns or negative environmental impacts associated with its production.

Scientifically Credible Approaches and Challenges

Advances in biotechnology provide unique opportunities to address current and foreseeable nutrition needs, without the significant environmental and climate impacts caused by animal agriculture. Processes using microflora encoded with genes to produce specific proteins are an important example. *Microflora* refers both to the plants of a specific region, as well as microorganisms collectively. Here, *flora* is a shorthand way to refer to the fungi, yeast, bacteria, and other organisms commonly used to produce ingredients via fermentation.

Of specific commercial interest are the dairy proteins casein and whey, which are produced in microflora by Perfect Day. Microflora are grown in fermentation tanks with a sugar feedstock to produce flora-based protein that is chemically and nutritionally equivalent to its farmed bovine counterpart. The protein is then separated and purified via filtration and dried into a powder. This fermentation process is similar to those widely employed by the food industry to produce ingredients such as vitamins, amino acids, enzymes, and natural flavors. Protein made using this approach enables dairy products to have the same great taste and texture as their conventional counterparts. No hormones or antibiotics are used, and lactose (i.e., milk sugar) is not present. The latter is especially noteworthy in that this technology allows people who are lactose-intolerant—approximately 70% of the world's adult population—to consume flora-based dairy products without digestive issues.

Additionally, microflora can be harnessed to produce high-demand food products with much lower environmental impact based on land and water use, greenhouse gas emissions, and energy consumption. Because the fundamental biology is analogous to protein production in animals, but without the wasteful step of producing live animals and their associated pollutants, flora enable "doing more with less." Further, while farm animal yields have begun to hit diminishing returns, there is rich opportunity for flora to become more efficient with future advances in biotechnology. For example, while currently, the most common fermentation feedstock for microflora is sugar obtained from commodity crops, the industry is developing the ability to use carbon sources that today have no appreciable commercial value (e.g., crop residue). This would render flora-based protein production more sustainable and better adhere to the principles of a circular economy.

As ingredients, flora-based proteins easily fit into the existing production infrastructure and business-to-business supply chain dynamic of the global food industry. This is critical because new technologies can only address the global challenge if they can be proliferated to the same extent as animal-sourced proteins.

An approach based on flora is inherently flexible; in theory, any biological product could be produced at-scale using standard processes and capital equipment, enabling flora to address growing demand across all types of protein. The potential economic opportunities are huge, both in valorizing existing facilities and in establishing new ones to expand global production. Additionally, since fermentation is feasible in any climate or geography, flora can bring protein independence to regions that currently import the majority of their protein. However, renovating and building new infrastructure is costly. Realizing the profound nutritional and environmental benefits of this technology will require global investment from both public and private entities in capital-intensive fermentation and separations capacity.

Evidence-Based Options and Real-World Opportunities

Creating a new category of products requires consumer education. Given increasing consumer skepticism toward food technology, it may be especially difficult for consumers to understand how flora-based products are made and what benefits they provide. Consumers seek transparency from food manufacturers but many are wary of foods developed through genetic engineering, despite rigorous exonerating safety data. The challenge for companies like Perfect Day is twofold: (i) build trust with consumers through transparency about biotech's processes and potential benefits and (ii) compete with existing products in a media zeitgeist that values simplicity and familiarity over scientific fact. A clear description of the protein production process and the safety credentials of biotech foods will help provide safety reassurance. Early research has indicated that, for most people, the benefits of such technologies outweigh the concerns. Still, the constraints of labeling could hurt the consumer appeal of flora-based products and encumber their adoption into the food system.

Clear labeling that accurately informs consumers is essential to communicate the non-animal origin of the protein, while differentiating from plant-sourced proteins. More critically, labeling needs to alert consumers to potential allergen risks. As an example, the well-known allergen risks of milk are shared by flora-based dairy proteins since they are chemically the same as proteins from cow's milk. Thus, it is imperative to clearly label on-package that these products contain a milk allergen, a responsibility that may challenge the regulatory paradigm that prohibits Perfect Day from using the word "milk."

Given the many perceived oxymorons, unique terminology is necessary to describe this new type of protein, its production, and the food products made from it. New terminology must avoid being confusing or misleading and must adequately differentiate fermentation-derived protein from that derived from either plants or animals. The term "plant-based" fails to distinguish the new approach from plants,

while phrases like "synthetic" or "lab-made" are virtually guaranteed to hinder consumer interest in this space. Vague words like "clean" or "green" appear to push a marketing agenda. The ideal terminology would be rooted in science so that it can be adopted in official contexts. As a pioneer in the field, Perfect Day has invested in identifying and assessing a wide variety of potential category names to address these many constraints and has arrived at the term "flora-based." To assess the clarity of this phrase in a fermentation context, Perfect Day commissioned a national survey with adults aged 21-60; 79% of respondents concluded that "flora-based dairy" accurately describes this new type of dairy. When asked how well the phrase "flora-based dairy products" helps them differentiate between this new source of dairy and conventional dairy, 77% said that it differentiates "very well" or "somewhat well."

Perfect Day is pioneering flora-based proteins for use in dairy applications, but it is critical to anticipate a world where similar processes are used to produce different kinds of flora-based food ingredients. The same approach could be used to manufacture fully designed novel proteins, in a transition that would mirror the development of the synthetic materials industry.

There is broad consensus for the need to increase protein production to meet global demand for optimal nutrition without further straining the planet's resources. With support from national and international regulatory bodies, flora-based protein has the potential to help fill the gap. To move toward a diversified protein future, specific actions must be considered:

- For finished products made with fermentation-derived protein from bioengineered microorganisms, develop labeling to allow a simple modifier such as "flora-based" (e.g., flora-based milk, flora-based frozen dessert). There is precedent for labeling food that does not meet the relevant standard by using a modifier to distinguish it from the standardized food (e.g., "yogurt drinks" and "frozen yogurt" are not subject to the standard of identity of "yogurt," and a vegan product may be labeled "mayo" if it bears the term "spread and dressing" to distinguish it from standard mayonnaise). Similarly, U.S. federal courts have held that "almond milk" and "soy milk" are appropriate names for beverages since they have an appropriate modifier to distinguish from "cow's milk."
- Ensure the allergen risks are appropriately communicated in labeling standards and guidelines for foods containing these new proteins.
- Because the proteins developed by Perfect Day are chemically the same as conventional casein and whey, label such products as "non-animal casein" and "non-animal whey protein." Such labeling accurately inform consumers that the casein and whey in flora-based foods are the same as those used in

traditional foods, but are not derived from cow's milk.

- The requirements underlying the current Food and Drug Administration (FDA) Generally Recognized As Safe (GRAS) notification process provide a navigable path to ensure the safety of novel foods and ingredients in the U.S. Adopt a similar process in European markets to lower the barrier for emerging companies.
- Support commercialization of flora-based ingredients through partnerships at the federal, state, and local levels to enhance production capacity. Specifically, investment is needed to construct production facilities at a scale that will enable flora-based products to make a significant contribution to the world's staggeringly large protein industries.

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**** A position paper prepared for presentation at the conference on Innovative Foods and Ingredients convened by the Institute on Science for Global Policy (ISGP), with support from the U.S. Food and Drug Administration, on June 23-27, 2019, in Minneapolis, Minnesota, United States.***

Debate Summary

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Rather, it is, and should be read as, an overview of the areas of agreement and disagreement that emerged from all those participating in the debate.

Current Realities

Fermentation, a process that can be used to produce such end products as milk proteins (e.g., whey, casein) without animals, is a technology that humans have utilized for centuries. It was suggested that the fermentation industry, particularly pertaining to the production of alternative dairy products, is expected to expand significantly because current demand is outstripping supply. While approximately 220,000 metric tons of whey protein are produced annually in North America, it was noted that there remains a shortage of approximately 50,000 tons when considering consumer demand. This supply-demand gap, it was proposed, may create opportunities for investment in advanced fermentation facilities in rural areas of the U.S., which would also create jobs.

Much discussion focused on how to label ingredients generated through the fermentation process. Whey and casein, for instance, are widely considered animal-based ingredients from the consumer perspective. However, with the use of yeast-, fungi-, or bacteria-based fermentation, these ingredients can be produced without animal involvement. Controversy arose regarding the labeling of these new products, with some advocating that the identity of the protein needs to be the focus of labeling, while others suggested that it was more important to identify the process by which the protein was created. Harmonization of labels was considered an important factor influencing the consistency and efficiency of communication to the consumer, while simultaneously minimizing consumer confusion. For example, if different states adopted different labeling requirements, a manufacturer may have to alter its labels to facilitate distribution to different parts of the U.S. It was generally understood as unfeasible to have labeling requirements vary from state to state.

It was generally understood that effective communication regarding food products can be achieved by creating a sense of connection to the land (e.g., a specific geographical region) and/or a cultural tradition. The labeling, therefore, could emphasize a connection through regional and/or cultural indications. It was asserted, however, that some labels could be considered disingenuous, such as images on packaging that erroneously suggest a food product being produced on a local farm. When searching for appropriate and non-misleading terminology in labeling, it was generally considered as essential for effective consumer communication that the U.S. Food and Drug Administration (FDA) standards of identity (i.e., determining factors for what ingredients a product contains and how it is manufactured) are met. Further, it was stated that if a company uses a label that does not comply with

a government standard, the company could imply standardization by creating a "common unusual" name that describes the basic and essential characteristics of the food.

More specifically, it was noted that when ingredients are considered animal-free dairy products, it is crucial to distinguish the differences between this alternative type of milk and traditional milk. The FDA has allergen labeling requirements that mandate the disclosure of milk and other significant allergens. Nonetheless, it was pointed out that no clear labeling for protein allergenicity currently exists. This issue is often significant for many consumers who *believe* they are allergic to lactose in milk, whereas the majority of consumers are *actually* allergic to casein. Throughout the debate, it was noted that producers of innovative products, particularly those involving alternative dairy, must find pathways to consider, navigate, and clearly communicate allergenicity.

While it was emphasized that it may not be necessary to distinguish a new ingredient from the traditional ingredient it is replacing, even when new and old products are chemically identical, the food could be identified for marketing purposes as a new product. It was further noted that, within the process of labeling, companies need to be wary when they pioneer their own terms and differentiate themselves from existing products. Concern was expressed that such invented labeling solidifies a certain image or expectation of a new term, which can potentially harm future uses of the term. It was generally understood that terminology and consumer understanding of newly developed ingredients will evolve over time, and thus it is difficult to predict how new terms will fully impact the future food landscape.

Another topic of concern was the need to safeguard the national bioeconomy (i.e., the production of renewable biological resources). It was emphasized that best practices for this protection already exist to a certain extent within the food system. As an example, existing practices already ensure that production disruptions, such as the introduction of foreign proteins, are detected quickly. Coinciding with maintaining the safety of consumption, it was noted that it is vital to ensure the security, integrity, and quality of business and infrastructure operations while protecting the interests and equities of stakeholders and investors.

Scientifically Credible Approaches and Challenges

A significant portion of the debate focused on the terminology used and/or required for labeling fermented milk proteins. It was generally agreed that appropriate language and lexicon needs to be considered for effective public communication, with priority given to the adoption of phrases that will be immediately comprehensible

for consumers. Furthermore, it was noted that terms like flora, synthetic, and lab-made are unlikely to resonate with consumers. The Perfect Day company presents a labeling terminology challenge in that its product is dairy, but is neither animal- nor plant-based. It was emphasized that consumers will not immediately comprehend new food terms, so it will be necessary to engage consumers in conversations about fermentation technology and why it is being used. It was emphasized that efforts regarding labeling need to be balanced with the reality that many consumers do not read the ingredients list on food packaging.

With new products (e.g., fermented whey and casein), it was generally agreed that there is a challenge in finding ways to alert consumers to the presence or absence of allergens. Since consumers with food allergies (e.g., lactose intolerance) are familiar with allergen labels, there is great difficulty in finding effective ways to communicate seemingly contradictory ingredients, such as the simultaneous presence of milk protein and the absence of lactose.

