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.

Note: Definition adapted from Vermont Consumer Protection Rules, CP 119.01(b).

(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.

Note: Definition adapted from the National Organic Standards, 7 C.F.R. § 205.2.

Comment: This definition hinges on the process by which ingredients are transported, stored and processed. It does not prohibit all unintentional commingling of ingredients; however, the transportation and storage systems must be designed to avoid such commingling.

As noted in this definition, if unpackaged food produced without genetic engineering is transported in a closed container that identifies the contents as produced without genetic engineering, there is no commingling.

(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).

Note: Definition adapted from the Food and Drug Administration definition, 21 U.S.C. § 321(f).

Comment: Dietary supplements are currently excluded from the labeling requirements because consumers do not generally consider them "food" and the legislative history of Act 120 does not support their inclusion.

- (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.

Comment: The definition of "genetic engineering" from Act 120 was supplemented in this rule with language drawn from the National Organic Standards, 7 C.F.R. § 205.2. This addition excludes additional techniques that do not overcome natural physiological, reproductive, or recombination barriers.

(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.

Comment: This term is meant to clarify how to calculate what portion of a food is produced with genetic engineering when determining whether a person can use the modifier "Partially" under subsection 121.02(b)(ii)(B), or whether a food is exempt under subsection 121.03(e). This definition permits the person responsible for labeling to aggregate multiple exemptions to the labeling requirement when determining whether a label is required.

Illustration: If a product contains eggs (sec. 121.03(a)(i)), alcohol produced with genetic engineering (sec. 121.03(d)), a processing aid produced with genetic engineering (sec. 121.03(c)), certified organic sugar (sec. 121.03(f)(i)), and the remaining ingredients are produced with genetic engineering, but do not equal more than .9% of the weight of the food, the food does not need to be labeled.

- (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.

Note: Definition adapted from the Food and Drug Administration, 21 U.S.C. § 321(bb).

(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.

Note: Definition adapted from the Food and Drug Administration, 21 U.S.C. § 321(bb).

(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.

Note: Definition adapted from the Food and Drug Administration, 21 U.S.C. § 321(k).

(12) "Label" (verb) means to affix a label or to print packaging that includes a label.

Comment: This term permits the use of stickers, stamps or additional printing on existing packaging as a means of complying with the labeling requirements of section 121.02 so long as all disclosure criteria are met when the food is offered for retail sale.

Use of a sticker, stamp or printing, as described above, to comply with this rule does not guarantee compliance with other applicable labeling laws, including federal labeling laws and copyright law.

- (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;

Comment: If a person (e.g., a retailer) chooses to apply a sticker with the disclosure required under section 121.02 in order to bring a food produced by another person into compliance with this rule, that person (e.g., the retailer) may be considered a "manufacturer" for the purposes of this rule, including section 121.04(e) on penalties.

- (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.

Comment: This definition provides an express limitation on the words prohibited by subsection 121.02(c)(i). The use of any of these words only, alone or in combination with other words, could be in violation of subsection 121.02(c)(i).

- (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.

Comment: The "one-third" packaging rule delineates labeling responsibility between the manufacturer and the retailer. In general, when a manufacturer chooses to include its name on the packaging of a raw agricultural commodity, the manufacturer is responsible for labeling in accordance with this rule if there is sufficient space for the required disclosure under subsection 121.02(b)(i) on the package.

Illustration: A paper bag of apples, which has the producer's name on it, is "packaged" under this definition; a bunch of bananas with a single sticker with the producer's name on it is not. Likewise, a head of lettuce contained in a plastic slip-cover identifying the producer is packaged; a head of broccoli held together with a rubber band is not. (Of note: There are currently no commercially available varieties of apples or bananas produced with genetic engineering, though genetically engineered apples have been approved by the FDA.)

- (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.

Comment: This could include rennet used in the production of cheese, or defoaming agents used in the production of maple syrup.

- (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.

Comment: This definition expressly excludes bake sales and other informal and irregular retail sales of food from the labeling requirements of this rule.

