

GMOs 2.0: **Synthetic Biology**

A guide to protecting natural products





GMOs 2.0

Protecting the integrity of the natural products industry has never been as critical as it is now. Although responsible companies already have control processes to reliably exclude first generation transgenic GMOs, a new generation of genetic engineering techniques, broadly dubbed synthetic biology or GMOs 2.0, is rapidly entering the marketplace. Ingredients produced via synthetic biology techniques have entered natural products supply chains without labeling or notice and may be evading pre-existing company control procedures. These new genetic engineering techniques and their products present environmental, justice and safety concerns that go beyond those of first generation GMOs. If not addressed, they could undermine consumer trust in the natural products industry. Consumers want more transparency and honesty about products, they want authentic ingredients, and that means truly natural and sustainable sourcing.

Entering the Market

It's critical that companies are vigilant about the new wave of emerging genetic technologies that may be misleadingly

marketed by biotechnology companies as “sustainable” and “natural” options. In fact, the production methods for GMOs 2.0 are highly “un-natural” and claims of sustainability may be unsubstantiated. As consumers in the U.S. and abroad scrutinize the integrity of their products, companies need to protect themselves from sourcing ingredients that may later be shown to be harmful. There are now at least one hundred products of synthetic biology either already being commercially sold or coming to market in the near future. Many of these have likely already moved into the supply chains of the natural products industry, particularly in the form of flavorings, fragrances, oils, supplements or cosmetic ingredients.

There are even eco-certifiers (Ecocert, Natural Products Association, and Environmental Working Group) that have applied their “eco” certification label to multiple synthetic biology ingredients and at least one synthetic biology cosmetic product (Neossance Squalane) is being erroneously sold as non-GMO. This is likely to confuse both consumers and companies.

Ingredients produced via synthetic biology may already have entered natural products supply chains without labeling or notice and may be evading preexisting company control procedures.

Protect Your Supply Chain

The concerns about possible health, social and environmental impacts from next generation genetic engineering and the lack of transparency throughout this emerging industry may create novel risks for consumers, investors and companies. Labels and ingredients are under more scrutiny than ever, and companies interested in avoiding the potential risks should be asking these questions:

- Do our suppliers know what next generation genetic engineering/synthetic biology is?
- Do our products include ingredients that may be produced via synthetic biology or novel genetic engineering techniques?
- Do our suppliers sell ingredients derived from genetic engineering processes, including synthetic biology?
- Can our suppliers trace their ingredients all along the supply chain back to the producers?
- Do we (or our consumers) regard this next generation of genetic engineering ingredients as “sustainable,” “fair” or “safe?”
- How are these new ingredients regulated and assessed?
- Are there reputational risks/potential brand damage associated with use of ingredients derived from new genetic engineering techniques/synthetic biology?

Ensure Authenticity

We have developed the following information to help companies identify if any ingredients may now or in the future be a product of synthetic biology or novel genetic engineering techniques and to offer guidance to ensure these ingredients don't inadvertently end up in your products. We hope to assist the natural products industry to minimize risks to consumers, companies and natural ecosystems.

You will find synthetic biology policy recommendations accompanied by a sample list of synthetic biology ingredients taken from the new “GMO 2.0 Ingredients Database” available online at <http://database.synbiowatch.org>. This tool will help inform companies and suppliers about what to look for. We also provide recommendations to help companies update their purchasing guidelines. The following document will help companies in the natural products industry access information about ingredients from next generation genetic engineering, synthetic biology and potential concerns. It will:

- Recommend actions companies can take and information that companies can request from suppliers.
- Define new genetic engineering techniques and synthetic biology and describe how these technologies are entering the market.

It is critical to stay ahead of the curve and proactively ensure that your company avoids numerous potential risks and builds public confidence in your company as a champion of transparency, authenticity and safe, just, sustainable products.



This document is intended to help companies in the natural products industry access information about ingredients from synthetic biology and potential concerns.



