

SANCO FRAMEWORK CONTRACT ON EVALUATION, IMPACT ASSESSMENT AND RELATED SERVICES

Term of Reference (task specification) for assignments relating to impact assessment and ex-ante evaluation

1. Title of the assignment

Quantification of costs and benefits of amendments to the EU plant health regime.

2. Context of the assignment

2.1. Description of the Policy Area to be covered

This assignment relates to the Common plant health regime (CPHR) of the European Union (EU). Plant health is a cornerstone for sustainable and competitive agriculture, global food security and environmental protection.

In several aspects, plant health is a public good. Healthy crops are essential to ensure food security for the ever-growing global population world-wide. Entry and establishment of harmful organisms often results in increases of pesticide use and could impact negatively on the environment and, in some cases, on food safety. Prevention of entry of new harmful organisms and diseases helps limiting the use of pesticides. Moreover, for a number of regulated pests and diseases there are no curative treatments possible at all. Furthermore, citizens value an unspoilt landscape and are concerned about the rapid loss of natural habitats, biodiversity and plant resources worldwide. Entry and establishment of harmful organisms may lead to serious damage to amenity trees, public and private green, recreational forests and to disruption and loss of natural ecosystems and habitats. Due to climate change, forests and natural ecosystems become increasingly susceptible to invading pests and pathogens. Massive forest death due to plant pests may accelerate climate change by changing forests from a carbon sink into a carbon source.

Plant health is also a private good since plant health measures may equally serve to protect the economic value of plants and plant products in agriculture, forestry and trade. Buyers and sellers of plants and plant products do not have the same information on the health status of the materials (seemingly healthy material may be infected inside). Such so-called information asymmetry is known to lead to market failure: the free market does not itself correct this. Regulation of plant health is therefore of interest for the private sector as well.

2.2. Specific and operational objectives of the activity/action

The specific objectives of the current EU plant health regime are:

- To protect the EU territory against the entry, establishment and spread of harmful organisms that so far do not occur in the EU or, if present, to a very limited extent and under control (the main objective currently being to protect agriculture and horticulture);

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- To ensure the availability and use of healthy plant material at the beginning of the chain of production (prevention of the spread of harmful organisms occurring in the EU with plants-for-planting);
- To control harmful organisms of still limited distribution which are so harmful that strict control on further spread is needed;
- To secure safe trade by establishment of EU import requirements for plants and plant products and EU internal movement requirements for certain plants.

2.3. Legal basis, budget and duration of the activity/action

The CPHR is the product of decades of legislation. The basic structure of the current CPHR was conceived in 1977 with Council Directive 77/93/EEC. This Directive considered that systematic eradication of harmful organisms within Member States (MS) would have only a limited effect if protective measures against their introduction were not applied at the same time and that national plant health provisions needed to be harmonized. To this end, a framework was created governing import into the EC and intra-Community trade, building on the framework already provided in 1952 by the International Plant Protection Convention (IPPC). Harmful organisms were listed in Annexes to the Directive. With the introduction of the EU internal market in 1993, the concept of plant passports was introduced so as to allow free movement of plants and plant products between and within MS. Since the 2000 codification, the basic legal framework is known as Council Directive 2000/29/EC.

In addition to the core Directive, which relates to eradication and containment of harmful organisms spread via movements of plants and plant products, a limited set of Council Directives regulates the control of specific harmful organisms of potatoes which have become established in parts of the EU.

The annual budget available for the regime is at present approximately 3 million euro, for co-financing of measures to eradicate or contain outbreaks (the so-called "solidarity regime"). EU payments in practice serve to co-finance the costs incurred by MS competent authorities for implementing such measures. While Directive 2000/29/EC allows coverage of losses of growers from imposed official measures, this has not been put in practice so far.

The CPHR is open-ended.

2.4. Instruments of the activity/action and objectives of the review

Instruments

The CPHR legislation is transposed by the Member States into national legislation and implemented by the national competent authorities.

Apart from EU funding of research projects under the Framework Programmes of DG RTD, scientific research to support the regime and diagnostic infrastructures currently are not a part of the regime (this is addressed at Member State level).

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Problem analysis

An evaluation of the regime was carried out in 2009-2010 by the Food Chain Evaluation Consortium (FCEC). Based on their analysis, the shortcomings and weaknesses of the regime in its current form can be summarised as follows:

- Insufficient focus on prevention¹: the evaluation report therefore recommends horizon scanning for emerging risks, compulsory contingency planning, where necessary import bans and post-entry quarantine, introduction of mandatory EU-wide surveillance for priority pests and rapid emergency action;
- Insufficient focus on major risks: the evaluation report recommends better risk targeting and prioritisation (resources / objectives). The regime should move to a truly EU (rather than MS interest) approach for more joint action to tackle risks of significance to the entire EU;
- Lack of incentives: to support the regime's objectives, EU co-financing is recommended for losses of growers from destroyed material. The perverse incentive to hide outbreaks needs to be removed. In general, the balance between public and private costs and responsibilities needs to be reconsidered;
- Lack of resources: EU co-financing is recommended for future mandatory EU-wide contingency planning, surveillance and eradication actions of MS authorities (including measures against natural spread). In essence, the lack of resources is an awareness problem (lack of recognised justification of the regime's benefits)²;
- Need for substantial upgrade of the plant passport and protected zone systems, which jointly define the *balance between free movement of plants and plant products on the internal market*³, versus protection of pest free zones within the EU. In the context of plant passports, the overlapping remit for plant health controls with the EU seed & propagating material regime also needs to be addressed⁴;
- Insufficient stable support for the regime from R&D and diagnostic infrastructures: to counteract the erosion of critical plant health expertise underpinning the regime, the evaluation report recommends improvements as concerns capacities, organisational structures and resources;
- Need to align the scope of the regime with the revised International Plant Protection Convention⁵: the evaluation report recommends that the future EU plant quarantine provisions, apart from pests and diseases, should include invasive plant species.