(22) "Retail Premises" means the physical location in Vermont where a retailer offers food for retail sale to consumers.

Comment: This definition limits the geographical reach of the labeling prohibition in subsection 121.02(c)(i) to the physical retail premises in Vermont. Read in conjunction with the definition for "retail sale," 121.01(21), it also limits the labeling requirements in section 121.02 to physical retail stores in Vermont. The labeling requirements do not extend to Internet-only sales.

Except as noted above, any physical location wherein a retailer offers food for retail sale is a retail premises: for example, retail outlets housed in a manufacturing facility, farm stands, vending machines, or mobile vendor kiosks.

- (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.

Note: Definition adapted from the National Organic Standards, 7 C.F.R. § 205.2 (definition of "commingling").

Comment: This definition hinges on the process by which ingredients are transported, stored and processed. It does not prohibit all unintentional commingling; however, the transportation and storage systems must be designed to segregate non-GE foods.

As noted in this definition, if unpackaged food produced without genetic engineering is transported in a closed container that identifies the contents as produced without genetic engineering, the food has been segregated.

(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.

Comment: The proviso in this definition places the responsibility for labeling on the retailer if the retailer chooses to market a packaged processed food, but removes the otherwise compliant labeling, e.g., for single serving items or items not labeled for individual retail.

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.

Comment: If there is no sign identifying the product or product price and the bin, shelf or container holds multiple types of raw agricultural commodities, the label must clearly and conspicuously identify which types are produced with genetic engineering.

(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.

Comment: Act 120 did not specifically address the labeling of such bulk, deli or bakery foods; however, nothing in the Act suggested such foods were purposely exempt. This labeling requirement combines the requirements for raw agricultural commodities (unpackaged) and processed foods.

If the bin, shelf or container holds multiple types of unpackaged processed foods, the label must clearly and conspicuously identify which types are produced with genetic engineering.

(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

Comment: For the purposes of this subsection, the weight of the food should be calculated exclusive of added water and salt, and the percentage of genetically engineered material must be rounded up to the nearest whole number. For foods that are sold cooked or baked, the weight should be calculated before cooking or baking the food.

(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.

Comment: The most reasonable use for the "may be" modifier occurs when a product has a variable ingredient base (e.g., oil for potato chips) that depends upon changing ingredient availability and may include a substitute ingredient produced with genetic engineering. If the manufacturer cannot reasonably guarantee whether the contents of a given package contain materials produced with genetic engineering because of this variable supply, the manufacturer should so indicate through use of the "may be" modifier.

The "reasonable inquiry" element requires the person responsible for labeling to make an active attempt to determine whether the food in question is produced with genetic engineering. At a minimum, the person responsible for labeling must inquire of the person from whom they purchased the food whether it was produced without genetic engineering. Inability to obtain a sworn statement pursuant to subsection 121.03(b) indicates that the food may be produced with genetic engineering and may require inquiry into the source of the food in question and whether it was segregated from and not commingled with food or seed 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.

Comment: The "easily found" and "easily read" requirements do not require that the disclosure be clear and conspicuous. Rather, they require only that a consumer seeking out whether the food was produced with genetic engineering be able to readily find and interpret that information. Because the disclosure must be easily found when viewing the outside of the package, it cannot be under a flap or panel. Nor can it be included in the middle or end of a lengthy disclosure of additional material in the same or a similar font. It could, however, appear at the beginning of a lengthy disclosure, as permitted under subsection 121.02(c)(ii), that is then followed by additional material in the same or similar font.

If the required disclosure will not fit on the information panel because the packaging of the food is too small, a manufacturer can place the disclosure on an alternate panel on the package so long as the placement and printing of the disclosure otherwise meets the easily read and easily found standards.

As a general principle, when a manufacturer chooses to place the required disclosure in a location different from the information panel or principal display panel, the manufacturer must take added care with font size and color contrasts to ensure the disclosure is easily found.

(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).

Comment: The prohibition on use of the word natural or any words of similar import extends to any advertising at the physical retail premises and includes instore advertisements, regardless of media (e.g., printed circulars, window signs, billboards, dedicated television or other digital displays).