- What are GMOs 2.0? Scope and Definitions** 5
- Environmental & Health Risks**..... 5
- Synthetic Biology in Natural Products**..... 5
- Consumer Rejection**..... 6
- Company Leadership Opportunities**..... 6
- Recommended Actions** 6
- Questions for Suppliers**..... 7
- Regulatory Status and Labeling** 7
- Conclusion**..... 8
- Resources** 8
- Appendix** 10
 - List of Synthetic Biology Ingredients..... 10
 - How does Synthetic Biology Work?..... 12
 - Illustrative List of Synthetic Biology Approaches and Techniques 12
 - Definition of Synthetic Biology 13
 - Sample Company Policy Statements..... 13
 - Sample Policy Statement..... 14
 - Frequently Asked Questions 15
- Endnotes**..... 18

What are GMOs 2.0? Scope and Definitions

GMOs 2.0 describes the next generation of genetically engineered ingredients made with a set of new genetic tools and techniques. Some of these techniques are referred to as synthetic biology (synbio) and represent new ways to produce GMO plants, animals and processed ingredients. (See appendix for various definitions of synthetic biology.) Instead of swapping existing genes from one species to another (a technique known as “recombinant DNA” or “transgenics”), synthetic biologists use newer techniques that allow them to more significantly redesign the genetic makeup of living organisms through adding, deleting, silencing or completely rewriting DNA. New genetic engineering techniques include (but are not limited to) genome editing (including CRISPR), RNA interference, metabolic engineering and directed evolution. (See appendix for a more complete list of techniques.)

Environmental & Health Risks

Changing the genetic sequences in an organism can have unintended consequences for how that organism behaves and unpredictable impacts on a plant, species or ecosystem. While the synthetic biology industry claims that synthetic biology could theoretically reduce impacts on land by producing products in labs rather than via natural plants, the synthetic biology industry is currently creating an increased demand for sugar and other bio-feedstocks. This could exacerbate the current destruction of critical ecosystems and pollution associated with the industrial agriculture production of these feedstocks.

Companies working with certain organisms such as engineered algae create additional risks. Complete containment of synthetic biology organisms is not likely feasible. The escape of engineered synthetic biology organisms into the environment could have serious and unforeseeable consequences, including genetic contamination of wild species, disruption of natural ecosystems and potential health implications.

Synthetic Biology in Natural Products

The first wave of ingredients produced via new genetic engineering techniques are now entering the market. These initial ingredients are often newly manufactured versions of familiar compounds that are commonly intended for use in:

- Food (flavorings, fragrances, sweeteners, flavor enhancers)
- Fragrances
- Cosmetics
- Supplements (sports nutrition, amino acids, vitamins, omega 3 DHA/EPA, antioxidants and more)
- Household products (cleaners, soaps, scents)
- Oils
- Industrial materials
- Packaging

These new ingredients are produced by genetically engineered organisms — commonly yeast, algae or bacteria — that’s DNA has been deliberately re-engineered. These engineered organisms commonly feed on sugar in industrial fermentation vats to produce flavors, fragrances, oils, crude protein and industrial chemicals. Some companies are also exploring using methane gas (e.g. from fracking) as a feedstock.



Natural vanilla beans produced by small farmers in countries including Madagascar, Mexico, and across Southeast Asia could soon be displaced by synthetic biology derived vanillin falsely marketed as “natural.”

SOURCE:  creative commons



Consumer Rejection

Consumers are increasingly looking for products that are authentic, sustainable, natural, organic and non-GMO — it is critical that companies that want to meet those values ensure that GMOs 2.0 and synthetic biology ingredients do not enter products, or they may risk losing credibility with consumers. Countries across the world, including 19 EU countries, are banning the cultivation of some first generation GMOs.¹ Over 40,000 products now carry ‘non-GMO’ claims on packaging. The market for next-generation synthetic biology products is predicted to grow to almost \$40 billion by 2020 and is being propelled by major international agrichemical, flavor, fragrance, fuel and pharmaceutical companies. Some of these ingredients have already entered the market with virtually no independent safety assessment or required sourcing information or labeling and in advance of agreed oversight frameworks.

Consumer backlash to GMOs 2.0 may be significant. When “green” company Ecover/Method trialed synthetic biology-derived algal oil in its European line of laundry detergent, there was significant international outcry from its consumers who asked the company to maintain its commitment to sustainability and not use synthetic biology ingredients. In response to this consumer concern, Ecover/Method reconsidered its use of this algal oil. This incident became a test case for how natural products consumers may react to trusted brands adopting synthetic biology ingredients.

Hart Research and Woodrow Wilson Institute surveyed Americans’ reactions to synthetic biology. They note:

“Many participants associate synthetic biology with things that are artificial, fake, or man-made.”

Those polled expressed most negative reactions towards the use of synthetic biology in food and flavor ingredients such as artificial sweetener, vanilla and citrus flavorings with women showing the highest level of concern.²

Consumers are increasingly looking for products that are authentic, sustainable, natural, organic and non-GMO — it is critical that companies that want to meet those values ensure that GMOs 2.0 and synthetic biology ingredients do not enter products, or they may risk losing credibility with consumers.

