

NOMAD Bioscience Receives Its First Regulatory Allowance In USA

December 2015

Munich, Germany, December 19, 2015. NOMAD Bioscience received a formal ‘no questions’ letter from FDA in response to NOMAD’s GRAS notice GRN593 describing use of Colicins for control of major foodborne pathogenic strains of *Escherichia coli* on vegetable foods. The FDA’s response represents the first regulatory marketing allowance for products under development at NOMAD.

Enterohemorrhagic or Shiga toxin–producing *Escherichia coli* contaminating food products are a leading cause of bacterial enteric infections in USA and worldwide. Currently, other than thermal inactivation, there are no effective methods to control pathogenic bacteria in the food chain, especially on fresh (non-processed) fruits and vegetables. NOMAD product candidates described in the notification are simple mixtures of two or more bacterial Colicins produced in plants and applied at low concentrations; the products are highly and broadly active against all major pathogenic *E. coli* „Big Seven“ strains causing food poisoning.

Plant-produced Colicins and Endolysins are being developed by NOMAD as inexpensive food additives and food processing aids for the broad control of pathogenic bacteria (*E. coli*, *Salmonella*, *Listeria* and *Clostridium*) in food products. NOMAD is in the process of preparing GRAS notifications for use of Colicins to control *E. coli* in beef/pork meats and *Salmonella* in poultry meats.

„We are very pleased to receive a ‚no questions‘ response from FDA, which allows us to proceed with further development and marketing plans for our products“, said Prof. Yuri Gleba, NOMAD’s CEO. „Food contamination with pathogenic bacteria and viruses is a growing concern, including the USA, as recently evidenced by multi-state November outbreaks in a popular restaurant chain. Almost half of *E. coli* outbreaks are typically due to contaminated produce. Non-antibiotic antimicrobials such as Colicins and Endolysins can be easily and inexpensively produced in plants, and simple mixtures of selected Colicins can provide excellent control of all major pathogenic *E. coli* strains. NOMAD’s Colicin and Endolysin product candidates are being developed with the intent to provide new highly effective ways to prevent food poisoning, as well as to replace antibiotics in medicine and animal husbandry.“

About NOMAD Bioscience GmbH. Nomad Bioscience GmbH is a plant biotechnology company developing a broad range of biotechnology products manufactured in plants.

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).