

**Organisation and implementation of training activities on
Evaluation and Authorization Procedures for Plant Protection Products**

Contract ID 2017.96.10

COURSE Assessment of Efficacy of Plant Protection Products

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.

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.**

- Improve participants’ knowledge on the latest EPPO standard PP1/296(1) Principles of efficacy harmonization of assessment of the potential risk of resistance development
- Improve participants’ ability to evaluate realistic uses of a representative plant protection product using the available data and the principles of biological extrapolation

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 Assessment of Efficacy of Plant Protection Products

Participants who have previously completed the BTSF courses on **assessment of efficacy of plant protection products** 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 Assessment of efficacy of plant protection products

Yes/No

Participant must:

- have completed previous courses **on toxicological risk assessment and /or ecotoxicological risk assessment for terrestrial and aquatic environment /ecotoxicological risk assessment on environmental fate and behaviour in soil, air and water.**

OR

- 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 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** 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 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 authorisation of plant protection products.**

Max 12.5 points

	<p><u>Scoring</u></p> <p>less than 3 years = 0 points; ≥ 3 years = 5 points; 5 - 10 years = 10 points; > 10 years = 12.5 points</p>	
b)	<p>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</p> <p><u>Scoring</u></p> <p>no experience = 0 points; < 2 years = 5 points; 2-5 years = 7.5 points; > 5 years = 10 points</p>	Max 10 points
c)	<p>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</p> <p><u>Scoring</u></p> <p>no experience = 0 points; < 2 years = 5 points; 2-4 years = 10 points; > 4 years = 12.5 points</p>	Max 12.5 points
d)	<p>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.</p> <p><u>Scoring</u></p> <ol style="list-style-type: none"> 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 = 0 points 	Max 15 points
Maximum total score		50

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, www.trainsaferfood.eu/base/contact or by email at info@trainsaferfood.eu as soon as possible, providing an explanation.

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

Table 1: Seats allocation

Training Courses	Dates	Registration Deadline	Number of participants for your country
Assessment of Efficacy of Plant Protection Products	15 - 17 Jun 2021	01-Jun-21	3
Assessment of Efficacy of Plant Protection Products	05 - 07 Jul 2021	18-Jun-21	3

4. Training dates

2 training sessions of 2 days/each training session in Virtual Classroom (VC) training courses will be delivered between **June and July 2021** with approximately 50 people in each **session**.

Here below is presented the training schedule for each day of the training session:

Tuesday 15 June 2021 / Monday 05 July 2021

Time	Activity	Method	Tutor(s)
09:00 – 10:00	Opening of On Line session and registration Welcoming of the participant in the virtual lobby	Event manager/ Assistant event manager	
10:00 – 10:45	Welcome and presentation of Better Training for Safer Food Initiative and Introduction to this BTSF session: what to expect and is expected, general principles, technical content, description of break-out sessions and networking time. BTSF video	BTSF video	Event manager TC: Ettore Capri
10:45 – 10:50	Break		
10:50 – 11:30	Initial knowledge Presentation of each participants, and discussion of participants' role and professional background - Initial knowledge test to evaluate the general background of the attendants as a group <ul style="list-style-type: none"> • Multi-choice questionnaire • Anonymous 	Diagnosis test with interactive tool: Kahoot	TC: Ettore Capri or Maura Calliera
11:30 – 11:45	Coffee-break and networking		
11:45 – 12:30	Introduction to the efficacy evaluation of plant protection products guidance on general principles of the efficacy evaluation of plant protection products and pesticides active substances in the framework of the Regulation (EC) No 1107/2009.	Lecture 1	Dr. Santomauro
12:30 – 12:35	Break		
12:35 – 13:35	Continue: Introduction to the efficacy evaluation of plant protection products guidance on general principles of the efficacy evaluation of plant protection products and pesticides active substances in the framework of the Regulation (EC) No 1107/2009.	Continue: Lecture 1	Dr. Santomauro
13:35 – 14:35	Lunch Break		
14:35 – 15:35	Introduction to the efficacy evaluation of plant protection products. Practical verification including the harmonized dose expression for the zonal evaluation of plant protection products. Hands on"	Group work in break-out room	Dr. Santomauro
15:35 – 16:05	General discussion Participants will discuss in general assembly about aspects addressed in lectures 1 and in the practical exercise. Main problems encountered by participants will be discussed.		Emilia Markellou
16:05 – 16:20	Coffee Break		
16:20 – 18:30	Social Event and group photo		
18:30	Closing of the first day		