Company Leadership Opportunity

The U.S. natural and organic products industry is expected to grow from sales of \$153 billion in 2013 to \$252 billion by 2019. Companies are continuing to exclude synthetic pesticides, GMOs, artificial hormones and nano-ingredients from their products and have helped build trust among consumers that natural product brands take precaution, transparency and authenticity seriously. Those natural product companies that are committing to not using ingredients derived from synthetic biology are affirming the trust placed in them by their consumers to only use trustworthy ingredients. They may emerge as leaders both in the U.S. and internationally in identifying and avoiding unassessed and unregulated emerging technologies.

Recommended Actions:

- Update company policies on GMOs to exclude the use of ingredients sourced from the next generation of genetic engineering techniques (including synthetic biology) in products. The policy should be aligned with existing policies on use of GMOs such as Non-GMO Project verification and USDA

Organic certification. The policy should be publicly viewable in company materials and website.

- Company supplier standards should align with Non-GMO Project and USDA Organic Certification standards to avoid the use of ingredients derived from all forms of genetic engineering or synthetic biology (not just transgenics) and should reveal the sources of ingredients. (For example, a company could request proof or assurance that a vanillin or patchouli oil is sourced botanically or by non-genetic engineering techniques.)
- Conduct regular supply chain analyses and request sourcing information from suppliers.
- Ask suppliers to provide documentation regarding transportation, storage and handling of non-genetically engineered ingredients to ensure segregation from genetically engineered or unidentified materials.

Questions for Suppliers:

Does the company understand new genetic engineering techniques and how genetic modification is changing?

- Does the company understand what synthetic biology is and its relationship with genetic engineering?
- Does the company understand what synthetic biology-derived ingredients are? (See representative list of sample synthetic biology ingredients below.)
- Does the company endorse the use of genetic engineering or synthetic biology?
- Does the company sell any ingredients produced with the assistance of genetically modified or synthetic biology yeast, algae or other microorganisms? (See representative list of sample of synthetic biology techniques below.)
- If the company uses ingredients or processing aids that are the product of synthetic biology, on what basis has the company made this decision (e.g. cost, availability, quality, ease of use, function, performance)?
- Does the company use ingredients that require feedstocks in these categories:

sugar, fiber, starch or methane? Are any of the feedstocks derived from genetically engineered crops? Are any of the algae, yeast or enzymes products of genetic engineering?

- Does the company know from where the ingredients are originally sourced?
- If the product or its ingredients are derived from an animal source, is the company able to provide documentation ensuring no genetically engineered growth hormones, supplements or foods were administered to the animal during its life?
- Does the company's existing Standard Operating Procedures (SOPs) include standards specific to genetic engineering and address management of traceability and segregation?
- Would the company sign an affidavit confirming the ingredients being sold to the brand are produced through processes that do not use synthetic biology or other genetic engineering techniques?
- Does the company do spot purchasing? Has it verified that materials are not genetically engineered or produced with synthetic biology before making the purchase?
- If the company is currently sourcing or using a product of synthetic biology or genetic engineering, what would be needed for the company to source or use a non-genetically engineered equivalent?
- Has the company explored alternatives to the use of ingredients derived from synthetic biology and genetic engineering? Would the company provide examples of products that have been replaced with ingredients that are not derived from synthetic biology or genetic modification processes?
- Has the company issued any public statements on the sale of GMO or synthetic biology-derived ingredients?

Regulatory Status and Labeling

Products of synthetic biology are not currently subject to special regulations or oversight. Synthetic biology-derived food products coming onto the market, such as synthetic biology vanillin, grapefruit flavor and stevia, have so far been accepted by the FDA as

Already there are synthetic biology derived products being marketed as non-GMO despite being a product of genetically engineered yeast. This erroneous labeling could mislead consumers and companies.

“Generally Regarded as Safe” (GRAS) on the basis that they mimic an existing compound or more often self-approved as by the companies themselves. Others, such as fragrance ingredients, do not trigger new regulatory scrutiny.

Synthetic biology companies argue that because the ingredients are products of “fermentation,” they are “natural,” even though the organism doing the fermenting is far from natural. They argue that synthetic biology derived ingredients can even be called “non-GMO” even though they are produced by genetically engineered organisms in industrial production systems. For example, the cosmetic product Neossance is being marketed as non-GMO, despite being a product of genetically engineered yeast. This erroneous labeling could mislead consumers and companies.

The Non-GMO Project Verified certification excludes food products derived from genetic engineering and synthetic biology. The National Organic Standards Board clarified that modern biotechnology and synthetic biology techniques are excluded methods and are not allowed in USDA-certified organic food and personal care products. It is less clear whether such ingredients are clearly prohibited under the various private (non-USDA) certifications available for personal care products.

