

SUBJECT: CONSUMER PROTECTION – LABELING FOODS PRODUCED WITH
GENETIC ENGINEERING
ATTORNEY GENERAL – PUBLIC PROTECTION DIVISION
ADOPTED PURSUANT TO 2013, NO. 120 (Adj. Sess.) § 3

CONSUMER PROTECTION RULE 121

Effective Date: 7/1/16

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CP 121.01 Definitions

Words used in this rule shall have the definitions given below.

- (1) “Clear and conspicuous” means presented in such a manner, given its font, size, color, contrast and proximity to other disclosures on the shelf, bin, container or package as to be readily noticed and understood by consumers. A disclosure is not clear and conspicuous if, among other things, it is obscured by the background against which it appears.
- (2) “Commingle” means permitting physical contact between unpackaged food produced without genetic engineering and unpackaged food produced with genetic engineering during production, processing, transportation, storage or handling, other than during the manufacture of a multi-ingredient product containing both types of food. Unpackaged food in a closed container identifying it as produced without genetic engineering is not commingled while the container is intact.
- (3) “Consumer,” as defined in 9 V.S.A. §§ 2451a and 3042, means any person who purchases, leases, contracts for, or otherwise agrees to pay consideration for goods or services not for resale in the ordinary course of his or her trade or business but for his or her use or benefit or the use or benefit of a member of his or her household, or in connection with the operation of his or her household or a farm whether or not the farm is conducted as a trade or business, or a person who purchases, leases, contracts for, or otherwise agrees to pay consideration for goods or services not for resale in the ordinary course of his or her trade or business but for the use or benefit of his or her business or in connection with the operation of his or her business.
- (4) “Enzyme,” as defined in 9 V.S.A. § 3042, means a protein that catalyzes chemical reactions of other substances without itself being destroyed or altered upon completion of the reactions.
- (5) “Food” means (1) articles used for food or drink for humans, (2) chewing gum, and (3) articles used for components of any such article. Food does not include dietary supplements, as defined in 21 U.S.C. § 321(ff), or drugs, as defined in 21 U.S.C. § 321(g).

- (6) “Genetic engineering,” as defined in 9 V.S.A. § 3042, 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.

The term “genetic engineering” does not encompass a change of genetic material through the application of traditional breeding techniques, conjugation, fermentation, traditional hybridization, *in vitro* fertilization, or tissue culture.

- (7) “Genetically engineered material” means any component of a food not exempt under section 121.03, in which any aspect or portion of the component has been produced with genetic engineering.
- (8) “*In vitro* nucleic acid techniques,” as defined in 9 V.S.A. § 3042, 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 such as micro-injection, chemoporation, electroporation, micro-encapsulation, and liposome fusion.
- (9) “Know” means (1) to have actual knowledge of the information; or (2) to act in deliberate ignorance or reckless disregard of the truth or falsity of the information.
- (10) “Knowingly” means (1) having actual knowledge of the information; or (2) acting in deliberate ignorance or reckless disregard of the truth or falsity of the information.
- (11) “Label” (noun) means a display of written, printed, or graphic material on a packaged processed food or packaged raw agricultural commodity or any such material affixed to any shelf or bin in which an unpackaged raw agricultural commodity or unpackaged processed food is displayed for retail sale.
- (12) “Label” (verb) means to affix a label or to print packaging that includes a label.
- (13) “Manufacturer,” as defined in 9 V.S.A. § 3042, means a person who:
- (a) produces a processed food or raw agricultural commodity under its own brand or label for sale in or into the State;
 - (b) sells in or into the State under its own brand or label a processed food or raw agricultural commodity produced by another supplier;
 - (c) owns a brand that it licenses or licensed to another person for use on a processed food or raw commodity sold in or into the State;
 - (d) sells in, sells into, or distributes in the State a processed food or raw agricultural commodity that it packaged under a brand or label owned by another person;

