Modernizing Food Labeling: The Narratives of Food Innovation and Deciphering Mixed Messages

Nicole Negowetti, Lecturer on Law and Clinical Instructor, Harvard Law School

"NonGMO Labels"—Absence Claims—The Law, Congressional Intent, and FDA Policy

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Discussant: **Nigel Barrella**, Attorney, Barrella Law PLLC
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FDLI Symposium

November 15, 2019

“We are on the cusp of the deepest, fastest, most consequential disruption in food and agricultural production since the first domestication of plants and animals ten thousand years ago.”

RethinkX, Rethinking Food and Agriculture 2020-2030 (Sept. 2019)

The United States Meat Industry at a Glance

The meat and poultry industry is the largest segment of U.S. agriculture. U.S. meat production totaled 52 billion pounds in 2017 and U.S. poultry production totaled 48 billion pounds in 2017.

In 2017, the meat and poultry industry processed:
9 billion chickens
32.2 million cattle and calves
241.7 million turkeys
2.2 million sheep and lambs
121 million hogs

North American Meat Institute (2017)

Predicting the Future of Food

“By 2030, demand for cow products will have fallen by 70%. Before we reach this point, the U.S. cattle industry will be effectively bankrupt. By 2035, demand for cow products will have shrunk by 80% to 90%. Other livestock markets such as chicken, pig, and fish will follow a similar trajectory.” — RethinkX

“We wanted to enjoy the dairy foods we love without compromising on taste or our commitment to animals and the environment. Flora-based protein is as nutritious and delicious as traditional dairy protein, but with less impact on the earth.”

Mixed Messages

Fake meat	Plant-based meat; meat
Not meat	Better than meat
Unhealthy	Healthy for people + planet
Processed junk food	Innovative food tech
Unsafe/Risky	Clean, animal-free meat
Unproven environmental benefits	Sustainable
“GMO”	Non-GMO, Natural

What is “Meat”?

Amino acids, lipids, carbohydrates, minerals, and water.

U.S. Cattlemen May 2018 USDA Petition

- Limit the definition of “beef” to “product from cattle that have been born, raised, and harvested in the traditional manner.”

- The definition of “meat” should be limited to products derived from “the tissue or flesh of an animal harvested in the traditional manner.”

State Labeling Laws

Mississippi S.B. 2922

"[a] food product that contains cultured animal tissue produced from animal cell cultures outside of the organism from which it is derived shall not be labeled as meat or a meat food product. A plant-based or insect-based food product shall not be labeled as meat or a meat food-product."

Mo. Rev. Stat. 265.494(7)

Prohibits "misrepresenting" a product as "meat" if that product is "not derived from harvested production livestock or poultry."

A violation of the Statute carries a penalty of incarceration up to one year as well as a fine of as much as $1,000.

Arkansas Act 501

"Meat" means a portion of a livestock, poultry, or cervid carcass that is edible by humans.

"Meat" does not include:

(i) Synthetic product derived from a plant, insect, or other source; or

(ii) Product grown in a laboratory from animal cells.

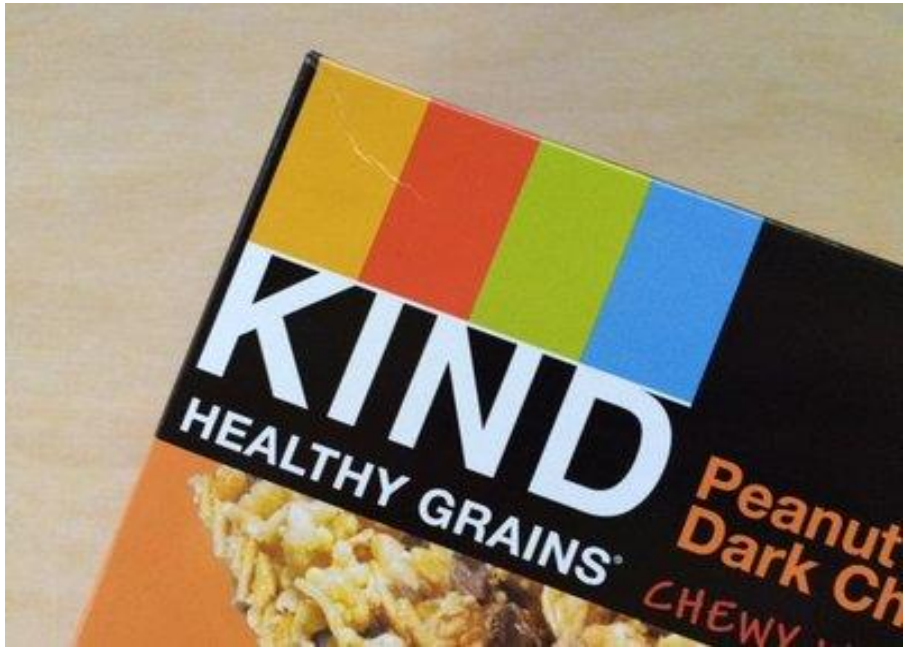
The Real Marketing Edible Artificials Truthfully (MEAT) Act of 2019

- Would amend the FDCA “to ensure that consumers can make informed decisions in choosing between meat products such as beef and imitation meat products.”
- Would require the FDA to find any “imitation meat food product,” to be misbranded unless its label bears, . . . the word ‘imitation’ immediately before or after the name of the food and a statement that clearly indicates the product is not derived from or does not contain meat.
- Would also define the term ‘beef’ or ‘beef product’ to mean “any product containing edible meat tissue harvested in whole form from domesticated Bos indicus or Bos taurus cattle.”