Wednesday 16 June 2021 / Tuesday 06 July 2021

Time	Activity	Method	Tutor(s)
09:00 – 09:30	Gathering of the participants in the main lobby, making sure everyone is connected and offer technical support if needed		Event Manager
09:30 – 10:30	Addressing data requirements: minor uses and biological extrapolations. To stimulate discussion regarding the need of national guidance and harmonization of approaches at the zonal and EU level	Lecture 2	Emilia Markellou
10:30 – 10:45	Coffee Break and networking		
10:45 – 11:45	Continue: Addressing data requirements: minor uses and biological extrapolations.	Continue: Lecture 2	Emilia Markellou
11:45 – 12:30	“Hands on”: efficacy evaluation of plant “protection product x” (reasoned case study)	Group work in break-out rooms	Emilia Markellou and Dr. Santomauro
12:30 – 13:00	General discussion	Discussion and exchange	Emilia Markellou & Dr. Santomauro
13:00 – 14:00	Lunch Break		
14:00 – 15:30	Virtual FIELD Visit & demonstration activities	Exchange and Videos	All tutors & TC or DTC
15:30 – 15:45	Coffee Break and networking		
15:45 – 17:15	Continue: Virtual FIELD Visit & demonstration activities	Continue: Exchange and Videos	All tutors & TC or DTC
17:15	Closing of the second day		

Thursday 17 June 2021 / Wednesday 07 July 2021

Time	Activity	Method	Tutor(s)
09:00 – 09:30	Gathering of the participants in the main lobby, making sure everyone is connected and offer technical support if needed		Event Manager
09:30 – 10:30	Other Efficacy aspects. Influence of risk mitigation measures on the efficacy of a PPP	Lecture 3	Emilio Gil and Maura Calliera
10:30 – 10:45	Coffee break and networking		
10:45 – 11:45	Continue: Other Efficacy aspects. Influence of risk mitigation measures on the efficacy of a PPP	Continue: Lecture 3	Emilio Gil and Maura Calliera
11:45 – 12:45	On site wrap-up and workshop with participants divided in groups	Working groups in break-out rooms	Emilio Gil and Maura Calliera
12:45 – 13:45	Lunch break		
13:45 – 14:45	. Low risk substances: - Overview and regulatory aspects; - Microbial biocontrol agents, semiochemicals, botanicals; - Guidance documents;	Lecture 4	Edoardo Puglisi
14:45 – 14:50	Break		
14:50 – 15:50	Continue: . Low risk substances: - Overview and regulatory aspects; - Microbial biocontrol agents, semiochemicals, botanicals; - Guidance documents;	Continue: Lecture 4	Edoardo Puglisi
15:50 – 16:00	Coffee break		
16:00 – 17:00	conclusion Knowledge test recommendation importance of dissemination and networking	Discussions Kahoot	TC: Ettore Capri
17:00	Closing of the training		

Table 3: Training dates

Year	Training session	Proposed dates	Location	Course Title
2021	Training session 8	15 - 17 June 2021	Webex	Risk assessment of efficacy of plant protection products
	Training session 9	05 - 07 July 2021	Webex	Risk assessment of efficacy of plant protection products

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.

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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.

Main topics covered in the training

The following modules are proposed

- Module 1- general principles of the efficacy evaluation of plant protection products in the framework of the Regulation (EC) No 1107/2009, practical guidance and discussion on the efficacy evaluation of PPPs.

Introduction to the efficacy evaluation of plant protection products (PPPs):

- ✓ regulatory framework
- ✓ principles of acceptable efficacy
- ✓ zonal assessment of PPPs
- ✓ minor uses and biological extrapolations

At the end of the module the trainees should be improved in his/her ability to evaluate realistic uses of a representative plant protection product using the available data and the principles of biological extrapolation

- Module 2- harmonization among members state Principles of efficacy evaluation for low-risk plant protection products and related regulatory aspects
 - ✓ Harmonized dose expression for the zonal evaluation of plant protection products
 - ✓ Resistance risk analysis
 - ✓ Biopesticides and low risk Plant Protection Products

At the end of the module the trainees should be improved in his/her knowledge on the latest EPPO standard PP1/296(1) Principles of efficacy harmonization of assessment of the potential risk of resistance development

Annex 2: Legislation and guidance

- Guidance on general principles of the efficacy evaluation of plant protection products and pesticides active substances in the framework of the Regulation (EC) No 1107/2009.
- Latest EPPO standard PP1/296(1) Principles of efficacy evaluation for low-risk plant protection products and related regulatory aspects.

Annex 3: Agenda



Agenda Efficacy
Assessment of PPP v

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 Zoom platform. They will also receive some general information on the course and have the opportunity to ask questions.

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

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 für Internationale Zusammenarbeit GmbH GIZ, International Services Brussels Office

Project Manager is Mr. Sergio Ninotti

Training Coordinator for Course Assessment of Efficacy of Plant Protection Products is Mr Ettore Capri

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 + 322292796 telephone number.

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