



General Assembly

January Session, 2013

Substitute Bill No. 6527



AN ACT CONCERNING GENETICALLY ENGINEERED BABY FOOD.

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

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 Section 21a-92 of the general statutes is repealed and the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

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

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

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

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

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

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

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

40 (6) "Device", except when used in subdivision [(15)] (17) of this
41 section and in subsection (i) of section 21a-93, subsection (f) of section
42 21a-102, subsection (c) of section 21a-106 and subsection (c) of section
43 21a-112, means instruments, apparatus and contrivances, including
44 their components, parts and accessories, intended (A) for use in the
45 diagnosis, cure, mitigation, treatment or prevention of disease in man
46 or other animals or (B) to affect the structure or any function of the
47 body of man or other animals;

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

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

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

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

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

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

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

86 (12) "Genetically engineered" or "genetic engineering" means the
87 production of food from or with an organism or organisms with
88 materially altered genetics through the application of: (A) In vitro
89 nucleic acid techniques, including recombinant ribonucleic acid (RNA)
90 techniques, recombinant deoxyribonucleic acid (DNA) techniques and
91 the direct injection of nucleic acid into cells or organelles; or (B) fusion
92 of cells, including protoplast fusion, or hybridization techniques that
93 overcome natural physiological, reproductive or recombination
94 barriers, where the donor DNA, RNA, cells or protoplasts do not fall
95 within the same taxonomic family, in a way that does not occur by
96 natural multiplication or natural recombination. A food shall
97 otherwise be considered to be genetically engineered if the organisms
98 from which the food is derived have been injected or otherwise treated
99 with a genetically engineered material, except that the use of manure
100 as a fertilizer for raw agricultural commodities may not be construed
101 to mean that such commodities are produced with a genetically
102 engineered material, or the food contains an ingredient, component or
103 other article that is genetically engineered;

104 [(12)] (13) "Immediate container" shall not include package liners;

105 (14) "In vitro nucleic acid techniques" means techniques, including,
106 but not limited to, recombinant deoxyribonucleis acid techniques, that
107 use vector systems and techniques involving the direct introduction
108 into organisms of hereditary materials prepared outside the organisms
109 such as microinjection, macroinjection, chemoporation,
110 electroporation, microencapsulation and liposome fusion;

111 [(13)] (15) "Intrastate commerce" means any and all commerce
112 within the state of Connecticut and subject to its jurisdiction, and shall
113 include the operation of any business or service establishment;

114 [(14)] (16) "Label" means a display of written, printed or graphic

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

122 [(15)] (17) "Labeling" means all labels and other written, printed or
123 graphic matter (A) upon any article or any of its containers or
124 wrappers, or (B) accompanying such article; provided, if an article is
125 alleged to be misbranded because the labeling is misleading, or if an
126 advertisement is alleged to be false because it is misleading, then, in
127 determining whether the labeling or advertisement is misleading, there
128 shall be taken into account, among other things, not only
129 representations made or suggested by statement, word, design, device
130 or sound, or any combination thereof, but also the extent to which the
131 labeling or advertisement fails to reveal facts material in the light of
132 such representations or material with respect to consequences which
133 may result from the use of the article to which the labeling or
134 advertisement relates under the conditions of use prescribed in the
135 labeling or advertisement thereof or under such conditions of use as
136 are customary or usual, and provided the representation of a drug, in
137 its labeling or advertisement, as an antiseptic shall be considered to be
138 a representation that it is a germicide, except in the case of a drug
139 purporting to be, or represented as, an antiseptic for inhibitory use as a
140 wet dressing, ointment or dusting powder or for such other use as
141 involves prolonged contact with the body;

142 [(16)] (18) "Natural food" means food (A) which has not been treated
143 with preservatives, antibiotics, synthetic additives, artificial flavoring
144 or artificial coloring, [and] (B) which has not been processed in a
145 manner that makes such food significantly less nutritive, [. Processing]
146 provided processing of food by extracting, purifying, heating,
147 fermenting, concentrating, dehydrating, cooling or freezing shall not,

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

151 [(17)] (19) "New drug" means (A) any drug the composition of
152 which is such that such drug is not generally recognized, among
153 experts qualified by scientific training and experience to evaluate the
154 safety and effectiveness of drugs, as safe and effective for use under
155 the conditions prescribed, recommended or suggested in its labeling or
156 (B) any drug the composition of which is such that such drug, as a
157 result of investigation to determine its safety and effectiveness for use
158 under such conditions, has become so recognized, but which has not,
159 otherwise than in such investigations, been used to a material extent or
160 for a material time under such conditions, except that the provisions of
161 this subsection pertaining to "effectiveness" shall not apply to any drug
162 which (i) was commercially sold or used in the United States on
163 October 9, 1962, (ii) was not a new drug as defined by this subsection
164 prior to the enactment of these provisions, and (iii) was not covered by
165 an effective application under section 21a-110 or under Section 355 of
166 the federal act, when such drug is intended solely for use under
167 conditions prescribed, recommended, or suggested in labeling with
168 respect to such drug on whichever of the above dates is applicable;

169 [(18)] (20) "Official compendium" means the official United States
170 Pharmacopoeia, official Homeopathic Pharmacopoeia of the United
171 States, official National Formulary, or any supplement to any of them;

172 [(19)] (21) "Organically grown" means (A) produced through
173 organic farming methods, which involve a system of ecological soil
174 management and mechanical or biological methods to control insects,
175 weeds, pathogens and other pests and which rely on crop rotation,
176 crop residues, composted animal manures, legumes, green manures,
177 composted organic waste or mineral-bearing rocks, and (B) not grown,
178 raised, manufactured, cultured or created in any way through the
179 process of genetic engineering;

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

182 [(20)] (23) "Person" includes any individual, partnership,
183 corporation, limited liability company or association;

184 [(21)] (24) "Pesticide chemical" means any substance which, alone, in
185 chemical combination or in formulation with one or more other
186 substances is an "economic poison" within the meaning of the federal
187 Insecticide, Fungicide and Rodenticide Act, 7 USC 135-135k, and
188 which is used in the production, storage or transportation of raw
189 agricultural commodities;

190 [(22)] (25) "Raw agricultural commodity" means any food in its raw
191 or natural state, including all fruits that are washed, colored or
192 otherwise treated in their unpeeled natural form prior to marketing;

193 [(23)] (26) The term "safe" has reference to the health of man or
194 animal;

195 [(24)] (27) "Sale" means any and every sale and includes (A)
196 manufacture, processing, packing, canning, bottling or any other
197 production, preparation or putting up; (B) exposure, offer or any other
198 proffer; (C) holding, storing or any other possessing; (D) dispensing,
199 giving, delivering, serving or any other supplying; and (E) applying,
200 administering or any other using.

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

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

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

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

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

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

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

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

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

256 (c) The Department of Consumer Protection, in consultation with
 257 the Departments of Agriculture, Energy and Environmental Protection
 258 and Public Health, shall adopt regulations, in accordance with chapter
 259 54 of the general statutes, necessary for the implementation and
 260 enforcement of sections 2 to 4, inclusive, of this act.

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

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

Statement of Legislative Commissioners:

In section 1(12), "any food that is produced from" was changed to "the production of food" for clarity and in section 1(14), "mean" was changed to "means" and "the organisms" was changed to "organisms" for clarity and consistency.

KID *Joint Favorable Subst. -LCO*