Network on Risk Assessment in Plant Health Minutes of the 9th meeting

Held on 13 October 2015, Parma

(Agreed on 08 June 2016)[1]

Participants

- **Network Representatives of Member States (including EFTA Countries):**

Country	Name[2]
Austria	Sylvia BLUEMEL (participated by web-conference)
Belgium	Kristien BRAEKEN
Bulgaria	Irena BOGOEVA
Cyprus	Anthemis MELIFRONIDOU
Croatia	Dario IVIC
Czech Republic	-
Denmark	Bettina GYLDEN
Estonia	-
Finland	Matti PUOLIMATKA
France	Natalie FRANQUET
Germany	Jens UNGER
Greece	Athanasios LAGKOURANIS
Hungary	Gabor SZALKAI
Ireland	Oliver McEVOY
Italy	-
Latvia	Liga GRISANE
Lithuania	Gustina LEIPUTE
Luxembourg	-
Malta	-

1 The publication of the minutes shall be made without delay in compliance with the Founding Regulation and no later than 15 working days following the day of their agreement.

2 Indicate first full name and them surname (John Smith) all throughout the document

Netherlands	Dirk Jan VAN DER GAAG
Poland	Witold KARNKOWSKI
Portugal	-
Romania	-
Slovakia	Martin PASTIRCAK
Slovenia	Anita BENKO
Spain	Gerardo SÁNCHEZ PEÑA
Sweden	Kristof CAPIEAU
United Kingdom	Richard MCINTOSH
Iceland	-
Liechtenstein	-
Norway	Elin THINGNAESS
Switzerland	-

- **European Commission:**

- Harry ARIJS (DG SANTE)

- **European and Mediterranean Plant Protection Organisation (EPPO):**

- Martin WARD

- **EFSA:**

ALPHA Unit: Giuseppe STANCANELLI (Chair); Ciro GARDI; Gabor HOLLO; Svetla KOZELSKA; Marco PAUTASSO; Tomasz OSZAKO;Sara TRAMONTINI; Ioannis KOUFAKIS; Miren ANDUEZA
AMU Unit: Olaf MOSBACH-SCHULZ

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Czech Republic, Estonia, Iceland, Italy, Luxembourg, Malta, Portugal and Romania, as well as from Switzerland (observer).

2. Adoption of agenda

The agenda was adopted without changes

3. Declarations of interest

No additional interests were declared by the network members.

4. Agreement of the minutes of previous meetings of the Network on Risk Assessment in Plant Health

The minutes of the 7th meeting of the Network held on 20-21 November 2014 in Parma were agreed on 13 October 2015.

It was decided that the minutes of the 8th meeting of the Network held on 23-24 of April 2015 in Parma. will be agreed by written procedure with deadline 23 October 2015.

5. Topics for discussion

5.1. Items suggested by Member States

Before the meeting two proposals from Member States (MSs) were received:

5.1.1. Proposal by the Netherlands

To give a presentation on "Probability of transfer of a pest from an imported commodity". The presentation is addressed under agenda point 5.3.3.

5.1.2. Proposal by Germany

To discuss the implications of the new plant health regulation for pest risk assessments and early warning activities. The discussions took place under agenda point 5.3.1.

5.2. Update on EFSA plant health activities: recently published and ongoing work

5.2.1 Recently published opinion

- Hot water treatment of *Vitis* sp. for *Xylella fastidiosa*

Following a request from the European Commission, the EFSA Panel on Plant Health reviewed the Italian technical guidelines and the ANSES (Agence Nationale de Sécurité Sanitaire de l'Alimentation, de l'Environnement et du Travail, France) opinion on the use of hot water treatment on *Vitis* sp. planting material, assessing its efficacy in the elimination of *Xylella fastidiosa*[3].

According to EFSA's opinion the standard hot water treatment of 50°C for 45 min already in place to eliminate Flavescence dorée phytoplasma from dormant planting material is also efficient for controlling *X. fastidiosa* in grapevine. Within the context of the good production practices for nursery materials, hot water treatment is considered as a robust and reliable measure to guarantee the health status of the material treated and to safeguard freedom from pathogens and pests.

