Table 2. – Summary of Principal Changes to the Proposed Notification Procedure

Proposed Rule	Final Rule
Would not define any terms	Defines the terms "amendment," "GRAS," "GRAS notice," "notified substance," "notifier," "qualified expert," "supplement," "we, our, and us," and "you and your."
Referred to a "GRAS determination"	Refers to a "GRAS conclusion" or "conclusion of GRAS status"
Referred to the statutory GRAS provision as an "exemption"	Refers to the statutory GRAS provision as an "exclusion"
Would not use "Plain Language" techniques as outlined in a Presidential Memorandum dated June 1, 1998 (Ref. 21) and in "Improving Electronic Dockets on Regulations.gov and the Federal Docket Management System: Best Practices for Federal Agencies" (Ref. 22)	Uses "Plain Language" techniques such as pronouns and short regulatory sections
Was silent on whether a GRAS notice could incorporate specifically identified data and information previously submitted to CFSAN or CVM	Expressly provides for incorporation into a GRAS notice specifically identified data and information previously submitted to CFSAN or CVM
Would not specify individual parts of a GRAS notice	Specifies the seven parts of a GRAS notice
Would require three paper copies of a GRAS notice	Provides that you may submit a GRAS notice either in electronic format that is accessible for our evaluation or on paper. If you send your GRAS notice on paper, a single paper copy is sufficient.
Referred to dated and signed statements in a GRAS notice as a "claim"	Refers to dated and signed statements in a GRAS notice as "signed statements"
Assumed that a notice will not contain any information that is protected from public disclosure under the FOIA	Specifies that a GRAS notice must not include any information that is trade secret or confidential commercial information in certain sections of the signed statements, but does not otherwise prohibit the submission of information that is protected from public disclosure under the FOIA.
Would require that the "common or usual name" of the notified substance	Requires an "appropriately descriptive term" for the notified substance
Would not require GRAS notice to state view as to whether any data and information in the GRAS notice are exempt from disclosure under the FOIA	Requires GRAS notice to state view as to whether any of the data and information in the GRAS notice are exempt from disclosure under the FOIA (*e.g.*, as trade secret or as commercial or financial information that is privileged or confidential)

Would not expressly require a signed certification regarding the representative and balanced nature of the GRAS notice	Expressly requires a signed certification that to the best of notifier's knowledge, the GRAS notice is a complete, representative, and balanced submission that includes unfavorable information, as well as favorable information, known to the notifier and pertinent to the evaluation of the safety and GRAS status of the use of the substance
For a notified substance of natural biological origin, would require source information such as genus and species	For a notified substance of natural biological origin, requires source information that includes applicable data and information at the sub-species level (*e.g.*, variety, strain) in addition to genus and species
Would require the method of manufacture (excluding any trade secrets)	Requires a description of the method of manufacture of the notified substance in sufficient detail to evaluate the safety of the notified substance as manufactured; the description may include trade secret information
Would not expressly require relevant data and information bearing on the physical or other technical effect the notified substance is intended to produce	When necessary to demonstrate safety, expressly requires relevant data and information bearing on the physical or other technical effect the notified substance is intended to produce, including the quantity of the notified substance required to produce such effect
Would require consideration of dietary exposure as part of a comprehensive discussion of the data and information that you rely on to establish safety, using the statutory language of section 409(c)(5)(A) and (B) of the FD&C Act	Separates the statutory language of section 409(c)(5)(A) and (B) of the FD&C Act into two distinct parts of the GRAS notice: (1) Part 3, which addresses how much of the notified substance consumers would eat as part of the total diet (including exposure from its intended use and all sources in the diet), as well as how much consumers would eat of other substances (*e.g.*, contaminants or by-products); and (2) Part 6, which requires that a GRAS notice to address, in the narrative, the safety of the notified substance, considering all dietary sources and taking into account any chemically or pharmacologically related substances in such diet
Would require a "comprehensive discussion" of, and citations to, generally available and accepted scientific data, information, methods, or principles relied on to establish safety	Requires a narrative (Part 6 of a GRAS notice) and a list of supporting data and information (Part 7 of a GRAS notice)
Would not require consideration of dietary exposure as part of a comprehensive discussion of the data and information relied	Expressly requires consideration of dietary exposure, regardless of whether the conclusion of GRAS status is through scientific procedures or