¹ In essence, this is a mix of missing legal instruments and inadequate implementation (partly due to lack of resources).

² This links in to the issue of public/private responsibilities and cost sharing.

³ Striking a proper balance between the objectives of free movement of plants and plant products across the EU, versus protecting Member States against the spread of harmful organisms with such movements, was at the heart of the previous (1993) review of the regime.

⁴ This also links in to the issue of public/private responsibilities and cost sharing.

⁵ The EU and its MS are contracting parties to the revised IPPC (1997).

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Objectives of the review

The objective of the review is to resolve the existing shortcomings and weaknesses of the regime.

In terms of global objectives, the new EU plant health regime should serve to better promote sustainable production, support food security, protect the environment, forests, landscape and biodiversity, and in this context mitigate the plant health impacts of globalisation and climate change. The regime should continue to support competitiveness of EU agriculture and forestry, economic growth and the free EU internal market.

In terms of specific and operational objectives, the modernisation of the regime should result in an updated scope as concerns organisms covered by the regime and the remit for preventive action (also for sake of environmental concerns) to counteract the plant health problems resulting from globalisation and climate change. It should result in better protection at import and more effective intra-EU movement provisions to reduce the risk of entry and spread of harmful organisms, and in improved surveillance and rapid and effective eradication of outbreaks. The new regime should be more risk-based. It should include appropriate financial incentives. Its organisational structures (laboratories, databases, training, communication, interaction with private sector) and support from research and development should where appropriate be improved.

The new regime should address the needs of the future: its principles should be sufficiently robust to remain valid up for 15 years after adoption of the new EU plant health law by Council and European Parliament (i.e, up to 2025 or 2030).

3. Description of the assignment

3.1. Purpose and objective of the assignment

The study which is the purpose of this assignment should support the development by the Commission services (DG SANCO) of the impact assessment accompanying the legislative proposal of the Commission, by providing supplementary economic data on impacts (costs⁶ and benefits). Such data have in part been collected already during the CPHR evaluation study (see the Terms of Reference for the evaluation study and the evaluation report itself). The study which is the subject of the current assignment should supplement the CPHR evaluation report with a quantification of the costs and benefits of several potential amendments to the EU plant health regime. The contractor must consult the CPHR evaluation report for in-depth information on the regime.

⁶ This could among others relate to: operating costs for owner/producers, processors and traders of plants and plant-related products; cost for plant importers and exporters; operating costs for transporting and logistic companies; costs for public authorities, laboratories, research and development, innovation; costs for consumers resulting from increased plant health costs elsewhere in the production chain. The impacts could also relate to costs for third countries.

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The study should provide data (figures and figure estimates, where appropriate), analytical and descriptive inputs necessary for DG SANCO to complete its impact assessment and to fill the existing knowledge gaps. The collected data should be presented in a format that facilitates their analysis and further use by DG SANCO. For each of the issues to be addressed in the assignment, the consultant shall gather the necessary data and integrate them in tables, spreadsheets and other impact calculation support tools, as appropriate. This should allow the Commission services to study the possible impact on the various stakeholders of different options, including new variants developed in the course of the impact assessment, for review of the current legal framework.

In this context, preliminary results should be made available to the Commission services already during the study and as early as possible.

3.2. Scope of the assignment (operational, temporal, geographical...)

The scope of the assignment is the same as for the evaluation of the CPHR. It covers the entire EU-27.

3.3. Issues to be addressed

The current assignment is restricted to issues which have been identified as key areas for possible policy change that are likely to have significant economic, social or environmental impacts and should therefore be included in the impact assessment⁷:

1. Scope of the CPHR
 - a. Invasive alien species (IAS)
 - b. Regulated non-quarantine pests (RNQP)
2. Import control
3. Intra-EU surveillance obligations
4. Plant passport system
 - a. (a) Scope
 - b. (b) Harmonisation
5. Protected zones system
6. Incentives for effective implementation
 - a. (a) Co-financing of measures against natural spread
 - b. (b) Coverage of losses of growers, cost-responsibility sharing, plant health fund, sanctions

The tasks for the contractor following from these issues are detailed in chapter 3.4. Background information on the purpose of the tasks in relation to the underlying problems of the regime is provided in the Annexes.

The assignment is restricted to issues which have not been resolved in the evaluation study and which cannot be covered sufficiently by DG SANCO itself.

⁷ The scope of the impact assessment as concerns the recommendations from the evaluation report was subject to a targeted public consultation in the context of the conference "Towards a new EU plant health law" on 28 September 2010.

3.4. Specification of tasks

Task 1: Analysis of costs of introduction of mandatory intra-EU surveillance for priority harmful organisms and costs of EU-financing of such surveillance

For a selection of 10 harmful organisms provided in the Annexes, the contractor should estimate an appropriate level of surveillance from best practices among the Member States and by comparison with the known surveillance levels for other important harmful organisms, including potato pests under the Control Directives (brown rot, potato ring rot and potato cyst nematodes).

The contractor should estimate the total annual costs for the MS and the EU of introducing mandatory surveillance (visual inspection + laboratory testing⁸ as appropriate) for the selected organisms at these levels, in absence and in presence of EU co-financing ("*EU surveillance requirements*" option).

The contractor should also estimate the total annual costs for the MS and the EU (at 50% co-financing) of introducing mandatory surveillance for the selected harmful organisms without fixed surveillance levels, in absence and in presence of EU co-financing ("*EU surveillance facilitation*" option).