5.2.2 Ongoing work

- Working Group (WG) on *Vitis* response to *X. fastidiosa* strain CoDiRO

EFSA is requested to provide an opinion on the scientific report concerning pathogenicity tests and analysis to assess the susceptibility of *Vitis* sp. to the *X. fastidiosa* strain CoDiRO prepared by the National Research Council of Bari and the Università degli Studi Aldo Moro of Bari. The tasks presented in the report are (i) survey in vineyards located in the contaminated area, (ii) artificial (needle) inoculations and (iii) exposure of grapes to infective *Philaenus spumarius*. The deadline for the EFSA opinion is November 2015.

[3] Link to the opinion

- Database on host plants of *Xylella fastidiosa*

EFSA is requested to maintain and keep up to date a comprehensive database on the host plants of *Xylella fastidiosa* on the basis of new scientific developments. To fulfil the task the existing database has been adapted for migration into "Distiller" and a new extensive literature search for the period 2014-2015 is realized using "Distiller" for literature screening and data extraction.

- WGs on seven pests for "step 2" pest risk assessment

Following the pest categorizations delivered in 2014-2015, EFSA is now requested to (i) complete the pest risk assessments, (ii) identify risk reduction options, (iii) assess the effectiveness of the current EU phytosanitary requirements and (iv) take into account the recommendations which have been prepared on the basis of the EFSA pest categorisations and discussed with Member States in the relevant Standing Committee, for following seven pests:

- *Ceratocystis platani*
- *Cryphonectria parasitica*
- *Diaporthe vaccinii*
- Grapevine Flavescence dorée phytoplasma
- *Ditylenchus destructor*
- *Radopholus similis*
- *Eotetranychus lewisi*

The deadline to provide these scientific opinions is May 2016.

In the context of the "step 2" mandate, an overarching WG on Methods has been established to ensure (i) harmonised and consistent approach for the risk assessments, for risk reduction options and for rating, (ii) reproducibility of the risk assessments, (iii) interaction with risk managers on fit for purpose scientific advice and (iv) revision of current guidance document.

The data needs for the "step 2" pest risk assessments were presented and discussed in detail. An update is needed from those MSs that did not respond to the EFSA questionnaire on pest status requested in 2014.

More specific data are needed for Grapevine Flavescence dorée (FDP) risk assessment from some MSs, such as:

- data on control methods that are currently applied against FDP from countries where FDP is/was present (Austria, Croatia, France, Germany, Hungary, Italy, Portugal, Slovenia, Spain) and
- data on surveillance of the FDP and its vector from other grape wine growing countries (Belgium, Bulgaria, Cyprus, Czech Republic, Greece, Luxemburg, Malta, Poland, Romania, Slovakia, The Netherlands, United Kingdom).

To facilitate the provision of the above data, the Network members were asked to identify a contact person in the relevant Member States.

- EFSA WG on Flumioxazin

EFSA received a mandate from DG SANTE for scientific assistance as regards the evaluation of data on evidence that the application of flumioxazin is necessary to control a serious threat to plant health.

Flumioxazin is an active substance included in Annex I to Council Directive 91/414/EEC (concerning the placing of plant protection products on the market) and deemed to be approved under Regulation (EC) No 1107/2009, for which the notifier applied for renewal.

Based on (i) the EFSA conclusion on the peer review of the draft renewal assessment report and (ii) the ECHA opinion, both classifying flumioxazin as toxic for reproduction category 1B (H360D) and M=1000 for Aquatic Chronic 1, the Commission proposed a non-approval to the relevant Standing Committee. Subsequently integrative data provided by the applicant were made available to the Commission and MSs and therefore EFSA was tasked by the Commission the above specified mandate. The deadline to provide this scientific advice is December 2015.

Network members expressed concern that such type of mandate could compete for EFSA ALPHA Units and EFSA Plant Health Panel resources. EFSA explained to the Network that this mandate was not a mandate for a scientific opinion of the EFSA Plant Health Panel (under art. 29 of the founding regulation 178/2002) but a mandate requesting scientific and technical assistance to EFSA (under art. 31 of Reg. 178/2002) and this request was assigned to the EFSA Pesticides and ALPHA Unit.

- Apple database

EFSA has been requested for scientific and technical assistance on a pilot project to gather information on pests and diseases of apple fruit (*Malus domestica*) in the EU. In the terms of reference EFSA is specifically requested to collect data and information on the pests and diseases of apple fruit present in the EU, by setting up a database with regard to:

- prevalence and distribution of the pests in the EU MS,
- regulatory status in the EU,
- biology, e.g., lifecycle, host range, plant parts affected and symptoms/damage, means of dispersal/spread,
- consequences, expressed in terms of loss of yield or quality in affected areas (including ranking of the pests in relation to their potential for causing consequences),
- methods used for surveillance, detection or diagnosis, if applicable,
- control measures applied in affected areas.

