

STATE OF NEW YORK

8615

IN SENATE

February 21, 2024

Introduced by Sen. KAVANAGH -- read twice and ordered printed, and when printed to be committed to the Committee on Agriculture

AN ACT to amend the agriculture and markets law, in relation to reporting of GRAS substances

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

1 Section 1. Section 198 of the agriculture and markets law is amended
2 by adding a new subdivision 7-a to read as follows:

3 7-a. The term "generally recognized as safe substance" or "GRAS
4 substance" means any substance added to food that is not excepted from
5 the definition of "food additive" under subdivision seven of this
6 section because it is generally recognized, among experts qualified by
7 scientific training and experience to evaluate its safety, as having
8 been adequately shown to be safe under the conditions of its intended
9 use:

10 (a) through scientific procedures; or

11 (b) in the case of a substance used in food prior to January first,
12 nineteen hundred fifty-eight, through either scientific procedures or
13 experience based on prolonged use in food.

14 § 2. Subdivision 4 of section 199-a of the agriculture and markets
15 law, as amended by chapter 671 of the laws of 1966, is amended to read
16 as follows:

17 4. All data submitted to the commissioner in support of the food or
18 color additives report under this section shall be considered confiden-
19 tial by the commissioner and shall not be revealed to any person other
20 than to a person authorized by the commissioner in the performance of
21 his official duties under this article. In case of an actual controversy
22 as to the validity of an order or decision of the commissioner respect-
23 ing the test data or report in which a proceeding to review has been
24 instituted as authorized by section two hundred two-c of this article
25 the petition, data and report shall be transmitted by the commissioner
26 to the clerk of the court in which the review proceeding is instituted,
27 together with a record of the proceedings on which the commissioner
28 based his order or decision, and such transmittal shall not be construed

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

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1 to be a violation of confidence. Subdivisions two and three of this
2 section shall not apply to food additives or color additives which are
3 safe within the meaning of the federal food, drug and cosmetic act as
4 amended.

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

7 § 199-g. Reporting of GRAS substances. 1. a. Except as provided in
8 subdivision two of this section, unless a report described in paragraph
9 b of this subdivision has been submitted to the commissioner and such
10 report is made available in the database described in subdivision five
11 of section one hundred ninety-nine-b of this article, it shall be unlaw-
12 ful for any person, firm, association, or corporation to:

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

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

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

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

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

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

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

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

29 (4) intended conditions for the use of any GRAS substance discussed in
30 the report, including the foods in which the substance will be used, the
31 levels of such use in such foods, and the purposes for which the
32 substance will be used, including, when appropriate, a description of
33 any subpopulation expected to consume such GRAS substance or substances;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

47 (iv) Self-limiting levels of use in circumstances where the amount of
48 the notified substance that can be added to human food or animal food is
49 limited because the food containing levels of the notified substance
50 above a particular level would become unpalatable or technologically
51 impractical.

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

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

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

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

17 (3) either:

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

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

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

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

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

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

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

40 (viii) Any previous GRAS substance notices submitted to the federal
41 food and drug administration on the reported substance and the federal
42 food and drug administration's responses.

43 (ix) All relevant currently available safety information.

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

46 a. Any GRAS substance for which the federal food and drug adminis-
47 tration has received a GRAS notice and issued a letter stating that the
48 federal food and drug administration has no questions regarding the
49 conclusion that the substance is generally recognized as safe under its
50 intended conditions of use;

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

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

55 d. Any substances subject to regulation approving its intended use for
56 food;

1 e. A food ingredient of natural biological origin that has been widely
2 consumed for its nutrient properties in the United States prior to Janu-
3 ary first, nineteen hundred fifty-eight without known detrimental
4 effects, which is subject only to conventional processing as practiced
5 prior to January first, nineteen hundred fifty-eight, and for which no
6 known safety hazard exists; and

7 f. Any substance determined safe to be added to foods by the commis-
8 sioner through rulemaking.

9 3. Any person may file a report to the commissioner under this
10 section.

11 4. Small businesses, as defined section one hundred thirty-one of the
12 economic development law, shall be exempt from the requirements of this
13 section.

14 5. Data establishing the general recognition of safety shall be based
15 on publicly available information and shall not be based on trade
16 secrets.

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

19 5. The commissioner:

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

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

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

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

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

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

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

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

38 (i) a projected completion date;

39 (ii) a description of obstacles to development and implementation of
40 the database system; and

41 (iii) an estimate of the costs to complete the implementation of the
42 database system; and

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

46 § 5. The second undesignated paragraph of section 202-c of the agri-
47 culture and markets law, as amended by chapter 671 of the laws of 1966,
48 is amended to read as follows:

49 The commissioner may institute such action at law or in equity as may
50 appear necessary to enforce compliance with sections one hundred nine-
51 ty-nine-a, one hundred ninety-nine-g, two hundred and two hundred one of
52 this article, and any rule or order respecting a GRAS substance, food
53 additive, or color additive promulgated pursuant to sections one hundred
54 ninety-nine-b and two hundred fourteen-b of this article and, in addi-
55 tion to any other remedy under this chapter or otherwise, may apply for
56 relief by injunction to protect the public interest without being

1 compelled to allege or prove that an adequate remedy at law does not
2 exist. In an action instituted by the commissioner to enforce compliance
3 with said sections one hundred ninety-nine-a, two hundred and two
4 hundred one the commissioner shall not be required to prove that the
5 food, food additive or color additive mentioned in the complaint is
6 unsafe and the claim or defense of the defendant as to its safety shall
7 be immaterial, provided, however, that the recognition by the federal
8 food and drug administration of a food additive or color additive as
9 safe may be alleged as a proper defense.

10 § 6. This act shall take effect immediately.