The natural products industry can help ensure robust health and environmental assessment and oversight are in place for new technologies like synthetic biology before they enter into food and consumer products. Current problems with regulations and preventative measures to safeguard against unforeseen consequences include:

- Existing environmental and health regulations and laws (both nationally and internationally) are inadequate to protect against novel risks caused by synthetic biology interventions.
- There are no rules or procedures to guard against synthetic biology-derived ingredients displacing plant-based ingredients and negatively impacting small farmers or driving other socio-economic harms.
- Potential direct environmental contamination and damage from the production process of novel synthetic biology ingredients as well as indirect environmental harms are inadequately assessed.
- Current USDA (non-organic) rules allow manufacturers of most ingredients derived from new genetic engineering techniques to make erroneous and misleading “natural” and non-GMO claims.

Conclusion

In absence of adequate assessment, oversight and labeling, and until we understand the long-term ramifications of new genetic engineering and synthetic biology techniques for our health and environment, it is critical that responsible companies have clear policies that keep ingredients derived from genetically engineering out of food and consumer products, particularly those marketed as natural and non-GMO. Proactively addressing this issue may help your company to avoid future risks while building public confidence in your company as a champion of transparency and safe, sustainable products.

Resources

- [SynBioWatch](http://www.synbiowatch.org): www.synbiowatch.org
- [ETC Group](http://www.etcgroup.org): www.etcgroup.org
- [Friends of the Earth U.S.](http://www.foe.org): www.foe.org
- [Shoppers Guide to Synthetic Biology](http://www.synbiowatch.org/shoppers-guide/): www.synbiowatch.org/shoppers-guide/
- [Synthetic Biology Ingredient Database](http://database.synbiowatch.org): <http://database.synbiowatch.org>
- [Woodrow Wilson Center Synthetic Biology Products and Applications Inventory](http://www.synbioproject.org/cpi): <http://www.synbioproject.org/cpi>



Just as a consumer would want to know if milk was produced by a genetically engineered cow or honey from a genetically engineered bee, the same holds for ingredients that are produced via synthetically engineered yeast or algae — especially in cases when they are fed with a GMO feedstock.

Novel Synthetic Biology Ingredients

Using synthetic biology techniques, scientists are designing algae, bacteria and yeast to secrete substances that are similar to those found in naturally occurring animal and plant-based ingredients. For example by engineering yeast cells, Perfect Day has produced casein proteins similar to those found in cow's milk in hopes of creating vegan milk, and Clara Foods is designing genetically engineered yeast that excretes proteins similar to those found in egg whites. Although these companies suggest that these products may be more sustainable than animal agriculture, there are many unresolved concerns: about safety implications of unintended effects, about the sustainability of feedstocks, the further industrialization of agriculture, questions and about unintended escape of engineered organisms. Meanwhile, companies such as Amyris, Gingko Bioworks and Evolva are attempting to replace vanilla, saffron, rose oil, patchouli and other botanical ingredients with biosynthesized compounds that may compete with small farmers and affect their livelihoods.



Sample Synthetic Biology Ingredients List

The following is a small sample of synthetic biology ingredients. To see more from the GMOs 2.0 ingredient database and to help determine whether your company may be at risk of using synthetic biology ingredients, ETC Group has developed an extensive database of over 200 ingredients that may be affected by synthetic biology. To explore this database visit <http://database.synbiowatch.org>.

Product	Brand Name	Method	Natural Source	Producer	Assoc. Producer	Market Status
Algal Oil (culinary)	AlgaWise, Thrive	GM Algae	Olive Oil, Coconut Oil	TerraVia		On the Market
Algal Oil/Lauric Oils	unknown	GM Algae	None	TerraVia	Unilever, Ecover	On the Market
Algal Oil (Cosmetics)	AlgaPür	GM Algae	Soybean Oil, Canola Oil, Palm Oil	TerraVia		On the Market
Anthocyanins (Pigments)	AnthoPure™ technology	GM Algae		ChromaDex Corporation	Rensselaer Polytechnic Institute	On the Market
Beta -Elemene	Beta- Elemene Pure	GM Yeast	Curcuma Wenyujin (Ginger Root)	Isobionics		On the Market
Betaine Surfactant	Dehyton AO45	GM Algae	Amidopropyl Betaine from Coconut Oil	TerraVia	BASF	On the Market
Cannabinoids (including Cannabidiol-CBD)	unknown	unknown	Hemp, Cannabis Sativa	HyasynthBio		Under Development
Egg Proteins	unknown	unknown	Chicken Egg	Clara Foods		2017 Projection
Flavor Enhancer (Succinic Acid)	unknown	GM Yeast	Amber	BioAmber	Cargill	2017 Projection