EFSA has established a database structure within the frames of the EFSA data warehouse with the help of plant health experts and launched a public procurement procedure for the data collection that was awarded to the Austrian Agency for Health and Food Safety (AGES). The project is closely monitored by EFSA together with European Commission and in cooperation with the Canadian Food Inspection Agency. In addition, the EU MSs have been involved in a consultation to comment on the relevant pest list on their territories for which the data collection will be made.

According to the project plans, at the beginning of 2016 an evaluation of the database (populated with data for 12 organisms) will be carried out, as well as an update and revision of the database structure, if found necessary. As a follow-up step, the updated/revised database could be completed with data on the remaining pests of apple fruit and/or used for other data collection.

After introducing this mandate the Network members raised several questions and focused its discussion mainly on

- reasoning why apple pest were chosen to develop such database: it was explained that this was discussed by Commission and MSs within the Roosendaal Working Group, as pilot project linked to trade agreements with Third Countries,
- importance and possible use of the apple pest database, e.g. in the frame of the possible changes of the fresh fruit market flows: the database model is expected to be fit to different data collection and modular.
- feasibility of the database and feedback received: testing of the database is now performed with 12 pests, continuous feedback during the project development was received AGES, as well as from CFIA.
- criteria which were used to identify the 12 pests for testing the database: database is focusing only on pests of the apple fruit pest, information is obtained based on search of scientific and technical literature, diseases and pests of apple fruit with a worldwide distribution are not included in the database, the 12 pests were selected to be representative of different types of pests.
- details of the MS consultation process: an e-mail with documentation was circulated to the MSs at the end of July 2015 with the request for validation of the relevant pest list identified by the project as present in the respective MS's territory (MS pest list); a second e-mail was sent to extend the deadline of responses to 16 October 2015, and also containing more information on the EU pest list, as requested by some MS. This EU-list made it possible for the MSs to see which organisms were found relevant for data collection at the EU level, apart from their own MS pest list.

5.3. Fit for purpose methodologies for pest risk assessment to support the forthcoming new EU plant health rules

5.3.1. Update on the new EU plant health rules

The European Commission representative (Harry ARIJS) provided the participants with an update on new EU plant health rules. The legal proposal of the new EU plant health rules was drafted in 2011-2012 and adopted by the European Commission in May 2013. It has been also notified to the WTO-SPS Secretariat. Now the co-decision procedure is taking place (discussion between the 3 EU institutions, i.e. the European Parliament, the European Commission and the European Council). The objective is to reach a common agreement on the text of the legislation by the end of this year and adopt it at the beginning of next year. The new regulation will enter into force three years after adoption. In the meantime, the current legislation remains in force. The preparedness for crisis management was stressed to be very important as well as MSs data collection and surveillance.

5.3.2. Update on EFSA methodological development for pest risk assessment to support the forthcoming new EU plant health rules

The new methodological approach on pest risk assessment (including the risk reduction options) proposed by the EFSA Panel on Plant Health was explained in

detail and the three pillars – the adaptive, the mechanistic and the quantitative approach/component – of the methodology were presented. Further details are available in the presentation accessible on the DMS. The case study PRAs to test the new approach are now under development.

In the follow-up discussion, it was stressed the importance in the new methodology of a steps-approach allowing for interactive feedback from risk managers on the fitness for purpose of the assessment: this could be done with a 3-steps approach, starting with the pest categorisation (step 1), followed, when needed for risk management decision, by a complete risk assessment with a first identification/assessment of risk reducing options (step 2), and, as a final stage, a detailed evaluation of different risk reduction scenarios (step 3) as chosen/indicated by the risk managers.