Task 2: Analysis of the impacts of introducing post-entry quarantine in the import regime

The contractor should estimate, in coordination with the MS competent authorities and DG SANCO, for how many cases (regulated harmful organisms/plants/origin) post-entry quarantine⁹ would be advisable and should draw up a representative selection of 10 of these cases. The total annual costs for the MS, the EU and the private sector of the introduction of post-entry quarantine¹⁰ should be estimated.

Task 3: Analysis of the financial impact of expanding the EU solidarity regime to an emergency fund for plant pests with co-financing not only costs of MS authorities but also losses of private operators

The contractor should analyse the costs, feasibility and rationale of the introduction in the CPHR¹¹ of a Plant Health Fund¹² to financially compensate private operators for the losses¹³ suffered due to officially imposed measures. The study should clarify to

⁸ The surveillance cost estimates should include visual inspection and, depending on the commodity and harmful organism, laboratory testing for the presence of invisible (latent) pests.

⁹ Official post-entry inspections should be carried out after the quarantine period and prior to official release of the material for free circulation on the internal EU market.

¹⁰ Costs could among others pertain to additional inspections, laboratory testing for latent pests, delayed release for the internal EU market, increased or extra fees, administrative burden.

¹¹ Article 23, point 3 of Directive 2000/29/EC in principle already provides such a framework, which however has not been put into practice.

¹² In analogy with the existing Animal Health Fund and taking account of the current evolution of that fund (including the development of cost-responsibility sharing schemes).

¹³ The CPHR evaluation report recommends to extend the current scope of solidarity to cover losses of destroyed material (i.e., to compensate growers for the lost value of material that had to be destroyed because of official

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what extent the Animal Health Fund structure would be feasible for plant health, what amendments are needed, what criteria should be used to allow for compensation, and what the modalities and level of cost-sharing could be. The expected costs for the EU and the Member States and the volume of payments to private operators should be quantified.

The contractor should assess the order of magnitude of direct (destroyed material) and indirect losses of private operators that would be eligible for EU co-financing when the solidarity regime would be expanded in this sense. This should be done in such a way that the outcome is sufficiently representative for all affected sectors (agriculture, horticulture, seed industry, forestry, wood industry).

Estimates should be provided for a scenario in which the co-financed costs would be in line with the current level / number of measures imposed by competent authorities today on private operators. Estimates should also be provided in case the study would indicate that the Member States will impose and co-finance plant health measures at an increased level because of the availability of EU co-financing (multiplier effect).

Task 4: Analysis of the financial impact of expanding the EU solidarity regime to also include natural spread of plant pests

The contractor should provide a reliable estimate of the impacts for the EU and the MS from expansion of the solidarity regime so as to in future also cover prevention measures for natural spread¹⁴. The order of magnitude should be inferred from, among others, cases in which co-financing for natural spread was not accepted in the past (e.g. *Diabrotica virgifera virgifera*, *Rhynchophorus ferrugineus*) and by predictions for possible future outbreaks (e.g. outbreaks followed by natural spread of Pine Wood Nematode (*Bursaphelenchus xylophilus*) outside of Portugal, or outbreaks and subsequent natural spread of *Anoplophora chinensis*, *A. glabripennis* or *Phytophthora ramorum*).

Tasks 3 and 4 are interlinked (including natural spread would impact on the co-financing of losses of private operators, and vice versa). This should be taken into consideration in the cost / impact calculations.

Task 5: Analysis of the economic weight of harmful organisms impacting on agriculture, horticulture, forests and the environment

Through a desk study on the available literature, the contractor should quantify (monetise) the current / potential economic weight of high-impact harmful organisms. The analysis should comprise a sufficiently balanced and representative¹⁵ selection of such organisms. It should provide a reliable and justifiable estimate of the potential

phytosanitary measures). The report does not recommend to also cover business losses (i.e., in addition, indirect business losses other than the value of the destroyed material).

¹⁴ So far, solidarity co-funding is restricted to measures addressing outbreaks or spread resulting from human activities related movements (excluding natural spread).

¹⁵ In relation to agriculture, horticulture, forestry/landscape, and natural ecosystems/biodiversity and as concerns the main types of harmful organisms (insects, nematodes, fungi, bacteria, viruses).

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economic benefits of regimes, such as the CPHR, to prevent the entry and spread of harmful organisms of plants. Where appropriate the timescale of impacts (costs, benefits) should be indicated.

Cases to be anyhow included in the desk study are the pine wood nematode (*Bursaphelenchus xylophilus*) in Europe and Asia; the longhorn beetles *Anoplophora chinensis* and *A. glabripennis*; the mountain pine beetle (*Dendroctonus ponderosae*) in Canada; the western corn rootworm (*Diabrotica virgifera virgifera*) in Europe and in the US; potato brown rot (*Ralstonia solanacearum*), potato ring rot (*Clavibacter michiganense* ssp. *sepedonicus*), potato cyst nematodes (*Globodera* spp.).

Task 6: Analysis of the costs and benefits of amending the scope of the EU plant health regime in relation to the EU seed and propagating material regime

This task consists of three sub-tasks related to the coherence between the CPHR and the EU seed and propagating materials (S&PM) regime:

Task 6a. Positioning of regulated non-quarantine pests¹⁶

The contractor should quantify the economic impact (costs and administrative burden for private operators, MS and EU authorities) of moving regulated harmful organisms from one regime to the other according to the options (i) to (iv) below, and assess the impacts of these options – if any – on attaining the objectives of the two regimes (respectively "plant health" and "health and quality of seed and propagating material").

