MEMORANDUM

I. States Have the Right to Require Food Labeling

Consumers overwhelmingly desire the right to know whether their food was produced with genetic engineering. Consumer surveys routinely show that more than 90 percent of Americans—regardless of age, income, gender or even party affiliation—want to know whether the ingredients in their food have been genetically modified.[1]

While the Food and Drug Administration has the authority[2] to require GE labeling, it has thus far declined to do so. In the wake of strong consumer demand for information about genetic engineering and the absence of federal action, three states—Connecticut, Maine, and Vermont—have passed mandatory labeling laws. Massachusetts and New York are also actively considering GMO labeling bills.

The existing and proposed state GMO labeling laws are consistent with the role Congress has long recognized for the states with regards to food labeling.[3] The National Labeling and Education Act (NLEA) of 1990 does not preempt state food labeling laws, including GMO labeling laws.[4] When declining to preempt states, Congress explicitly recognized the longstanding role that states have played in food labeling, and the Supreme Court recently reiterated the narrowness of NLEA's preemption provision in *POM Wonderful LLC v. Coca-Cola*.[5] What's more, these state labeling laws address legitimate state interests[6]—such as

[1] *See, e.g.*, The Mellman Group, Inc., *Support for Mandatory Labeling of Genetically Engineered Foods Is Nearly Unanimous*, JustLabelIt.org (Mar. 22, 2012), http://www.justlabelit.org/wp-content/uploads/2012/01/Mellman-Survey-Results.pdf.

[2] For example, FDA has compelled disclosures unrelated to nutrition and health, including mandatory labeling for irradiation. When issuing the rule requiring irradiated foods be labeled, FDA concluded that irradiation was "material" because consumers view such information as important. 51 Fed. Reg. 13376, 13388 (Apr. 18, 1986). FDA has also required mandatory labeling for protein hydrolysates, noting that "the food source of a protein hydrolysate is information of material importance for a person who desires to avoid certain foods for religious or cultural reasons." 56 Fed. Reg. 28592, 28600 (June 21, 1991).

[3] *Holk v. Snapple Beverage Corp*., 575 F. 3d 329, 334 (3rd Cir. 2009). States have required state-specific labels for food containing potentially hazardous ingredients, *see, e.g.,* Cal. Health & Safety Code § 25249.6 (for food that has been previously frozen), *see, e.g.,* Md. Code., Health-Gen. § 21-210(b)(11) (for cheese), Wis. Stat. §97.177(3), as well as "cottage industry" foods, *see, e.g.,* Tex. Health & Safety Code § 437.0193. In addition, states set different requirements for "use by" and "sell by" dates. See, e.g., 105 Mass. Code Regs. 520.119.

[4] NLEA expressly preserved a role for the states to regulate food labeling. Pub L. No. 101-535, Sec. 6(c)(1), 104 Stat. 2353, 2364 (1990) (providing that the NLEA "shall not be construed to preempt any provision of State law, unless such provision is expressly preempted."). In addition, courts have held that FDA's natural policy is not "entitled to preemptive effect." *Holk v. Snapple Beverage Corp.,* 575 F. 3d 329, 240 (3rd Cir. 2009).

[5] *Pom Wonderful LLC v Coca Cola,* 134 S. Ct. 2228, 2238 (2014) (finding "it is significant that the complex preemption provision distinguishes among different FDA requirements.") *See also Wyeth v. Levine*, 129 S. Ct. 1187, 1200 (2009) ("the case for federal preemption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them.").

[6] *Zauderer v. Office of Disciplinary Council of the Sup. Ct. of Oh*., 471 U.S.C. 626 (1985). *Zauderer* establishes that an informational disclosure is subject to "rational" review – that is, whether the required disclosure is reasonably related to the state's interest. *See also Walters v. Nat'l Ass'n of Radiation Services*, 473 U.S. 305 (1985).

consumer confusion,[7] economic injury,[8] and environmental impacts[9]—without placing an impermissible burden on interstate commerce.[10]

II. State GMO Labeling Laws Are Consistent & Would Not Lead to a "Patchwork" of Requirements

State GMO labeling laws are in line with the role states have long played in food labeling and consistent with each other. They meet legitimate state interests without placing an impermissible burden on interstate commerce. Nonetheless, detractors often argue that the state labeling laws could lead to an unworkable "patchwork." However, a closer look at the passed and proposed laws show that they are largely consistent and a simple "produced with genetic engineering" disclosure would meet the requirements for each state.

A. Definition

The definition of "genetic engineering" used by the states is modeled after the definition adopted by the UN Codex Alimentarius.[11] All state definitions include in vitro nucleic acid techniques and cell fusion as forms of genetic engineering to varying degrees of specificity. Connecticut, Vermont, New York, and Massachusetts have robust definitions of genetic engineering that largely mirror one another. Their definitions list different kinds of in vitro nucleic acid techniques and cell fusion methods that would be considered genetic engineering.[12] Maine, on the other hand, has a broader, less specific definition, but still includes in vitro nucleic acid techniques and cell fusion in the definition. As such, any product that meets the definitional requirements of the other state laws would likely also fall under Maine's definition.

B. Threshold

All five states have a uniform requirement pertaining to the threshold for genetic content that would trigger a labeling requirement. No food is required to be labeled if the amount of

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[7] *See Edenfield v. Fane,* 507 U.S. 761 (1993) (state has a substantial interest "in ensuring the accuracy of commercial information in the marketplace.") Consumer surveys have shown that many consumers wrongly believe that foods labeled as "natural" are GMO-free. *See* Natural Marketing Inst. (NMI), 2014 GMO Consumer Insight Report 28 (2014); Consumer Reports National Research Center, Food Labels Survey 7 (2014), *available at* http://www.greenerchoices.org/pdf/ConsumerReportsFoodLabelingSurveyJune2014.pdf. State GMO laws could play a role in dispelling this consumer confusion.

[8] *See, e.g.*, *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2741, 2756 (2010) (affirming that gene flow "injury has an environmental as well as an economic component").

[9] *See e.g.* John M. Pleasants & Karen S. Oberhauser, *Milkweed Loss in Agricultural Fields Because of Herbicide Use: Effect on the Monarch Butterfly Population*, Insect Conservation and Diversity (2012), *available at http://www.mlmp.org/results/findings/pleasants_and_oberhauser_2012_milkweed_loss_in_ag_fields.pdf*

[10] *National Electronic Manufacturers Association v. Sorrell*, 272 F. 3d 104, 110 (2nd Cir. 2001). The Second Circuit held that a labeling requirement that could lead manufacturers to "arrange their production and distribution processes to label products solely for Vermont" did not create a burden for commerce clause purposes.

[11] *See* World Health Organization, Food and Agriculture Organization of the United Nations, Codex Alimentarius, Foods Derived from Modern Biotechnology (2d edition 2009), *available at* http://www.bibliotecapleyades.net/archivos_pdf/foods-derived-modern-biotechnology.pdf (defining modern biotechnology as the application of (i) in vitro nucleic acid techniques, including DNA and direct injection of nucleic acid into cells or organelles, or (ii) fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombinant barriers that are not techniques used in traditional breeding and selection).

[12] See Annex A.

genetically engineered content amounts to less than .9% of the total weight of the processed food. This is the same threshold required in the European Union[13] as well as by the Non-GMO Project for foods certified to be non-GMO.[14]

C. Labeling Requirements

State labeling requirements vary slightly. However, a common thread permitted across all fives states is a "Produced with Genetic Engineering" disclosure.[15] Specifically:

- Vermont: Vermont's law allows for three types of disclosure, "Produced with Genetic Engineering"; "Partially Produced with Genetic Engineering"; and "May Be Produced with Genetic Engineering." The "Partially Produced" label can only be used when a processed food contains less than 75% genetic engineered material by weight. The "May Be" label may be used only when the manufacturer does not know, after reasonable inquiry, whether the food is, or contains a component that is, produced with genetic engineering.
- Connecticut and Maine: These states have only one labeling requirement on packaged foods and raw foods: "Produced with Genetic Engineering."
- Massachusetts: Massachusetts' proposal allows for three types of disclosure, "Genetically Engineered"; "Produced with Genetic Engineering"; and "Partially Produced with Genetic Engineering."
- New York: New York's bill requires a "Produced with Genetic Engineering" disclosure but also allows for any other derivative of those words, like the initials "GE", "GM", "GMO", or derivatives of those phrases.

As such, industry could use a "produced with genetic engineering" disclosure and be in compliance in every state. A manufacturer with a smaller market that is not selling in all five of these states would have more flexibility to choose which kind of disclosure to make.

D. Exemptions

All five states share many common exemptions, including:

- Food consisting entirely of, or derived entirely from, an animal that has not itself been produced with genetic engineering, regardless of whether the animal has been fed with any GMO feed or treated with any drug or vaccine that has been produced with genetic engineering;
- Restaurants; and
- Alcoholic beverages.

In addition to these common exemptions, Connecticut excludes farm products sold directly to a consumer at a farm stand or farmers market.[16] Vermont[17] and New York[18] also exempt any processed food that would be subject to the labeling requirement solely because one or more of the processing aids or enzymes used in its production were produced with or derived from

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[13] European Commission, Plants, Traceability and Labeling, *available at* http://ec.europa.eu/food/plant/gmo/traceability_labelling/index_en.htm.
[14] Non-GMO Project, The Non-GMO Project Verified Seal, *available at* http://www.nongmoproject.org/learn-more/understanding-our-seal/.
[15] *See* Annex B
[16] Substitute House Bill No. 6527, Public Act No. 13-183, Sec. 3(b)(3) (Conn. 2013).
[17] H. 112, Act No. 120 § 3044(3)(Vermont 2014).
[18] S. 617 Sec. 2(2)(D)(III) (New York 2015).

genetic engineering. In the other states, industry would have to label if genetically engineered enzymes or processing aids were used in production, but only if those enzymes or processing aids along with other genetic ingredients contributed to more than .9% of the total weight of the product. Becomes enzymes and processing aids usually constitute a small fraction of product weight, it is unlikely that a company would have to provide a disclosure based solely on the presence of enzymes or processing aids.

III. Conclusion

The three states that have GMO labeling disclosure requirements, along with New York and Massachusetts that have pending laws, all have remarkably similar requirements. Industry can comply with all five states' rules with a simple, on-pack "produced with genetic engineering disclosure." This uniformity and ease of compliance should dispel concerns about having an untenable patchwork of state laws and or unduly burdening interstate commerce. Furthermore, all state GMO labeling laws were enacted or proposed with the intent of furthering legitimate state interests such as reducing consumer confusion. With the continued absence of a federal mandatory standard, there is no reason to preempt state GMO labeling laws.

Annex A: State Genetic Engineering Definitions

State	Genetic Engineering Definitions
Connecticut[19]	"Genetic engineering" means a process by which a food or food ingredient that is produced from an organism or organisms in which the genetic material has been changed through the application of: (A) In vitro nucleic acid techniques, including recombinant DNA (deoxyribonucleic acid) techniques and the direct injection of nucleic acid into cells or organelles; or (B) fusion of cells, including protoplast fusion, or hybridization techniques that overcome natural physiological, reproductive or recombination barriers, where the donor cells or protoplasts do not fall within the same taxonomic group, in a way that does not occur by natural multiplication or natural recombination; "In vitro nucleic acid techniques" means techniques, including, but not limited to, recombinant deoxyribonucleic acid techniques, that use vector systems and techniques involving the direct introduction into organisms of hereditary materials prepared outside the organisms such as microinjection, macroinjection, chemoporation, electroporation, microencapsulation and liposome fusion;
Maine[20]	"Genetically engineered" means the application of in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid and direct injection of nucleic acid into cells or organelles, or the fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection.
Vermont[21]	"Genetic engineering" is a process by which a food is produced from an organism or organisms in which the genetic material has been changed through the application of: (A) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) techniques and the direct injection of nucleic acid into cells or organelles; or (B) fusion of cells (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers, where the donor cells or protoplasts do not fall within the same taxonomic group, in a way that does not occur by natural multiplication or natural recombination. "In vitro nucleic acid techniques" means techniques, including recombinant DNA or ribonucleic acid techniques, that use vector systems and techniques involving the direct introduction into the organisms of hereditary materials prepared outside the organisms