It was emphasized that it would be counterproductive (i.e., in terms of effectively communicating to build trust with consumers) to use scientific names for innovatively produced dairy proteins (e.g., "whey protein" is more comprehensible to customers than "beta-globulin"). Furthermore, it was considered necessary to create ways to distinguish non-dairy milk protein from other sources of whey protein. It was suggested that a facilitated group discussion among government, industry, and consumer groups would help address these issues, although there are numerous challenges (e.g., time, resources, connections) that bar a small company from spearheading this effort. Such an endeavor could be useful to avoid litigation from consumer groups and individuals concerned with private sector deception of the consumer.

It was mentioned that there is an ever-changing nomenclature used to describe alternative proteins, and accurately describing a product without confusing the consumer is a significant challenge. To minimize these complications, it was considered necessary to pioneer a term for a specific novel product that could be used by all producers. There were diverging views on the term flora, suggested by some to represent yeast, bacteria, and fungi, since it could appear to deceive consumers. Specifically, if yeast, for example, is not present in the product (i.e., if the casein protein is extracted from yeast cells, but the yeast cells are not in the product itself), then the term "flora" could be construed as misleading. If the product is labeled "flora," a consumer expecting a true flora-based milk product with the associated health benefits may lose trust in the product upon discovering that flora are not present.

Another difficulty was emphasized concerning the need to protect company

assets (i.e., intellectual property [IP]). It was expressed that theft and the subsequent sale of IP before a product reaches the market are security breaches that occur frequently. Existing cybersecurity measures are ineffective if a malicious entity has the time, resources, and desire to access a company's proprietary information.

Evidence-Based Options and Real-World Opportunities

It was generally agreed that labeling for innovative foods needs to be clear, transparent, and relatable to consumer understanding. One suggestion was that the government require quick response (QR) codes linked to a website that provides information about the food or ingredient. These QR codes could provide data supporting the equivalence of technologically and non-technologically derived products. A website could be further utilized as a platform for explaining the technology and how it is used to make novel foods. Such a requirement would help a consumer gain trust through education and understanding of specific products. While many companies might elect to use this strategy, there were diverging opinions on the suggestion. It was noted that new labeling strategies need to use simple terms, such as "non-animal whey," and be connected to a web link with detailed descriptions.

The point was raised that companies producing similar products (e.g., alternative dairy proteins) may all adopt a similar terminology for consumers, especially for those with allergen concerns, to provide clarity of product ingredients. As an example of this potential harmonization at the corporate level, it was noted that rather than labeling an ingredient as "milk," it might be differentiated by naming it "milk protein." The concern was raised, however, that this terminology-based differentiation may lead the consumer to believe the products themselves are different, though this is not the case when examining the final chemical composition. Questions also remained as to whether labels and food messaging could be crafted in such a way to recognize and respect value-based concerns. There was general agreement that the value-based concerns of health and environmental benefits associated with a product need to be clearly communicated in a way that is appealing to consumers.

Consumer acceptance, it was generally agreed, will partially rely on reaching a target audience. In the case of fermented dairy products, this target audience was noted to include sports nutritionists and vegans, two audiences demanding different communication strategies. To reach an audience such as sports nutritionists would require the use of a compelling and appropriate story, such as the fact that a product has 40% high branch chain amino acids. It was noted that, contrary to many other consumer groups, the use of a more scientific lexicon was accepted within sports nutrition. Vegan consumers would need to be approached in a different manner,

as their focus is on the absence of animal use. It was noted that vegans are already consuming non-animal-based milk products in large amounts, and thereby provide an example of acceptance of fermentation technology.

Participants noted an opportunity to embrace like-minded coalitions to explore ways to address food system concerns (e.g., environmental, trade, investment). For example, it was suggested that fermentation companies could proactively work with the dairy industry, even though each group has its own goals for sustainability. It was noted that it is worth emphasizing to the dairy industry that fermented milk proteins are a potentially environmentally cleaner alternative to animal-produced protein, while recognizing there will always be a demand for animal production.

It was also unclear how to best classify these milk protein products under international trade agreements. It was stated that a code for a generic category of proteins is currently utilized for international trade, and a subcode could be created specifically for fermented milk proteins. Along with ease of trade, investments from federal funding or other sources are needed to establish additional capacity for the entire industry. This additional capacity could potentially come in the form of new production facilities and other infrastructural developments.

Cost was noted as a major barrier to fermentation products entering the marketplace. However, it was emphasized that costs for fermentation are expected to fall substantially, eventually providing a 30% to 40% advantage over the animal-derived product, even without the aid of subsidies. It was noted that, ultimately, the larger influences of society will determine whether the use of fermentation in the creation of novel foods and ingredients will become widespread.

Safety, Benefits, and Transparency Are Critical to Consumer Acceptance of Innovative Foods**

Gregory Jaffe, J.D., Biotechnology Project Director, Center for Science in the Public Interest, Washington, D.C.

Summary

Innovative foods are in the marketplace and new ones are forthcoming. To obtain consumer acceptance, innovative foods must be safe, they must provide benefits, and there must be transparency. The Food and Drug Administration (FDA), or some similar independent body, must review safety data from the developer and confirm the product's safety. Innovative food developers, and producers and retailers using these ingredients in their products, need to articulate the societal and individual benefits of the technologies they are using and the resulting products containing those ingredients. Traditional on-package and electronic information about innovative foods must be truthful and non-misleading, and it must clearly differentiate the products from foods produced using conventional methods. Without an independent safety determination, an explanation on the benefits of each application, and meaningful transparency, consumers could become suspicious of innovative foods and reject them.

Current Realities

Innovative foods will continue to be part of the food supply. Just as society has become increasingly technological, so has our food. Genetically modified (GM) crops have been grown for over 20 years, and ingredients from those crops are estimated to be present in more than 70% of foods in U.S. supermarkets. The Impossible Burger, with its soy leghemoglobin produced with GM yeast, is sold in over 5,000 restaurants in the United States, Hong Kong, Macau, and Singapore. Two gene-edited crops – a high oleic soybean and an herbicide-resistant canola – are grown by U.S. farmers and made into oils used in food production. On the horizon are products such as food proteins produced in algae with induced mutations or lab-grown meat-free gelatin. In the future, foods produced using multiple technologies will be marketed, making product categorization difficult, and presenting transparency, regulatory, and labeling challenges.

Some consumers express concerns about innovative foods. Although ingredients

from GM crops are widespread in food, they are not acceptable to some consumers. According to the Pew Research Center, 57% of consumers believed GM foods are unsafe, despite the international consensus that GM crops currently grown in the U.S. are indistinguishable from their conventional counterparts. The absence of a mandatory pre-market approval process at the FDA and the lack of transparency about the development and availability of these foods have contributed to acceptance issues for GM foods and could pose similar problems for other new technologies. Consumers are bombarded with inaccurate information in the marketplace and on the internet about alleged hazards of different foods. Similar campaigns may be expected for the next generation of innovative foods.

The current food marketplace contains many differentiated products. Today's food manufacturers differentiate and distinguish their products to satisfy consumer demand for safe, nutritious, sustainably produced food. Products are labeled organic, non-GMO, gluten-free, healthy, simple, natural, and many others. Some product claims are overseen by the government (e.g., organic), some by private certifiers (e.g., Non-GMO Project), while others are indirectly regulated through court cases (e.g., determining when products labeled "natural" are misleading). As technologies enter the marketplace, the government, private certifiers, and courts will determine which products can carry a particular label claim. For example, the Non-GMO Project has prohibited gene-edited foods and ingredients from qualifying for their certification. The National Organic Standards Board voted in 2016 to prohibit gene-editing in organic agriculture, and some organic bodies advocate that crop varieties produced using conventional "mutagenesis" techniques (e.g., using chemicals or irradiation) also be excluded. At the same time, companies producing innovative foods will want to distinguish these foods, arguing to consumers that they provide a nutritional or sustainability benefit that deserves a premium price. The proliferation of product claims likely will bring more consumer confusion rather than clarity, and the lack of clarity will be an impediment for innovative products.

There will be regulatory asymmetry for innovative foods across countries. In most countries, GM foods and ingredients require mandatory pre-market approval before they are grown, sold, and eaten by humans or animals. The regulatory landscape for gene-edited crops varies by country, with some countries exempting certain gene-edited products from oversight and other countries requiring pre-market approval applying GM regulations.

For innovative foods, the regulatory landscape may be unclear. For example, the Impossible Burger completed the FDA Generally Recognized As Safe (GRAS) process and filed a food coloring application. Innovative food oversight will vary by product, process, and country, and international harmonization is unlikely. There

are few proposals for how to rationalize regulatory requirements according to the risk posed by a new ingredient or technology. Unclear regulatory pathways may slow or discourage investment and impact trade, such as requiring segregation from conventional products.

Scientifically Credible Approaches and Challenges

If innovative foods and technologies are to have positive impacts, they must succeed in the marketplace. *To obtain consumer acceptance, innovative foods must be safe, they must provide benefits, and there must be transparency.*

Innovative foods must receive an affirmative safety determination before marketing. The FDA, or some similar independent body, must review safety data from the developer and confirm the product's safety. Given the broad range of innovative foods that have been produced to date and the wide range of possibilities in the future, there will not be a single method for determining safety or a single regulatory process that can be uniformly applied. Yet each product or type of product needs a science- and risk-based evaluation of the risks of both the product, including its ingredients and claims, and its production process before entering the food supply. These evaluations could be done on a product-by-product basis, as is done with GM crops, or carried out for categories of products, as was done for cloned animals. The FDA and similar bodies in other countries need to play an active and independent role in designing, revising, validating, and overseeing those safety determinations.

Once a product is found safe, consumers will embrace it if it is beneficial to them and it reflects their values. Some consumers want foods that are more nutritious, tastier, or have a longer shelf life. Other consumers care that a food was sustainably produced or does not include animal products. Innovative food developers, and producers and retailers using these ingredients in their products, need to articulate the societal and individual benefits of the technologies they are using and the resulting products. This must be done using both traditional (e.g., information on the package) and electronic (e.g., electronic disclosures, social media) methods. If consumers are to embrace innovative foods, they need to understand the reasons for using that technology so they may connect the benefits with the food innovation.

Finally, in today's world—with consumers having access to nearly unlimited amounts of information (some high quality and some not so high quality)—transparency to consumers around innovative foods is essential. That information must be truthful and non-misleading, and it must clearly differentiate the products from foods produced using conventional methods. For example, the Impossible

Burger may use the term "burger" if other information on the package (e.g., words and pictures) makes it clear the product is a plant-based meat substitute. Regulatory agencies must review label information and take necessary actions if the label does not meet legal standards. Without transparency, consumers could become suspicious that innovative ingredients are being hidden from them, resulting in consumer rejection.

Evidence-Based Options and Real-World Opportunities

Innovative foods are in the marketplace and new ones are forthcoming. The following actions by developers, food companies, and regulators are needed for consumer acceptance:

- Developers of innovative foods and ingredients need to use a variety of communication tools (e.g., websites, press releases, QR codes, and package labels) to communicate to consumers: (i) why they developed their products; (ii) who benefits from those products and how; and (iii) where their products can be found in the food supply. Developers also need to make publicly available on their websites their safety evaluation of their products and what standards they used.
- Before products are marketed, developers must meet with stakeholders with different perspectives on innovative foods and establish procedures to consider and address the issues raised, including segregation when necessary.
- The FDA and its international counterparts must understand the technologies being used and their potential applications, meet with different stakeholders to understand their safety concerns with potential products, and then establish the necessary tests, analyses, and production procedures needed to ensure those innovative foods are safe.
- The FDA and its international counterparts must work with food companies and developers to ensure there is a safety evaluation before products enter commerce and that the evaluation is publicly available. Those regulatory agencies must independently approve the food's safety based on that evaluation.
- Marketing information and labeling must explain the differences between the novel food and conventional foods so consumers understand there is a difference and can make an informed choice.
- Regulatory agencies must establish national definitions and standards

(e.g., "organic") so that product claims are uniform and understood by consumers. They must make sure those labeling standards are complied with.

