THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL No. 1770 Session of 2013

INTRODUCED BY P. DALEY, CUTLER, MUNDY, ROZZI, KINSEY, SCHLOSSBERG, KIM, BOBACK, CALTAGIRONE, BROWNLEE, D. MILLER, COHEN, PAINTER, FLECK, MAHONEY, KULA, MURT, GILLEN, DELUCA, V. BROWN, BISHOP AND O'BRIEN, OCTOBER 17, 2013

REFERRED TO COMMITTEE ON AGRICULTURE AND RURAL AFFAIRS, OCTOBER 17, 2013

AN ACT

1 2 3	Amending Title 3 (Agriculture) of the Pennsylvania Consolidated Statutes, providing for labeling of genetically engineered food.
4	The General Assembly of the Commonwealth of Pennsylvania
5	hereby enacts as follows:
6	Section 1. Title 3 of the Pennsylvania Consolidated Statutes
7	is amended by adding a chapter to read:
8	<u>CHAPTER 58</u>
9	LABELING OF GENETICALLY ENGINEERED FOOD
10	<u>Sec.</u>
11	5801. Scope of chapter.
12	5802. Definitions.
13	5803. Labeling.
14	5804. Mislabeling.
15	5805. Regulations.
16	5806. Penalties.
17	<u>§ 5801. Scope of chapter.</u>

1	<u>This chapter relates to the labeling of genetically</u>
2	engineered food.
3	<u>§ 5802. Definitions.</u>
4	The following words and phrases when used in this chapter
5	shall have the meanings given to them in this section unless the
6	context clearly indicates otherwise:
7	"Advertisement." All representations, other than labeling,
8	disseminated in any manner or by any means for the purpose of
9	inducing or which are likely to induce, directly or indirectly,
10	the purchase of food, drugs, devices or cosmetics.
11	"Color additive."
12	(1) A material with or without intermediate or final
13	change of identity, from a vegetable, animal, mineral or
14	other source, both which:
15	(i) Is a dye, pigment or other substance made by:
16	(A) a process of synthesis or similar artifice;
17	or
18	(B) extracted, isolated or otherwise derived;
19	and
20	(ii) When added or applied to a food, drug, cosmetic
21	or to the human body or a part of the human body is
22	capable, alone or through reaction with other substance,
23	of imparting color thereto.
24	(2) The term does not include material exempted by
25	regulation under the Federal Food, Drug, and Cosmetic Act or
26	material which the department determines is used, or intended
27	to be used, solely for a purpose or purposes other than
28	<u>coloring.</u>
29	(3) The term includes black, white and intermediate
30	grays, as well as all other colors.

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1	(4) Nothing in this definition shall be construed to
2	apply to any pesticide chemical, soil or plant nutrient or
3	other agricultural chemical used or intended to be used
4	solely because of its effect in aiding, retarding or
5	otherwise directly or indirectly affecting the growth or
6	other natural physiological processes of produce of the soil
7	which thereby affects its color, whether before or after
8	harvest.
9	"Cosmetic."
10	(1) Articles intended to be rubbed, poured, sprinkled or
11	sprayed on, introduced into or otherwise applied to the human
12	body or a part of the human body for cleansing, beautifying,
13	promoting attractiveness or altering the appearance.
14	(2) The term shall also include all articles intended
15	for use as a component of any articles.
16	(3) The term does not include soap.
17	"Device." Except when used in the definition of drug in this
18	section, the term includes instruments, apparatuses and
19	contrivances, including their components, parts and accessories,
20	intended for use in the diagnosis, cure, mitigation, treatment
21	or prevention of disease in humans or other animals or to affect
22	the structure or a function of the body of humans or other
23	animals.
24	"Distributor." A person that sells, supplies, furnishes or
25	transports food in this Commonwealth that the person does not
26	produce.
27	"Drug."
28	(1) The term includes the following:
29	(i) An official compendium.
30	(ii) Articles intended for use in the diagnosis,