The discussion focused on several aspects and can be summarised as follows:

- An agreement on applying a fit for purpose and quantitative approach was expressed and the participants welcomed the possibility of an increased interaction between risk assessors and risk managers.
- The third pillar of this methodology, i.e. the quantitative approach applied for risk assessments, was considered the most challenging due to the lack of data, particularly in the view of the need to speed up the decision making processes.
- It was suggested also the benefit of comparing the new approach with the old system. The new methodology could help in a fast response because of the steps-approach and also because of the possibility to focus on particular elements of the risk assessment to be assessed (e.g. entry versus spread depending on the specific pest under consideration). EFSA will keep the Network informed and up to date with the development and results.
- EPPO referred to the difficulties of the EPPO Panel on Phytosanitary Measures with quantification; the main problem is always the lack of data. However, the benefits of quantification were recognised. EPPO expressed its interest to collaborate with EFSA on this approach.
- The Commission representative emphasized that the scenario concept of current trade data has to be treated carefully, as trade patterns and flows may change rapidly. All pathways should be considered (at least briefly), taking into account also the possibility of future trade – or when no data or forecasts are available mentioning that there is currently no trade of such type. The difficulties with new trade from new areas, e.g. Asia, of plant species, for which only limited literature is available, were mentioned by the participants. The question was also posed whether and how the new approach would be applicable to the analysis of pathways and how it would cover the needs for upcoming pathway analysis. In this context EFSA clarified that the application of this new approach to the analysis of pathways needs to be investigated, once the first batch of case studies has been completed. It was also explained that the EFSA Plant health panel has already conducted two commodity-risk assessments (on pollen and on soil and growing media) and worked on a quantitative pathway analysis (on Karnal bunt, *Tilletia indica*). Results of the completed (see section 4.4.3. below) and the ongoing EFSA funded projects on quantitative pathway analysis of non-food and food plant commodities will also provide useful elements. Dealing with situations

when no data are available will however remain a key challenge for risk assessment

- The question whether there are any elements in this new approach that address the needs of the new plant health regime was raised and EFSA explained that since the risk is quantified, it can be prioritised, which is expected to be an important element in the new plant health regime. Concretely, this exercise is contributing to prepare for the future start of the new plant health regime by providing advice to risk managers for the (re-) assessment and reclassification when necessary of the pests listed in the Annexes of Directive 2000/29/EC.
- Some of the participants saw a certain simplification in the new method, particularly with regard to the steps/tiered approach and welcomed the closer link with the risk managers. It should be further discussed and analysed how the new strategy for pathways, in particular for woody plant species, could be addressed by this new approach.
- Concerns were raised with regard to the time needed for the quantification of risks with this methodology, as in the future more risk assessments are expected and there is a wish that these could be done in a fast way.

5.3.3. Probability of transfer of a pest from an imported commodity

Dirk Jan VAN DER GAAG presented the results of the EUPHRESCO project on "Practical tools to assess the risk of pest transfer from an imported commodity helping to provide improved rationale for reduced inspection strategies".
The objective of the project was to develop a (semi-) quantitative model to better assess the probability of transfer (including first egg laying) from plant product (cut flowers/branches, fruits and vegetables). The scientific and technical background of the project was explained and case studies were presented.

The model is available in Excel. The entry of data is manual and users can choose among 2–5 different score levels for each question. The probability of transfer at different points in the trade chain and the overall probability can be obtained applying the model. The results of a sensitivity analysis are provided for case study pests. The model does not automatically provide a sensitivity analysis. The model will be downloadable after permission from EUPHRESCO.

In the follow-up discussion the participants appreciated the presented study and focused mainly on the following issues:

- the importance to consider also the possible vectors within the model,
- the suitability of the model to rate also the waste and to cope with regional variations (important for taking decisions),
- the implications for the risk managers

5.4. Cooperation in data collection

5.4.1. Inventory of data sources for pest risk assessment - joint collaboration EFSA-EPPO, timeline and MS contributions

Giuseppe STANCANELLI from the ALPHA Unit updated the participants regarding the joint collaboration of EFSA and EPPO. In particular, a joint activity regarding a common inventory of data sources for pest risk assessment was presented. The collaboration will start in 2016 with the aim to compare EFSA (PRASSIS project) and EPPO (PRATIQUE-CAPRA) inventories of data sources, to agree on a common structure and to merge the two databases. In 2017 it is planned to consult the Network on this common database with the aim to check the data regarding MS national inventories. The final output should be a consolidated repository for data sources for pest risk assessment to be used by EFSA, EPPO and the Network Members, that would be maintained and kept up to date jointly by EFSA and EPPO.

Information were provided by EFSA and EPPO on the progress of the roadmap of the EFSA–EPPO cooperation. A memorandum on cooperation between EFSA and EPPO is under preparation and once signed, a more detailed outline of this activity will be presented to the Network.

