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Introduced by M. of A. KELLES, COLTON, GIBBS, GLICK, JACKSON, LEE, LEVENBERG, RAGA, REYES, ROSENTHAL, SAYEGH, SEAWRIGHT, SHIMSKY, SIMON, STECK, STIRPE, TAPIA, CLARK, P. CARROLL, HEVESI, TORRES, CRUZ, NORBER, DINOWITZ, KAY, LUNSFORD, GALLAGHER, SLATER, PAULIN, BURROUGHS, SCHIAVONI, DE LOS SANTOS, TAGUE, ANGELINO, MEEKS, GALLAHAN, ALVAREZ, OTIS, SANTABARBARA, BROOK-KRASNY, BICHOTTE HERMELYN, KASSAY -- read once and referred to the Committee on Agriculture -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee -- again reported from said committee with amendments, ordered reprinted as amended and recommitted to said committee -- again reported from said committee with amendments, ordered reprinted as amended and recommitted to said committee -- reported and referred to the Committee on Codes -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee -- again amended on third reading, ordered reprinted, retaining its place on the order of third reading -- ordered to a third reading, amended and ordered reprinted, retaining its place on the order of third reading -- again amended on third reading, ordered reprinted, retaining its place on 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 used or intended for human consump-
8 tion.

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

LBD01051-15-6

1 5. (a) Notwithstanding any other provision of law to the contrary, on
2 or after the date one year after the effective date of this paragraph it
3 shall be unlawful for any person, firm, association, or corporation to
4 manufacture, compound, brew, distill, produce, process, sell, deliver,
5 distribute, hold, offer or expose for sale any of the following
6 substances as food additives or food color additives or any food or food
7 product containing any of the following substances used or intended for
8 human consumption:

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

10 (ii) Potassium bromate; or

11 (iii) Propylparaben.

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

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

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

42 7-a. The term "generally recognized as safe substance" or "GRAS
43 substance" means any substance added to food that is exempted from the
44 definition of "food additive" under subdivision seven of this section
45 because it is generally recognized, among experts qualified by scientifi-
46 c training and experience to evaluate its safety, as having been
47 adequately shown to be safe under the conditions of its intended use:

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

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

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

1 4. All data submitted to the commissioner in support of the food or
2 color additives report under this section shall be considered confiden-
3 tial by the commissioner and shall not be revealed to any person other
4 than to a person authorized by the commissioner in the performance of
5 [~~his~~] their official duties under this article. In case of an actual
6 controversy as to the validity of an order or decision of the commis-
7 sioner respecting the test data or report in which a proceeding to
8 review has been instituted as authorized by section two hundred two-c of
9 this article the petition, data and report shall be transmitted by the
10 commissioner to the clerk of the court in which the review proceeding is
11 instituted, together with a record of the proceedings on which the
12 commissioner based [~~his~~] the order or decision, and such transmittal
13 shall not be construed to be a violation of confidence. Subdivisions
14 two and three of this section shall not apply to food additives or color
15 additives which are safe within the meaning of the federal food, drug
16 and cosmetic act as amended.

17 § 5. The agriculture and markets law is amended by adding a new
18 section 199-h to read as follows:

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

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

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

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

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

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

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

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

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

42 (4) intended conditions for the use of any GRAS substance discussed in
43 the report, including the foods in which the substance will be used, the
44 levels of such use in such foods, and the purposes for which the
45 substance will be used, including, when appropriate, a description of
46 any subpopulation expected to consume such GRAS substance or substances;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

36 (3) specifications for food-grade material; and

37 (4) when necessary to demonstrate safety, relevant data and informa-
38 tion bearing on the physical or other technical effect the GRAS
39 substance is intended to produce, including the quantity of the GRAS
40 substance required to produce such effect.

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

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

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

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

54 (4) sources of any food consumption data used to estimate dietary
55 exposure, in accordance with clauses one through three of this subpara-
56 graph; and

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

3 (iv) Self-limiting levels of use in circumstances where the amount of
4 the notified substance that can be added to human food or animal food is
5 limited because the food containing levels of the notified substance
6 above a particular level would become unpalatable or technologically
7 impractical.

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

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

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

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

28 (3) either:

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

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

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

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

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

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

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

51 (viii) Any previous GRAS substance notices submitted to the federal
52 food and drug administration on the reported substance and the federal
53 food and drug administration's responses.