The options (modified from the evaluation report) are:

- (i) Status quo;
- (ii) Alignment of the implementing provisions of the two regimes for plant health controls (allowing combined inspections);
- (iii) Transfer of all RNQPs (those with zero tolerance requirements and those with tolerance thresholds) from the S&PM regime to an Annex¹⁷ of the EU plant health regime;
- (iv) Transfer of all harmful organisms currently regulated under the EU plant health regime, but exclusively for plants for planting¹⁸, to the S&PM regime.

Guidance on expected types of impacts is provided in a footnote¹⁹.

¹⁶ The CPHR evaluation report recommends to amend the scope of the EU plant health regime, so as to also comprise certain so-called regulated non-quarantine pests (RNQPs). Such pests are currently regulated under the EU seed and propagating material (S&PM) regime - albeit without using the name RNQP - and, partially, the EU plant health regime (Article 3 of Directive 2000/29/EC).

¹⁷ A separate new Annex or Annex II, Part A, Section II of Directive 2000/29/EC.

¹⁸ A draft list of such harmful organisms, drawn up by the Commission in 1991, is provided in the Annexes.

Other candidate harmful organisms for such a transfer, for example, apple proliferation mycoplasma and pepino mosaic virus, need to be identified in coordination with MS authorities, stakeholders and DG SANCO.

¹⁹ Inclusion of RNQPs in the EU plant health regime (option iii) would necessitate costs for MS authorities and private operators from mandatory import controls for RNQPs. Under the Marketing Directives, random import controls are provided for but these may not be systematic; they are however also carried out in some MS in the

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Task 6b. Costs and benefits of merging the plant passporting and certification schemes

Irrespective of the positioning of RNQPs (Task 6a), the contractor should quantify what the costs and benefits would be for private operators (administrative burden, fees) and for MS competent authorities to merge the visual inspection based plant passports of the CPHR with the sampling and laboratory testing based health certificates of the S&PM regime²⁰.

The contractor should assume that in such a merger the current technical requirements for the certification schemes will be extrapolated to the CPHR for the plant material in case²¹. The contractor should investigate the economic impacts for private operators and competent authorities (CPHR and S&PM) of upgrading the plant passport requirements for propagating material to the level of the S&PM regime, compared to maintenance of the status quo. The study report should list for which pests / plants upgrading would be expected.

Task 6c. Development of options for the role of the private sector in implementation of the health controls for issuance of the new health document

Based on the CPHR evaluation report and consultation with MS competent authorities and private stakeholders, the contractor should develop scenarios (options) for fully or partly²² harmonised provisions for delegation of control tasks to the private sector²³. A solid, clear logic should be presented for these options in relation to the objectives of the regime (balance public / private), the nature of the different sectors of private operators and the prospects for cost / responsibility sharing. The options should each be compared with the intervention logic and legal provisions for comparable cases in Regulation 882/2004/EC. The impact of each option on cost effectiveness and administrative burden for private operators and MS competent authorities should be assessed.

context of final certification. The import controls would where appropriate include sampling and laboratory testing of seed and propagating material lots (according to ISTA rules). Transfer of specific harmful organisms from the CPHR to the S&PM regime (option iv) would similarly imply that costs for import controls may be lower. In options (ii) and (iii), plant health controls under the S&PM certification schemes could be combined with the plant health controls for plant passporting under the EU plant health regime. In option (iii), the costs for certification of seed and propagating material as concerns quality may increase if no longer combined with the health controls. Costs for surveillance, eradication and containment of RNQPs would not be applicable in any of the options since harmful organisms can be listed as RNQPs only if widely established in the EU.

²⁰ Thus, the current three controls (plant health under the CPHR; plant health under the S&PM regime; quality under the S&PM regime) would be rearranged into two controls (one plant health control + one quality control).

²¹ Downgrading the certification requirements is not acceptable and therefore does not need to be investigated for its financial impacts.

²² For example, different "safety levels" in relation to delegation could apply to different Annexes.

²³ At present, the provisions in the CPHR and S&PM regimes are different as concerns the allowable delegation of tasks to the private sector.

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Task 7: Analysis of the costs and benefits of amendments to the plant passport system²⁴

This task consists of three sub-tasks, two of which follow the recommendations in the evaluation report (revise the scope of application of the plant passport; harmonise the plant passport document) and a third to introduce an incentive for compliance.

Task 7a. Amendments to the scope of the plant passport system

Based on the evaluation report and in consultation with the stakeholders and MS competent authorities, the contractor should quantify (or as a minimum provide the data and spreadsheets that will allow DG SANCO to monetise) the impacts on private operators and MS competent authorities of:

- (i) Introducing plant passporting obligations to individual smallest units of plants used in trade;
- (ii) Expanding plant passporting obligations up to the stage that plants are sold to the final consumer (instead of excluding end products);
- (iii) Expanding plant passporting obligations which currently apply only to Protected Zones or to Demarcated Areas to the entire EU territory;
- (iv) Expanding plant passporting obligations to a generalised use of a simplified plant passport for all plants for planting in the EU.

Task 7b. Harmonisation of the plant passport document

The contractor should investigate the feasibility and financial impacts (costs, benefits, administrative burden) for private operators and competent authorities, compared to the status quo option, of:

- (a) Replacement of the current diversity of plant passports by a single, in terms of form and contents²⁵ fully harmonised label, applicable and affixable to all plants and plant products covered by plant passporting requirements. If necessary, the label could be applied in different sizes on packaging materials (bags, boxes, paper envelopes, ...);
- (b) Replacement of the current plant passports by a new EU plant passport logo (to be developed) containing exclusively an identification number relating to the product, linked to a new EU database²⁶ containing the information that is registered on the label in options (a) and (b). In case the costs of a central database would be

²⁴ The objectives of the plant passport system are twofold: providing a visible guarantee to buyers that the sold product is healthy; and allowing for tracking and tracing of the infestation sources in case a product would nevertheless prove to be infested.