Product	Brand Name	Method	Natural Source	Producer	Assoc. Producer	Market Status
Hemisqualane	Neossance, Biossance	GM Yeast	Olive	Amyris		On the Market
L-Methionine (Amino Acid)	InoLa	GM Bacteria		Evonik	Metabolic Explorer	On the Market
Microalgae Oil DHA	AlgaPrime	GM Algae	Microalgae	TerraVia		On the Market
Milk Proteins	Perfect Day	GM Yeast	Dairy Milk	Perfect Day		2017 Projection
Musk Fragrance (Fatty Acid)	Musk Fragrance	GM Bacteria		Renewable Energy Group, Inc.	Aroma Chemical Services (ACS) International	Under Development
Nootkatone (Grapefruit Flavor)	BioNootkatone	GM Yeast	Grapefruit, Orange Derivative	Isobionics	DSM Nutritional	On the Market
Patchouli	Clearwood	GM Yeast	Patchouli Plant	Amyris	Firmenich, IFF and Givaudan	On the Market
1,3 Propanediol	Zemea	GM Bacteria		DuPont	Tate & Lyle	On the Market
Phycocyanin (blue pigment)	unknown	GM Algae		Matrix Genetics		On the Market
Resveratrol	Veri-té	GM Yeast	Grape Skins/ Japanese Knotweed	Evolva		On the Market
Rose Oil	unknown	GM Yeast	Rose	Ginko Bioworks	Robertet	On the Market
Saffron	unknown	GM Yeast	Saffron (Crocus Sativus)	Evolva		2017 Projection
Sclareol (Fragrance)	Ambrox Super	GM Yeast, Fungi or Bacteria		Amyris	Firmenich	On the Market
Steviol Glycosides	EverSweet	GM Yeast	Stevia Rebundia	Evolva	Cargill	2018 Projection
Squalane	Neossance, Biossance	GM Yeast	Olive	Amyris		On the Market
Valencene (Orange Flavoring)	ValencenePure™ BioValencene	GM Yeast	Valencia Oranges, other Citrus	Isobionics	DSM Nutritional	On the Market
Vanillin	Within the "Always Vanilla" line.	GM Yeast	Vanilla Orchid	Evolva	IFF	On the Market
Vitamin D2	Vitamin D2	GM Yeast		Nucelis		On the Market
Yeast Oil	Yarrowia Oil	GM Yeast		Nucelis		On the Market
Zemea (Solvent/ Humectants)	unknown	GM Yeast	None	Tate and Lyle	DuPont	On the Market

How Does Synthetic Biology Work?

Common approaches in the field of synthetic biology include adding designed sequences of synthetic (human-made) DNA to an organism to force that organism to produce chemicals that they would not produce naturally. For example, a yeast or algae cell might be genetically engineered with synthetic DNA to produce plastics or fragrance chemicals. Synthetic biologists are also using techniques that “edit” DNA in an organism – attempting to “rewrite” the chemical instructions

of life as if re-editing a document. The engineered organism that is produced may be commercially used in different production systems, including using the organism in fermentation vats or releasing into open ponds and fields. At this point most of the commercial work in synthetic biology involves re-engineering microbes such as yeast, bacteria and algae – however, work is also ongoing in applying synthetic biology, especially gene editing, to fungi, crops, animals and even human beings.

Illustrative List of Synthetic Biology Approaches and Techniques

Synthetic biology is a rapidly evolving field. As such, it is difficult to present a definitive list of synthetic biology techniques. *The following is an illustrative but incomplete list:*

Clustered Regularly Interspersed Short Palindromic Repeats (CRISPR)

Directed Evolution

DNA-based Genetic Circuits

DNA Synthesis and Assembly

Epigenetic Modification

Expanded Genetic Alphabets

Genome Editing

Genome-level Engineering

Genome Shuffling

Gibson Assembly

Minimal Genomes

Multiplex Automated Genome Engineering

Oligonucleotide Directed Mutagenesis

Protocell Construction

Refactoring of Genomes

RNA-Directed DNA Methylation (RDDM)

RNAi (RNA Interference)

Standard Modular DNA ‘parts’ or ‘Biobricks’

Synthetic Metabolic Pathway Engineering

Synthetic Genomics

Transcription-Activator-like Effector Nucleases (TALENs)

Xenobiology

Zinc Finger Nucleases(ZFN)



Definition of Synthetic Biology

While synthetic biology as a field covers a number of different techniques and approaches, international governments are now moving closer to agreement on standard definitions. The European Union has adopted a formal operational definition of synthetic biology for regulatory purposes and the United Nations Convention on Biological Diversity has adopted a formal definition for its own use. For companies seeking to exclude synthetic biology ingredients, these formally-agreed upon definitions can help identify if a specific ingredient is derived from synthetic biology.

