Organisation and implementation of training activities on Evaluation and Authorization Procedures for Plant Protection Products Contract ID 2017.96.10 COURSE Ecotoxicological risk assessment for the terrestrial and aquatic environment under the "Better Training for safer Food" Initiative

1. Course objectives

General objective

Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market has introduced a new legal framework in Europe for the assessment and approval of active substances and for authorisations of plant protection products containing them. Among the main provisions introduced: a full harmonisation for risk assessment, decision making, strict criteria for approval of active substances, the substitution principle to be applied to the substances identified as candidates for substitution, incentives for low risk active substances, the zonal system for the assessment and authorisations of plant protection products and the mutual recognition of such authorisations with strict deadlines.

Despite above-mentioned Regulation is fully applicable since June 2011, in several areas of risk assessment national requirements are still substantially hampering the functioning of the zonal system and the respect of set deadlines. The lack of proper implementation of zonal system and mutual recognition is thoroughly described in the recently published Overview Report on Plant Protection Products authorisations (SANTE/2017/6250**) where it is concluded "the majority of Member States fail to use the zonal authorisation system as envisaged in the regulation and fail to comply with almost all legal deadlines".

Currently, the degree of harmonisation is low concerning the mitigation techniques and measures available in the different Member States, their use by the Competent Authorities in granting authorisations and their documentation on the label. A legal obligation to notify PPP-specific, additional, national safety phrases ('precautionary statements' under GHS) to the Commission seems to be largely ignored by Member States, as so far only two of them have done so.

Therefore, training is an essential tool to improve the spreading of knowledge and awareness and to promote a common understanding of the operation of EU and national control systems.

The workshops of the project will allow an analysis and exchange on **risk assessment methodologies** applied at national level for the **assessment of plant protection products** performed in accordance with the EU legislation on pesticides, Regulation (EC) No 1107/2009 and in accordance with the Uniform Principles set out in Regulation (EU) No 546/2011.

The risk mitigation measures assessed during in the risk assessment of plant protection products to allow for an acceptable use are fundamental to define the conditions for use of pesticides in each crop. Indeed, once defined they become part of the authorisation conditions and, if applicable, have to be reported on the labelling of the products in the form of specific conditions of use or as Safety Precaution Phrases (SP-phrase), according to Regulation (EU) No 547/2011.

In this context, a part of the workshops will follow up on the results of **MAgPIE project** which provides the toolbox of **risk mitigation measures** designed for the use on the pesticides for agricultural purposes.

This project will generally focus on:

deepening how Member States and/or zones implement the Uniform principles for **evaluation** and **authorisation** of **plant protection products**,

• examination of national **risk assessment methodologies** and identify which degrees of flexibility in the models used could still be adjusted to not undermine potential mutual recognition,

• examining some specific cases of **risk reduction** goals deriving from the risk assessment and how they are pursued through identification of effective **risk mitigation measures**,

• comparing and discussing possible equivalent risk mitigation measures,

• exchanging views on experience gained in implementing the Guidance Document (SANCO/11244/2011 rev. 5) on the preparation and submission of dossiers for plant protection products according to the "**risk envelope Approach**".

Specific Objectives:

With respect to the issues covered by the project, the objective of the courses is to **bridge some knowledge** gaps between risk assessment and risk management generated by the difference in the parameters considered with a particular focus on the exposure and on how this can be managed.

- To improve cognitive skills, knowledge and comprehension of the difference between hazard and risk and the general rules for the ecotoxicological risk evaluation;
- To offer a uniform overview of the EU legislative framework in the evaluation of PPPs
- To know how to evaluate the exposure and the its effects in environmental risk assessment;
- To know how to use the the MAgPie toolbox of measure and guideline available for management of pesticide risk;
- To know how to determine and to apply mitigation measures

2. 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 Course Ecotoxicological risk assessment for the terrestrial and aquatic environment

Participants who have previously completed the BTSF courses on **Ecotoxicological risk assessment for the terrestrial and aquatic environment** should be assessed for their eligibility for this training based on the criteria below. Only **eligible participants** should be further assessed against the minimum requirements below.

The training is addressed to experienced staff involved in evaluations and decision making for authorisation of plant protection products in Member States.

These officials must be identified and proposed by Member States' competent authorities through previously identified National Contact Points (NCPs) for these countries.