*** A position paper prepared for presentation at the conference on Innovative Foods and Ingredients convened by the Institute on Science for Global Policy (ISGP), with support from the U.S. Food and Drug Administration, on June 23-27, 2019, in Minneapolis, Minnesota, United States.*

Debate Summary

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Current Realities

While it was generally agreed that consumers regularly accept moderate levels of risk when consuming foods and products that are deemed familiar, it was noted that consumers tend to be more cautious when making choices regarding unfamiliar novel or innovative foods. Further, it was suggested that consumer resistance to food innovation is not solely informed by scientific findings or government certification, but often by cultural and religious practices and traditions. A prominent theme was that risks associated with innovative foods need to be minimized to garner consumer support. It was also generally understood that the perceived risk of bringing innovative foods and ingredients to market as it pertains to consumer demand may stifle innovation.

It was generally agreed that there is adequate trust in the U.S. Food and Drug Administration (FDA) and the food safety certifications it directly determines. Because of this, it was consistently expressed that consumers may demand safety

guarantees in the form of government certifications (e.g., organic, rBST-free) on food labels and packaging. It was also stated that consumers are currently uninformed about product supply chains and the processes of producing and developing foods, especially innovative foods, and that labels may be used to address this information gap. While it was asserted that an excess of information about food production will overwhelm consumers, it was generally acknowledged that the public will increasingly demand transparency throughout the entire food production process.

Given the novelty of many innovative foods, the need to standardize language and definitions surrounding food innovation was consistently articulated. Further, the definition of innovative foods was, itself, called into question. It was expressed that language standardization is crucial not only to avoid consumer confusion, but also to ensure that stakeholders within a supply chain can best coordinate and communicate their efforts.

Support was repeatedly expressed for pre-market safety evaluations to establish credibility and consumer trust in products and processes, as long as such evaluations are not so onerous as to reduce innovator participation. By contrast, it was noted that extensive regulatory processes will disproportionately burden small businesses. The collective view was that federal agencies currently lack the resources to conduct mandatory pre-market evaluations for all novel food products in a timely and efficient manner, and therefore mandatory evaluations would hinder innovation.

There was a general concern regarding the extent to which new developers approach the FDA for safety certification. The Generally Recognized as Safe (GRAS) certification was noted as being an inadequate assurance of food safety. It was repeatedly articulated that food developers may abuse the GRAS self-certification's lack of mandatory oversight and introduce foods to market without an independent safety review by the FDA. It was further noted that innovators have experienced difficulty in developing partnerships with larger companies because GRAS self-certification was viewed as insufficient to ensure product safety and more rigorous FDA oversight was preferred. In addition to apprehensions regarding companies notifying for GRAS self-certification, there was also a concern about a lack of consumer confidence in the expertise of GRAS panel members, and concern that the process is not sufficiently transparent to the public. However, questions were also raised regarding the redundancy of a mandatory consultation process since many producers, specifically in the plant biotechnology sector, voluntarily undergo risk assessments through the FDA.

A significant portion of the debate focused on language standardization and the need for labeling harmonization. There was general agreement that consumers are increasingly demanding information about their food choices and the processes

involved in their production. A recurring example of labeling confusion was that of plant-based milks and the use of the word "milk" to describe a non-dairy process and product. While it was noted that most consumers understand that plant-based milks are not dairy milks, it was nevertheless agreed that careful attention to food labeling language is needed to prevent confusion in the future. It was recognized that the use of technology and innovation in food production will continue to grow and, consequently, refined language is needed to distinguish innovative foods from more traditional, familiar foods and ingredients.

It was recognized that an increase in the number of food labels present on the outer packaging of products will eventually become unhelpful, overwhelming, and irrelevant to consumers. Since some existing labels (e.g., non-genetically modified organism (non-GMO)) are not regulated by federal agencies, it was mentioned that consumers may perceive such labels as marketing, rather than informational, tools. Much support was expressed for the creation of a hierarchy of label importance. For example, allergens or certifications relating to cultural significance (e.g., kosher) were viewed as highly important. In contrast, labels referring to the processing of the food item (e.g., carbon footprint, water usage) were seen as valuable but as having the potential to overwhelm and confuse consumers. As food innovation continues to evolve, the language used to describe or make claims about novel foods will need to be carefully monitored to protect consumers and to distinguish marketing from government-certified claims. It was suggested that as Quick Response (QR) codes and online resources allow consumers to learn about the entire supply chain, language standardization and terminology development will also be necessary for communication among manufacturers, producers, distributors, and consumers.

It was widely asserted that consumer trust in products may decrease if the labeling of genetically modified (GM) or gene-edited foods and ingredients is not mandated. However, there were divergent opinions regarding the extent to which GM labels decrease demand. It was also expressed that producers are reticent to label trace amounts of GM ingredients for fear of losing customers due to perceived risks of consuming GM products. It was also mentioned that international discrepancies between label requirements pose challenges to companies using GM products that may be restricted in some countries and not in others. Regardless, it was widely agreed that public education and outreach efforts are needed to address these discrepancies in perception of genetic modification of food items.

Scientifically Credible Approaches and Challenges

It was broadly recognized that increasing consumer confidence in product safety requires altering public perceptions regarding the use of technologies and innovation

to produce food. The collective view was that public education and outreach campaigns necessitate interdisciplinary efforts and must involve federal agencies, the media, academics, and NGOs, among other groups. These institutions, it was agreed, can improve consumer understanding of new technologies by providing science-based descriptions of food production processes (e.g., biofermentation). Regarding product benefits, it was noted that parties engaged in public education campaigns need to differentiate personal benefit from societal benefit of novel products. Novel foods aside, efforts need to be made to better inform consumers about the meaning and justification behind existing labels. For example, it was noted that consumers may choose kosher products, mistaking religious importance as a signifier of health benefits. A discussion on the extent to which innovators have the liberty to make claims about product benefits that are not necessarily certified by FDA or other agencies evoked concerns over the concept of free speech. Despite this point of contention, it was widely agreed that consumers deserve transparency about the meaning of specific certifications.

It was consistently mentioned that consumer research (i.e., polling, surveying) is an increasingly useful tool for understanding consumer perception of specific food modification technologies. Challenges arise, it was noted, in ensuring that such research informs the use of technologies and ingredients throughout the entire food supply system. Nonetheless, consumer research can better prepare innovators in understanding how to proceed with obtaining safety certifications, labeling, and marketing to best accommodate consumer expectations. However, it was widely agreed that there needs to be careful monitoring of the uses of such consumer research. Ultimately, regardless of the plethora of research methods available, it was noted that consumer choice is not always informed by logic and, therefore, the scope of consumer outreach initiatives may still be inadequate to address all concerns that reflect consumer choices.

A concern was expressed that excessive stakeholder engagement may lead to the inclusion of nonscientific information in the FDA decision-making process. Others expressed apprehensions about who comprises the safety evaluation panels convened by the FDA and to what extent such individuals are capable of making nonpartisan, primarily scientifically motivated decisions. Thus, an interest was expressed in improving accountability and transparency in the design of product-approval committees.

Much discussion pertained to the need for premarket testing to create product credibility and to establish product safety (e.g., testing novel proteins for allergens). Broadly, it was agreed that the FDA can execute premarket testing that evaluates the final product rather than the processes by which the product was created. It was

noted that, as novel methods of producing chemically identical end products develop (e.g., beet sugar versus sugar cane), there will be a challenge in communicating product differences without explanations of the processes by which the product was created. It was suggested that the FDA and similar agencies can do more to engage food technology developers to better understand product and process safety and market reception for novel foods.

It was widely acknowledged that the FDA routinely works with developers for this very purpose. Increased mandatory safety regulations were recognized as being unduly and disproportionately burdensome for smaller developers, thereby perpetuating the market success of large corporations. To manage this issue, it was suggested that agencies reexamine methods of communicating the safety of existing regulations (e.g., GRAS certification, voluntary FDA consultation) and place more emphasis on public education and outreach.

Recognizing that more innovative foods continue to enter the marketplace, there was general support for the ongoing refinement of language to distinguish characteristics of various products. For example, since the labeling of almond milk was referenced as being potentially confusing to consumers, there is a need to explicitly define the word "milk." This language and labeling consistency was noted as being important for consumer clarity, but also for consumer protection against possible allergens (e.g., dairy).

Evidence-based Options and Real-world Opportunities

It was generally agreed that consumers will increasingly demand more detailed and nuanced information about food products (i.e., sourcing, processing, transportation, nutritional composition). A pointed facet of this argument was that consumers have a growing curiosity about the environmental impact (i.e., carbon footprint, water usage) of food production. While there was disagreement about the extent to which online platforms need to present this information in lieu of labels, the use of QR codes and online information centers was broadly supported. However, the concern remained that the continued expansion of available information is making it increasingly difficult for consumers to distinguish product information from advertising.

It was specifically expressed that the National Bioengineered Food Disclosure Standard will be instrumental in defining to what extent information is presented on the food label rather than online. Additionally, to bolster transparency, centralize information, and prevent confusion, there was support for the creation of a national registry of all products on the market that would be established and maintained by the government.

The efforts to render these tools more widely accessible and relevant was largely seen as the responsibility of institutions that would undertake extensive community outreach (e.g., meetings, pamphlet/brochure distribution). QR codes and the online designation of information can contribute to these efforts regarding transparency and consumer knowledge by providing real-time information about changes to product safety (e.g., recalls, contaminants). However, it was broadly agreed that the use of QR codes will not replace the inclusion of key information (i.e., nutrition facts, allergens, kosher, halal) on product packaging.

Because of concerns regarding claims about the benefits of certain foods, it was expressed that amendments to the Food, Drug, and Cosmetic Act need to focus on establishing methods for evaluating the validity of claims prior to products entering the market. Specifically, it was asserted that an opportunity exists for the FDA to be more involved in overseeing GRAS determinations to proactively evaluate product safety. More broadly, it was mentioned that the burden of implementing mandatory evaluation could be alleviated by the FDA evaluating products on a case-by-case basis and creating categories with varying levels of regulatory oversight as appropriate. For example, proteins may be subject to different levels of evaluation than sugars. To support this suggestion, the FDA 1992 Statement of Policy, Foods Derived from New Plant Varieties, was referenced. In the instance that food claims are found to be untrue or misleading, it was noted that there is a need for federal protection of those groups working to expose such false claims.

To address concerns about inadequate government funding and staffing, support was expressed for the implementation of user fees in the event that a mandatory evaluation process is implemented. Additionally, it was suggested that *ad hoc* coalitions comprised of consumers, citizens, and industry members be established to garner further support of these FDA regulatory initiatives and to support the FDA in staying apprised of evolving technologies and products. The strongest area of agreement articulated a need for national standards for future and existing labels and that these definitions be monitored and established by federal agencies rather than independent or private entities (e.g., The Non-GMO Project).

Licensing Innovative Food Additives and Ingredients by FDA**

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Summary

The current system for ensuring the safety of innovative food additives and ingredients was developed by Congress in 1958. It is inadequate in today's marketplace where supply chains are more complex, dynamic, and global, and our understanding of health risks has greatly advanced. The food supply is at risk for allowing unsafe substances to threaten serious long-term health effects as long as the Food and Drug Administration (FDA) allows companies to self-certify that a substance's use is Generally Recognized As Safe (GRAS*) without the agency's or the public's knowledge. Rather than embracing innovation, consumers increasingly recognize the risk, and most see substances added to food as their most important food-safety issue. Congress needs to modernize the mechanisms that ensure safety in a way that supports innovators who develop safe substances through a process that consumers can trust. To be successful, the dynamic needs to change from a race to the bottom with respect to safety research to one which strongly incentivizes companies to invest in robust safety studies by protecting them from "copycat" competitors who rely on the innovator's research and granting a longer license from FDA when the evidence is compelling.