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1	cure, mitigation, treatment or prevention of disease in
2	humans or other animals.
3	(iii) Articles, other than food, intended to affect
4	the structure or a function of the body of a human or any
5	other animal.
6	(iv) Articles intended for use as a component of any
7	articles specified in this paragraph.
8	(2) The term does not include devices or their
9	components, parts or accessories.
10	"Enzyme." A protein that catalyzes chemical reactions of
11	other substances without being destroyed or altered upon
12	completion of such reactions.
13	"Federal Food, Drug, and Cosmetic Act." The Federal Food,
14	Drug, and Cosmetic Act (52 Stat. 1040, 21 U.S.C. § 301 et seq.).
15	"Food." Articles used for food or drink for humans or other
16	animals, chewing gum and articles used for components of food,
17	drink or chewing gum.
18	"Genetically engineered" or "genetic engineering."
19	(1) A process whereby food intended for human
20	consumption is produced from an organism or organisms in
21	which the genetics are materially altered through the
22	application of at least one of the following:
23	(i) In vitro nucleic acid techniques, including
24	recombinant DNA (deoxyribonucleic acid) techniques.
25	(ii) The direct injection of nucleic acid into cells
26	<u>or organelles.</u>
27	<u>(iii) Encapsulation.</u>
28	(iv) Gene deletion and doubling.
29	(v) Methods of fusing cells that do not fall within
30	the same taxonomic family, that overcome natural

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1	physiological reproductive or recombinant barriers and
2	that are not techniques used in traditional breeding and
3	selection such as conjugation, transduction and
4	hybridization.
5	(2) The term includes food which is treated with a
6	material described in this definition, except manure that is
7	<u>used as a fertilizer for a raw agricultural commodity or</u>
8	contains an ingredient, component or substance described in
9	this definition.
10	"Label." A display of written, printed or graphic matter
11	upon the immediate container of an article. The term immediate
12	container as used in this definition does not include package
13	liners.
14	"Labeling." All labels and other written, printed or graphic
15	matter on an article or its containers, wrappers or other
16	material accompanying the article.
17	"Manufacturer." A person who produces seed, seed stock or
18	food and sells the item to a retailer or distributor.
19	"Natural food."
20	(1) Food which has not been:
21	(i) Treated with preservatives, antibiotics,
22	synthetic additives, artificial flavoring or artificial
23	<u>coloring.</u>
24	(ii) Processed in a manner that makes such food
25	significantly less nutritive.
26	(iii) Genetically engineered.
27	(2) The term does not automatically exclude the
28	processing of food by extracting, purifying, heating,
29	fermenting, concentrating, dehydrating, cooling or freezing.
30	<u>"New drug."</u>
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1	(1) A drug not generally recognized among experts
2	qualified by scientific training and experience to evaluate
3	the safety and effectiveness of drugs, as safe and effective
4	for use under the conditions prescribed, recommended or
5	suggested in its labeling.
6	(2) The term also includes any drug which, as a result
7	of investigation to determine its safety and effectiveness
8	for use under such conditions, has become so recognized, but
9	which has not, other than in investigations, been used to a
10	material extent or for a material time under those
11	conditions.
12	(3) A drug's effectiveness shall not be considered with
13	regard to the following:
14	(i) either:
15	(A) a drug which was commercially sold or used
16	in the United States on or before October 9, 1962; or
17	(B) was not a new drug prior to the enactment of
18	this chapter; and
19	(ii) was not covered by an effective application
20	under section 355 of the Federal Food, Drug, and Cosmetic
21	Act, when the drug is intended solely for use under
22	conditions prescribed, recommended or suggested in
23	labeling with respect to the drug on whichever of the
24	dates under this paragraph is applicable.
25	"Official compendium." The official United States
26	Pharmacopoeia, official Homeopathic Pharmacopoeia of the United
27	States, official National Formulary or a supplement to any of
28	them.
29	"Organism." A biological entity capable of replication,
30	reproduction or transferring genetic material.
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1	"Pesticide chemical." A substance which alone, in chemical
2	combination or in formulation with one or more other substances
3	is an "economic poison" within the meaning of the Federal
4	Insecticide, Fungicide, and Rodenticide Act (61 Stat.
5	163, 7 U.S.C. § 136 et seq.), and which is used in the
6	production, storage or transportation of raw agricultural
7	commodities.
8	"Processed food." A food other than a raw agricultural
9	commodity. The term includes a food produced from a raw
10	agricultural commodity that has been processed through canning,
11	smoking, pressing, cooking, freezing, dehydration, fermentation
12	<u>or milling.</u>
13	"Processing aid." The term includes any of the following:
14	(1) A substance that is added to a food during the
15	processing of the food, but that is removed in some manner
16	from the food before the food is packaged in a finished form.
17	(2) A substance that is added to a food during
18	processing, that is converted into constituents normally
19	present in the food and that does not significantly increase
20	the amount of the constituents naturally found in the food.
21	(3) A substance that is added to a food for its
22	technical or functional effect in the processing, but that is
23	present in the finished food at insignificant levels and that
24	does not have any technical or functional effect in the
25	finished food.
26	"Raw agricultural commodity." A food in its raw or natural
27	state, including all fruits that are washed, colored or
28	otherwise treated in their unpeeled natural form prior to
29	marketing.
30	"Retailer." A person or entity that engages in the sale of