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 Ecotoxicological risk assessment for the ter and aquatic environment | rrestrial Yes/No |
|---|--------------------------|
| Participant must: | |
| have completed previous courses on assessment of efficacy of plant proproducts and /or on toxicological risk assessment and /or eco-toxicological assessment on environmental fate and behaviour in soil, air and water <u>OR</u> | ogical risk |
| Have worked in functional areas of evaluations and decision making for authorisation of plant protection products with a minimum of 3 years of professional experience or Had experience of setting up and implementation of risk assessment a | of |
| analytic of setting up and implementation of risk assessment a management for authorisation of plant protection products as well as knowledge about the latest developments as regards guidance assessment in a Competent Authority (covering areas of food/ feed safe health or animal welfare). | s in depth e for risk |

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 Course 2 | Enter Score |
|----|---|--------------------|
| a) | Experience in evaluations and decision making for authorisation of plant protection products within a competent authority in areas of food/feed safety, animal health or animal welfare, in particular in areas such as risk assessment for | Max 12.5 points |

| | authorisation of plant protection products. | |
|----|--|--------|
| | Scoring | |
| | less than 3 years = 0 points; \ge 3 years = 5 points; 5 - 10 years = 10 points; > 10 years = 12.5 points | |
| b) | Experience in implementing of evaluations and decision making for authorisation of plant protection products within a competent authority in areas of food/feed safety, animal health or animal welfare, in particular in areas such as risk management for authorisation of plant protection products <u>Scoring</u> | |
| | no experience = 0 points; < 2 years = 5 points; 2-5 years = 7.5 points; > 5 years = 10 points | |
| c) | Contribution towards very specific risk assessment and/or risk management for authorisation of plant protection products as well as in depth knowledge about the latest developments as regards guidance for risk assessment. Scoring 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; | Max 15 |
| | 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 Points 1, 2 plus preparing informative articles in the professional national journals = 15 points | points |
| | no commitment = 0 points | |

3. Country allocations

A total of **50 seats/per each session** will be invited.

Please note that the number of allocated seats for each country may be subject to variation.

Should you consider that the number of allocated seats is insufficient to meet your country's training needs, please contact the Project Manager at GIZ International Services Brussels Office, <u>www.trainsaferfood.eu/base/contact</u> or by email at <u>info@trainsaferfood.eu</u> as soon as possible, providing an explanation.

The contractor will evaluate your request and pass it to the Contracting Authority for consideration

| Training Course | Dates | Deadline | Number of participants for your country |
|--|----------------------|-----------|---|
| Ecotoxicological risk assessment for the terrestrial and aquatic environment | 28 Jun - 02 Jul 2021 | 14-Jun-21 | 1 |

4. Training dates

1 Training session of **5** days in Virtual Classroom (VC) training course will be delivered between **26**th of June and **2**nd of July **2021** with approximately 50 people in each session.

Here below is provided the agenda of the training session for each of day.

DAY 1

| TIME | Session Title | Tutors |
|--|---|---|
| 10.00-11.00 | Registrations-instructions | GIZ event managers |
| 11.00-11.30 | Welcome and presentation of: -Logistic arrangements - BTSF video -Tutors -BTSF programs and course -Presentation of each participants, and discussion of participants' role and professional background | TC and TUTORS and GIZ event managers |
| 11.30-12.00 | Knowledge test to participants | GIZ event managers |
| 12.00-14.00 | Lunch break | |
| 14.00-15.00 (40-45 min duration) | Presentation 1a : general protection goals in ERA- Unwrapping the EU legislative framework in the evaluation of PPPs: in the context of the EU legislative framework on pesticide risk evaluation and sustainability including the pesticide package, information on IPM and the different methodologies available and the link with other regulations as the WFD (the Directive 2000/60/EC) | Ettore Capri (IT) |
| 15.00-16.00 | (time to switch should be included) Presentation 1a: continued | Ettore Capri (IT) |
| (40-45 min duration) | The importance of risk mitigation and mitigation strategy Discussion | |
| 16.00-16.30 | Coffee Break | |
| 16:30-18:00 (90 min duration) Anticipated time is: Theory 40-45 min + 30 min practice | Presentation 1b: Interactive session with Q/A for trainees' participation (theory & practice): Ecotoxicological Risk Assessment (basic principles, steps); problem formulation and hypothesis testing; specific protection goals Instructions and solutions also switches and breaks are included | Evgenia Chaideftou (GR) Willie Peijnenburg (NL) |
| 18:00 | Closing of Day 1 | |