²⁵ The contents of the plant passport should be identical to the minimum requirements of the current legislation as comprised in Council Directive 2000/29/EC, Commission Directive 92/105/EEC and Commission Directive 2005/17/EC (nothing less, nothing more), however in a fixed format and physical form.

²⁶ The database (probably an extension of TRACES) would be managed by the European Commission and filled by the Member State competent authorities and the private operators.

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excessive, the study should clarify for which segments of the CPHR traceability through such a database would be critical and affordable.

The deliverables should include basic cost data and spreadsheets that DG SANCO can use to further examine the financial impacts of other options for the future plant passporting system as might come up later on.

Task 7c. Introduction of burden of proof inversal

The contractor should estimate the financial impact of a possible introduction of a liability inversal provision in relation to the issuance of plant passports as an incentive for compliance. The provision would introduce liability for losses due to CPHR-regulated harmful organisms for private operators who sell plants or plant products accompanied by a plant passport, unless they can provide evidence of having complied with the relevant provisions of the EU plant health regime (burden of proof inversal). The costs for private operators from such a provision could relate among others to administrative burden.

Task 8: Analysis of the costs and benefits of amendments to the protected zones system

The contractor should carry out an analysis of the costs and benefits of mandatory surveillance targets and of mandatory de-listing procedures for infested protected zones. This should be related to the economic benefits of such zones. To this end, the overall economic benefits should be estimated for a representative selection of the current PZs (in comparison to their theoretical deregulation):

- *Erwinia amylovora* – Italy, Latvia
- *Bemisia tabaci* (European populations) – UK, Finland
- *Ips amitinus* – Ireland, Greece
- *Cryphonectria parasitica* – Czech Republic, Sweden
- *Globodera pallida* - Slovakia

A technically justifiable level of surveillance (visual inspection as well as laboratory testing) for these PZs should be defined on basis of MS best practices and the total costs of introducing mandatory surveillance at that level should be estimated. A recommendation should be given concerning the appropriate repartitioning of these costs over MS competent authorities and private operators, and what this should imply for stakeholder involvement in the management of PZs.

In relation to a mandatory de-listing procedure for infested protected zones the contractor should estimate the economic impact of mandatory de-listing of the

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selected protected zones (a) when infestations have not been fully eradicated after 2 years; and (b) immediately (PFA approach²⁷).

Task 9: Analysis of the costs and benefits of including specific categories of invasive alien species in the scope of the EU plant health regime

DG SANCO will provide the contractor with a selection of 5 IAS plant species (agricultural weeds, environmental weed/shrub IAS and IAS plants with important human health impacts). Using this selection, the contractor should deliver a global cost estimate for the EU (order of magnitude) for the consequences of inclusion of IAS in the CPHR. The assumption should be that such IAS would be dealt with in the same way as currently regulated harmful organisms (i.e, inclusion in the Annexes of Council Directive 2000/29/EC), including:

- Costs for MS authorities and private operators from mandatory import controls for plants and plant products consisting of or possibly contaminated with such IAS;
- Surveillance costs for MS authorities;
- Costs for MS authorities and private operators from mandatory eradication and containment and costs of EU co-financing of MS costs and private operator losses;
- Costs for MS authorities and private operators from mandatory intra-EU movement requirements of plants and plant products consisting of or possibly contaminated with such IAS;
- Costs for EU and MS authorities in terms of additional resources (staff; other costs) to operate such a regulatory system.

3.5. Expertise required from the contractor

The preparation of this report will require expertise in plant health (in relation to agriculture, horticulture, forestry and environment), regulated harmful organisms, the EU legislative regimes for plant health and for seed and propagating material, economics, statistics and impact analysis.

Given the specialised nature of the subject matter that has to be studied, the assessment team is expected to comprise members with specific expertise in these sectors.

3.6. Other specific tasks to be carried out under the assignment

Stakeholder consultation is to be organised by the contractor as an important part of the study to which these Terms of Reference refer. In addition, stakeholder consultation will be organised by DG SANCO in the first semester of 2011 in the framework of the Working Group on Plant Health of the Advisory Group for the Food Chain, Animal and Plant Health of DG SANCO.

²⁷ A Pest-Free Area (PFA; https://www.ippc.int/file_uploaded/1146657783053_ISPM4.pdf) is an area in which a specific pest does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained. The requirements for PFAs are thus more stringent than for PZs, where a certain level of infection may be tolerated for a certain period of time.

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3.7. Reporting and deliverables

The assignment includes the submission of a series of deliverables: reports, calculation tools and presentations.

The contractor will deliver the following reports at key stages of the process: inception report, interim progress report, draft final report and final report. Each report should be written in English, professionally edited, and critically assessed as it provides the basis for tracking the quality of the work done by the contractor. The contractor will attend four specific meetings with the Commission, first at the Kick-off meeting and subsequently to present and discuss the progress of the work after the submission of the inception report, the interim report and the draft final report²⁸. The contractor is requested to take notes at the meetings and to submit them to the Commission for approval the week following the meeting.

In the course of the project, coordination meetings with Commission services may be organised as appropriate.

Inception report – at the latest six weeks after the signature of the contract

The inception report completes the structuring phase of the report preparation. It aims to describe the organisation of the work, and to adapt and substantiate the overall approach, the methodology proposed and the work plan outlined in the proposal. It should set out in detail how the proposed methodology will be implemented and in particular lay out clearly in tabular form how the report will be constructed and prepared. The inception report should include enough detail for the Commission to gain a good understanding of the approach, method and timing proposed.

The known sources of information as well as the way the contractor will interact with stakeholders and MS competent authorities will be fully clarified at this stage.

The inception report will be submitted to the Commission which will discuss on this basis with the contractor and may request changes and improvements.

