General Assembly

Substitute Bill No. 6527

January Session, 2013

HB06527JUD 050713

AN ACT CONCERNING GENETICALLY ENGINEERED BABY FOOD.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Section 21a-92 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2013*):

For the purposes of this chapter**,** **[**and**]** section 21a-65 and sections 2 and 3 of this act, the following terms shall have the meanings hereinafter specified:

(1) "Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of food, drugs, devices or cosmetics;

(2) (A) "Color additive" means a material which (i) is a dye, pigment or other substance made by a process of synthesis or similar artifice, or extracted, isolated or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral or other source, and (ii) when added or applied to a food, drug or cosmetic, or to the human body or any of its parts, is capable, alone or through reaction with other substance, of imparting color thereto, except that the term "color additive" does not include any material exempted by regulation under the federal act, or which the commissioner, by regulation, determines is used, or intended to be used, solely for a

purpose or purposes other than coloring; (B) the term "color" includes black, white and intermediate grays, as well as all other colors; (C) nothing in subparagraph (A) of this subdivision shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical used, or intended to be used, solely because of its effect in aiding, retarding or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil which thereby affects its color, whether before or after harvest;

(3) "Commissioner" means the Commissioner of Consumer Protection;

(4) "Contaminated with filth" applies to any food, drug, device or cosmetic not securely protected from dust or dirt, and as far as may be necessary, by all reasonable means, from all foreign or injurious contaminations;

(5) "Cosmetic" means (A) articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into, or otherwise applied to the human body or any of its parts for cleansing, beautifying, promoting attractiveness or altering the appearance and (B) articles intended for use as a component of any such articles; except that such term shall not include soap;

(6) "Device", except when used in subdivision **[**(15)**]** (17) of this section and in subsection (i) of section 21a-93, subsection (f) of section 21a-102, subsection (c) of section 21a-106 and subsection (c) of section 21a-112, means instruments, apparatus and contrivances, including their components, parts and accessories, intended (A) for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals or (B) to affect the structure or any function of the body of man or other animals;

(7) "Director" means the director of the agricultural experiment station;

(8) "Drug" means (A) articles recognized in the official United States

Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary, or any supplement to any of them; (B) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; (C) articles, other than food, intended to affect the structure or any function of the body of man or any other animal; and (D) articles intended for use as a component of any articles specified in this subdivision; but shall not include devices or their components, parts or accessories;

(9) "Federal act" means the federal Food, Drug and Cosmetic Act, as amended, Title 21 USC 301 et seq.: 52 Stat. 1040 et seq.;

(10) "Food" means (A) articles used for food or drink for man or other animals, and (B) chewing gum, and (C) articles used for components of any such article;

(11) "Food additive" means any substance the intended use of which results or reasonably may be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food; and including any source of radiation intended for any such use, if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food, to be safe under the conditions of its intended use; except that such term does not include (A) a pesticide chemical in or on a raw agricultural commodity; or (B) a pesticide chemical to the extent that it is intended for use or is used in the production, storage or transportation of any raw agricultural commodity; or (C) a color additive; or (D) any substance used in accordance with a sanction or approval granted prior to June 12, 1963, or the federal Food, Drug and Cosmetic Act, the Poultry Products

Inspection Act (21 USC 451 et seq.) or the Meat Inspection Act of March 4, 1907, as amended;

(12) "Genetically engineered" or "genetic engineering" means the production of food from or with an organism or organisms with materially altered genetics through the application of: (A) In vitro nucleic acid techniques, including recombinant ribonucleic acid (RNA) techniques, 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 DNA, RNA, cells or protoplasts do not fall within the same taxonomic family, in a way that does not occur by natural multiplication or natural recombination. A food shall otherwise be considered to be genetically engineered if the organisms from which the food is derived have been injected or otherwise treated with a genetically engineered material, except that the use of manure as a fertilizer for raw agricultural commodities may not be construed to mean that such commodities are produced with a genetically engineered material, or the food contains an ingredient, component or other article that is genetically engineered;

[(12)**]** (13) "Immediate container" shall not include package liners;

(14) "In vitro nucleic acid techniques" means techniques, including, but not limited to, recombinant deoxyribonucleis 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;

[(13)**]** (15) "Intrastate commerce" means any and all commerce within the state of Connecticut and subject to its jurisdiction, and shall include the operation of any business or service establishment;

[(14)**]** (16) "Label" means a display of written, printed or graphic

matter upon the immediate container of any article, provided a requirement made by or under authority of this chapter that any information or other word or statement appear on the label shall not be considered to be complied with unless such information or other word or statement also appears on the outside container or wrapper, if any, of the retail package of such article, or is easily legible through the outside container or wrapper;

[(15)**]** (17) "Labeling" means all labels and other written, printed or graphic matter (A) upon any article or any of its containers or wrappers, or (B) accompanying such article; provided, if an article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading, then, in determining whether the labeling or advertisement is misleading, there shall be taken into account, among other things, not only representations made or suggested by statement, word, design, device or sound, or any combination thereof, but also the extent to which the labeling or advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual, and provided the representation of a drug, in its labeling or advertisement, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment or dusting powder or for such other use as involves prolonged contact with the body;

[(16)**]** (18) "Natural food" means food (A) which has not been treated with preservatives, antibiotics, synthetic additives, artificial flavoring or artificial coloring, **[**and**]** (B) which has not been processed in a manner that makes such food significantly less nutritive, **[**. Processing**]** provided processing of food by extracting, purifying, heating, fermenting, concentrating, dehydrating, cooling or freezing shall not,

of itself, prevent the designation of such food as "natural food", and (C) which has not been grown, raised, manufactured, cultured or created in any way through the process of genetic engineering;