5.4.2. Update on ISEFOR database of trade data of plants for planting

Giuseppe STANCANELLI from the ALPHA Unit updated the participants regarding the ISEFOR database of trade data of plants for planting. Two steps are planned to be done: (i) send a request to the data providers to ask the consent to share the ISEFOR database with the EFSA, the EFSA PLH Network and the EPPO for the purpose of conducting pest risk assessment, and (ii) ask the MSs for provision of data for at least one recent year to increase the coverage and the value of the database. The participants were interested in having as soon as possible the access to the ISEFOR database. Some concerns were expressed regarding the need to check, before providing free access, that the database does not include sensitive or personal data. EFSA will check this, but the level of aggregation of the data seems addressing this concern.

5.4.3. Data availability and modelling: case studies from the EFSA funded project on quantitative pathway analysis for non-food plant products

Olaf MOSBACH-SCHULZ from the EFSA Assessment and Methodological Support (AMU) Unit presented the EFSA project on Probabilistic pathway models for pest risk assessment, delivered by the University of Wageningen and INRA.

The presentation focused on several aspects of the project, providing explanations on:

- how to model pest introduction (pests are introduced via pathways; a pathway model is a mathematical description of a pathway; description regards pest, carrier and movement, area of origin and destination):
- data requirements (measurements of state variables such as size of consignments; consignment infested/not infested; number of infested plants per consignment);
- two pathway-model approaches (individual-based pathway model which keeps track of individual consignments/lots and flow-based pathway model which distributes the flow of infested material over the network),
- approach for developing pathway model for 5 case studies:
    - Conceptual and qualitative description of the pathway model

- Description of the product part + product specific parameters
- Description of the pest part + pest specific parameters
- Sensitivity and uncertainty analysis
- Model output

- Case study on tomato seeds and *Clavibacter michiganensis* subsp. *michiganensis* (Cmm) and its conclusions (pathway model for seeds is a simple pathway; gives insight how seed pathway contributes to spread of Cmm, parameters are difficult to obtain due to differences in treatments and commercial sensitivities of data).

Overall conclusions on project results were given stating that pathway models are a feasible tool to make quantitative estimations on pest entry. This project provided (i) guidance on how to model pathways, (ii) first examples, software codes and a manual, and (iii) recommendations for data collection. The approach is now ready to be implemented. Report and models can be downloaded from EFSA website[4].

6. Meeting calendar and Venues

The following meeting dates and locations were agreed for 2016:

- **10th PLH Network meeting:**

Date and Location: 24 May 2016 (10.00-17.00), Brussels. Attached to PLH Panel open plenary held in Brussels on 25-26 May 2016 with the possibility to register as observers.

- **11th PLH Network meeting:**

Date and Location: 14 December 2016 (15.00-18.00), Parma 15 December 2016 (09.00-12.30), Parma.

Attached to EFSA-EPPO Conference on Modelling for Pest Risk Assessment held in Parma on 12-14 December 2016 in Parma. Registration at http://www.efsa.europa.eu/en/events/event/161212 Extended deadline 17 June 2016.

6.4. EFSA trainings open to Network Members

Training Courses on Advanced Aspects of Risk assessment open for Network Representatives

- Training course on environmental risk assessment (23/11/2015 – 25/11/2015, further courses available in 2016)

Network members should register on the respective contractors' websites available below and inform/pre-alert EFSA on their application to the training/s.

More information: http://www.wageningenur.nl/en/Research-Results/Projects-and-programmes/EFSA-training-courses.htm

Other trainings of potential interest for PLH Network members in 2016:

- Systematic literature review

[4] http://www.efsa.europa.eu/en/supporting/pub/809e

- Expert knowledge elicitation

Member states interested should contact the ALPHA Unit for further information.

7. Conclusions

- To facilitate the provision of the data needed for the Grapevine Flavescence dorée (FDP) risk assessment, the Network members were kindly asked to identify and provide to EFSA a contact person in the relevant Member States regarding:
  - data on control methods that are currently applied against FDP from countries where FDP is/was present (Austria, Croatia, France, Germany, Hungary, Italy, Portugal, Slovenia, Spain), and
  - data on surveillance of FDP and its vector from other grape wine growing countries (Belgium, Bulgaria, Cyprus, Czech Republic, Greece, Luxemburg, Malta, Poland, Romania, Slovakia, the Netherlands, United Kingdom).
- MSs interested in the trainings on Systematic literature review and Expert knowledge elicitation should contact ALPHA Unit for further information.

8. Closure of the meeting

The Chair closed the meeting.