DAY2

| TIME | Session Title | Tutors |
|---|---|--|
| 08:30-09:00 | Registrations | GIZ event managers |
| 09:00-09:45 (30 min duration) | Presentation 2 (part a): Exposure & effect characterisation in ERA. Exposure evaluation, general approaches on chemical, physical characteristics that influence the fate of a chemical in the environment and current state of knowledge on multimedia fate models. (interactive time with Q/A included) | Willie Peijnenburg (NL) Evgenia Chaideftou (GR) |
| 09:45-10:30 (30 min duration) | Presentation 2 (part b): Exposure & effect characterisation in ERA. Hazard/ Effect characterisation (Effect assessment). From screening to first tiers (interactive time with Q/A included) | Evgenia Chaideftou (GR) Willie Peijnenburg (NL) |
| 10:30-11:00 | Coffee break | |
| 11.00:12.15 | Practical 2 (part a) exposure pathways & procedures/ models; Example of model application to define and to understand the fate and behaviour of a pesticide active ingredient, to understand the movement of a chemicals in the environment and to predict a concentration in different environmental compartments (breakout exercise; interactive time with Q/A included) Chat function of similar will be used to guide and help the participants during the exercise with the support of the Event Manager and the Assistant Event Manager | Willie Peijnenburg (NL) Evgenia Chaideftou (GR) |
| | Short 5min break | |
| 12.20:13.00 | Practical 2 (part b) Effect characterisation in ERA. Choice of effect endpoint; Exercise from Aquatic GD PPPs. (breakout exercise; interactive time with Q/A included) | Evgenia Chaideftou (GR) Willie Peijnenburg (NL) |
| 13:00-14:00 | Lunch break | |
| 14:00-15:30 | Presentation 3 : Risk characterisation (combination of the effect and the exposure assessment; examples of risk characterisation). | Sebastian Stehle (DE) |
| 15:30-16:00 | Coffee break | |
| 16:00-17:00 | Practical 3 : Risk assessment exercise from EFSA Guidance on PPPs (e.g. Aquatic GD, or ERA of soil organisms)- wrap-up (breakout exercise; interactive time with Q/A included) | Willie Peijnenburg (NL) Evgenia Chaideftou (GR) Sebastian Stehle (DE) |
| 17:00-17:30 | Discussion on ERA (integrating the issues of the day) | Willie Peijnenburg (NL) Evgenia Chaideftou (GR) Sebastian Stehle (DE) |
| 17.30-18.00 | Break | |
| 18:00 | Social activity | |

DAY 3

| TIME | Session Title | Tutors |
|-------------|--|--|
| 08:30-09:00 | Registrations | GIZ event managers |
| 9:00-10:30 | Point Source Contamination and Diffuse Source Contamination ; Presentation and interactive session with time for Q/A | Maura Calliera (IT) Gabriele Sacchetini (IT) |
| 10:30-11:00 | Coffee break | |
| 11:00-13:00 | Practical: Dissemination activities: Introduction led by tutor Practical exercise and Interactive session to discuss: -the importance of dissemination -platforms networks available -awareness raising campaigns and material at different national levels | Gabriele Sacchetini (IT) Maura Calliera (IT) |
| 13:00-14:00 | Lunch break | |
| 14:00-14.30 | Dissemination activities Interactive session: wrap up of the practical session | Gabriele Sacchetini (IT) Maura Calliera (IT) |
| 14.30-15.30 | Non-target exposure evaluation and the mitigation measures applicable: tools available for the evaluation of different sources of exposure Presentation and interactive session | Maura Calliera (IT) Gabriele Sacchetini (IT) |
| 15:30-16:00 | Coffee break | |
| 16:00-17:30 | Presentation and practical exercise Instructions: the MAgPie toolbox of measure and guideline available for management of pesticide risk; and introduction to Practical exercise on mitigation measure: trainees act out a real-life situation | Maura Calliera (IT) Gabriele Sacchetini (IT) |
| 17.30-18.00 | Group discussion analysis and exchange on risk assessment methodologies applied at national level for the assessment of plant protection products and authorisations process | Maura Calliera (IT) Gabriele Sacchetini (IT) |
| 18.00 | Closing of Day 3 | |

DAY4

| TIME | Session Title | Tutors |
|-------------|---|--|
| 08:30-09:00 | Registrations | GIZ event managers |
| 9.00-11.00 | Practical exercise on mitigation measure: trainees act out a real-life situation. | Maura Calliera (IT) Gabriele Sacchetini (IT) |
| 11.00-11.30 | coffee break | |
| 11:30-12:30 | Interactive session: wrap up of the practical session | Maura Calliera (IT) Gabriele Sacchettini (IT) |
| 12:30-14:00 | Lunch break | |
| 14.00-15.30 | field visit-part A Movie with the owner João Coimbra of the Estate (intensive production, green infrastructures on less productive areas to improve natural pest | Paulo Sousa (PT) Ettore Capri (IT) Maura Calliera (IT) |

| | control and pollinators and where they use decision support systems to minimise PPP input; focus on soil and arthropod organisms). | Gabriele Sacchettini (IT) |
|-------------|--|--|
| 15:30-16:00 | Coffee break | |
| 16.00-18.00 | Discussion (focus group dynamics) on specific topics (implementation of green infrastructures as one of the ways to reduce PPP inputs and risk | Paulo Sousa (PT) Ettore Capri (IT) Maura Calliera (IT) Gabriele Sacchettini (IT) |
| 18.00 | Closing of Day 4 | |