- (e) imports into the United States for sale in or into the State a processed food or raw agricultural commodity produced by a person without a presence in the United States; or
 - (f) produces a processed food or raw agricultural commodity for sale in or into the State without affixing a brand name.
- (14) “Natural or any words of similar import” means the words nature, natural, or naturally.
- (15) “Organism,” as defined in 9 V.S.A. § 3042, means any biological entity capable of replication, reproduction, or transferring of genetic material.
- (16) “Packaged” means offered for retail sale, fully or partially contained or wrapped in material, and upon which material a manufacturer is identified. For the purposes of this rule, “partially contained or wrapped” means more than one-third of the food is covered by packaging material.
- (17) “Processed food,” as defined in 9 V.S.A. § 3042, means any food other than a raw agricultural commodity and includes any food produced from a raw agricultural commodity that has been subjected to processing such as canning, smoking, pressing, cooking, freezing, dehydration, fermentation, or milling.
- (18) “Processing aid,” as defined in 9 V.S.A. § 3042, means:
- (a) a substance that is added to a food during the processing of the food but that is removed in some manner from the food before the food is packaged in its finished form;
 - (b) a substance that is added to a food during processing, is converted into constituents normally present in the food, and does not significantly increase the amount of the constituents naturally found in the food; or
 - (c) a substance that is added to a food for its technical or functional effect in the processing but is present in the finished food at levels that do not have any technical or functional effect in that finished food.
- (19) “Produce” (verb) means to develop, grow or process food.
- (20) “Raw agricultural commodity,” as defined in 9 V.S.A. § 3042, means any food in its raw or natural state, including any fruit or vegetable that is washed, colored, or otherwise treated in its unpeeled natural form prior to marketing.
- (21) “Retail sale” means offering food for sale from a retail premises to a consumer for any purpose other than for resale. This term does not include isolated or occasional sales of food by a person who is not regularly engaged in the business of such sales.
- (22) “Retail Premises” means the physical location in Vermont where a retailer offers food for retail sale to consumers.
- (23) “Retailer” means a person located in Vermont offering any raw agricultural commodity or processed food for retail sale.
- (24) “Segregate” means to require physical separation of food produced without genetic engineering from food that is produced with genetic engineering during production, processing, transportation, storage or handling, other than during the manufacture of a

multi-ingredient product containing both types of food. Unpackaged food in a closed container identifying it as produced without genetic engineering is considered segregated while the container is intact.

- (25) “Unpackaged” means offered for retail sale, but otherwise not “packaged” as defined in this rule, provided that, for the purposes of subsection 121.02(a)(ii) of this rule, processed foods are considered unpackaged if a retailer removes the packaging that contains any information required by the United States Food and Drug Administration, as referenced in 21 C.F.R. § 101.2(b), or any disclosure required by section 121.02 of this rule, prior to offering the food for retail sale, even if the food would otherwise meet the definition of “packaged” under this rule when offered for sale.

CP 121.02 Labeling

(a) Unpackaged Food Labeling by Retailers

Any unpackaged food produced with genetic engineering and offered for retail sale in Vermont, unless a label is not required by section 121.03 of this rule, shall be labeled by the retailer as follows:

- (i) For any unpackaged raw agricultural commodity, retailers shall post a label on or immediately adjacent to each sign that identifies the product or the product price with a clear and conspicuous disclosure reading “Produced with Genetic Engineering.” If there is no sign identifying the product or product price, the retailer shall post such label containing a clear and conspicuous disclosure reading “Produced with Genetic Engineering” on the bin, shelf or container in which the food is displayed.
- (ii) For any unpackaged processed food, retailers shall post a label containing a clear and conspicuous disclosure reading “Produced with Genetic Engineering,” “Partially Produced with Genetic Engineering,” or “May be Produced with Genetic Engineering,” as appropriate under subsection 121.02(b)(ii), on the bin, shelf, or container in which the food is displayed.

(b) Packaged Food Labeling by Manufacturers

Any packaged food produced with genetic engineering and offered for retail sale in Vermont, unless a label is not required by section 121.03 of this rule, shall be labeled by the manufacturer as follows:

- (i) Disclosures on packaged, raw agricultural commodities shall be clear and conspicuous and shall read “Produced with Genetic Engineering.”
- (ii) Disclosures on packaged, processed foods shall read “Produced with Genetic Engineering,” “Partially Produced with Genetic Engineering,” or “May be Produced with Genetic Engineering,” as appropriate.
 - (A) The disclosure “Produced with Genetic Engineering” shall be used when food was produced with genetic engineering, provided that:
 - (B) “Partially” may be used to modify “Produced with Genetic Engineering” only when a processed food contains less than 75% genetically engineered material by weight; and