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1	food to a consumer.
2	"Secretary." Includes an authorized representative, employee
3	or agent of the Department of Agriculture.
4	<u>§ 5803. Labeling.</u>
5	(a) General ruleOn and after October 1, 2014, any food,
6	seed or seed stock offered or intended for retail sale in this
7	Commonwealth that is or may have been entirely or partially
8	genetically engineered, shall be labeled as follows:
9	(1) In the case of food for retail sale contained in a
10	package, by the manufacturer, distributor or retailer of the
11	food, with the clear and conspicuous words "Produced with
12	<u>Genetic Engineering."</u>
13	(2) In the case of food that is a raw agricultural
14	commodity, on the package offered for retail sale or, in the
15	case of any such commodity that is not separately packaged or
16	labeled, on the retail store shelf or bin that holds the
17	commodity displayed for sale, by the retailer, with the clear
18	and conspicuous words "Produced with Genetic Engineering."
19	(3) In the case of any seed or seed stock, on the
20	container holding the seed or seed stock displayed for sale,
21	the sales receipt or any label identifying ownership or
22	possession of the commodity, by the manufacturer or
23	distributor, with the clear and conspicuous words "Produced
24	with Genetic Engineering."
25	(b) PlacementThe information, other words or statements
26	indicating that the food was produced with genetic engineering
27	shall appear on the outside container or wrapper, if any, of the
28	retail package of the article or shall be easily legible through
29	the outside container or wrapper.
30	(c) ExceptionThis section does not apply to a processed
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1	food in which one or more processing aids or enzymes were
2	produced or derived from genetic engineering.
3	<u>§ 5804. Mislabeling.</u>
4	(a) General ruleA food shall be deemed to be mislabeled
5	if the food which is subject to this chapter has labeling that
6	is false or misleading in any of the following ways:
7	(1) A statement on the label or labeling either directly
8	or indirectly implying that the product is recommended or
9	endorsed by an agency of the Federal or State government
10	shall be considered misleading, unless the agency concerned
11	has approved the statement prior to its use.
12	(2) If a food is offered for sale under the name of
13	another food.
14	(3) If a food is an imitation of another food, unless
15	its label bears, in type of uniform size and prominence, the
16	word "imitation" and, immediately thereafter, the name of the
17	food imitated.
18	(4) If a food's container is so made, formed or filled
19	<u>as to be misleading.</u>
20	(5) If in package form, unless it bears a label
21	containing the name and place of business of the
22	manufacturer, packer or distributor and an accurate statement
23	of the quantity of the contents in terms of weight, measure
24	or numerical count. Reasonable variations shall be permitted,
25	and exemptions as to small packages shall be established by
26	regulations promulgated by the department.
27	(6) If information, other words or statements required
28	by or under authority of this chapter to appear on the label
29	or labeling is not prominently placed on the labeling with
30	the conspicuousness, as compared with other words,

