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Foreword

This report summarises the discussion and outcomes of an OECD Expert Group on BioPesticides (EGBP) seminar on Emerging Risk Assessment Approaches for Biopesticides. This three half-days seminar was held on 25 and 26 February 2025, before the annual meeting of the EGBP, a sub-group of the OECD Working Party on Pesticides (WPP). The seminar was the thirteenth in a series of EGBP (formerly the BioPesticides Steering Group, BPSG) seminars focusing on biopesticide-related issues of interest to OECD governments and other stakeholders.

Emma Babij (Health Canada) and Eric Liégeois (EC) chaired the seminar. A total of one hundred and twenty-five experts from nineteen OECD member countries, the European Commission, Brazil, Bulgaria, Rumania, the UN Food and Agricultural Organization (FAO), the European and Mediterranean Plant Protection Organization (EPPO), the International Council on Animal Protection in OECD Programmes (ICAPO), the Business and Industry Advisory Committee to the OECD (BIAC), the International Biocontrol Manufacturers Association (IBMA), and research institutes/universities participated in the Seminar. The complete list of participants can be found in Annex B.

The primary objective of the seminar was to facilitate the exchange of information on the experiences of the OECD countries and relevant stakeholders in Emerging Risk Assessment Approaches for Biopesticides, covering 1) peptides used for pest control, 2) taxonomic changes *of Bacillus thuringiensis* (Bt) and 3) semiochemicals. The seminar also provided an opportunity to identify critical issues and challenges in these areas and initiate a dialogue about the next steps for OECD countries and key stakeholders in both OECD and non-OECD countries to address the identified issues.

The present seminar report was reviewed by the OECD EGBP in July-September 2025 and received approval by the OECD WPP by written procedure in October 2025.

This document is being published under the responsibility of the Chemicals and Biotechnology Committee, which has agreed that it be declassified and made available to the public.

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1 Introduction

This report presents the results and recommendations of an OECD Seminar on Emerging Risk Assessment Approaches for Biopesticides. It aims to provide an overview of the issues associated with this topic from the perspective of research, industry, and regulatory experts and provide input to the potential future development of recommendations for possible further OECD work.

The seminar aimed to foster dialogue on Emerging Risk Assessment Approaches for Biopesticides and initiating a process to make recommendations by exchanging information on governments' or organisations' experiences and challenges in this area.

The seminar focused on Emerging Risk Assessment Approaches in Biopesticides, with presentations and discussions over three half-days dedicated to specific topics of interest, covering three critical areas 1) protein and peptides used for pest control, 2) taxonomic changes of *Bacillus thuringiensis* (Bt) and 3) semiochemicals.

Multiple topics for the Seminar have emerged from the discussions in the 2024 EGBP Meeting. The title "Emerging Risk Assessment Approaches in Biopesticides" was selected as an overarching title to cover the diversity of the topics.

Participants

People attending the OECD Seminar included:

- members of the OECD Working Party on Pesticides (WPP) and Expert Group on BioPesticides (EGBP);
- invited experts from key stakeholder groups such as the pesticide industry and manufacturers of biopesticides (BIAC and IBMA);
- invited experts from research institutes (academia), and
- regulators, risk assessors and evaluators from governmental or intergovernmental bodies.

Purpose and Scope of the Seminar

This Seminar provides a forum to exchange information and experiences encountered by OECD countries and relevant stakeholders when developing and reviewing Emerging Risk Assessment Approaches.

Session 1 "Regulatory Considerations for Peptides[1]"

This topic, "Regulatory Considerations for Peptides", was selected for inclusion in the 2025 Seminar as it is a topic of interest to members of the EGBP. Naturally occurring and synthetic proteins and peptides have been proposed for use in pest control, and they are anticipated to be a significant emerging area of pesticide research and development. For example, proteins and peptides have been registered that elicit natural plant defence mechanisms to control disease or as insecticides. These peptides act through wide variety of modes of action. Major questions have been raised about how to define peptides as biocontrol agents, data needs to assess human and environmental risks, and harmonising regulatory approaches. These issues have presented challenges to regulators assessing the risks of peptides, and further challenges are anticipated as more interest is gained in developing peptides as plant protection products.

Purpose

The purpose of this session will be to review the nature of the Peptide technology for biological plant protection and explore best practices in its regulation. Participants will hear from experts on current research on the development of proteins and peptides as biological plant protection products and regulatory challenges and considerations for peptides. The session will provide a forum for regulators and industry to discuss the types of peptides that exist or are in development, consider what kinds of proteins and peptides may fall into the definition of biocontrol agents and how those may be defined, and the regulatory needs for assessing human and environmental risks.

Scope

The main objectives of this EGBP Seminar on proteins and peptides include:

- to exchange information between regulators, scientists, researchers and other stakeholders
- learn about the different types of peptides that exist or are in development
- identify the considerations necessary to classify certain peptides as biocontrol agents and
- learn about regulatory experiences of registration/authorisation of pesticidal peptides
- discuss the regulatory needs, data that have been considered, and risk assessment approaches to ensure the safe use of peptides
- discuss further steps for OECD countries and key stakeholders in OECD and non-OECD countries to harmonise the regulatory and risk assessment approaches for peptides as biocontrol agents

Structure

The Seminar programme of the session is provided in Annex A. Invited speakers included:

- Researchers in this area to provide background information and perspective
- Speakers to provide case studies as examples of proteins and peptides developed as pesticides
- Representative from industry or government to discuss refining the biocontrol definition to accommodate proteins and peptides, acknowledging their diversity

[1] For this report, the term "Peptides" will be used as an umbrella term to encompass both peptides and protein technologies in their various forms and applications in the field of plant protection. This is intended to reflect the diversity of technologies discussed during the seminar.

- Representative from authorities to discuss the considerations of an emergency authorisation of new Peptide technologies
- Representatives from government to discuss the regulatory challenges for proteins and peptides and how they have been resolved

After each presentation, there was a short discussion/question period. A Panel discussion took place with the speakers to focus on the definition of proteins and peptides as biocontrol agents and significant regulatory considerations that must be made to assess human and environmental risks.

Session 2 "Taxonomic changes of *Bacillus thuringiensis* (Bt)"

The topic "Taxonomic changes of *Bacillus thuringiensis* (Bt)" was selected for inclusion in the 2025 Seminar as it is a topic of interest for many members of the EGBP. *Bacillus thuringiensis* (Bt) has been utilised as a microbial insecticide in OECD countries for decades and has been regarded as relatively low risk. In recent years and with the help of new genomic tools for identification, the taxonomy of the *Bacillus cereus* (Bc) group has been re-examined, raising questions about the reliance on the presence of Cry protein in distinguishing Bt. Additionally, there is uncertainty with regards to whether pesticidal Bt strains have been causal agents in foodborne outbreaks. These issues have presented challenges to regulators assessing the safety of Bt, thereby warranting discussion in the format of this Seminar.

Purpose

The purpose of this session was to hear from experts on the evolving taxonomic classification of the *Bacillus cereus* sensu lato group, and to determine how strains should be classified, as well as to hear information on potential associations with foodborne disease. The session will also provide a forum for regulators to discuss implications of such classifications for assessing the already registered or prospective microbial pest control agents.

Scope

- The objectives of this EGBP Seminar on Bt include:
- to exchange information between regulators, scientists, researchers and other stakeholders (including public health experts)
- identify the challenges when assessing risk of pesticidal Bt strains and possible ways of managing them
- to learn about other regulatory frameworks where this information has been considered, and to exchange information on OECD countries' current activities and processes in the area of Bt taxonomy and data requirements
- to suggest and discuss options of further steps for OECD countries and key stakeholders in OECD and non-OECD countries to harmonise the risk assessment of Bt**.**

Structure

After each presentation, there was a short discussion/question period. A Panel discussion took place with the speakers. Also, a tour de table was held for participants to share perspectives and challenges.

Session 3 “Risk Assessment of Semiochemicals"

The topic “Risk Assessment of Semiochemicals” was selected for this seminar session based on discussions at the 2024 Expert Group on Biopesticides (EGBP) meeting and the ongoing OECD project, "Review and Applicability of the Calculation Method Presented in OECD ENV/JM/MONO(2017)33 for Determining Natural Background Levels of Semiochemicals." The project, which was presented during the 13th EGBP seminar and is close to finalisation, included organising a tailored workshop to address concerns surrounding semiochemicals and their application in plant protection.

During the 2024 EGBP meeting, the proposal to host this session as part of the 2025 seminars was discussed.

This seminar session will foster collaboration, knowledge-sharing, and harmonisation, driving the effective and timely adoption of semiochemicals across OECD countries. With the overarching goal to harmonise risk assessment approaches for semiochemicals, fostering mutual acceptance of evaluations conducted by OECD member countries and expediting the implementation of these innovative approaches.

Purpose

This seminar serves as an essential opportunity to consolidate the ongoing efforts surrounding semiochemicals, present the findings of the OECD project, and facilitate the exchange of knowledge and experiences among OECD countries and key stakeholders. The overarching goal is to harmonise risk assessment approaches for semiochemicals, fostering mutual acceptance of evaluations conducted by OECD member countries and expediting the implementation of these innovative approaches.

Semiochemicals are widely acknowledged as posing minimal concerns when utilised for plant protection purposes. These substances, emitted by plants, animals, and other organisms, are integral to intra- and inter-species communication. With a target-specific and non-toxic mode of action, semiochemicals are naturally occurring and effective at very low application rates, often comparable to their natural background levels. Current scientific and technical knowledge supports their classification as low-concern substances, as stated in Regulation (EU) 2017/1432:

“Semiochemicals are substances emitted by plants, animals, and other organisms which are used for intra- and inter-species communication, have a target-specific and non-toxic mode of action, and are naturally occurring. They are generally effective at very low rates, often comparable to levels that occur naturally. In light of current scientific and technical knowledge, it is also appropriate to provide that semiochemicals should be considered as low-risk substances.”

As the availability of conventional active ingredients continues to decline, it becomes increasingly critical to provide regulatory tools for the evaluation of low-concern substances such as semiochemicals that take into consideration their unique characteristics and science-based risk assessment frameworks. These frameworks are essential for facilitating more efficient evaluations, enabling faster market access, and ensuring that farmers have access to innovative and sustainable pest management tools.

By addressing these needs, the seminar aims to pave the way for the broader acceptance and utilisation of semiochemicals, contributing to the global transition toward sustainable agriculture.

Scope

The main objectives of this EGBP Seminar on semiochemicals:

- Facilitate information exchange among regulators, scientists, researchers, and stakeholders.

- Enhance understanding of semiochemicals' scientific properties and their impact on risk assessment.
- Showcase effective regulatory frameworks tailored to semiochemicals' unique characteristics.
- Share current OECD country activities and work towards harmonising risk assessment frameworks.
- Propose next steps for fostering mutual acceptance of semiochemical risk assessments among OECD and non-OECD countries.

Structure

This half-day seminar session included four presentations, each followed by a brief discussion, and concluded with a general discussion session covering the following topics:

1. Semiochemicals' intrinsic natural characteristics and their role in plant protection.
2. Practical examples from the OECD project updating OECD ENV/JM/MONO(2017)33.
3. Insights from a pioneering regulatory agency implementing a proportionate risk assessment scheme.
4. Addressing misconceptions about semiochemicals in agriculture.

2 Abstracts and summary of presentations

Session 1: Regulatory Considerations for Peptides

Natural and natural-like peptides – considerations for inclusion as biocontrol agents

Andrea CHINI, National Biotechnology Centre, Spain

Natural peptides are short chains of amino acids, often arbitrarily restricted to short proteins of 2 to 100 amino acids, that occur naturally in plant, animal and microbial cells. These peptides are key components of the plant highly-interconnected signalling networks regulating i) growth and development, and ii) responses to environmental cues and biotic challenges. For example, natural peptides in plants act as signalling molecules modulating fundamental developmental processes like cell division, differentiation and organogenesis. In addition, peptides play a pivotal role in regulating plant defence mechanisms, for example, activating immune responses against a wide spectrum of pathogens and pests. Finally, plant peptides are crucial in modulating responses to abiotic stresses, including drought, salinity, and temperature fluctuations. Through highly-interconnected regulatory pathways, peptides considerably contribute to the adaptability and resilience of plants to different environmental conditions.

The regulatory landscape and classification of natural and natural-like plant peptides, as well the potential use as biocontrol agents, is not an exclusive and universally-accepted concept. Conversely, the definition is still a multifaceted and evolving notion. It involves considerations of several factors, including genetic modification, chemical alterations, intended use and mode-of-action. It is important to note that the classification can vary, and what is considered natural in one context might not be considered natural in another. In addition, the regulatory context takes into account

several factors in addition to the scientific notions to define biocontrol agents.
As scientific research advances continue, the regulatory frameworks also evolve, shaping the definition of natural, natural-like and their prospective use as biocontrol agents. Therefore, this debate cannot be represented as fixed image, but it should be considered as an evolving concept.

Andrea CHINI opened the session on “Regulatory considerations for peptides” by outlining the role of natural peptides in plant protection and summarising the current state of research in this field. He explained the various sources of natural peptides and their potential effects on plant pests and pathogens. He highlighted the mechanisms by which peptides can regulate various plant processes, facilitating adaptation to the environment and enhancing defence responses to pests. Andrea CHINI noted that the first plant protection peptide was identified approximately 35 years ago and has since been shown to have anti-pest activity.

Natural peptides are those derived from unmodified animals, plants, or organisms through naturally occurring processes or traditional breeding. Andrea CHINI noted that the field is rapidly evolving, with new biosynthetic processes and techniques that enable better identification and study of peptides. He discussed the various strategies used to identify natural peptides, including both bioinformatic and experimental-based approaches. Techniques such as ribosome profiling and mass spectrometry were highlighted as tools for identifying peptides, including their limitations in terms of labour and cost. He emphasised the potential of artificial intelligence and machine learning in identifying new peptides and relevant research activities in the field.

The presentation further explored the functional aspects of peptides, including their mode of action and potential synergistic effects when different peptides are combined or amino acids of one peptide are substituted to enhance activity or acquire potentially new activity. Andrea CHINI emphasised that understanding the peptide structure and its mode of action could potentially help classify peptides as biocontrol agents, as there is still debate whether modified/optimised peptides should be classified as "natural" or ”not-natural". He acknowledged the challenges in defining peptides as biocontrol agents due to lack of a clear definition and limited knowledge. The role of chemical and genetic modifications in enhancing peptide activity was also discussed. These modifications could also play a role in defining peptides as biocontrol agents in the future, as modifications that occur in nature may be included within the definition of biocontrol agents.

The presentation concluded with a discussion on the challenges and future directions in the field of natural peptides, focusing on distinguishing between naturally occurring and those that are nature-like peptides. Andrea CHINI closed the presentation by acknowledging the dynamic nature of peptide research and the need for ongoing research to fully understand their potential and define natural and natural-like peptides.

It was noted that the definition of natural versus unnatural peptides might differ across regulatory jurisdictions. It was clarified that unnatural peptides are not chemicals themselves, but rather molecules involved in modifications that do not occur in nature. These modifications would most likely fall under chemical regulations. It was noted whether it would be easier to examine the polymorphism of the genes encoding peptides rather than investigating variations or modifications in peptides. Regarding the first peptide identified, Andrea CHINI mentioned that it did not reach the market, possibly due to limitations in production methods or other factors.

Target-oriented functional peptides for plant disease control. Development and challenges

Emilio MONTESINOS, Institute of Food and Agricultural Technology, University of Girona, Spain

Crop losses in Agriculture due to pests and diseases, excluding weeds, have been estimated to one third of the potential productivity, despite the measures of protection taken, and the damage due to plant diseases is currently estimated at a 13%. Chemical and biological control are still one of the main pillars of crop protection, but a strong reduction in active substances, has happened in the last years in many countries. This reduction in conventional pesticides has not been compensated by sufficient novel compounds or biopesticides, and several diseases may be insufficiently or non-controlled.

Functional peptides have been the object of a strong research effort in the field of crop protection, as in many other fields. Peptides are polypeptides up to 50-60 amino acids but also include pseudopeptides with peptide bonds and non-natural or modified amino acids. Most peptides originate from living organisms, and are involved in antagonism or antibiosis in microorganisms, or are responsible of the first immune defence barrier and in stress mitigation in animals and plants, but there have been numerous synthetic compounds. The knowledge of the chemical structure and physic-chemical and biological properties of natural peptides provide the basis to develop analogues or newly designed compounds, which can be chemically synthetized to build-up peptide libraries.

Antimicrobial peptides are the most known group of functional peptides, but another important mechanism of action is priming the plants by inducing defence responses against pathogens. There are peptides against plant pathogenic viruses, plant pathogenic prokaryotes or fungi and oomycetes, or even against nematodes. Peptides with simultaneous mechanisms of action or mixtures of peptides that combine mechanisms are interesting in plant protection to counteract resistance in the pathogen and to improve its activity.

Future issues in this field are (1) the development of new functional peptides using target-oriented approaches as in the pharma area with improved selectivity and stability and low toxicity, (2) the design and validation of formulations to optimize the stability and shelf-life of the peptides in the plant environment, (3) to provide suitable methods of delivery of the peptide formulations to the plant host, and especially of endotherapy devices for trees to protect them against endophyte pathogens, and (4) to perform field tests with the most relevant diseases

and crops for the evaluation and validation of plant protection products composed of functional peptides.
The future of functional peptides as plant protection products depends on the capacity to produce large quantities under industrial platforms, obtained from natural sources, chemical synthesis, and using genetically improved microbial strains or through heterologous expression in living biofactories. However, the main requirement to arrive to the market are the requirements of a specific regulatory framework.

Emilio MONTESINOS began by emphasising the importance of peptides in defence mechanisms against biotic and abiotic stresses, highlighting their ubiquitous presence in living organisms. He introduced the development of a peptide library through a discovery platform, which involved collaboration with the peptide chemistry group at the University of Girona. This library was screened for hemolytic activity, protease stability, preliminary toxicity and efficacy, leading to the refinement of peptides through several rounds of testing.

Emilio MONTESINOS discussed the mechanisms of action of these peptides, noting their effectiveness against bacterial and fungal cells. He mentioned peptides that affect internal processes, such as protein synthesis and ribosome function, as well as those that target external structures, like lipopolysaccharides in Gram-negative bacteria. Some peptides inhibit spore germination, while others are nematicidal. He provided examples of peptides, which were improved through chemical modifications and demonstrated significant antimicrobial and antifungal activity. He also highlighted the development of peptides that inhibit biofilm production and mobility of bacteria.

Emilio MONTESINOS elaborated on the use of peptides as plant defence elicitors, focusing on pathogen-triggered immunity (PTI). He explained the complex system of reception and induction of various components and processes in plants. He described the development of peptides based on natural sequences found in plants, which were used to induce strong plant responses. He provided examples and emphasised the low concentrations required for these peptides to be effective, making them a potential solution for plant protection.

Furthermore, he discussed the challenges of producing peptides in a cost-effective manner. He discussed various production methods, including natural sources, microbial production, and chemical synthesis. He highlighted the potential of microbial biofactories and plant biofactories for peptide production. He concluded by emphasising the importance of microbial biofactories for the future of peptide production.

Finally, Emilio MONTESINOS mentioned ongoing projects funded by the EU as well as collaborations with scientists from various countries and companies.

Case studies as examples of peptides proposed as plant protection products

Eva VAN HENDE, Biotalys and Matthew ORR, Vestaron

Biotalys is an innovative Agricultural Technology (AgTech) company dedicated to developing protein-based biocontrol solutions that offer sustainable and safer alternatives to conventional chemical pesticides. Utilising its groundbreaking AGROBODY™ technology platform, Biotalys is creating a robust and diverse pipeline of effective product candidates with

favorable safety profiles. These products are designed to combat key crop pests and diseases throughout the entire value chain, from soil to plate. Founded in 2013 as a spin-off from the Flanders Institute for Biotechnology (VIB), Biotalys has been listed on Euronext Brussels since July 2021 and is headquartered in the biotech cluster of Ghent, Belgium.
In this case study, Biotalys will delve into the specifics of its AGROBODY™ technology platform. Originally successful in the pharmaceutical field, AGROBODY™ bioactives are now being developed as biocontrol products. The potential of these bioactives is immense, as multiple AGROBODY™ bioactives can be developed to target a wide range of plant pathogens with various modes of action. These nature-inspired polypeptides are highly attractive due to their high binding capacity and specificity, stability, rapid degradation into natural amino acids, multi-deployability, and manufacturability in microbial cells.
Moreover, AGROBODY™ bioactives represent a unique and identifiable group of proteins with very low toxicity and ecotoxicity profiles, making them an appealing new class in the biocontrol product landscape.

Eva VAN HENDE introduced Biotalys, a Belgian company established ten years ago. She explained that the technology behind company's products is antibody-based, specifically using a small functional fragment of a heavy chain only antibody found in camelids. The technology originated from a field experiment in the 90s, where it was discovered that dromedary antibodies differ from those of other mammals. The company uses the active part of these antibodies, which has high binding capacity, specificity, and stability, making them ideal for crop protection.

The process involves exposing llamas to specific targets, which then produce a library of antibodies. The company selects the most effective functional fragment of a heavy chain only antibody for developing products. Company's expertise lies in understanding pathogen life cycles and identifying critical targets for their antibodies. This selection process ensures not only effectiveness, but also easy production in microbial cells through fermentation.

Eva VAN HENDE highlighted the potential of the technology, which can target different pathogens by combining small functional fragments of heavy chain only antibodies. She noted that the regulatory process is currently hindering the application of this technology in plant protection. The regulatory process is ongoing in both the US and Europe. She noted that novel technologies require in depth evaluation, which in the long term can facilitate the process of setting regulatory standards for future approvals of protein-based biocontrols. She shared the experience from the pharmaceutical industry that has undergone a significant transformation over the past few decades, shifting from a dominance of small-molecule drugs to a strong focus on biologicals, particularly monoclonal antibodies. This shift involved the establishment of new data requirements and adaptation of the assessment framework to register biologicals in pharmaceutical sector, which could be adapted or inspire the plant protection registration for products of similar origin. The presenter highlighted the opportunities for collaboration with regulators from the pharmaceutical sector.

Vestaron is leading a global revolution in crop protection by creating novel, effective, and sustainable solutions our customers need to meet the

growing challenges of modern agriculture. Founded in 2005 and headquartered in Kalamazoo, MI (USA), Vestaron has built a robust pipeline of powerful insecticides with novel modes of action based on peptides derived from the venom of spiders and other species.
Naturally soft on pollinators, beneficials, and local biodiversity, our innovations have earned recognition from the Crop Science Awards, the EPA's Green Chemistry Challenge and the ELO's European Bee Award for "Application of innovative technological solutions." In 2024, Vestaron became the first agriculture and food company inducted into the Global CleanTech 100 Hall of Fame.
In this case study, Vestaron will describe the insecticide platform containing the active ingredient, GS-omega/kappa-Hxtx-Hv1a, a peptide originating from the venom of the Australian Blue Mountain funnel web spider. This product combines a novel neuromuscular mode of action (IRAC Group 32) with an attractive consumer safety and environmental profile, providing growers with a cost-effective and efficacious new tool. It is currently registered for use in the US, Canada, and Mexico across a variety of indoor and outdoor crops for the treatment of whitefly, mites, and a wide range of lepidopteran pests. The product features a 4-hour re-entry interval, a 0-day pre-harvest interval, and exemption from residues. Since commercialisation in 2020, it has been applied to over 365,000 hectares, where it has displaced conventional chemical insecticides with no reported decline in performance.
Vestaron now seeks to bring its novel biocontrol products to Europe and is working diligently to secure registration in the EU. In the past 12 months, its product has been granted emergency use authorisations in Greece, Cyprus, and Italy, where it has proven to be an effective treatment to address the devastating and invasive tomato leafminer (*Tuta absoluta*) pest.

Matthew ORR introduced Vestaron Cooperation, a small, privately funded startup based in the United States, which is celebrating its 20th anniversary this year. The company focuses on developing peptide-based bioinsecticides derived from the venom of spiders, scorpions, and other species. These peptides selectively target and kill insects, providing an alternative to conventional synthetic insecticides.

One of the products of the company is derived from the venom of the Australian Blue-Mountain Funnel-web Spider (*Hadronyche versuta*). The amino acid sequence of the peptide has been modified to optimise its stability and yield. The product is biologically manufactured via fermentation using a strain of food-safe yeast that has been engineered to express the peptide. This peptide binds to the nicotinic acetylcholine receptor. It works as a contact insecticide against soft-bodied insects and, when administered orally in combination with *Bacillus thuringiensis* (Bt), which produces cry proteins that perforate the insect's gut wall, enhancing the peptide's bioavailability.

The product has received regulatory approvals in the United States, Mexico, Canada, and is under evaluation in the EU. It has shown excellent performance in field trials, particularly against the tomato leaf miner in Europe. The product is considered non-toxic to bees and other beneficial insects. It has been applied in California, replacing chemical insecticides and no concerns about efficacy have been noted.

Matthew ORR closed the presentation by emphasising his company's aim to revolutionise the plant protection sector with sustainable biocontrol technologies and by sharing ongoing work to investigate additional neuromuscular receptors as targets for future products.

A question was raised about the combination of the peptide with Bt and whether it would be possible to use just the Cry protein for perforating insects' midgut. It was explained that the commercial product contains only the peptide, and growers are recommended to apply it in a mix with commercially available Bt. Company's research team is investigating the possibility of a co-formulated product with Cry protein. Another question focused on the concern of developmental neurotoxicity by neonicotinoids, which also target the nicotinic acetylcholine receptor. It was noted that no specific neurotoxicity testing has been conducted, but the large size of the molecules prevents them from penetrating the blood-brain barrier.

Reviewing the definition of biocontrol in light of new peptide technologies for plant protection

Jennifer LEWIS, IBMA and Emmanuelle BONNERIS, Bayer

IBMA's biocontrol definition is a living definition and so is open to periodic review in light of new technological developments. There is a specific reference to peptides and proteins in the IBMA definition of biocontrol which more generally refers to natural substances sourced from nature or nature-identical if synthesised.

In response to requests, in 2023 the IBMA Council agreed to further review engineered peptides/proteins and enzymes for potential inclusion in the IBMA biocontrol definition. The conclusion of the November 2023 IBMA review was that peptides and proteins for which the amino-acid sequence is demonstrated to be present in nature fall within the scope of "nature-identical". Following further review, the IBMA Scoping Committee, with input from the IBMA Professional Group for Natural Substances concluded the following amendments to the natural substances biocontrol definition:

Natural substances consist of one or more components that originate from nature, including but not limited to: plants, algae/microalgae, animals, minerals, bacteria, fungi, protozoans, peptides, proteins (e.g. enzymes, antibodies), viruses, viroids, and mycoplasmas. They can either be sourced from nature or are nature identical if synthesised. This definition excludes semiochemicals and microbials, which have their own definition.

Among natural substances, IBMA considers that peptides and proteins containing sequence modifications of a peptide/protein sourced from nature are deemed nature-identical provided all of the following conditions are met (1) they contain only naturally occurring amino-acids (2) such modifications

do not change the 3-dimensional structure (3) such modifications do not change the biological function and (4) the biological breakdown occurs in a predicted way according to a natural pathway. The biocontrol industry is developing peptides for crop protection. Innovation in this area is moving fast, and this is the 2024 Nobel prize winning field. This indicates the importance of these innovations for the future of all industries, including biocontrol. Faster authorisation is necessary to bring more biocontrol to market to accelerate the transition to a more sustainable agriculture. However, how to use existing regulatory initiatives worldwide to approve this technology?
Overall, regulatory frameworks should follow a “need to know” decision tree approach, enabling faster authorisation while ensuring a full safety evaluation in considering problem formulation principles, i.e., OECD Problem Formulation for the Risk Assessment of BioPesticides Seminar of the 26th of February 2024. Alignment within different initiatives amongst problem formulation is needed to ensure consistency on how we want to regulate peptide technologies. Establishment of criteria on how to address areas of potential adverse effects (harm) for this specific technology is needed for submission of relevant data requirements. New peptide technologies are so diverse in types, e.g. neuropeptides, antibodies, harpin protein that we might envisage grouping similar technologies for faster approvals. In such context, specific guidance documents for novel technologies such as proteins/peptides in the OECD program should be envisaged. Finally, a pre-submission consultation guidance on the information/data requirements should jointly be elaborated to facilitate the submission of a more complete data package/dossier, which will in turn facilitate the review and decision-making process.

Jennifer LEWIS began the presentation by discussing the concept of biocontrol and its significance. She explained that biocontrol involves using natural substances to manage pests and diseases, and highlighted the four types of biocontrol: invertebrates, microbials, natural substances, and semiochemicals. She introduced peptides and proteins within the category of natural substances, noting that they can be sourced from nature or be nature-identical if synthesised. She also discussed the process IBMA followed to define and include proteins and peptides in their biocontrol definition, which involved extensive scientific and technical consultation and review.

Jennifer LEWIS introduced the innovation involved in Peptide technology, providing examples of promising Peptides for plant protection, and highlighting AI-based predictive tools that help in understanding the 3D structure of Peptides. She discussed the potential of proteins and peptides in plant protection and the importance of considering their natural and modified forms. Finally, she concluded that the proposed definition should be considered an evolving concept as science and regulatory frameworks continue to advance.

Emmanuelle BONNERIS discussed the importance of problem formulation in risk assessment of proteins and peptides for plant protection that considers their unique characteristics, mode of action, production

process, and potential human and environmental impacts. She emphasised the need for tailored data requirements and the application of new approach methodologies where possible to avoid unnecessary testing.

Emmanuelle BONNERIS presented the evaluation outcome of the peptide-based product derived from the venom of the Australian Blue-Mountain Funnel-web Spider presented earlier in one of the OECD countries. She emphasised the importance of aligning regulatory frameworks across different geographies to facilitate the approval of peptide technologies and the need for flexibility to accommodate the diversity of peptide technologies. She proposed structural grouping and read across approaches for the other example on small functional fragments of heavy chain only antibodies. She closed by proposing the need for a strong regulatory framework that supports innovation while ensuring safety and efficacy.

During the follow-up questions, one participant commented on the concept of group registration for peptides, noting that the legislation in some OECD countries does not currently allow such an approach. Another participant raised concerns about the regulatory acceptance of in silico models for read-across of peptides at this early phase, and noted the efforts in the chemical sector for more than two decades to address the challenges encountered with this approach.

Regulatory challenges for peptides within plant protection products and how they are resolved

Jacobijn VAN ETTENT, Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb), The Netherlands

{abstract not submitted by the speaker}

Jacobijn VAN ETTENT opened her presentation by noting that although the current focus of the Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) is on microbials, more diverse active ingredients, including peptides and proteins, are expected in the near future, with the first dossier of these already in the pipeline. She discussed the favourable profile of peptides in agriculture due to their pest specificity, expected biodegradability, and low toxicity to non-target organisms. However, she highlighted the challenges associated with complex mixtures of peptides and other amino acid-based polymers, which differ from conventional chemical active substances, in setting specifications and applying alternative approaches to address data requirements.

Jacobijn VAN ETTENT emphasised the importance of understanding the tertiary structure of peptides and proteins and using this information to demonstrate that the structure in the test item for human health and ecotoxicological testing is intact. It was mentioned that the rapid degradation of peptides renders standard ecotoxicological testing results questionable if not adjusted. She suggested that alternative approaches and a case-by-case strategy might be needed to address these challenges. Harmonising the assessment process and ensuring clear communication between registrants and assessors could facilitate building experience and trust.

The presenter highlighted that understanding the mode of action of peptides could facilitate the development of fit-for-purpose risk assessments tailored to these active ingredients. All relevant information should be provided, and any data waiving should be clearly explained for the peptides' safety evaluation. She mentioned the potential benefits of group registration by introducing procedures to expand the registration of proteins, such as antibodies, as they are expected to be applied in a mixture of various types. As fermentation is used for peptide and protein production, assessment of the manufacturing process may be necessary. Finally, the need for guidance on nomenclature conventions for peptide categories was noted.

In conclusion, Jacobijn VAN ETTENT reiterated that peptide-based plant protection products offer innovative, sustainable, and potential alternatives to conventional chemicals. However, to advance with their registration, clear communication between dossier submitters and regulatory authorities, along with the use of problem formulation approaches to harmonise case-by-case situations, would be needed.

It was clarified that the difficulty in ecotoxicological testing of the peptides under assessment lay in the different fermentation lines of components tested, and that the mode of action helped them interpret the studies and conclude on the assessment. Testing the tertiary structure of peptides for human health was questioned, as it might lead to irrelevant results. Although there was an agreement on this point, the elaboration of the answer allowed the presenter to reiterate the importance of ensuring that the peptide's structure remains intact during testing to assess its mode of action. A final comment was made about the stability issue, suggesting that testing the formulated product might be more relevant, which the speaker agreed on.

Canada’s Experience Regulating Peptides as Pest Control Products

Emma BABIJ and Emily HOPWOOD, Health Canada, Canada

Peptides are poised to present many new opportunities in the management of pests and disease in the agricultural industry. In Canada, naturally occurring and synthetically-produced equivalents can be considered for regulation under the Guidance for the Registration of Non-Conventional Pest Control Products, where data requirements are tiered. This framework allows sufficient flexibility to consider rationales to waive an in vivo study when scientifically justified.
In this presentation, Canada’s experience regulating three peptide active ingredients is shared, focusing on the approach to the human health assessment.

Emily HOPWOOD introduced Health Canada's Pest Management Regulatory Agency (PMRA) and its role in evaluating microbial and biochemical pesticides, with a focus on human health considerations. She informed the participants that PMRA has assessed three peptide active ingredients to date: BLAD polypeptide, GS-omega/kappa-Hxtx-Hv1a, and Flg22-BT peptide. She provided an overview of the regulatory process for these peptides, explaining that they are assessed according to PMRA's requirements for non-conventional pest control products. This category includes substances like botanical essential oils, plant extracts, and food items. She explained that while the chemistry, environment, and efficacy assessments for non-conventional plant protection products are typically conducted similarly to conventional chemicals, there is more flexibility in the health risk assessment. Additionally for peptides, there can be flexibility in the chemistry assessment.

Emily HOPWOOD then discussed the specific health data requirements for non-conventional pesticides, which follow a tiered approach. The tier one requirements include acute toxicity studies, short-term oral studies, prenatal development toxicity studies, and genotoxicity assays. She explained that additional studies may be required depending on the nature of active ingredient and its proposed application. For example, allergenicity information was requested for peptides. She provided details about how these data requirements were addressed for the three peptides. For the BLAD polypeptide, the requirements were met through a combination of test guideline studies and various lines of information to address concerns

regarding allergenicity. Rationales were accepted to waive repeat-dose toxicity, developmental toxicity, and genotoxicity studies. For GS-omega peptide/kappa-Hxtx-Hv1a , the data requirements were addressed almost entirely with test guideline studies. Additional microbial data requirements for product characterisation were triggered due to manufacturing method that involves expression of the peptide in a genetically modified yeast strain followed by purification. For Flg22-BT peptide, the requirements were met with test guideline studies and additional data showing rapid degradation in simulated gastric and intestinal fluid in order to waive repeat-dose toxicity studies. Emily HOPWOOD provided links to the PMRA's non-conventional pest control products registration guidance and the proposed registration decisions for each of the three peptides.

Following a clarifying question, Emily acknowledged that the problem formulation approach is somewhat embedded in how PMRA approaches non-conventional pest control products. She emphasised the importance of pre-submission consultations to tailor data requirements based on the product's properties. Furthermore, she explained that all peptide products have been registered with only tier one requirements so far, and there has been no need to request second-tier studies. Similarly, it was noted that, to date, there have been no requirements for maximum residue limits (MRLs) for the peptide products assessed by the PMRA.

Panel Discussion of Sessions 1

The panel discussion brought together the session speakers to respond to questions addressed by the participants related to the regulation of peptides as plant protection products. It began with an intervention from industry that emphasised the importance of not classifying modified peptides as chemicals as certain modifications can also be found in nature. They reiterated their support for the problem formulation approach, not only for proteins and peptides, but also for other biocontrol products. The discussion then moved to the need for an OECD harmonised definition of biochemical pesticides and a guidance document on data requirements for registering these types of pesticides.

The panelists discussed the readiness of regulators to adopt peptide technology. One academic expressed scepticism, noting that more in-depth knowledge is needed and that some peptides can be hazardous. The discussion highlighted the need to classify peptides into different groups based on structure, degradability and mode of action, as a first step. This classification would facilitate the creation of a more structured regulatory approach. The input from the panelists highlighted the need for a case-by-case approach in regulatory requirements due to the diversity of peptide products. The EC representatives informed the participants that the European Union is updating its data requirements to better define substances of biological origin which are chemicals (i.e., and not microorganisms), including peptides. The aspiration is to rely on the experience gained from the registration of microorganisms, and instead of setting predefined data requirements specific on peptides, a problem formulation approach would be applied.

The conversation then shifted to the grouping approach for registering peptides as plant protection products. Canada explained that their legislation does not allow group registration but encourages a tailored approach based on the body of knowledge of the active ingredient. It was reiterated the importance of pre-submission consultations to discuss data requirements from the beginning. The panelists agreed that creating a comprehensive guidance document for all types of peptides would be challenging, but a considerations document might be helpful.

The discussion concluded with reflections on the importance of innovation and the need for more targeted technologies in the agricultural sector. The panelists emphasised the need for flexibility in regulatory approaches to accommodate new technologies, such as peptides, and the importance of training the next generation of regulators to assess the risks associated with these innovations. The session ended with a call for continued collaboration and information sharing among regulators, industry, and academia.

Session 2: Taxonomy and safety considerations for *Bacillus thuringiensis*-based pesticides

Bacillus cereus sensu lato – phylogenetic tree

Martin Steen MORTENSEN, National Food Institute, Technical University of Denmark (DTU), Denmark

Around one hundred years ago the *Bacillus cereus* group was defined with only three species. They were similar but each caused disease in their own way, one caused anthrax, one caused vomiting or diarrhea, while the last were toxic to specific insects.
From there the group has grown and complexity has multiplied.
Bacillus cereus sensu lato presents with all the different types of complications that can occur for taxonomic classification, the original phenotypic classifications do not align with the genome based phylogenetic clustering, the genomic clustering is uneven and varies based on both the method and the framework used.
This presentation will provide insight into the current state *Bacillus cereus sensu lato* taxonomy.

Martin Steen MORTENSEN opened the seminar session on "Taxonomy and safety considerations for *Bacillus thuringiensis*-based pesticides by introducing the complexities and challenges in classifying the *Bacillus cereus* group, which includes, among other species *Bacillus anthracis*, *Bacillus cereus*, and *Bacillus thuringiensis*. He began by shedding light on the phenotypic and phylogenetic classifications of these species through the years, highlighting that while they produce different toxins and associated diseases, their genomes do not differentiate clearly. This has led to taxonomic issues, as the genomes and phenotypes are not clearly distinct, making it difficult to standardise species definitions.

The presenter discussed the four main taxonomic issues affecting the *Bacillus cereus* group. Firstly, the genome species threshold problem, where the variation within each species is not consistent (Variable Genomospecies Threshold Problem). Secondly, the difficulty in grouping genomes around a central point due to overlapping and varying distances (Type Strain Centroid Problem). Thirdly, the Sub-optimal Genomospecies Threshold Problem that doesn't allow the selected threshold to delineate genomospecies clusters due to diversity within species. Lastly, the phenotypes do not align with the genomes, complicating the identification of species based on their sequences (Phenotype-Centric Species Delineation Problem).

Martin Steen MORTENSEN presented various efforts to classify the *Bacillus cereus* group, noting that traditional phenotypic methods (BAM Protocol for *B. cereus*) recognise five species, while other databases like NCBI, GTDB, and mOTUs/specI have higher number of species due to application of different classification methods and approaches. He proposed a hybrid standardised approach using genome-defined species with subspecies and biovars to explain toxin production and associated clinical conditions. However, he clarified that the phylogeny does not support this approach.

In conclusion, Martin Steen MORTENSEN pointed out that the taxonomic space has been changing frequently over the past 25 years and involves unstandardised nomenclature that complicates communication between researchers and stakeholders. He emphasised the importance of considering both genomic and phenotypic information for applications of *Bacillus cereus* group as plant protection products, despite the abovementioned challenges, because genome sequences cannot be trusted as indicators of pathogenicity or insecticidal properties.

During the Q&A session, there was support for the hybrid standardised approach proposed by the presenter to classify atypical *Bacillus thuringiensis.* However, it was noted that several factors should be considered when discussing changes in regulatory approaches. These factors include the availability of reliable phenotypic tests, the impact of horizontal gene transfer, and the accessibility of proprietary data from existing *Bacillus thuringiensis* strains available on the market.

Bacillus cereus sensu lato as microbial contaminants in food

Angela CATFORD, Health Canada, Canada

The objective of this presentation is to share a Canadian experience in food safety health risk assessment related to the evolving taxonomic classification of *Bacillus thuringiensis* and *Bacillus cereus*.
The Bureau of Microbial Hazards, part of the Food and Nutrition Directorate of Health Canada, aims to enhance the microbiological safety of the Canadian food supply and oversees novel foods. This mission is achieved through the development and communication of policies, guidelines and standards; conducting laboratory research, risk assessments and pre-market assessments; and providing science-based information to the Canadian public and stakeholders to enable them to make informed decisions.
Health Canada is responsible for the Interpretive Summary which includes Standards and Guidelines for Microbiological Safety of Food. Two microbiological criteria in the Interpretive Summary address the presence and amount of *Bacillus cereus* as a foodborne hazard. Additionally, Heath Canada conducts Health Risk Assessments when foodborne hazards are detected in food.
As current practical testing methods in the food safety context cannot distinguish between *Bacillus cereus* and *Bacillus thuringiensis*, and Health Canada's microbiological criteria designed solely for *Bacillus cereus*, decision-making guidance was needed to interpret food safety testing results with the framework of these criteria. This presentation will discuss Health Canada's approach to conduct risk assessment in the face of uncertainty.

Angela CATFORD's presentation aimed to share her organisation's food safety risk assessment experience with the evolving taxonomic classification of *Bacillus thuringiensis* and *Bacillus cereus*. She

reminded the participants that her organisation's perspective comes from post-market food safety assessments and the actions taken when a food risk is identified. The mission of her team and the Canadian food safety partners is to respond to food safety issues by investigating, conducting health risk assessments, removing contaminated food from the market, and conducting any follow-up activities.

The speaker explained the regulatory framework in Canada, highlighting the shared responsibility between regulators from her office in Health Canada, the Canadian Food Inspection Agency (CFIA) and provincial and territorial authorities. This involvement of regulators from various authorities adds a layer of complexity, especially when dealing with food contamination linked to the *Bacillus cereus* group, as many uncertainties exist in relation to their taxonomic classification. She noted that harmonising regulations across different jurisdictions would be a significant regulatory process.

Angela CATFORD, then, presented the microbiological criteria for the *Bacillus cereus* group in Canada, which are under review as part of a Regulatory Modernisation project currently underway, covering also Health Canada's microbiological guidelines and standards. For *Bacillus cereus* group, there are specific criteria for its presence in different food categories, such as spices and infant foods. She emphasised that Canada has an official compendium of methods to ensure accurate detection of microbes (https://www.canada.ca/en/health-canada/services/food-nutrition/research-programs-analytical-methods/analytical-methods/compendium-methods/official-methods-microbiological-analysis-foods-compendium-analytical-methods.html). This compendium is an important regulatory tool, as reliable methods are essential for identifying pathogens in food. However, due to taxonomic challenges associated with *Bacillus cereus* group, these methods require continuous review and updates to remain relevant with the advancements in science.

She discussed the rapid response process for food safety investigations and recalls. She described a four-step process guided by international standards, particularly the Codex Alimentarius, which includes: 1) hazard identification: this step involves identifying the potential hazard in the food product; 2) hazard characterisation: this step involves understanding the nature of the hazard and its potential impact on human health. For *Bacillus cereus*, it is considered less severe compared to other foodborne pathogens like *E. coli* O157; 3) exposure assessment: this step assesses the level of exposure to the hazard in the food product; and 4) risk characterisation: the final step characterises the overall risk to public health based on previous steps. She emphasised that this process allows for quick decision-making, often within 24 to 48 hours, to protect public health. She provided examples of *Bacillus cereus* group outbreaks in Canada reported in the publicly available international foodborne outbreak database and discussed the challenges of distinguishing between different species within this group. A retrospective study aimed to re-characterise *Bacillus* food-poisoning strains from 39 outbreaks in British Columbia identified four outbreak-linked strains of *Bacillus thuringiensis*.

She concluded that in practice, current testing in a food safety health risk assessment context is unable to distinguish between *Bacillus cereus* and *Bacillus thuringiensis.* Outbreak data and literature indicate that *Bacillus cereus* and some strains of *Bacillus thuringiensis* can cause foodborne illness. She shared a recent Health Canada clarification that MFLP-42 enumeration results shall be interpreted as a confirmation of the levels reported for the *Bacillus cereus* group, even though they cannot differentiate between strains, in order to apply microbiological criteria and take precautionary actions when necessary within the health risk assessment process and risk management response. She noted that for foods without specific microbiological criteria, such as certain soybean products, decisions are made on a case-by-case basis to ensure public safety.

A clarifying question posed by participants about the gap in reported outbreaks between 1999 and 2023 in Canada underscored the challenges in reporting foodborne illness of microbiological origin, especially for self-resolving illnesses like those caused by *Bacillus cereus* group. The speaker noted that *Bacillus cereus* is not federally reportable in Canada and relies on investigations initiated by health workers, one factor among others which could explain the gap in reported cases.

It was also clarified that food companies in Canada are responsible for developing preventive control plans, such as the Hazard Analysis Critical Control Point (HACCP) system, as part of their licensing process. These plans identify and control potential hazards in their products. While companies are expected to monitor complaints and illnesses, it is not always mandatory for them to share this information with regulatory authorities. On the whole, tracing back food safety issues is a complicated process that must be performed to protect public health.

Identification of Genetic Markers for the Detection of *Bacillus thuringiensis* Strains of Interest for Food Safety

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Bacillus cereus sensu lato is a group of bacteria of concern in terms of food safety, as they are capable of sporulating and triggering food poisonings through the production of various toxins (emetic toxins and enterotoxins). This group includes *Bacillus thuringiensis* (Bt), which is widely used for its insecticidal properties in agriculture. Due to its ability to produce enterotoxins, and to its regular identification during food poisoning investigation, it is necessary to develop monitoring tools for Bt strains used as biopesticides. From genomic analyses (Genome-Wide Associated approach), specific gene markers were identified, allowing the classification of Bt biopesticides ssp *kurstaki* and *aizawai* in four genomic proximity clusters. To go further Single Nucleotide Polymorphisms were identified to discriminate the best-selling Bt strains in France. This enabled to assign to Bt pesticide strains more than 90% of Bt isolated from food fresh products during a prevalence study.

Mathilde BONIS began by providing context, noting that approximately 2,000 foodborne outbreaks are reported annually in France, with *Bacillus cereus* being a leading cause. This bacterium accounts for 20-25% of total foodborne outbreaks (FBOs) in France, surpassing *Staphylococcus aureus* and *Salmonella*. However, these figures are likely underestimated due to a lack of consistency in reporting. Furthermore, FBOs depend on several variables, including host immune status, ingested dose, and bacterial strain.

The presenter explained that *Bacillus cereus* can cause two main types of poisoning: emetic syndrome, caused by the toxin cereulide, and diarrheal syndrome, caused by enterotoxins such as *Hbl, Nhe, and Cyt K1/2*. In line with the previous speaker, she reminded the participants that the classification of *Bacillus cereus* is complex and has evolved over time, with no consensus reached to date. Historically, species

were defined based on phenotypic traits, but molecular typing methods have been proposed more recently. She presented the diversity of *Bacillus cereus* group associated with FBOs in France between 2004 and 2023 and discussed the FBP investigation process in France. In terms of food safety regulation, in Europe, there are specific food safety criteria for *Bacillus cereus* in dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age. These criteria are outlined in Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs.

Mathilde BONIS shared the starting point for looking into *Bacillus thuringiensis* in FBOs, including an EFSA report and a retrospective analysis conducted by Anses that looked into 250 *Bacillus cereus* associated FBOs. The latter concluded that specific genomic tools are needed to detect biopesticide strains of *Bacillus thuringiensis*, especially given the genetic closeness of *Bacillus thuringiensis* strains. Using a Microbial Genome-Wide Association Study (mGWAS) approach, her team identified several gene markers associated with *Bacillus thuringiensis* species, subspecies, and specific clusters. They developed a tool called Bt_typing available online (https://github.com/afelten-Anses/Bt_typing), which automates the search for these markers and follows a workflow (decision tree) to attribute genomes to specific *Bacillus thuringiensis* strains.

The speaker also discussed the challenges encountered in distinguishing some biopesticide *Bacillus thuringiensis* strains within certain clusters. Despite these challenges, her team identified Single-nucleotide polymorphisms (SNPs) markers that could distinguish specific strains through specific analysis after the global (pangenome) SNP analysis. She closed her presentation by presenting results from a study on organic fruits and vegetables, where they isolated and sequenced *Bacillus thuringiensis* strains, attributing more than 90% of isolates to known *Bacillus thuringiensis* biopesticide strains.

Mathilde BONIS concluded her presentation by summarising the key findings and implications of her research on *Bacillus thuringiensis* strains and their relevance to food safety. She emphasised the importance of continuous reviewing and updating of the Bt_typing tool to include new markers as they are discovered.

It was acknowledged that the FBO reporting systems vary across European countries, and this might explain the discrepancy in the numbers with neighbouring countries. It was noted that in France, *Bacillus cereus* group is identified to the species level and relies on the collection of multiple isolates per food product to understand the diversity and ensure accurate identification, which might not be the case in other countries. The questions also underscored the importance of epidemiology for establishing a sound link between FBOs and etiological microorganisms.

The questions provided an opportunity to clarify that the goal of the study was to develop molecular markers to distinguish *Bacillus thuringiensis* strains for routine FBO investigations and to understand the prevalence of *Bacillus thuringiensis* in such outbreaks. It was mentioned that whole genome sequencing (WGS) for distinguishing *Bacillus thuringiensis* strains can be applied, but it is not routinely conducted. Developing suitable gene markers helps ensure accurate identification of FBO causative microorganisms in a more efficient manner.

Key considerations for assessing the hazard potential of *B. thuringiensis* strains detected in foods

Sophia JOHLER, Chair of Food Microbiology, Competence Center for Food Safety, Ludwig Maximilian University of Munich, Munich, Germany

The United Nations' 2030 Agenda and Sustainable Development Goals aim to end hunger and assure human health, while developing a sustainable

and resilient circular bioeconomy and protecting ecosystems. These ambitious, concerted efforts necessitate a disruptive transformation process towards sustainable, resilient, fair, and environmentally friendly agricultural production and food systems. The use of *Bacillus thuringiensis* biopesticides for control of agricultural pests plays a crucial role in this transformation process. Still, *B. thuringiensis* is phylogenetically intermingled with the foodborne pathogen *B. cereus sensu stricto* and was denied QPS status due to safety concerns. While in the past, data constraints compromised robust risk analysis regarding to the use of *B. thuringiensis* in food production, in recent years, data has become increasingly available and the challenge to assess the benefits, risks, and trade-offs across sectors seems far more relevant. Novel concepts balancing risks and trade-offs between different sectors are urgently needed. Recently, Risk negotiation was proposed (Ehling-Schulz, 2024). This AI-assisted multi-stakeholder process can be used to assess, manage, and communicate risks across disciplines. Conventional risk assessment often overlooks intersectoral trade-offs and the complexity of multi-sectoral food systems. AI-assisted risk negotiation integrates artificial intelligence into risk analysis within a One Health framework, facilitating structured, participatory decision-making that can integrate big data. By leveraging AI tools such as large language models and predictive analytics, this approach enhances transparency, reduces biases, and balances food safety with sustainability, security, and economic feasibility.

Sophia JOHLER began by providing context on the importance of *Bacillus thuringiensis* in the transformation of agroecosystems, especially considering the planetary boundaries and the Sustainable Development Goals of the United Nations. *Bacillus thuringiensis* is widely used as a biopesticide in pest control and produces a range of pathogenic factors that are non-hazardous to humans. However, the close relation of Bt strains to *Bacillus cereus* sensu lato group, which can cause foodborne toxic infections, has sparked interest in their hazardous potential.

The presenter reiterated that Bt strains are genetically intermingled with *Bacillus cereus sensu stricto*, making taxonomic differentiation challenging. She proposed as a solution to move from taxonomic risk assessment to strain-specific risk assessment. She, then, addressed the questions raised by an EFSA opinion, such as whether biopesticide strains express enterotoxins, their ability to multiply in food, and potential links to outbreaks.

Sophia JOHLER shared findings from her own laboratory work, where they compared the enterotoxicity of biopesticide, food, and outbreak isolates. Some food isolates were found to be extremely toxic, while outbreak and biopesticide isolates showed low to mid-level toxicity. She also discussed the limited data on Bt strains' ability to grow in food, noting that meaningful growth occurs only under prolonged temperature abuse. Additionally, she presented evidence of genetic similarities between outbreak strains and biopesticide strains, suggesting potential spillover from pest control to food production.

The talk concluded with a discussion on the need for an innovative approach to enhance risk analysis by incorporating big data, better communication, and an inclusive process. This framework aims to create a

more comprehensive and inclusive approach for evaluating and managing risks, particularly in complex scenarios such as is the case with *Bacillus thuringiensis*. She introduced the concept of "risk negotiation," which involves a stakeholder roundtable to jointly formulate, assess, and negotiate risks, with the help of artificial intelligence (AI), and a human moderator, who evaluates the outputs generated by AI. Preliminary results from using large language models in this context showed promise in finding joint, data-driven and balanced solutions. In summary, the risk negotiation framework combines traditional methods with modern technologies and participatory processes to create a more comprehensive and effective approach to risk management.

Follow-up discussion raised the question of the applicability of the cytotoxicity method used for testing Bt, the incubation time required for Bt to cause symptoms, and the regulation of enterotoxin genes. It was noted that the cytotoxicity method can be used for different strains across the *Bacillus cereus* group. She clarified that the toxicoinfection caused by Bt would require a longer incubation period compared to foodborne intoxications, and enterotoxins are unlikely to survive the hostile environment of the stomach. The discussion also touched on the need for post-approval monitoring and the challenges in understanding the regulation of enterotoxin genes.

Bacillus thuringiensis: Taxonomy, Agricultural Use, and Implications for food safety

José CARVALHO, Certis Biological on behalf of IBMA, Belgium

Bacillus thuringiensis (Bt) is a bacterium known for its insecticidal properties. A few Bt strains have been selected and commercialized as biological crop protection products for more than 80 years. Typically, Bt strains used in bio-insecticides have been characterized by the production of crystal-shaped parasporal inclusion bodies, composed of one or more types of insecticidal crystal proteins. Each crystal protein has its own insect toxicity spectrum (target pests).

The wide availability of genome sequences allowed microbial taxonomy to move from phenotypic classification into a comprehensive evolutionary framework, a longstanding goal of taxonomists. However, bigger and more complex genomic datasets need an equally rapid evolution of mathematical tools, as well as adaptation of the concept of bacterial species.

Differentiating organisms capable of causing illness from those used in agriculture is essential for risk assessments and outbreak preparedness. However, current species definitions facilitate species-phenotype incongruences.

Bacillus cereus sensu lato s.l. is a group of bacteria displaying close phylogenetic relationships but a high ecological diversity. The three most studied species are *Bacillus anthracis, Bacillus cereus sensu stricto and Bacillus thuringiensis*, and members of this group vary immensely in their ability to cause illness. Due to genetic proximity and limitations of current methodologies, *Bacillus thuringiensis* has been suspected of being able to

cause diarrheal food infections, similar to those caused by *B. cereus sensu stricto* (*s.s.*). The association of pathogenicity to *Bacillus cereus* s.l. strains is based on their isolation in the context of a Food Borne Outbreak. Yet, data collected from Food Borne Outbreak (FBO) reporting in Europe is mostly weak-evidence data, meaning that there is a high level of uncertainty in the implication of an isolate as the causative agent of a given FBO.

Current scientific knowledge does not (yet) allow to predict the entero-toxigenic potential of a *Bacillus cereus* s.l. strain, based on genome or other intrinsic characteristic of strains from this group, since manifestation of the disease (diarrhea) is the result of a multifactorial process and highly complex gene regulation. A better understanding of the underlying mechanisms of enterotoxicity of *Bacillus cereus* s.l. is key for developing and validating effect biomarkers for the (entero)pathogenicity of a strain. Such research should rely on comparison with control strains of proven enterotoxicity.

José CARVALHO started his presentation by reiterating the significant changes in taxonomy and terminology over the past decade in the *Bacillus cereus* group. He explained how important it is to consider phenotypes in addition to genome sequencing, as the latter alone cannot predict associated human health effects for *Bacillus cereus* group and other prokaryotic species. He highlighted the complexity of phylogenetic trees and their use in risk assessment, noting that they are suitable for demonstrating the evolution of organisms but not for identifying potential pathogenicity in *Bacillus* spp.

He then addressed the limitations of genomics in answering all questions related to risk assessment. José CARVALHO explained that while genomics can be useful, there is still much to learn about gene regulation, expression, conditions of expression, environmental niche of the organism, and other epigenetic factors. He used the example of human monozygotic twins to illustrate how genetical identical organisms can lead to different phenotypes, including complex diseases.

He also discussed the challenges in understanding the mechanisms of enterotoxicity in the *Bacillus cereus* group. He mentioned the high variability of toxins produced between strains (distribution, genetic organisation, gene expression and toxin secretion), the several known virulence factors and their lack of individual relevance for adverse effects, and also the lack of valid models for enterotoxicity. He pointed out that many strains identified in past foodborne outbreaks may not have been the actual cause, , pointing out that presence is not causality, leading to difficulties in distinguishing pathogenic from non-pathogenic strains.

In the latter part of his presentation, he highlighted the issues with the current European foodborne outbreak reporting system, which doesn't always adhere to the updated EFSA's technical specifications for harmonised reporting of food-borne outbreaks. He explained that the lack of standardisation and the presence of weak evidence cases cannot determine causality between causative agent and disease. He emphasised the importance of understanding the mechanisms of enterotoxicity and the need for improved data aggregation and standardised reporting.

Finally, José CARVALHO concluded by discussing the potential sources of false positives in identifying *Bacillus cereus* stains as a causative agent. He explained that the presence of spore-forming bacteria like *Bacillus cereus* group is easier to isolate and culture compared to other microorganisms that cause similar

diseases. He closed the presentation by emphasising the need for identification and risk assessment of Bt strains, considering genomic characterisation in conjunction with genetic regulation, virulence factors, and gene expression, as well as ecology, including growth conditions, phenotypic characteristics, and mammalian exposure data.

After the presentation, a question arose regarding the potential for reducing application rates or frequencies of Bt. The speaker questioned the rationale behind such measures, suggesting that there should be a serious concern for applying such measures. José CARVALHO also discussed the importance of correlating real-world data to understand the impact of Bt exposure. He mentioned that areas with higher exposure should have more reports, and analysing this data could provide valuable insights. He mentioned the value of post-monitoring observations and surveillance, which should be conducted by authorities. Finally, there was a discussion about the need for better understanding and monitoring of Bt applications. It was agreed that post-monitoring discussions are essential and that stakeholders such as registrants should be involved in these discussions to ensure comprehensive monitoring and assessment.

New Bt Strains and Identity

Nina JOERGENSEN and Rosa CRIOLLO, FMC

Experience from regulatory review of a novel FMC *Bacillus thuringiensis* strain, which does not contain Cry protein have resulted in several reflections related to identity and biological properties requirements for the species in a PPP regulatory context. The main findings are the following:
Cry protein is plasmid-borne and not species specific. Therefore, relying on Cry protein presence for *B. thuringiensis* identification should not be used for species identification in a regulatory context.
Today whole genome sequence (WGS) is the state-of-the-art methodology in genomic science to explicitly recognise a specific strain of *B. thuringiensis*.
Regulatory authorities globally to consider moving away from phenotypic, physiological and biochemical characteristics as main route of identifying *B. thuringiensis* and accept WGS tool as a reliable methodology for taxonomic identification in their regulatory framework
Harmonized approach needed for identification of toxins relevant for registration purposes and replacement of Mouse IP assay with alternative method as post registration requirement in quality control settings is required to avoid routine animal sacrifice.

Nina JOERGENSEN provided industry's perspective on the registration process of a novel Bt strain. A Bt strain that does not produce Cry protein was discovered about ten years ago and entered the registration process in 2002 in various countries, including the EU, the US, Canada, and Brazil. Only Brazil has recently approved the registration of this new Bt strain. The entire process has been challenging, as this new strain couldn't be easily fit into existing evaluation approaches, leading to numerous inquiries.

Nina JOERGENSEN discussed the challenges around strain identity, due to the ongoing scientific debate about the *Bacillus cereus* group. She noted that the absence of Cry protein has been a point of contention, as many authorities regulate Bt strains based on their ability to produce Cry protein. The ability to synthesise these crystals is encoded by plasmid-borne cry genes, which can be acquired or lost by the organisms. These genes serve as the marker for all approved Bt strains. Despite extensive genomic assessments indicating that this new strain, which does not produce Cry protein, is a *Bacillus thuringiensis*, questions persist about its identity. Recent scientific literature indicates that the presence or absence of virulence plasmids and cry genes is largely uncorrelated with the phylogenetic position of the host bacteria.

The presenter noted that the current data requirements in many countries do not necessarily align with state-of-the-art scientific developments, resulting in additional work and delays. She highlighted the diverse list of toxins required by different countries, making it challenging for applicants to know what to address upfront, which often leads to post-submission deficiencies. She also discussed the outdated requirement for a mouse injection assay to rule out *Bacillus anthracis* contamination, which remains in place in some countries. Finally, she emphasised the need for greater acceptance of genomic methods in taxonomy and toxin screening for Bt species, as well as the replacement of animal methods with in vitro methods wherever possible.

During the follow-up questions, a discussion arose about the potential for phage typing assays to replace the mouse injection assay, with industry interest in collaborating with authorities to establish new, validated methods. Another question addressed the efficacy of the Bt strain without Cry proteins, to which it was explained that the target pests are soil insects and nematodes. This Bt strain acts as a repellent and nematocidal through other metabolites.

Bacillus thuringiensis - QPS assessment

Lieve HERMAN, EFSA, vice-chair of the EFSA BIOHAZ Panel and chair of the Biological Hazards Qualified Presumption of Safety (QPS) Working Group, ILVO, Institute of Agricultural, Fisheries and Food Research, Flemish Community, Belgium

Summary based on the EFSA BIOHAZ Panel QPS statement 21 on the suitability of taxonomic units notified to EFSA until September 2024.*EFSA Journal* 2025 23(1), 9169. https://doi.org/10.2903/j.efsa.2025.9169
Ana Allende, Avelino Alvarez-Ordóñez, Valeria Bortolaia, Sara Bover-Cid, Alessandra De Cesare, Wietske Dohmen, Laurent Guillier, Liesbeth Jacxsens, Maarten Nauta, Lapo Mughini-Gras, Jakob Ottoson, Luisa Peixe, Fernando Perez-Rodriguez, Panagiotis Skandamis, Elisabetta Suffredini, Marianne Chemaly, Pier Sandro Cocconcelli, Pablo Salvador Fernández Escámez, Miguel Prieto Maradona, Amparo Querol, Lolke Sijtsma, Juan Evaristo Suarez, Ingvar Sundh, Angela Botteon, Baptista Carolina, Barizzone Fulvio, Sandra Correia, Lieve Herman

Upon an internal request to EFSA, the QPS assessment of *Bacillus thuringiensis* was performed based on an extensive literature search from January 2015 till July 2024. *B. thuringiensis* belongs to the *B. cereus* sensu lato (s.l.) group also known as the *B. cereus* group, characterized by the

production of crystal proteins. The strains containing the genes for these proteins were detected across various *B. cereus* s.l. lineages. The subspecies *kurstaki, aizawai, israelensis, tenebrionis, morrisoni* were defined only based on flagellin amino acid sequence.
B. thuringiensis is transferred to edible parts of the plants by biopesticide application and from the soil, where they are naturally present. A concentration from 10^4 to 10^5 cfu/g was found on treated spinach and from 100 till 850 on non-treated ones. Theoretically estimated concentrations of *B. thuringiensis* on treated vegetables range from 10^5 to 10^6 cfu/g just after application of the biopesticide; a decrease in concentration during pre-harvest growth is expected.
B. cereus s.l. strains may cause at human level the diarrheal syndrome mainly associated with the production of heat-labile enterotoxins in the small intestine (genes *hbl, nhe, cytK*) and the emetic syndrome caused by the emetic toxin cereulide (genes *ces* cluster).
Most *B. thuringiensis* strains, also the biopesticide strains, contain the genes known to be related to the diarrheal syndrome *hbl, cytK2,* genes of the *nhe* complex; they were not found positive for the *ces* genes. They also produce other virulence factors which may play a role in both the insecticidal activity and potential human impact. Expression of virulence factors has been demonstrated in food models for most of the commercial *B. thuringiensis* strains tested. Retrospective studies carried out using strains collected during former foodborne outbreak investigations indicate that a substantial part of the foodborne outbreaks with *B. cereus* s.l. are correlated with the presence of *B. thuringiensis* strains, mainly of the subspecies *aizawai* and *kurstaki*; subspecies *israelensis* and *tenebrionis/morrisoni* biopesticide strains were not linked to foodborne outbreaks. This could be explained by the fact that they are not used in agriculture or not on edible plant parts. Another reason could be that they are less virulent because they have a disrupted promoter of the *nheA* gene and no *cytK2* gene.
The QPS assessment concluded not to recommend *B. thuringiensis* for the QPS status due to safety concerns.

Lieve HERMAN began by introducing the Qualified Presumption of Safety (QPS). The QPS assessment is a regular exercise performed on taxonomic units submitted to EFSA. Recently, it was requested for *Bacillus thuringiensis*. The assessment involves evaluating the species level of the organism, and if deemed safe, all strains belonging to that species are considered safe. The QPS assessment is based on taxonomic identification, scientific knowledge, and any potential safety concerns.

Lieve HERMAN explained that during the QPS assessment, an extensive literature search was conducted, covering the period from 2015 to 2024, which resulted in nearly 6,000 hits and 64 references. The assessment focused on the production of Cry proteins, which are phenotypically and microscopically

observed, to ensure strains' identification. The literature review and genome based taxonomy revealed that *Bacillus thuringiensis* strains were scattered across different *B. cereus* s.l. lineages, and the subspecies identity was defined based on the amino acid sequence of flagellin and not due to presence or absence of other genes, e.g. virulence genes.

Theoretically estimated concentration of *B. thuringiensis* spores on treated vegetables ranges from 10^5-10^6 cfu/g just after application of the biopesticide to approximately 10^2-10^3 cfu/g concentration during pre-harvest growth in open field conditions. It is not clear if the reduction seen in open field grown vegetables would be as prominent in greenhouse grown treated produce. *B. thuringiensis* spores can survive dehydration and food processing and end up in a variety of food products, where they can further proliferate under appropriate conditions.

Lieve HERMAN emphasised the safety concerns related to *Bacillus thuringiensis*, noting that it is associated with the diarrheal syndrome rather than the emetic syndrome. The presentation mentioned that *Bacillus thuringiensis* strains produce other virulence factors, such as phospholipase C and sphingomyelinase, which may play a role in both insecticidal activity and human impact. The expression of these virulence factors has been demonstrated in food models and cell lines.

The presentation concluded with a discussion on foodborne outbreaks and the identification of *Bacillus thuringiensis* in routine food outbreak investigations. Lieve HERMAN noted that many foodborne outbreaks with *Bacillus cereus sensu lato* are correlated with the presence of *Bacillus thuringiensis* biopesticide strains. She concluded with the recent EFSA ‘s BIOHAZ Panel QPS statement that *Bacillus thuringiensis* is not recommended for QPS status due to safety concerns.

A question was raised regarding the criteria used to assess the reliability of the publications used for the QPS statement. It was noted that all assessed papers were peer-reviewed and carefully read by a group of people, with only the most relevant and scientifically correct papers being included. It was further clarified that while *Bacillus thuringiensis* strains do not produce the emetic toxin, they are associated with the diarrheal syndrome. Concerns were expressed about the use of *Drosophila melanogaster* in studies to determine the pathogenicity of *Bacillus thuringiensis*. It was acknowledged the limitations of such studies and the need for careful interpretation of the results.

Panel Discussion of Sessions 2

The panel discussion began with a focus on the regulatory perspective of assessing *Bacillus thuringiensis* (Bt) plant protection products. The panelists discussed the importance of determining the safety of Bt strains, particularly how to assess the safety of strains with enterotoxin genes. Panelists highlighted the complexity of taxonomy and the importance of focusing on specific genes rather than species names. They also discussed the limitations of current models, such as the rat infectivity model for assessing enterotoxicity, and the need for more accurate testing methods. One academic emphasised the need for relevant data derived from cytotoxicity assays, sphingomyelinase activity, and whole-genome sequencing to assess potential risks.

Panellists shared their experiences and recommendations for enhancing regulatory assessments, emphasising the need for collaboration among scientists, regulators, and industry stakeholders to develop more effective methodologies and data collection practices. The importance of understanding the epidemiology and limitations of the current available data was also discussed, with a focus on improving systems to gather more accurate epidemiological data.

The panel concluded with a discussion on the relevance of exposure data and the challenges of setting thresholds for Bt products. Panelists debated the balance between ensuring food safety and avoiding unnecessary food waste. They also discussed the potential impact of different application methods on

plants and the need for more research on the persistence and behaviour of Bt spores after application in agricultural settings.

Overall, the panel discussion highlighted the complexity of assessing the safety of Bt strains included in plant protection products and the need for a tailored approach that includes relevant data collection through standardised testing methods, expert assessment of epidemiological data and collaboration among stakeholders.

Tour de table: Regulatory responses and challenges

The tour de table discussion provided participants with the opportunity to share their perspectives and experiences. Participants from various countries and organisations discussed the challenges they face in regulating Bt strains and the need for more research and data. They emphasised the importance of understanding the mechanisms of enterotoxicity and the need for better testing methods.

Participants shared their experiences with different regulatory approaches and the challenges of implementing new testing methods. They discussed the need for flexibility in regulatory frameworks to accommodate new scientific developments and the importance of ongoing research to improve the understanding of potential association of Bt strains used in plant protection with foodborne illnesses.

Participants also discussed the importance of risk communication. They highlighted the need for clear and consistent messaging to the public and the importance of addressing public concerns about pesticidal Bt strains and their potential implication in foodborne outbreaks.

The discussion also touched on the importance of international collaboration and the need for harmonised regulatory frameworks. Participants emphasised the importance of sharing data and best practices to improve the safety and efficacy of Bt strains in plant protection globally. They also discussed the potential benefits of post-market monitoring to identify and address any emerging issues that may arise.

The seminar session covered the revised classification of Bt and challenges in determining the involvement of pesticidal Bt strains in foodborne outbreaks. There was discussion on the regulatory significance of Bt strains that possess enterotoxins and the lack of epidemiological evidence to confirm the link between the presence of Cry proteins and foodborne illness. Considerations for virulence factors of pesticidal Bt strains and pathways for addressing safety questions through relevant test methods during evaluation were also discussed. Participants agreed that the taxonomic classification of a Bt strain is multifactorial and challenging and should be based not only on the genotype but also on the phenotype of the strains. There was acknowledgment that some scientific reviews are pointing to the possible implication of Bt strains with foodborne illness, but many uncertainties remain as regards the causal link and the possible confusion with other species belonging to the *Bacillus cereus* sensu lato. Uncertainties remain due to limitations in epidemiological studies, monitoring data, and difficulties in self-reporting of symptoms. The session also highlighted the importance of risk communication and the need for clear and consistent messaging to the public. International collaboration was encouraged to address the challenges of assessing the safety of Bt strains. An agreement was reached that this should remain a point of ongoing collaboration among OECD countries and stakeholders.

Session 3: Risk Assessment of Semiochemicals

Technical Overview of Semiochemicals

Vicente NAVARRO-LLOPIS, Aitor GAVARA and Sandra VACAS, CEQA-IAM. Universitat Politècnica de València, Spain

Pheromones are semiochemicals produced to transmit information among individuals of the same species. These compounds are biogenic, species-specific, and enable communication between individuals at considerable distance, in the absence of light, through dense foliage, or even in complex environments. Pheromones are increasingly used in pest management as an alternative to synthetic insecticides due to their high efficacy in reaching target organisms at very low concentrations and their low toxicity. In general, pheromones are biosynthesized by insects from natural fatty acids or terpenes found in the natural biosynthesis pathways. These compounds are then transformed by specific enzymes, producing different isomers and derivative compounds that are unique and ephemeral, providing time-limited and specific communication. As a result, pheromones are non-toxic compounds with natural synthesis and degradation pathways, making them suitable for crop protection without the drawbacks of traditional pesticides. The use of pheromones and semiochemicals in pest management has steadily increased over the past 40 years. During this time, new pheromones have been identified, and more effective dispensers and devices have been developed, enhancing the effectiveness of these pest control systems. The attract-and-kill and mating disruption methods have proven to be effective in regulating pest populations in a sustainable manner, without the use of toxic substances that could harm producers, consumers or the environment.

Vicente NAVARRO-LLOPIS introduced his research work on pheromones, a class of semiochemicals in pest control, which are substances emitted by various organisms and play a role in communication between species. He presented the various types of semiochemicals, including sex pheromones used for mating, aggregation pheromones for joint plant attacks, and alarm pheromones released when insects are attacked, as well as other types such as trail, marking, and primer pheromones. In the introduction, he emphasised that these compounds are valuable tools in the context of pest control solutions to reduce or replace synthetic chemicals.

The speaker noted that the chemical structure of pheromones typically consists of unsaturated hydrocarbons with functional groups such as alcohols, esters, or aldehydes. He explained the specificity of the pheromones demonstrated for each species, which is achieved by the addition of double bonds, and

positional or geometric isomers or branching that leads to multiple isomers, by presenting examples. He then introduced the biosynthesis pathways of pheromones, which start from fatty acids and proceed with chemical reactions like elongation, desaturation, and oxidation. He shared a database for searching information on pheromones and other semiochemicals. According to this database, around 20,000 references about pheromones and other semiochemicals have been published in the last 25 years. The pheromones of the most economically important pests are known, highlighting their importance in pest management due to their species specificity, low toxicity, biodegradability, and lack of resistance development.

The presentation also covered the mechanism by which pheromones are detected by the pests and the bioassays used to measure insects' response. The speaker also explained the various methods used to apply pheromones in pest control, noting that the choice of method depends on the type of pheromone and its production cost. For example, low-cost pheromones can be used for mating disruption, while more expensive ones are suitable for monitoring or mass trapping.

The presentation concluded with a discussion about the challenges of measuring pheromone concentrations in the air, especially in complex environmental matrices, due to other interfering compounds such as car exhaust gases. He noted that despite these challenges, studies show that the low concentrations of pheromones used in pest control are far below the threshold limit values of several toxic substances measured in air. Before closing, he informed the participants about the potential of using plant-released pheromones for pest control, where plants emit defensive substances when attacked, which can be detected and used to alert neighboring plants. He closed by emphasising the importance of continuing the research and discovery of new interactions between species to develop more effective pest control methods.

The discussion progressed on the technical challenges of measuring pheromones in different settings. According to the presenter, the main difficulty in detecting pheromones in complex matrices like the air in open fields lies in their low concentration and the interference with measurements of similar compounds with hydrocarbons. He noted that even in controlled environments like indoors, the concentrations are very low, and scientific findings support that these levels are not of concern with respect to their toxicity.

A significant point of discussion centered on the difference in potential risk posed by pheromones sprayed into fields compared to those applied using dispensers. The speaker acknowledged that the passive dispensers release very low quantities of pheromones, making it difficult to detect them deposited on plant leaves. In contrast, sprayable pheromones are deposited or absorbed by leaves or fruits and released over time. In all cases, pheromone concentrations drop significantly within 24 hours.

Finally, the dialogue explored the potential of using plant-released pheromones for early pest detection. The response indicated that detecting these compounds from other plants early enough to prevent damage could be challenging due to the complex environmental matrix. However, the speaker acknowledged this possibility in controlled environments like laboratories and noted that this approach could still be useful for alerting neighboring plants to produce defensive substances.

Revised Calculation Method

Tomasz MAGACZ, SynTech Regulatory, GAB Consulting GmbH, Germany

Several distinct functional and physicochemical properties of semiochemicals are critical factors in developing realistic risk assessment scenarios for semiochemical-containing plant protection products. These compounds are characterized by poor water solubility, high volatility, and

rapid environmental degradation. These properties are intrinsically linked to their biological roles in intra-species and inter-species communication. Consequently, the default approach for assessing risks to operators, consumers, and the environment associated with conventional pesticides is not suitable for semiochemicals. Therefore, a key parameter in the risk assessment of semiochemicals is the natural background level. This level corresponds to the exposure that might naturally occur in the environment from a high-density population of emitting organisms. Such exposure is expected to be experienced by humans and other non-target organisms without causing any detrimental effects.

The current approach for determining background levels can be managed either by establishing a fixed threshold value (i.e. 375 g semiochemical/ha (150 g/acre) per year) which was proposed by EPA and reiterated in the first OECD Guideline[2]. In time a new method based on calculation was introduced and published in several official, FAO[3], OECD[4] and EU[5] documents.

Within the scope of the current OECD project, the suitability of the calculation method was confirmed through an experimental phase, which yielded similar exposure results. This phase also highlighted the methodological challenges associated with field determination of semiochemical content in the air. Moreover, an additional step involving the verification of the reliability of peer-reviewed input data was introduced. This step is based on a scoring grid that assesses the reliability of the main input parameters, namely: the release rate of an individual organism, the number of plants per hectare, and the ratio of female to male individuals per plant. This verification is to be performed before the actual calculation step. The updated calculation including the reliability of input data step applied to derive natural exposure levels for 16 Straight-Chained Lepidopteran Pheromones (SCLPs) and for the pheromones emitted by 7 Hemiptera species and together with the practical examples is to be included in in the new release of OECD Semiochemical Guideline. It is to be noted that any calculation method based on a single species heavily underestimates the actual exposure. In practice during the realistic field conditions the actual

[2] OECD (2002), *Guidance Document on Semiochemical Active Substances and Plant Protection Products, First edition*, Series on Pesticides and Biocides, OECD Publishing, Paris, https://doi.org/10.1787/2e61f31f-en.

[3] WHO/HTM/NTD/WHOPES/2017.05

[4] OECD (2018), *Guidance Document on Semiochemical Active Substances and Plant Protection Products*, Series on Pesticides and Biocides, No. 93, OECD Publishing, Paris, https://doi.org/10.1787/fe2261bf-en.

[5] Guidance document on semiochemical active substances and plant protection products'. DG SANTE, SANTE 12815/2014 rev. 11 January 2024

exposure is much higher than calculated due to the fact that the same molecule can be emitted by different co-existing species as well as closely related ones from other organisms. Thus, it shall be considered conservative enough for Risk Managers to extend the group approach to align with natural background levels. A harmonized threshold value of 99.0 mg/ha per hour is recommended for SCLPs, while a threshold of 25 mg/ha per hour is suggested for Hemiptera and terpenoid-like sex pheromones. This new approach will facilitate the development of new threshold values to streamline the decision-making process during the registration of semiochemical-based products.
In conclusion, the updated calculation method, which includes the data evaluation step and the resulting proposed threshold values, serves as a valuable tool for determining the natural background levels of semiochemicals for regulatory purposes. Its flexibility allows for conservative predictions of values across different arthropod families, providing a reliable reference for assessing the acceptability of the intended uses of plant protection products containing semiochemicals.

Tomasz MAGACZ presented the OECD project to revise the calculation method in the OECD Guidance Document on Semiochemicals Active Substances and Plant Protection Products [ENV/JM/MONO(2017)33] for the determination of the natural background levels of semiochemicals. The project aims to refine the calculation method by including steps that enable verification of the reliability of the data derived from peer-reviewed papers. He reiterated that determining semiochemical levels in the field is a complex issue because the amounts found are too low for accurate measurements.

He explained the calculation method that involves determining the release rate of semiochemicals from the population of a certain insect in nanograms per hectare per hour based on the release of the individual organism and number of releasing organisms. He discussed the necessity of using reliable data sources that come from peer-reviewed literature and the challenges involved in validating these sources. He presented the criteria developed by the subgroup to assess the reliability of the data used to validate the calculation.

He then provided examples demonstrating how the revised calculation method is applied. Examples included various common pests, such as some Lepidopterans and Hemipterans, and their semiochemical release rates, considering various crops. He mentioned the challenges in finding reliable data for certain species and discussed how surrogate data can be used for calculations.

In the last part of the presentation, there was a proposal for potential harmonised background levels for a set of semiochemicals. and a discussion about their impact on risk assessment. He emphasised the importance of having scientifically based background levels of semiochemicals for different groups of insects and the need for flexibility in the calculation method.

It was clarified that the revised draft OECD Guidance Document on Semiochemicals Active Substances and Plant Protection Products, which includes the new calculation method and criteria, is available to EGBP members for comments. Interventions expressed appreciation for the work because it also confirmed the accuracy of the existing assessment framework for semiochemicals.

The EU amended Guidance Document on Semiochemicals

Eric LIÉGEOIS, EC, DG Santé, Belgium

Eric LIÉGEOIS' presentation focused on the recent amendments to the EU Guidance Document on Semiochemicals published in January 2024. This Guidance Document was initially drafted in 2014 and has undergone its 11th revision. He explained that the amendments aim to provide practical solutions on how procedures and data requirements can be applied to facilitate the approval of semiochemicals. The guidance doesn't cover semiochemicals used as attractants in combination with insecticides or for monitoring purposes, as these do not require approval as active substances.

He explained that the guidance document elaborates on the experience from the renewed approval of a well-known group of Straight Chain Lepidopteran Pheromones (SCLPs) in mid-2022. These pheromones are characterised by their unbranched aliphatic chains, which range from 9 to 18 carbons, and may contain up to three double bonds, ending in functional groups such as alcohol, acetate, or aldehyde. The extensive work carried out by France was acknowledged as the basis for amending the guidance document. This work involved grouping SCLPs according to their structural similarities.

The revised guidance document includes three groups of substances, each with specific definitions and related pests. The first group corresponds to the Straight Chain Arthropod Pheromones (SCAPs) that require compliance with the SCLPs definition but can contain a possible triple bond and potentially disrupt other orders such as Coleoptera, Diptera, Hemiptera, Acarida, Thysanoptera and Hymenoptera. The second group includes Other Chained Arthropod Pheromones (OCAPs), which are structurally similar to SCLPs definition, i.e. consisting of acyclic, branched or unbranched aliphatics, containing five to thirty carbons, zero to three unsaturated bonds and having zero to several functional alcohol, ester, aldehyde, ketone or epoxide groups. The last group, named Other Arthropod Pheromones (OAPs), is not directly structurally related to SCLPs definition, i.e. consisting of branched or unbranched aromatic or aliphatic (straight or cyclic) hydrocarbons and containing two to thirty carbons zero to several unsaturated bonds and having zero to several functional alcohol, ester, aldehyde, ketone or epoxide groups. He noted that this grouping of pheromones is designed to simplify the risk assessment process by leveraging structural similarities and scientific knowledge.

He discussed the need-to-know approach outlined in the guidance document, which allows for tailored data requirements dictated by the chemical structure of the semiochemicals and the available scientific knowledge. This approach requires the use of non-testing methods, such as QSAR (Quantitative Structure-Activity Relationship), that assist in predicting potential toxicological concerns. He closed the presentation by expressing his confidence that these amendments would facilitate the approval of new semiochemicals and accelerate the risk assessment process for this category of plant protection products.

The discussion progressed on the importance of collaboration among regulators from different jurisdictions to facilitate the approval of biocontrol solutions by encouraging the harmonisation of these categories for semiochemicals across various geographies. Industry was encouraged to consider submitting these semiochemical groups for Global Joint Reviews. Australia shared their approach, which includes, among others, acceptance of assessments from comparable overseas regulatory authorities, provided the supporting data is accessible and the risk assessments cover the same endpoints.

Another point of discussion centered on the acceptability of QSAR data for the semiochemicals risk assessment. It was explained that QSAR data is broadly accepted when presented in line with OECD guidance, particularly for excluding toxicity alerts. However, QSAR predictions for certain endpoints may not always be accepted/ applied for risk assessment purposes. It was noted that QSAR methodologies are well accepted for determining the potential toxicity of impurities during the specification process of SCLPs.

Debunking Myths About Semiochemicals

Alessandra MOCCIA, Suterra, Spain, IBMA

Semiochemicals, including pheromones, play a crucial role in pest management by modifying insect behavior rather than acting as toxic agents. Despite their well-established low-risk profile, misconceptions exists regarding their formulation, efficacy, and environmental impact. This presentation aims to clarify these aspects.

All semiochemical-based plant protection products function as dispensers, as semiochemicals are highly volatile and would otherwise dissipate too rapidly to be effective. In nature, pheromones are emitted in minute, controlled amounts, creating a localized plume that insects detect through specialized receptors on their antennae. When used for plant protection purposes, this natural mechanism must be replicated to ensure sustained efficacy. Without a controlled release system—whether through vapor-phase (VP), aerosol emitter (AE), or capsule suspension (CS) formulations—the pheromone would rapidly evaporate, rendering the product ineffective.

Unlike conventional pesticides, which often have broad-spectrum activity across multiple pests and crops, pheromone-based products exhibit species-specific efficacy that is independent of the crop in which they are applied. The efficacy of pheromone-based products is not influenced by the crop type, climatic conditions, or whether the application occurs in an open field, a greenhouse, or another environment.

Finally, standard aquatic toxicity testing protocols, designed for conventional pesticides, are poorly suited for assessing the environmental impact of pheromones. These compounds have intrinsic physicochemical properties that make them highly volatile, poorly soluble in water, and rapidly degradable in natural environments. As a result, the likelihood of significant aquatic exposure is minimal. In regulatory risk assessments, forcing semiochemicals into artificial aquatic testing conditions—where solvents or stabilizers must be added to maintain their presence in water—creates unrealistic exposure scenarios that do not reflect real-world conditions. The key regulatory question should not be whether these compounds exhibit toxicity in artificially sustained aquatic environments but whether aquatic organisms are realistically exposed to them at all.

Alessandra MOCCIA's presentation aimed to debunk common myths about semiochemicals applied as plant protection products. She began by providing a historical overview from the time that the first semiochemical was identified in 1959 until the commercialisation of sex pheromones in the 1980s for insect mating disruption. Alessandra MOCCIA emphasised that while semiochemicals are not new, their unique

properties are often misunderstood, and through the presentation, she clarified three key aspects of semiochemicals that are frequently misunderstood.

The first aspect discussed was the technology behind the application of semiochemical products. She presented the various platforms currently authorised to enable release of pheromones for mating disruption. There are various types of dispensers used to release pheromones, and Alessandra MOCCIA explained the differences between passive and active dispensers, which correspond to retrievable and non-retrievable dispensers, as presented in the OECD and EU guidance documents. She emphasised that one of the most important and technical aspects of pheromone products application is to obtain a controlled release. To ensure effective plant protection, emphasis is given to the engineering of dispensers that can achieve pheromone release in a controlled manner. For example, capsule suspension formulations and any sprayable formulation are micro-dispensers and consist of microcapsules of naturally occurring substances and have been on the market for more than two decades.

The second aspect covered was the efficacy of pheromones in nature. The speaker described the natural process of female insects releasing sex pheromones, which males detect by the receptors on their antennae and follow to locate the females. She pointed out that the rapid degradation of pheromones dictates their efficient biological function. There is a misconception that climatic conditions, crop type and density and indoor/outdoor settings influence the efficacy levels of semiochemicals. In contrast, according to an EPPO guideline, semiochemicals' efficacy data can be extrapolated across different crops. Similarly, scientific knowledge supports extrapolation of efficacy data from greenhouse cultured crops to crops growing in open fields and vice versa. To extrapolate to other geographies, certain factors need to be taken into account, such as temperature and number of target pest species generations.

The final aspect focused on the challenges relevant to aquatic toxicity testing for semiochemicals, given their intrinsic properties, such as poor solubility in water, high volatility, and rapid degradation. Alessandra MOCCIA discussed the difficulties in maintaining relevant concentrations of tested semiochemicals and the unrealistic conditions required for aquatic testing that involve using solvents, closed or semi-static systems, and stabilisers. She questioned the necessity of such testing, which results in no acceptable data from the regulators. Finally, she suggested that if aquatic organisms are not exposed to the active substances due to their physicochemical properties, conducting studies may not be appropriate.

Canada mentioned that aquatic non-target testing for semiochemicals is not typically required unless the product is applied directly to water. Similarly, Germany confirmed that they had no issues with aquatic testing, mainly due to the use of passive dispensers, which result in negligible exposure to non-target organisms. Following a question about the solubility values of different pheromones, Alessandra MOCCIA acknowledged that the values might have been reported at different temperatures, and this will be checked. Another point raised was whether the potential exposure of aquatic organisms to spray applications of non-retrievable dispensers needs to be considered. The speaker agreed that this exposure needs to be addressed, noting that while risk assessments should be conducted, the quality of generated data remains a challenge due to the physicochemical properties of the semiochemicals.

Finally, the discussion shifted to the potential classification of semiochemicals as low-risk substances in Europe and the need for a more pragmatic approach in regulatory frameworks. Participants suggested that the current hazard-based criteria might not be suitable for semiochemicals, and a balance should be found to ensure both regulatory compliance and practical applicability.

Panel Discussion of Sessions 3

The panel discussion brought together the session speakers to address questions posed by the participants related to semiochemicals and the presentations. The conversation began by informing the group about recent advancements in in vitro testing for volatiles, and there was a question whether this

knowledge could be transferred to aquatic toxicity testing for semiochemicals. It was noted that while in vitro methods are more advanced for mammalian toxicity, there are no aquatic tests that could adequately test volatile compounds such as semiochemicals. The discussion reiterated again the challenges of maintaining test concentrations in aquatic methods and the unrealistic modifications often required for testing.

The potential application of semiochemicals in water was discussed with respect to managing invasive marine pests such as the crown-of-thorns starfish on the Great Barrier Reef. To be effective, such an approach should overcome the technical challenge of achieving a constant release of pheromones in water, which may require active pumping systems. Given the testing challenges, it was acknowledged that the evaluation of semiochemicals for aquatic toxicity could potentially be adapted within various regulatory systems to take into account these challenges.

An interesting and successful case study on the application of pheromones in the rice fields of Valencia, Spain, was shared with the participants. This regional biocontrol project significantly reduced the use of synthetic pesticides and restored ecological balance in a nearby UNESCO-protected wetland. The example illustrated the potential benefits of semiochemicals in integrated pest management (IPM) and their importance for long-term ecological benefits.

The panel discussed the high costs and long timelines for Research & Development, as well as the registration of semiochemicals, which can be prohibitive for small companies and startups. There was a consensus that regulatory systems need to evolve to facilitate faster market access for semiochemicals. The idea of extrapolating efficacy conclusions from one crop to another (all crops affected by the same pest), in all conditions (open crops, protected crops, greenhouses), in all geographies (taking into account the temperature, number of pest generations which might differ) was suggested as a potential solution and there is a possibility to be considered in an EPPO Guidance Document, which is under revision.

The panel also addressed the broader benefits of using biologicals, including their role in reducing greenhouse gas emissions. It was noted that regulatory systems often focus on hazard data and may not fully account for the long-term benefits of biocontrol products. The discussion emphasised the need for a more holistic approach to risk assessment of plant protection products, such as semiochemicals, that considers the overall impact on ecosystems and food production systems.

The panel highlighted the need for regulatory frameworks to adapt to the unique characteristics of semiochemicals. The discussion underscored the importance of considering both the immediate and long-term benefits of biocontrol methods in achieving sustainable pest management.

In conclusion, this seminar session provided a platform to consolidate ongoing efforts related to semiochemicals and present the progress and findings of the OECD project on the revision of the Guidance Document on Semiochemicals Active Substances and Plant Protection Products. Semiochemicals, which are naturally occurring substances emitted by plants, animals, and other organisms, play a crucial role in intra- and inter-species communication. These substances are recognised for their minimal concerns when used as plant protection products (PPPs) due to their target-specific and non-toxic mode of action. Although they have variable chemical structures, their properties indicate low concern as they are emitted and active at very low concentrations, often comparable to their natural background levels. They are degradable, non persistent, and non bioaccumulative. During the seminar, a revised calculation method of background levels, confirmed based on reliability criteria, was presented and integrated into the draft updated OECD guidance document, which is now available for comments by the EGBP. It was encouraged to carry out fit-for-purpose risk assessments in line with the existing OECD guidance document and scoping work of other groups than SCLPs. Additionally, potential future OECD activities were discussed, focusing on identifying cases where existing risk-assessed semiochemicals could be applied in other regions to facilitate mutual recognition of assessments. There was consensus that this should remain a point of ongoing collaboration among OECD countries and stakeholders

Presentation Slides

All presentation slides can be found online at Seminar on Emerging Risk Assessment Approaches for Biopesticides.

Annex A. Programme of the 13th Expert Group on BioPesticides Seminar on "Emerging Risk Assessment Approaches for Biopesticides"

Day 1 – 25 February 2025

Session 1: Regulatory Considerations for Peptides

***Chair*: Emma BABIJ,** Health Canada, Canada and **Eric LIÉGEOIS**, EC, DG Santé, Belgium

9h30

Introduction

Purpose and structure of the session

Magda SACHANA, OECD Secretariat

9h40

Natural and natural-like peptides – considerations for inclusion as biocontrol agents

Andrea CHINI, National Biotechnology Centre, Spain

10h10

Target-oriented functional peptides for plant disease control. Development and challenges

Emilio MONTESINOS, Institute of Food and Agricultural Technology, University of Girona, Spain

10h30

Case studies as examples of peptides proposed as plant protection products

Eva VAN HENDE, Biotalys and **Matthew ORR,** Vestaron

Tea/Coffee break (10h50-11h15)

11h15

Reviewing the definition of biocontrol in light of new peptide technologies for plant protection

Jennifer LEWIS, IBMA and **Emmanuelle BONNERIS**, Bayer

11h40

Regulatory challenges for peptides within plant protection products and how they are resolved

Jacobijn VAN ETTENT, Ctgb, The Netherlands

12h00

Canada's Experience Regulating Peptides as Pest Control Products

Emily HOPWOOD, Health Canada, Canada

12h15

Panel Discussion of Sessions 1

Considerations for defining certain peptides as biocontrol agents

Discussion on regulatory needs to assess human and environmental risks and risk management

Panelists: Emmanuelle BONNERIS, Andrea CHINI, Jennifer LEWIS, Emilio MONTESINOS, Matthew ORR, Jacobijn VAN ETTENTBD, Eva VAN HENDE

Moderators: **Emma BABIJ,** Health Canada, Canada and **Eric LIÉGEOIS**, EC, DG Santé, Belgium

Lunch break (13h00-14h00)

Session 2: Taxonomy and safety considerations for *Bacillus thuringiensis*-based pesticides

***Chairs*: Emma BABIJ,** Health Canada, Canada and **Eric LIÉGEOIS**, EC, DG Santé, Belgium

14h00

Introduction

Purpose and structure of the session

Emma BABIJ, Health Canada, Canada

14h10

***Bacillus cereus* sensu lato – phylogenetic tree**

Martin Steen MORTENSEN, DTU National Food Institute, Denmark

14h25

***Bacillus cereus* sensu lato as microbial contaminants in food**

Angela CATFORD, Health Canada, Canada

14h40

Identification of Genetic Markers for the Detection of *Bacillus thuringiensis* Strains of Interest for Food Safety

Mathilde BONIS, French Agency for Food, Environmental and Occupational Health & Safety-ANSES, France

15h10

Key considerations for assessing the hazard potential of *B. thuringiensis* strains detected in foods

Sophia JOHLER, Ludwig Maximilian University of Munich, Germany

Tea/Coffee Break (15h40-16h00)

16h00

***Bacillus thuringiensis*: Taxonomy, Agricultural Use, and Implications for food safety**

José CARVALHO, Certis Biological on behalf of IBMA, Belgium

16h15

New Bt Strains and Identity

Nina JOERGENSEN and **Rosa CRIOLLO**, FMC

16h30

***Bacillus thuringiensis* - QPS assessment**

Lieve HERMAN, *EFSA, Chair of EFSA's Scientific Panel on Biological Hazards Qualified Presumption of Safety of Bacillus group, ILVO, Belgium*

16h45

Panel Discussion of Sessions 2

Food-borne outbreaks – Can *Bacillus thuringiensis* approved strains play a role?

Panelists: Mathilde BONIS, Angela CATFORD, José CARVALHO, Lieve HERMAN, Nina JOERGENSEN, Sophia JOHLER, Martin STEEN MORTENSEN.

Moderators: **Emma BABIJ,** Health Canada, Canada and **Eric LIÉGEOIS**, EC, DG Santé, Belgium

17h30

Regulatory responses and challenges

Tour de table to share experiences, perspectives and challenges for regulators, businesses, and consumers.

17h50

Wrap-up and way forward

Emma BABIJ, Health Canada, Canada and **Eric LIÉGEOIS**, EC, DG Santé, Belgium

18h00 END OF DAY 1

Day 2 – 26 February 2025

Session 3: Risk Assessment of Semiochemicals

***Chairs*: Emma BABIJ,** Health Canada, Canada and **Eric LIÉGEOIS**, EC, DG Santé, Belgium

9h30

Introduction

Purpose and structure of the session

Eric LIÉGEOIS, EC, DG Santé, Belgium

9h40

Technical Overview of Semiochemicals

Vicente NAVARRO-LLOPIS, Universitat Politècnica de València, Spain

10h10

Revised Calculation Method

Tomasz MAGACZ, SynTech Regulatory, GAB Consulting GmbH, Germany

10h40

The EU amended Guidance Document on Semiochemicals

Eric LIÉGEOIS, EC, DG Santé, Belgium

Tea/Coffee break (11h10-11h30)

11h30

Debunking Myths About Semiochemicals

Alessandra MOCCIA, Suterra, Spain, IBMA

12h00

Panel Discussion of Sessions 3

Considerations for internationally accepted background levels
Discussion on an internationally harmonised risk assessment framework

Panelists: Tomasz MAGACZ, Alessandra MOCCIA, Vicente NAVARRO-LLOPIS

Moderators: **Emma BABIJ,** Health Canada, Canada and **Eric LIÉGEOIS**, EC, DG Santé, Belgium

13h00 END OF SEMINAR
Lunch break (13h00-14h00)

Annex B. Participants list

Participants List for 9th Meeting of the Expert Group on Biopesticides (EGBP)
Liste des Participants pour 9th Meeting of the Expert Group on Biopesticides (EGBP)

25/2/2025 - 26/2/2025

Australia/Australie

Mr. Bartley BAUER	*Director, Efficacy and Safety* *APVMA*
Mr. Scott HANSEN	*Chief Executive Officer* *Australian Pesticides and Veterinary Medicines Authority (APVMA)*
Dr. Selma KAASINEN	*Director, Health Assessment* *Australian Pesticides Veterinary Medicines Authority*
Mr. Mizanur RAHMAN	*Senior Risk Evaluator* *APVMA*
Dr. Maria TRAINER	*Executive Director* *Registration Management* *Australian Pesticides and Veterinary Medicines Authority*

Austria/Autriche

Mr. Christoph GASSNER-SCHNECKENLEITHNER	*Plant Protection Products* *Austrian Agency of Health and Food Safety (AGES)*
Ms. Verena HAUDEK-PRINZ	*Department for Plant Protection Products* *Austrian Agency of Health and Food Safety (AGES)*

Belgium/Belgique

Dr. Lieve HERMAN	*Unit Head- Technology and Food Science* *ILVO - Flanders Institute for Agriculture, Fisheries and Food*

Canada

Ms. Emma BABIJ	*Head of Microbial and Biochemical Evaluation Section,* *Pest Management Regulatory Agency* *Health Canada*
Ms. Angela CATFORD	*Section Head, Bureau of Microbial Hazards* *Food and Nutrition Directorate, Health Products and Food Branch* *Health Canada*
Ms. Emily HOPWOOD	*Senior Scientific Evaluator, Microbial and Biochemical Section* *Pest Management Regulatory Agency, Health Evaluation Directorate* *Health Canada*
Mr. Jonas PTASINSKI	*Senior Scientific Evaluator, Microbial and Biochemical Section, Health Evaluation Directorate* *Pest Management Regulatory Agency* *Health Canada*
Ms. Esther SETO	*Senior Scientific Evaluator, Microbial and Biochemical Evaluation Section* *Pest Management Regulatory Agency* *Health Canada*
Ms. Émilie TURGEON	*Senior Scientific Evaluator, Bureau of Microbial Hazards* *Health Products and Food Branch* *Health Canada*

Costa Rica

Mr. Andrés ARAYA	*Health Ministry* *Registry* *Health Ministry*
Ms. Silvia DELGADO GRANADOS	*Unidad de Registro de Agroquímicos y Equipos de Aplicación*
Ms. Adriana MORA BERROCAL	*Laboratorio de Análisis de Residuos de Agroquímicos* *State Phytosanitary Service*
Ms. Jeannette VENEGAS ALVARADO	*Unidad de Evaluación Ambiental de Agroinsumos* *Dirección de Gestión de Calidad Ambiental, Ministerio de Ambiente y Energía*

Denmark/Danemark

Mr. Martin MORTENSEN	*Senior Researcher* *National Food Institute, Technical University of Denmark (DTU)*
Dr. Birte Fonnesbech VOGEL	*Ph.D. Chemical Engineer* *Danish Environmental Protection Agency* *Ministry of Environment of Denmark*

Estonia/Estonie

Dr. Priit KERSEN	*Chief Specialist (toxicology)* *Estonian Agriculture and Food Board*

France

Ms. Mathile BONIS	*Anses - Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail*

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Mme Marie Louisa RAMAROSON	*Ministère de l'Agriculture, de l'Agroalimentaire et de la Forêt*

Germany/Allemagne

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Dr. Sabrina FEUSTEL	*Department Pesticides Safety* *German Federal Institute for Risk Assessment (BfR)*
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Dr. Joerg WENNMANN	*Julius Kühn-Institute*
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Dr. Julia EBELING	*German Federal Institute for Risk Assessment (BfR)*
Dr. Hendrik FRENTZEL	*Unit Bacterial Toxins. Food Service* *German Federal Institute for Risk Assessment (BfR)*
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Greece/Grèce

Ms. Ourania MELITA	*Department of Plant Protection Products* *Ministry of Rural Development and Food*

Italy/Italie

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Japan/Japon

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Mexico/Mexique

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Ms. Rosa CRIOLLO	*Regulatory* *FMC Agricultural Solutions*
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Ms. Edwiges FERREIRA	

LMU Munich

Professor Sophia JOHLER	*Chair of Food Microbiology* *Competence Center for Food Safety*

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Dr. Vicente NAVARRO LLOPIS	*Instituto Agroforestal del Mediterráneo-CEQA*

University of Girona

Professor Emilio MONTESINOS	*Professor of Plant Pathology and Microbiology* *Institute of Food and Agricultural Technology*

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Ms. Kalliope PAPADOPOULOU