[(17)**]** (19) "New drug" means (A) any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended or suggested in its labeling or (B) any drug the composition of which is such that such drug, as a result of investigation to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions, except that the provisions of this subsection pertaining to "effectiveness" shall not apply to any drug which (i) was commercially sold or used in the United States on October 9, 1962, (ii) was not a new drug as defined by this subsection prior to the enactment of these provisions, and (iii) was not covered by an effective application under section 21a-110 or under Section 355 of the federal act, when such drug is intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on whichever of the above dates is applicable;

[(18)**]** (20) "Official compendium" means the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them;

[(19)**]** (21) "Organically grown" means (A) produced through organic farming methods, which involve a system of ecological soil management and mechanical or biological methods to control insects, weeds, pathogens and other pests and which rely on crop rotation, crop residues, composted animal manures, legumes, green manures, composted organic waste or mineral-bearing rocks, and (B) not grown, raised, manufactured, cultured or created in any way through the process of genetic engineering;

(22) "Organism" means any biological entity capable of replication, reproduction or transferring of genetic material;

[(20)**]** (23) "Person" includes any individual, partnership, corporation, limited liability company or association;

[(21)**]** (24) "Pesticide chemical" means any substance which, alone, in chemical combination or in formulation with one or more other substances is an "economic poison" within the meaning of the federal Insecticide, Fungicide and Rodenticide Act, 7 USC 135-135k, and which is used in the production, storage or transportation of raw agricultural commodities;

[(22)**]** (25) "Raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored or otherwise treated in their unpeeled natural form prior to marketing;

[(23)**]** (26) The term "safe" has reference to the health of man or animal;

[(24)**]** (27) "Sale" means any and every sale and includes (A) manufacture, processing, packing, canning, bottling or any other production, preparation or putting up; (B) exposure, offer or any other proffer; (C) holding, storing or any other possessing; (D) dispensing, giving, delivering, serving or any other supplying; and (E) applying, administering or any other using.

Sec. 2. (NEW) (*Effective October 1, 2013*) (a) For the purposes of this section, (1) "infant formula" means a milk-based or soy-based powder, concentrated liquid or ready-to-feed substitute for human breast milk that is intended for infant consumption and is commercially available, and (2) "baby food" means a prepared solid food consisting of a soft paste or an easily chewed food that is intended for consumption by children two years of age or younger and is commercially available.

(b) Except as provided in subsection (c) of this section, on and after July 1, 2015, no person shall manufacture, sell, offer for sale or

distribute in this state any infant formula or baby food containing any genetically engineered materials unless such infant formula or baby food includes labeling stating "produced with genetic engineering" pursuant to section 3 of this act.

(c) A person may sell or distribute his or her existing inventory of infant formula or baby food containing genetically engineered materials as of October 1, 2013, until July 1, 2016, provided such person can demonstrate that such infant formula or baby food was purchased or acquired prior to October 1, 2013, in a quantity comparable to the infant formula or baby food purchased or acquired during the same period of the prior year.

(d) The provisions of this section may be enforced, within available appropriations, by the Commissioner of Consumer Protection.

(e) Any person found to knowingly violate this section shall be liable for a civil penalty not to exceed one thousand dollars per day, per product. Calculation of such civil penalty shall not be made or multiplied by the number of individual packages of the same product displayed or offered for retail sale. Civil penalties assessed under this section shall accrue and be assessed per each uniquely named, designated or marketed product.

Sec. 3. (NEW) (*Effective October 1, 2013*) (a) On and after July 1, 2015, any infant formula or baby food that is partially or entirely produced with genetic engineering and is offered or intended for retail sale in the state shall include labeling that states in a clear and conspicuous manner, "produced with genetic engineering". Such labeling shall be displayed in the same size and font as the ingredients in the nutritional facts panel on the food label.

(b) Infant formula or baby food that is produced partially or entirely with genetically engineered materials that does not display "produced with genetic engineering" in a clear and conspicuous manner on its labeling according to subsection (a) of this section shall be deemed

misbranded pursuant to section 21a-102 of the general statutes, except that (1) such infant formula or baby food shall not be considered misbranded if it is produced by a person who (A) was without knowledge that such infant formula or baby food was created with materials that were partially or entirely produced with genetic engineering, and (B) obtains a sworn statement from the party that sold such materials to such person that such materials have not been knowingly genetically engineered and have not been knowingly commingled with any genetically engineered materials; and (2) on and before July 1, 2019, such infant formula or baby food shall not be considered misbranded if it is subject to the labeling requirement of subsection (a) of this section solely because it includes one or more materials produced with genetic engineering that in the aggregate account for nine-tenths of one per cent or less of the total weight of the infant formula or baby food.

(c) The Department of Consumer Protection, in consultation with the Departments of Agriculture, Energy and Environmental Protection and Public Health, shall adopt regulations, in accordance with chapter 54 of the general statutes, necessary for the implementation and enforcement of sections 2 to 4, inclusive, of this act.

Sec. 4. (NEW) (*Effective October 1, 2013*) A distributor or retailer that sells or advertises a product that fails to conform to the labeling requirements in section 3 of this act shall not be found liable or negligent in any civil proceeding brought to enforce the provisions of section 3 of this act.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*October 1, 2013*	21a-92
Sec. 2	*October 1, 2013*	New section
Sec. 3	*October 1, 2013*	New section
Sec. 4	*October 1, 2013*	New section

KID *Joint Favorable Subst. -LCO*

PH *Joint Favorable*

JUD *Joint Favorable*