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1	statements, designs or devices, in the labeling, and in
2	terms, as to render it likely to be read and understood by
3	the ordinary individual under customary conditions of
4	purchase and use.
5	(7) If it purports to be or simulates or is represented
6	as a food for which a definition and standard of identity has
7	been prescribed by regulations by the department, it conforms
8	to the definition and standard, and its label fails to bear
9	the name of the food specified in the definition and
10	standard, and, so far as may be required by regulations, the
11	common names of optional ingredients, other than spices,
12	flavoring and coloring, present in the food.
13	(8) If it purports to be or is represented as any of the
14	following:
15	(i) A food for which a standard of quality has been
16	prescribed by regulation and its quality falls below that
17	standard, unless its label bears a statement that it
18	falls below the standard.
19	(ii) A food for which a standard of fill of
20	container have been prescribed by regulation and it falls
21	below the standard of fill of container, unless its label
22	bears a statement that it falls below the standard.
23	(iii) A food for which no definition and standard of
24	identity and no standard of quality has been prescribed
25	by regulations and it falls below the standard of purity,
26	quality or strength which it purports or is represented
27	to possess.
28	(9) If it purports to be or is represented to be for
29	special dietary uses, unless its label bears the information
30	concerning its vitamin, mineral and other dietary properties
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as is necessary in order to fully inform purchasers as to its 1 2 <u>value.</u>