Modernizing “Healthy”

Healthy is defined in 21 C.F.R. 101.65(d) as an implied nutrient content claim that characterizes a food as having “healthy” levels of total fat, saturated fat, cholesterol and sodium.

In late 2016, FDA opened a comment period on regulation of the term “healthy” which extended until April 2017, and in 2017 FDA hosted a public meeting to discuss the issues related to revising the regulation.



Themes from FDA 2017 Public Meeting Re: "Healthy"

- Foods are healthy only within the context of a healthy dietary pattern; overconsumption of any food regardless of the food components or nutrients can be unhealthy;
- "Healthy" is a broad term subject to wide interpretation; devising a universal, one-size-fits-all definition of "healthy" could prove challenging because health, and one's perception of what that means, is subjective.
- Consumers can sometimes merge "healthy" with other product claims such as "organic," "non-GMO," "gluten free," and "hormone free."

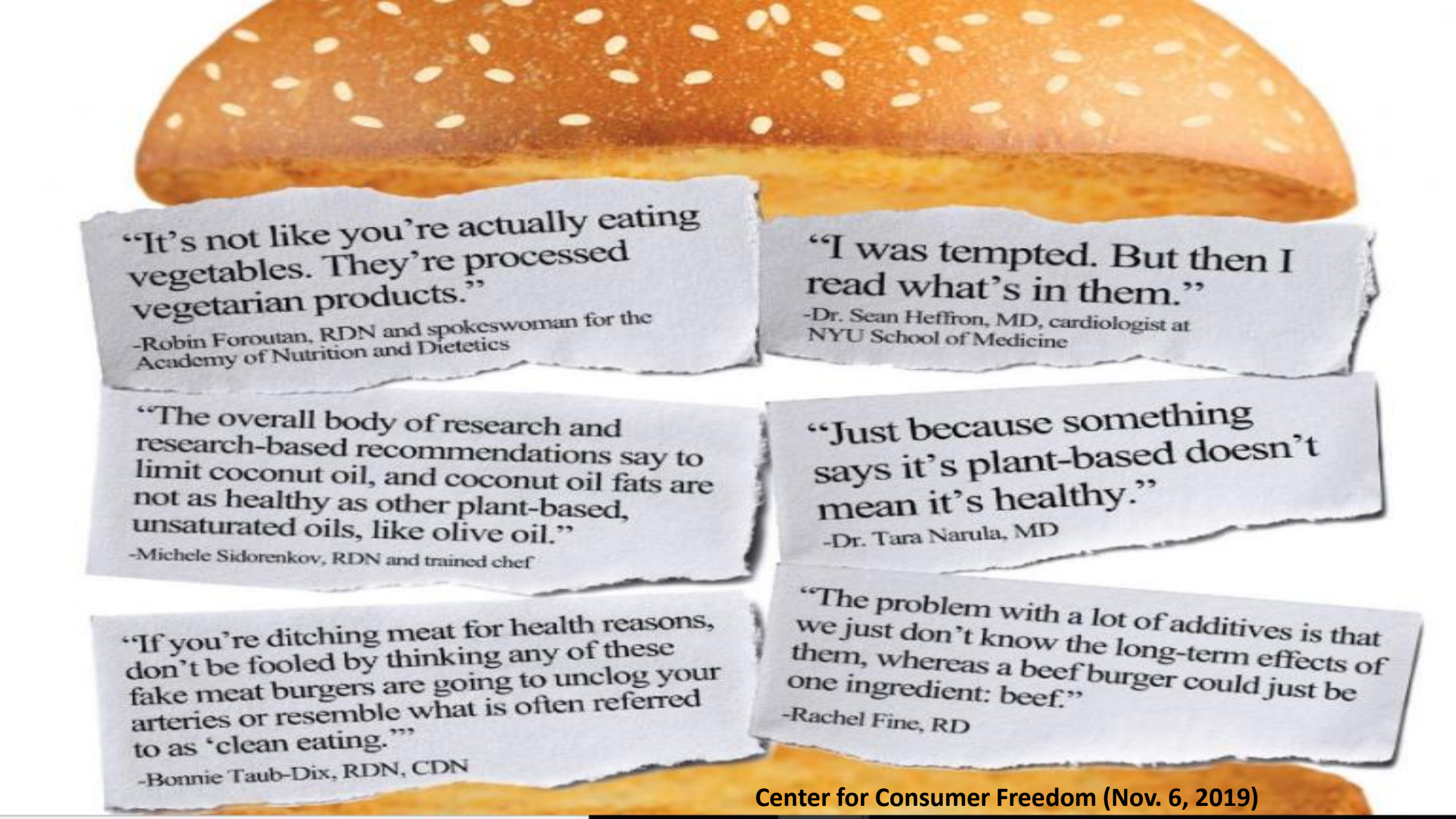
VIEWPOINT

Can Plant-Based Meat Alternatives Be Part of a Healthy and Sustainable Diet?

