



COUNCIL OF
THE EUROPEAN UNION

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OUTCOME OF PROCEEDINGS

from : Working Party of Chief Plant Health Officers (COPHS)
on : 11 - 12 June 2009
Subject : Plant Health matters

I. INTRODUCTION

At its meeting on 11 - 12 June 2009 the Working Party of Chief Plant Health Officers ("COPHS") discussed various phytosanitary matters, in particular, *guidelines for EC coordination in the pest risk analysis process, the revision of the plant health regime, ongoing talks with certain third countries* and strategic aspects on the *eradication of the pinewood nematode in the EC*, and agreed on draft Council Conclusions on *the possible evaluation of control measures relating to certain harmful organisms*.

In addition the COPHS took note of the incoming Presidency work programme in the plant health sector.

II. MAIN RESULTS

- 1. Possible evaluation of the control measures laid down in Council Directives 74/647/EEC and 2006/91/EC (carnation leaf-rollers and San José scale)**

Previous discussions at the Working Party on Plant Health had considered the possible repealing of these two legal acts as their respective control measures appeared to be obsolete¹, thus inviting the Commission to evaluate this question. In the light of discussions held the Presidency prepared a Note² containing draft Council Conclusions.

The COPHS finalised the related text and decided to submit it to the COREPER and the Council for adoption as an "A" Agenda Item.³

- 2. Guidelines for EC coordination on Pest Risk Analysis (PRA) process**

Following the results of previous discussions, the COPHS felt the need to clarify some aspects of two documents which had been approved during the Slovenian and French Presidencies (11184/08 and 17021/08 ADD 1, respectively).

On the basis of a working document drawn up by the Presidency⁴, the COPHS finalised a text focusing on the roles and responsibilities of various institutions when issuing PRA technical/scientific documents. The approved document is set out in Annex I.

In this context, the COPHS felt that all three documents constitute, from now on, a sound guidance for EC coordination in the PRA decision-making process.

In addition, the COPHS welcomed a presentation by an expert from the European Food Safety Authority (EFSA) concerning this agency's role in the phytosanitary sector. It was also noted that EFSA is preparing a guidance document on this matter, Member States being encouraged to participate in this work.

¹ Documents 9800/09, 9660/09, 8060/09 and 7639/09.

² Document 10462/09.

³ Document 10942/09.

⁴ Document 10464/09.

3. Evaluation of the EC Plant Health regime

Following last year's deliberations by the COPHS,¹ the Commission representative briefed the Working Party on the various steps leading to a comprehensive evaluation of Council Directive 2000/29/EC whose process had recently been launched by the European Commission.²

In welcoming this initiative, the COPHS underlined the importance of drawing up a new EU strategy in the phytosanitary field focusing, in particular, on preventive measures, increased financial resources and World-wide standards applied to trade. It also agreed that the COPHS should monitor this evaluation process in a systematic manner.

The Commission representative indicated that a consultation process with stakeholders and national authorities will start immediately³ with a view to issuing a final report by May-June 2010. He also undertook to keep the COPHS regularly informed on progress and pointed out that no legislative proposals are expected before 2012.

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¹ See, in particular, document 17021/08 approved during the French Presidency.

² The related website can be found in http://ec.europa.eu/food/plant_strategy.

³ A Conference with stakeholders is foreseen to take place in October/November 2009.

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5. Strategic aspects for the eradication of the pinewood nematode in the EC

The Commission representative briefed the Working Party with an outline of a new strategy leading to an enhanced control and possible eradication of this harmful organism in the EC territory. Five main elements are foreseen in that strategy:

- as a starting point, an updated Pest Risk Analysis is expected to be available in September 2009;
- the existing emergency measures have to be adjusted in order to become applicable to all EC Member States in a permanent manner;

- an increased scientific research is needed, in particular, involving environmental, forestry and agricultural experts;
- additional professional training is required, with some actions already foreseen to take place in Spain and Portugal during the second half of 2009;
- the Commission is preparing a draft proposal containing a long term, EU-wide strategy, including due consideration of financial resources, which is to be discussed at the Standing Committee in due course.

