

NOMAD Bioscience Receives Its GRAS Regulatory Clearance In USA For Plant-Made Natural Thaumatin II As Flavour Modifier

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NOMAD Bioscience GmbH received a formal 'no questions' letter from the US Food and Drug Administration (FDA) in response to NOMAD's GRAS notice GRN 920 describing use of plant-produced Thaumatin II as flavour modifier. Thaumatin II is natural non-caloric high intensity sweetener and flavour modifier under development at NOMAD. GRAS is a facilitated US regulatory marketing allowance pathway for food substances and ingredients that are 'Generally Recognized As Safe' under conditions of intended use. The FDA's response represents the eighth regulatory concurrence from the Agency in response to NOMAD's GRAS submissions.

Thaumatins are natural non-caloric sweeteners/flavour modifiers. Thaumatins are intensely sweet-tasting protein mixtures consisting mainly of Thaumatin I and Thaumatin II. Thaumatin mixtures purified from its natural source plant *Thaumatococcus* received regulatory approvals as sweetener or flavour modifier decades ago, and they are on the market in US, EU, Japan and many other countries. The much wider use of the product is however limited because of low and unreliable supply of natural plant species and low yield per hectare resulting in high price of bulk substance. The microbial fermentation-based production of thaumatins is not economically viable. NOMAD has received its first regulatory GRAS clearance for thaumatins made in other plant hosts as sweeteners in 2018 (GRAS 738) and for Thaumatin II as sweetener in 2020 (GRAS 910). NOMAD's current petition claims safe use of Thaumatin II in beverages (water-based, non-alcoholic), fruit juice drinks, flavoured milks and milk drinks, fruit juices, nectars, smoothies, fermented dairy products, coffee, tea, imitation dairy beverages, and vegetable juices at a maximum use level of 7 mg/l.

NOMAD and its former subsidiary Icon Genetics, have developed unique processes of manufacturing proteins in plants that is based on high yield expression of proteins such as thaumatins. This manufacturing process is currently being brought to an industrial level by NOMAD and its partners in Spain and Germany.

Thaumatin II is the NOMAD's lead product candidate with new superior sweetener and flavour modifier attributes; it aims to reduce sugar and eliminate artificial sweeteners and flavour modifiers in drink and food products, and it can be produced in plant crops grown in temperate climates thus assuring an unlimited substance supply and low commercially competitive selling price.

"We are pleased to receive a 'no questions' response from FDA", said Prof. Yuri Gleba, NOMAD's CEO. "This designation concludes our efforts to open U.S. drink and food markets for Thaumatin II, and allows us to turn our registration activity to markets in other important geographies. NOMAD is in the process of filing a petition to register its Thaumatin II in WHO/FAO supervised *Codex Alimentarius* with the aim of Thaumatin II being accepted in multiple countries."

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 antiviral biologics, non-antibiotic antimicrobials (bacterial bacteriocins and phage endolysins) for food safety and medicine markets, as well as natural high intensity non-caloric sweetener proteins thaumatins as sugar replacements. Corporate offices are headquartered in Munich, Germany and the Company's Research Division is located in Halle, Germany. NOMAD Bioscience GmbH has also a wholly owned subsidiary UAB Nomads (Vilnius, Lithuania).

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