Current Realities

In 1958, Congress created a groundbreaking system intended to ensure the safety of food additives, (which includes food ingredients) by requiring the FDA's pre-market approval of a substance's use unless it was GRAS or was covered by another approval process (e.g., pesticides and color additives). New substances and uses were presumed unsafe unless "there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use" (21 CFR §170.3). When the law was passed, it generally worked because food processing was regional, the scientific understanding of safety was more limited, and the FDA could move quickly through a rulemaking process.

Today's reality is fundamentally different: innovative food ingredients dominate the marketplace; supply chains are more complex, dynamic, and global; and the scientific understanding of the impact of chemicals on human health has greatly advanced. Innovators, in a rush to get their products to the marketplace, are likely to bypass FDA review and self-certify a substance's use as GRAS to avoid risk of delays and uncertainties. As a result, unsafe products that threaten consumers' health enter the food supply without the FDA's or public's knowledge. The public recognizes the risk: In a 2019 survey, 50% of consumers rated substances added to food (i.e., chemicals in food, carcinogens in food, food additives and ingredients, allergens, and biotechnology products) as their most important food safety issue.

Figure 1 describes the two paths to market for companies producing innovative food ingredients pursuant to the Food Additives Amendment of 1958 to the Federal Food, Drug, and Cosmetic Act. Once a food's use is allowed by either path, there is no effective and systematic reassessment of its safety, even when questions are raised. The two paths are:

- For a food additive petition, a company can secure the FDA's pre-market approval by filing a petition pursuant to 21 CFR Part 171 asking the agency to issue a regulation expressly approving a substance's use. The substance may not be used until the process is completed, which typically takes more than a year and often involves many iterations. Once the FDA approves the product, competitors can develop "copycat" products without seeking agency approval if the specifications and manufacturing process are equivalent.
- For self-certified GRAS, the FDA allows a company to make its own determination that a substance's use is safe and that its safety is considered GRAS by "competent experts" pursuant to 21 CFR Part 170. The company may market and use the substance immediately based on its self-certification of GRAS status. To improve the substance's marketability to food manufacturers and retailers, a company may voluntarily seek to have the FDA review the decision. Competitors may rely on the notice to develop and self-certify copycat products without seeking agency concurrence.

Due to delays and uncertainties in marketing and using a substance in food, innovators rarely use the food additive petition path today. Almost all companies choose to self-certify a substance's use as GRAS. However, the GRAS program has come under intense criticism from the U.S. Government Accountability Office and public health advocates, including the American Academy of Pediatrics. The main concerns are: (i) conflicts of interest when a company makes a safety determination, especially when it does not voluntarily seek FDA review of the decision; and (ii) lack

of transparency, which makes it impossible for the FDA and companies to ensure a substance's use is safe. Transparency is critical because no one can adequately consider, as required by law, the "cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substance or substances in such diet" when the precise identities of ingredients and their uses in food are not publicly known.

Scientifically Credible Approaches and Challenges

The self-certified GRAS program has created a "race to the bottom" when it comes to the quality and quantity of evidence needed to conduct a safety evaluation. To get their innovative substances to the market as soon as possible, companies have strong incentives to do only the minimum to assess a substance's safety. The threat of legal liability, consumer backlash, and FDA intervention are often too intangible to offset the benefits of conducting the minimal amount of research needed to pass muster. For its part, the agency has strived to set high standards but slipped to avoid discouraging companies from submitting voluntary notifications. This shift is evidenced by: (i) the failure to consistently consider all pharmacologically-related substances in the diet; and (ii) lack of a rigorous evaluation of substances using the agency's guidance on recommended toxicology studies that are based on the amount expected in the food supply.

A credible framework to begin to address the concerns is the FDA's Food Contact Substance Notification (FCN) program established by Congress in 1997. Companies making innovative food contact substances for food packaging and handling equipment submit a notification to the same office that handles food ingredients. If the agency does not object within 120 days, the notice is deemed "effective." The FDA has consistently made timely decisions, although about 20% of the notices are withdrawn to avoid an objection. A company with an effective FCN essentially receives a "license" from the agency, which is critical because, unlike food additive petitions and GRAS determinations, competitors with copycat substances must either pursue their own license or make a self-certified GRAS determination.

Any approach must recognize that scientific knowledge evolves and so does our understanding of risk. Therefore, any system to ensure innovative food ingredients are safe requires periodic reassessment as new evidence emerges. Unfortunately, the FDA lacks any effective means to know what chemicals are actually used and in what quantities, and the agency typically intervenes only when the evidence is compelling or when it is forced to by public attention. As a result, harm that develops over time and is not obviously connected to a substance may go unaddressed. The best example is trans fatty acids in partially hydrogenated oils (PHOs). In 2015, FDA

ruled the use of PHOs was no longer GRAS in response to a 1994 petition from the Center for Science in the Public Interest, a lawsuit from an academic researcher, and two Institute of Medicine panels citing serious risks. The agency estimates these substances contribute to as many as 58,000 cases of coronary heart disease and 23,000 deaths per year.

Evidence-based options and real-world opportunities

The objective should be a system that ensures ingredients are safe and is robust and credible enough that consumers can embrace innovative food ingredients for their potential sustainability benefits. While mandated FDA safety review and approval and improved transparency of that process are essential changes needed, they are unlikely to be sufficient on their own. The system needs to incentivize innovators to conduct the research necessary to ensure their products are safe—to move from a race to the bottom to a system in which new data and scientific evidence are valued. Two key incentives are: (i) protection from copycat competitors who rely on the innovator's research to demonstrate safety and more quickly reach the market; and (ii) a longer license from FDA when the evidence is robust to reduce the uncertainties around license renewals and convey FDA's confidence in the substance's safety to food manufacturers.

To achieve this objective, Congress needs to substantially revise the framework it established in 1958 and build on—and improve upon—the FCN approach it created in 1997. The changes would only be prospective in order to address the challenge of innovative food ingredients. While it is critical to address the legacy of the thousands of substances already allowed in food, a framework moving forward for new substances is an important first step.

Figure 1 describes the new process and compares it to the current approach. Congress should:

- Eliminate GRAS for new substances so FDA review and approval is needed for all innovative food ingredients. FDA review will level the playing field among competitors and build credibility and transparency with the public.
- Expand the FCN process to include innovative food ingredients and make it a true license granted by FDA. The agency would vary the license from 3–10 years, based on the quantity and quality of the toxicology and exposure evidence. Competitors would need to pursue their own license for their copycat products and must secure the approval of the company that funded any pivotal research conducted in the past three years on which they rely.
- Improve the information in the notice so it is more transparent and useful to FDA, food manufacturers, and the public. The notice would have to:

(i) identify all chemically and pharmacologically related substances in the diet; (ii) identify and evaluate all relevant health, safety, or exposure studies; and (iii) indicate which studies published in the past three years are pivotal while documenting that the notifier has secured approval to reference the study from the company that funded the research.

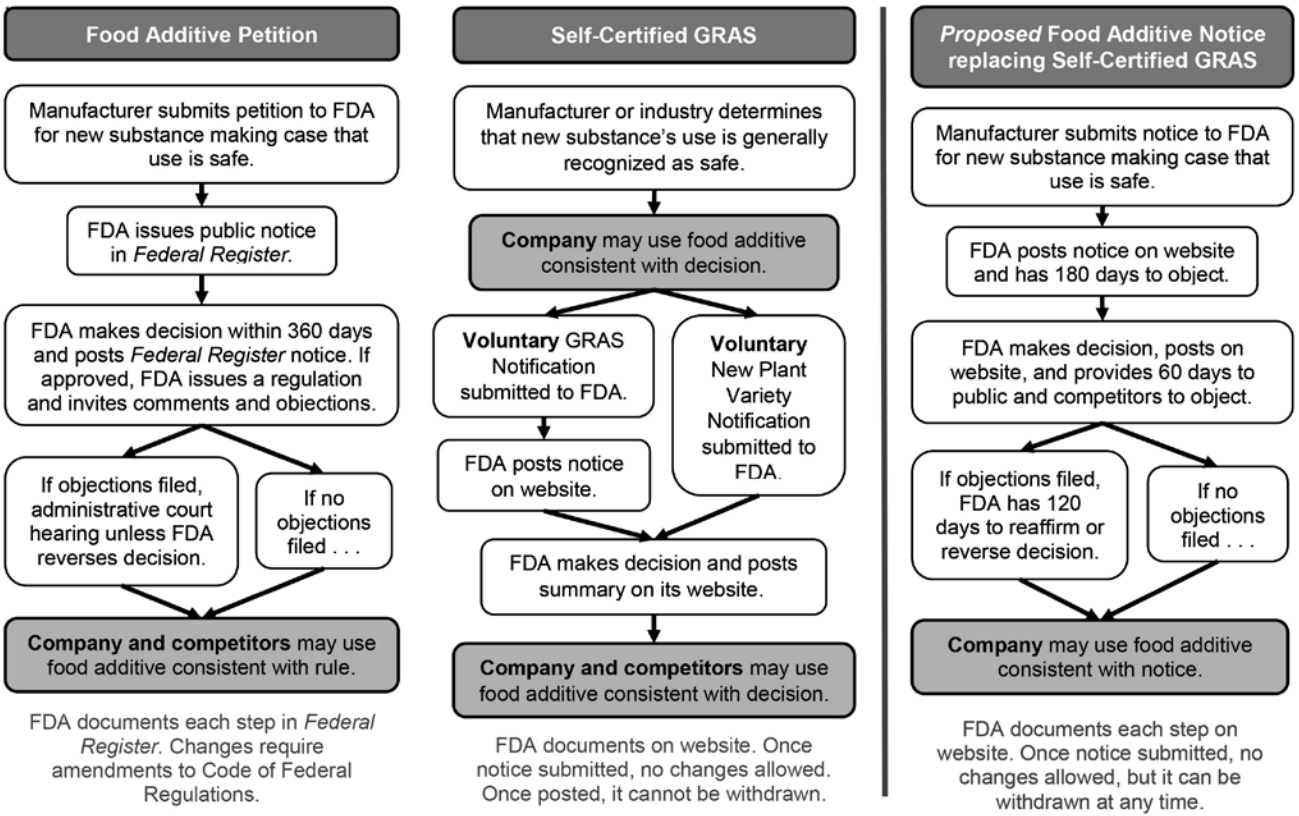
- Enhance the transparency and credibility of the review process by: (i) ensuring FDA has sufficient resources through application fees and other funding to enable the agency to conduct a thorough review in a timely manner; (ii) allowing 180 days instead of 120 days for the FDA to complete the review since it is likely to be more complex than food contact substances; (iii) directing the FDA to post receipt of the notice and, when the decision is made, both the notice and the decision on its website; (iv) providing the public and competitors a 60-day opportunity to file objections to the notice based on safety concerns or reliance on a pivotal study published in the previous three years without approval; and (v) if an objection is filed, giving the FDA 120 days to publish a decision regarding the objection.
- Authorize the FDA to require periodic reporting by licensees so the agency can identify issues.

Reference

International Food Information Council, 2019 Food and Health Survey, May 22, 2019, http://foodinsight.org/thanks-for-your-interest-in-the-ific-2019-food-health-survey.

