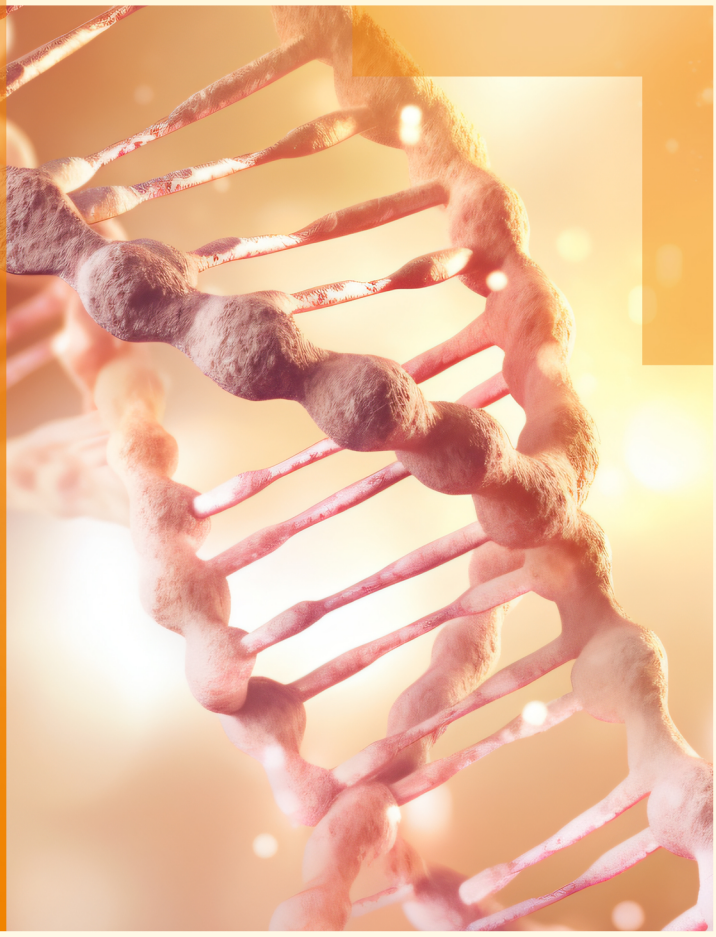
CIRS

Global Expert in New Food Ingredient Registration

Guide to U.S. GRAS Notification

White Paper Series on Global Novel Food and Feed Ingredient Submissions



U.S. Local Team: Based in Virginia, our U.S. team includes full-time food regulatory and toxicology experts, including 2 DABTs, 1 ERT, and 24 DCSTs. We support clients with U.S. compliance services covering FDA GRAS, NDI, CAP, Animal Food GRAS, FDA AFIC, and AAFCO SRIS.

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https://www.cirs-group.com/en/food

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Chapter 1: Compliance Pathways for Food Ingredients in the United States

Pursuant to Sections 201(s) and 409 of the U.S. Federal Food, Drug, and Cosmetic Act (FD&C Act), any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA. Unless qualified experts unanimously agree that the substance is generally recognized as safe (GRAS) under its intended conditions of use, or the substance's use does not fall under the definition of a food additive (for example, substances meeting the definition of pesticides, dietary ingredients in dietary supplements, color additives, new animal drugs, or substances authorized or approved for use prior to September 6, 1958, are excluded from the definition of food additives).

Based on the legal framework above, compliance for new food ingredients in the United States currently follows four primary pathways:

1. Food Additive Petition (FAP)
2. Color Additive Petition (CAP)
3. Generally Recognized as Safe (GRAS)
4. New Dietary Ingredient Notification (NDIN, NDI notification)

The first three pathways apply to conventional food ingredients in the United States, while the NDI notification pathway applies to dietary supplement ingredients, which have their own unique regulatory framework. The main characteristics of these four pathways are as follows:

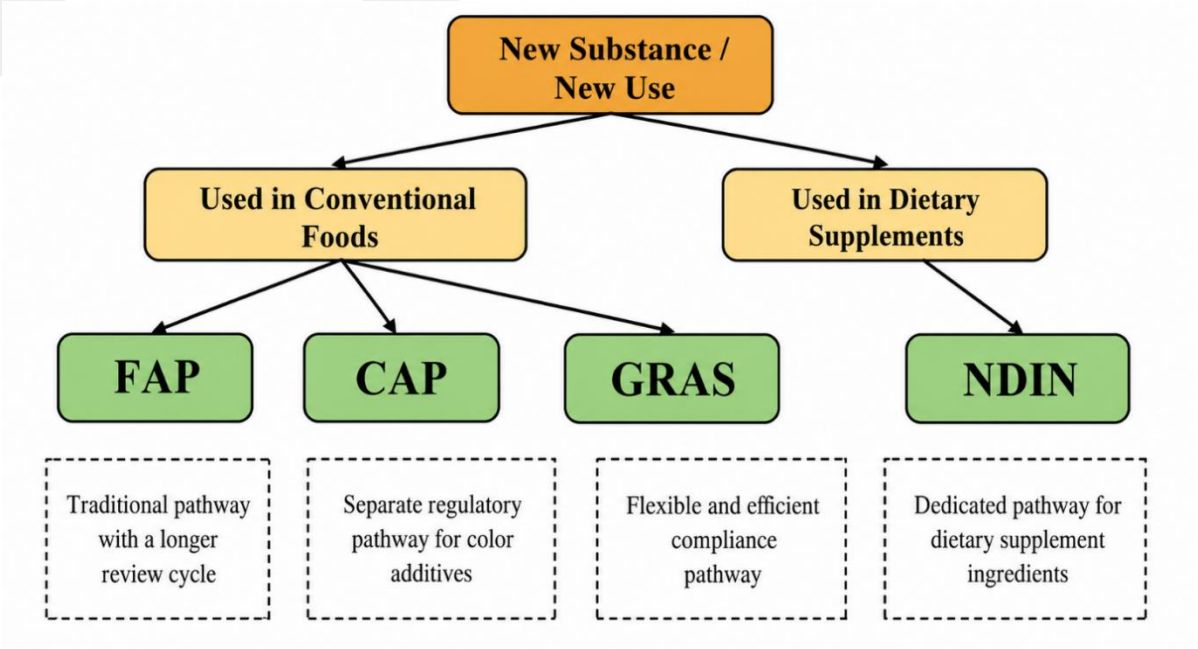
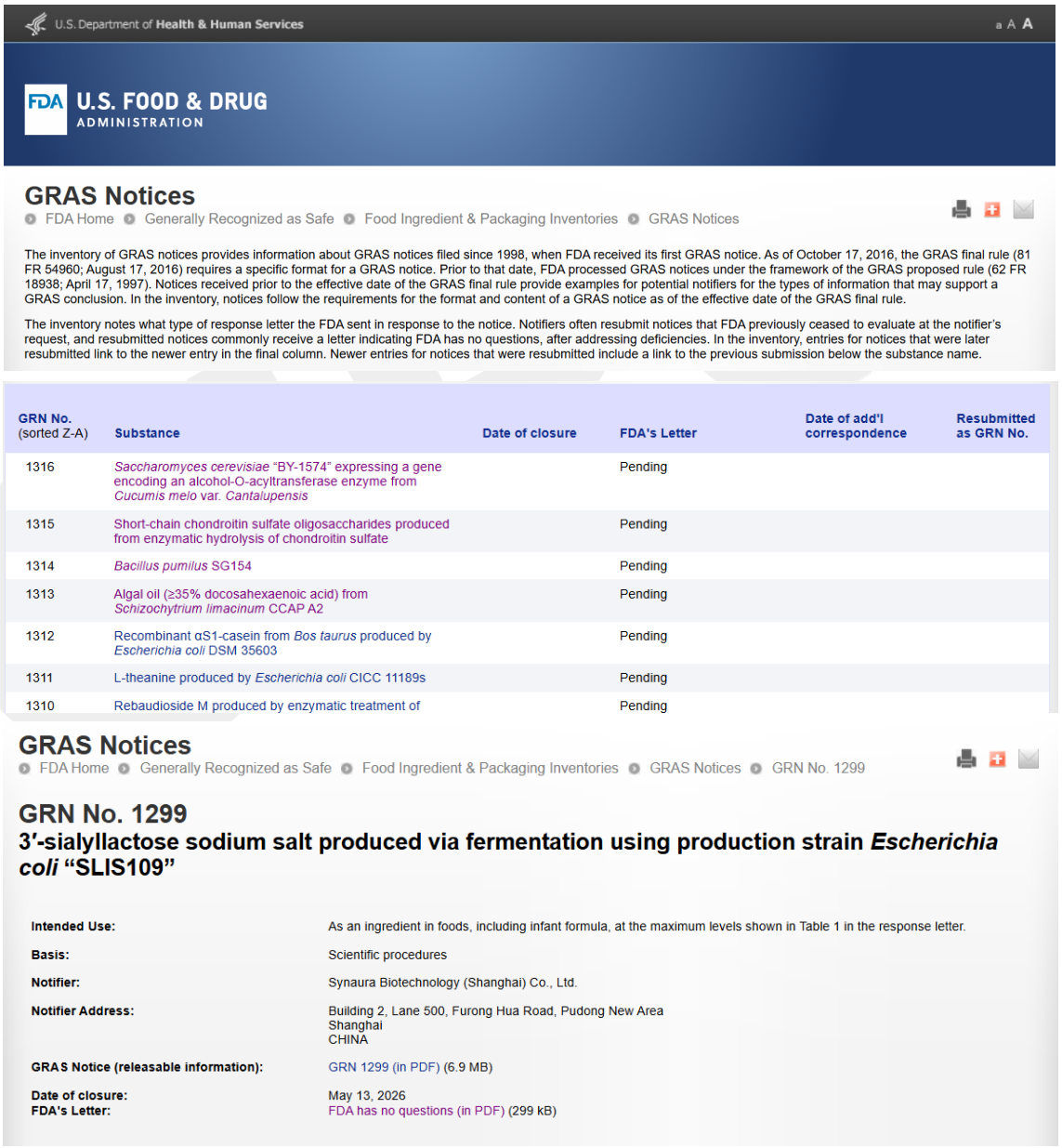