Example Synthetic Biology Definitions:

United Nations Convention on Biological Diversity: Synthetic biology is a further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems.

U.S. Government (President's Bioethics Commission): Synthetic biology is the name given to an emerging field of research that combines elements of biology, engineering, genetics, chemistry and computer science. The diverse but related endeavors that fall under its umbrella rely on chemically synthesized DNA, along with standardized and automatable processes, to create new biochemical systems or organisms with novel or enhanced characteristics.

Sample Company Policy Statements:

Non-GMO Project: Cloned animals and their progeny are also considered GMOs under this (Non-GMO Project) Standard, as are the products of synthetic biology. Any organism or input from an organism — whether used as inputs or as process elements in the creation of substances or materials — is a product of synthetic biology if it is associated with synthetically created nucleic acid sequences and/or genes...Cloned animals and their progeny are considered GM, as are the products of synthetic biology.

Ben & Jerry's: We are aware that some food ingredients may soon be available on the market that are derived from new applications of genetic engineering techniques and approaches sometimes referred to as synthetic biology. We consider the food ingredients produced in this way to be inconsistent with Ben & Jerry's criteria for sourcing and therefore we will not use them in our products.

Nutiva: Nutiva is committed to sourcing non-GMO ingredients. Thus, we seek to avoid synthetic biology derived products. We also support labeling of such products in the marketplace.

Dr. Bronner's: Dr. Bronner's uses only certified organic and fair trade forms of all major ingredients in our soaps. We do not and will not use synbio ingredients since a major goal of our organization is benefitting small-holder farmers and farmworkers engaged in the production of major agricultural commodities around the world. What concerns us most about the introduction of synbio ingredients is that they are unlabeled and passed off as natural, which compete unfairly and undercut farmers of real natural ingredients like vanilla.

Sample Policy Statement

Introduction

As a central part of our sustainable business model, [Company] is committed to a supply chain which is economically, socially and environmentally responsible.

A new generation of genetic engineering techniques and approaches, sometimes referred to as synthetic biology, is now being developed and commercialized ahead of adequate assessment and oversight and may pose risks to human health, the environment and small farmers. [Company] is extending its [non-GMO/organic/sustainability] commitment to also cover an exclusion of ingredients derived from organisms created using synthetic biology techniques.

Definition of Synthetic Biology

As this is an emerging field of technology, there is still no consensus on the definition for the term “synthetic biology”. However, the term is understood to cover a range of next-generation genetic engineering techniques. The current operational definition agreed by 196 countries to the UN Convention on Biological Diversity reads as follows:

Synthetic biology is a further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems

Position

[Company] will not use any ingredients derived from techniques and approaches regarded as synthetic biology for the following reasons:

[Company] product mission guides us to use “natural ingredients” in our products. We believe synthetic biology approaches and techniques fall outside any reasonable definition of “natural” and therefore we will not use any such ingredients in our products.

[Company] is committed to sourcing ingredients from developing countries through supply relationships built on fair trade principles. We have chosen this approach in order to ensure that these ingredient purchases support smallholder farmers and create economic opportunity in producer communities. We are concerned that food ingredients produced via synthetic biology techniques and approaches may disrupt markets for naturally produced materials, threatening the livelihood and well-being of smallholder farmers.

We support a precautionary approach to novel ingredients in the food supply. Currently the field of synthetic biology is virtually unregulated, while the technology presents a range of potential risks. Consistent with the recommendations of the UN Convention on Biological Diversity, we believe national and international regulations based on scientific risk assessments must be developed and implemented before raw materials derived from synthetic biology are commercialized. We believe these risk assessments must consider risks to biodiversity as well as human health, food security and socio-economic impacts.

In addition, [Company] supports disclosure and transparency for food products with ingredients derived from synthetic biology, including mandatory labeling. [Company] will work with others within the natural products industry to inform consumers and address policy challenges related to synthetic biology.

Frequently Asked Questions

A hand is shown writing the words "ANY QUESTIONS?" in large, white, chalk-like letters on a dark grey chalkboard. The hand is positioned on the right side of the frame, holding a piece of white chalk and finishing the question mark. The background is a dark, textured surface.

How is synthetic biology different from “GMO?”