on to establish safety for a conclusion of GRAS status through experience based on common use in food	through experience based on common use in food
Would require a comprehensive discussion of any reports of investigations or other information that may appear to be inconsistent with the GRAS determination	Requires that the GRAS notice either: (1) Identify, discuss, and place in context, data and information that are, or may appear to be, inconsistent with the conclusion of GRAS status; or (2) state that the notifier has reviewed the available data and information and is not aware of any data and information that are, or may appear to be, inconsistent with the conclusion of GRAS status
Would not require identification of data and information that viewed as exempt from disclosure under the FOIA	If the notifier views any of the data and information in the notice as exempt from disclosure under the FOIA, requires the specific data and information to be identified
Would not require that explanation of how there could be a basis for a conclusion of GRAS status if qualified experts generally do not have access to non-public, safety-related data and information	Requires that explanation of how there could be a basis for a conclusion of GRAS status if qualified experts generally do not have access to non-public, safety-related data and information
Would require that the comprehensive discussion include the basis for concluding that there is consensus among qualified experts that there is reasonable certainty that the substance is not harmful under the intended conditions of use	Uses the term "generally recognized" rather than the term "consensus"
Was silent on whether you could submit an amendment to a GRAS notice	Expressly provides for a timely "amendment" to a GRAS notice before FDA responds to, or ceases to evaluate, a GRAS notice
Considered that it was implicit that notifier could ask FDA to cease to evaluate a GRAS notice	Expressly provides that notifier may ask FDA to cease to evaluate a GRAS notice, and expressly provides that FDA will inform notifier of its decision regarding the request
FDA would acknowledge receipt of a GRAS notice within 30 days of receipt	FDA will conduct an initial evaluation of a submission to determine whether to file it as a GRAS notice for further evaluation. If FDA files the submission as a GRAS notice, it will send a letter that informs the notifier of the date of filing. If FDA does not file the submission as a GRAS notice, it will send a letter informing the notifier of that fact and providing its reasons for not filing the submission as a GRAS notice.
FDA would respond to a GRAS notice in writing within 90 days of receipt	Within 180 days of filing, FDA will with a letter based on its evaluation of the notice. FDA may extend the 180 day timeframe by 90 days on an as

	needed basis. If FDA extends the timeframe, it will inform the notifier of the extension as soon as practicable but no later than within 180 days of filing.
Was silent on procedures that apply when the intended conditions of use of a notified substance include use in a product or products subject to regulation by USDA's FSIS	Specifies procedures that apply when the intended conditions of use of a notified substance in human food include use in a product or products subject to regulation by USDA's FSIS.
FDA noted that, although the decision to submit a GRAS notice would be voluntary, the provisions governing the GRAS notification procedure, including the information to be submitted, would be mandatory	The data and information in a GRAS notice are considered a mandatory, rather than voluntary, submission for purposes of its status under the FOIA and FDA's public information requirements in part 20
Was silent on whether notifier could submit additional information to a GRAS notice after FDA responded to it	Expressly provides for submission of a "supplement" to a GRAS notice after FDA has responded to a GRAS notice or ceased to evaluate it
Would presumptively convert any filed, pending GRAS affirmation petition to a notice on the effective date of the rule. If FDA did not receive an amendment from the petitioner within 90 days of the effective date of the rule, with information and statements analogous to those in the proposed "GRAS exemption claim," it would consider the converted petition to be inadequate as a notice and would send the petitioner a letter to that effect.	On the effective date of the rule, FDA will close the docket for any GRAS affirmation petition that is still pending. Any person who submitted a GRAS affirmation petition that is closed may submit a GRAS notice and request that we incorporate the GRAS affirmation petition.