***** A position paper prepared for presentation at the conference on Innovative Foods and Ingredients convened by the Institute on Science for Global Policy (ISGP), with support from the U.S. Food and Drug Administration, on June 23-27, 2019, in Minneapolis, Minnesota, United States.***

Figure 1.
Subsequent graphics illustrate two existing paths to market for innovative food additives and ingredients and proposed replacement for self-certified GRAS



Debate Summary

This not-for-attribution Debate Summary was prepared by the ISGP staff from the audio recording, and its transcription, of the debate of the position paper prepared by Mr. Neltner (see above). Mr. Neltner initiated the debate with a 5-minute statement of his views and then actively engaged the conference participants, including other authors, throughout the remainder of the 90-minute period. This Debate Summary represents the ISGP's best effort to accurately capture the comments offered and questions posed by all participants, as well as those responses made by Mr. Neltner and other participants. Given the not-for-attribution format of the debate, the views comprising this summary do not necessarily represent the views of Mr. Neltner, as evidenced by his position paper. Rather, it is, and should be read as, an overview of the areas of agreement and disagreement that emerged from all those participating in the debate.

Current Realities

Over the past few years, a consolidation among major food and agricultural companies has been observed. It was suggested that such mergers have resulted in large entities bringing fewer innovations into the food system and, as a result, major food and agriculture companies now depend on small and medium enterprises (SMEs) for innovative solutions. This was generally viewed as significant because innovation is needed to address emerging environmental and human health challenges while, in parallel, maintaining food safety.

Significant disagreement arose concerning whether the current regulatory system is effective in ensuring food safety, especially with respect to the U.S. Food and Drug Administration's (FDA) Generally Recognized as Safe (GRAS) program. Specifically, it was suggested that the GRAS program may, if irresponsibly exploited, result in unsafe foods and ingredients reaching the market for human consumption. As an example, it was noted that users of the GRAS process have notified the FDA and received feedback identifying negative effects on human health (e.g., a given product demonstrated endocrine disruption or allergen risk). Despite the FDA's indication of potential health risks, GRAS self-certification has permitted such products to reach the market. It was also noted that FDA notification of self-certification is not required by the GRAS process, and thus it is impossible to be certain how many products on the market have been self-certified without submission to the FDA. Furthermore, despite the 1958 mandate requiring the FDA to consider the cumulative effect of chemically and pharmacologically related substances in the context of a full human diet when making a GRAS determination, neither of these factors is being addressed

uniformly in the GRAS evaluation process. While it was observed that the FDA has provided guidance on recommended studies since 1982, apparently few companies follow or acknowledge such guidance in GRAS submissions. Further, it was observed that while companies are not required to submit a GRAS notification, they are also disincentivized to do so given that the dossiers become available online, opening them up to exploitation by competitors who can copy their data.

There was some disagreement that the food system itself is at risk from loopholes within the GRAS process, as well as concern that GRAS itself could be seen as a loophole to regulation. It was noted that most consumer-packaged goods (CPG) companies require innovators to submit a GRAS notification for any ingredient used in their products, thereby assuring that the FDA has the needed information to monitor and ensure food safety. If all companies participated in this practice, it was suggested that concern regarding effective oversight of the food system would be significantly diminished. Indeed, it was emphasized that notification-requiring companies are concerned that other companies will not demonstrate the same level of integrity and transparency, which could result in an overall negative impact on public perception.

The topic of public perception was a central theme in other respects. The position paper suggested that 50% of consumers rated substances added to food (i.e., chemicals in food, carcinogens in food, food additives and ingredients, allergens, biotechnology products) as their most important food safety issue. This assertion was challenged by recognizing that the data reported by the International Food Information Council for these categories of food additives were combined to achieve the final percentage. In addition to food safety, it was noted that it has become increasingly important for consumers to understand the environmental impact of the food they consume. However, many observed that there is not a standard mechanism for consumers to obtain such information.

Within the context of these divergent opinions, the pervading theme of the debate centered on the position paper's proposal of a new regulatory system that eliminates GRAS for all new foods and ingredients moving forward. It was suggested that eliminating GRAS and instituting a new mandatory review process would provide the needed preventive policy approach to food safety, as compared to the current system, which was noted as being reactive to food safety concerns.

Scientifically Credible Approaches and Challenges

Most attention centered on understanding the exact details of the Environmental Defense Fund (EDF) proposal to eliminate the GRAS program and implement a new, mandatory review process. It was repeatedly noted that the EDF views the GRAS

program as contrary to existing law and, as a result, EDF has challenged it in court. Although many were not in support of the EDF proposal and expressed significant concern and hesitancy with regard to its impact on innovation and competition, there was interest expressed in exploring ways the GRAS process might be improved through the collective efforts of all present stakeholders (private sector entities, public advocacy and not-for-profit organizations, subject-matter experts, government regulators; see "Participant Landscape") to identify alternative approaches.

In clarifying the EDF proposal, it was noted that existing GRAS determinations would be maintained, and that the new procedure would apply to all new products following its implementation. It was also noted that products that are substantially equivalent to those with existing GRAS determinations would qualify under those same determinations. Moving forward, it was suggested that applications for approval would remain confidential until a product is approved, at which point both the notice and the decision would be published online and open for public comment. It was not clarified whether the notice would be redacted. Once a product is approved within the 180-day deadline, the food or ingredient would be reassessed every 3 to 10 years, depending on what the product is and how well its safety is understood. Approved applicants would be granted a time-limited license preventing other competitors from using the data in their applications.

Many were concerned that the EDF proposal to eliminate GRAS would potentially have negative impacts on competition and stifle innovation. Many were also apprehensive that small businesses and public research institutions would be prevented from entering the market due to regulatory burden, increased cost, and time to market, as well as inability to use data from prior, related applications. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was noted as an example in which the implementation of a similar program led to consolidation within the agrichemical industry. The pharmaceutical industry, and specifically the high cost of medicine, was also noted as a key example of potential negative outcomes if the EDF proposal was implemented.

In response to such concerns, it was suggested that food licensure fees would be less burdensome as compared with the pharmaceutical industry, perhaps thousands, rather than millions, of dollars. In addition, it was suggested that the successes and failures of FIFRA can serve as a guideline to help create more balanced regulation. The Department of Justice could also play a role by enforcing antitrust laws should a concern arise. However, little faith in the enforcement of antitrust laws was expressed. Despite some disagreement with regard to the need for new regulation and the degree to which the EDF proposal would impact competition, it was generally agreed that measures need to be taken to ensure an economically

competitive environment which encourages innovation.

There was broad agreement regarding the need to assess the FDA's ability to effectively implement the proposed changes, given the concern of impracticality based on current staffing and funding constraints. Specifically, there was apprehension regarding the increased volume of new applications, as well as the need to periodically reevaluate previously approved products. While it was suggested that a user fee would help expand resources at the FDA to adapt to such increasing responsibilities, there were a number of proposed solutions to further streamline the process. First, it was proposed that the new system could allow for continual innovation by implementing a truncated process for expanded uses under a former license. It was also suggested that the EDF process incorporate standard elements of risk assessment, including human exposure, for products such as flavors and processing aids, and adjust the regulatory requirements accordingly. The European approach to reevaluating E-numbers (i.e., codes used to identify permitted food additives) in groups according to a tiered risk assessment was noted as a potential model for streamlining the regulatory process in a manner consistent with food safety.

Several questioned whether the EDF proposal to eliminate the GRAS program and implement a new, mandatory review process could bring the United States closer to regulatory harmony with foreign entities, such as the European Food Safety Authority. It was clarified that certain parts of the proposal resemble regulations in other countries, though others do not. Additional details on targeting and achieving regulatory harmony were left open to future debate. However, it was noted that reassessment of product safety over time is an effective means of ensuring that food regulation is agile in adapting to continuously evolving scientific understanding of health and nutrition, and it was further suggested that other countries and international regulatory structures could build upon this practice.

Some discussion focused on the potential to expand the role of the FDA in regulating food. There were suggestions that there may be a role for FDA in assessing environmental impacts of new products, despite its current focus on food safety. Nonetheless, there was concern that the FDA would not have the capacity to expand into environmental life-cycle analysis and that food safety needs to continue as its primary role. It was stated that the EDF proposal would, however, fill several regulatory gaps that exist within the current GRAS certification process by including a mandatory assessment of the cumulative chemical and pharmacological traits of products in the context of a full human diet, as well as exposure throughout the supply system.

Significant attention was given to the likelihood of building political will in

Congress to change the GRAS certification system. Without the occurrence of a high-profile disaster (e.g., foodborne illness outbreak), some did not envision members of Congress perceiving a need to change GRAS. In response, it was stated that an Institute on Science for Global Policy (ISGP) conference of diverse stakeholders could focus on identifying an iteration of the EDF proposal. With broader stakeholders (e.g., farmers, a wider range of consumer groups), such an ISGP conference could provide a pathway toward legislative adaptation. Without Congressional action, it was noted that the removal and/or replacement of the GRAS system likely will be pursued in court by parties that feel such action is necessary (e.g., EDF).

With regard to public perception, there was an interest in understanding how the EDF proposal would affect public views on the safety of the food supply and the adequacy of the regulatory system. While some agreed that the proposed legislation could be used to inspire public trust, others thought that a lawsuit would only serve to further undermine confidence in the food supply. Recent updates via the Food Safety Modernization Act were noted as examples in which public trust was not improved despite implementation of more rigorous policy. However, this point was disputed.

There was also a minor discussion focused on the usefulness of opening approvals for public input. Some felt that creating space for public commentary is necessary for building trust in the FDA and an important forum for raising scientific concerns that would not otherwise be addressed or monitored by the private sector and/or government regulators. Others doubted its effectiveness in contributing to FDA decisions regarding food safety given that FDA's assessments are focused on scientific evidence and comments are often not science-based.

Evidence-Based Options and Real-World Opportunities

In general, there was significant doubt that the political will required to implement the EDF's proposal could be achieved in Congress without a high-profile disaster to inspire it. However, it was noted that several cases of stakeholders working together to push legislation through Congress have proven effective in reforming policy. As an example, it was suggested that the success of the environmental groups and the wood products industry establishing new policy on formaldehyde use in wood products could be used as a model for the implementation of EDF's proposal.

To succeed, it was widely agreed that the EDF will need to develop a similar multi-stakeholder coalition, including members of the private sector, nonprofit, academic, and governmental communities. In addition to these stakeholders, the importance of engaging farmers, venture capitalists, and small companies in the process of further developing the proposal was widely emphasized. There was also

significant interest expressed in bringing such stakeholders together to establish ongoing discussions to identify and proactively address concerns from all parties with regard to food safety and innovation broadly.

To address public perception concerning innovation of foods and their safety, several potential avenues were considered. It was suggested that nonprofit organizations need to be more vocal about the role of food innovation in promoting economic prosperity, environmental sustainability, and improving human health. Specifically, it was suggested that consumer groups (e.g., EDF) engage in public comment periods as advocates for the safety and benefits of innovative foods and ingredients, where appropriate. It was also noted that consumer perception could be improved by the FDA opining on safety to the public, which is not currently possible given that products can enter the market without the FDA's knowledge or approval. Since the EDF proposal to replace GRAS ensures that all products undergo a regulatory approval process, the FDA would only know what is available to consumers but also will have more data to evaluate the safety of products. It was also suggested that having products evaluated through a mandatory review process benefits companies since the review could be leveraged to advertise food safety.

Acknowledgment

Numerous individuals and organizations have made important contributions to the Institute on Science for Global Policy (ISGP) as it organized the Innovative Foods and Ingredients (IFI) program under the sponsorship of the U.S. Food and Drug Administration (FDA). The IFI conference that highlighted this program was convened June 23-27, 2019, in Minneapolis. Minnesota. Other contributions aided the ISGP in preparing the material presented in this book, including the eight position papers prepared by invited subject-matter experts and the not-for-attribution summaries of the views presented in the discussions, critical debates, and caucuses that ensued.

The ISGP greatly appreciates the willingness of those in the scientific, public advocacy, and private sector communities who agreed to be interviewed by the ISGP staff in their efforts to prepare and organize the content of this IFI conference. Of special significance were the efforts of those invited by the ISGP to present their views of food and ingredient innovations and the impact of the emerging novel foods and ingredients on consumer choices. Their willingness to engage regulators, policy makers, scientists, and private sector stakeholders in the vigorous debates and caucuses that comprise all ISGP conferences was especially noteworthy and appreciated. The biographies of these eight authors of the position papers used in the debates are provided in this ISGP book.