Interim report – 4 months after the signing of the contract

This report be presented to the Commission services and will provide information on the progress, along with intermediate results and an initial analysis of data collected. The contractor should already be in a position to provide: a) spreadsheets with data, models, simulations in relation to the Tasks and where appropriate options, b) preliminary findings related to the purpose and objective of the report (see above paragraph 3.1), and c) draft layout and content. The report will provide the Commission with an opportunity to check whether the work is on track and whether it has focused on the specified information needs.

The Interim Report shall comprise the draft outcome for the urgent and/or more complex Tasks 3, 4, 5, 6 and 7.

The contractor will define in agreement with the Commission the table of contents and structure of the draft final report. A document outlining the latter must be submitted in advance of the meeting by the contractor. It will serve as a basis for the discussion.

²⁸ Some of these meetings may coincide with meetings of the Inter-Service Steering Group for the impact assessment.

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Draft final report and final report

a) Draft final report:

The contractor must provide the Commission services with a written and oral presentation on the draft final results, where appropriate accompanied by the requested calculation tools. The draft final report will be clearly based on evidence generated through the analysis. The draft final report should include an executive summary of not more than 15 pages (synthesis of main analyses and conclusions), the main report (presenting the results of the analyses in full, conclusions and recommendations), technical annexes (one of which will be the Task Specifications) and a draft one-page summary on the Key Messages of the report.

The Draft Final Report shall comprise the outcome for all Tasks.

The draft final report will be submitted at the latest 6 months after the signature of the contract.

b) Final report

The contractor must provide the Commission services with a written and oral presentation on the final results, where appropriate accompanied by the requested calculation tools, at the latest 7.5 months after the signature of the contract. The final report will take into account the results of quality assessment and discussions with the Commission Services about the draft final report. The final executive summary and Key Messages page will be part of it. The final report should have the same structure as the draft final report. The contractor should provide the final report in both MS-Word and Adobe Acrobat (PDF). *The contractor should also provide a PowerPoint presentation of key aspects and findings of the study, together with speaking notes.* The Commission will hold the copyright of the reports.

The Commission Services may ask after consultation and in mutual agreement for complementary information or propose adjustments in order to redirect the work when necessary. Deliverables must be acceptable to the Commission. With work progressing and in the light of new findings, revisions of deliverables already approved may be necessary. The contractor will be expected to respond to and take into account comments of the Commission.

Deliverables shall be drafted in a concise and easily understandable language. The presentation of the texts, tables and graphs has to be clear and complete and correspond to commonly recognised standards for studies to be published. They should be accompanied, where requested, by appropriate annexes. All reports and presentations are to be submitted in electronic format in accordance with the deadlines set in the time-schedule specified below.

The volume of final deliverable text will not exceed 200 pages (Times New Roman 12 or equivalent, excluding annexes). The core text has to be concentrated on the assessment of the main study items. An executive summary of between 10 and 15 pages (1500 characters/page) should be included in the final report. Background information should be presented in annexes.

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3.8. Organisation, methodology and timetable

As part of the bid, the contractor should identify the team of personnel to be involved, describe their skills and qualifications, quantify the input of each member of the team in terms of days and explain the distribution of tasks between the different members.

The bid should clarify the resources attributed to the Tasks described in Chapter 3.4 and demonstrate that the resources attribution is in line with the relative weight of these Tasks.

The bid should demonstrate an excellent understanding of the issues at stake and should be effective to address the underlying needs of DG SANCO described in these Terms of Reference.

In case the requested deliverables under the Tasks cannot be offered for the maximum budget available, the bid should specify what simplifications will be made to the Tasks while still addressing the underlying needs of DG SANCO concerning the nine Tasks.

Access to data

Access to data and information will be given to the consultant, who will also gather data and - where necessary - opinions of interested parties (European Commission, stakeholders and other relevant persons and organisations) through interviews and bilateral contacts.

Key stakeholders' organisations are provided in the Annexes.

The consultant that has been chosen will receive access to relevant data generated by the evaluation and owned by the Commission.

For collected data, a specification should be given of the sources from which the data were obtained, the assumptions that were made, where appropriate the model that was used to generate them, and the model outcome. Such specification should allow for verification of the data reliability. The contractor shall coordinate with the Commission services on the methods to collect the data and the spreadsheets, models and simulations to be used.

The study should specify where data are interconnected during to cross-influence of the options selected for the various recommendations. A separate matrix should be provided to clarify such interconnectedness.

The study should, in addition to the CPHR evaluation report (2010), utilise the reports of the Financial Aspects Evaluation of the CPHR (2008) and the Evaluation of the Community Acquis on the Marketing of Seed and Plant Propagating Material (2008).

Confidentiality

In the context of the assignment, data of a confidential nature may have to be collected, such as expenditure made by stakeholders as part of the administrative costs for complying with certain provisions of the EU legislation. These data shall be handled with due confidentiality.

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Data included in the Final report remains the property of the Commission and should be treated as confidential.

Methodology

The methodology must be drawn by the contractor taking into account the scope and objectives above and the establishment of good practice. The contractor is expected to develop and implement a methodology ensuring that all the components presented under chapters 3.1 to 3.4 are sufficiently well covered and that clear conclusions can be drawn.

The contractor is required to clearly detail the different steps of the design, summarising the methodology in a table format.

Collection, analysis and assessment of the data to be gathered in this study should be done in consultation and coordination with the stakeholders of the regime and, where appropriate, the MS competent authorities. To this end, the contractor shall consult an appropriately balanced and representative selection of the key EU-level stakeholders organisations (where appropriate: MS competent authorities) listed in the Annexes to these Terms of Reference. The consultation should be carried out as early as possible and should comprise plenary meetings²⁹ and interviews (face to face, by phone or through e-mail). The possible use of questionnaires is left to the judgment of the contractor. The results obtained (and estimates made) should be validated with the stakeholders (where appropriate: MS competent authorities) in a later stage of the study.