DAY 5

| TIME | Session Title | Tutors |
|-------------|---|-----------------------|
| 08:30-09:00 | Registrations | Marius Flintoaca |
| 09:00-09:45 | Special issues in ERA: | Sebastian Stehle (DE) |
| | Higher tier case study – Risk assessment for aquatic organisms | |
| | (interactive time with Q/A, or other upon tutor to include) | |
| 09.45-10.30 | Special issues in ERA: | Willie Peijnenburg |
| | New developments case study - | (NL) |
| | Nano-based pesticides and environmental risk assessment | |
| | (interactive time with Q/A, or other upon tutor to include) | |
| 10:30-10:45 | Coffee break | |
| 10:45-11:30 | Wrap-up discussion on the MAgPie and related mitigation, and ERA | TC, tutors & |
| | approaches; | GIZ event managers |
| 11.30-12.30 | On-line evaluation by the participants; | GIZ event managers |
| | Evaluation of the ERA course and the tutors-knowledge questionnaire | |
| 12:30-13:30 | Conclusion | TC, tutors & |
| | Recommendation | GIZ event managers |
| | Importance of dissemination and networking | |
| | Distribution of certificates | |
| | Group photo | |
| 13.30 | Closing of last Day | |

Table 3: Training dates

| Year | Training session | Proposed dates | Location | Course Title |
|------|--|----------------------|----------|---|
| 2021 | 2 nd (the first training session on this topic was held in 2019/2020 in face to face format) | 28/06- 02/07/2021 | Webex | Ecotoxicological risk assessment for the terrestrial and aquatic environment |

Annex 1: Background and main topics covered in training

Background

Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market has introduced a new legal framework in Europe for the assessment and approval of active substances and for authorisations of plant protection products containing them. Among the main provisions introduced: a full harmonisation for risk assessment, decision making, strict criteria for approval of active substances, the substitution principle to be applied to the substances identified as candidates for substitution, incentives for low risk active substances, the zonal system for the assessment and authorisations of plant protection products and the mutual recognition of such authorisations with strict deadlines.

Despite above-mentioned Regulation is fully applicable since June 2011, in several areas of risk assessment national requirements are still substantially hampering the functioning of the zonal system and the respect of set deadlines. The lack of proper implementation of zonal system and mutual recognition is thoroughly described in the recently published Overview Report on Plant Protection Products authorisations (SANTE/2017/6250**) where it is concluded "the majority of Member States fail to use the zonal authorisation system as envisaged in the regulation and fail to comply with almost all legal deadlines".

Currently, the degree of harmonisation is low concerning the mitigation techniques and measures available in the different Member States, their use by the Competent Authorities in granting authorisations and their documentation on the label. A legal obligation to notify PPP-specific, additional, national safety phrases ('precautionary statements' under GHS) to the Commission seems to be largely ignored by Member States, as so far only two of them have done so.

The workshop of the project will allow an analysis and exchange on **risk assessment methodologies** applied at national level for the **assessment of plant protection products** performed in accordance with the EU legislation on pesticides, Regulation (EC) No 1107/2009 and in accordance with the Uniform Principles set out in Regulation (EU) No 546/2011.

The risk mitigation measures assessed during in the risk assessment of plant protection products to allow for an acceptable use are fundamental to define the conditions for use of pesticides in each crop. Indeed, once defined they become part of the authorisation conditions and, if applicable, have to be reported on the labelling of the products in the form of specific conditions of use or as Safety Precaution Phrases (SP-phrase), according to Regulation (EU) No 547/2011.

In this context, will follow up on the results of **MAgPIE project** which provides the toolbox of **risk mitigation measures** designed for the use on the pesticides for agricultural purposes.