- (C) “May be” may be used to modify “Produced with Genetic Engineering” only when the food’s manufacturer does not know, after reasonable inquiry, whether the food is, or contains a component that is, produced with genetic engineering.
- (iii) Disclosures on packaged, processed foods required by section 121.02(b) shall be located on the package so as to be easily found by consumers when viewing the outside of the package. Such disclosures shall be in any color that contrasts with the background of the package so as to be easily read by consumers, and shall be either: (1) in a font size no smaller than the size of the words “Serving Size” on the Nutrition Facts label required by the United States Food and Drug Administration in 21 C.F.R. § 101.9(d), or (2) in a font size no smaller than the Ingredient List required by 21 C.F.R. § 101.4(a) and printed in bold type-face. A disclosure that satisfies the font and color requirements of this rule and is located on the same panel as the Nutrition Facts Label or Ingredient List shall be presumed to satisfy the “easily found” requirement.
- (c) Labeling Practices
- (i) The manufacturer of a food that is produced entirely or partially with genetic engineering and offered for retail sale in Vermont shall not make any statement about the food that contains the word natural or any words of similar import: (1) in advertising at or in the retail premises, (2) on signs identifying the product at the point of display in the retail premises, or (3) on the label of the food. This prohibition does not apply to a food’s trade, brand, or product name, or any information required by the United States Food and Drug Administration, as referenced in 21 C.F.R. § 101.2(b).
- (ii) Subject to other applicable legal requirements, including subsection 121.02(c)(i) of this rule, a person may, in connection with offering food produced with genetic engineering for retail sale in Vermont, make other disclosures about the food on its packaging, including that the United States Food and Drug Administration does not consider food produced with genetic engineering to be materially different from other foods.
- (d) Nothing in this section shall be construed to require the listing or identification of any ingredient or ingredients that were genetically engineered; or require the placement of the term “genetically engineered” or a similar phrase immediately preceding or following any common name or primary product descriptor of a food; or require the placement of any disclosure required under section 121.02 of this rule as “intervening material” under 21 C.F.R. § 101.2(e); or otherwise require adding to or amending the information required by the United States Food and Drug Administration, as referenced in 21 C.F.R. § 101.2(b).

CP 121.03 Exemptions and Exceptions

Section 121.02 of this rule does not apply to the following:

- (a) Animal Products and Foods Bearing USDA Approved Labels

- (i) Foods consisting entirely of or derived entirely from an animal that is itself not produced with genetic engineering, regardless of whether the animal has been fed or injected with any food, drug, or other substance produced with genetic engineering.
 - (ii) Packaged, processed food containing meat or poultry, the label of which requires approval by the United States Department of Agriculture, under 21 U.S.C. §§ 451-472, 601-695, or the state equivalent, under 6 V.S.A. §§ 3302-3318.
- (b) Foods Certified as Not Produced with Genetic Engineering
- (i) Food for which the person otherwise responsible for complying with section 121.02 of this rule obtains a sworn statement from whomever sold the food to that person. The sworn statement must affirm that the food (1) was made or grown from food or seed that has not been knowingly or intentionally produced with genetic engineering and (2) has been segregated from and has not been knowingly or intentionally commingled with food or seed that may have been produced with genetic engineering.
 - (ii) When providing a sworn statement under this rule, a person may rely solely on a sworn statement that contains the above affirmation by whoever sold the food to that person.
- (c) Processing Aids
- Processed foods that would be required to be labeled under section 121.02 of this rule solely because the food includes one or more processing aids or enzymes produced with genetic engineering.
- (d) Alcoholic Beverages
- Beverages regulated under the provisions of Title 7 of the Vermont Statutes.
- (e) Foods with Minimal Genetically Engineered Content
- Processed foods that would otherwise be required to be labeled under section 121.02 of this rule, if the aggregate weight of the genetically engineered materials in the food is no more than 0.9 percent of the total weight of the food.
- (f) Foods Verified by a Qualifying Organization
- (i) Food that has been certified as “organic” under 7 C.F.R. § 205.301 by an organization accredited to make such certifications under the USDA National Organic Program.
 - (ii) Food that has been verified as not having been produced with genetic engineering by an organization that the Attorney General has authorized to make such verification.
- (g) Food for Immediate Consumption
- (i) An unpackaged processed food that is prepared and intended for immediate consumption.
 - (ii) An unpackaged food that is served, sold, or otherwise provided in a restaurant or other establishment primarily engaged in the sale of food prepared and intended for immediate consumption.

- (iii) For the purposes of this rule, “prepared and intended for immediate consumption” includes: (1) food that is or may be purchased as a “taxable meal” as provided in 32 V.S.A. § 9202(10)(A), (B), (C); and (2) food as described in 32 V.S.A. § 9202(10)(D)(ii) except that food purchased under the Supplemental Nutrition Assistance Program as recognized in 32 V.S.A. § 9202(10)(D)(ii)(X) shall be subject to labeling unless otherwise exempt under this section.
- (iv) For the purposes of this rule, an establishment is “primarily engaged in the sale of food prepared and intended for immediate consumption” if more than 50% of the establishment’s total sales of food in the previous taxable year is, or if the first taxable year is reasonably projected to be, food taxable under 32 V.S.A. § 9202(10)(B) and food taxable under 32 V.S.A. § 9202(10)(C) and food not exempt from taxation under 32 V.S.A. § 9202(10)(D).

(h) Medical Food

Medical food, as that term is defined in 21 U.S.C. § 360ee(b)(3).