The COPHS welcomed this Commission's approach and recalled previous discussions¹ on this matter which had shown the need to urgently assess whether or not the adoption of specific EC legislation is required.

6. Impact assessment on *Diabrotica virgifera* Le Conte (Western Corn Rootworm)

A presentation by Commission experts of the final report² leading to an impact assessment on this harmful organism, allowed the COPHS to hold a preliminary exchange of views on possible long-term policy options at EC level.

Discussions focused on possible economic, social and environmental impacts and the need to better assess the related cost/benefit analysis, most of the delegations having considered it necessary to further discuss this matter at technical level.

The Commission representative informed that stakeholders will be consulted on 1 July 2009 by means of a presentation of the said report, and asked delegations willing to send in written comments to do so by 3 July 2009 at the latest.³ She also indicated that the Commission would like to draw up the necessary impact assessment as soon as possible, thus allowing the Standing Committee to examine the document by the end of 2009. Possible legislative proposals are not expected before May-June 2010.

¹ See documents 15709/08 and 17021/08.

² The Report has been recently issued by the Commission services and can be found at the following website: <http://circa.europa.eu/>.

³ Depending on the comments received, the Commission might convene a Standing Committee meeting on 16-17 July 2009.

7. Other business

a) Updated information on EUPHRESCO network (ERA-Net)

The COPHS endorsed a set of recommendations contained in a report by the EUPHRESCO governing board¹. The report is set out in Annex III.

b) EU Strategy on Invasive Alien Species

The Presidency presented a state of play concerning a document² containing draft Council Conclusions which are to be adopted at the next Environment Council on 25 June 2009. The Working Party broadly welcomed this initiative, some delegations having called for clarification on some sections of the document related to plant health matters, in particular, points 31 and 32. Consequently, the Presidency invited delegations wishing to submit drafting changes to do so as soon as possible, and liaise with their national experts dealing with this file.

c) The Food and Veterinary Office (FVO) draft Programme of Missions (Presentation by the FVO)

The COPHS took note of the draft FVO programme for 2010, in particular, potential priorities for inspections and specific audits both in Member States and in third countries. The FVO representative informed that the draft programme³ will be discussed at the next meeting of this Agency's governing body (24/6/09, Grange, Ireland), and invited Member States to participate. He also indicated that the said programme is expected to be adopted by the second half of 2009.

III. FUTURE WORK

The incoming Swedish Presidency outlined its work programme in the phytosanitary field, as set out in Annex IV (to be noted that all the dates are subjected to confirmation).

¹ Since 2005 the said governing board is chaired by the UK.

² 10256/09.

³ The draft will be posted in the FVO portal (http://ec.europa.eu/food/fvo/index_en.cfm) in due course.

Guidelines for EC coordination and handling of Pest Risk Analysis documents and other scientific and technical justification documents supporting the decision-making process for EC phytosanitary measures

Introduction:

The objective of this paper is to set guidelines for the initiation, coordination and handling of Pest risk analysis (PRA) documents and other scientific and technical justification documents within the current European Community (EC) legislative environment, considering the available resources and with the aim of improving transparency and consistency.

These guidelines stipulate the specific procedures for commissioning and reviewing PRA documents. They also apply to other scientific and technical justifications as supporting documents (hereinafter also referred to as justification documents) for amendment of applicable phytosanitary measures within the scope of the decision-making process.

Furthermore this document describes a specific fast track procedure to produce preliminary PRA documents. In some cases it may be appropriate to combine or omit certain stages of the procedure.

The detailed description of the completion of the PRA document within the EC framework including the completeness check and review, the management decision making process, the risk communication procedure and the role and responsibilities of the relevant organisations is described in the document no. 17021/08 (Addendum to Outcome of proceedings from COPHS, 4-5 December 2008). These guidelines reflect the content of that document and the procedures described, but with some refinements.