The success of every ISGP conference critically depends on the active engagement of all invited participants in the often-intense debates and probing caucuses. The exchange of strongly held views, innovative proposals, and critiques generated from comments and questions throughout the debates and informal sessions fosters an unusual, and even unique, environment focused on clarifying understanding for both the specialist and non-specialist. These debates and caucuses address specific questions related to formulating and implementing effective public and private sector policies that span regulatory, public messaging, and wide range of business decisions. The ISGP is greatly indebted to all those who participated in these not-for-attribution (Chatham House Rule) debates and caucuses.

The members of the ISGP Board of Directors also deserve recognition for their time and efforts in helping to create a viable, increasingly relevant not-for-profit organization focused on addressing many of the most important scientific, technological and societal questions of our time. Their brief biographical

backgrounds are presented in this book.

The energetic, highly professional interviewing, organizing, and writing skills of the ISGP staff were essential to not only organizing and structuring the conference itself, but also to recording the often-diverse views and perspectives expressed in the critical debates, accurately capturing the evidence-based options and real-world opportunities from the caucuses, and persevering through the extensive editing process needed to assure the accuracy of the material published here. Their biographies are provided in this book.

In general, ISGP receives financial support from U.S. government agencies and departments and from unrestricted gifts and donation from private-sector entities and philanthropic organizations and individuals. In the specific case of the IFI program and conference, financial support was provided by an FDA contract channeled through the Institute on Food Safety and Health at Illinois Institute of Technology.

Dr. George H. Atkinson
Founder and Executive Director
Institute on Science for Global Policy
July 28, 2019

ISGP books from ISGP conferences listed below are available to the public without charge and can be downloaded from the ISGP Web site: www.scienceforglobalpolicy.org. Hardcopies of these books are available by contacting info@scienceforglobalpolicy.org.

ISGP Signature Conferences (ISC) conferences and books:

Emerging and Persistent Infectious Diseases (EPID):

- *Focus on Antimicrobial Resistance,* convened March 19–22, 2013, in Houston, Texas, U.S., in partnership with the Baylor College of Medicine.
- *21st Century Borders/Synthetic Biology: Focus on Responsibility and Governance*, convened December 4–7, 2012, in Tucson, Arizona, U.S., in partnership with the University of Arizona.
- *Focus on Societal and Economic Context*, convened July 8–11, 2012, in Fairfax, Virginia, U.S., in partnership with George Mason University.
- *Focus on Mitigation*, convened October 23–26, 2011, in Edinburgh, Scotland, U.K., in partnership with the University of Edinburgh.
- *Focus on Prevention*, convened June 5–8, 2011, in San Diego, California, U.S.

- *Focus on Surveillance*, convened October 17–20, 2010, in Warrenton, Virginia, U.S.
- *Global Perspectives*, convened December 6–9, 2009, in Tucson, Arizona, U.S., in partnership with the University of Arizona.

Food Safety, Security, and Defense (FSSD):

- *Equitable, Sustainable, and Healthy Food Environments*, convened May 1–4, 2016 in Vancouver, British Columbia, Canada, in partnership with Simon Fraser University.
- *Food Security and Diet-linked Public Health Challenges*, convened September 20–23, 2015 in Fargo, North Dakota, in partnership with North Dakota State University.
- *Focus on Food and the Environment*, convened October 5–8, 2014, in Ithaca, New York, in partnership with Cornell University.
- *Focus on Food and Water,* convened October 14–18, 2013, in Lincoln, Nebraska, U.S., in partnership with the University of Nebraska–Lincoln.
- *Focus on Innovations and Technologies,* convened April 14–17, 2013, in Verona, Italy.
- *Global Perspectives,* convened October 24, 2012, in Arlington, Virginia, U.S., in partnership with George Mason University.

ISGP Global Challenges (IGC) conferences and books:

ISGP Climate Change Program (ICCP)

- *The Shore's Future: Living with Storms & Sea Level Rise*, convened November 20–21, 2015, in Toms River, New Jersey, in cooperation with the Toms River Working Group, Barnegat Bay Partnership, Barnegat Bay Foundation, and the Jay and Linda Grunin Foundation.
- *Sea Level Rise: What's Our Next Move?*, convened October 2–3, 2015, in St. Petersburg, Florida, in cooperation with the St. Petersburg Working Group.

ISGP Climate Change Arctic Program (ICCAP)

- *Sustainability Challenges: Coping with Less Water and Energy,* convened June 5, 2015, in Whittier, California, in cooperation with the Whittier Working Group.
- *Living with Less Water*, convened February 20–21, 2015, in Tucson Arizona, in cooperation with the Tucson Working Group.

ISGP Academic Partnerships (IAP) conferences and books:

- *Socioeconomic Contexts of Sustainable Agriculture,* convened October 14–15, 2016, in Danbury, Connecticut, in partnership with Western Connecticut State University.
- *Water and Fire: Impacts of Climate Change*, convened April 10–11, 2016, in Sacramento, California, in partnership with California State University.
- *Communicating Science for Policy*, convened August 10–11, 2015, in Durham, North Carolina, in partnership with Sigma Xi, The Scientific Research Society.
- *Food Security: Production and Sustainability*, convened April 24–25, 2015, in St. Petersburg, Florida, in partnership with Sigma Xi, The Scientific Research Society, and Eckerd College.
- *Safeguarding the American Food* Supply, convened April 10–11, 2015, in Collegeville, Pennsylvania, in partnership with Sigma Xi, The Scientific Research Society, and Ursinus College.
- *Focus on Pandemic Preparedness,* convened April 11–12, 2014, in Collegeville, Pennsylvania, U.S., in partnership with Ursinus College.

ISGP Science and Governance (S&G) conferences and books:

- *Climate Impact on National Security (CINS–1, CINS–2A, CINS–2B),* convened November 28–December 1, 2016, April 3–4, 2017, and May 17–19, 2017 in partnership with the U.S. Army War College in Carlisle, Pennsylvania.
- *The Genomic Revolution,* convened September 6, 2014, in cooperation with the Parliamentary Office on Science and Technology of the British Parliament within the House of Lords. London, United Kingdom.

Biographical information of Presenters

Algae Biomass Organization

The Algae Biomass Organization (ABO) is a not-for-profit organization with a mission to promote the development of viable commercial markets for renewable and sustainable commodities derived from algae.

Presenter: ***Jill Kauffman Johnson, Board Vice Chair, Algae Biomass Organization (ABO)***

Ms. Kauffman Johnson also is Head of Global Market Development, Algae Ingredients, at Corbion, a Netherlands-based global leader in food and bio-based ingredients. Prior to joining Corbion, she was a Principal and Managing Director of California Environmental Associates (CEA), a consulting firm working at the intersection of policy, philanthropy, and the private sector to address some of today's most serious environmental challenges.

Amai Proteins

Amai Proteins is a designer protein company working, as a first focus, to devise sugar substitutes by redesigning sweet proteins found in the equatorial belt. Amai applies Agile Integrative Computational Protein Design (AI-CPD) and fermentation to adapt the proteins fit for the mass food market. Other applications include alternative proteins, hypoallergenic proteins and more.

Presenter: ***Ilan Samish, Founder and CEO***

Dr. Samish's mission to reduce global sugar consumption began after he published the world's leading book on computational protein design which he thought is fit for the task. He also founded and co-chairs the Israeli Academia-Industry Sweet Science Forum, which gathers scientists to discuss proactive healthy food solutions. Prior to founding Amai Proteins, he taught courses in Genetics, Biochemistry, Physical Chemistry and Computational Biology at the Weizmann Institute, Hebrew University, and Braude College.

Calyxt, Inc./University of Minnesota Center for Precision Plant Genomics

Calyxt is a food- and agriculture-focused company that uses TALENs® gene-editing technology to develop healthier food ingredients, such as healthier oils and high fiber wheat, for consumers and crop traits that benefit the environment and reduce pesticide applications, such as disease tolerance, for farmers.

Presenter: ***Daniel Voytas, Chief Scientific Officer/Professor and Director***
In addition to his role as Chief Scientific Officer of Calyxt, Dr. Voytas is Director of the Center for Precision Plant Genomics and Professor of Genetics, Cell Biology and Development at the University of Minnesota. His current work is focused on optimizing delivery of nucleases and donor DNA molecules to plant cells to more efficiently achieve targeted genetic alterations.

Center for Science in the Public Interest

The Center for Science in the Public Interest (CSPI) is an independent, science-based consumer advocacy organization that provides nutrition, food safety, and health advice for communities seeking healthy food environments.
Presenter: ***Gregory Jaffe, Director, Biotechnology Project***
Mr. Jaffe is an international expert on agricultural biotechnology and biosafety and works on biosafety regulatory issues in the U.S. and throughout the world. He currently works for the Center for Science in the Public Interest, a non-profit consumer advocacy organization working on food and nutrition issues. Before joining CSPI, he worked for the U.S. Department of Justice's Environmental and Natural Resources Division, the Environmental Protection Agency's Air Enforcement Division.

Pairwise

Pairwise brings together leaders in agriculture and technology to harness the potential of genome editing to address the needs of consumers and farmers.
Presenter: ***Haven Baker, Co-Founder, Chief Business Officer***
Dr. Baker formerly Senior Vice President and General Manager of Simplot Plant Sciences and was responsible for launching the Innate Potato, one of the first agricultural biotechnology products in the U.S. with benefits to both farmers and consumers. He is the son of a farmer, giving him unique insight into the production challenges of specialty crops in modern agriculture.

Parabel, Inc.

Parabel's proprietary technology enables the company to grow, harvest, and process water lentils to create feed and food products for global markets.
Presenter: ***Cecilia Wittbjer, Vice President Marketing***
Ms. Wittbjer is a brand strategist with experience leading corporate and product communications for large companies. Recently she has led the international marketing strategy for LENTEIN®, introducing the plant protein to the global food system in an effort to improve health and sustainability across the globe.

Perfect Day

Perfect Day, formerly known as Muufri, is a San Francisco-based cellular agriculture company using microflora to produce the common milk proteins casein and whey.

Presenter: ***Ryan Pandya, CEO and Co-Founder***

Mr. Pandya is the Chief Executive Officer and co-founder of Perfect Day. He studied Chemical & Biological Engineering at Tufts University, where he contributed to seminal research on tissue engineered meat at the Kaplan Lab before graduating and going on to work at MassBiologics, a small biopharmaceutical company in Boston, MA. He realized that the same technology used in the pharmaceutical industry could solve other world issues, including one that was particularly personal to him: the need for better dairy alternatives.

The Environmental Defense Fund (EDF)

The EDF is a U.S.-based not-for-profit environmental advocacy group focused on global warming, ecosystem restoration, oceans, and human health.

Presenter: ***Tom Neltner, Chemicals Policy Director***

Dr. Neltner leads the efforts to remove or minimize hazardous chemicals from products and the marketplace through cross-cutting policy initiatives. His primary focus is on (i) food additive safety, in which he promotes corporate partnerships and advances federal regulatory efforts to improve public health and the environment; and (ii) lead, in which he works to advance legislative, regulatory and collaborative efforts to reduce lead exposure.

