§ 570.225 Part 1 of a GRAS notice: Signed statements and certification.

(a) Part 1 of your GRAS notice must be dated and signed by a responsible official of your organization, or by your attorney or agent.

(b) Except as required by paragraph (c)(8) of this section, you must not include any information that is trade secret or confidential commercial information in Part 1 of your GRAS notice.

(c) In Part 1 of your GRAS notice, you must:

(1) Inform us that you are submitting a GRAS notice in accordance with this subpart;

(2) Provide the name and address of your organization;

(3) Provide the name of the notified substance, using an appropriately descriptive term;

(4) Describe the intended conditions of use of the notified substance, including stating whether the substance will be added to food (including drinking water) for animals in which the substance will be used; identifying the foods to which it will be added, the levels of use in such foods, and the animal species for which these foods are intended (including, when appropriate, a description of a subpopulation expected to consume the notified substance); and the purposes for which the substance will be used;

(5) Inform us of the statutory basis for your conclusion of GRAS status (*i.e.*, through scientific procedures in accordance with § 570.30(a) and (b) or through experience based on common use in animal food in accordance with § 570.30(a) and (c));

(6) State your view that the notified substance is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act based on your conclusion that the notified substance is GRAS under the conditions of its intended use;

(7) State that, if we ask to see the data and information that are the basis for your conclusion of GRAS status, either during or after our evaluation of your notice, you will:

(i) Agree to make the data and information available to us; and

(ii) Agree to both of the following procedures for making the data and information available to us:

(A) Upon our request, you will allow us to review and copy the data and information during customary business hours at the address you specify for where these data and information will be available to us; and

(B) Upon our request, you will provide us with a complete copy of the data and information either in an electronic format that is accessible for our evaluation or on paper;

(8) State your view as to whether any of the data and information in Parts 2 through 7 of your GRAS notice are exempt from disclosure under the Freedom of Information Act, 5 U.S.C. 552 (*e.g.*, as trade secret or as commercial or financial information that is privileged or confidential);

(9) Certify that, to the best of your knowledge, the GRAS notice is a complete, representative, and balanced submission that includes unfavorable information, as well as favorable information, known to you and pertinent to the evaluation of the safety and GRAS status of the use of the substance; and

(10) State both the name and the position or title of the person who signs the GRAS notice.

§ 570.230 Part 2 of a GRAS notice: Identity, method of manufacture, specifications, and physical or technical effect.

In Part 2 of your GRAS notice, you must include:

(a) Scientific data and information that identifies the notified substance.

(1) Examples of appropriate data and information include 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.

(2) When the source of a notified substance is a biological material, you must include data and information sufficient to identify:

(i) The taxonomic source (*e.g.*, genus, species), 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; and

(iii) Any known toxicants that could be in the source;