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Report of the 11th Expert Group on Biopesticides Seminar on Different Aspects of Efficacy Evaluation of Biopesticides

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REPORT OF THE 11TH EXPERT GROUP ON BIOPESTICIDES SEMINAR ON DIFFERENT ASPECTS OF EFFICACY EVALUATION OF BIOPESTICIDES

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Foreword

This report summarises the discussion and outcomes of an OECD Expert Group on BioPesticides (EGBP) seminar on Different Aspects of Efficacy Evaluation of Biopesticides. This one-day and a half seminar was virtually held on 28 and 29 June, 2021, before the annual meeting of the EGBP, a sub-group of the OECD Working Party on Pesticides (WPP). This seminar was originally planned to be held in June 2020 but was postponed due to the Covid-19 situation. The seminar was the eleventh in a series of EGBP (formerly the BioPesticides Steering Group, BPSG) seminars that focus on biopesticide related issues of interest to OECD governments and other stakeholders.

The seminar was chaired by Shannon Borges (US EPA), chair of the EGBP. Ninety five experts from ten OECD member countries, the European Commission, 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 list of participants can be found at Annex 2.

The seminar was organised to present and discuss the similarities and differences of the efficacy evaluation of the different categories of biopesticides. Biological pesticides involve: microbials, pheromones and other semiochemicals, plant extracts (botanicals) and invertebrates as biological control agents. The seminar was also an opportunity to identify key issues and challenges in the area of efficacy evaluation of biopesticides and initiate a dialogue about the further steps for OECD countries and key stakeholders in OECD and non-OECD countries to address the identified issues.

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Introduction

This report presents the results and recommendations of an OECD Seminar on “Different Aspects of Efficacy Evaluation of Biopesticides”. Its aim is to provide an overview of the issues associated with this topic from the perspective of research, industry and regulatory experts, and to provide input to the potential future development of recommendations for possible further OECD work.

The seminar focused on promoting a dialogue on “Different Aspects of Efficacy Evaluation of Biopesticides” and initiating a process to make recommendations for improvements by exchanging information on governments’ or organisations’ experiences and challenges in the area of "efficacy evaluation of biopesticides" with the potential to recommend possible further harmonisation of trial methods and improvement of regulatory requirements in the area of efficacy evaluation of biopesticides.

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

The main objective of the EGBP Seminar was to discuss the following issues and statements:

- Efficacy data should not be generated on the standard indicator organisms, but efficacy levels should be determined on target pests and side effect levels on relevant pest antagonists;
- Efficacy data should include appropriate positive controls and trial numbers as well as variability;
- How should efficacy testing of biopesticides be compared to conventional pest control chemicals;
- There is no role for efficacy testing in (bio)pesticide regulation and market forces should rule;
- How does the different use of biostimulants and biopesticides (especially microorganisms) in agriculture affect the efficacy testing requirements, since as pesticidal testing focuses on control of the pest and diseases whereas biostimulants testing focuses on effects on abiotic stresses;
- The use of extrapolation possibilities should be maximized especially for categories of biopesticides that require limited or no evaluation of efficacy;

- Current standards for efficacy evaluation are not appropriate to assess modern techniques such as Precision Agriculture (PA) and Wireless Sensor Network (WSN);
- How should the efficacy of biopesticides be evaluated when applied as part of one or more different IPM modules;
- How should the overall agricultural benefit, in terms of the level of pest control/reduction achieved, be expressed to justify the use of the biopesticide;
- How to improve the use of international efficacy data and/or assessments for the efficacy evaluation of biopesticides.
- The effective dose for semiochemicals can be reduced with continual usage of the semiochemical plant protection product (e.g. continuous flow from a dispenser) and therefore establishing a minimum effective dose is inappropriate.
- The concept of minimum effective dose is especially inappropriate in the case of microbials because they tend to multiply when they meet their target organism. Efficacy is not proportionate to the application rate, there is no simple cumulative effect.
- For invertebrates a simple registration process at EU-level should be developed.

Structure of the Seminar

The Seminar programme is provided in Annex 1. Invited speakers included:

- International experts in this field;
- Government representatives; and
- Representatives from industry and research institutes.

Presentations were grouped into the following three sections:

- Introduction to the topic
- Stakeholders' experience and perspectives
- Government experience and perspectives

There was a short discussion after each set of presentations and a more general discussion at the end of the seminar.

Introduction to the topic

Application and Management of Biopesticides for Efficacy and Reliability (AMBER)

by David Chandler, The University of Warwick, UK [PPT 1]

At the beginning, David Chandler introduced the Application and Management of Biopesticides for Efficacy and Reliability (AMBER) project, which is funded by the UK agriculture and horticultural development board and aims to help growers improve their use of biopesticides by identifying the reasons why biopesticides can be inconsistent in commercial practice and by developing generic management tools and practices to improve performance. Then, he provided a broad overview of how the project has been operating and highlighted the main achievements. He clarified that invertebrate biocontrol agents were not considered at the AMBER project and that the main focus, until now, has been on microbials used in protected edibles, protected ornamentals, and free stock crops.

Within the project, a series of benchmarking trials were performed that were not classic efficacy trials but based on natural pests and disease outbreaks. The approach included comparison of biopesticides with the performance to a standard chemical treatment and allowed the collection of detailed quantitative and qualitative information on the performance of both the biopesticide and also the grower. The main lesson learned was that biopesticides require targeted precision application systems and that labels for the products were difficult to follow, which explains why the companies now provide additional guidance.

The researchers also observed that the spray equipment being used is not fit-for-purpose for microbials. They noted that water volumes were often too high, which led to run-off and lower deposition of product on the crop. These observations resulted in improved recommendations for growers - for example, water volumes based on floor area are not appropriate for vertical crops - which were shared through knowledge exchange sessions.

The researchers also observed that biopesticides do not have an instantaneous mode of action and, consequently, their performance is significantly affected by speed of effectiveness (i.e., speed of pest kill). A mathematical tool was developed to test out pesticide strategies that include biopesticides that can help precision application. The model considers the number of individuals at each life stage, tracks maturation to next life stage, reproduction, and life stage. It can interpose biopesticide mortality against different life stages and test out strategies *in silico.* The researchers concluded that biopesticides have a very important role in future crop protection, but they are not applied well enough and for this reason there is need to assess their performance under real world conditions.

Although the project was focused on indoor glasshouse crops, the conclusions related to the need for precision application are also relevant to outdoor crops. There are research projects underway looking at biopesticides as part of IPM on outdoor horticultural crops. It was emphasised that there is an opportunity to learn from other crop sectors, for example, on smart decision support. It was confirmed that the area where the knowledge is probably poorest is on spray application and it was recommended that we should all work together to address these cross general themes about spray application and effective dose interactions in IPM.

The Commission des essais biologiques (CEB) of the French plant protection association "Végéphyl"

by Philippe Cagnieul, CEB, France [PPT 2]

In this presentation, Philippe Cagnieul began by introducing the Commission des essais biologiques (CEB), the French Commission for Biological Trial that began 70 years ago with the combined contribution of different actors, including the plant protection industry, government agencies, advisors, and professional agricultural organisations. From the very beginning, CEB has built an extensive catalogue of guidelines and technical documents, mostly for chemical plant protection products and the speaker provided some examples.

CEB guidelines always contain five main chapters: experimental conditions, treatments, assessment and scoring, statistical analysis, and interpretation of results. It was emphasised that the CEB guidelines are fully compatible with official standards recognised at the European level.

For the last 15 years, CEB analysed potential differences between plant protection products of chemical and natural origin. CEB has published a number of recommendations for field testing that are applicable to natural products. These technical recommendations include optimised experimental design that consider the mode of action of natural products and the various treatment applications.

He concluded that there is need for flexibility in the experimental protocols when applied to biopesticides, as they are special compared to chemical pesticides from a methodological point of view.

Update on EPPO Standards relevant to efficacy assessment of biopesticides

by Ewa Matyjaszczyk, EPPO, France [PPT 3]

Ewa Matyjaszczyk started her presentation by describing EPPO, which is the European and Mediterranean Plant Protection Organisation that engages with the development of EPPO standards on plant protection products (PPPs). All standards are available through the EPPO database and these standards are grouped into general and specific categories. General standards cover general aspects of efficacy evaluation, while specific standards cover usually one type of PPP; one combination of pest and crop; several pests in one crop; one pest in several crops; or several pests in several crops and provide details for individual field trials.

The remainder of her presentation focussed on EPPO standards that are relevant to biopesticides efficacy assessment. However, she explained that standards which are not focused on biopesticides are also relevant to biopesticides efficacy assessments because EPPO standards are interlinked. Similarly, standards for minor crops may be relevant to some biopesticides and their efficacy assessment. The general principles for efficacy evaluation of PPPs with a plant defence induction mode of action are also applicable to the efficacy evaluation of microbial pesticides. However, PPPs based on microorganisms may be highly specific to a given pest and may require specific environmental conditions to achieve optimal effectiveness. In addition, standard principles of effective evaluation for low risk PPPs are applicable for microorganisms. Of particular importance are the principles of efficacy evaluation for mating disruption pheromones.

She concluded by saying that many EPPO standards are useful for efficacy assessment of biopesticides but six of them have particular focus on biopesticides.

Government Experience and Perspectives (Part 1)

Swiss experience with efficacy evaluation of fungicidal and resistance inducer products of natural origin

by Lucius Tamm, Research Institute of Organic Agriculture FiBL, Switzerland [PPT 4]

Lucius Tamm began his presentation by explaining that his talk will cover a number of examples focusing on products of natural origin, their uses from a practical point of view, the application strategies, and the efficacy expectations for this type of product. He also shared examples on how they evaluated the efficacy of such products within IPM strategies or as standalone PPPs.

He emphasised the importance of knowing about the biology of the target pathogen or disease because it determines the correct time of application. With respect to the complex issue of inducing plant resistance, the plant defends itself better against microbial attack either by triggering induced resistance on the aerial parts of a plant or the rhizosphere.

He explained that susceptibility is variable during the lifecycle of the plant. For example, the plant tissue becomes susceptible when the plant growth is very rapid and natural resistance increases towards the end of the season as the age of the leaf tissue increases. Consequently, it is critical to apply the biopesticide during periods of greater susceptibility and not at a time when the plant is already resistant by its own natural triggers. This information can be translated into a plant protection strategy that is optimised to the needs of the plant.

He stressed also the importance to look at the disease pressure in the untreated controls when evaluating efficacy, especially when efficacy looks high. Usually, it is expected maximum efficacy level no matter what the disease pressure or what the climate conditions are. However, in case of natural extracts, good efficacy mainly is expected in case of low to moderate disease levels. The efficacy seems to drop at higher disease pressures. That is why the strategy chosen should aim to suppress an epidemic and why the above mentioned information should be taken into account in efficiency trials.

Dr. Tamm listed a number of efficacy challenges for biopesticides, including UV stability of active substances, their limited uptake into plant tissue in case of rain, and the physiological stage and nutritional state of the plant itself. Optimisation of efficacy trials can be achieved by taking into consideration all these parameters within a strategy, but this approach is labour intensive and costly. And in most cases, efficacy can be evaluated better once a new biopesticide is incorporated into a strategy where multiple treatments are applied against certain pests and/or diseases to demonstrate the added value.

He concluded that standard field trials following EPPO standards are essentially designed to explore the potential and the limits of biopesticides. However, application protocols should be adapted to the product properties and take any existing experience into account to meet efficacy expectations. It is more difficult to demonstrate the added value, which is often there, as they need to be embedded in plant protection strategies. In addition, untreated controls often create unrealistic expectations as overwhelming disease pressure in plants might lead to the underestimation of the value of a biopesticides, which could perform better once included in a plant protection toolbox and used in a larger scale. He closed his talk by mentioning that they often see variability of efficacy between field trials, something that is expected due to the mode of action of biopesticides. Even when a specific

trial is not giving any decent level of efficacy, it helps to understand how to better use the product for the benefit of the farmers.

Value Assessment of Biopesticides in Canada

by Michael Downs, PMRA, Canada [PPT 5]

Michael Downs started by explaining that his talk would provide a brief and high level overview of Canada's approach to conducting a value assessment of biopesticides. He clarified that the value requirements include efficacy and crop tolerance information, considerations of the level of control and other benefits information. According to PMRA, biopesticides include three different types or classes covering microbials; pheromones and other semiochemicals (naturally occurring or synthetically derived); and non-conventional chemical pesticides (i.e. naturally occurring substances that have low hazard or toxicity to mammals and other non-target organisms, are not persistent in the environment, have a non-toxic mode of action against the pest, and have low potential for resistance to develop).

He explained that the *Pest Control Products Act* is the legislation that governs how pesticides are regulated within Canada, and the value of a pesticide is defined within that act. The definition of the value of a product considers the actual or potential contribution to pest management, and takes into account the proposed conditions of registration that are included in the label based on consideration of the product's efficacy, health, safety or environmental benefits, as well as social and economic impacts. And the latter factors weigh more heavily for the biopesticides.

Consideration of product efficacy takes into account traditional trial data, but it is supplemented by benefits information provided by the registrants that help determine the acceptable value of certain biopesticides, especially in cases where the efficacy is less than typically required for a conventional pest control product (e.g. partial suppression or alternative lower level types of claims).

With respect to efficacy and crop tolerance, Canada considers both laboratory and field trials. He mentioned that they assess application rates - including the proposed rate range based on a number of treatments that include positive or negative controls - the treatment proposed for registration, and ideally a registered comparative treatment. In addition, they consider use history information if a product is already registered and used in a foreign jurisdiction, as long as it is relevant to Canada. Finally, relevant published scientific literature and scientific rationales can also be used.

For non-conventional products, including biopesticides, a claim of partial suppression (e.g. between 30 and 60% compared to control) is accepted in addition to the claims typical of conventional pesticides (e.g. control or suppression). Additional claims linked to the mode of action of biopesticides (e.g. reduction of inoculum) or claims of reduction in damage to the crop and reduction in the pest population are also considered.

He elaborated on the benefits beyond efficacy and crop safety that relate to social and economic impacts. For example, information that demonstrates how the proposed use of the product could impact the competitiveness of Canadian farmers or address key pest management priorities. The PMRA also consider health, safety, and/or environmental benefits not otherwise considered in the risk assessment. For example, if the product controls a poisonous weed or reduces the formation of harmful mycotoxins in diseased plants, these could be considered health benefits. Other benefits that can be considered under the value assessment include contributions to resistance management, integrated pest management, and risk reduction.

He concluded that the ultimate goal is to determine whether the value of the product is acceptable. The PMRA uses a weight of evidence approach that considers a number of different types of information that is broader than efficacy and crop safety. Those different types of information could be weighted differently depending on the situation. For biopesticides in particular, the benefits information could weigh in a lot more heavily and there is flexibility and consideration of the level of control is claimed.

He noted that there are cases where a set of efficacy data can be applied to multiple different crops and extrapolated. The usual situation would be for herbicides, where the weeds present are not specific to the crop itself. However, while certain claims for insects and plant pathogens could be general in nature, many are host and/or pest-specific. In those cases, specific crop pest data is required in order to support the efficacy claim.

Although it is not clear that the efficacy evaluation of biopesticides in Canada has helped with their adoption in agriculture, there is some level of comfort among users that label claims have been vetted and approved by the PMRA. It was noted that it could take several years for users to become comfortable and familiar with biopesticides.

Experience with evaluating the efficacy of biopesticides in the US

by Helen Hull-Sanders, US EPA, US [PPT 6]

Helen Hull-Sanders opened the presentation by providing the definition of biopesticides in the United States that covers pesticides that are derived from natural materials, including animals, plants, bacteria, certain minerals that can be classified into microbial pesticides, bio derived chemicals, plant incorporated protectants, and RNA interference pesticides.

The basis for requiring efficacy data by the United States EPA (US EPA) is to ensure that labelling on the products provides consumers with accurate information concerning rate of application; methods of application; and precautions to protect human health and the environment when using pesticides against pests of concern, especially public health pests. The efficacy data applies to both vertebrate and invertebrate pests. All companies are required to obtain and maintain efficacy data for any pest listed on the label and the Agency reserves the right to review, on a case by case basis, product performance data for any pesticide product registered or proposed for registration. All data are reviewed for products proposed to treat pests of public health concern, wood-destroying pests, structural pests, and certain invasive species.

She explained that US EPA has guidance on acceptable labelling claims and product performance testing.

She then provided some examples and emphasised that the US EPA looks at the product to make sure that the labelling claims are accurate, particularly when the effectiveness of a treatment is not readily apparent to the applicator at the time of application. She clarified that the US EPA does not require review of the data for agricultural invertebrate pests or household pests that do not fall under pests of public health concern, structural pests, or invasive species. However, registrants are required to maintain data on all pests listed on their label and the US EPA may call in the data on a case by case basis. Pesticide efficacy data are reviewed, especially for skin-applied repellents (considered as biocides in some OECD member countries), as well as residual and contact sprays.

She indicated that the US EPA provides guidance for data generation but does not provide guidance on the development of protocols. Protocols are submitted and reviewed by a panel of scientists for scientific validity and probability of generating data that will yield accurate

efficacy claims. Most data are generated from laboratory studies, small scale field plots, or large scale field trials under actual use conditions. The process of efficacy data review starts when the registrant submits an efficacy related package that might include data to support a new product, a new pest, and/or a new efficacy-related labelling claim on an existing product. The reviewers evaluate the data and write a review, which contains a summary of the data and the conclusion about the efficacy-related labelling claims supported by the data. She presented a number of US EPA guidelines that are available, noting that some are currently being updated.

Stakeholders' Experience and Perspectives

How to successfully evaluate the efficacy of semiochemical products

by Alessandra Moccia and Daniel Casado, Suterra Europe Biocontrol, Spain [PPT 7]

Alessandra Moccia started the presentation by clarifying that semiochemicals technically fall outside of the definition of a pesticide. Although semiochemicals are typically considered 'biopesticides', the term 'pesticide' means literally something that is killing pests; however, the mode of action of semiochemicals is non-toxic. Semiochemicals interfere and influence the behaviour of the target pest. This is important when designing and evaluating efficacy trials for semiochemical products because no killing effect is observed.

Semiochemicals are naturally occurring substances that are used for communication between different organisms. If the organisms belong to the same species, these are named pheromones. If the organisms belong to different species, they are referred to as allelochemicals. All semiochemicals are target-specific, function by a non-toxic mode of action, and have short environmental persistence. Semiochemicals are usually effective at very low doses that are comparable to naturally occurring concentrations.

Semiochemicals for pest control rely on two techniques that are both characterised by a nontoxic mode of action: mating disruption and luring. In the case of mating disruption, sex pheromones are used as the active substance to actively disrupt the mate-finding behaviour of the target pest. The other technique in which similar chemicals are involved for pest control is luring and is used in combination with a killing agent or a trap. In this case, the specificity might be lower, depending on the attractant that is used.

She highlighted that there are some principles to be taken into consideration when setting up efficacy trials for semiochemicals. First, the specific mode of action of the product needs to be considered as it is associated with changes in the behaviour of the target pest so the trial design needs to account for the target pest biology and behaviour. Second, the trial should reflect the desired label claims and should include broader consideration of value, including contribution to an integrated pest management system.

EPPO standards are considered to be useful to setup efficacy trials for semiochemicals and help to extrapolate to other crops because the direct effect is on the pest and independent from the crop. Since semiochemicals are effective on a certain pest, in geographies with similar conditions, where the pests have a similar life cycle, then same efficacy trials can be used and shared. She closed her part by encouraging countries also outside the EPPO region to adopt these specific to semiochemicals standards for efficacy trials.

Daniel Casado continued the presentation by explaining why semiochemicals are special from an efficacy point of view and why typical pesticide trial designs are not appropriate for these products. He reiterated that semiochemicals are manipulating pests' behaviour and the plants are not directly protected. For this reason, one of the most specific requirements for efficacy trials is for plots to be relatively large. In trials where pheromones for mating disruption are used, the danger is that females might mate outside of the plot and come into the trial area to lay their eggs, altering the results and for this reason efficacy trials should take place in relatively large areas. Captures in pheromone-baited traps are typically strongly inhibited in mating disrupted areas. This is an indicator of efficacy, but not proof of it. Proof of efficacy should always be evaluated on crop. Finally it is important

to stay away from cage studies that may bias results. Semiochemicals affect insect behaviour and cages create an unnatural scenario that may condition insect behaviour. On the other hand, when semiochemicals are used in luring products, information provided by traps is uninformative. As in the case of mating disruption, efficacy should be established by evaluation on the crop. Application rates should be established on the basis of these evaluations of crop health, never on studies of attraction radius of the lures being used.

He emphasised that the replication of trials for semiochemicals is very challenging for mobile insects and large plots should be considered together with appropriate statistical analysis. In contrast, trials on small square plots can be considered in case of immobile or almost immobile insects to achieve replication of results. The economic point of view needs also to be taken into account as most of the semiochemical products will end up in a niche market. In general, untreated controls are not included but rather some kind of standards and good practices are used, otherwise this would lead to a very expensive trial. Using models, he illustrated how the establishment of a minimum efficacious rate lacks of a technical-base for semiochemical-based biopesticides. The reason being that the effect is density dependent. The same dose of one of these products may have different efficacy in situations with varying pest pressure. With lower pressure, lower doses will be successful. Furthermore, overtime use of this type of products typically results in a decrease of pest populations, hence over time it is possible to reduce doses achieving the same results.

He concluded that semiochemicals should be evaluated based on the reduction of crop damage from pests and other collateral benefits. Large trials are recommended in most of the cases for semiochemicals, especially for flying pests and establishing a minimum efficacious rate should not be required for them.

Natural background levels might be more important for the efficacy of food attractants than sex pheromones. Regulators often focus on the importance of establishing a minimum effective dose, which may not be relevant to semiochemical products. The EPPO standard recommends the assessment of only one dose that is lower than the target dose and not multiple doses. It was noted that flexibility in concentration of active constituent is necessary because effective control may be achieved with progressively lower concentrations as the insect population declines following successive years of mating disruption. It was clarified that there is no need for a minimum effective dose, one for a high and one for low insect population, but there is need for additional application of pheromones throughout the year and integration in IPM.

Efficacy of Invertebrate BCAs

by Caroline Reid, Bioline Agrosciences, UK [PPT 8]

Caroline Reid, in the beginning of her presentation, highlighted that invertebrate biocontrol agents (BCAs) do not fit directly into the classical definition of plant protection products and that, similar to semiochmicals, the evaluation of their efficacy is challenging. She explained that EPPO standards are not applicable to invertebrate BCAs because they work in a very different way to conventional chemicals or other biopesticides since they either infect the insects or parasitize them. With respect to resistance, she indicated that most beneficial insects do not have a detoxification mechanism. Some adaptation of pests to fight off beneficial insects has been observed but this is uncommon.

The efficacy of invertebrate BCAs depends on the size and density of the pest population. She stressed that, like semiochemicals, if invertebrate BCAs cannot keep pace with the pest population they will be ineffective and that it is important to conduct efficacy tests in large

trial areas to be spatially separated, or even have them caged, as they choose whether to prey on or parasitize a specific pest. She emphasised that invertebrate BCAs are mostly preventative, and are less commonly used to cure a pest outbreak, although this is sometimes how they are used. Invertebrate BCAs are usually introduced by low numbers on a regular and preventative basis, usually before the pest infection.

The selection of a new invertebrate BCA comes from the literature or a laboratory study. The potential of an invertebrate species as a predator or parasitoid comes from the research and depends on a number of parameters e.g. selectivity, pest pressure, availability of other foodstuffs, plant production conditions, pest spectra etc. It needs also to be able to be commercially produced, harvestable, packaged, usable, transportable and releasable.

A multitude of factors will influence the control effect of a natural enemy and these can include: 1) integrated interactions (i.e. when beneficial control agents eat each other), 2) availability of other foodstuffs (e.g. alternative prey hosts, sugar sources), 3) plant resistance, 4) changes in the plant irrigation or fertilization that might alter crop growth and 5) neighbouring crops.

In addition, an invertebrate BCA needs to be licensed but the regulatory criteria for invertebrates are not efficacy-based but instead consider environmental impact (e.g. establishment is a negative characteristic). The criteria vary depending on whether the product is a native or non-native species. She explained that conventional efficacy methodology does not work because some invertebrate BCAs are mobile. Caged plots is a solution but this changes the micro environment for invertebrates and affects the efficacy. Micro experiments are possible but they have a high rate of false positives.

Apart from the obvious environmental benefits, the invertebrate BCAs continue working after application until crop production. If there is food for them to feed on, they will breed and increase in number as time goes on. She concluded that invertebrate BCAs can be an efficient way of controlling pests, but efficacy testing is not always relevant. The products are initially selected based on recorded parameters of predation and parasitism, but they are tested further to define their commercial value. She concluded that reliability and success of a biocontrol agent depends on the action of the biocontrol, pest control, suitability for production, suitability for release and capacity to be established in the environment. Finally, she emphasised that also compatibility of invertebrate BCAs with chemical pesticides is important and needs to be taken into account.

During the discussion, it was noted that EPPO standards for efficacy might be useful in greenhouse settings and that there is need to be more careful when talking about compatibility with chemicals within IPM programs as there have been cases of invertebrate BCAs that proliferated harming other beneficial insects or microorganisms.

Considerations for appropriate assessment of efficacy of biopesticides in the field

by Denise Manker, Bayer Crop Science and Edith Ladurner, CBC Europe – Biogard Div., France [PPT 9]

Denise Manker started the presentation by expressing the importance of adopting the EPPO efficacy standards by all OECD member countries for consistency purposes. She pointed out that efficacy protocols should take into consideration the mode of action of microorganisms used as biopesticides and the standards used for comparison. She emphasised that evaluation of microorganisms' efficacy within IPM programs and the overall value of bioprotectants could also dictate real use patterns. There are several EPPO

standards that are supporting the consideration of efficacy data, but it is difficult sometimes to apply those thoughts and patterns to the wide range of biological treatments. She expressed the need for flexibility in developing these efficacy protocols to make sure that they not only demonstrate the appropriate efficacy but also the value of these different products and particularly how they can provide value in sustainable practices.

Edith Ladurner continued by providing a number of examples to support the argument that the adoption of the efficacy general standards is important but having flexibility would be helpful. She illustrated that the appropriate timing of the applications for a successful establishment of a microorganism on the plant to be protected is important. In addition, she presented the challenges for finding an appropriate standard and compare through a number of examples. IPM approaches are especially needed for the difficult and long season target pests or diseases, which are usually controlled only by applying several different PPPs with different mode of action in combination or in alternation. A possible option to test efficacy would be the selection of an application window for microorganisms. Another option would be to select one generation out of many or several pest generations and try to replace a single chemical application within an IPM program. This approach would allow to have both completely untreated control and partially untreated control in the trial design. She provided an example and concluded that a microbial control agent can be included in an IPM program during a delicate phase or even be challenged by choosing the period of highest risk of infection for a plant. She emphasised that the additional value of microbial control agent can be seen better if included within an IPM strategy.

Denise Manker closed the presentation by summarising that the examples provided show the diversity of the kinds of trials that need to be set up to account for: 1) the different modes of action of microorganisms used as PPPs, 2) the importance of the application timing, and 3) the value of microbial control agents with an IPM program. She concluded that there are policy discussions that are asking for more bio protection products to be available in agriculture and in order to achieve this, there is need for appropriate regulations for these products with predictable paths for registration and a reasonable timeline for review, to really address the demand that is observed from consumers and from growers as well. To that end, better understanding of the modes of action of these products to get protocols to reflect accurately what efficacy these products can provide, and how they can fit into IPM programs can only be achieved by having flexibility in the development of protocols. Having improvements in the review and approval process for biopesticides with respect their efficacy data and their added value would help to achieve this kind of a goal for the growers.

It was clarified that microbial control agents can have more than one mode of action and this issue makes it more complex and valuable, but it also makes it more challenging to develop the right kind of efficacy protocols. It was noted that flexibility is important as it is not pragmatic to have multiple efficacy testing protocols for each situation and in addition to describe efficacy within an IPM strategy. The absence of a reference product is another difficulty but microbial control agents can be considered as a solution for minor uses. It was discussed that efficacy should not be a reason for preventing the authorisation of biopesticides, but on the other hand farmers need a clear indication on the label about their use that has been agreed with the competent authorities.

Government Experience and Perspectives (Part 2)

French experience of efficacy evaluation of biopesticides

by Benedicte Gautier, French agency for food, environmental and occupational health and safety, ANSES, France [PPT 10]

Benedicte Gautier opened the presentation by explaining the European Union's process for placing any plant protection product (PPP), including biopesticides, on the market relies on evaluations performed at the member state level and authorisation that is granted at national level. She emphasised that in France the term "biocontrol" is used instead of biopesticide and is defined as the use of agents and products involving natural mechanisms in the context of integrated pest management (IPM). She clarified that in France, microorganisms, substances of natural origin, and pheromones are regulated by European legislation, whereas a national regulation applies for invertebrates. Her presentation further focused on the experience gained on the evaluation of the level of effectiveness of the substances of natural origin and microorganisms. She noted that quantifying the effectiveness of these products is challenging because of the high intrinsic variability. The minimum number of direct efficacy trials required for low-risk PPPs has been decreased relative to conventional PPPs, according the EPPO standards. She highlighted the dilemma in the EPPO 1/296 standard that aims to facilitate the placement of low risk products by being more flexible regarding effectiveness and by accepting less supporting trials, but also requires the generation of sufficient data to demonstrate acceptable efficacy and provide the user with the conditions under which the product would provide optimal performance.

According to the ANSES's experience, the evaluation of biopesticide dossiers, based on the received data, typically concludes that the effectiveness level of the product is partial and variable. The data provided are often insufficient to identify the conditions of use that allow the best level of effectiveness. Another point she made was on the usefulness of practical value trials (i.e. testing a combined strategy which includes the biopesticide). However some limitations are often identified in experimental design and in quality of statistical analysis.

She emphasised that the summary of the efficacy data is usually sufficient for conventional pesticide products but inadequate for biopesticides. Correct interpretation of the results requires evaluators to open each trial report to better understand the conditions of the trials, check all the assessments, and review the statistical analysis.

With respect to the active substances evaluation, the requirements for effectiveness data are more flexible than for PPP application and might include even fewer trials. On the basis of the partial data submitted, it may be difficult to conclude that the new « biopesticide » active substance is sufficiently effective.

She closed her presentation by suggesting some improvements for the demonstration of the effectiveness of plant protection products based on microorganisms or substances of natural origin, including 1) improvement of the quality of the trials by choosing the appropriate trial design, improving the quality of the sampling, and choosing the appropriate statistical analysis; 2) developing the use of practical value trials which demonstrate the effect in an agronomic programme with other PPPs or non-chemical practices; and 3) better identify the conditions under which the product will provide optimal performance. She concluded that to achieve all these, there is a need to adapt the existing methodology for performing more robust efficacy trials that are applicable for biopesticides.

It was clarified that in France, when there are no EPPO guidelines on certain topics available, then the Commission des essais biologiques (CEB) guidelines can be taken into account and it was noted that the CEB guidelines conform to EPPO guidelines. It was also noted that data from efficacy trials may be helpful to address some of the questions related to the residues of the biopesticides.

Efficacy assessment of biopesticide and supporting Label claims: UK perspective

by Sue Mattock, HSE, UK [PPT 11]

Sue Mattock started by introducing the UK biopesticide scheme that is currently under consultation and was lastly reviewed in 2013 following its inception in 2006. She mentioned that one of their key lessons was to find ways of early engagement and to provide additional support to biopesticide applicants. To this end, HSE established a working group with the UK IBMA.

The approach taken was to: 1) discuss and gain familiarity with EPPO methodology and identify relevant guidance needs; 2) build upon existing knowledge so that the mode of action can be taken into consideration in the trials methodology; and 3) promote good experimental practice and encourage official recognition of trials. The outcome was to produce a UK guideline that not only discussed some of the trial design issues but also explained how to address the data requirements that eventually became an EPPO standard. And she emphasised the importance of building on experience and developing a guidance through collaborative work with relevant industries.

An additional output of this work was the development of the principles of efficacy evaluation for microbials that also became EPPO standards. The aim was to build industry's confidence and to highlight the importance of EPPO standards and principles. Through engagement, they were able to deliver relevant guidance such as the recent EPPO Principles of efficacy evaluation for low-risk plant protection products.

With respect to the EPPO Principles of efficacy evaluation for low-risk plant protection products, Sue Mattock agreed with France that there is a discrepancy between the goal of facilitating access to market for biopesticides and needing to evaluate efficacy to a satisfactory level before approval. This is a point where compromise is needed and where the understanding of the mode of action and trials methodology is so important.

She then focused her talk on the use of preliminary data and information on effectiveness, including dose justification and she touched upon the resistance. Other areas of efficacy data requirements are related either to generate direct or indirect crop safety impacts. Those can be addressed either by reason case, or by observations in the effectiveness trials. She pointed out that there are a number of environmental agronomic factors that are going to be impacted and that there is need to try and determine the conditions that help the performance be optimised. Variable performance can be supported if there is good understanding what those factors are and their impact.

She emphasised that preliminary data from published papers provide an important step in understanding the mode of action, potentially reducing the number of field trials to optimise the efficacy and communicate with growers. Arguments in relation of naturally occurring levels, toxin production and host specificity, formulation and the viability growth are considered important in interpretation of efficacy data and understanding why a certain dose was selected. She reminded the audience that it is possible to adapt and deviate from the EPPO standards as long there is explanation. She pointed out that is important to test under a range of conditions to understand the variability and how to use the product in

practice and to further inform the label. Although it is not a requirement, it is useful, if possible, to have trials where an attempt is made to understand how the biopesticide is going to fit within the integrated programs with conventional chemistry. She informed the group that EPPO has formed an expert Working Group looking at consistency of labelling.

The UK is moving to a position that where the mode of action group is known, then it must be added to the label by 2023. She highlighted that another relevant group in the UK is the resistance action group that works towards the development of relevant guidance and discuss any new cases of resistance. An additional thing that the UK does is to promote to applicants the use of the minor use extrapolation tables to maximize the benefit of that data by extrapolating wherever possible.

She summarised that biopesticides have started to play an increasingly important role in pest management. Knowing the mode of action and making the best use of a range of published research is really critical to understand efficacy data. Efficacy is a central part in optimising product performance, explaining variability, developing recommendations, and supporting the risk assessment and the product label. She closed the presentation by indicating that industry and regulators should continue to develop guidance that is built on experience and that early engagement and support is important before starting with field trials for efficacy.

Experience with evaluating the efficacy of biopesticides in the Netherlands

by Henk Brouwer, Ctgb, NL [PPT 12]

Henk Brouwer described in his presentation the approaches taken in efficacy evaluation of biopesticides in the Netherlands within the last five to six years, and presented the results, the current situation and discussed any remaining issues.

He provided background information about the European Union low risk products that benefit from reduced data requirements for efficacy. He noted that biopesticides do not always receive the low risk status; however, his presentation would focus on biopesticides that are considered low risk products.

He explained that the situation half a decade ago, was that for example the dossiers for the microorganisms were presented with highly variable data and low efficacy, and the outcome of the evaluation was leading to the request of additional data. The level of efficacy that would be required was also questionable as biopesticides are a very diverse group of products with a variety of modes of action. This diversity also prevented researchers from following the same approach for all the types of biopesticides and that primarily there was a lack of guidance. There were some useful standards, but the new low risk status was not accommodated and it was not clear how the number of trials can be reduced.

The first step was for the Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) to establish a green team with members of all expertise and background in microbiology. He highlighted that this was a very important step because efficacy is very central to many of the issues raised during the evaluation of biopesticides, as the mode of action can be a driver for many aspects of the risk assessment. This led to the drafting of a biopesticides evaluation manual that is available on the Ctgb website to assist applicants on how to submit a dossier and they also encouraged to have pre-submission meetings.

All this experience was integrated in an EPPO standard to address the issues for these low risk products and to reduce the data requirements. He highlighted some parts of the guidance, including: 1) minimum effective dose trials are not required if explanation is

provided and focus is placed on the advantages of the product, 2) understanding the mode of action and having available data sets for best crop combinations is important, and 3) if a product has multiple modes of action, there is need to explain which is the most relevant. This paved the way to develop more standards, covering also pheromones and there is a lot of positive momentum in Europe to have these guidance published.

As regards the current situation, he noted that about 30% of new active substance applications in the European Union seems to belong to low risk substances and this aligns with the current big drive to have more environmentally friendly crop protection in the future and to replace chemical products with biopesticides. He explained that for this reason guidance and good harmonisation for biopesticides is important. He closed his presentation by referring to some outstanding issues: 1) lack of integration of IPM strategies within efficacy, 2) current evaluation of active substance and product dossiers conducted in isolation, 3) low risk status for a product determined by the risk assessment usually informs the evaluation of efficacy when is already at the final stage, 4) lack of considerations for new application methods (e.g., sensor driven applications), new modes of action (e.g., RNAi, bacteriophages) and agricultural practices (e.g., strip cropping).

Summary of Presentations

All abstracts of presentations are presented in Annex 3. All presentation slides can be found online at: https://www.oecd.org/env/ehs/pesticides-biocides/seminar-on-efficacy-evaluation-of-biopesticides.htm.

Summary of Discussions, Ideas and Recommendations for Possible Future Work

Summary

This seminar is the 11th in a series of seminars on biopesticides organised by the OECD Expert Group on BioPesticides (EGBP). This seminar was originally planned to be held in June 2020 but was postponed due to the Covid-19 situation. The EGBP is a sub-group of the OECD Working Party on Pesticides (WPP). The EGBP Seminars focus on key issues on biopesticides of interest to OECD governments.

"Different aspects of efficacy evaluation of biopesticides" was selected as the topic of this Seminar based on discussions in the 2019 meeting of the OECD Expert Group on BioPesticides. In the framework of the Seminar 'efficacy' comprises the efficacy against pests[1] as well as adverse effects on pest antagonists and on the cultivated plant itself, i.e. phytotoxicity. The Seminar covered the efficacy evaluation of the different categories of biopesticides, new application techniques, efficacy evaluation of biopesticides based on plant defence inducers (PDI) when applied to plants to induce defence responses against pests, comparison of efficacy requirements for biostimulants *versus* biopesticides, how to evaluate different Integrated Pest Management (IPM) modules, and registration pathways with limited or no evaluation of efficacy (e.g. minor-use registrations).

The Seminar covered the similarities and differences of the efficacy evaluation of the different categories of biopesticides. Biological pesticides involve: microbials, pheromones and other semiochemicals, plant extracts (botanicals) and invertebrates as biological control agents. 'Microbials' are generally defined as any microbiological entity cellular or non-cellular, capable of replication or of transferring genetic material, e.g. bacterium, fungus, protozoa, virus, viroid, mycoplasma. In some jurisdictions 'microbials' also include non-viable micro-organisms, whereas these are excluded in others. 'Semiochemical active substances' refer to active substances that are emitted by plants, animals, and other organisms and are used by these organisms for communication. The term 'plant extract' or 'botanical active substance' covers an extremely heterogeneous group of substances ranging from simple plant powders to unprocessed and processed plant extracts. Furthermore, plant extracts may be highly refined (i.e. one single active substance) or represent a complex mixture of components of which all or only some are biologically active. Invertebrates refer in general to natural enemies and nematodes. New application techniques (sprayers, nozzles, precision agriculture, etc.) make agriculture more efficient and effective as these techniques ensure that the crops receive exactly what they need to optimize productivity and sustainability. According to the EPPO Standard (EPPO PP 1/319 General principles for efficacy evaluation of plant protection products with a mode of action as plant defence inducers), 'plant defence inducers'- also known as 'plant defence elicitors' - include any substance (of synthetic, or natural origin or micro-organisms) which, when applied to a plant, can induce a state of local and/or systemic resistance against biotic stress, significantly higher when compared to an untreated plant. Plant defence inducers are perceived by the plants as a signal of danger and do not target the pest directly. They will act in such a way as to develop or implement different defence mechanisms, leading to increased plant resistance to pests. According to Regulation (EU) 2019/1009 plant biostimulants contain substances and/or microorganisms whose function when applied to

[1] In this document 'pests' refer to 'pests, diseases and weeds'.

plants or to soil is to stimulate natural processes to enhance or benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress and crop quality. What are the differences in efficacy requirements to get a biostimulant *versus* a biopesticide registered? The general principles of Integrated Pest Management (IPM) are: 1. prevention, 2. monitoring, 3. decision-making, 4. non-chemical methods, 5. use pesticides as specific as possible for the target, 6. limit the use of pesticides to levels that are necessary, 7. anti-resistance strategies, and 8. learn and optimise. How is the relative efficacy evaluated of different IPM modules (especially steps 4, 5 and 6) e.g. comprising of alternate spray of chemical pesticides, biopesticides and botanicals against a certain pest? Currently, within some jurisdictions, there is a development towards a two-class classification system in which Plant Protection Products with low impact can be authorized in risk categories ("low-risk products") with reduced efficacy requirements. Other parallel registration pathways that include limited or no evaluation of efficacy exist in the EU for basic substances and minor-use registrations. OECD has recently published a working document on how to extrapolate from major to minor crops for efficacy evaluations. Standards on the safe use of biological control provide guidelines for assessing and reducing the risks associated with various aspects of the introduction and use of biological control agents and, as appropriate, for comparing them with the benefits in terms of efficacy.

The presentations covered the following topics:

- Research activities toward improving efficacy of biopesticides
- Standards and guidance for conducting efficacy testing
- Efficacy testing requirements and input on evaluation of these studies from various OECD member countries
- Stakeholder input on efficacy testing challenges for biopesticides that do not fit into typical efficacy testing protocols or standards

The main discussion points are listed below:

- Effective use of biopesticides requires increased application precision and user knowledge; what steps are needed to make these improvements such that users are better able to utilize biopesticides?
- Requirements to demonstrate efficacy and efficacy standards vary globally; what flexibilities and/or harmonization may improve registration of biopesticides, and how can the demonstration of efficacy improve biopesticide adoption?
- Not all biopesticides may fit into typical efficacy testing protocols; what are general design considerations or other flexibilities that are needed, and how can these be communicated?
- What other conclusions from the presentations and discussions should be explored further by the EGBP?

Conclusions/Recommendations

The following conclusions and recommendations were discussed as outcome of the seminar:

- Requirements for efficacy testing of plant protection products vary, but flexibilities are often built in for biopesticides efficacy trials
- Efficacy of biopesticide plant protection products can be highly variable

- Not all biopesticides fit into typical efficacy testing protocols (e.g., pheromones, invertebrate biocontrol agents); additional flexibility in study design is needed
- There is a need for improved application precision, user knowledge, and label use instructions; use of digital tools will help
- More details about the active substance (e.g., mode of action, optimum use conditions, and how the minimum effective dose was established) would help regulators in their evaluation of efficacy data
- Consideration should be given to evaluating efficacy of biopesticides as part of integrated pest management programs, rather than as stand-alone treatments.

Annex 1 – Seminar Programme

The 11th Expert Group on BioPesticides

Seminar on "Different aspects of efficacy evaluation of biopesticides"

Monday 28 June 2021 (12.00-16.00)

Tuesday 29 June 2021 (12.00-13.30)

OECD, Zoom meeting

Chair: Shannon Borges, US EPA

DAY1 (28 June) 12.00 – 12.10	**General Introduction** - Purpose and structure of the seminar by *Shannon Borges*
	Introduction to the topic
12.10 – 12.30	- Application and Management of Biopesticides for Efficacy and Reliability (AMBER) by *David Chandler (The University of Warwick)*
12.30 – 12.50	- The Commission des essais biologiques (CEB) of the French plant protection association "Végéphyl" by *Philippe Cagnieul (CEB)*
12.50 – 13.10	- Update on EPPO Standards relevant to efficacy assessment of biopesticides by *Ewa Matyjaszczyk (EPPO)*
13.10 – 13.20	**Coffee break**
	3. Government Experience and Perspectives (Part 1)
13.20 – 13.40	- Swiss experience with efficacy evaluation of fungicidal and resistance inducer products of natural origin by *Lucius Tamm (Research Institute of Organic Agriculture FiBL, Switzerland)*
13.40 – 14.00	- Value Assessment of Biopesticides in Canada by *Michael Downs (PMRA, Canada)*

14.00 – 14.20	- Experience with evaluating the efficacy of biopesticides in the US by *Helen Hull-Sanders (US EPA)*
14.20 – 14.30	**Coffee break**
	Stakeholders' Experience and Perspectives
14.30 – 14.50	- How to successfully evaluate the efficacy of semiochemical products by *Alessandra Moccia* (*Chair of the IBMA PG on Semiochemicals / Suterra Europe) and Daniel Casado* (*Suterra Europe Biocontrol)*
14.50 – 15.10	- Efficacy of Invertebrate BCAs by *Caroline Reid (PhD) (Chair of IBMA's Invertebrate BCA Professional Group, Bioline Agrosciences)*
15.10 – 15.30	- Considerations for appropriate assessment of efficacy of biopesticides in the field by *Denise Manker (Bayer) and Edith Ladurner (CBC Europe – Biogard Div.)*
15.30 – 16.00	**Discussion and Wrap up of Day-1**
DAY-2 (29 June)	**6. Government Experience and Perspectives (Part 2)**
12.00 – 12.20	- French experience of efficacy evaluation of biopesticides. An overview of the issues by *Benedicte Gautier (Anses, France)*
12.20 – 12.40	- Efficacy assessment of biopesticide and supporting Label claims: UK perspective by *Sue Mattock (HSE, UK)*
12.40 – 13.00	- Experience with evaluating the efficacy of biopesticides in the Netherlands by *Henk Brouwer (Ctgp, NL)*
13.00 – 13.30	**Summary of the Discussion, Ideas for Follow-up, Recommendations for possible further OECD work (with reference to the seminar outline)**
13.30	End of the seminar

Annex 2 – List of Participants

Participants list for the 11th Expert Group on Biopesticides Seminar on Different Aspects of Efficacy Evaluation of Biopesticides

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Annex 3 – Abstracts for Presentations

Application and Management of Biopesticides for Efficacy and Reliability (AMBER)

by David Chandler, The University of Warwick, UK [PPT 1]

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In the UK, as in other regions of the world, an increasing number of biopesticide products are coming on to the market. These are still mainly for use in horticulture, particularly for crops grown under protection. UK growers are keen to adopt biopesticides within their crop protection programmes as part of a general drive to reduce reliance on conventional synthetic chemical pesticides. Most growers already practice IPM and some sectors - noticeably protected edibles - base their arthropod pest management around biological control. In principle, biopesticides could fit in well with these programmes. However, the experience of UK growers with biopesticides is something of a mixed bag. While some products give good results, others have low efficacy or - more importantly - the amount of control they give is inconsistent / unreliable and does not match up to the results obtained from efficacy evaluations used for registration. The reasons for this drop in performance are often not readily apparent.

AMBER (Application & Management of Biopesticides for Efficacy and Reliability) is a biopesticide research project funded by the UK Agriculture and Horticulture Development Board, and which is intended to identify the reasons for suboptimal performance of biopesticides and to deliver generic management tools, practices and advice that can help solve the problems. The project focuses on protected edibles & ornamentals, but the findings are relevant to other crops. The work started with a set of 'benchmarking' trials in which six different growers tested out at least one commercially available biopesticide product within their existing crop protection system. We used a total of five different microbial biopesticides applied against three pests and three diseases on seven crops (2 edibles and 5 ornamentals). The growers all run large or medium scale businesses and included some of the largest nurseries in the country, although none had much knowledge of biopesticides. The products were applied to natural pest or disease outbreaks and were used on a whole crop scale. AMBER team members worked with the growers to ensure that best practice guidelines were followed. A wide range of observations were made that included efficacy, storage, preparation, application characteristics, spray equipment and its performance, and product persistence on the crop. Performance varied across a full range from no control to better than a chemical standard. We also engaged with biopesticide companies. From this we identified a set of issues that looked to be common across the different crops. The main issues we found were all connected with the need for targeted, precision application but a lack of ways to make this happen: (1) product labels were generally hard to follow; (2) there was a lack of readily accessible 'underpinning' information on things like mode of action, product preparation, environmental requirements etc.; (3) biopesticide companies don't know what the effective dose is (spores per mm2), or won't say; (4) spray equipment was generally not fit for purpose and

application was poor, with water volumes far too high leading to run off. Some of these issues are being addressed by companies but more needs to be done, particularly with respect to spray application. In AMBER, we are working to help deliver targeted, precision biopesticide use through improvements to spray application, the development of decision support models, and knowledge exchange. The hope is that these will help improve the delivery of biopesticides to the right place, at the right time, at an effective dose under the right environmental conditions.

The Commission des essais biologiques (CEB) of the French plant protection association "Végéphyl"

by Philippe Cagnieul, CEB, France [PPT 2]

CEB, « Commission des Essais Biologiques » in French (Commission for biological trials) was set up in 1952 and is today one of the 13 commissions of Vegephyl, the French association for plant health.

Seventy years ago, the rise of innovation within chemical based products to control pests in the crops, made required the development and implementation of widely recognized methodology to carry out the field trials. CEB has actively worked with the plant protection industry, the government agencies, the advisors and professional agricultural organizations to ensure a methodologic alignment. This is probably why CEB has such an impressive heritage data base (guidelines, technical documents etc.).

At that time CEB had a fully French oriented approach. During the past 10 years, CEB had a more forward-looking approach to the European methodology needs, with the willingness to translate in English the key CEB guidelines and put forward proposals to EPPO.

All specific guidelines produced follow the same template, from the experimental conditions of the trial to the results reporting. Nevertheless, for a number of decades, this type of document was designed to be used mainly for active ingredients derived from chemical synthesis.

The arrival of new solutions in the plant protection market, based on biocontrol products or new mode of action (plant defense inducers) has led CEB to put in place a comprehensive analysis of existing documents to ensure that these new product concepts are taken into account.

Finally the option chosen was to generate a policy statement encapsulating whole existing guidelines, and so pointing in each chapter the critical changes related to specific biocontrol products characteristics.

Update on EPPO Standards relevant to efficacy assessment of biopesticides

by Ewa Matyjaszczyk, EPPO, France [PPT 3]

The European and Mediterranean Plant Protection Organization (EPPO) is an intergovernmental organization responsible for cooperation in plant health within the Euro-Mediterranean region. Founded in 1951 by 15 European countries, EPPO now has 52 members. EPPO is a standard-setting organization which has produced a large number of Standards in the areas of plant protection products (PPP) and plant quarantine. EPPO promotes the exchange of information between its member countries by maintaining information services and databases on plant pests, and by organizing many conferences and workshops.

EPPO Standards regarding PPP are focused on efficacy evaluation. Other major aspects relevant to PPP registration (ecotoxicity, residues) are internationally covered by other bodies. The Standards are intended to be used by member governments, in particular by authorities responsible for registration of PPP and related advisory services. EPPO Standards are also of interest to agrochemical companies which apply for registration of PPP.

EPPO Standards on PPP are divided in two groups:

- General Standards cover general aspects of efficacy evaluation to help countries in understanding and fulfilling their obligations in PPP registration

- Specific Standards cover one type of PPP and give details for individual field or glasshouse trials.

Access to General Standards is free whereas access to Specific Standards is payable.

While presenting EPPO Standards relevant to efficacy assessment of biopesticides it is worth remembering that many EPPO General Standards are relevant to biopesticides efficacy assessment. Even if they are not focused on biopesticides they give advice relevant to all PPP (including biopesticides), such as advice on design, conduct, reporting and analysis of trials, analysis of resistance risk and climatic considerations.

The following EPPO Standards are focused on biopesticides or mating disruption:

PP1/276 - Principles of efficacy evaluation for microbial plant protection products

PP1/296 - Principles of efficacy evaluation for low-risk plant protection products

PP1/319 - General principles for efficacy evaluation of plant protection products with a mode of action as plant defence inducers

PP 1/264 Principles of efficacy evaluation for mating disruption pheromones

PP 1/314 - Evaluation of mating disruption techniques against Lepidopteran pests in grapevine, pome and stone fruits under field conditions

PP 1/323 - Evaluation of mating disruption techniques against Lepidopteran pests in grapevine, pome and stone fruits under semi-field conditions

Swiss experience with efficacy evaluation of fungicidal and resistance inducer products of natural origin

by Lucius Tamm, Research Institute of Organic Agriculture FiBL, Switzerland [PPT 4]

{abstract not available}

Value Assessment of Biopesticides in Canada

by Michael Downs, PMRA, Canada [PPT 5]

This presentation provides an overview of the value data requirements to register biopesticides in Canada. The components of the value assessment, the associated types of data, and the decision-making framework will be discussed.

Experience with evaluating the efficacy of biopesticides in the US

by Helen Hull-Sanders, US EPA, US [PPT 6]

The U.S. Environmental Protection Agency regulates the registration, distribution, sale and use of all pesticides including insecticides, herbicides, rodenticides, fungicides, disinfectants, and sanitizers and establishes maximum levels for pesticide residues in crops, thereby safeguarding the United States' food supply. The EPA Office of Pesticide Programs BioPesticide and Pollution Prevention Division reviews all scientific data relating to the use of biochemical and microbial pesticides as well as emerging biologically-based technologies. In addition to providing risk assessment evaluations on the product chemistry and toxicology, EPA scientists review and evaluate the efficacy of certain products in an effort to ensure that labeling provides consumers with accurate information on the use and duration of a pesticide product. Efficacy data is required for all EPA registered products; however, only a sub-set of data relating to public health pests, structural (wood-destroying) pests, and invasive species are required to be reviewed by EPA scientists. The EPA has established guidelines for conducting such studies, as well as standards by which efficacy is evaluated.

How to successfully evaluate the efficacy of semiochemical products

by Alessandra Moccia and Daniel Casado, Suterra Europe Biocontrol, Spain [PPT 7]

Semiochemicals are naturally occurring compounds belonging to different chemical classes that regulate intra- and inter-specific communication. They are released by one organism (emitter) and generate a change on behavior (or physiology) in another organism (receiver). Based on the identity of the emitter and the receiver, semiochemicals can be classified as pheromones (communication between co-specifics) or allelochemicals (communication between individuals of different species). Semiochemicals mediate a number of behavioral processes, such as mate finding, food foraging, oviposition site location, etc.

Semiochemicals are a cornerstone of integrated pest management. Firstly, because they are extremely useful for pest monitoring. Secondly, because they provide a powerful tool for pest control by altering insect behavior.

There are two techniques that include the virtual totality of semiochemical-based biopesticides: mating disruption and luring. Shortly, mating disruption consists in hindering the mate finding process of the pest hence reducing reproductive output of its population. Luring consist on attracting individuals of the species typically to a device or a trap where they are intoxicated or captured. Regardless of the technique being used, semiochemicals never play a toxic role, as they are characterized by a species-specific and non-toxic mode of action.

Differently from all other pesticides, semiochemical-based products do not directly protect the individual plants, but they somehow manipulate the insect behavior. As individual plants are not protected, classic experimental designs for pesticide efficacy studies are not suitable for semiochemical-based ones. Typically, large contiguous surfaces of crop per thesis are needed in the experimental design. The plot size per replicate required depend largely on the capacity of dispersion of the pest. Highly mobile species require replicates to be several hectares in size, while for less mobile ones surfaces of one half of an hectare or less may be suitable. These plot sizes pose great challenges for site finding, economic risk, pest distribution homogeneity and replication.

Another major difference between semiochemical-based products and other pesticides is the concept of minimum effective dose. In one hand, with regular pesticides individuals acquire a toxic agent that has been sprayed onto a crop. Efficacy is linked to the interaction of each pest individual with the dose of pesticide. Dose-effect is independent of population density. On the other hand, semiochemical-based efficacy is not independent of pest population density. Given a dose, efficacy will be lower the larger the density of population. Also, continuous use of semiochemical-based products, year after year, typically results in a gradual reduction of population density and lower doses may be efficacious as generations go by. For this reason, talking about minimum effective dose for this kind of biocontrol products lack of meaning.

In conclusions, whenever assessing the efficacy of semiochemical based products, it is extremely important to take into considerations the specific mode of action of the product, the biology and behavior of the target pest as well as the desired efficacy claims.

Efficacy of Invertebrate BCAs

by Caroline Reid, Bioline Agrosciences, UK [PPT 8]

Invertebrate Biocontrol Agents IBCA's present a unique set of challenges in efficacy testing – they are living creatures which are usually used preventatively as they breed and increase in number over time. Guidelines usually used for efficacy testing of PPP's or even microbiological products are not suitable for these products. The presentation will discuss the ways that efficacy testing can be applied to IBCA's and how they differ from PPP's.

Considerations for appropriate assessment of efficacy of biopesticides in the field

by Denise Manker, Bayer Crop Science and Edith Ladurner, CBC Europe – Biogard Div., France [PPT 9]

There is a great need for more registered bioprotectant products for agriculture and end-users need good tools for plant protection. There is also a consumer demand for lower conventional chemical pesticide residues and more sustainable growing practices. However, to achieve this, for bioprotectants there needs to be fewer unnecessary barriers in the registration process and more flexibility in efficacy test methodology and protocol development and trial set-up that will appropriately demonstrate efficacy and value in sustainable practices. To achieve this, bioprotectants need to be evaluated as such and not as conventional chemical pesticides. Testing and evaluation are necessary but need to be adjusted to fit to the intended use of the product. There is a need for appropriate regulations for these types of products with predictable paths and a reasonable timeline for review. Finally, in many OECD countries there are policy discussions that are leading to the call for the addition of more bioprotectants for pest and disease management to be employed in agriculture. Making improvements to the regulatory review and approval process for bioprotectants – including in the consideration of efficacy data – will be an important aspect of achieving this policy goal. To this end, there are four areas that need to be addressed.

1) The guidance contained in the relatively recent EPPO guidance on bioprotectant testing should be referenced and utilized by regulatory authorities in their regulatory review & consideration of efficacy data. While some OECD member countries have taken on board some of the principles and practices outlined in the updated EPPO guidance, there is a need for this guidance to be routinely reflected in regulatory reviews and decisions.

2) There is a need for a better understanding of the mode of actions of bioprotectants in order to prepare protocols for efficacy evaluation which allow for observation of the

effectiveness based on appropriate uses. This requires flexibility in methodology to suit the product and correctly consider its mode of action. Some country's desired demonstration of minimum effective dose may be appropriate for conventional chemical pesticides; however, bioprotectants are known to have different dose response curves making this an invalid indicator.

3) Detailed considerations like the selection of appropriate standards as a comparator in efficacy testing and regulatory review as outlined in the updated EPPO guidance are an important component in improving the regulatory process and procedures for bioprotectants. In the point above, a reference would need to have a similar mode of action of the bioprotectant being evaluated so that appropriate protocols are used. There are many situations where a conventional chemical pesticide is not the appropriate standard for a bioprotectant; conversely, a comparison to the untreated control may be the best comparator for these products, for example in scenarios where there may be no relevant standard for comparison.

4) Since many plant protection tools in practice are going to be utilized in a plant production system, consideration of how bioprotectants fit into an integrated pest management program should be acknowledged in the regulatory review and in consideration of efficacy data. From a historical perspective, the lack of an integrated approach where bioprotectants are utilized with other plant protection tools and practices has played an important role in the lack of adaption to bioprotectants – making it even more important for this product category to have an integrated approach be considered in the regulatory process.

French experience of efficacy evaluation of biopesticides

by Benedicte Gautier, French agency for food, environmental and occupational health and safety, ANSES, France [PPT 10]

In France, evaluation and authorisation of plant protection products are the responsibility of the French Agency for Food, Environmental and Occupational Health and Safety (ANSES).

The evaluation of efficacy data provided for the registration of "biopesticides" is performed by the Efficacy evaluation unit for pesticides and fertilizers of the Regulated Products Assessment Department of ANSES.

This overview focuses on the ANSES's practical experience on the evaluation of the level of effectiveness of two types of biopesticides, based on micro-organisms or substances of natural origin, which cover various modes of action.

Our experience has shown that the effectiveness of such biopesticides is most of the time variable and partial, with many factors that can influence it. A relevant average of effectiveness is difficult to establish because of its high intrinsic variability. The agronomic interest of the PPP may be also difficult to demonstrate when used alone. EPPO standard on low-risk products gives some recommendations that can be difficult to put into practice. Indeed, on the one hand, a lower number of direct effectiveness trials is advised compared to conventional PPPs. On the other hand, it advises to generate sufficient data to identify the conditions under which the product will provide optimal performances.

ANSES's evaluation of "biopesticides" PPPs concludes most of the time that the level of effectiveness is partial and variable, but considered acceptable considering the type of product. This conclusion takes into account the agricultural context and the need for alternative solutions, in complement to the demonstration of a minimum agronomic interest. This demonstration is sometimes based on practical value trials (i.e. testing the

interest of the "biopesticide" in programme) that can be very useful to show the interest of the "biopesticide". However this type of trials may suffer from a methodology not fully suitable.

From this experience, some improvements could be suggested to applicants and authorities. The first one is to improve the quality of the trials realized (e.g. experimental design, sampling, statistical analyses…). The second one is to develop the use of practical value trials which allow to demonstrate the effect of the biopesticide in a programme with other PPPs or with non-chemical practices (IPM). The third one is to test various conditions in order to identify the conditions under which the biopesticide will provide optimal performances.

All these improvements are interdependent and may imply developing or adapting the methodology of experimentation to perform more robust effectiveness trials.

Efficacy assessment of biopesticide and supporting Label claims: UK perspective

by Sue Mattock, HSE, UK [PPT 11]

The UK launched the 'biopesticide scheme' in 2006, based on experiences of running a pilot project. The scheme has illustrated the need to establish early contact and support for applicants, often unfamiliar with the regulatory processes, and provide more guidance on addressing data requirements and using reasoned cases.

The CRD efficacy specialists worked with IBMA to gain familiarity with product types and developed both UK and EPPO guidance. More recently CRD have worked in the EPPO expert working group for biopesticides to develop relevant guidance and promote extrapolation possibilities.

Preliminary data/published information has a key role in understanding mode of action, supporting all areas of the risk assessment, and reducing the number of efficacy trials. The UK operate differential product label claims, based on a range of control levels, provided there is a demonstrable benefit. Whilst biopesticides can deliver more variable performance, generating appropriate data identifies those conditions which will optimise efficacy. Supporting product label recommendations is key to grower communication and developing their understanding on using biopesticides successfully within integrated programmes.

Biopesticides are an increasingly important tool and Efficacy is a critical area in supporting their use. As part of this, developing further guidance and continuing engagement with industry and regulators is an important strategy.

Experience with evaluating the efficacy of biopesticides in the Netherlands

by Henk Brouwer, Ctgp, NL [PPT 12]

The presentation gives an overview of the problems that were initially encountered during the efficacy evaluation of biopesticides in the Netherlands.

An overview is given of the approach that was taken to address these issues. This approach included cooperation between efficacy and evaluators from other aspects as problems were often multidisciplinary. A "green team" was started with experts with a background in microbiology, and a manual for applicants on how to write dossiers for biopesticides (evaluation manual) was published.

In addition cooperation within the EU was sought. On a European level, a new EPPO standard was published for low risk products that addresses many of the issues for this group of products.

Overall it can be concluded that a number of issues with the efficacy evaluation of biopesticides have been addressed. Remaining issues and ongoing developments are briefly discussed.