

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

May 2018

NOMAD Bioscience received a formal 'no questions' letter from the US Food and Drug Administration (FDA) in response to NOMAD's GRAS notice GRN 738 describing use of plant-produced Thaumatin (Thaumatin I and Thaumatin II) as sweeteners. Thaumatin is a natural non-caloric high intensity sweetener under development by 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 third regulatory concurrence from the Agency in response to NOMAD's GRAS submissions.

Thaumatin is a natural non-caloric sweetener/flavour modifier. Thaumatin is intensely sweet-tasting protein (on a molar basis about 100,000 times as sweet as sucrose and on a weight basis, about 2,000-3,000 times sweeter than sucrose). Thaumatin mixtures (consisting mainly of Thaumatin I and Thaumatin II) purified from its natural source plant *Thaumatococcus* received regulatory approvals as sweetener or taste modifier, and they are on the market in US, EU, Japan and many other countries as multiuse non-caloric sweeteners/taste modifiers. The much wider use of the products is however limited because of low and unreliable supply of natural plant species, low yield per hectare resulting in high price of bulk substance; and the fact that the microbial fermentation production of Thaumatin is not competitive. NOMAD's proposition based on production of natural Thaumatin in other plants is unlimited supply of highly pure specific Thaumatin such as Thaumatin I and Thaumatin II with different taste attributes; significantly lower cost of goods; freedom to operate; and now, GRAS regulatory approval in USA as a sweetener.

NOMAD and its former subsidiary Icon Genetics, have developed a unique process of manufacturing in plants that is based on transient, rather than transgenic, expression of proteins such as Thaumatin. This transient fermentation process is currently being brought to an industrial level by NOMAD and its partners. Thaumatin is NOMAD's product candidate with new taste attributes aimed to replace sugar and other high caloric sweeteners in food products that can be produced in many plant crops thus assuring an unlimited substance supply and low commercially viable cost of goods.

"We are very pleased to receive a 'no questions' response from FDA", said Prof. Yuri Gleba, NOMAD's CEO. "One third of people globally are overweight, 0.5 Billion are obese, and 2.8 Million die annually as a result. High consumption of sugars is the main reason, it should be below 60% of the current level (worldwide at 21 kg/y, and in the US, at 34 kg/y). The regulatory clearance of our product candidate provides a clear commercial path to products that are superior to the existing high intensity sweeteners".

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 late development are non-antibiotic antimicrobials (bacterial Colicins, colicin-like proteins and phage Endolysins) for food safety and medicinal markets, as well as high intensity non-caloric sweeteners Thaumatin 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 two subsidiary companies: Nambawan Biotech GmbH (Halle, Germany) and UAB Nomads (Vilnius, Lithuania).

Contact info: gleba@nomadbioscience.com