54 (ix) All relevant currently available safety information.

55 c. A report that includes the information specified in paragraph b of
56 this subdivision and has been submitted to the commissioner and made

1 available in the database described in subdivision five of section one
2 hundred ninety-nine-b of this article, shall be applicable to subsequent
3 uses of a GRAS substance that is the subject of such report that is to
4 be used under the same conditions of intended use, regardless of who
5 submitted such report.

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

8 a. Any GRAS substance for which the federal food and drug adminis-
9 tration has received a GRAS notice and issued a letter stating that the
10 federal food and drug administration has no questions regarding the
11 conclusion that the substance is generally recognized as safe under its
12 intended conditions of use;

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

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

17 d. Any substances subject to regulation approving its intended use for
18 food;

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

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

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

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

50 4. Notwithstanding the provisions of subdivision one of this section,
51 a retail food store as defined in subdivision two of section five
52 hundred-a of this chapter, a food service establishment as defined in
53 subdivision one of section five hundred-a of this chapter, a food relief
54 organization as defined in subdivision one of section four hundred
55 fifty-one of this chapter, a supermarket, a grocery store, a specialty
56 food store, a farmer's market, or any other vendor that, in the regular

1 course of business, sells food at retail directly to the public on prem-
2 ises located in the state, shall not be found in violation of subpara-
3 graph (iii) of paragraph a of subdivision one of this section for sell-
4 ing or offering or exposing for sale any food or food product containing
5 an unreported GRAS substance or combination of GRAS substances if such
6 retailer, as identified in this subdivision, has a valid written
7 contract or renewal agreement with the manufacturer, producer, distrib-
8 utor, or supplier for the purchase of any food or food product that
9 provides such food or food product sold to such retailer, as identified
10 in this subdivision, is compliant with this section. This subdivision
11 shall not affect the applicability of this act to manufacturers, produc-
12 ers, distributors, or suppliers of GRAS substances, food, or food
13 products.

14 5. This section shall only apply to food or food products used or
15 intended for human consumption.

16 6. A small business, defined as a business that is independently owned
17 and operated, and employs one hundred or fewer persons, shall be exempt
18 from the requirements of this section.

19 7. Data establishing the general recognition of safety shall be based
20 on publicly available information and shall not be based on trade
21 secrets.

22 8. Nothing in this section shall impose any requirement regarding food
23 labelling not otherwise required by law.

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

26 5. The commissioner:

27 a. shall make reports submitted pursuant to section one hundred nine-
28 ty-nine-h of this article available to the public in a database on its
29 website. The database shall:

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

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

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

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

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

39 d. may refuse to list a GRAS substance if the commissioner determines
40 the report does not contain the information required by section one
41 hundred ninety-nine-h of this article;

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

45 (i) a projected completion date;

46 (ii) a description of obstacles to development and implementation of
47 the database system; and

48 (iii) an estimate of the costs to complete the implementation of the
49 database system; and

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

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

1 The commissioner may institute such action at law or in equity as may
2 appear necessary to enforce compliance with sections one hundred nine-
3 ty-nine-a, one hundred ninety-nine-h, two hundred and two hundred one of
4 this article, and any rule or order respecting a GRAS substance, food
5 additive, or color additive promulgated pursuant to sections one hundred
6 ninety-nine-b and two hundred fourteen-b of this article and, in addi-
7 tion to any other remedy under this chapter or otherwise, may apply for
8 relief by injunction to protect the public interest without being
9 compelled to allege or prove that an adequate remedy at law does not
10 exist. In an action instituted by the commissioner to enforce compliance
11 with said sections one hundred ninety-nine-a, two hundred and two
12 hundred one the commissioner shall not be required to prove that the
13 food, food additive or color additive mentioned in the complaint is
14 unsafe and the claim or defense of the defendant as to its safety shall
15 be immaterial, provided, however, that the recognition by the federal
16 food and drug administration of a food additive or color additive as
17 safe may be alleged as a proper defense.

18 § 8. This act shall take effect one year after it shall have become a
19 law; provided, however, that paragraph (c) of subdivision 5 of section
20 199-a of the agriculture and markets law as added by section two of this
21 act shall take effect immediately. Effective immediately, the addition,
22 amendment and/or repeal of any rule or regulation necessary for the
23 implementation of this act on its effective date are authorized to be
24 made and completed by the commissioner of agriculture and markets on or
25 before such effective date.