

NOMAD Bioscience Receives Its Second GRAS Regulatory Clearance In USA

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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 GRN 676 describing use of Colicins as 'Food Processing Aids' for control of major foodborne pathogenic strains of *Escherichia coli* on beef, pork and lamb meats. Colicins are natural non-antibiotic antibacterial products under development by NOMAD. The FDA's response represents the second regulatory concurrence from the Agency that Colicins are safe to use on foods. The first submission (GRN 593) described the use of Colicins for the post-harvest treatment of fruits and vegetables and also received a formal 'no questions' letter from the reviewing agency. 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.

Because the efficacy of antimicrobials applied to US meats is under the jurisdiction of the US Department of Agriculture (USDA), the USDA's Food Safety and Inspection Service (FSIS) co-reviewed with FDA NOMAD's data package and concluded that Colicins met USDA suitability criteria for use on meats. FSIS intends to include Colicins in its positive list of 'Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products'. These regulatory actions allow NOMAD to market its Colicin products to help protect a wide range of foods.

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 or chemical treatments that can alter the treated foods, there are no effective methods to control pathogenic bacteria in the food chain.

NOMAD's product candidates described in the application are simple mixtures of two or more bacterial Colicins produced in plants and applied at very low concentrations; the products are highly and broadly active against all major pathogenic *E. coli* strains causing food poisoning ('Big Seven') defined by USDA/FSIS as requiring priority control.

NOMAD is in the process of preparing GRAS filings for use of Salmocins, which are Colicin-like Bacteriocins, for control of *Salmonella* in poultry, beef and pork meats. Plant-produced Colicins, Colicin-like Bacteriocins, and bacteriophage 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.

„We are very pleased to receive a ‚no questions‘ response from FDA“, said Prof. Yuri Gleba, NOMAD's CEO. „Food contamination with pathogenic bacteria and viruses is a growing concern, including in the USA, judging from the growing number of food poisoning outbreaks, and because of the rapid increase of multi-drug resistant bacteria in our foods. FDA and USDA accepted NOMAD's Colicins as first-in-class GRAS natural non-antibiotic antimicrobials for treating fruits & vegetables (GRN 593) and meat products (GRN 676). Our regulatory experience to date suggests that additional plant-made Colicins, bacteriophage-derived Endolysins, and other bacteriocins could also gain marketing allowance through the accelerated GRAS pathway. Colicins are classified as rapid-acting but non-persistent Food Processing Aids and as such their listing in the food product's ingredient label is not required.“

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).