The "trade, brand or product name" means the primary name of the manufacturer or product listed on the package.

(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.

Comment: Though this subsection permits "other disclosures about the food," the fact that a food does not have to be labeled pursuant to section 121.02 does not necessarily permit a manufacturer to label the food as "Non-GE" or "Non-GMO."

(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).

Comment: This subsection makes clear that nothing in this law requires the identification of a specific ingredient as being produced with genetic engineering; however, subject to other applicable legal requirements, CP 121 does not prevent voluntary identification.

CP 121.03 Exemptions and Exceptions

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

Comment: For a description of the documents required for establishing that an exemption or exception under section 121.03 applies, see *Comment* to subsection 121.04(b).

- (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.

Comment: This subsection exempts all animal products, including processed dairy products, unless the product requires labeling because of additional ingredients (e.g., ice cream produced with genetically engineered sugar).

(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.

Comment: This subsection exempts products whose labels are subject to approval by the USDA, whether generic approval, pursuant to 9 C.F.R. § 412.2, or sketch, special statement and claim, or temporary claim approval, pursuant to 9 C.F.R. § 412.1.

- (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.

Comment: This subsection permits sellers to rely on the sworn statement of the person from whom they purchased the food, without making further inquiry. The person otherwise responsible for labeling need go no further up the supply chain to obtain a sworn statement than the person who sold the food. However, if that seller does nor or will not provide a formal sworn statement, the person otherwise responsible cannot rely on this exemption from the labeling requirement.

(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.

Comment: Beverages containing less than one percent alcohol content by volume are not regulated under Title 7 and are therefore <u>not</u> exempt from the labeling requirements of section 121.02. *See* 7 V.S.A. §§ 2(14), (20), (23).

(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.

Comment: For the purposes of this subsection, the weight of the food should be calculated exclusive of added water and salt. For foods that are sold cooked or baked, the weight should be calculated before cooking or baking 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.

Comment: The Attorney General's Office has listed the requirements for authorizing verification organizations on its website: ago.vermont.gov. Authorized verification organizations will also be listed on the website.

- (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.

Comment: For foods capable of being sold either as a taxable meal or grocery item based on the quantity purchased (e.g., bakery goods that can be purchased singly or in quantities greater than three), unless the retailer limits the quantity a consumer can purchase to ensure the food will always be a taxable meal under Meals and Rooms Tax Regulations § 1.9202(10)-1(B)(3), a retailer must label the food pursuant to subsection 121.02(a).

Processed packaged foods that are sold as part of a restaurant or food establishment meal and not otherwise labeled for retail sale (e.g., individual packages of condiments), are exempt under this subsection.

The requirement that food purchased under the Supplemental Nutrition Assistance Program ("SNAP") be labeled "unless otherwise exempt under this section" is meant to ensure that food that would not be taxed because it is a grocery item (and not a "taxable meal" under 32 V.S.A. § 9202(10)) is not excluded from the labeling requirement simply because it can also be purchased with SNAP benefits. Foods that would otherwise be exempt as a taxable meal are still exempt from labeling because they are "prepared and intended for immediate consumption."

Illustration: A sandwich (unless frozen) is a taxable meal and therefore exempt from labeling, even though it would not be otherwise taxed if purchased with SNAP benefits.

- (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.

Comment: Sworn statements can also be incorporated into another document, e.g., an invoice, so long as they are signed and include the required affirmations.

A given sworn statement is valid for the food directly referenced therein, even if the food is delivered in multiple shipments over an extended period of time, so long as the person swearing to and signing the statement intends the products to be covered by their statement. A good practice is listing the lot numbers or delivery dates or otherwise clearly identifying the products the statement is intended to cover.

For imported products, the manufacturer may rely on the sworn statement of the person from whom the product is purchased.

(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.