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3	(10) If it bears or contains artificial flavoring,
4	artificial coloring, artificial sweetening or chemical
5	preservative, unless it bears labeling stating that fact. To
6	the extent that compliance with the requirements of this
7	paragraph is impracticable, exemptions shall be established
8	by regulations promulgated by the department.
9	(11) If it is genetically engineered and does not bear
10	labeling as required in accordance with this chapter, unless
11	it is a food produced without the producer's knowledge that a
12	seed or other component of the food was genetically
13	engineered on or before July 1, 2019, it is a processed food
14	solely because it contains one or more materials that are
15	genetically engineered if the genetically engineered
16	materials do not, in the aggregate, account for more than
17	0.9% of the total weight of the processed food.
18	(b) ExceptionsIf it is not subject to this chapter,
19	unless its label bears the common or usual name of the food and,
20	if it is fabricated from two or more ingredients, the common or
21	usual name of each ingredient. Spices, flavorings and colorings,
22	other than those sold as such, may be designated as spices,
23	flavorings and colorings without naming each to the extent that
24	compliance with the requirements of this chapter is
25	impracticable or results in deception or unfair competition.
26	Exemptions shall be established by regulations promulgated by
27	the department.
28	(c) InvestigationIf an article that is regulated by this
29	chapter is alleged to be misbranded because the labeling is
30	misleading or if an article's advertisement is alleged to be
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1	false because it is misleading, the department shall conduct an
2	investigation. In determining whether the labeling or
3	advertisement is misleading, the department shall take into
4	account at least the following:
5	(1) The representations made or suggested by statement,
6	word, design, device or sound or any combination thereof.
7	(2) The extent to which the labeling or advertisement
8	fails to reveal material facts in light of the
9	representations or material facts with respect to
10	consequences which may result from the use of the article to
11	which the labeling or advertisement relates under the
12	conditions of use prescribed in the labeling or advertisement
13	thereof or under conditions of use as are customary or usual.
14	(3) If the article is a drug, its labeling or
15	advertisement as an antiseptic shall be considered to be a
16	representation that it is a germicide, except in the case of
17	a drug purporting to be or represented as an antiseptic for
18	inhibitory use as a wet dressing, ointment or dusting powder
19	or for other use that involves prolonged contact with the
20	body.
21	<u>§ 5805. Regulations.</u>
22	Notwithstanding other provisions of law, the department may
23	promulgate regulations to carry out this chapter.
24	<u>§ 5806. Penalties.</u>
25	(a) Criminal penaltiesA person who violates a provision
26	of this chapter or a rule, regulation, standard or order made
27	under this chapter commits a summary offense for the first or
28	second offense. A person who violates this chapter or a rule,
29	regulation, standard or order made under this chapter commits a
30	misdemeanor of the third degree if the violation is a third or
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1	subsequent offense and if the violation occurs within two years
2	of the date of the last previous offense.
3	(b) Civil penaltiesIn addition to proceeding under any
4	other remedy available at law or in equity for a violation of
5	this chapter, or a rule or regulation adopted or any order
6	issued under this chapter, the secretary may assess a civil
7	penalty not to exceed \$10,000 upon an individual or business for
8	each offense. No civil penalty shall be assessed unless the
9	person charged has been given notice and opportunity for a
10	hearing in accordance with law. In determining the amount of the
11	penalty, the secretary shall consider the gravity of the
12	violation. Whenever the secretary finds a violation which did
13	not cause harm to human health, the secretary may issue a
14	warning in lieu of assessing a penalty. In case of inability to
15	collect the civil penalty or failure of any person to pay all or
16	any portion of the penalty as the secretary may determine, the
17	secretary may refer the matter to the Attorney General, who
18	shall recover the amount by action in the appropriate court.
19	<u>(c) Guaranty</u>
20	(1) No prosecution shall be sustained under the
21	provisions of this chapter for the manufacture, delivery,
22	consignment, bailment, holding or sale of or offering for
23	sale, exposing for sale or having in possession with intent
24	to sell a mislabeled or misbranded article against a person
25	from whom the article of food, sample or portion was obtained
26	by the department if the person can establish a guaranty to
27	the effect that the article of food is not mislabeled or
28	misbranded within the meaning of this chapter, was mislabeled
29	or misbranded prior to coming into the possession of the
30	person and the person did not know or have reason to know of

1	the mislabeling or misbranding or was mislabeled or
2	misbranded after it left the possession and control of the
3	person. The guaranty must be signed by the supplier,
4	manufacturer, wholesale dealer, jobber or distributor from
5	whom the articles of food were purchased or procured.
6	(2) The guaranty to afford protection shall contain the
7	name and address of the supplier, manufacturer, wholesale
8	dealer, jobber or distributor making the sale of the article
9	of food to the person holding the guaranty. A supplier,
10	manufacturer, wholesale dealer, jobber or distributor giving
11	a guaranty under the provisions of this chapter may be held
12	responsible and may be proceeded against for the mislabeling
13	or misbranding of any article of food sold under the guaranty
14	and shall be subject to the penalties provided for violation
15	of this chapter. A guaranty shall not operate as a defense to
16	prosecution for a violation of the provisions of this chapter
17	if the person holding the guaranty continues to sell the same
18	food after written or printed notice from the secretary that
19	the article is mislabeled or misbranded within the meaning of
20	this chapter. However, if the person violated the provisions
21	of this chapter by having stored, transported, exposed or
22	kept the article in a way or manner to render it diseased,
23	contaminated or unwholesome, the person may be proceeded
24	against for a violation.
25	(d) Minor violationsNothing in this chapter shall be
26	construed as requiring prosecution or institution of a
27	proceeding under this chapter for minor violations of this
28	chapter if the secretary believes that the public interest will
29	be adequately served in the circumstances by a suitable written
30	notice or warning.
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