

NOMAD Bioscience Extends Its GRAS Regulatory Clearance In USA For Plant-Made Natural Thaumatin II As Sweetener, Amendment GRN 910S

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NOMAD Bioscience received a formal 'no questions' letter from the US Food and Drug Administration (FDA) in response to NOMAD's GRAS notice amendment GRN 910S describing broader use of plant-produced Thaumatin II as sweetener. Thaumatin II is natural noncaloric high intensity sweetener under development at NOMAD. GRAS is a facilitated US regulatory marketing allowance pathway for food additives and ingredients that are 'Generally Recognized As Safe' under conditions of intended use. The FDA's response represents the ninth regulatory concurrence from the Agency in response to NOMAD's GRAS submissions.

NOMAD submitted an amendment to the supplement on June 9, 2021, providing additional information regarding the cumulative dietary exposure to the ingredient, Thaumatin II. FDA previously evaluated GRN 910 and sent 'no questions' letter at that time regarding NOMAD's conclusion that Thaumatin II is GRAS for use as a non-nutritive sweetener in a variety of food categories at levels ranging from 5 to 400 mg/kg or mg/L food or beverage.

The supplement expands the uses of Thaumatin II as a non-nutritive sweetener to include those listed in Table 1:

Table 1. Food Categories and Intended Maximum Use Levels

Food Category	Use Level (mg/kg)
Beverages (water-based, non-alcoholic)	10
Beverages (carbonated, non-alcoholic)	10
Juice fruit drinks and ades	10
Flavored milks and milk drinks	10
Fruit juices/nectars/fruit-based smoothies	10
Fermented dairy products	10
Coffee and teas	10
Imitation dairy beverages	10
Vegetable juices	10

Thaumatins are natural non-caloric sweeteners/flavour modifiers. Thaumatins are intensely sweet-tasting protein mixtures (consisting mainly of Thaumatin I and Thaumatin II), about 2000-3000 times sweeter than sucrose on a weight basis. Thaumatin mixtures purified from its natural source plant *Thaumatococcus* received regulatory approvals as sweetener or taste modifier decades ago, and they are on the market in US, EU, Japan and many other countries. The wide use of the products as sugar replacements is however limited because of low and unreliable supply of natural plant species and low yield resulting in high price of the product; and the fact that the microbial fermentation production process of Thaumatins is not competitive. NOMAD has developed alternative process of natural Thaumatins, specifically the superior protein Thaumatin II, in alternative plant hosts that opens way to unlimited and economical production of the protein. To date, NOMAD has received four GRAS clearance for Thaumatins made in other plant hosts as sweeteners and taste modifiers in 2018-20 (GRN 738, GRN 910, GRN 920, GRN 910S).

About NOMAD Bioscience GmbH. NOMAD Bioscience GmbH is a plant biotechnology company developing a broad range of biotechnology products manufactured in plants. Among the product candidates in development are non-antibiotic antimicrobials (bacterial bacteriocins and phage lysins) for food safety and medicine markets, as well as natural high intensity non-caloric

sweetener proteins Thaumatin and Brazzein as sugar replacements and taste modifiers. Corporate offices are headquartered in Munich, Germany and the Company's Research Division is located in Halle, Germany. NOMAD Bioscience GmbH has a subsidiary company UAB Nomads (Vilnius, Lithuania). Nomad's spin off Nambawan Biotech GmbH (Germany) has been incorporated in 2021 and it will commercialize NOMAD's products for food and veterinary markets.

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