Biographical information of ISGP Board of Directors

Dr. George Atkinson, Chairman

Dr. Atkinson founded the Institute on Science for Global Policy (ISGP) and is an Emeritus Professor of Chemistry, Biochemistry, and Optical Science at the University of Arizona. He is former head of the Department of Chemistry at the University of Arizona, the founder of a laser sensor company serving the semiconductor industry, and Science and Technology Adviser (STAS) to U.S. Secretaries of State Colin Powell and Condoleezza Rice. He launched the ISGP in 2008 as a new type of international forum in which credible experts provide governmental and societal leaders with understanding of the science and technology that can be reasonably anticipated to help shape the increasingly global societies of the 21st century. Dr. Atkinson has received National Science Foundation and National Institutes of Health graduate fellowships, a National Academy of Sciences Post Doctoral Fellowship, a Senior Fulbright Award, the SERC Award (U.K.), the Senior Alexander von Humboldt Award (Germany), a Lady Davis Professorship (Israel), the first American Institute of Physics' Scientist Diplomat Award, a Titular Director of the International Union of Pure and Applied Chemistry, the Distinguished Service Award (Indiana University), an Honorary Doctorate (Eckerd College), the Distinguished Achievement Award (University of California, Irvine), and was selected by students as the Outstanding Teacher at the University of Arizona. He received his B.S. (high honors, Phi Beta Kappa) from Eckerd College and his Ph.D. in physical chemistry from Indiana University. He was recently the President of Sigma Xi, The Scientific Research Society. His educational scientific research and diplomatic achievements have be recognized with distinguished appointments and awards in 16 countries.

Dr. Ben Tuchi, Secretary/Treasurer

Dr. Tuchi is chairman of the board of directors of the Arizona Research Park Authority. He received his B.S. and M.S. degrees in Business Administration from the Pennsylvania State University and his Ph.D. in Finance from St Louis University. His full time teaching career began in 1961 at St. Francis College and continued until 1976 at West Virginia University. From 1976 through 1996 he served in cabinet levels at West Virginia University, The University of Arizona, The University of North Carolina at Chapel Hill, and finally as Senior Vice Chancellor for Business and Finance of the University of Pittsburgh. During those assignments he was simultaneously a tenured professor of finance. He retired from the last executive

post in 1996 and returned to a full-time teaching position as Professor of Finance at the University of Pittsburgh, until his retirement in 1999. For the two years prior to his retirement he was the Director of Graduate Programs in Business in Central Europe, at Comenius University, making his home in Bratislava, The Slovak Republic.

Dr. Janet Bingham, Member

Dr. Bingham is former President and current Member of the George Mason University (GMU) Foundation and Vice President of Advancement and Alumni Relations. GMU is the largest university in Virginia. Previously, she was President and CEO of the Huntsman Cancer Foundation (HCF) in Salt Lake City, Utah. The foundation is a charitable organization that provides financial support to the Huntsman Cancer Institute, the only cancer specialty research center and hospital in the Intermountain West. Dr. Bingham also managed Huntsman Cancer Biotechnology Inc. In addition, she served as Executive Vice President and Chief Operating Officer with the Huntsman Foundation, the private charitable foundation established by Jon M. Huntsman Sr. to support education, cancer interests, programs for abused women and children, and programs for the homeless. Before joining the Huntsman philanthropic organizations, Dr. Bingham was the Vice President for External Relations and Advancement at the University of Arizona. Prior to her seven years in that capacity, she served as Assistant Vice President for Health Sciences at the University of Arizona Health Sciences Center. Dr. Bingham was recognized as one of the Ten Most Powerful Women in Arizona.

Dr. Mike Buch, Member

Dr. Buch holds B.A., M.S., and Ph.D. degrees in Analytical Chemistry and Biotechnology. He has nearly 3 decades of experience in the consumer healthcare industry in various roles of increasing responsibility with some of the world's leading companies. He has broad-based knowledge of consumer healthcare and currently serves as Chief Science Officer and Board Member at Young Living Essential Oils, a rapidly growing multibillion-dollar international wellness company and the largest provider of essential oils in the world. He is directly responsible for leading Research, Development, Product Management, and Quality Assurance across Young Living. Dr. Buch has expertise in leading global strategic development programs, open innovation programs, licensing programs, consumer healthcare R&D, advanced technologies labs, advanced optical analysis labs, and biosensor design and research. His work has directly led to the development of consumer healthcare products with annual sales exceeding $3 billion and his products have been marketed in more than 100 countries. His success has resulted in more than a dozen patents in the health care field, several books, and numerous articles published in peer-reviewed

journals. He is also a member of several prestigious associations, including the American Chemical Society, The New York Academy of Science, and the American Association for the Advancement of Science.

Mr. Fred Downey, Member

Mr. Downey is a former U.S. Army strategist and longtime defense and international affairs expert on Capitol Hill and was vice president of national security at Aerospace Industries Association (AIA). Downey joined AIA from the office of Connecticut Senator Joe Lieberman where he served as Senior Counselor and Legislative Aide for Defense and Foreign Affairs. He had been the senator's key staff person on these issues for 12 years. As Lieberman's representative to the Senate Armed Services Committee, Downey staffed the senator in his role as chairman of the Airland Subcommittee, overseeing Army and Air Force policy and budget issues and the annual defense authorization bill. Before joining Lieberman, Downey worked on defense analytical services for TASC. That came after a 24-year career in the U.S. Army, including Pentagon postings as Assistant to the Director of Net Assessments at OSD and Strategy Team Chief for the Strategic Plans and Policy Directorate on the Department of the Army Staff.

Dr. Tom Fingar, Member

Dr. Fingar is the inaugural Oksenberg-Rohlen Distinguished Fellow in the Freeman Spogli Institute for International Studies at Stanford University. Previously, he served as the first Deputy Director of National Intelligence for Analysis and, concurrently, as Director of the National Intelligence Council. He previously served as Assistant Secretary of the Department of State's Bureau of Intelligence and Research, Principal Deputy Assistant Secretary, Acting Assistant Secretary of State for Intelligence and Research, Deputy Assistant Secretary for Analysis, Director of the Office of Analysis for East Asia and the Pacific, and Chief of the China Division. Between 1975 and 1986, he held a number of positions at Stanford University, including Senior Research Associate in the Center for International Security and Arms Control and Co-Director, US-China Education Clearinghouse, Committee on Scholarly Communication with the People's Republic of China. He participates in regular, and increasingly frequent, meetings with and hearings before members of Congress. He graduated from Cornell University, and received his master's degree and Ph.D. in political science from Stanford University.

Mr. Jim Kolbe, Member

For 22 years, Mr. Kolbe served in the United States House of Representatives, elected in Arizona for 11 consecutive terms, from 1985 to 2007. Mr. Kolbe is currently

serving as a Senior Transatlantic Fellow at the German Marshall Fund of the United States, and as a Senior Adviser to McLarty Associates, a strategic consulting firm. He advises on trade matters as well as issues of effectiveness of U.S. assistance to foreign countries, on U.S.-European Union relationships, and on migration and its relationship to development. He is also Co-Chair of the Transatlantic Taskforce on Development with Gunilla Carlsson, the Swedish Minister for International Development Cooperation. He also is an adjunct Professor in the College of Business at the University of Arizona. While in Congress, he served for 20 years on the Appropriations Committee of the House of Representatives, was chairman of the Treasury, Post Office and Related Agencies subcommittee for four years, and for his final six years in Congress, he chaired the Foreign Operations, Export Financing and Related Agencies subcommittee. He graduated from Northwestern University with a B.A. degree in Political Science and then from Stanford University with an M.B.A. and a concentration in economics.

Mr. Joseph Nimmich, Member

Mr. Nimmich is a Partner at Potomac Ridge Consulting. He formerly was Senior Executive Advisor at Booz Allen Hamilton's Civil and Commercial Group. Prior to Booz Allen Hamilton, he served as the Deputy Administrator of the Federal Emergency Management Agency (FEMA) from September of 2014 until January 2017. During his tenure, his primary focus was on strengthening and institutionalizing FEMA's business architecture over the long term to achieve the Agency's mission. He joined FEMA in 2013, as the Associate Administrator for the Office of Response and Recovery. He was responsible for directing the Response, Recovery, and Logistics Directorates, as well as the Office of Federal Disaster Coordination. Prior to joining FEMA, he was the Director of Maritime Surveillance and Security at Raytheon Corp., where he directed maritime surveillance and security operations, as well as their emergency response capabilities. He served in the U.S. Coast Guard for more than 33 years, retiring as a Rear Admiral. His Coast Guard assignments included the First Coast Guard District based in Boston, Massachusetts, where he was responsible for all Coast Guard operations across eight states in the northeast and 2,000 miles of coastline from the U.S.-Canadian border to northern New Jersey. He earned his M.B.A. from the Stern School of Business at New York University.

Dr. Charles Parmenter, Member

Dr. Parmenter is a Distinguished Professor Emeritus of Chemistry at Indiana University. He also served as Professor and Assistant and Associate Professor at Indiana University in a career there that spanned nearly half a century (1964-2010). He earned his bachelor's degree from the University of Pennsylvania and served as a

Lieutenant in the U.S. Air Force from 1955-57. He worked at DuPont after serving in the military and received his Ph.D. from the University of Rochester and was a Postdoctoral Fellow at Harvard University. He has been elected a Member of the National Academy of Sciences and the American Academy of Arts and Sciences, and a Fellow of the American Physical Society and the American Association for the Advancement of Science. He was a Guggenheim Fellow, a Fulbright Senior Scholar, and received the Senior Alexander von Humboldt Award in 1984. He has received the Earle K. Plyler Prize, was a Spiers Medalist and Lecturer at the Faraday Society, and served as Chair of the Division of Physical Chemistry of the American Chemical Society, Co-Chair of the First Gordon Conference on Molecular Energy Transfer, Co-organizer of the Telluride Workshop on Large Amplitude Motion and Molecular Dynamics, and Councilor of Division of Chemical Physics, American Physical Society.

Mr. Thomas Pickering, Member

Mr. Pickering is Vice Chairman of Hills & Co, international consultants, and Strategic Adviser to NGP Energy Capital Management. He co-chaired a State-Department-sponsored panel investigating the September 2012 attack on the U.S. diplomatic mission in Benghazi. He served as U.S. ambassador to the United Nations in New York, the Russian Federation, India, Israel, El Salvador, Nigeria, and the Hashemite Kingdom of Jordan. Mr. Pickering also served on assignments in Zanzibar and Dar es Salaam, Tanzania. He was U.S. Under Secretary of State for Political Affairs, president of the Eurasia Foundation, Assistant Secretary of State for Oceans and International Environmental and Scientific Affairs, and Boeing Senior Vice President for International Relations. He also co-chaired an international task force on Afghanistan, organized by the Century Foundation. He received the Distinguished Presidential Award in 1983 and again in 1986 and was awarded the Department of State's highest award, the Distinguished Service Award in 1996. He holds the personal rank of Career Ambassador, the highest in the U.S. Foreign Service. He graduated from Bowdoin College and received a master's degree from the Fletcher School of Law and Diplomacy at Tufts University.

Dr. Eugene Sander, Member

Dr. Sander served as the 20th president of the University of Arizona (UA), stepping down in 2012. He formerly was vice provost and dean of the UA's College of Agriculture and Life Sciences, overseeing 11 academic departments and two schools, with research stations and offices throughout Arizona. He also served as UA Executive Vice President and Provost, Vice President for University Outreach and Director of the Agricultural Experiment Station and Acting Director of Cooperative Extension

Service. Prior to his move to Arizona, Dr. Sander served as the Deputy Chancellor for biotechnology development, Director of the Institute of Biosciences and Technology, and head of the Department of Biochemistry and Biophysics for the Texas A&M University system. He was Chairman of the Department of Biochemistry at West Virginia University Medical Center and Associate Chairman of the Department of Biochemistry and Molecular Biology at the College of Medicine, University of Florida. As an officer in the United States Air Force, he was the assistant chief of the biospecialties section at the Aerospace Medical Research Laboratory. He graduated with a bachelor's degree from the University of Minnesota, received his master's degree and Ph.D. from Cornell University and completed postdoctoral study at Brandeis University. As a biochemist, Dr. Sander worked in the field of mechanisms by which enzymes catalyze reactions.