Synthetic biology is a general term for an evolving suite of genetic engineering techniques that are now being applied to produce food ingredients, flavors, cosmetic ingredients, supplements, industrial chemicals, pharmaceuticals and more. While conventional GMOs are altered by swapping existing genes and DNA from one species to another (known as transgenics), synthetic biology may use synthetic (human-made) DNA to change the genetic information in a living cell. DNA may also be added or deleted to existing DNA (gene editing) or “rationally designed” through other techniques.

Synthetic biology techniques go further than previous genetic engineering techniques — they aim to more fully “redesign” an organism’s genetic information and allow for more radical and novel changes than conventional genetic engineering. In many cases, the final ingredient, for example synthetic biology vanillin, is not itself a genetically engineered organism, but the organism that produces it is. This will likely change as synthetic biology techniques begin to be applied to crops and animals and the current generation of GMOs are replaced by these synthetically engineered organisms.

Is synthetic biology addressed by existing non-GMO policies?

Currently, most GMO regulations worldwide do not directly address these new genetic engineering techniques, and some fall entirely outside of the scope of existing regulations. The Non-GMO Project is currently one of the few third-party certifiers that specifically addresses synthetic biology and clearly prohibits synthetic biology ingredients from non-GMO verification. The National Organic Standards Board has also clarified that synthetic biology ingredients are excluded from USDA certified organic products.

Most non-GMO policies exclude ingredients made from transgenic crops (e.g. soy, corn, and canola) and animals raised with transgenic feed. But newer genetic engineering techniques, like RNA techniques and CRISPR, also extend beyond transgenics and may not be addressed. Also, ingredients may be products of organisms engineered with synthetic biology, but may not have been engineered directly. It is critical that any non-GMO company policies clarify that genetic engineering techniques include new techniques that fall under synthetic biology, and that these will be excluded from products.



Will synthetic biology ingredients be labeled?

Currently there are no federal labeling requirements enforced in North America for any GMOs and that includes synthetic biology derived ingredients. Europe and other markets have mandatory GMO labeling, however the biotechnology industry is arguing that ingredients derived from some synthetic biology techniques should be exempted from labeling. Some synthetic biology companies have argued that a genetically engineered organism that makes an ingredient is just a “processing aid” and that the final ingredient should not require labeling (see question below). At present, the legal international language for GMO labeling (under the Codex Alimentarius Commission and under the UN’s Biosafety Protocol) could mostly cover synthetic biology techniques as “techniques of modern biotechnology.”

Will my ingredient supplier know which ingredients are derived from synthetic biology?

Suppliers may not know about new genetic engineering products or synthetic biology — even in their own products. A manufacturer of ingredients may not use the term “synthetic biology,” but instead may refer to the ingredients as “bio-based,” “fermentation-

derived,” “cultured,” “plant based” or produced “through a biotechnology process.” Intermediary suppliers may not be aware of the techniques used to manufacture ingredients and be misled by “natural” and “sustainable” claims made by synthetic biology companies.

Do synthetic biology derived ingredients pose a threat to human health or the environment?

Synthetic biology techniques are more powerful than previous genetic engineering techniques, but threats will depend on the specific application. There is little to no data that reliably predicts impacts, including health risks from various applications of the techniques. Like those from other genetic engineering techniques, synthetic biology organisms may produce novel contaminants and could have significant implications for ecosystems if they are released or escape into an ecosystem and continue to multiply.

There are also overall impacts on farmers, land use for industrial production of feedstocks and concerns about the trending consolidation of corporate power.

If the production is contained, are there risks?

There may be insufficient understanding about new genetic engineering and synthetic biology techniques or about how to contain the engineered organisms. Although some production of synthetic biology organisms (algae and yeast) is done in fermentation vats, even organisms and viruses from high containment laboratories routinely escape through human error. Commercial synthetic biology facilities are not necessarily containment-level facilities, and synthetic biology facilities have already experienced spills and escapes of synthetic biology organisms. Containment only addresses environmental risks, not health or justice concerns.

Are synthetic biology organisms processing aids?

For regulatory reasons, synthetic biology companies will claim that some engineered organisms are “processing aids.” This means that the engineered organisms produce a product for use, but do not themselves appear in the final ingredient. By analogy, a cow might be considered a “processing aid” for milk, or a bee considered a “processing aid” for honey.

The biotechnology industry argues the focus of environmental and health assessments should be only when final products are part of the engineered organisms, however, the assessment needs to be of the entire lifecycle of the production. Just as a consumer would want to know if milk was produced by a genetically engineered cow or honey from a genetically engineered bee, the same holds for ingredients that are from synthetically engineered yeast or algae — especially in cases when they are fed with a GMO feedstock.