Main topics covered in the training

The following modules are proposed:

- Module 1 General approaches to risks evaluation: difference between hazard and risk and the pesticide risk assessment evaluation approach, effects evaluation on non-target organism, exposure assessment, the significance of the relationship between effects and exposure, the importance of risk characterization.
 - ✓ general approaches and current state of knowledge on models to defining end points and other criteria related to intrinsic characteristic of the active ingredients and the dose that could express an effect on non-target organism,
 - ✓ general approaches on chemical, physical characteristic that influence the fate of a chemical in the

environment and current state of knowledge on multimedia fate models to define and to understand the fate and behaviour of a pesticide active ingredient and in order to understand the movement of a chemicals in the environment and to predict a concentration in different environmental compartments (exposure)

- ✓ general approach in defining the non-target organism, the food chain, the bioaccumulation and biomagnification, the ecosystems and examples of risk characterisation
- ✓ the exposure sources: Point Source Contamination and Diffuse Source Contamination
- Module 2 the EU **legislative framework on pesticide risk evaluation and sustainability** including the pesticide package, information on IPM and the different methodologies available and the link with other regulations as the WFD (the Directive 2000/60/EC).

An analysis and exchange on **risk assessment methodologies** applied at national level for the assessment of plant protection products and authorisations process will be performed

Participants will be asked, after the confirmation of the course participation, to respond to a questionnaire prepared by the trainers' staff, on this subject to share the data that will emerge and discuss the differences between the various approaches, and the limit of harmonization

- Module 3 evaluation of the exposure and the mitigation measure applicable
 - ✓ the decision supporting systems available to prevent environmental contamination after a pesticide treatment
 - ✓ and the comparative management assessment
 - ✓ diagnostic tools of run off in different contexts
 - ✓ drift diagnosis tools: machine calibration and SDRT related reduction percentages from MAgPie and Mitigation Measure for drift limitation in different contexts
 - ✓ level of risk reduction degree of the principal mitigation measure applied in risk assessment to obtain safe use and the link with MAgPie evaluation
 - ✓ pesticide label reading and mitigation measure label evaluation, safe and risk phrases
 - ✓ Inventory of the mitigation measure in MAgPie, the evaluation of their efficacy taking into account the additional effect of more than one mitigation, the diversity of the tools developed and implemented throughout European countries, as well as the number of regulatory frameworks to which they relate or with which they may overlap

An analysis and exchange on the mitigation measure applicability in different context will be developed. A case study will be presented and working group will be organised to analyse different situation in different context and culture.

Annex 2: Legislation and guidance

- EU legislative framework in the evaluation of PPPs: in the context of the EU legislative framework on pesticide risk evaluation and sustainability including the pesticide package, information on IPM and the different methodologies available and the link with other regulations as the WFD (the Directive 2000/60/EC)
- the MAgPie toolbox of measure and guideline available for management of pesticide risk;
- Risk assessment from EFSA Guidance on PPPs (e.g. Aquatic GD, or ERA of soil organisms).

Annex 3: Agenda



Annex 4: Technical requirements

The VC sessions will be organised with the use of the Webex web conferencing tool. The participants will take part in a short Webex test training session in the weeks before the actual session. The Webex test training will help participants to become familiar with the Webex platform. They will also receive some general information on the course and have the opportunity to ask questions.

The participants should have <u>a computer with a working camera and audio system (speaker and</u> <u>microphone) as well as a good internet connection.</u>

To avoid delays, the registered participants will be contacted for a technical test of their equipment a few days before the training sessions. This will allow participants to test their equipment and view the main features of the VC application platform. During this brief test, participants will have the chance to learn all the tools of the VC platform.

During this meeting, the Event Manager and Assistant Event Manager will also go through the main aspects of the agenda and different sessions that are foreseen. Additionally, in the morning of Day 1 of the VC, time will be dedicated to a technical session to refresh participants on the main features of the platform, and ensure connections are working properly.

Annex 5: 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. Preparatory videos will introduce the specific topic and provide background information to participants.

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. Participant agree to be registered in the BTSF Academy and agree to be recorded during Virtual Classroom Training sessions and to take a group photo of the participants and tutors at the end of the training. Videos and photo will be published in the BTSF Academy in the corresponding Training course section and will be visible only to the registered participants in that Training course.

Please find more information regarding data protection here:

https://btsfacademy.eu/training/mod/page/view.php?id=417

Annex 6: Contractor contact details

The project is managed by Deutsche Gesellschaft fur Internationale Zusammenarbeit GmbH GIZ, International Services Brussels Office

Project Manager is Mr. Sergio Ninotti

Training Coordinator for Course Ecotoxicological risk assessment for the terrestrial and aquatic environment is Ms Evgenia Chaideftou

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 info@trainsaferfood.eu or by phone to **+ 3222292796** telephone number.

The project website is <u>www.trainsaferfood.eu</u>. The website will be regularly updated with details of forthcoming courses.