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Introduced by Sens. KAVANAGH, SEPULVEDA, CLEARE, FAHY, FERNANDEZ, GONZALEZ, HOYLMAN-SIGAL, JACKSON, MAY, MYRIE, OBERACKER, RHOADS, C. RYAN, WEBER, WEIK -- read twice and ordered printed, and when printed to be committed to the Committee on Agriculture -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee -- reported favorably from said committee and committed to the Committee on Health -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee -- reported favorably from said committee, ordered to first and second report, ordered to a third reading, amended and ordered reprinted, retaining its place in the order of third reading -- again amended and ordered reprinted, retaining its place in the order of third reading

AN ACT to amend the agriculture and markets law, in relation to enacting the "food safety and chemical disclosure act"

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

1 Section 1. Short title. This act shall be known and may be cited as
2 the "food safety and chemical disclosure act".

3 § 2. The section heading of section 199-a of the agriculture and
4 markets law, as amended by chapter 797 of the laws of 1961, is amended
5 and a new subdivision 5 is added to read as follows:

6 Prohibition as to adulterated or misbranded food and certain food
7 additives and food color additives intended for human consumption.

8 5. (a) Notwithstanding any other provision of law to the contrary, on
9 or after the date one year after the effective date of this paragraph it
10 shall be unlawful for any person, firm, association, or corporation to
11 manufacture, compound, brew, distill, produce, process, sell, deliver,
12 distribute, hold, offer or expose for sale any of the following
13 substances as food additives or food color additives or any food or food

EXPLANATION--Matter in italics (underscored) is new; matter in brackets
[-] is old law to be omitted.

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1 product containing any of the following substances intended for human
2 consumption:

3 (i) FD&C Red No. 3;

4 (ii) Potassium bromate; or

5 (iii) Propylparaben.

6 (b) Notwithstanding the provisions of paragraph (a) of this subdivi-
7 sion, a retail food store as defined in paragraph (b) of subdivision one
8 of section five hundred of this chapter, a food service establishment as
9 defined in paragraph (a) of subdivision one of section five hundred of
10 this chapter, a food relief organization as defined in subdivision one
11 of section four hundred fifty-one of this chapter, a supermarket, a
12 grocery store, a specialty food store, a farmer's market, or any other
13 vendor that, in the regular course of business, sells food at retail
14 directly to the public on premises located in the state shall be permit-
15 ted to sell, deliver, distribute, hold, offer or expose for sale any
16 food or food product containing any of the substances listed in para-
17 graph (a) of this subdivision until the expiration date, "best by" date,
18 or "sell by" date printed on the packaging of the food or food product
19 by the manufacturer or producer, but no later than three years after the
20 effective date of this paragraph, provided that such food or food prod-
21 uct was acquired for sale within the state by such retail food store,
22 food service establishment, food relief organization, supermarket,
23 grocery store, specialty food store, farmer's market, or other vendor
24 before the effective date of this paragraph.

25 (c) No less than one hundred eighty days before the effective date of
26 paragraphs (a) and (b) of this subdivision, the commissioner shall amend
27 the exemption list maintained pursuant to subdivision three of this
28 section to indicate that in this state the substances prohibited in this
29 subdivision shall not be deemed to be safe for human consumption on or
30 after the three hundred sixty-fifth day after the effective date of this
31 subdivision, and to further indicate that the provisions of paragraph
32 (b) of this subdivision shall apply until three years after the effec-
33 tive date of paragraphs (a) and (b) of this subdivision.

34 § 3. Section 198 of the agriculture and markets law is amended by
35 adding a new subdivision 7-a to read as follows:

36 7-a. For purposes of this section, the term "generally recognized as
37 safe substance" or "GRAS substance" means any substance added to food
38 that is exempted from the definition of "food additive" under subdivi-
39 sion seven of this section because it is generally recognized, among
40 experts qualified by scientific training and experience to evaluate its
41 safety, as having been adequately shown to be safe under the conditions
42 of its intended use:

43 (a) either through scientific procedures using the same quantity and
44 quality of scientific evidence as is required to obtain approval of the
45 substance as a food additive; or

46 (b) for a substance used in food prior to January first, nineteen
47 hundred fifty-eight, through experience based on common use in food.

48 § 4. Subdivision 4 of section 199-a of the agriculture and markets
49 law, as amended by chapter 671 of the laws of 1966, is amended to read
50 as follows:

51 4. All data submitted to the commissioner in support of the food or
52 color additives report under this section shall be considered confiden-
53 tial by the commissioner and shall not be revealed to any person other
54 than to a person authorized by the commissioner in the performance of
55 ~~his~~ their official duties under this article. In case of an actual
56 controversy as to the validity of an order or decision of the commis-

1 sioner respecting the test data or report in which a proceeding to
2 review has been instituted as authorized by section two hundred two-c of
3 this article the petition, data and report shall be transmitted by the
4 commissioner to the clerk of the court in which the review proceeding is
5 instituted, together with a record of the proceedings on which the
6 commissioner based ~~his~~ the order or decision, and such transmittal
7 shall not be construed to be a violation of confidence. Subdivisions
8 two and three of this section shall not apply to food additives or color
9 additives which are safe within the meaning of the federal food, drug
10 and cosmetic act as amended.

11 § 5. The agriculture and markets law is amended by adding a new
12 section 199-g to read as follows:

13 § 199-g. Reporting of GRAS substances. 1. a. Except as provided in
14 subdivision two or subdivision three of this section, unless a report
15 described in paragraph b of this subdivision has been submitted to the
16 commissioner and such report is made available in the database described
17 in subdivision five of section one hundred ninety-nine-b of this arti-
18 cle, and notwithstanding any other provision of law to the contrary, it
19 shall be unlawful for any person, firm, association, or corporation to:

20 (i) sell or offer or expose for sale for use in or on food, or to use
21 in the manufacturing, compounding, brewing, distilling, producing, or
22 processing of any food or food product, any GRAS substance or combina-
23 tion of GRAS substances;

24 (ii) make any new use of any GRAS substance or combination of GRAS
25 substances in or on food; or

26 (iii) sell or offer or expose for sale any food or food product
27 containing any GRAS substance or combination of GRAS substances.

28 b. The report required pursuant to paragraph a of this subdivision
29 shall include but not be limited to the following information:

30 (i) Signed statements and a certification, including:

31 (1) the date and signature of a responsible official of the reporter
32 or reporting organization;

33 (2) the name and address of the reporter or reporting organization;

34 (3) the name of any GRAS substances discussed in the report, using an
35 appropriately descriptive term;

36 (4) intended conditions for the use of any GRAS substance discussed in
37 the report, including the foods in which the substance will be used, the
38 levels of such use in such foods, and the purposes for which the
39 substance will be used, including, when appropriate, a description of
40 any subpopulation expected to consume such GRAS substance or substances;

41 (5) the statutory basis for the conclusion of GRAS status;

42 (6) a statement that the reported substance is not subject to the
43 premarket approval requirements of the federal food, drug, and cosmetic
44 act based on the conclusion that the notified substance is GRAS under
45 the conditions of its intended use;

46 (7) a statement that, if asked to see the data and information that
47 are the basis for the GRAS conclusion, the reporter will agree to:

48 (A) make the data and information available to the commissioner; and

49 (B) upon the commissioner's request, both of the following procedures
50 for making the data and information available to the commissioner:

51 (I) allow the commissioner to review and copy the data and information
52 during customary business hours at the address specified for where these
53 data and information will be available; and

54 (II) provide a complete copy of the data and information either in an
55 electronic format or on paper;

(8) views as to whether any of the data and information in the GRAS report are exempt from disclosure under the freedom of information law;

(9) certifications that, to the best of the reporter's knowledge, the GRAS report is a complete, representative, and balanced submission that includes both unfavorable and favorable information known to the reporter and pertinent to the evaluation of the safety and GRAS status of the use of the substance; and

(10) the name and position or title of the person who signs the GRAS report.

(ii) The identity, method of manufacture, specifications, and physical or technical effect of the notified substance, including:

(1) scientific data and information that identifies the GRAS substance, including:

(A) examples of appropriate data and information including the chemical name, applicable registry numbers (such as a chemical abstracts service (CAS) registry number or an enzyme commission (EC) number), empirical formula, structural formula, quantitative composition, and characteristic properties; and

(B) when the source of a notified substance is a biological material, data and information sufficient to identify:

(I) the taxonomic source (e.g., genus, species) of the GRAS substance, including, as applicable, data and information at the sub-species level (e.g., variety, strain);

(II) the part of any plant or animal used as the source of the GRAS substance; and

(III) any known toxicants that could be in the source of the GRAS substance;

(2) a description of the method of manufacture of the GRAS substance in sufficient detail to evaluate the safety of the notified substance as manufactured;

(3) specifications for food-grade material; and

(4) when necessary to demonstrate safety, relevant data and information bearing on the physical or other technical effect the GRAS substance is intended to produce, including the quantity of the GRAS substance required to produce such effect.

(iii) Dietary exposure to the notified substance, including information about dietary exposure (i.e., the amount of relevant substances that consumers are likely to eat or drink as part of a total diet), including:

(1) an estimate of dietary exposure to the notified substance that includes exposure from its intended use and all sources in the diet;

(2) when applicable, an estimate of dietary exposure to any other substance that is expected to be formed in or on food because of the use of the notified substance (e.g., hydrolytic products or reaction products);

(3) when applicable, an estimate of dietary exposure to any other substance that is present with the notified substance either naturally or due to its manufacture (e.g., contaminants or by-products);

(4) sources of any food consumption data used to estimate dietary exposure, in accordance with clauses one through three of this subparagraph; and

(5) any assumptions made to estimate dietary exposure, in accordance with clauses one through three of this subparagraph.

(iv) Self-limiting levels of use in circumstances where the amount of the notified substance that can be added to human food or animal food is limited because the food containing levels of the notified substance

1 above a particular level would become unpalatable or technologically
2 impractical.

3 (v) If the statutory basis for GRAS status is through experience based
4 on common use in food, evidence of a substantial history of consumption
5 of the notified substance for food use by a significant number of
6 consumers prior to January first, nineteen hundred fifty-eight.

7 (vi) A narrative that provides the basis for the conclusion of GRAS
8 status, including:

9 (1) an explanation for why the data and information in the report
10 provide a basis for that the notified substance is safe under the condi-
11 tions of its intended use. Such explanation shall address the safety of
12 the notified substance, considering all dietary sources and taking into
13 account any chemically or pharmacologically related substances in such
14 diet, and identify what specific data and information discussed in
15 accordance with this clause are generally available and not generally
16 available, by providing citations to the list of data and information
17 required in subparagraph (vii) of this paragraph;

18 (2) an explanation of how the generally available data and information
19 relied on to establish safety in accordance with clause one of this
20 subparagraph provides a basis for the conclusion that the reported
21 substance is generally recognized, among qualified experts, to be safe
22 under the conditions of its intended use;

23 (3) either:

24 (A) data and information that are, or may appear to be, inconsistent
25 with the conclusion of GRAS status; or

26 (B) a statement that the available data and information was reviewed
27 and the reporter is not aware of any data and information that are, or
28 may appear to be, inconsistent with the conclusion of GRAS status;

29 (4) if any data and information in the report is exempt from disclo-
30 sure under the freedom of information law, a statement that identifies
31 such data and information; and

32 (5) for non-public, safety-related data and information considered in
33 reaching a conclusion of GRAS status, an explanation of how there could
34 be a basis for a conclusion of GRAS status if qualified experts do not
35 have access to such data and information.

36 (vii) A list of the generally available data, information, and methods
37 the notifier cites in the GRAS notice, including:

38 (1) a list of all of the data and information required by subparagraph
39 (vi) of this paragraph to provide a basis for determining that the noti-
40 fied substance is safe under the conditions of its intended use, as
41 described in accordance with clause one of subparagraph (vi) of this
42 paragraph; and

43 (2) identification of specific data and information listed in accord-
44 ance with clause one of this subparagraph that are generally available
45 and not generally available.

46 (viii) Any previous GRAS substance notices submitted to the federal
47 food and drug administration on the reported substance and the federal
48 food and drug administration's responses.

49 (ix) All relevant currently available safety information.

50 c. A report that includes the information specified in paragraph b of
51 this subdivision and has been submitted to the commissioner and made
52 available in the database described in subdivision five of section one
53 hundred ninety-nine-b of this article, shall be applicable to subsequent
54 uses of a GRAS substance that is the subject of such report that is to
55 be used under the same conditions of intended use, regardless of who
56 submitted such report.

1 2. The following substances are exempt from the reporting requirements
2 of subdivision one of this section:

3 a. Any GRAS substance for which the federal food and drug adminis-
4 tration has received a GRAS notice and issued a letter stating that the
5 federal food and drug administration has no questions regarding the
6 conclusion that the substance is generally recognized as safe under its
7 intended conditions of use;

8 b. Any substances recognized in federal regulations as prior sanc-
9 tioned or GRAS substances for use in food or food packaging;

10 c. Any food contact substance for which there is an effective premar-
11 ket notification demonstrating safety for its intended use;

12 d. Any substances subject to regulation approving its intended use for
13 food;

14 e. A food ingredient that has been widely consumed in the United
15 States prior to January first, nineteen hundred fifty-eight without
16 known detrimental effects, which is subject only to conventional proc-
17 essing as practiced prior to January first, nineteen hundred fifty-
18 eight, and for which no known safety hazard exists;

19 f. Any substance for which the federal food and drug administration
20 has received a new dietary ingredient notification and issued a letter
21 of acknowledgement without objection that the substance is safe under
22 its notification's intended conditions of use; and

23 g. Any substance determined safe to be added to foods by the commis-
24 sioner through rulemaking.