Apart from stakeholder consultation, data may be collected through literature and database searches.

The data and other inputs shall be consistent with the policy requirements, quality and standards necessary to conform with the Commission's Guidelines on Impact Assessment. Where appropriate, the Standard Cost Model (Administrative cost of obligations under EU legislation) should be used.

Elements of the methodology should be:

- Desk research, classification, mapping and review of data from the readily available resources (among others, those provided in the web-links, further references and Annexes of this Task Description)
- Interviews as and when required
- Economic analysis
- Stakeholder consultations

²⁹ Stakeholder consultation is to be organised by the contractor as part of the current consignment. In addition, stakeholder consultation will be organised by DG SANCO in the first semester of 2011 in the framework of the Working Group on Plant Health of the Advisory Group for the Food Chain, Animal and Plant Health of DG SANCO.

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The consultant may propose other tools for data collection and analysis as he/she may see fit including focus groups, questionnaires, workshops, a support board (experts from private sector, competent authorities and academia), etc.

Contractors are expected not to restrict themselves to these minimum requirements. Proposals for additional methodological and descriptive tools that may contribute to meeting the objectives of the study in a more satisfactory manner will be considered positively when evaluating the proposals.

Timetable

The Service order has a maximum duration of 7½ months. It is due to start in December 2010. A detailed work plan should be submitted together with the bid, building on the time-schedule summarised below. It should be updated with the Inception Report.

The draft final report should be delivered in May 2011 and the final report by the end of July 2011, thus allowing ongoing interaction between DG SANCO and the contractor up to the completion of the impact assessment (end of July 2011).

What	By
Kick-off meeting with the contractor	December 2010
Inception report	January 2011
Inception meeting	February 2011
Interim Report (on urgent / complex tasks 3, 4, 5, 6, 7)	March 2011
Interim meeting	April 2011
Draft final report (on all tasks)	May 2011

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Meeting on the draft final report	June 2011
Final report	July 2011

3.9. Quality assessment

In order to ensure the necessary level of quality for this report, contractors should always bear in mind that:

- The report must respond to the information needs, in particular as expressed in the Task Specifications and following discussions with the Commission;
- The methodology and design must be appropriate for completing the report and made explicit;
- The collected data must be appropriate for their intended use and their reliability must be ascertained;
- Data must be analysed systematically to cover all the information and presentational needs in a valid manner;
- Findings must follow logically from and be justified by, the data/information analysis and interpretations based on the pre-established criteria and rationale;
- To be valid, conclusions must be non-biased and fully based on findings.

The Inter-Service Steering Group set up for the Impact Assessment may also be invited to supervise the study assignment in order to ensure that it will be conducted in line with the Terms of Reference. The Steering Group may advise the Deputy Director-General on whether or not to approve the inception, progress and final reports delivered by the consultant.

3.10. Budget

Maximum indicative budget is € Budget line is 17 01 04 01.

3.11. Special requirements

The study should be provided in final form in electronic (MS Word and Adobe pdf) and paper versions.

4. References

4.1. Other existing documentation/data and how to access it

Annex 1: Policy area description and results of the evaluation of the regime

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- Annex 2: Background information on issues to be addressed in this assignment
- Annex 3: Contact details of the Chief Officers for Plant Health
- Annex 4: Contact details of key stakeholders' organisations at EU level
- Annex 5: List of 20 important harmful organisms regulated by the Community Plant Health Regime
- Annex 6: List of harmful organisms considered in 1991 as candidates for transfer from Directive 77/93/EEC to the certification schemes
- Annex 7: Discussion Document concerning the coherence of the EU plant health regime and seed & propagating material regime, presented to the Member State competent authorities on 8 October 2010

4.2. Useful web-links

- SANCO website on Europa on the review of the plant health regime, containing the CPHR evaluation report as well as links to further pages on the evaluation (http://ec.europa.eu/food/plant/strategy/index_en.htm)
- SANCO website on the review of the seed & propagating material regime, containing the evaluation report as well as information to the review of the regime (http://ec.europa.eu/food/plant/propagation/evaluation/index_en.htm)
- Roadmap New EU Plant Health Strategy (http://ec.europa.eu/governance/impact/planned_ia/docs/148_sanco_plant_health_en.pdf)
- ENV website concerning Invasive Alien Species (http://ec.europa.eu/environment/nature/invasivealien/index_en.htm)
- Commission's impact assessment guidelines (http://ec.europa.eu/governance/impact/key_docs/key_docs_en.htm)
- Recommended methodology for calculating “Administrative cost of obligations under EU legislation” (http://ec.europa.eu/governance/docs/sec_2005_0791_anx_10_en.pdf)
- Food and Veterinary Office of DG SANCO (http://ec.europa.eu/food/fvo/index_en.htm)
- European Food Safety Authority (www.efsa.europa.eu)
- International Plant Protection Convention (<https://www.ippc.int/IPP/En/default.jsp>)
- European and Mediterranean Plant Protection Organisation (<http://www.eppo.org>)
- International Seed Testing Association (ISTA)
Secretariat: Zürichstrasse 50, 8303 Bassersdorf, CH - Switzerland
Tel: +41448386000 / Fax: +41448386001

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E-mail ista.office@ista.ch
(www.seedtest.org)

- PRATIQUE: enhancement of pest risk analysis techniques
(<https://secure.fera.defra.gov.uk/pratique/>)