Burger Nutrition Comparison

Nutrition information serving size	 **Ground beef** **80% lean, 20% fat** (100 grams)	 **Beyond Burger** (113 grams)	 **Impossible Burger** (113 grams)	 **Morning Star Black Bean** (67 grams)	 **Boca Burger** (71 grams)
Calories	270 calories	290 calories	240 calories	110 calories	100 calories
Saturated Fat	6.7g	5g	8g	0.5g	1g
Protein	26g	20g	19g	9g	13g
Sodium	75mg	450mg	370mg	320mg	350mg

The "Health Halo" Effect



Center for Consumer Freedom (Nov. 6, 2019)

"Formulations of food substances often modified by chemical processes and then assembled into ready-to-consume hyper-palatable food and drink products using flavors, colors, emulsifiers and . . . other cosmetic additives."

Carlos A. Monteiro et al., *Ultra-processed Foods: What They Are and How to Identify Them*, 22(5) Public Health Nutr. 936, 937 (2019).

Grassfed Organic Burger Ingredients

- Lean organic grass feed beef

Ingredients that may be found in a Meat-Replacement product

- Soy protein concentrate*
- Maltdextrin*
- Natural flavors including "smoke"
- Hydrolyzed corn or soy protein*
- Caramel color
- Pea protein isolate
- Leghemoglobin (soy)*
- Gum Arabic
- Cellulose
- Soy protein isolate*
- Carrageenan
- Autolyzed yeast extract*
- Oleoresin paprika (color)
- Potassium chloride
- Xanthan gum*

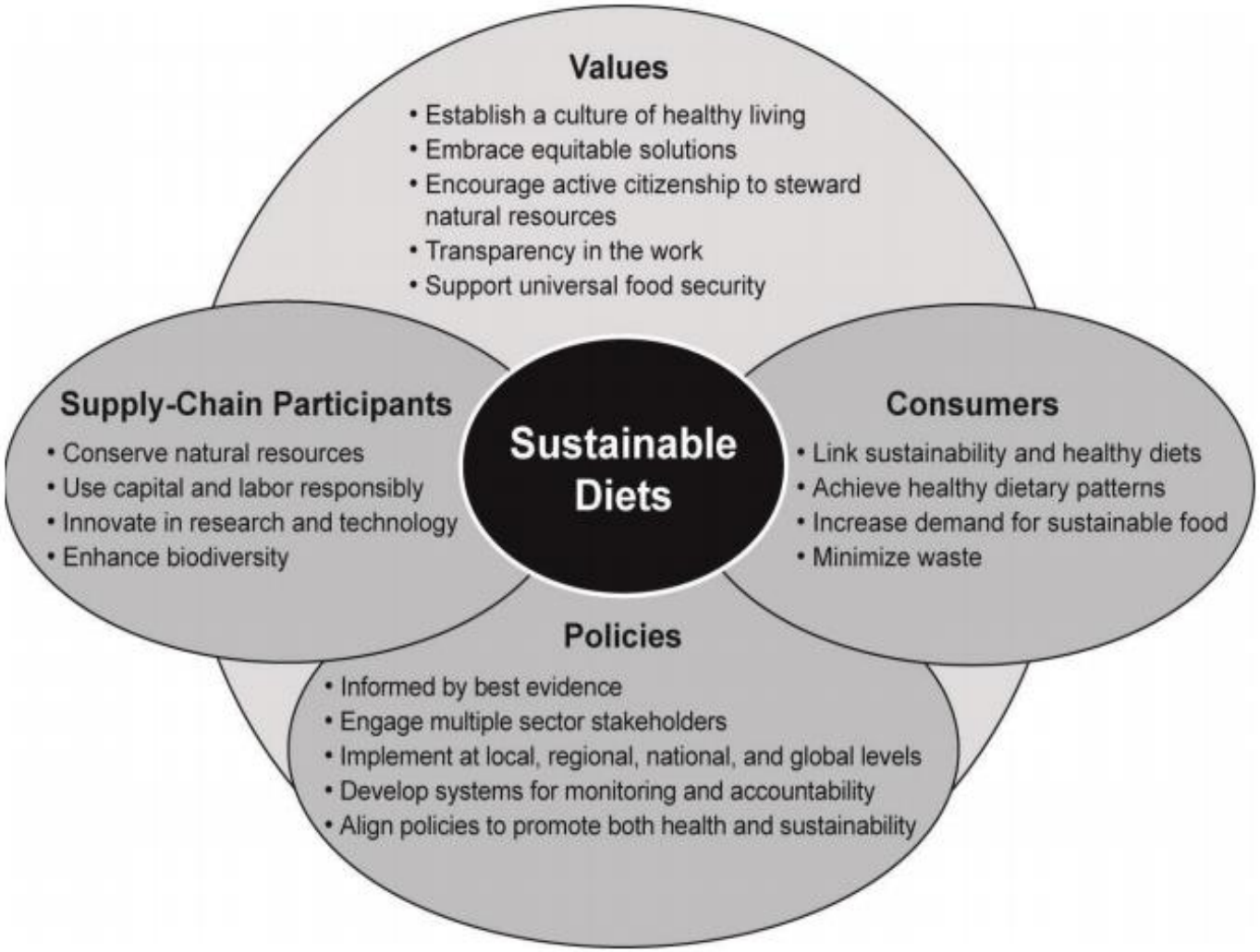
* Ingredients which may be derived from genetic engineering

FROM LAB TO FORK

CRITICAL QUESTIONS ON LABORATORY-CREATED ANIMAL PRODUCT ALTERNATIVES

Friends of the Earth

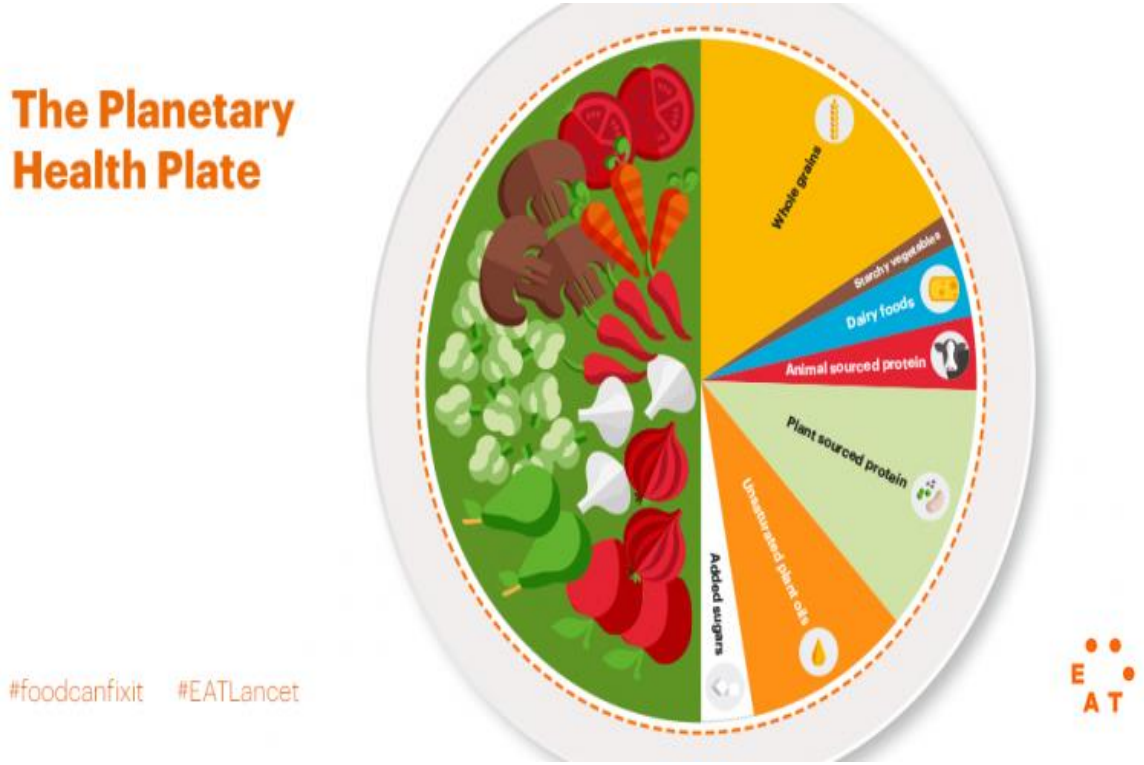
Linking Sustainability to Health: Towards A Broader Definition of "Healthy"



- "Sustainable diets are a pattern of eating that promotes health and well-being and provides food security for the present population while sustaining human and natural resources for future generations."
- "Linking health, dietary guidance, and the environment will promote human health and the sustainability of natural resources and ensure current and long-term food security."

2015 Dietary Guidelines Advisory Committee Report

Planetary Health



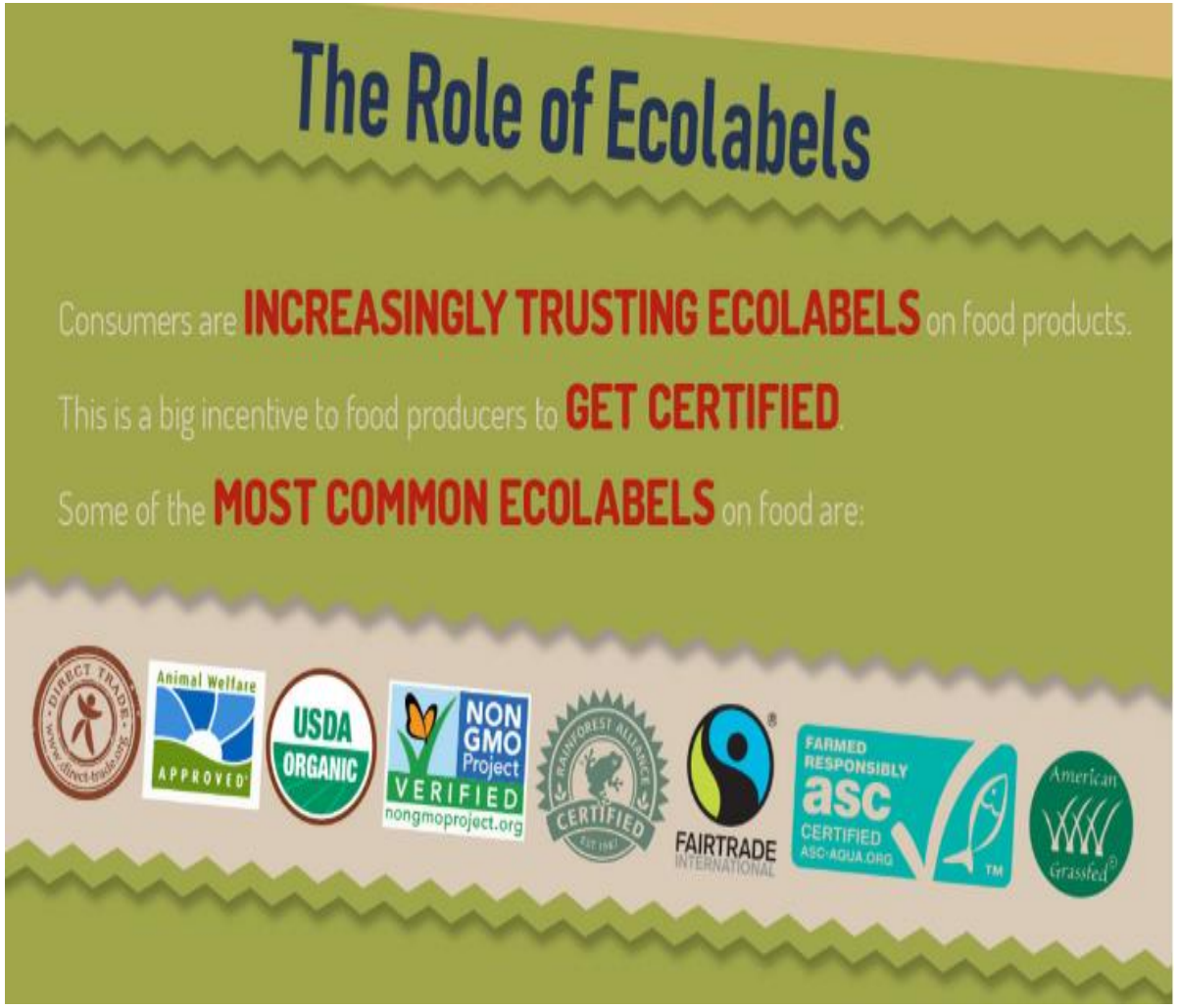
Food in the Anthropocene: The EAT–Lancet Commission on Healthy Diets from Sustainable Food Systems (2019)

- Defined as “the health of human civilization and the state of the natural systems on which it depends.”
- “Human diets inextricably link health and environmental sustainability, and have the potential to nurture both.”
- EAT-Lancet report calls for more than doubling the consumption of healthy foods such as fruits, vegetables, legumes and nuts, and **a greater than 50% reduction in global consumption** of less healthy foods such as added sugars and **red meat.**

IMPACT CATEGORY	UNIT	IMPOSSIBLE™ BURGER	BEEF BURGER	DIFFERENCE
Aquatic Eutrophication Potential	g PO4-eq	1.3	15.1	-92%
Global Warming Potential	kg CO2-eq	3.5	30.6	-89%
Land Occupation*	m2.y	2.5	62.0	-96%
Water Consumption	liters	106.8	850.1	-87%

**Land occupation is reported at an LCI level. Based on best available LCA-related information on food production, in accordance with ISO 14044 standard*

Communicating Sustainability on Food Labels



Communicating Biotech Processes

<u>Bioengineered Food Disclosure Standard</u>

Defines the term “bioengineering” as referring to a food “(A) that contains genetic material that has been modified through in vitro recombinant DNA techniques; and (B) for which the modification could not otherwise be obtained through conventional breeding or found in nature.” 7 U.S.C. § 1639(1).

Is this plant-based meat non-GMO?

start here

Is the product Non-GMO Project Verified?

Yes — This would be your best option for avoiding GMOs. The Non-GMO Project has North America's most rigorous standard for GMO avoidance.

No — Is it certified organic?

No — Does it contain major GMO risk ingredients like soy, canola, corn, and/or potato?

Yes — This product is high risk for containing GMOs.

No — Does this product contain minor ingredients such as yeast extract, lecithin, soy protein, soy isolate, soy leghemoglobin, and maltodextrin?

Yes — GMOs are found in many minor ingredients including flavorings, vitamins, and other texturizers.

No — This product has a low risk of containing GMOs. However, if you still aren't sure, always look for the Butterfly!

Yes — While USDA rules prohibit GMOs, organic certification does not require testing. Therefore, the best way to avoid GMOs is to look for the Non-GMO Project Verified mark along with organic certification.

NON GMO Project VERIFIED nongmoproject.org

GMOs & Plant-Based Meat

GMOs are living organisms whose genetic material has been artificially manipulated in a laboratory through genetic engineering. Some plant-based meats are a double whammy, using GMO yeast microbes for special flavorings and GMO commodity crops (e.g. soy) as a protein base.