Mr. Richard Armitage, Special Adviser

Mr. Armitage is the President at Armitage International, where he assists companies in developing strategic business opportunities. He served as Deputy Secretary of State from March 2001 to February 2005. Mr. Armitage, with the personal rank of Ambassador, directed U.S. assistance to the new independent states (NIS) of the former Soviet Union. He filled key diplomatic positions as Presidential Special Negotiator for the Philippines Military Bases Agreement and Special Mediator for Water in the Middle East. President Bush sent him as a Special Emissary to Jordan's King Hussein during the 1991 Gulf War. Mr. Armitage also was Deputy Assistant Secretary of Defense for East Asia and Pacific Affairs in the Office of the Secretary of Defense. He graduated from the U.S. Naval Academy. He has received numerous U.S. military decorations as well as decorations from the governments of Thailand, Republic of Korea, Bahrain, and Pakistan. Most recently, he was appointed an Honorary Companion of The New Zealand Order of Merit. He serves on the Board of Directors of ConocoPhillips, ManTech International Corporation, and Transcu Ltd., is a member of The American Academy of Diplomacy as well as a member of the Board of Trustees of the Center for Strategic and International Studies.

Biographical Information of ISGP Staff, Senior Fellows, and Adjunct Fellows

ISGP Staff and Senior Fellows

George H. Atkinson, Founder and Executive Director

The professional career of Dr. Atkinson spans several diverse arenas including academic responsibilities for teaching, scientific research, grant preparation, and administration within university communities, duties as the Founder and Chief Executive Officer of Innovative Laser Corp. that designed high sensitivity laser sensors for the semiconductor industry, and public service as a science and technology adviser within the U.S. government. His U.S. government activities crossed different agencies and departments and included service as the Science and Technology Adviser to the Secretaries of State Colin Powell and Condoleezza Rice. His recent efforts, facilitating the use of credible scientific understanding in the formulation and implementation of governmental, private sector, and societal policies worldwide, are reflected in his launching of the Institute on Science for Global Policy (ISGP). Dr. Atkinson is an Emeritus Professor of Chemistry, Biochemistry, and Optical Sciences at the University of Arizona. He has been recognized for his teaching (Outstanding Teacher at the University of Arizona; Distinguished Alumni Award, Indiana University; Honorary Doctorate and MacArthur Award, Eckerd College) and research (Senior Alexander Humboldt Award and Senior Fulbright Fellow, Germany; Senior SERC Awards at the Royal Institution of Great Britain and Oxford University, U.K; Lady Davis Professorships at Hebrew University and the Technion, Israel; Distinguished Visiting Professor, University of Tokyo, Japan; Distinguished Professor Award, University of California, Irvine). He was elected in 2014 President of the Sigma XI, The Scientific Research Society.

Daniela Baeza Breinbauer, Senior Fellow

Ms. Baeza Breinbauer is a Project Officer and Researcher at LSE Consulting where she oversees all projects in the fields of Environment; Health; and Behavioural Science. She has previously consulted for a variety of government and non-government institutions including the United Nations, European Commission, EU Committee of the Regions, and the Government of India. She previously worked as a Contributing Researcher with the Economist Intelligence Unit on a project in partnership with the Johns Hopkins Centre for Health Security and the Nuclear Threat Initiative to develop a Global Health Security Index assessing countries' technical, financial,

socioeconomic, and political capabilities to prevent, detect, and rapidly respond to epidemic threats. She holds an M.Sc. in International Development Management with a focus on Economics from the London School of Economics, and a double B.A. in Global Affairs/International Relations and Political Science, with a focus on Human Rights Law, from Eckerd College.

NiCole Bice, Program Assistant

Ms. Bice has a diverse background in both education and business experience. Before joining the ISGP, she was an Academic Coordinator at a Professional Sports Academy and has served as an Administrator, Lab Facilitator, Teacher, and Curriculum Supervisor at a variety of schools and organizations. She attended the University of Arizona in Tucson and graduated with a B.A. degree. She has a lifelong interest in education, business, and current science-related topics. She recently received certifications in both global education perspectives and business management.

Jennifer Boice, Program Coordinator

Ms. Boice worked for 25 years in the newspaper industry, primarily at the Tucson Citizen and briefly at USA Today. She was the Editor of the Tucson Citizen when it was closed in 2009. Additional appointments at the Tucson Citizen included Business News Editor, Editor of the Online Department, and Senior Editor. She also was a business columnist. She received her M.B.A. from the University of Arizona and graduated from Pomona College in California with a degree in economics.

KathrynAnn H. Fields, Associate Director

Ms. Fields is a 2018 graduate of the Bush School of Government and Public Service at Texas A&M University, completing a master's degree in Public Service and Administration with an emphasis in Public Policy Analysis. She has received numerous scholarships and awards including from the American Society of Animal Science. She is a member of Sigma Xi Scientific Research Society and Gamma Sigma Delta Honor Society of Agriculture. She has conducted research in Central America to collect data at the second largest coral reef system in the world and developed an economic model for managing an invasive fish species for her thesis. She examined and assessed the Red River Flooding in Caddo Parish, Louisiana for her capstone project. Ms. Fields received her B.S. in 2013 and M.S. in 2015 in Food and Resource Economics at the University of Florida.

Samantha Innis, Senior Fellow

Ms. Innis, a guest contributor to ISGP's the Forum podcast, is a third-year medical student at Drexel University College of Medicine. There, she is pursuing her M.D. with a goal of specializing in pediatric genetics. Simultaneously, she is completing a

scholarship pathway in Medical Humanities, directing the Medical Genetics Interest Group, sitting on multiple institutional task forces, and actively participating in a number of local, national, and international organizations including the AMA, AMWA, and Sigma Xi. She received a Bachelor of Science degree in Biology with cum laude distinctions from Ursinus College in 2014.

Christina Medvescek, Senior Fellow

Ms. Medvescek is a community dialogue specialist with the Center for Community Dialogue and Training, in Tucson, where she helps organizations and individuals navigate challenging issues in skilled, civil and respectful ways. A longtime journalist, editor and former vice president of publications for the Muscular Dystrophy Association, she also is a certified mediator for the U.S. Postal Service.

Aubrey Paris, Senior Fellow

Dr. Paris also serves as manager and founding co-host of ISGP's bi-weekly podcast, The Forum. Concurrently, Dr. Paris is the 2019-2020 IEEE-USA Science and Engineering Diplomacy Fellow at the U.S. Department of State. Previously, she was an NSF Graduate Research Fellow and Energy and Climate Scholar at Princeton University, where her research involved the discovery and optimization of catalysts active in the electrochemical transformation of carbon dioxide to chemical feedstocks and fuels. She has also worked on projects related to Chinese financing of coal-fired power plants and the future of U.S. nuclear energy in the face of climate change. Dr. Paris received her Ph.D. in Chemistry and Materials Science from Princeton University in 2019, M.A. in Chemistry from Princeton University in 2017, and B.S. degrees in Chemistry and Biology from Ursinus College in 2015.

Cleo Warner, Senior Fellow

Ms. Warner is the audio editor and founding co-host of ISGP's podcast, The Forum. Concurrently, she is a technical writer for the Natural History Museum of Utah's Exhibits Team, where she helps translate scientific research into the designing of dioramas and interactive exhibit materials. Her previous academic research focused on the intersections of climate justice, community development, place studies, and urban food systems. She has worked on numerous socio-environmental projects in the U.S. and abroad, the latest being an urban farm in Salt Lake City that employs women facing homelessness. She received her M.S. in Environmental Humanities from the University of Utah in 2019 and B.A. degrees in Environmental Studies and Literature from Eckerd College in 2015.

Katie (Kat) Wheeler, Associate Program Director

Ms. Wheeler is a recent graduate of the environmental studies program at Eckerd College and focuses her work in food systems. Most recently, she worked on a farm-to-school program in Michigan, coffee and third-party certifications in Costa Rica, and farm workers' rights in Immokalee, Florida. Her key interest in food security center on nutrition, social justice, climate resiliency, and peace. She has long been immersed in the world of good food, having been raised among the roasting chiles and bubbling cauldrons of pinto beans and pozole in her hometown of Santa Fe, New Mexico.

ISGP Adjunct Fellows

Hazel Chew, Adjunct Fellow

Ms. Chew was born in the garden city of Singapore and now resides in Minnesota, where she recently graduated with a B.A. in Biology and Environmental Studies from Macalester College. In her spare time, she often cooks without a measuring scale, combining ingredients using the estimation of her eyes and taste buds. She aspires to work with researchers, farmers and consumers to improve our food system to feed people with healthy and delicious food, while preserving the environment.

William Donaghy, Adjunct Fellow

Mr. Donaghy is a plant science student at the University of Florida specializing in sustainable crop production. He belongs to an eighth generation Florida logging family from Jacksonville, Florida, and grew up working on an agritourism operation. He is involved in campus initiatives such as intercollegiate meat judging, the Challenge 2050 program, College of Agricultural and Life Sciences Ambassadors, and Collegiate Farm Bureau. He has worked on research in environmental horticulture and is now working on the efficacy of hemp in Florida agronomic systems for his undergraduate honors thesis. He hopes to pursue his M.S. in agroecology.

Ciaran Fitzpatrick, Adjunct Fellow

Mr. Fitzpatrick recently graduated with Honors from Eckerd College, where he received a B.S. in Biology, as well as a second major in International Relations & Global Affairs. At Eckerd, he was a Ford Apprentice Scholar, and investigated the efficacy of intercropping in agriculture. He also worked as a cell biology research assistant, studying C. elegans as model genetic organisms for Parkinson's disease. In the Summer of 2018, he completed an internship with Heart to Heart International, an organization that provides health access, humanitarian development, and crisis relief locally and abroad. He hopes to become a biological researcher, using scientific communication to bridge the gap between research and policy. He takes special

interest in the fields of food security and sustainability, global health, climate change, ecology, biodiversity, and genomics.

Jake Innis, Adjunct Fellow

Mr. Innis is a high school history teacher with classes focusing on American history and culture as well as restorative justice. He also mentors the Ethics Bowl team and is an administrator for the Positive Behavior Intervention and Support (PBIS) Program. He attended Temple University graduating with a B.S. in History and Education, and Villanova University, receiving a M.A. in History. In 2015 Jake served as a moderator for the ISGP conference on Safeguarding the American Food Supply at Ursinus College. He also provided technical support and music for ISGP's NextGenMed event in partnership with the University of Pennsylvania.

Keagan Ringling, Adjunct Fellow

Mr. Ringling is a graduate student in the Department of Food Science and Nutrition, advised by Dr. Len Marquart. His PhD research aims to improve pennycress seed meal composition for food use. His core cross-disciplinary research interests include plant genetics, food and nutrition science, supply chain assessments, applied economics, and food regulations.

Riva Silver, Adjunct Fellow

Ms. Silver was a 2018 summer intern with "The Forum" and now serves as a Science Communications Fellow as well as an Adjunct Fellow with the ISGP. For "The Forum," she specializes in educator resource development and high school student engagement. She is currently working to co-author a paper that explores the connection between water infrastructure and high school graduation rates in West Texas Colonias. She has served on multiple robotics teams across the U.S. and plans to pursue a degree in engineering.

Jim Kincheloe, Adjunct Fellow

Dr. Kincheloe is a veterinarian and scientist who works across the spectrum of medicine in food system security, safety, and sustainability. He has extensive experience collaborating with a wide variety of stakeholders in food supply and health issues, from working as an on-the-ground instructor to small lot farmers and animal health workers in Uganda to participating in statewide disease response and control research, planning, and policy. He received his doctorate in Veterinary Medicine from the University of California, Davis, and is currently a public health resident veterinarian at the Center for Animal Health and Food Safety at the University of Minnesota.

Arleigh Truesdale, Adjunct Fellow

Ms. Truesdale studied Environmental Studies and Sociology/Anthropology at St. Olaf College. Most recently, she has served as Sustainability Coordinator for a small not-for-profit organization, working to provide grant opportunities for young environmentalists, with a focus on equity. Her upbringing in Chicago, Illinois, has greatly influenced her desire to rekindle the relationship between community, food, water, and development through ISGP and an upcoming position at Seven Generations Ahead.