CP 121.04 Enforcement and Penalties

(a) Sworn Statements

A sworn statement used to comply with subsection 121.03(b) must be signed by the person otherwise responsible for complying with the requirements of section 121.02, and must contain the affirmations set forth in subsection 121.03(b)(i). A standard-form sworn statement containing these affirmations is provided in Appendix A. Electronic or facsimile copies of original sworn statements are acceptable under this rule.

(b) Manufacturer and Retailer Records Retention

Manufacturers shall retain records sufficient to demonstrate their compliance with this rule for three (3) years from the date the manufacturer sells the food. Retailers shall retain records sufficient to demonstrate their compliance with this rule for one (1) year from the date the retailer sells the food. Manufacturers and retailers shall make such records available to the Attorney General upon a request pursuant to 9 V.S.A. § 2460. Electronic copies of such records are sufficient to comply with this subsection.

For the purposes of subsection 121.04(b) only, the term “retailer” means any person who is primarily engaged in retail sales, regardless of whether they produce a processed food or raw agricultural commodity for retail sale.

(c) Notice of Retailer Violation and Safe Harbor

- (i) If the Attorney General has reason to believe that a retailer has failed to label a food as required by this rule, prior to issuing a civil investigative demand, filing a complaint, or otherwise commencing an enforcement action for such failure, the Attorney General shall issue a corrective action notice.
- (ii) If, after 30 days from issuance of the notice, the Attorney General continues to have reason to believe that a retailer has failed to label in accordance with subsection 121.02(a), the Attorney General may commence an enforcement action.

(iii) If, during the 30-day period, the retailer obtains and presents a sworn statement in accordance with subsection 121.03(b) of this rule certifying that the food that is the subject of the notice of violation is exempt from section 121.02 of this rule, the Attorney General shall not issue a civil investigative demand, file a complaint, or otherwise commence an enforcement action against the retailer for failure to label the food.

(iv) Provisions of subsection (c) are not applicable when a retailer produces a processed food or raw agricultural commodity.

(d) **Presumption of Manufacturer Compliance**

(i) Any packaged, processed food subject to the provisions of this rule and offered for retail sale in Vermont before January 1, 2017, that does not comply with this rule, is presumed to have been packaged and distributed prior to July 1, 2016, and the manufacturer shall not be liable for failure to comply with this rule unless there is evidence that the food was distributed on or after July 1, 2016.

(ii) Upon written request of the Attorney General, any manufacturer of any packaged, processed food offered for retail sale before January 1, 2017, shall provide the Attorney General with documentation regarding the labeling and distribution of such food within 10 business days of the date of the request.

(e) **Penalties**

(i) Except as provided in subsection 121.04(e)(ii), any person who violates the requirements of this rule, including providing a false statement under subsection 121.03(b) of this rule, shall be liable for a civil penalty of not more than \$1,000 per day, per product. Calculation of this civil penalty shall not be made or multiplied by the number of individual packages of the same product displayed or offered for retail sale, or by the number of identically labeled products with the same stock keeping unit. Civil penalties assessed under this section shall accrue and be assessed per each uniquely named, designated, or marketed product.

(ii) Any person who violates the requirements of subsection 121.04(b) shall be liable for a civil penalty of not more than \$1,000 total for the first violation. Any subsequently violation of subsection 121.04(b) shall be subject to the penalties described in subsection 121.04(e)(i).

CP 121.05 Purpose and Scope

The purpose of this rule is to implement Act 120, and compliance with the requirements of this rule shall satisfy the requirements of Act 120. Nothing in this rule shall limit the rights or remedies available to the State of Vermont or to consumers under any other provision of Vermont law, including 9 V.S.A. § 2453.

CP 121.06 Effective Date

This rule shall become effective on July 1, 2016.

APPENDIX A

**Sworn Statement Form
Certifying Food NOT Produced with Genetic Engineering**

NAME OF MANUFACTURER OR PRODUCER: _____

ADDRESS: _____

CITY: _____ STATE: _____

ZIP CODE: _____

AGENT SIGNING ON BEHALF OF MANUFACTURER: _____

AGENT CONTACT PHONE NUMBER: _____

AGENT EMAIL: _____

NAME OF PRODUCT(S): _____

UPC CODE, LOT NUMBER OR OTHER IDENTIFICATION NUMBER:

I, _____, as the authorized agent of the Manufacturer/
Producer listed above, hereby depose and state as follows:

The above named product(s) were made or grown from food or seed that has not been knowingly or intentionally produced with genetic engineering and has been segregated from and has not been knowingly or intentionally commingled with food that may have been produced with genetic engineering.

I declare or affirm, under penalty of perjury, that the above statement is true and correct to the best of my knowledge.

Agent Signature: _____ Date: _____

Agent Printed Name: _____