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S T A T E O F R H O D E I S L A N D

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2015

A N A C T

RELATING TO FOOD AND DRUGS -- GENETICALLY ENGINEERED FOOD

Introduced By: Representatives Hull, MacBeth, Bennett, Handy, and Slater

Date Introduced: January 14, 2015

Referred To: House Health, Education & Welfare

It is enacted by the General Assembly as follows:

SECTION 1. Title 21 of the General Laws entitled "FOOD AND DRUGS" is hereby amended by adding thereto the following chapter:

CHAPTER 37

GENETICALLY ENGINEERED FOOD

21-37-1. Definitions. -- For the purposes of this chapter, 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)(i) "Color additive" means a material which:

(A) 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

(B) 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(s), 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;

(ii) The term "color" includes black, white and intermediate grays, as well as all other

colors;

(iii) Nothing in subsection (2)(i) of this section 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) "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.

(4) "Cosmetic" means 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 articles intended for use as a component of any such articles, except that such term shall not include soap.

(5) "Device" means instruments, apparatus and contrivances, including their components, parts and accessories, intended:

(i) For use in the diagnosis, cure, mitigation, treatment or prevention of disease in persons or other animals, or

(ii) To affect the structure or any function of the body of persons or other animals.

(6) "Director" means the director of health or the director's duly appointed agents.

(7) "Distributor" means a person or entity that sells, supplies, furnishes or transports food intended for human consumption in this state that such person or entity does not produce.

(8) "Drug" means:

(i) 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;

(ii) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in persons or other animals;

(iii) Articles, other than food, intended to affect the structure or any function of the body of persons or any other animal; and

(iv) 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) "Enzyme" means a protein that catalyzes chemical reactions of other substances without being destroyed or altered upon completion of such reactions.

(10) "Federal act" means the Federal Food, Drug and Cosmetic Act, as amended, Title 21

U.S.C. 301 et seq.; 52 Stat. 1040 et seq.

(11) "Food" means:

(i) Articles used for food or drink for persons or other animals;

(ii) Chewing gum;

(iii) Infant formula; and

(iv) Articles used for components of any such article.

(12) "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:

(i) A pesticide chemical in or on a raw agricultural commodity;

(ii) 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;

(iii) A color additive;

(iv) 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 U.S.C. 451 et seq., or the Meat Inspection Act of March 4, 1907, as amended, 21 U.S.C. 601 et seq.

(13) "Genetic engineering" means a process by which a food or food ingredient that is produced from an organism or organisms in which the genetic material has been changed through the application of:

(i) In vitro nucleic acid techniques, including recombinant DNA (deoxyribonucleic acid) techniques and the direct injection of nucleic acid into cells or organelles; or

(ii) 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.

(14) "Immediate container" shall not include package liners.

(15) "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.

(16) "Intrastate commerce" means any and all commerce within the state of Rhode Island and subject to its jurisdiction, and shall include the operation of any business or service establishment.

(17) "In vitro nucleic acid techniques" means techniques, including, but not limited to, recombinant deoxyribonucleic acid techniques, that use vector systems and techniques involving the direct introduction into organisms of hereditary materials prepared outside the organisms such as microinjection, macroinjection, chemoporation, electroporation, microencapsulation and liposome fusion.

(18) "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.

(19) "Labeling" means all labels and other written, printed or graphic matter:

(i) Upon any article or any of its containers or wrappers; or

(ii) 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.

(20) "Manufacturer" means a person who produces food intended for human consumption or seed or seed stock that is intended to produce food for human consumption and

sells such item to a retailer or distributor.

(21) "Natural food" means food:

(i) Which has not been treated with preservatives, antibiotics, synthetic additives, artificial flavoring or artificial coloring;

(ii) Which has not been processed in a manner that makes such food significantly less nutritive; and

(iii) Which has not been genetically engineered. 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."

(22) "New drug" means:

(i) 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

(ii) 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:

(A) Was commercially sold or used in the United States on October 9, 1962;

(B) Was not a new drug as defined by this subsection prior to the enactment of these provisions; and

(C) Was not covered by an effective application 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.

(23) "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.

(24) "Organically grown" means 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.

(25) "Organism" means any biological entity capable of replication, reproduction or

transferring genetic material.

(26) "Person" includes any individual, partnership, corporation, limited liability company or association.

(27) "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 U.S.C. 136 et seq., and which is used in the production, storage or transportation of raw agricultural commodities.

(28) "Processed food" means any food intended for human consumption other than a raw agricultural commodity and includes any such food produced from a raw agricultural commodity that has been processed through canning, smoking, pressing, cooking, freezing, dehydration, fermentation or milling.