1. Standard procedure for handling PRAs and other justification documents

1.1. Sources of PRAs and other justification documents

The need for a PRA document at the EC level is identified by the European Commission (hereinafter referred to as the Commission) or by Member States. European Food Safety Authority (EFSA) too, within its remit of identifying emerging risks, may make a proposal for an assessment of plant health risk to the Commission. In general prioritisation of proposals, including those for broadening a national PRA, updating an existing PRA, is considered by the Standing Committee on Plant Health (SCPH), taking into account the European and Mediterranean Plant Protection Organisation (EPPO) plan for preparing PRA documents, so as to avoid duplication of efforts.

The Commission in consultation with the SCPH opens the initiation process for PRA at the EC level. The PRA document is then produced by a Member State (MS) or group of MS¹. On the request of the Commission, Member States, European Parliament or on EFSA own initiative an assessment of plant health risk plus an assessment of risk management options can be prepared by EFSA². When EFSA is asked to produce a risk assessment, this will be done according to the EFSA internal guidance³ (in preparation), which is based on Regulation 178/2002/EC. If an additional detailed quantitative economic assessment is needed, it will be arranged by the Commission.

Member States may produce PRA and justification documents based on their own initiative. Third countries produce justification documents to support an application for modification of the EC phytosanitary measures. PRAs produced by EPPO may also be used at the EC level.

PRA and justification documents supporting the decision-making process are made available to the MS by the Commission on CIRCA (Communication & Information Resource Centre Administrator), usually once they are scheduled to be considered by the SCPH.

1.2. Completeness check⁴

PRA documents prepared and submitted by a MS or a group of MS are subject to a completeness check. Due to the procedure for producing EPPO PRA documents and EFSA risk assessments⁵, secondary completeness check is usually not necessary in these cases. A completeness check is also not appropriate for justification documents.

At the SCPH the Commission asks the Member States (other than authors) to volunteer to provide the completeness check, or decides that the Commission's Annexes Working Group (AWG) should perform the completeness check. This decision must guarantee the independence of the completeness check performance.

When the PRA is confirmed to be complete, it goes to the review process. If the PRA is found to be incomplete, the Commission asks the submitter (or a volunteer MS) to complete the document.

¹ Not notwithstanding the MS right to produce their PRA documents in their own language it is recognised that submission of documents in the English language would result in a significant shortening, simplification and speeding up of the administration and evaluation process. To facilitate the evaluation of PRA documents, it is desirable that the documentation contains references to the data sources. Unpublished data should be made available on request, under a confidentiality clause, if considered applicable by the applicant.

² The Commission is to formulate appropriate Terms of references, taking into account the outcome of discussions at SCPH. Such Terms of references are to respect the Regulation 178/2002/EC which stipulates the competences and working rules of EFSA.

³ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=ALL>

⁴ The completeness check and review is described in the document no. 17021/08 (Addendum to Outcome of proceedings from COPHS, 4-5 December 2008).

⁵ EFSA risk assessments do not address socio-economic factors relevant to and influencing risk management decisions.

1.3. Review¹

Depending on the origin of the document, different types of review procedures may be implemented.

1.3.1. Documents drafted by MS

Each document is presented at the SCPH by the MS that submitted the document to the Commission. The presentation should include details of the purpose, objective and intention of the presented document.

The document is discussed at the SCPH in the scope of the review. In advance of this discussion the risk assessment experts of the Member States may assess the document. The exchange of views at the SCPH will show whether there is a sufficient technical base to decide on a risk management approach. If that is the case, the document is forwarded to the decision-making process. If it is not the case, the Commission considers the possibility of handover of the document to EFSA for evaluation² and/or expanding the scope of the assessment to the whole EU. If the document is considered to be insufficient, the SCPH recommends on the basis of the review results that the Commission returns the document to the submitter for revision.

