STATE OF NEW YORK

9295

IN ASSEMBLY

February 23, 2024

Introduced by M. of A. KELLES -- read once and referred 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:

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

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

(a) through scientific procedures; or

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

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

4. All data submitted to the commissioner in support of the **food or color additives** report under this section shall be considered confidential by the commissioner and shall not be revealed to any person other than to a person authorized by the commissioner in the performance of his official duties under this article. In case of an actual controversy as to the validity of an order or decision of the commissioner respecting the test data or report in which a proceeding to review has been instituted as authorized by section two hundred two-c of this article the petition, data and report shall be transmitted by the commissioner to the clerk of the court in which the review proceeding is instituted, together with a record of the proceedings on which the commissioner 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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to be a violation of confidence. Subdivisions two and three of this section shall not apply to food additives or color additives which are safe within the meaning of the federal food, drug and cosmetic act as amended.

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

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

(i) sell or offer or expose for sale for use in or on food, or to use in the manufacturing, compounding, brewing, distilling, producing, or processing of any food or food product, any GRAS substance or combination of GRAS substances;

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

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

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

(i) Signed statements and a certification, including:

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

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

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

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

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

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

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

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

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

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

(II) provide a complete copy of the data and information either in an 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 above a particular level would become unpalatable or technologically impractical.

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

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

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

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

(3) either:

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

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

(4) if any data and information in the report is exempt from disclosure under the freedom of information law, a statement that identifies such data and information; and

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

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

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

(2) identification of specific data and information listed in accordance with clause one of this subparagraph that are generally available and not generally available.

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

(ix) All relevant currently available safety information.

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

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

b. Any substances recognized in federal regulations as prior sanctioned or GRAS substances for use in food or food packaging;

c. Any food contact substance for which there is an effective premarket notification demonstrating safety for its intended use;

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

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

f. Any substance determined safe to be added to foods by the commissioner through rulemaking.

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

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

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

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

5. The commissioner:

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

(i) be searchable by members of the public;

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

(iii) accommodate reasonably anticipated and actual public use.

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

c. shall update the database with any new information that the commissioner receives relating to the safety of the GRAS substance;

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

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

(i) a projected completion date;

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

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

f. may charge a fee to the reporter of a GRAS substance in order to recover the costs incurred in listing such GRAS substance and maintaining the database.

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

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

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

§ 6. This act shall take effect immediately.