Figure 1-1: Major Compliance Pathways for New Food Ingredients in the United States

Chapter 3: Current Status of FDA GRAS Notifications

3.1 GRAS Notice Database

The U.S. FDA has established the FDA GRAS database to publicly disclose information on GRAS Notices submitted to the FDA. The public can access and search this database. The inventory includes information dating back to the first GRAS notice received by FDA in 1998, including the GRN number, substance information, notifier information, the submitted GRAS dossier, and FDA's response. FDA updates the database approximately once per month.



U.S. Department of Health & Human Services

U.S. FOOD & DRUG ADMINISTRATION

GRAS Notices

FDA Home › Generally Recognized as Safe › Food Ingredient & Packaging Inventories › GRAS Notices

The inventory of GRAS notices provides information about GRAS notices filed since 1998, when FDA received its first GRAS notice. As of October 17, 2016, the GRAS final rule (81 FR 54960; August 17, 2016) requires a specific format for a GRAS notice. Prior to that date, FDA processed GRAS notices under the framework of the GRAS proposed rule (62 FR 18938; April 17, 1997). Notices received prior to the effective date of the GRAS final rule provide examples for potential notifiers for the types of information that may support a GRAS conclusion. In the inventory, notices follow the requirements for the format and content of a GRAS notice as of the effective date of the GRAS final rule.

The inventory notes what type of response letter the FDA sent in response to the notice. Notifiers often resubmit notices that FDA previously ceased to evaluate at the notifier's request, and resubmitted notices commonly receive a letter indicating FDA has no questions, after addressing deficiencies. In the inventory, entries for notices that were later resubmitted link to the newer entry in the final column. Newer entries for notices that were resubmitted include a link to the previous submission below the substance name.

GRN No. (sorted Z-A)	Substance	Date of closure	FDA's Letter	Date of add'l correspondence	Resubmitted as GRN No.
1316	*Saccharomyces cerevisiae* "BY-1574" expressing a gene encoding an alcohol-O-acyltransferase enzyme from *Cucumis melo* var. *Cantalupensis*		Pending		
1315	Short-chain chondroitin sulfate oligosaccharides produced from enzymatic hydrolysis of chondroitin sulfate		Pending		
1314	*Bacillus pumilus* SG154		Pending		
1313	Algal oil (≥35% docosahexaenoic acid) from *Schizochytrium limacinum* CCAP A2		Pending		
1312	Recombinant αS1-casein from *Bos taurus* produced by *Escherichia coli* DSM 35603		Pending		
1311	L-theanine produced by *Escherichia coli* CICC 11189s		Pending		
1310	Rebaudioside M produced by enzymatic treatment of		Pending		

GRAS Notices

FDA Home › Generally Recognized as Safe › Food Ingredient & Packaging Inventories › GRAS Notices › GRN No. 1299

GRN No. 1299

3′-sialyllactose sodium salt produced via fermentation using production strain *Escherichia coli* "SLIS109"

Intended Use:	As an ingredient in foods, including infant formula, at the maximum levels shown in Table 1 in the response letter.
Basis:	Scientific procedures
Notifier:	Synaura Biotechnology (Shanghai) Co., Ltd.
Notifier Address:	Building 2, Lane 500, Furong Hua Road, Pudong New Area Shanghai CHINA
GRAS Notice (releasable information):	GRN 1299 (in PDF) (6.9 MB)
Date of closure:	May 13, 2026
FDA's Letter:	FDA has no questions (in PDF) (299 kB)

Figure 3-1: Screenshot of a portion of the FDA GRAS Notice Inventory

Reference URL: https://hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices