INVITATION LETTER TO BTSF NATIONAL CONTACT POINTS SEEKING APPLICATIONS FOR BTSF TRAINING ACTIVITIES ON "RISK ASSESSMENT OF MICROORGANISMS USED AS PESTICIDES OR BIOCIDES" UNDER THE "BETTER TRAINING FOR SAFER FOOD" INITIATIVE

SERVICE CONTRACT NUMBER 2019 96 04

PHASE 2

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1. COURSE OBJECTIVES

The Regulation (EC) No 1107/2009 provides rules for placing plant protection products in the market, based on a risk assessment, which encourages the development of less harmful substances. This Regulation includes chemical active substances and microorganisms, where, according to this Regulation, microorganisms are defined as "any microbiological entity, including lower fungi and viruses, cellular or non-cellular, capable of replication or of transferring genetic material".

Microorganisms used as active substances in plant protection or biocidal products have a very different risk profile than chemicals. Many Microbial Pest Control Agents (MPCAs) have gained favour in recent years due, in part, to the perception that, because they are of natural origin, they are safer and/or more organic than the synthetic pesticides. However, there is no reason to believe that all forms of biocontrol are intrinsically safe. Studies are needed to identify the real risks of MPCAs and Microbial Pest Control Products (MPCPs) to human health and to the environment as a basis for appropriate regulation of these beneficial organisms.

In the current EU registration procedure, microorganisms used as active substances and plant protection products containing microorganism are primarily treated as potentially risky organisms that are not only able to produce toxic substances, but are also potentially dangerous because they can multiply, spread and perhaps genetically adapt. It is important to be aware that placing a high inoculum of a microorganism in the environment can be treated as equivalent to a pesticide, as they fall under the same regulations as their chemical counterparts. The risk assessment for a microorganism active substance is different than that for chemicals (for instance their potential pathogenicity for humans and non-target organisms present in the environment, or their contribution to the possible development of resistance to antibiotics), and should be considered in full before allowing the use of the microorganism as an active substance on the EU market.

The objective of the training is to support development of expertise as regards the risk assessment methodologies for microorganisms to be used in plant protection products and biocides. This shall also enhance competences in evaluating dossier admissibility/validity and risk assessment, and will also aim to promote, as much as possible, harmonisation of the procedures of evaluation, and authorisation of such microorganisms within the EU.

2. TRAINING DATES

A three-day training will be held in Belgium, Spain, Romania, Latvia, Malta and Portugal over four days. Face-to-face training courses will be delivered between February 2024 and March 2025 with approximately 35 people in each session.

An introductory session in the afternoon of the first day will be followed by 3 days of training. The course agenda is attached (Annex 3).

Table 2: Training dates

Year	Training session	Course title	Location	Proposed dates	Organiser	Deadlines
2024	1	Risk Assessment of microorganisms used as pesticides and biocides	Brussels, Belgium	20/02/24-23/02/24	AETS	09/01/24
	2	Risk Assessment of microorganisms used as pesticides and biocides	Valencia, Spain	16/04/24 – 19/04/24	AINIA	20/02/24
	3	Risk Assessment of microorganisms used as pesticides and biocides	Bucharest, Romania	04/06/24-07/06/24	AETS	09/04/24
	4	Risk Assessment of microorganisms used as pesticides and biocides	Riga, Latvia	17/09/24-20/09/24	AINIA	23/07/24
	5	Risk Assessment of microorganisms used as pesticides and biocides	La Valette, Malta	10/12/24-13/12/24	AETS	25/10/24
2025	6	Risk Assessment of microorganisms used as pesticides and biocides	O Porto, Portugal	03/02/25-06/02/25	AINIA	13/12/24

3. SELECTION CRITERIA FOR PARTICIPANTS

Participant must:
1. Fulfil the eligibility criteria
2. Meet the minimum requirements
3. Be selected using the evaluation criteria

1. Eligibility criteria for Risk Assessment of Microorganisms used as Pesticides or Biocides
Only **eligible participants** should be further assessed against the minimum requirements below.

Participants must meet the minimum requirements below to ensure they can follow and fully participate in this course. Participants who do not meet the minimum requirements should not be proposed for the training.

2. Minimum requirements for Risk Assessment of Microorganisms used as Pesticides or Biocides	**Yes/No**
Participant must: ▪ Have worked in functional areas of risk assessments and decision making of active substances and plant protection and/or biocidal products in the context of the EU regulations mentioned above with a minimum of 2 months of professional experience or ▪ Have experience of setting up and implementation of that topic in a Competent Authority (covering areas of food/feed safety, animal health or animal welfare).	

The evaluation criteria should be used as a tool to prioritise participation (higher score indicates higher priority), but there is no minimum score necessary.

3. Evaluation criteria for Risk Assessment of Microorganisms used as Pesticides or Biocides		**Enter Score**
a)	Experience in a position related to Official assessments within a competent authority in areas of active substances and plant protection and/or biocidal products <u>Scoring</u> less than 3 years = 0 points; ≥ 3 years = 5 points; 5 - 10 years = 10 points; > 10 years = 12.5 points	
b)	Experience in risk assessments and decision making of active substances and plant protection and/or biocidal products in the context of the EU regulations mentioned above <u>Scoring</u> no experience = 0 points; < 2 years = 5 points; 2-5 years = 7.5 points; > 5 years = 10 points	

c)	Contribution towards risks assessments of plant protection and/or biocidal products <u>Scoring</u> no experience = 0 points; < 2 years = 5 points; 2-4 years = 10 points; > 4 years = 12.5 points	
d)	During the course, participants will be provided with a training package to be used as support dissemination material. Commitment to disseminate the knowledge received is a prerequisite for course participation. <u>Scoring</u> 1. Commitment to distribute the training material among their colleagues = 5 points; 2. Point 1 plus preparing and giving presentations based on the training material for the staff of national Competent Authorities/uploading training material to national Competent Authorities' intranets/websites = 10 points 3. Points 1, 2 plus preparing informative articles in the professional national journals = 15 points 4. no commitment = **NO INVITATION**	
Maximum total score		**50**

4. COUNTRY ALLOCATIONS

A total of 210 seats will be allocated across the 6 sessions which will take place from February 2024 to March 2025, according to the tables below. Please note that the number of allocated seats for each country may be subject to variation.

Table 1: Suggested allocation for EU Member States and Candidate Countries

	Country / suggested allocation					
Member States	Austria	7	France	8	Malta	5
	Belgium	7	Germany	8	Netherlands	6
	Bulgaria	8	Greece	8	Poland	7
	Croatia	7	Hungary	7	Portugal	7
	Cyprus	5	Ireland	7	Romania	7
	Czech Republic	6	Italy	8	Slovakia	6
	Denmark	6	Latvia	6	Slovenia	6
	Estonia	6	Lithuania	6	Spain	8
	Finland	6	Luxembourg	5	Sweden	7
	Total Member States					***180***
Candidate Countries and potential candidate countries	Albania	2	Montenegro	2	Ukraine	2
	Bosnia Herzegovina	2	North Macedonia	2	Kosovo	2
	Georgia	2	Serbia	2		
	Moldova	2	Türkiye	2		
	Total Candidate Countries					***20***
Global participation EU Member States and Candidate Countries						***200***

Table 2: Suggested allocation for other non-EU Countries

	Country / suggested allocation					
EFTA/ EEA countries / countries with special agreements	Iceland	2	Norway	2		
	Liechtenstein	2	UK (Northern Ireland)	2		
	Total EFTA/EEA Countries					***8***
Other non-EU countries	Switzerland	2				
	Total other non-EU countries					***2***
Global participation other non-EU Countries						***10***

You are welcome to nominate more participants for the reserve list than indicated in the table above. If seats will become available you will be informed in due time.

5. FACE-TO-FACE LOGISTICAL ARRANGEMENTS

In the case of face-to-face training sessions, the European Commission will fund in full the visa, travel, accommodation, meals, and field visit costs for all training participants. No daily allowance will be paid on top of this. Any other costs are to be paid by the participants themselves.

Participants will arrive at the training venues on Tuesday morning and training will commence on Tuesday afternoon (depending on travel connections, participants may be requested to arrive at the training venues on Monday evening). Return travel will be on Friday afternoon or Saturday morning according to flight connections.

AETS team will liaise further with the nominated participants for all logistics and practical aspects.

ANNEX 1: BACKGROUND AND MAIN TOPICS COVERED IN TRAINING

Regulation (EC) No 1107/2009 sets the legal framework for the assessment and approval of active substances used in plant protection products (PPP), and for the authorisations of plant protection products containing them. Regulation (EU) No 528/20125 sets a similar legal framework for the assessment and approval of active substances used in biocidal products (BP), and for authorisations of biocidal products containing them. Under both regulations, active substances may be chemicals or microorganisms.

The regulations state that an applicant has to submit a dossier compliant with the data requirements established in the respective regulations and relevant guidance. A competent authority of a Member State evaluates the admissibility of the dossier and requires more data from the applicant should the information provided be considered not sufficient. Afterwards, it performs a risk assessment and proposes to approve or non- approve (or renew or non-renew the approval) of the active substance for particular use(s). This risk assessment is peer reviewed by all Member States and European agencies (the European Food Safety Authority for PPP, and the European Chemicals Agency for BP).

Notably, risk assessment methodology has to be fit for purpose, it is driven by the inherent properties of the active substances, and it evolves with societal and, when applicable, industrial needs incorporating new scientific developments and best available practice.

Microorganisms used as active substances in plant protection or biocidal products have a very different risk profile than chemicals. Although considered to be in general of low risk, their characteristics call for the assessment of potential risks which are different than those for chemicals (for instance their potential pathogenicity for humans and non-target organisms present in the environment, or their contribution to the possible development of resistance to antibiotics), before the use of the microorganism can be allowed as an active substance on the EU market.

Compared to chemical active substances, there is much less experience on the regulatory risk assessment of microorganisms used as active substances in plant protection or biocidal products. Also the data requirements and the information usually provided in application dossiers are less exhaustive for micro-organisms than for chemicals. For instance, dossiers on microorganisms often contain many references to scientific peer-reviewed literature and less “classical” regulatory (eco)toxicological test studies compared to chemical dossiers. This leads to difficult evaluations of dossier admissibility/validity as well as complex risk assessments, delaying the placement on the market of new microbial plant protection and biocidal products.

In order to support Member States in their role of risk assessors, it is key to increase the expertise in the EU as regards to how to assess the potential risks of microorganisms to be used in biocidal and plant protection products. An increased expertise on this topic is expected to enhance in EU the availability of microorganisms to be used in plant protection products and biocidal products, to foster

the marketing of low risk substances and products, and to achieve a more sustainable plant protection and biocidal products use.

Topics addressed:

- Biological properties of microorganisms and biocontrol
  - ✓ Principles of Augmentative Biological Control (ABC).
  - ✓ Modes of action of microorganisms against target organisms (e.g. parasitism, hyperparasitism, competition, effect via production of secondary metabolites, induced resistance, phagocytosis).
  - ✓ Geographical origin and distribution and its relevance for risk assessment purposes.
  - ✓ Harmonized definitions on technical terminology (e.g. species, strain, isolate, origin/source of microorganisms).
  - ✓ State of art of the academic knowledge in the area of biological control (e.g. most updated and relevant research, microorganisms currently used with this purpose).
  - ✓ Methods to evaluate efficacy of microorganisms used under different conditions (e.g. in ABC).
  - ✓ International networks of risk assessors, managers and scientists in the area of microorganisms used in biocontrol (e.g. workshops and conferences).

- Background on pesticides and biocides regulation in the EU
  - ✓ Overview of the EU regulatory framework on pesticides and biocides, differences between microbial and chemical pesticides. Overall comparison with regulations from non-EU Countries.

- Elements of risk assessment of microorganisms
  - ✓ Steps in the risk assessment (problem formulation, hazard identification, hazard characterisation i.e. dose-response assessment, exposure assessment, risk characterisation). How these steps depend on the biological characteristics of the microorganism assessed.
  - ✓ Instruction to retrieve relevant scientific information (e.g. tailored scientific literature databases, bioinformatics databases). Methods to perform and appraise a literature review. Systematic literature review methodology.
  - ✓ Characterisation of the microorganism:
    - Species, strain, isolate, origin/source of microorganism.
    - Manufacturing processes including quality control (e.g. impurity, contaminant limits, continuous and batch process).
    - Genetics of microorganisms (including concepts of genome stability, polymorphisms and molecular markers).

- Antimicrobial resistance (AMR). Difference between intrinsic and acquired AMR, cross-resistance, antibiotics and disinfectants resistances.
- Secondary metabolites of potential concern and natural background concentrations.
- Storage stability (shelf-life) of the microbial plant protection and biocidal product.

✓ Potential pathogenicity for humans and relevance of residues for human health. Living residues of microbial plant protection and biocidal products and their differences with chemical residues.

✓ Environmental dynamics of microorganisms in the context of ABC:

- Environmental persistence, resilience, dynamic of growth (e.g. in soil and into/onto plant tissues/surfaces), dispersal of microorganisms (e.g. aerial).
- Introduction of non-indigenous microorganisms in the environment, and interaction with autochthonous populations (e.g. competition, populations' dynamics, effects on microbiological biodiversity).

✓ In the context of ABC: interaction with non-target organisms (including humans), and evaluation of exposure (e.g. operators), potential risks, and effects.

- Analytical methods

✓ Sampling techniques (e.g. from soil and plant tissues), and spatial variability of environmental samples (i.e. uncertainty linked to sampling approach chosen). Issues and approaches for harmonized methodologies.

✓ Phenotypic and genotypic approaches (including Whole Genome Sequencing and molecular markers) to perform analyses, such as identification and quantification of microorganisms, detection of AMR, evaluation of production of secondary metabolites of potential concern, pathogenicity, infectivity, assessment of toxicity (e.g. test of crude extracts of microorganisms), efficacy.

✓ Analytical units: types, appropriate use according to the different needs (e.g. measuring bacteria, viruses or conidia).

- Risk mitigation measures related to the use of microorganisms (e.g. correct choice of pre-harvest interval, operators equipment).

- Case studies should be presented, including for instance, practical examples and exercises on how to assess which data are needed depending on the biological properties of the microorganism and the use proposed (problem formulation), the admissibility of data provided in dossiers, and how to identify potential data gaps which are essential for a proper risk assessment.

ANNEX 2: LEGISLATION AND GUIDANCE

The following table is a compilation of the EU legislation relevant to EU legislation and technical documents relevant to plant protection products and biocides.

Regulation (EC) No 1107/2009 - placing on the market of plant protection products	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.
Regulation (EU) No 1432/2017	Commission Regulation (EU) 2017/1432 amending Regulation (EC) No. 1107/2009 of the European Parliament and the Council concerning the placing of plant protection products on the market as regards the criteria for the approval of low-risk active substances.
Regulation (EU) No 283/2013 - setting data requirements for active substances	Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market Text with EEA relevance.
Regulation (EU) No 284/2013 - setting data requirements for PPPs	Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market Text with EEA relevance.
Regulation (EU) No 546/2011 - uniform principles for evaluation and authorisation of PPPs	Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorization of plant protection products Text with EEA relevance.
Regulation EU 540/2011 - approved substances [Updated 16/12/2023]	Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (Text with EEA relevance).
Regulation EU 547/2011 - labelling requirements for PPPs	Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products Text with EEA relevance.
Regulation (EU) 2022/1439	COMMISSION REGULATION (EU) 2022/1439 of 31 August 2022 amending Regulation (EU) No 283/2013 as regards the information to be submitted for active substances and the specific data requirements for micro-organisms
Regulation (EU) 2022/1440	COMMISSION REGULATION (EU) 2022/1440 of 31 August 2022 amending Regulation (EU) No 284/2013 as regards the information to be submitted for plant protection products and the specific data requirements for plant protection

	products containing micro-organisms
Regulation (EU) 2022/1441	COMMISSION REGULATION (EU) 2022/1441 of 31 August 2022 amending Regulation (EU) No 546/2011 as regards specific uniform principles for evaluation and authorisation of plant protection products containing micro-organisms
Regulation (EU) 2022/1438	COMMISSION REGULATION (EU) 2022/1438 of 31 August 2022 amending Annex II to Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards specific criteria for the approval of active substances that are micro-organisms
Communication	Commission communication in the framework of the implementation of Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market Text with EEA relevance.
REGULATION (EC) No 396/2005	Regulation (EC) No 396/2005 of the European Parliament and of the council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC.
Assessment	Assessment of the equivalence of technical grade active ingredients for identical microbial strains or isolates. https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_phys-chem-ana_equiv_micro-organisms.pdf
Working Document	The working document on microbial contaminant limits. https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf
Templates draft Registration Report	Templates draft registration report for micro-organisms. https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_doss_temp-reg-rprt_micro-organisms.zip
Assessment	Assessment of new isolates of baculovirus species already included in Annex I. https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_aas_guidance_baculovirus.pdf
Guidance	Guidance on the characterisation of microorganisms used as feed additives or as production organisms. EFSA Journal 2018;16(3):5206, 24 pp. https://doi.org/10.2903/j.efsa.2018.5206
OECD 29	OECD 29, Guidance document on the use of taxonomy in risk assessment of micro-organisms: bacteria
OECD 43	OECD 43, Working document on the evaluation of microbials for pest control. http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2008)36&doclanguage=en

OECD 65	OECD 65, Issue paper on microbial contaminant limits for microbial pest control products. http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2011)43&doclanguage=en
EPPO	EPPO Standards – PM 6 Safe use of biological control

EU legislation can be found on the EUR-LEX website at http://eur-ex.europa.eu/RECH_menu.do

The language required can be selected at the top right.

Click on 'natural number' to select the original legislation or if there have been many amendments, click on 'consolidated version' to find the legislation including the amendments. Enter the year and document number where indicated and click 'search'.

The consolidated version may not have the latest amendments, so it is best to click on 'natural number', enter the year and document number, click 'search' and then click on 'Bibliographic notice' for the legislation concerned. This will show the list of all the amendments and the latest consolidated version. At the start of consolidated versions there is a list of the amendments it includes. This can be compared against the list of amendments in the bibliographic notice to see if there are recent amendments which have not yet incorporated into the latest consolidated version.

ANNEX 3: AGENDA

BETTER TRAINING FOR SAFER FOOD

TRAINING COURSE ON RISK ASSESSMENT OF MICROORGANISMS USED AS PESTICIDES OR BIOCIDES

Day 1 - Tuesday

	TIME		TITLE OF SESSION	TRAINING OBJECTIVE/ SUBJECTS COVERED	RESPONSIBLE TUTOR
	13:00 – 14:30	1.0	Welcome lunch		
	14:30 – 15:00	1.1	General introduction to the training session– GEM01	▪ Welcome ▪ Presentation of tutors and staff ▪ Presentation of participants and their expectations ▪ Information on the Facebook group created for this BTSF project Present the Better Training for Safer Food initiative to participants	Event Manager/ Training Coordinator José-Luis Alonso-Prados
	15:00 – 15:15	1.2	Pre-Course Test – GEM02	Interactive tool will be used to assess and collate answers to opening questionnaire- survey style 16 questions asked with interactive tool (4 per topic)	Training Coordinator José-Luis Alonso-Prados
	15:15 – 15:50	1.3	**Lecture:** Principles of Augmentative Biological Control - ABC	▪ Principles of biological control and Integrated Pest Management (IPM) ▪ Biological control by habitat manipulation (plants as refugees of natural enemies; sterile insect technique, populations of natural enemies) Principles of biopesticides. Types of biopesticides. Advantages and disadvantages of the use of plant protection products (PPP) based on microorganisms	Marieke van Hulten

Day 1 - Tuesday

	Time		Title of Session	Training Objective/ Subjects Covered	Responsible Tutor
	15:50 – 16:25	1.4	**Lecture:** Modes of action of microorganisms against target organisms (e.g. parasitism, hyperparasitism, competition, effect via production of secondary metabolites, induced resistance, phagocytosis) - MOA	▪ Modes of action of microorganisms based on target organisms: • Control of **plant diseases or other organisms not targeting plants** (microbial antagonist): Parasitism and predation/ Hyperparasitism/ Competition/Induced resistance in the host/ Antibiosis/Phagocytosis/ pH effect/ Lysis • Control of **plant insects or other pests and nematodes (entomopathogens)**: organism with a peroral mode of action/contact mode of action/induced resistance • Control of **weeds, (microbial herbicides)**: contact mode of action/induced resistance ▪ Importance of the mode of action for the **risk assessment** of PPP/biocides based on microorganism. (Examples of the main microorganisms used as PPP/biocides and its mode of action will be included throughout the presentation with special attention to the relevance for the risk assessment)	Marieke van Hulten
	16:25 - 16:55	Coffee break			
	16:55 - 17:30	1.5	**Lecture:** Geographical origin and distribution and its relevance for risk assessment purposes. Harmonised definitions on technical terminology (e.g. species, strain, isolate, origin/source of microorganisms) - GEOORI	▪ General introduction on microbiology ▪ Importance of the identification of the point of origin. Microorganism indigenous and non-indigenous, concept of **Invasive microorganism**. Relevance for risk assessment ▪ Distribution and origin of the main important microorganisms used as PPP/Biocides ▪ Identity phylogenetic relationship of the microorganisms with target organisms/ pathogens/ producer of toxins. Relevance for risk assessment ▪ Importance of the identification of the microorganisms at strain level. Genetic stability. Relevance for risk assessment ▪ (Examples of the main microorganisms used as PPP and its mode of action will be included throughout the presentation with special attention to the relevance for the risk assessment)	Anne Steenbergh
	17:30 - 17:45	1.6	Advance Questions	▪ Introduce and review questions sent in advance by participants (see initial questionnaire). ▪ Final remarks, summary of day 1, comments and instructions for joining the training the following day	Training Coordinator José-Luis Alonso-Prados
	19:30	1.7	Welcome drink and dinner		

Day 2 - Wednesday

	Time		Title of Session	Training Objective/ Subjects Covered	Responsible Tutor
	09:00 – 09:15	2.1	**Anchoring game:** Quiz	Interactive game to revise the previous day's content	Training Coordinator José-Luis Alonso-Prados
	09:15 – 10:15	2.2	**Lecture:** Overview of the EU regulatory framework on pesticides and biocides, differences between microbial and chemical pesticides. Overall comparison with regulations from non-EU Countries - REG	▪ Regulation EC 1107/2009 – Data requirements for microorganisms and uniform principles. Differences with the data requirements of chemical pesticides will be considered ▪ Development of new data requirements will be covered in the presentation. New data requirements should be based on the scientific knowledge developed in the last years ▪ Regulation (EU) 2017/1432 concerning the criteria for the approval of low-risk active substances ▪ Regulation (EU) 528/2012 will be considered and compared with Regulation 1107/2009 ▪ Comparison of the EU Regulation with other regulations of non-EU countries will be considered	José-Luis Alonso-Prados
	10:15 – 11:00	2.3	**Lecture:** Steps in the risk assessment (problem formulation, hazard identification, hazard characterisation i.e. dose-response assessment, exposure assessment, risk characterisation). How these steps depend on the biological characteristics of the microorganism assessed - STEPSRA	▪ **General principles** of the risk assessment: Problem formulation, hazard identification/characterisation, risk identification/quantification; safety factors. ▪ **Steps** of the environmental Risk Assessment of PPP/biocides based on microorganisms. Differences between the current regulatory framework and the (proposed) changes (e.g., more focussing on hazard identification) ▪ **Decisions on the risk** assessment **based on biological properties and ecology of the PPP/biocides** ▪ **Exposure assessment based on biological properties and ecology of the PPP/biocides** ▪ **Prediction of the environmental** fate and behaviour of a microorganism vs chemical active substances	Anne Steenbergh
	11:00 – 11:20		Coffee break		
	11:20 – 12:00	2.4	**Lecture:** State of art of the academic knowledge in the area of biological control (e.g. most up-to-date and relevant research, microorganisms currently used with this purpose) - ACAKNOW	▪ Omics in biocontrol: functional genomic, proteomic, metabolomics ▪ **Whole genome sequence (WGS)** and its analysis as a complete source for the risk assessment ▪ **Secondary metabolites** of potential concern and natural background concentrations	Anne Steenbergh

Day 2 - Wednesday

	Time		Title of Session	Training Objective/ Subjects Covered	Responsible Tutor
	12:00 – 12:15	2.5	Q&A	▪ Using an interactive communication system, participants will answer questions on the topics presented in the first half of the morning	Marieke van Hulten/ Anne Steenbergh
	12:15 – 13:30		Lunch break		
	13:30 – 14:00	2.6	Case study (I) - *CS1*	Practical examples and exercises on how to assess (1) which **data are needed** depending on the biological properties and ecology of the microorganism and the use proposed (2) The **admissibility** of data provided in dossiers (3) how to **identify potential data gaps** (4) which **data are essential** for a proper risk assessment. ▪ Two different case studies will be explained in parallel (a *bacillus thuringiensis* and a virus) in order to identify the **different approach for the risk assessment.**	José-Luis Alonso-Prados
	14:00 – 14:45	2.7	Practical session (I) - *PS1*	Participants will be divided into groups. Each group will evaluate a different PPP (*Bacillus Amyloliquefaciens*., *Mild Pepino Mosaic Virus, Spodoptera Littoralis, Phlebiopsis,* and *Phlebiopsis gigantea*). Based on the case study described in the previous session, a case study with a quiz will be prepared for each group of participants. The main objective of the practical session will be to **identify the most relevant data necessary for the evaluation** of a PPP based on a microorganism, special attention will be given to the (1) **identification** of the microorganism, (2) the **mode of action** and the production of (3) **secondary metabolites**. The data will be classified as: Essential/ needed/junk data (2) Admissible /no-admissible data and (3) Data gaps	Participants / Anne Steenbergh with José-Luis Alonso-Prados, Marieke van Hulten and Belen Guijarro
	14:45 – 15:30	2.8	**Lecture:** Methods to evaluate efficacy of microorganisms used under different conditions (e.g. in ABC) - EFF	▪ Laboratory test: *In vitro* and *in vivo* test: Dose response assessment (minimum effective dose); Techniques for the evaluation of the efficacy base on the mode of action ▪ Greenhouse and field trials ▪ Resistance evaluation. Difference with chemical PPP ▪ Viability. Influence of biotic and abiotic factor (temperature, inoculum density, non-target microorganism...) on survival and efficacy of the MPCAs ▪ Quantitative and qualitative evaluation of the efficacy ▪ Importance of environmental conditions ▪ EPPO Standards – PM 6 Safe use of biological control GAP table (units for microorganism)	Marieke van Hulten
	15:30 – 15:50		Coffee break		

Day 2 - Wednesday

	Time		Title of Session	Training Objective/ Subjects Covered	Responsible Tutor
	15:50 – 17:00	2.9	Practical session (II) - *PS2*	Participants will be divided into small groups. Based on the steps used in the approach for the evaluation of the efficacy provided in previous session, a case study based on the efficacy section of registration reports of PPP of *Bacillus_thuringiensis, Bacillus amyloliquefaciens, Pepino Mosaic Virus and Isaura fumorosea* will be prepared for each group of participants. • The **main objectives** of the practical session will be: (1**) identify the relevant data** that are necessary for the efficacy analysis, based on biological properties and ecology (as life cycle of the microorganism and the target organism/s (2) **Analysis of efficacy**/ difference with chemicals (3) **GAP tables information**: relevant information for the risk assessment, which data are needed depending on the biological properties of the microorganism and the use proposed.	Participants / Marieke van Hulten with Jose Luis Alonso-Prados and Belen Guijarro
	17:00 – 17:30	2.10	Practical session (II) - *PS2 – presentation of the results*	The rapporteur of the four groups presents their main results, the tutor valides and explains further if necessary.	Participants / Marieke van Hulten
	17:30 – 18:20	2.11	**Lecture:** Instruction to retrieve relevant scientific information (e.g. tailored scientific literature databases, bioinformatics databases) Methods to perform and appraise a literature review. Systematic literature review methodology - *SCIINFO*	▪ Global Catalogue of Microorganisms registration system of culture collections and the use of electronic markers "Globally Unique Identifiers" ▪ Main databases of scientific literature: Genome databases (i.e. Gen bank), antimicrobial resistance substance (WHO, CHIA, CIA) ▪ The importance of preserving the MPCAs in the culture collection's registration system and the use of electronic markers "Globally Unique Identifiers". System to track the flow of resources and related information ▪ Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 ▪ Difference with chemical PPP	Belen Guijarro
	18:20 – 18:40	2.12	**Plenary Session** – Review of Day 2	▪ Final remarks, summary of day 2, comments and instructions for joining the training the following day	Training Coordinator José-Luis Alonso-Prados

Day 3 - Thursday

	Time		Title of Session	Training Objective/ Subjects Covered	Responsible Tutor
	9:00 – 9:45	3.1	**Lecture:** Characterisation of the microorganism Phenotypic and genotypic approaches (including Whole Genome Sequencing and molecular markers) to perform analyses, such as identification and quantification of microorganisms, detection of AMR, evaluation of production of secondary metabolites of potential concern, pathogenicity, infectivity, assessment of toxicity (e.g. test of crude extracts of microorganisms), efficacy - *CHARACTMO*	▪ **Phenotypic and genotypic characterisation** of microorganisms (including concepts of genome stability, polymorphisms, fingerprint and molecular markers) ▪ **Manufacturing processes** including quality control (e.g. impurity, contaminant limits, continuous and batch process) ▪ **Antimicrobial resistance (AMR**). Difference between intrinsic and acquired AMR, cross-resistance, antibiotics and disinfectants resistances ▪ **Secondary metabolites of concern** and background concentrations ▪ **Storage stability** (shelf-life) of the microbial plant protection and biocidal product ▪ **Quantification of microorganism** ▪ Examples of the main microorganisms used as PPP/biocide and its mode of action (production of secondary metabolites) will be included throughout the presentation with special attention to the relevance for the risk assessment).	Belen Guijarro
	9:45– 10:30	3.2	Case study (II) - *CS2*	▪ Special case study will include the assessment of the (1) **antimicrobial resistance (2) secondary metabolites of concern**	Participants / Belen Guijarro
	10:30 – 10:50	Coffee break			
	10:50 – 11:30	3.3	**Lecture:** Environmental dynamics of microorganisms in the context of ABC - *ENVIDYN*	▪ **Persistence,** resilience, dynamic of growth assessing based on intrinsic properties of the microorganism (growth limitations) in different environmental compartments (e.g. in soil (rhizosphere) and into/onto plant tissues/surfaces) where the microorganism could be found in regard to its mode of action, application rate and crop/s ▪ **Dispersal** of microorganisms (e.g. aerial) ▪ **Environment Concentrations (PEC)** in the different environmental compartments (metabolites of concern and viable microorganism) ▪ **The risk of invasiveness and growth ability**. Introduction of non-indigenous microorganisms in the environment, and interaction with autochthonous populations (e.g. competition, populations' dynamics, effects on microbiological biodiversity)	Sari Autio

Day 3 - Thursday

	Time		Title of Session	Training Objective/ Subjects Covered	Responsible Tutor
	11:30 – 12:15	3.4	**Lecture:** Sampling techniques (e.g. from soil and plant tissues), and spatial variability of environmental samples (i.e. uncertainty linked to sampling approach chosen). Issues and approaches for harmonised methodologies - *SAMPTECH*	▪ **Background level information:** scientific literature search concerning the occurrence of any strain belonging to the same species as the microorganism in question in any environmental compartments ▪ **Population density:** estimated calculation of the density/ experimental data (predicted environmental density) ▪ **Population dynamics**: Estimated levels of the specified microorganism in a time course after use of the product under the proposed conditions of use ▪ **Qualitative assessment:** regarding the potential of the microorganism to disperse and establish outside of its expected ecological niche(s) following the representative use (based on existing knowledge of the ecology of the microorganism such as its ecological role (e.g. saprotrophic, parasite, endophyte), host range, target organism, life cycle, and growth requirements ▪ Examples of the main microorganisms used as PPP and its mode of action will be included throughout the presentation with special attention to the relevance for the risk assessment).	Belen Guijarro
	12:15 – 13:15	Lunch break			
	13:30 – 14:15	3.5	**Lecture:** In the context of ABC: interaction with non-target organisms and evaluation of exposure, potential risks, and effects - *NTO*	▪ Evaluation of exposure, potential risks, and effects of the MPCA based on: ▪ **Toxicity, pathogenicity, and infectivity** concerning the adverse effects on non-target organisms observed for the strains belonging to the same species (based on scientific literature search and intrinsic properties associated with the specific mode of action) ▪ **Production of toxins and/or metabolites of concern** confirmed (based on mode of action and ecology), then acute toxicity studies shall be conducted for the relevant non-target organisms ▪ **Microorganism can remain viable under normal conditions of use** (based on the elements of information of the fate and behaviour), then pathogenicity/infectivity studies are needed for the relevant non-target organisms ▪ Examples of the main microorganisms used as PPP and its mode of action will be included throughout the presentation with special attention to the relevance for the risk assessment.	Alberto Mantovani

Day 3 - Thursday

	Time		Title of Session	Training Objective/ Subjects Covered	Responsible Tutor
	14:15 – 15:00	3.6	**Lecture:** Potential pathogenicity for humans and relevance of residues for human health. Living residues of microbial plant protection and biocidal products and their differences with chemical residues - *HUMHEALTH*	▪ **Pathogenicity and infectiveness,** sensitisation (dermal and inhalation), medical data ▪ **Acute/short term toxicity studies** and genotoxicity studies for metabolites ▪ **Identification of relevant residues** (toxicological or pathogenic) – **Viable microbial residues** – **Non-viable microbial residues** – **Metabolites of concern (toxins and antimicrobial compounds)** ▪ **Maximum residue levels for metabolites of concern**, at defining pre-harvest intervals to protect consumers and waiting periods, to protect workers handling the treated crops and products from the occurrence of metabolites of concern Similarities and difference with chemical residues/Scientific Literature	Alberto Mantovani
	15:00 – 15:20	Coffee break			
	15:20 – 16:30	3.7	Practical session (III) - *PS3*	Participants will be divided into groups. Each group will work on different microorganism (*Bacillus amyloliquefaciens, Phlebiopsis gigantean*) based on the characterisation of the microorganism showed in previous sessions; a case study with a quiz will be prepared for each group of participants. The main objective of the practical session will be to identify the relevant data that are necessary for environmental risk assessment, • Based on the characterisation of the microorganism and its secondary metabolites of concern • Hazard identification for humans: Intrinsic toxicity, pathogenicity and/or infectiveness of the microorganism/ secondary metabolite; Specific adverse effects observed • Hazard identification for environment and NTO: Intrinsic toxicity, pathogenicity and/or infectiveness of the microorganism/ secondary metabolite towards non-target organisms; Specific adverse effects observed • Risk assessment for humans and NTO Possible risk mitigation measures to be used	Participants / Belen Guijarro, José-Luis Alonso-Prados, Sari Autio and Alberto Mantovani
	16:30 – 17:20	3.8	Practical session (III) – *PS3 – presentation of the results*	The rapporteur of the four groups presents their main results, the tutor valides and explains further if necessary.	Participants / Belen Guijarro

Day 3 - Thursday

	Time		Title of Session	Training Objective/ Subjects Covered	Responsible Tutor
	17:20 – 17:40	3.9	**Plenary Session** – Review of Day 3	Final remarks, summary of day 3, comments and instructions for joining the training the following day	Training Coordinator José-Luis Alonso-Prados

Day 4 - Friday

	Time		Title of Session	Training Objective/ Subjects Covered	Responsible Tutor
	9:00 – 9:45	4.1	**Lecture:** Analytical units: types, appropriate use according to the different needs (e.g. measuring bacteria, viruses or conidia) - *ANAUNIT*	▪ Harmonised units on technical terminology based on formulation, biological properties, production of secondary metabolites involved in the mode of action, target organisms (e.g. genome copies/L; CFU/L, viable/non-viable conidia, occlusion bodies/L). Examples of the main microorganisms used as PPP/biocide and its mode of action will be included throughout the presentation with special attention to the relevance for the risk assessment.	Sari Autio
	9:45 – 10:30	4.2	**Lecture:** Risk mitigation measures related to the use of microorganisms (e.g. correct choice of pre-harvest interval, operators' equipment) - *RMM*	▪ Reduction of exposure level envisaged through risk mitigation measures ▪ Similarities and difference with chemical residues	Sari Autio
	10:30 – 10:50	4.3	**Plenary Session** – Review of Day 4	▪ Final remarks and summary of day 4	Training Coordinator José-Luis Alonso-Prados
	10:50-11:15	Coffee break			
	11:15-11:35	4.3.1	Post-Course Test	Repetition of Pre-Course Test using interactive to identify the success of the training course	Training Coordinator
	11:35-11:50	4.3.2	Post-Course Test Answers	Review of Pre- /Post-Course Test with Answers	Training Coordinator
	11:50-12:15	4.4	Online Evaluation	Participants will evaluate the training using the CHAFEA on-line evaluation system	Event Manager
	12:15 – 12:30	4.5	Closing of the Training	Closing remarks (including the obligation for dissemination) and award of certificates, group photo, USB memory stick	Training Coordinator
	12:30	Lunch and transfer to the airport			

ANNEX 4: TRAINING MATERIAL, OUTCOMES AND DISSEMINATION ACTIVITIES

Training material

All participants will receive the training material well in advance of the training. The material will include additional pre-recorded material for offline studies and presentations. Preparatory videos will introduce the specific topic and provide background information to participants.

All participants will receive a Dissemination Kit electronically to enable them to actively disseminate course knowledge upon their return from BTSF training. Participants attending face-to-face courses will receive the information on the USB key.

Training material in your language

By registering for the BTSF ACADEMY all course participants will have the possibility to translate all the information and training materials in the BTSF ACADEMY, including this course, into 22 European languages. Information and training can also be viewed in additional languages using the automated translation features of common web browsers. This feature is accessible via the languages selector on the BTSF ACADEMY home page. It allows users to:

- Access the content of the BTSF ACADEMY translated to EU MS official languages
- Download documents in a translated version and the original language version to compare formatting/original meaning
- Follow the training activities more comfortably
- Improve their understanding of the topics related to their area/s of work
- Disseminate their acquired knowledge
- Use the materials to train other colleagues in their organisation
- Draft additional training material based on the available information translated into their language/s.

Whilst not perfect, the eTranslation service is continuously improving. The BTSF ACADEMY Team will keep working to ensure the maximum compatibility of the original content and to extend accessibility to a wider audience.

Those users interested in the eLearning modules in their own language in the BTSF ACADEMY and viewing the platform in additional languages to the eTranslation option, should follow the instructions in the ACADEMY home page here.

Dissemination Kit

This contains the following training materials:

- All course presentations
- Study notes on field trips and group activities/discussions and conclusions thereof
- The course syllabus
- The training information sheet
- Glossary of terms and abbreviations used in the course
- Additional references for further study
- Written guidance on how to actively disseminate course knowledge to colleagues upon participants' return to their home countries- different methodologies/examples/best practice
- Other information and material delivered from the course such as quizzes, FAQs etc

Dissemination questionnaire

Two to three months after the respective training session, participants will receive a standard questionnaire requesting information on the dissemination activities of the participant after the training, and details on differences in the approach adopted in day-to-day work following the training.

Self-assessment test

Furthermore, the programme will include an anonymous knowledge test to be carried out at the beginning and at the end of each training session in order to measure the impact of the training on the understanding of the participants of the subjects taught. Participants are expected to agree to carry out the above tests and to reply to the surveys and questionnaires.
By participating in the training, participants agree to:

- be registered in the BTSF Academy
- provide the details requested by the contractor to register in the BTSF ACADEMY (including the provision of requested Commission EU Login details including the (Unique Identifier at the Commission - uid) -instructions on how to do this will be supplied . Please note participants who do not provide details as requested will be able to register in BTSF ACADEMY and **will NOT receive a certificate of participation.**
- attend a group photo of the participants and tutors at the end of the training session. Photographs will be published in the BTSF Academy in the corresponding training course section and will be visible only to registered users of the BTSF ACADEMY.
- give their permission to be filmed, should this be required. At least one session of every series of workshops/videoconferences must be recorded. Videos and photo will be published in the BTSF Academy in the corresponding training course section and will be visible only to registered users of the BTSF ACADEMY.

Please find more information regarding data protection here:
https://btsfacademy.eu/training/mod/page/view.php?id=417

ANNEX 5: CONTRACTOR CONTACT DETAILS

The project is managed by Tara Alvarez.
Project manager: Tara Alvarez
Training Coordinator : Jose Luis Alonso Prados.

Separate notifications will be sent to National Contact Points for each course and will contain the names and contact details of the Event Manager and Assistant Event Manager as well as logistical details on the event.

All official communication between National Contact Points and the project will be maintained through the functional e-mail address 20199604.ramo@aets-consultants.com by phone to +33 (0)5 59 72 43 23

The project website is https://foodinfo-europe.com/ The website will be regularly updated with details of forthcoming courses.

All information on BTSF training can be found at the BTSF Academy website and at https://foodinfo-europe.com/ These websites will be regularly updated with details of forthcoming courses.