[19] Substitute House Bill No. 6527, Public Act No. 13-183, Sec. 2, ¶¶ 2-3 (Conn. 2013).
[20] 7 Maine Rev. Statutes § 1051(2); HP 0490, LD 718, § 2591 (126th Leg. Maine 2014).
[21] 9 V.SA. § 3042; H. 112, Act No. 120 § 3042(4)-(5)(Vermont 2014).

	such as micro-injection, chemoporation, electroporation, micro-encapsulation, and liposome fusion.
Massachusetts[22]	"Genetically engineered" means produced from an organism or organisms in which the genetic material has been changed through the application of: (a) In vitro nucleic acid techniques which include, but are not limited to, recombinant deoxyribonucleic acid or ribonucleic acid techniques that use vector systems, and techniques involving the direct introduction into the organisms of hereditary materials prepared outside the organisms such as biolistics, microinjection, macro-injection, chemoporation, electroporation, microencapsulation, and liposome fusion as well as direct injection of nucleic acid into cells or organelles, encapsulation, gene deletion, and doubling; or (b) Methods of fusing cells beyond the taxonomic family that overcome natural physiological, reproductive, or recombination barriers, and that are not techniques used in traditional breeding and selection such as conjugation, transduction, and hybridization.
New York[23]	"Genetically engineered," or "genetically modified," or any derivative of those words, as applied to any food for human consumption or seed means produced from or with an organism or organisms with genetics altered materially through the application of: (i) in vitro nucleic acid techniques, including but not limited to recombinant deoxyribonucleic acid (DNA) techniques and the direct injection of nucleic acid into cells or organelles; or (ii) the fusion of cells beyond the taxonomic family that overcomes natural physiological, reproductive, or recombinant barriers and that are not techniques used in traditional breeding and selection.

[22] H. 3242, Sec. 2 189th Leg. (Mass. 2015).
[23] S. 617 Sec. 2(1)(D) (New York 2015).

Annex B: State GMO Labeling Requirements

State	GMO Labeling Requirements
Connecticut[24]	"Produced with Genetic Engineering"
Maine[25]	"Produced with Genetic Engineering"
Vermont[26]	"Produced with Genetic Engineering" or can use "Partially Produced with Genetic Engineering" (only when < 75% by weight)[27] or "May Be Produced with Genetic Engineering"
Massachusetts[28]	"Genetically Engineered" or "Produced with Genetic Engineering" or "Partially Produced with Genetic Engineering"
New York[29]	"Produced with genetic engineering" or any other derivative of those words, the initials "GE", "GM", "GMO", or a derivative of those phrases.

[24] Substitute House Bill No. 6527, Public Act No. 13-183, Sec. 3 (Conn. 2013).
[25] HP 0490, LD 718, § 2592 (126th Leg. Maine 2014).
[26] H. 112, Act No. 120 § 3043(b)(Vermont 2014).
[27] Vermont Consumer Protection Rule 121, § 121.02(b)(ii)(B); http://www.ago.vermont.gov/assets/files/PressReleases/Consumer/Final%20Rule%20CP%20121.pdf.
[28] H. 3242, Sec. 3(3) 189th Leg. (Mass. 2015).
[29] S. 617 Sec. 2(2)(A)(New York 2015).