1.3.2. PRA document drafted by EPPO

A document drafted by EPPO is presented at the SCPH by the MS that submitted the document to the Commission or by the Commission itself. The exchange of views will show whether there is a sufficient technical base to decide on the risk management approach. If that is the case, the document is forwarded to the decision-making process. If it is not the case, the Commission considers the possibility of handover of the document to EFSA for evaluation².

1.3.3. Justification document submitted by a third country

A justification document submitted by a third country is presented by the Commission or a MS and discussed at the SCPH in the scope of the review. The presentation should include details of the purpose, objective and intention of the presented document. In advance of this discussion the risk assessment experts of the Member States may assess the justification document in line with the process for a PRA. Based on their findings the document is examined at the SCPH (advised if necessary by the AWG) to decide whether there is a need to send it to EFSA for evaluation². In case of evident insufficiency the document is returned to the respective submitters indicating what the problems are.

¹ The evaluation of PRA document done by EFSA is defined as “review” in the document 17021/08 ADD 1, other meanings of review are used in this section.

² The Commission is to formulate appropriate Terms of references, taking into account the outcome of discussions at SCPH. Such Terms of references are to respect Regulation 178/2002/EC which stipulates the competences and working rules of EFSA.

In each case (1.3.1–1.3.3) where EFSA is involved, it responds to the requests from the Commission in the form of a Scientific opinion that is submitted to the Commission and presented at the SCPH by an EFSA representative. To ensure that all available evidence is taken into account, there might be a need for EFSA to seek clarification with the respective authors and submitters, while developing an opinion. The final opinion and associated documentation (including the PRA where appropriate) are published.

Should the EFSA opinion confirm the conclusion of the document, the document enters the decision-making process; otherwise the Commission communicates the outcome to the submitter.

1.3.4. Document drafted by EFSA

A risk assessment document prepared by EFSA is presented at the SCPH. The Commission and the SCPH consider whether it will be forwarded to the decision-making process.

The above mentioned procedures are without prejudice to the Commission, MS and Parliament rights of initiative to consult EFSA

The Commission is responsible for making available PRA documents used in the decision making process in accordance with IPPC obligations.

1.4. Management decision making process

The Standing Committee on Plant Health is the relevant risk management (decision-making) body and is convened and chaired by the DG SANCO. It can be advised by the AWG which carries out preparatory work on assessing management options. Other technical working groups may carry out this work if necessary.

The SCPH votes on risk management requirements that are prepared by the Commission, on the basis of selection from the proposed options for risk management presented in:

- a PRA document or justification document discussed and approved at the SCPH;
- a PRA document and / or justification document together with an EFSA evaluation.

When it is concluded that the PRA document or the justification document does not provide a sufficient basis for regulation, a reason should be provided.

2. Fast-track procedure to produce a preliminary PRA document

The reason for initiating the emergency process is the situation of imminent danger as stated in the Council Directive 2000/29/EC Art.16 par. 2 and 3. For the confirmation of the imminent risk and justification of the emergency measures a preliminary PRA should be prepared.

A preliminary PRA document is prepared on the basis of any available indicative information, completed as soon as possible according to the emergency situation.

For permanent measures or inclusion in Council Directive 2000/29/EC a full PRA covering the whole EU territory is needed.

The need for a preliminary PRA at the EC level is identified by the Commission or by a MS or EFSA, when a new threat has been detected (see Art.16 par. 2 Council Directive 2000/29/EC). If a preliminary PRA is not already available, the Commission can request that one is produced by a MS or group of MS. On the Commission's request a preliminary risk assessment document could also be prepared by EFSA (including an assessment of risk management options)¹. When the Commission (or MS or Parliament) decides to request that EFSA prepares a preliminary risk assessment, this request will have priority over other requests sent to EFSA. A national PRA document (covering at least the territory of a MS) used to put in place national emergency measures, or an EPPO PRA document may be used as well for the purpose of considering the Community emergency measures.

The preliminary PRA document produced by a MS, group of MS, EPPO or EFSA is submitted immediately to the SCPH.

The source of information is in particular the MS proposing the fast-track procedure, other MS, EPPO, third countries and any published observation or scientific reports. For taking Community emergency measures it could be sufficient to have a preliminary PRA document covering only part of the EU territory or having partial data due to the emergent character of the threat.

In case a MS has already taken emergency measures according to Art. 16 par. 2 of Council Directive 2000/29/EC, the Commission shall examine the situation as soon as possible within the SCPH to decide whether Community emergency measures are needed.

The preliminary PRA document is placed on CIRCA, and reviewed by national risk assessment experts. Where appropriate the advice of the AWG could be sought. The preliminary PRA and any subsequent advice are then presented by the respective author or by the Commission at the SCPH as soon as possible according to the emergency situation.

When the outcomes from the preliminary PRA document confirm the risk, the SCPH considers proposed management options. The SCPH votes on the emergency measures as proposed by the Commission. Adoption as a new legal act and publication of the text is carried out by the Commission. In case the emergency measures are not accepted, the decision needs to be justified.

References

11184/08. Pests Risk Analysis in the EC. - Outcome of Proceedings of the COPHS, 12/13 June 2008, Annex II, part 2, p. 7-14.

17021/08 ADD1. Pests Risk Analysis process in the EC. - Addendum to Outcome of Proceedings of the COPHS, 4/5 Dec 2008, 12p.

Evaluation of pest risk assessments and risk management options prepared to justify requests for phytosanitary measures under Council Directive 2000/29/EC. Guidance of the Panel on Plant Health. SCIENTIFIC OPINION, Question No EFSA-Q-2008-259. The EFSA Journal (2009) 2654, 1-18.

¹ In order to fulfil the demand of the Commission pertinent to Regulation 178/2002/EC for preliminary or fast-track assessments of plant health risks EFSA states that it needs to explore its opportunities in terms of resources and build up an appropriate system. In scientific terms the availability of data is currently perceived by EFSA to be the major obstacle to this

activity.

ANNEX II

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EUPHRESCO Phytosanitary ERA-Net Progress Report**EUPHRESCO trans-national pilot research projects (2008):**

EUPHRESCO has successfully initiated 11 pilot research projects (duration of 12-18 months): 7 through competitive calls (total funds ca. 1.5 MEur); 4 through a non-competitive mechanism, all of which are validations of diagnostic methods. All the projects directly underpin plant health policy or operations; some complement EU-funded projects.

EUPHRESCO second round of transnational topics (2009):

In addition to the commissioned pilot research projects, EUPHRESCO partners are considering a second round of topics for 2009. Since a second round of topics was not envisaged within the current EUPHRESCO project (which ends in July 2010), most of these potential new topics will be restricted to non-competitive projects. The main aim of the second round of topics is to maintain momentum and to build on the success of the current trans-national research projects.

Framework Programme 7 plant health priorities:

Under its COPHS mandate, EUPHRESCO has advised the Commission that an ‘intervention strategies’ topic was the highest priority topic for plant health. This topic is included on an indicative list for 2011. However, the FP7 Food, Agriculture, Fisheries and Biotechnology (FAFB) Programme Committee has broadened the scope to also include ‘difficult to control indigenous pests’ and with a focus on IPM and climate change aspects. EUPHRESCO will continue to advise and comment on the potential text, via national programme committee representatives, to ensure that any phytosanitary project proposals would still have a fair chance if the topic does proceed.

In addition COPHS should note that a proposal (Q-DETECT) to the recent EU call on “*Detection tools for plant health inspection services*” has been successful and invited into contract negotiations by the Commission.

EUPHRESCO workshop on research strategy and agendas:

EUPHRESCO held an external workshop in May 2009 on “*Building and Influencing Trans-national Research Agendas*”. Key policy, science and other stakeholders from more than 20 countries attended, including representatives from the Commission’s DG-Research, EPPO and EFSA. Key outputs were:

The workshop highlighted the importance of research in underpinning plant health policy and the wider phytosanitary system (e.g. science and inspectorate activities).

The workshop encouraged countries to review and change national policies/rules on research commissioning that inhibited trans-national cooperation.

The strategic research areas and the network vision identified in the first draft of the common phytosanitary strategic research agenda developed by EUPHRESCO were broadly supported.

The workshop participants encouraged continued development of the longer-term and self-sustainable funder’s network with a continued link to the COPHS.

EUPHRESCO-II Proposal:

The EUPHRESCO Governing Board and the COPHS have supported lobbying for a second EU-funded Phytosanitary ERA-Net in FP7 in 2010 to ensure that a strong and self-sustainable network is achieved. It would broaden and deepen the coordination and cooperation. A call is expected in July 2009 for a "***Deepened and enlarged cooperation between phytosanitary (statutory plant health) research programmes***", with a proposal submission deadline in January 2010. The current EUPHRESCO network will develop a proposal and wants to encourage other European countries that are funding phytosanitary research, and not currently involved in EUPHRESCO, to join the proposal. A list of current EUPHRESCO partners is attached (Annex 1). In particular the EUPHRESCO-II proposal would seek the involvement of:

European countries that are missing from the current EUPHRESCO funders' network, especially: those undertaking significant phytosanitary research; those wanting to establish national or sub-national phytosanitary research programmes but who currently do not have them (especially current Observer countries); those which will help enhance European regional cooperation (e.g. Balkan and Baltic countries); those national research programmes which enhance cooperation on forestry plant health research.

Non-European countries (e.g. some key EPPO countries) may also be associated with the proposal.

Action requested from the COPHS

FP7 plant health priorities:

The COPHS should note the potential inclusion of the 'intervention strategies' topic in 2011, but that there has been an unexpected broadening of the scope by the FP7 FAFB Programme Committee to also include difficult to control indigenous pests with a focus on crops, IPM and climate change. EUPHRESCO will provide views to DG-Research and to the FP7 FAFB Programme Committee, to ensure statutory plant health can compete fairly within any broadened scope, and seek direct support from the COPHS in the future, as appropriate. However, COPHS are requested to also contact their own national FP7 FAFB Programme Committee members directly to:

Support continued inclusion of a plant health 'intervention strategies' topic in 2011;

Ask that the potential call text either focuses on plant health or, if broadened to include indigenous pests, that it does not unduly disadvantage statutory plant health proposals.

EUPHRESCO II:

COPHS members from countries not currently involved in EUPHRESCO (Annex 1) as full partners are asked to consider the new and unique opportunity to become more directly involved in a EUPHRESCO II proposal to the anticipated ERA-Net call in July 2009. COPHS members from such countries are asked to identify and encourage their research programme funders or managers, or other appropriate officials, to contact EUPHRESCO to discuss their potential involvement in the proposal and future longer-term network of research funders and managers:
alan.inman@fera.gsi.gov.uk or euphresco@fera.gsi.gov.uk

ANNEX 1:

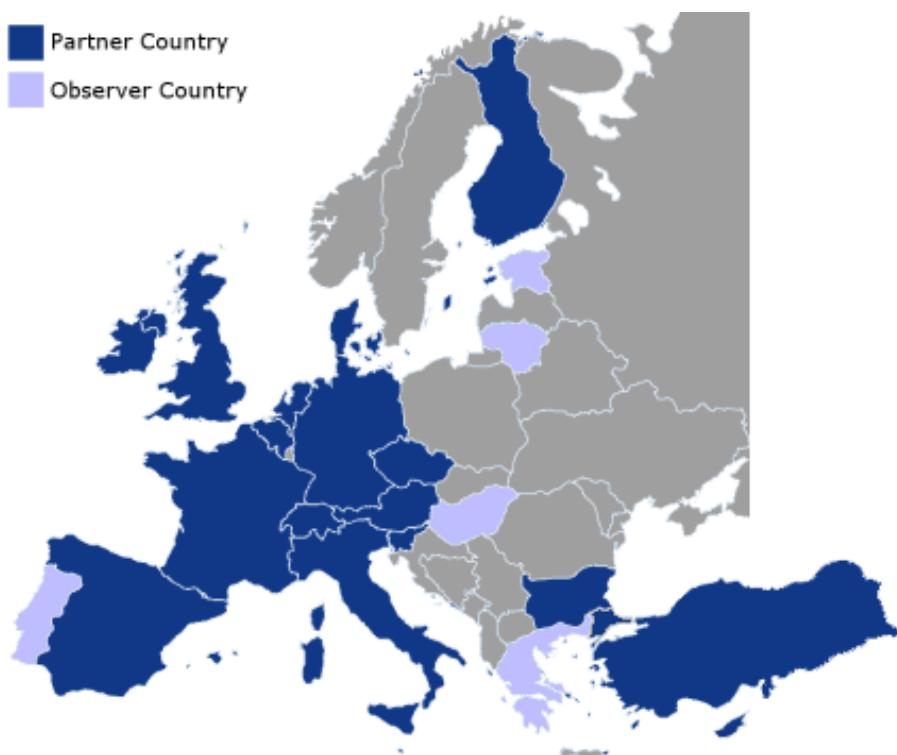
EUPHRESCO Scope:

"A phytosanitary ERA-Net for research policy and implementation in the area of statutory and emerging plant pests, diseases and invasive species (but not GMO's)"

EUPHRESCO Partners and Observers in the Current Project (2006–2010)

EUPHRESCO Partners	EUPHRESCO Observers
Austria (AGES; BMLFUW)	Estonia
Belgium (ILVO; FPS)	Hungary
Bulgaria (NSPP)	Greece
Cyprus (ARI)	Lithuania
Czech republic (NAAR)	Malta
Denmark (DFFAB)	Portugal
Eire (FAF)	
Finland (MMMF)	
France (INRA; DGAL)	
Germany (JKI; BMELV)	
Italy (CRA; MPAF)	
Netherlands (PPS; LNV)	
Switzerland (FOAG)	
Slovenia (MAF)	
Spain (INIA)	
Turkey (GDAR)	
UK (FERA)	

Current EUPHRESCO Project Partner (2006-2010)



ANNEX IV

Provisional dates for meetings in the phytosanitary area during the Swedish Presidency, July – December 2009

DATE	MEETING	CHAIRPERSON	SWEDISH PERM. REP. TO THE EU
July 24	F.19.c, Roosendaal	Fredrik Alfer Ministry of Agriculture fredrik.alfer@agriculture.ministry.se +46 8 405 81 74/ +46 76 788 55 63	
September 17-18	F.19.a, Inspection & Protection	Anna Niklasson Ministry of Agriculture anna.niklasson@agriculture.ministry.se +46 8 405 12 47/ +46 70 569 57 39	Mathilda Åberg mathilda.aberg@foreign.ministry.se +32 2 289 56 81 +32 479 36 14 66
September ¹	F.18 or F.19.d COPHS or Harmful organisms	Karin Nordin or Anna Niklasson	
October 2 <i>possible</i>	F.19.c Roosendaal	Fredrik Alfer	
October ²	F.18 or F.19.d COPHS or Harmful organisms	Karin Nordin or Anna Niklasson	
November 27 <i>possible</i>	F.19.c, Roosendaal	Fredrik Alfer	
December 3-4	F.18, COPHS	Karin Nordin Swedish Board of Agriculture karin.nordin@sjv.se +46 36 15 59 15/ +46 70 694 37 32	

¹ The exact date will be set later. Agenda:1) Commission proposal to change art.2.1.g in the Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and their spread within the Community 2) Commission paper on the pine weed nematode.

² The exact date will be set later. Agenda: see footnote 1.