(29) "Processing aid" means:

(i) Any substance that is added to a food intended for human consumption during the processing of such food but that is removed in some manner from the food before the food is packaged in a finished form;

(ii) Any substance that is added to such food during processing, that is converted into constituents normally present in the food, and that does not significantly increase the amount of the constituents naturally found in the food; or

(iii) Any substance that is added to such food for its technical or functional effect in the processing but that is present in the finished food at insignificant levels and that does not have any technical or functional effect in the finished food.

(30) "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.

(31) "Retailer" means a person or entity that engages in the sale of food intended for human consumption to a consumer.

(32) "Safe" has reference to the health of persons or animals.

(33) "Sale" means any and every sale and includes:

(i) Manufacture, processing, packing, canning, bottling or any other production, preparation or putting up;

(ii) Exposure, offer or any other proffer;

(iii) Holding, storing or any other possessing;

(iv) Dispensing, giving, delivering, serving or any other supplying; and

(v) Applying, administering or any other using.

21-37-2. Genetically engineered food. -- (a) Food intended for human consumption, and seed or seed stock that is intended to produce food for human consumption, that is entirely or partially genetically-engineered, except a processed food subject to the provisions of this chapter solely because one or more processing aids or enzymes were produced or derived from genetic engineering, shall be labeled as follows:

(1) In the case of such food that is sold wholesale and is not intended for retail sale, on the bill of sale accompanying such food during shipping, with the clear and conspicuous words: "Produced with Genetic Engineering";

(2) In the case of such food for retail sale contained in a package, with the clear and conspicuous words: "Produced with Genetic Engineering";

(3) In the case of such food that is a raw agricultural commodity, on the package offered for retail sale or, in the case of any such commodity that is not separately packaged or labeled, on the bill of sale or invoice for such commodity and on the retail store shelf or bin that holds such commodity displayed for sale with the clear and conspicuous words: "Produced with Genetic Engineering"; and

(4) In the case of any such seed or seed stock, on the container holding the seed or seed stock displayed for sale or on any label identifying ownership or possession of the commodity with the clear and conspicuous words: "Produced with Genetic Engineering." Such food labeling shall be displayed in the same size and font as the ingredients in the nutritional facts panel on the food label.

(b) The requirements of this section shall not apply to any of the following:

(1) Alcoholic beverages;

(2) Food intended for human consumption that is not packaged for retail sale and that either:

(i) Is a processed food prepared and intended for immediate consumption; or

(ii) Is served, sold or otherwise provided in any restaurant or other food facility that is primarily engaged in the sale of food prepared and intended for immediate consumption;

(3) Farm products that are sold by a farmer or the farmer's agent to a consumer at a pick-your-own farm, roadside stand, on-farm market or farmers' market; and

(4) Food consisting entirely of, or derived entirely from, an animal that was not genetically engineered, regardless of whether such animal was fed or injected with any genetically-engineered food or any drug that was produced through means of genetic engineering.

(c) Any person selling, offering for sale or distributing in this state any food, seed or seed stock required to be labeled as provided in this chapter shall be responsible for ensuring that such

food, seed or seed stock is so labeled.

21-37-3. Penalties for violations. -- (a) Any person found to knowingly violate this chapter shall be liable for a civil penalty not to exceed one thousand dollars ($1,000) 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 chapter shall accrue and be assessed per each uniquely named, designated or marketed product.

(b) Notwithstanding the provisions of this chapter, a retailer shall not be penalized or otherwise held liable for the failure to label pursuant to this chapter unless:

(1) The retailer is the producer or the manufacturer of the genetically-engineered food, seed or seed stock and sells the genetically-engineered food under a brand it owns; or

(2) The retailer's failure to label was knowing and willful. In any action in which it is alleged that a retailer has violated the provisions of this chapter, it shall be a defense that such retailer reasonably relied on:

(i) Any disclosure concerning genetically-engineered foods contained in the bill of sale or invoice provided by the wholesaler or distributor pursuant to § 21-37-2; or

(ii) The lack of any such disclosure.

(c) The director of the department of health may adopt rules and regulations to implement and enforce the provisions of this chapter.

21-37-4. Enforcement. -- All such proceedings for the enforcement, or to restrain violations, of this chapter shall be brought by either the department of health or the department of the attorney general.

SECTION 2. This act shall take effect on January 1, 2016.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

A N A C T

RELATING TO FOOD AND DRUGS -- GENETICALLY ENGINEERED FOOD

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This act requires that any genetically-engineered foods be labeled as such.

This act would take effect on January 1, 2016.

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