94% of all soy grown in the US is GMO

82% of all corn grown in the US is GMO

80% of all processed food in the US may contain GMO ingredients

658 Number of tofu, tempeh and alternative meat products currently Non-GMO Project Verified

Perfect Day™

flora

Does your protein contain GMOs?

No, flora-based protein does not contain GMOs.

The microflora we work with are really good at producing different kinds of protein naturally. We simply give them instructions for producing exactly the type of protein we want — in this case, the milk proteins casein and whey. We then filter out the modified flora, leaving only pure protein.

In other words, genetic modification is part of our process, but it is not present in the final product.

GMOs 2.0: UNPREDICTABLE, UNTESTED, UNJUST

"Genetic engineering is unpredictable. When you alter the genetics of living things they don't always behave as you expect."

Michael Hansen, PhD, Senior Scientist, Consumers Union

Companies are rushing synthetic biology products onto the market — without labeling them, and without understanding the impact on health, the environment, farmers and communities.

Why is this a problem?

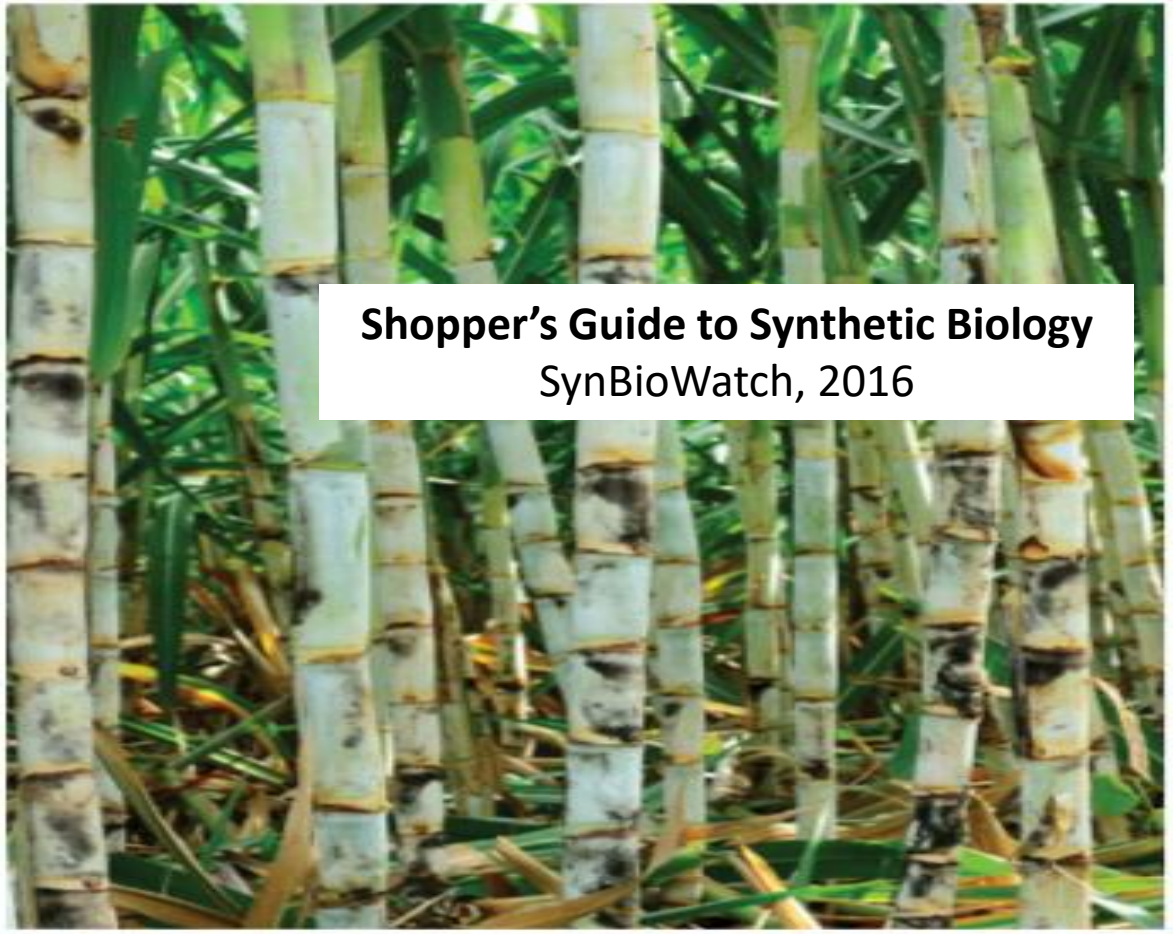
Unpredictable: Any change to genes can have unintended impacts on an organism, species or ecosystem. Some first generation GMOs had unexpected effects such as unwanted chemical compounds. GMOs 2.0 may be even more unpredictable.

Untested: Governments require little to no testing to ensure the safety of GMOs, and the same is true for GMOs 2.0. It's left up to companies to decide what's safe.

Unfair and Unjust: GMO crops linked to patented seeds or chemicals are already displacing farmers around the world. Now plant-based products may be replaced by synthetic biology that is falsely marketed as natural and sustainable.

Unsustainable: Some companies claim GMOs 2.0 are the solution for sustainability. But many current synthetic biology products depend on sugar from chemical-intensive monocultures or other polluting feedstocks such as fracked gas. GMO 2.0 products such as engineered algae may escape into the environment and become "living pollution."

How is that sustainable?



Shopper's Guide to Synthetic Biology
SynBioWatch, 2016

Industrial sugar cane production pollutes and degrades the environment and takes up land that could be used by small farmers.

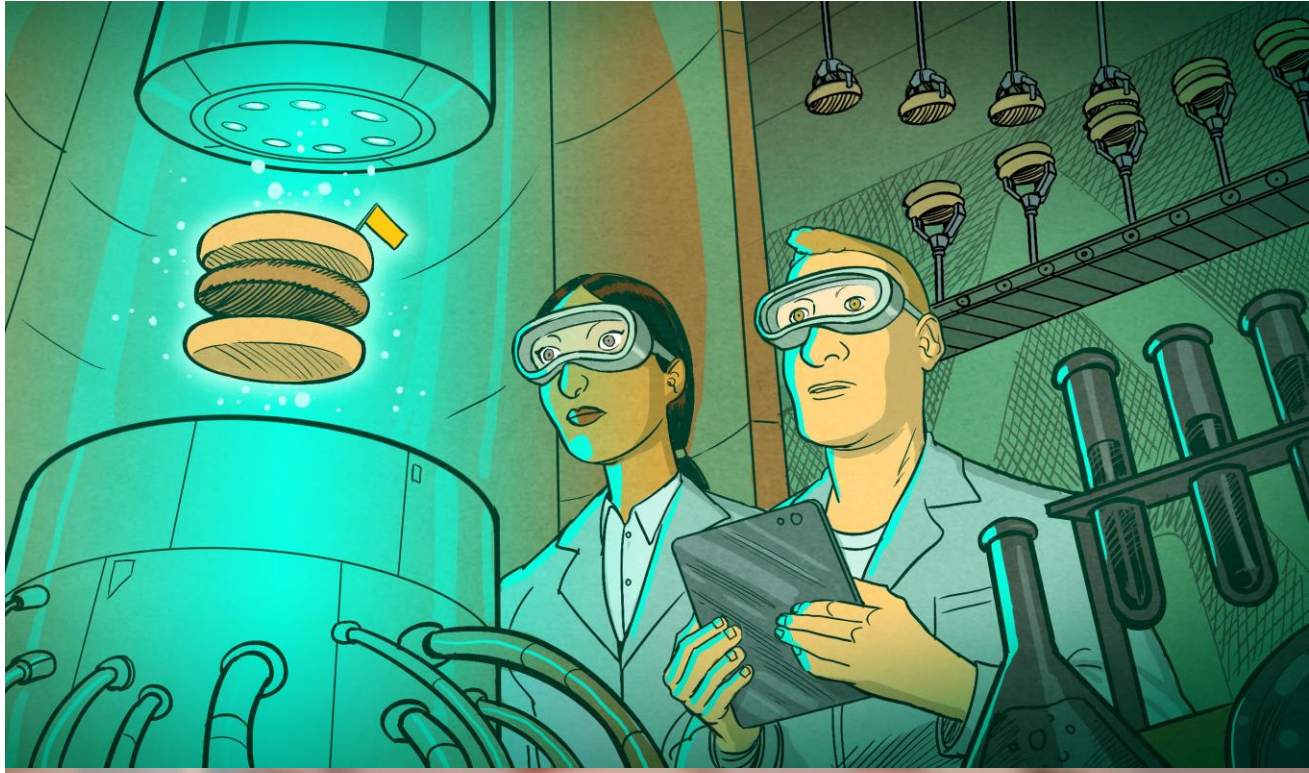
(Un)“Natural”

What’s really in these products?

“On the surface, the Impossible Burger’s goal to reduce meat consumption sounds important. There are urgent problems with animal factory farming. ***But at a time when consumers are pushing for more sustainably produced real food, are these biotech products the right answer?***

While we and many in the environmental and animal welfare community are fully in support of reducing unsustainable meat consumption, in an era where consumers are increasingly ***demanding transparency*** and ***“real” food*** and ***running full speed away from processed, industrial food***, it would seem that ***non-GMO, organic, plant-based meat alternatives that carry less inherent risks are a wiser direction***.”

Is “Food-Tech” the Future of Food? *by Dana Perls, Senior Food & Technology Campaigner Friends of the Earth*



“GMO-Free” Claims and False and Misleading Food Labels—Why Is FDA AWOL?

L. Val Giddings, Ph.D.
Senior Fellow, ITIF

Food & Drug Law Institute
15 November 2019

@prometheusgreen

About ITIF

- Independent, nonpartisan research and education institute focusing on intersection of technological innovation and public policy, including:
  - Innovation and competitiveness
  - IT and data
  - Telecommunications
  - Trade and globalization
  - Life sciences, agricultural biotech, and energy
- Formulates and promotes policy solutions that accelerate innovation and boost productivity to spur growth, opportunity, and progress
- World's top think tank for science and technology policy, according to the University of Pennsylvania's authoritative *Global Go To Think Tank* Index

ITIF | INFORMATION TECHNOLOGY & INNOVATION FOUNDATION


NON
GMO
Project
VERIFIED

What is a “GMO”?

- According to the Non-GMO Project a “GMO” is

> “…a plant, animal, microorganism or other organism whose genetic makeup has been modified in a laboratory using genetic engineering or transgenic technology. This creates combinations of plant, animal, bacterial and virus genes that do not occur in nature or through traditional crossbreeding methods.”

About this definition…

- “GMO” is not a scientific term.
- It arbitrarily stigmatizes some techniques vs others that can produce identical phenotypes.
- It insinuates danger where data/experience show there is none.
- Scientists producing “GMOs” use techniques found *in nature*, & enzymes/reagents *from nature* to mimic process and results found *in nature*.
- Every living thing is genetically modified.
- Nature is the all time champion at generating novel ”combinations of plant, animal, bacterial and virus genes”

In other words…

- “GMO” has no defensible meaning; it is literal “nonsense.”
- The term “GMO” therefore is intrinsically, inescapably misleading.
- The term “Non-GMO” is therefore also intrinsically, inescapably misleading.
- The Non-GMO butterfly wrongly stigmatizes “GMOs” and misleads consumers.

[NonGMO Project Executive Director Megan Westgate said]

"…the goal of the Non-GMO Project, which was started in 2005, is to shrink the market for existing GMO ingredients and prevent new commercial biotech crops." https://www.wsj.com/articles/more-foods-boast-non-gmo-labelseven-those-without-gmo-varieties-1440063000

What does the Non-GMO Project say about “GMO” safety?

- “…a growing body of evidence connects GMOs with health problems… contamination…”
- Exposure itself constitutes negative health consequences.
- “…no scientific consensus on the safety of GMOs.”
- Such false claims are found throughout the Non-GMO Project website & their social media.
- Butterfly is on more than 61,000 food items now in U.S. grocery stores.

What does FDA say about “GMO” Food Safety?

- “The agency is not aware of any information showing that foods derived by these new methods differ from other foods… or that [they] present any different or greater safety concern…”
- "FDA does not use the terms “genetically modified” or “genetically modified organism.”
- FDA has reaffirmed these views repeatedly over the past 30 years.


AT ITS CORE,
A NON-GMO LABEL
IS PURE, OPPORTUNISTIC
FEAR-BASED MARKETING.
– Alison Bernstein
Mommy, PhD
#Moms4GMOs
SCIENCE Moms

What does U.S. labeling law have to say about misleading consumers?

- The Food Drug and Cosmetic Act prohibits the “misbranding” of food. This was defined in the 1906 Food and Drug Act:

> …the term "misbranded," …shall apply to all drugs, or articles of food, or articles which enter into the composition of food, the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular…

What about Congressional intent?

"…the general prohibition against false and misleading representations was meant to be comprehensive in character and recognized that 'the labels of food… are not considered… to be the proper media for making any representations… which are not in accord with the facts.'"

It gets better…

"…even truthful information can mislead consumers… if voluntary labeling is to be employed, misleading implications must be avoided and information presented must appear in its proper context. Thus, FDA considers [labels for] genetic modification in a food to be potentially misleading…"

Safety claims must pass a strict test and high hurdle

- [NonGMO labels] …may leave the misimpression that the labeled food is somehow safer or better than its genetically manufactured counterpart, or that the use of genetic engineering techniques adversely effects the character, quality, or nature of the food.
- Such voluntary representations must be able to withstand the scrutiny under the standard adopted by the Supreme Court over seventy years ago for evaluating the propriety of information voluntarily placed on the food label.

Labels that mislead or deceive consumers are prohibited

- “The statute is plain and direct. Its comprehensive terms condemn every statement, design and device which may mislead or deceive.”
- Deception may result from the use of statements not technically false or which may be literally true.
- The aim of the statute is to prevent that resulting from indirection and ambiguity as well as from statements which are false.
- It is not difficult to choose statements, designs and devices which will not deceive… This test applies to “labeling” as well and, thus, governs promotional and display materials accompanying the sale of food.

Summary

Through its butterfly label and marketing materials, the Non-GMO Project makes misleading and inaccurate claims, resulting in misbranding.

It makes food safety claims that are false and misleading.

It’s claims interfere with consumers’ ability to make wise food purchase decisions.

All these are against the law, yet FDA has taken no action against the NonGMO Project.


FEAR
BASED
MARKETING
Project
VERIFIED

Sources

- FDA “Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants” March 8, 2019 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-voluntary-labeling-indicating-whether-foods-have-or-have-not-been-derived
- Petition to the Food and Drug Administration Requesting a Stop to Deceptive and Misleading “Non-GMO” Food Labels, http://www2.itif.org/2018-non-gmo-citizen-petition.pdf?_ga=2.45966887.2084179000.1543496003-1394096080.1536250378
- Green Paradox: Monarch Butterflies Turn Out To Be GMOs, https://www.science20.com/news_articles/green_paradox_monarch_butterflies_turn_out_to_be_gmos-157192 & https://journals.plos.org/plosgenetics/article?id=10.1371/journal.pgen.1005470

Thank You!

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