Comment: Retaining "records sufficient to demonstrate . . . compliance" requires a person to maintain documents demonstrating: (1) the product in question was properly labeled when offered for retail sale; (2) an exemption or exception under section 121.03 applied to the product or ingredient in question; or (3) a food is otherwise not knowingly and intentionally produced with genetic engineering (i.e., because there is no commercially available variety of the food produced with genetic engineering and it was not knowingly and intentionally commingled with any food produced with genetic engineering).

To establish that a product was properly labeled when offered for retail sale, the person should retain documents demonstrating how the product was labeled when offered for retail sale, e.g., the label or sign identifying the food at issue and any other documents demonstrating how it was labeled at the point of sale.

To establish that an exemption or exception under section 121.03 applies, a person should retain documents establishing where, when and by whom the product was purchased, manufactured or grown (as applicable), and the quantity and purpose of the specific ingredient in question. More specifically:

- For subsection 121.03(b): A compliant sworn statement under subsection 121.04(a), along with documents linking the statement to the product in question, is sufficient without more.
- For subsection 121.03(c): Documents establishing the purpose of the ingredient claimed as a processing aid and documents demonstrating that it fits the definition under subsection 121.01(4) or (18) are necessary.
- For subsection 121.03(e): Documents demonstrating the percentage of the weight of the ingredient(s) in question as a percentage of the total weight of the food (excluding added water and salt) are necessary.
- For subsection 121.03(f): Documents demonstrating certification or verification by an authorized third party, under subsection 121.03(f), are sufficient without more.
- For subsection 121.03(g): Documents required for filing meals and rooms tax returns with the Vermont Department of Taxes and documents proving that the retailer in question is a restaurant or food establishment under Vermont law, including this rule, are necessary.

To establish that a food is not otherwise knowingly or intentionally produced with genetic engineering, a person should retain documents demonstrating that there is no commercially available variety of the food or ingredient that is produced with genetic engineering, and documents establishing that the food was not knowingly or intentionally commingled with food produced with genetic engineering.

A manufacturer who purchases ingredients that are offered for retail sale may reasonably rely on any existing labeling on what they purchase (e.g., "Non-GE" or "Non-GMO"), though the absence of a disclosure regarding genetic engineering may be relied upon only if the product is purchased in Vermont after January 1, 2017 (or another jurisdiction where a similar disclosure is required).

Illustration: If a small-scale candy manufacturer purchases cooking oil at a retail grocery store and the oil constitutes more than .9% of the candy by weight, that manufacturer can rely on the labeling of the oil, subject to subsection 121.04(d)(i), to determine whether the oil is produced with genetic engineering and would require the candy to be labeled under this rule.

The records retention timeline starts when the manufacturer sells the product to the retailer or when the retailer sells the product to a consumer. If a retailer does not have a means of tracking when a specific product is sold, the timeline begins when the retailer receives its next shipment of the product or a reasonable replacement for the product.

(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.

Comment: Packaged, processed food that is produced and distributed by the manufacturer before July 1, 2016, is eligible for this presumption of compliance. Food produced before July 1, 2016, but distributed thereafter, does not receive this presumption. For the purposes of this presumption, "distributed" means sold or transported to the retailer, whether or not the food is offered for retail sale immediately thereafter.

The manufacturer of any food that is not properly labeled under this rule and is offered for retail sale <u>after</u> January 1, 2017, could be liable for penalties under subsection 121.04(e)(i).

(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.

Comment: These rules are intended to govern both enforcement actions by the State of Vermont and civil actions brought by private individuals. A retailer or manufacturer who is compliant with these rules should not face civil liability under this rule or 9 V.S.A. § 3048.

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:	
ZIP CODE:	
AGENT SIGNING ON BEHALF O	F MANUFACTURER:
AGENT CONTACT PHONE NUM	BER:
AGENT EMAIL:NAME OF PRODUCT(S):	
	, as the authorized agent of the Manufacturer/e and state as follows:
knowingly or intentionally produ	re made or grown from food or seed that has not been aced with genetic engineering and has been segregated from attentionally commingled with food that may have been ag.
I declare or affirm, under penalty of best of my knowledge.	perjury, that the above statement is true and correct to the
Agent Signature:	Date:
Agent Printed Name:	