BASECLEAR

EXPERTS MEETING

Microbial strain safety assessment for regulatory approval

Tuesday April 21th, 2020

Organized by BaseClear and
the Leiden Bio Science Park foundation

AGENDA

All times are Central European Time (CET)

CHAIR: DR. RADHIKA BONGONI

SESSION 1: EFSA REQUIREMENTS AND INTERPRETATION

10.00 **Welcome & Opening expert meeting**
Dr. Derek Butler – Commercial director, BaseClear

10.10 **Risk assessment of feed additives of microbial origin in the European Union**
Rosella Brozzi – Scientific Officer, European Food Safety Authority (EFSA)

10.30 **Decoding the EFSA requirements for microbial safety and the technical challenges**
Dr. Adalberto Costessi – Product manager Genomics & Regulatory Affairs, BaseClear

10.45 **Panel Discussion**

SESSION 2: FOOD & FEED APPLICATIONS

13.00 **Bringing novel microbes to market: Regulatory intelligence for current and (potential) future requirements**
Dr. Luis Gosálbez Cisneros-Miret – Managing Director, Sandwalk BioVentures

13.15 **Novel food applications and genetic engineering: agency requirements around the globe**
Stephen O'Rourke, MSc. – Regulatory Affairs Manager, Jennewein Biotechnologie

13:30 **Requirements to be met for securing the legality of use of microbial strains in food commercialized in EU, with special focus on their use as probiotics**
Dr. Tiia Asukas – Senior Regulatory Specialist, Chr. Hansen

13.45 **Panel Discussion 2**

SESSION 3: REGULATORY FRAMEWORK COMPARISON (EFSA VS. FDA) AND REQUIREMENTS

16.00 **Feed Additive Regulatory framework in the EU**
Dr. Helena Oliveira – Regulatory Affairs Manager, Trouw Nutrition

16:15 **A look at the scientific testing requirements to meet GRAS, NPN and QPS status for a bacillus probiotic**
Dr. John Deaton – Vice President of Science & Technology, Deerland probiotics & enzymes

16:30 **A look at probiotics food regulations outside of the EU and how they compare to the EU**
Solange Henoud – Global Regulatory Affairs Director, Lallemand Health Solutions

16.45 **Panel Discussion 3**

BaseClear hosts

Radhika Bongoni

Radhika is Business Developer at BaseClear, with focus on markets for application of microbial genomics in food, feed and pharma industries. Radhika received her Ph.D. in Food technology (2014) from Wageningen University & Research (the Netherlands) and an MBA (2015) from Tias School for Business & Society (the Netherlands). With techno-commercial expertise, she is involved in business growth and market penetration by fostering relationships with partners. Prior to BaseClear, Radhika was responsible for establishing dietary supplements market in western Europe, India, South Africa and Russia.

RADHIKA BONGONI, PHD
Business Developer

Derek Butler

Derek is the commercial director of BaseClear. Derek completed a bachelor's degree in Biotechnology at Dublin City University in 1995, specialising in Genetics and Immunology.
He continued his studies at University College Cork and in 2001 received his PhD degree for work on the genetic regulation of lactic acid bacteria. In the same year he took up a post-doctoral position at the University of Groningen where his work focused on the identification of novel enzymatic activities from thermophilic bacteria. In 2004 Derek joined Lactrys where he worked on vaccine development in probiotic bacteria before joining BaseClear in 2006. He has now more than 15 years' experience working on microbial genomics research projects together with industrial partners.

DEREK BUTLER, PHD
Commercial director

Risk assessment of feed additives of microbial origin in the European Union

Rosella Brozzi
Scientific Officer, European Food Safety Authority (EFSA)

ABSTRACT

Microorganisms can be used in animal nutrition as probiotics, as silage agents or as a source of other feed additives like enzymes, amino acids and vitamins. In the European Union, as provided for in Regulation 1831/2003 on all feed additives need, by law, to undergo a risk assessment, which is conducted by the European Food Safety Authority. A proper characterisation of the microorganism is fundamental for its safety assessment. This includes non-equivocal identification of the species, consideration of its pathogenic or toxigenic potential and potential resistance to antimicrobials, the genetic basis of which may need to be established. Genetically modified strains require a full characterisation of the modification. The characterisation of the micro-organism and resulting product determines the nature and extent of further tests to be done to establish the safety of the additive.

In 2018 EFSA issued a unique guidance document covering the complete set of data needed for the characterisation of microbial strains, both as products or as a source of them. The document streamlines the process of preparation and assessment of technical dossiers of microbial or microbial-based additives and aims to support applicants and assessors on the compilation and evaluation of technical dossiers for market authorisation purposes.

The main novelty introduced by this guidance document regards the use of whole genome sequence data in the identification and characterisation of microorganisms.

BIO

Rosella Brozzi graduated in Food Science and Technology and holds a Master Degree in Food Safety and Legislation from the University of Parma, Italy. After an experience as quality control laboratory analyst in a dairy multinational company, she joined the European Commission to work as Policy Officer. Since 2007 she is working as a Scientific Officer at the FEED Unit of the European Food Safety. She is currently coordinating the work of the FEEDAP Microbiology Working Group.

Decoding the EFSA requirements for microbial safety and the technical challenges

Dr. Adalberto Costessi
Product manager Genomics & Regulatory Affairs, BaseClear

ABSTRACT

Microorganisms have a long history of use in the food and feed industry across the world. Bacteria, yeasts and filamentous fungi are often used as food and feed additives or as production organisms for biomolecules like vitamins and enzymes. The European Union and other countries require a safety assessment and formal authorisation procedure before these products can be placed on the market.

In the last twenty years, advances in DNA sequencing technologies have impacted and accelerated developments in the food and feed industry. Importantly, genome sequencing technologies combined with advanced bioinformatic tools play also an increasingly important role in the safety assessment. Notably, the further development of genomic technologies is also enabling the governing bodies to crystallize their requirements.

We will discuss current requirements for EFSA safety assessment and technical approaches. Technical as well as regulatory challenges will be presented: examples include the availability of good databases for genome analysis, and the challenges of less standard microorganisms with increasing interest like algae and bacteriophages.

BIO

Adalberto is BaseClear's expert on the application of whole genome sequencing technologies to regulatory affairs. Adalberto graduated in Medical Biotechnology at the University of Trieste and he specialized in molecular biology and next-generation sequencing during his PhD at the Radboud University in Nijmegen.

Bringing novel microbes to market: Regulatory intelligence for current and (potential) future requirements

Dr. Luis Gosálbez Cisneros-Miret
Managing Director, Sandwalk BioVentures

ABSTRACT

Microorganisms are amongst the most popular microbiome-modulating strategies. Bringing a novel microbial strain to the market can be regulatorily challenging, and many legal requirements may affect how a novel microbe is not only marketed or advertised, but also clinically studied, biologically characterised and even initially selected for as a candidate. New scientific advances are increasing our understanding of how microbes work and how they communicate with humans at the molecular level, but may also make microbial characterisation even more challenging in the future.

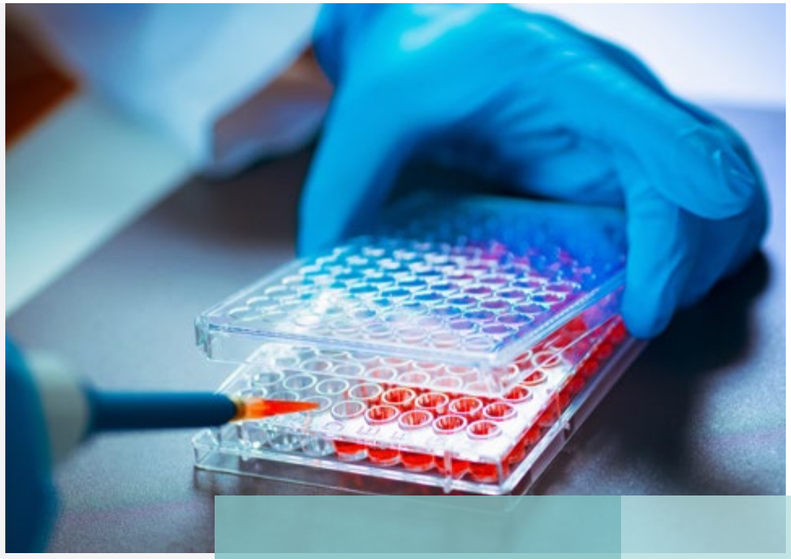
Despite their differences in many details, most regulatory processes, even for distinct purposes (e.g. food and pharma) and in different geographies, share many commonalities regarding information requirements, justification and product characterisation. In a globalised world with a fast-moving microbiome industry, a proper regulatory intelligence plan from the earliest stages of development becomes crucial to reduce risks and optimise investment.

BIO

Luis is the Managing Director and Co-Founder at Sandwalk BioVentures, a business, market and regulatory intelligence firm focused on microbiome technologies. He is also the Business Development Director at Clasado Biosciences, a prebiotic ingredient developer in the UK. Previously, he held different positions in the biotechnology industry and in pharmaceutical consulting in the UK, Spain and Germany. His scientific career was developed between Universidad Complutense de Madrid, Centro de Biología Molecular Severo Ochoa-CSIC (both in Spain) and the Korea Advanced Institute of Science and Technology (KAIST, South Korea). He received his BSc and MSc in Biotechnology from Universidad Complutense de Madrid, his PhD in Biology from the Catholic University of San Antonio (Spain) and a Master's in Bioscience Enterprise from the University of Cambridge in the UK.

Novel food applications and genetic engineering: agency requirements around the globe

Stephen O'Rourke, MSc.
Regulatory Affairs Manager, Jennewein Biotechnologie



ABSTRACT
Novel food applications around the world, regardless of jurisdiction, require many details from the applicant. With dossiers containing a whole host of information pertaining to the product in question, it is critical that the authorities receive the necessary information for decision making. In this talk, the various agency requirements will be discussed, with a special focus on genetic engineering, and real-life examples will be explored.

BIO
Stephen O'Rourke is originally from Ireland and has called Germany his home since 2012. In that time, he has worked for various biotech companies around Germany in a variety of roles, ranging from Application Scientist, Marketing Manager, Data Protection Officer, and lately Regulatory Affairs Manager at Jennewein Biotechnologie GmbH. His Regulatory interests include navigating the EFSA and USFDA dossier requirements and enjoys working as part of a multi-disciplinary team to get product approval across the finish line. Outside of biotech, you'll find him playing Ireland's ancient games Hurling & Gaelic Football with his club the Cologne Celtics Gaelic Sports Club e.V.

Requirements to be met for securing the legality of use of microbial strains in food commercialized in EU, with special focus on their use as probiotics

Dr. Tiia Asukas
Senior Regulatory Specialist, Chr. Hansen

ABSTRACT

According to the EU General Food Law regulation, "food shall not be placed on the market if it is unsafe" with regard to "normal conditions of use" and considering also the areas such as health sensitivities towards a specific consumer group. All the food, including ingredients, on the EU market shall fulfill the requirements.

Microbes with health benefits, known as "probiotics", are considered as food ingredients. Their safe use shall be documented. The safety of the microbes is evaluated by analyses, such as antibiotic resistance, biogenic amines production, toxin production, determined by the biosafety classification, the QPS status and the intended use.

Ingredients can be divided into those covered by the General Food Law and those requiring pre-market authorization before entering the EU market. Safe food ingredients can access the market without premarket authorization when there is a history of significant consumption in the EU prior to May 1997. In cases where an ingredient has not been consumed prior the cut-off day, it is considered as novel. Novel foods require authorization before accessing the market.

History of consumption shall be documented by food business operators. Different initiatives have been taken by various organizations and authorities to establish overviews of food cultures used or found in traditional fermented foods, such as the Danish list of notified microbial cultures, IDF/EFFCA list on microbial food cultures and FAO Bulletins on various fermented foods.

During the presentation we will focus on the division between ingredients with a history of use and novel food ingredients, with a special focus on probiotics. Also areas, such as strain safety and safety towards a specific target group, are briefly surveyed.

BIO

Tiia Elina Asukas is a Senior Regulatory Affairs Specialist with many years of experience in Regulatory Affairs. She is working at Chr. Hansen's headquarter located in Hørsholm, Denmark. Chr. Hansen is a Global leading bioscience company producing ingredients, such as enzymes, natural colors and microbes, for food, pharmaceutical and agricultural industries. At Chr. Hansen, Tiia is supporting the Human Health business by covering mainly microbes used for food supplements and foods for infants and young children. She is specialized in EU food law but is also working with route-to-market projects in a Global regulatory affairs team. In her earlier role as a Regulatory and Scientific Affairs specialist for Nestlé Nordics in Denmark, she was ensuring the compliance of the products of the infant nutrition business.

Tiia holds a Master's degree in Food Sciences from the University of Turku, Finland. Her Master's and Bachelor's theses were on healthy gut microbiota and factors affecting it.

Feed Additive Regulatory framework in the EU

Dr. Helena Oliveira
Regulatory Affairs Manager, Trouw Nutrition

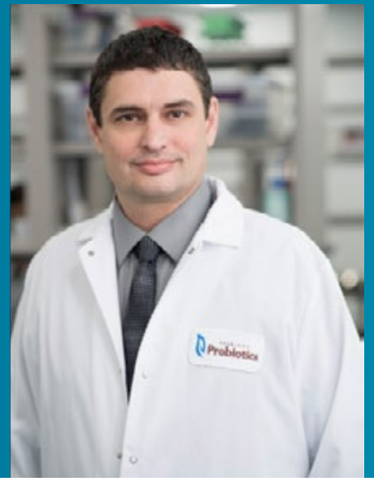
ABSTRACT
In the EU, feed additives do need to undergo a pre-market approval process before being legally placed in the market. Requirements may be more or less extensive depending of, between others, the safety profile and efficacy of the products in question.
During her presentation, Helena will try to summarise all the requirements that must be fulfilled by the industry to attain a successful feed additive authorisation in the EU.

BIO
Helena Oliveira holds an Engineer/Master degree in Animal Science from University of Trás-os-Montes and Alto Douro (Portugal). She currently works for Nutreco, mother company of Trouw Nutrition and Skretting, as Regulatory Affairs Manager and has more than 11 years of expertise in Regulatory Affairs. Throughout the years, Helena has specialised herself in the registration of feed ingredients around the globe with special focus on the EU, USA and Canada.

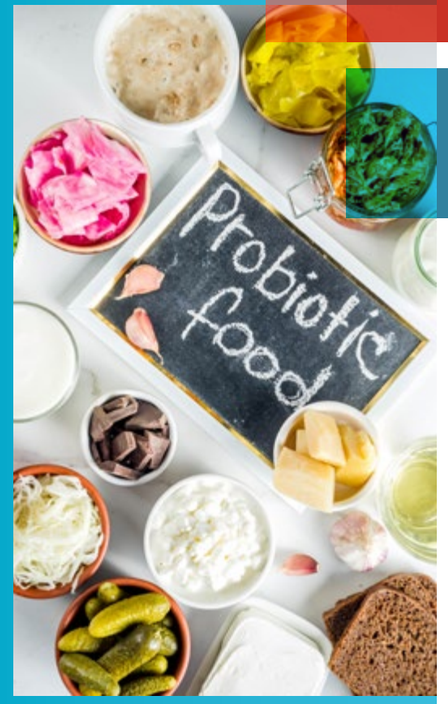
A look at the scientific testing requirements to meet GRAS, NPN and QPS status for a bacillus probiotic

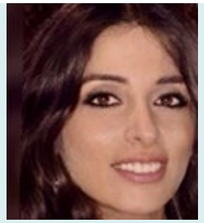
Dr. John Deaton
Vice President of Science & Technology, Deerland probiotics & enzymes

ABSTRACT
We will review the steps necessary for approval for a Natural product number (NPN), Generally Recognized as Safe (GRAS), and Qualified Presumption List (QPS) for a bacillus probiotic.



BIO
Dr. Deaton holds more than 20 years' experience working with proteins and enzymes. He holds a PhD in biochemistry from Texas A&M University, with post-graduate studies in microbiology, biophysics and cancer research. He has two papers published in the Proceedings of the National Academy of Sciences (PNAS) and is an eleven-year member of the Association of Official Analytical Chemists (AOAC), with four years served on the committee of microbiology.





A look at probiotics food regulations outside of the EU and how they compare to the EU

Solange Henoud
Global Regulatory Affairs Director,
Lallemand Health Solutions

ABSTRACT
Depending on the intended use, market, format and representation made to human consumers, probiotics can be classified as food ingredients, food supplements, biological drugs or other product categories. Subsequent applicable regulations are highly variable from a country to another, from a category to another. We will briefly review the differences and compare to the EU, while highlighting the importance of the EU role in establishing gold standard references for safety and clinical studies.

BIO
Solange leads regulatory affairs at the global level at Lallemand Health Solutions, actively represents the company in trade associations and is chair of the regulatory affairs committee at the International Probiotics Association (IPA). For more than 12 years so far, Solange has been involved in several successful company and industry initiatives advocating probiotics to Health authorities. The achievements mostly proud of with her regulatory team at Lallemand are the 35+ specific health claims in various indications and the footprint Lallemand probiotics have in 54+ countries under different regulatory categories including supplements, foods, food for special purposes and drugs.

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MORE INFORMATION?
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