CITIZEN PETITION

September 24, 2018

The undersigned submits this petition under Section 403 of the Federal Food, Drug, and Cosmetic Act, 21 USC 343. Because the “Non-GMO” Project butterfly logo and language on consumer foods and goods misleads and deceives consumers through false and misleading claims about foods, food ingredients and their characteristics related to health and safety, thus constituting misbranding under the law, we request that the Commissioner of Food and Drugs issue a regulation to prohibit the use of the term “Non-GMO” on consumer foods and goods, and to require distributors of foods and goods to revise their labeling to omit any “Non-GMO” term or claims.

STATEMENT OF GROUNDS: THE NON-GMO PROJECT BUTTERFLY LOGO WRONGLY STIGMATIZES SO-CALLED “GMOS” AND IN SO DOING MISLEADS CONSUMERS

The Non-GMO Project describes itself as “...a mission-driven nonprofit organization dedicated to building and protecting a non-GMO food supply... through consumer education and outreach programs; marketing support provided to Non-GMO Project Verified brands; and training resources and merchandising materials provided to retailers.”¹

Primarily visible to consumers through its Monarch butterfly logo, the Non-GMO project is but one example of the proliferation of “absence claim” labels making up a growing industry segment based on misleading and deceiving consumers.² The Non-GMO Project presumes the existence of a class of foods, “GMO,” that is arbitrary, has no basis in science, and is intrinsically misleading. It defines them as ...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.\textsuperscript{3}

This definition is not scientifically defensible.\textsuperscript{4} It seeks to draw a distinction between something done deliberately by humans and something that occurs spontaneously in "nature" about which we have learned only because of something done deliberately by humans, which is research driven by curiosity, an inarguably natural characteristic of our species. The sly implication is that what happens in nature is safer than what is done in the lab, and that its label can help consumers avoid risks that, in reality, do not exist.\textsuperscript{5} The arbitrarily stipulated definition presupposes humans and human activity are necessarily distinct and separate from anything that may be considered "natural"—something about which philosophers have argued for millennia and on which disagreements persist.\textsuperscript{6}

The techniques used to bioengineer crops and livestock to produce foods were discovered as natural phenomena, and the enzymes and reagents involved are all extracted or derived from sources in nature. While \textit{in vitro} bioengineering methods may produce "combinations of … genes that do not occur in nature or through traditional crossbreeding methods," recombination as it takes place in nature is also constantly generating novel combinations of genes, and there is nothing intrinsic to such novel combinations from either source that allows any predictions with regard to their safety. As the National Academy of Sciences has reaffirmed no less than 11 times in the 32 years since they first considered this issue, the fact that something has been genetically engineered/bioengineered/genetically modified/mutated, either in the lab or in nature, tells one absolutely nothing about the safety of the resulting product. Safety is entirely dependent on the specific characteristics involved, and those are independent of how they came to be.\textsuperscript{7} Considering this together


with the myriad forms of mutation omnipresent and ubiquitous throughout the living world, in the common meanings of the terms, every living thing on the planet is a "genetically modified organism" thus adding a further layer of indefensibility to the Non-GMO project claims.

The definition stipulated by the Non-GMO Project further begs questions as to the apparently allowable "traditional crossbreeding methods"—are these "natural," or not? If not, why are they not? And if they are acceptable, natural or not, why are they acceptable and the methods used to bioengineer "GMOs" are not? Whatever the terms "GMO" and "natural" may mean to some, they have no universally accepted and understood meanings, and, crucially for their use on a label, they provide no information relevant to health, safety, or nutrition that would be useful to a consumer contemplating food purchase choices. They are inescapably confusing and intrinsically misleading.

**STATEMENT OF GROUNDS: THE NON-GMO PROJECT MAKES FALSE CLAIMS ABOUT FOOD HEALTH AND SAFETY THAT ARE CONVEYED BY THE BUTTERFLY LOGO TO MISBRAND FOODS AND MISLEAD CONSUMERS**

Not only does the Non-GMO project attempt to draw a nonsensical line to separate "GMOs" from "Non-GMOs," they further claim this invidious distinction has implications for safety, falsely claiming "GMOs" are less safe than the arbitrary and no less genetically modified class they call "Non-GMO." The "risk categories" defined by the Non-GMO project are these:

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<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Definition</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-Risk</td>
<td>The input is derived from, contains derivatives of, or is produced through a process involving organisms that are known to be genetically modified and commercially available.</td>
<td>Alfalfa, Canola, Corn, Cotton, Papaya, Soy, Sugar beet, Yellow summer squash / zucchini, Animal products, Microbes and enzymes</td>
</tr>
<tr>
<td>Low-Risk</td>
<td>The input is not derived from, does not contain derivatives of, or is not produced through a process involving organisms that are presently known to be genetically modified and commercially available.</td>
<td>Lentils, Spinach, Tomatoes, Sesame seeds, Avocados</td>
</tr>
<tr>
<td>Non-Risk</td>
<td>The input is not derived from biological organisms and not, therefore, susceptible to genetic modification.</td>
<td></td>
</tr>
<tr>
<td>Monitored Risk</td>
<td>The Non-GMO Project carefully monitors the development of new genetically engineered products; we are currently tracking close to 100 products. Of those, we have included the following in our surveillance program, either because they will likely soon be widespread or because of known instances of contamination from GMOs.</td>
<td>Flax, Mustard, Rice, Wheat, Apple, Mushroom, Orange, Pineapple, Potato, Camelina (false flax), Salmon, Sugarcane, Tomato</td>
</tr>
</tbody>
</table>

The hazard creating the risk upon exposure to “GMOs” according to the Project’s risk taxonomy above is the mere presence of anything in this arbitrary and suspect class as if any exposure itself constitutes negative health consequences. Representations made by the Non-GMO project throughout their website and presence in various fora, including social media, make it clear they are overtly asserting and representing that negative health consequences are associated with consumption of “GMO” foods. Indeed, this conceit provides the entire *raison d'être* for the Non-GMO project. A representative entry from their facebook page, itself derived from their website, illustrates (emphasis added):

> A question we get asked a lot at the Non-GMO Project is “are #GMOs safe?” Here’s our take: Most developed nations do not consider GMOs to be safe. In fact, in more than 60 countries

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around the world, including Australia, Japan, and all of the countries in the European Union, there are significant restrictions or outright bans on the production and sale of GMOs. In the U.S. and Canada, GMOs have been approved based on studies conducted by the same corporations that created them and profit from their sale. A growing body of evidence connects GMOs with health problems, environmental damage and violation of farmers’ and consumers’ rights.

At the Non-GMO Project we hear from people on a daily basis who are deeply concerned about the potential impacts of GMOs and are taking matters into their own hands by choosing to opt out of the #GMO experiment.\textsuperscript{10}

This assertion of negative health consequences from mere exposure, let alone consumption, is not supported by data or experience, as FDA noted in promulgating its draft policy on labeling bioengineered foods: “The agency is not aware of any information showing that foods derived by these new methods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding.”\textsuperscript{11}

STATEMENT OF GROUNDS: THE NON-GMO PROJECT MAKES FALSE CLAIMS ABOUT THE SCIENCE OF “GMO” SAFETY AND IN SO DOING MISLEADS CONSUMERS

The Non-GMO project claims “There is no scientific consensus on the safety of GMOs.”\textsuperscript{12} The scientific literature shows this claim is false.\textsuperscript{13} Authoritative bodies around the world have examined the safety of so-called “GMOs” from multiple angles.\textsuperscript{14} Their overwhelming consensus is that the safety of foods derived from crops, livestock, and foods improved through biotechnology depends on the final characteristics of the food, and bears no relationship to the methodology through which it was derived, and that the “GMO” derived

\textsuperscript{10} Non-GMO Project Facebook post, May 8, 2018, at https://www.facebook.com/nongmoproject/.
foods on the market are, without exception, safe. The U.S. National Academy of Sciences has consistently reaffirmed this in no less than 11 major studies from 1986 through 2016. This finding of "GMO" safety (focused on products presently on the market) is grounded firmly in the overwhelming consensus of the peer reviewed scientific literature. Indeed, the only safety differentials reported between so-called "GMO" foods and their conventional or organic counterparts have found "GMO" foods to be safer.