How are synthetic biology-derived ingredients different from genetically engineered rennet?

They are similar. In 1990, some cheese-makers began using a new rennet (clotting agent) that was produced in a vat by genetically engineered yeast and later the yeast was re-engineered using synthetic DNA. This is a very early example of what today might be regarded as a synthetic biology-derived ingredient and it is widely used in our food supply, although it is excluded from organic production. Fortunately, human health issues have not been identified, but this single example cannot be extended for claiming safety or sustainability of other ingredients produced by other engineered organisms.

Are synthetic biology techniques safer or more predictable than GMOs?

There are a wide range of synthetic biology techniques that allow for novel combinations of genetic material and much greater intervention in how organisms are engineered. However, their side effects are poorly understood. Some scientists argue that synthetic biology is a

more predictable (and therefore safer) form of genetic engineering. While that may be a goal, these claims assume that living genetic systems are predictable and machine-like, an assumption that many scientists are finding to be invalid.

Is synthetic biology more “sustainable” because it’s “natural” and “bio-based?”

Several synthetic biology companies are misleadingly marketing its ingredients as “sustainable,” “natural” and “bio-based.” For example, although the engineered organisms carry out fermentation, a natural process, the organisms themselves are highly unnatural and synthetically constructed.

The term “bio-based” refers to the sugars and cellulose that synthetic organisms consume as well as the fact that the organisms themselves are “biological.” However, bio-based does not always mean “sustainable” or ecologically responsible. In addition to their significant ecological impacts from chemical contamination, feedstock industries, such as sugar, are associated with destructive forestry and farming operations, land grabs and land clearances of critical ecosystems, as well as harm to pollinators and other species.

Some synthetic biology companies claim that the ingredient being biosynthesized replaces one that would have been unsustainably extracted from the wild - e.g. palm oil or sandalwood. However, some of these claims are contested, do not deal with the complexity of the market and do not consider existing alternatives that present fewer risks. They need to be carefully scrutinized.

If the synthetic biology derived ingredient is “nature-identical” to the botanical version, what are the concerns?

Most of the synthetic biology derived ingredients currently being produced are for single flavor, fragrance and cosmetic compounds such as vanillin (vanilla flavor), nooktatone (grapefruit flavor), or squalane (moisturizing oil). Synthetic biology companies argue that the final compound produced is “nature-identical” (chemically similar) to the naturally derived version and therefore does



not need any additional assessment. However, in theory the synthetic biology processes may create unexpected and possibly harmful contaminants that may be difficult to prevent or detect. Without strict process-based assessments and regulations, it would be hard to track this. In addition, the process of replacing natural commodities with unnatural ones raises significant environmental concerns, and concerns about the impacts on small farmers livelihoods, cultures, and national economies.

Could synthetic biology help animal welfare and the environment by replacing animal products?

Spurred on by investors, a growing number of synthetic biology companies are attempting to produce synthetic versions of animal proteins, such as those found in egg whites and milk. There are also efforts to engineer lab-grown meat-like proteins. These synthetic substitutes may raise more health questions than flavors and fragrances as they may be consumed

in larger quantities and involve engineering proteins.

Whether they would offset animal-product production or merely create additional specialty markets is unclear. Significantly, this engineering approach creates a system in which food is treated as a collection of engineered biochemicals controlled and patented by tech companies. This is distinct from the sustainable agricultural vision promoted by the food movement which suggests a food sovereignty approach, which focuses on people collaborating with social and ecological standards as means to create a better, locally produced, sustainable and non-toxic food system. The new wave of synthetic biology-produced animal replacement products focus on high tech corporate “solutions” using proprietary technologies, replacing animal husbandry by people. It is critical to address the root problems of animal factory farming, and improve animal welfare with better animal agriculture practices, regulations, and consumer education.

Endnotes

1. Stearns, Jonathan. (Oct 4, 2015) “Most EU Countries to Ban Cultivation of 8 GMOs Using New Rules.” Bloomberg News. Retrieved from <http://www.bloomberg.com/news/articles/2015-10-05/most-eu-countries-to-ban-cultivation-of-8-gmos-using-new-rules>
2. <http://www.synbioproject.org/site/assets/files/1061/synbiosurvey2013.pdf>
3. European Commission Scientific Committees on Health and Environmental Risks (SCHER), Emerging and Newly Identified Health Risks (SCENIHR) and Consumer Safety (SCCS) “Opinion on Synthetic Biology I – Definition” available at http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_044.pdf