25 3. Notwithstanding the provisions of subdivision one of this section,
26 a retail food store as defined in paragraph (b) of subdivision one of
27 section five hundred of this chapter, a food service establishment as
28 defined in paragraph (a) of subdivision one of section five hundred of
29 this chapter, or a food relief organization as defined in section four
30 hundred fifty-one of this chapter, a supermarket, a grocery store, a
31 specialty food store, a farmer's market, or any other vendor that, in
32 the regular course of business, sells food at retail directly to the
33 public on premises located in the state shall be permitted to sell,
34 deliver, distribute, hold, offer or expose for sale any food or food
35 product the sale of which would otherwise be prohibited by the
36 provisions of subdivision one of this section, until the expiration
37 date, "best by" date, or "sell by" date printed on the packaging of the
38 food or food product by the manufacturer or producer, but no later than
39 three years after the effective date of this subdivision. This subdivi-
40 sion shall not affect the applicability of any provision of law other
41 than subdivision one of this section, provided that such food or food
42 product was acquired for sale within the state by such retail food
43 store, food service establishment, food relief organization, supermar-
44 ket, grocery store, specialty food store, farmer's market, or other
45 vendor before the effective date of this section.

46 4. A small business, defined as a business that is independently owned
47 and operated, and employs one hundred or fewer persons, shall be exempt
48 from the requirements of this section.

49 5. Data establishing the general recognition of safety shall be based
50 on publicly available information and shall not be based on trade
51 secrets.

52 6. Nothing in this section shall impose any requirement regarding food
53 labelling not otherwise required by law.

54 § 6. Section 199-b of the agriculture and markets law is amended by
55 adding a new subdivision 5 to read as follows:

56 5. The commissioner:

1 a. shall make reports submitted pursuant to section one hundred nine-
2 ty-nine-g of this article available to the public in a database on its
3 website. The database shall:

4 (i) be searchable by members of the public;

5 (ii) enable consumers to download and print displayed information; and

6 (iii) accommodate reasonably anticipated and actual public use.

7 b. shall redact from the public report any information that has been
8 designated by the submitter as a trade secret, provided, however, that
9 data establishing the general recognition of safety shall not be redact-
10 ed;

11 c. shall update the database with any new information that the commis-
12 sioner receives relating to the safety of the GRAS substance;

13 d. may refuse to list a GRAS substance if the commissioner determines
14 the report does not contain the information required by section one
15 hundred ninety-nine-g of this article;

16 e. shall provide an interim progress report concerning efforts to
17 develop and implement the database system required by this subdivision,
18 which shall include:

19 (i) a projected completion date;

20 (ii) a description of obstacles to development and implementation of
21 the database system; and

22 (iii) an estimate of the costs to complete the implementation of the
23 database system; and

24 f. may charge a fee to the reporter of a GRAS substance in order to
25 recover the costs incurred in listing such GRAS substance and maintain-
26 ing the database.

27 § 7. The second undesignated paragraph of section 202-c of the agri-
28 culture and markets law, as amended by chapter 671 of the laws of 1966,
29 is amended to read as follows:

30 The commissioner may institute such action at law or in equity as may
31 appear necessary to enforce compliance with sections one hundred nine-
32 ty-nine-a, one hundred ninety-nine-g, two hundred and two hundred one of
33 this article, and any rule or order respecting a GRAS substance, food
34 additive, or color additive promulgated pursuant to sections one hundred
35 ninety-nine-b and two hundred fourteen-b of this article and, in addi-
36 tion to any other remedy under this chapter or otherwise, may apply for
37 relief by injunction to protect the public interest without being
38 compelled to allege or prove that an adequate remedy at law does not
39 exist. In an action instituted by the commissioner to enforce compliance
40 with said sections one hundred ninety-nine-a, two hundred and two
41 hundred one the commissioner shall not be required to prove that the
42 food, food additive or color additive mentioned in the complaint is
43 unsafe and the claim or defense of the defendant as to its safety shall
44 be immaterial, provided, however, that the recognition by the federal
45 food and drug administration of a food additive or color additive as
46 safe may be alleged as a proper defense.

47 § 8. This act shall take effect one year after it shall have become a
48 law; provided, however, that paragraph (c) of subdivision 5 of section
49 199-a of the agriculture and markets law as added by section two of this
50 act shall take effect immediately. Effective immediately, the addition,
51 amendment and/or repeal of any rule or regulation necessary for the
52 implementation of this act on its effective date are authorized to be
53 made and completed by the commissioner of agriculture and markets on or
54 before such effective date.