The Non-GMO Project claims "Most of the research used to claim that GMOs are safe has been performed by biotechnology companies." Examination of "GMO" approval dossiers posted in government regulatory databases shows this is not the case. Even if it were true, a more telling comparison would examine the...


results from research performed by biotechnology companies and that done by independent academic researchers. This question has been examined, and the results demonstrate that rigorous peer-reviewed studies of “GMO” safety reach similar conclusions about safety regardless of who performs or funds them.\textsuperscript{20}

\textbf{STATEMENT OF GROUNDS: THE FOOD DRUG AND COSMETIC ACT PROHIBITS LABELS THAT ARE “FALSE OR MISLEADING IN ANY PARTICULAR”, AND THE BUTTERFLY LOGO IS FALSE AND MISLEADING ON MULTIPLE GROUNDS SUCH THAT FOODS CARRYING IT ARE MISBRANDED}

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

\begin{quote}
...the term "misbranded," as used herein, 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...\textsuperscript{21}
\end{quote}

This definition has carried forward through multiple legislative amendments to the law in effect today, which states “A food shall be deemed to be misbranded... (a)If (1) its labeling is false or misleading in any particular...”\textsuperscript{22}

The legislative record shows Congress’ intent was that “…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.”\textsuperscript{23}

Indeed, misleading food labels are so anathema under the law that

...even truthful information can mislead consumers... Accordingly... if voluntary labeling is to be employed, misleading implications must be avoided and information presented must appear in its proper context. Thus, FDA considers voluntary representations with regard to the presence or absence of genetic modification in a food to be potentially misleading, and the agency has said these must be crafted with care and caution.²⁴

This intent is maintained even through the “National Bioengineered Food Disclosure Standard” of 2016, and legal scholars have flagged the clarity of Congress’ intent to prohibit misleading labels, noting that even

...a ‘voluntary’ labeling initiative also may have the potential to mislead customers. For example, in the area of genetically engineered foods, routing a food as not being the subject of recombinant DNA technology may leave the misimpression on the part of the uninformed consumer that the labeled food is somehow safer or better than its genetically manufactured counterpart, or that somehow 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: “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.²⁵

Because the definition of "GMO/Non-GMO" is arbitrary, unscientific, and misuses terms in ways contrary to their common meaning, the Non-GMO project label is intrinsically and inescapably misleading. That it is used by design to suggest health risks where there are none adds yet another layer of deception consumers are generally ill equipped to penetrate.26

Consumers who see the Non-GMO Project butterfly logo are unavoidably misled on multiple levels. First, they are wrongly led to believe items carrying the label are safer to consume than those that do not. This alone is sufficient to compel FDA to take action to prohibit such deception. But the butterfly also often misleads consumers in another way: it is often found on items where there is no counterpart improved through biotechnology available on the market. Examples include amaranth, blueberries, buckwheat, milk, and many more.27 Such misbranded products have become so common throughout grocery stores as to elicit widespread criticism even on famously credulous social media, including a satirical video mocking brands that resort to such cynical, fear based marketing.28 Overlooking no opportunity to exploit baseless consumer fears in search of higher profits, the Non-GMO Project will even certify items that are abiatic, composed entirely of mineral or other non-living ingredients containing no genetic material, which could thus never be genetically modified in any way at all, such as kitty litter and "Himalayan Pink Salt." Indeed, the Canadian Food Inspection Agency (CFIA) has found the arguments made by the Non-GMO project so empty of coherence

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and the claims so unfounded that it recently concluded their Non-GMO label does not even, in fact, imply that no “GMOs” (however defined) are present in products labeled as “Non-GMO.”

Through such extremes of misleading and deceptive marketing the Non-GMO project represents the modern resurrection of the kind of widespread consumer fraud that led to the passage of the 1906 Food and Drug Act and gave birth to the modern FDA. In summary, through its butterfly logo label and associated marketing materials, the Non-GMO Project makes claims about food that are misleading and inaccurate, resulting in misbranding. It makes claims about food safety that are false and misleading. It makes claims that interfere with consumers’ ability to make wise food purchase decisions. It is time for FDA to put an end to this fraudulent scheme and protect consumers from misleading and deceptive food labels as the law requires.

ENVIRONMENTAL IMPACT:

This petition claims exemption from the requirement for an Environmental Impact Statement pursuant to § 10.30 Promulgation of regulations for the efficient enforcement of the law.

ECONOMIC IMPACT:

In accordance with 21 C.F.R. § 10.30, economic impact information is to be submitted only when requested by the Commissioner following review of the petition. Petitioner hereby commits to promptly provide this information, if so requested.

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CERTIFICATION:
The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

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