4.3. Further references

- European Commission, 2008. Interim evaluation Phytosanitary: Harmful Organisms – Financial Aspects. Final Report by the Food Chain Evaluation Consortium.
- Food Chain Evaluation Consortium, 2008. Analysis of the socio-economic and environmental impacts of banning or not banning the movement of susceptible wood products from Portugal for stopping the spread of pine wood nematode (PWN)
(http://ec.europa.eu/food/plant/organisms/emergency/Impact_assessment_study.pdf)
- Food Chain Evaluation Consortium, 2009. Analysis of the economic, social and environmental impacts of options for the longterm EU strategy against *Diabrotica virgifera* (Western Corn Rootworm), a regulated harmful organism of maize, to support the drafting of the Commission Impact Assessment.
(http://ec.europa.eu/food/plant/organisms/emergency/diabrotica_virgifera/index_en.htm)
- Shine, C., Kettunen, M., Mapendembe, A., Herkenrath, P. Silvestri, S. & ten Brink, P. 2009. Technical support to EU strategy on invasive species (IAS) – Analysis of the impacts of policy options/measures to address IAS (Final module report for the European Commission). UNEP-WCMC/Institute for European Environmental Policy (IEEP), Brussels, Belgium. 101 pp. + Annexes.
(http://ec.europa.eu/environment/nature/invasivealien/docs/Shine2009_IAS%20Task%203.pdf)

Annex 1: Policy area description and results of the evaluation of the regime

Policy area description

Nature of the EU plant health regime

Preventing the introduction of new pests and diseases (and thus preventing pesticide use) is better than cure: it avoids expensive campaigns to eradicate or control in a later stage. In this context, the Common plant health regime (CPHR) aims to protect the European Union (EU) territory against introduction and spread of regulated organisms which are harmful to plants. It lays down specific requirements for imports of all plants and some plant products into the EU and for internal movement of a limited number of plants within the EU. The fully harmonized regime allows free movement of consignments produced within the EU or, after import inspection, imported into the EU and at the same time allows to recognize protected zones that are free from specific harmful organisms³⁰ occurring elsewhere in the EU.

The objectives of the EU plant health regime can be summarized as follows:

- To protect the EU territory against the entry, establishment and spread of harmful organisms that so far do not occur in the EU, or if present, to a very limited extent and under control (the main objective being to protect agriculture and horticulture);
- To ensure the availability and use of healthy plant material at the beginning of the chain of plant production (prevention of the spread of harmful organisms occurring in the EU with plants-for-planting);
- To control harmful organisms of still limited distribution which are so harmful that strict control on further spread is needed;
- To secure safe trade by establishment of EU import requirements for plants and EU internal movement conditions for certain plants.

Political context and coherence with other EU policies

The political context of the CPHR is the need to promote sustainable production, to support food security, to protect the environment, forests, landscape³¹ and biodiversity, and in this context to mitigate the plant health impacts of globalisation and climate change. The regime furthermore supports competitiveness of EU agriculture and forestry. The ongoing review of the EU plant health regime aims at modernising and innovating the regime to more effectively address these challenges.

The CPHR relates to the EU climate change policy, the Common agriculture policy (CAP), the EU environment policy (including the policy for invasive alien species, biodiversity

³⁰ According to Council Directive 2000/29/EC, *harmful organisms* shall be considered to mean: any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products.

³¹ In addition to rural and heritage landscapes, this includes amenity and street trees, public and private gardens.

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protection, and forest protection against climate change), the EU customs policy, the EU trade policy, the EU internal market policy, and the EU research and development policy.

Affected parties

The regime affects the private sector (the seed industry; farmers / growers in agriculture, horticulture, forestry; traders of plants and plant products; logistic / transport companies transporting plants or plant products or using wood packaging material to transport other products; the wood packaging industry), private as well as public landscape managers, citizens, environmental NGOs, competent MS plant health and forestry authorities and third countries. It also impacts on public authorities in the Member States and on the European Commission.

Subsidiarity and EU added value

The CPHR is a fully harmonised regime and has been so since its inception in 1977. A broad territorial policy is needed to control pests and diseases, which can move throughout the EU by free trade and natural spread: diseases do not respect borders.

The CPHR has shown to be able to protect the EU against the entry, establishment and spread of many harmful organisms that are common elsewhere in the world but so far do not occur in the EU. Protecting the EU against their incursion and rapid eradication of outbreaks or, if that is not possible, their containment is the main reason of existence of the regime.

Results of the evaluation of the regime

Evolution of the EU plant health regime

The plant health regime of the EU is the product of decades of legislation. The basic structure of the current CPHR was conceived in 1977 with Council Directive 77/93/EEC. This Directive considered that systematic eradication of harmful organisms within Member States (MS) would have only a limited effect if protective measures against their introduction were not applied at the same time and that national plant health provisions needed to be harmonized. To this end, a framework was created governing import into the EC and intra-Community trade, building on the framework already provided in 1952 by the International Plant Protection Convention (IPPC). Harmful organisms were listed in Annexes to the Directive. With the introduction of the EU internal market in 1993, the concept of plant passports was introduced so as to allow free movement of plants and plant products between and within MS. Since the 2000 codification, the basic legal framework is known as Council Directive 2000/29/EC.

Since its inception, various major changes and developments have taken place in relation to the CPHR: (i) the enlargement of the European Community; (ii) the internal market concept; (iii) developments concerning international treaties; (iv) globalisation and changed expectations from society; (v) decreasing resources for public services; (vi) erosion of the scientific expertise underpinning the CPHR; (vii) the establishment of EFSA; and (viii) evolution of related Community regimes.

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In recent years, moreover, major outbreaks have occurred in the EU of very damaging harmful organisms previously absent from the EU, such as the Pine Wood Nematode (*Bursaphelenchus xylophilus*), the Citrus Long-horned Beetle (*Anoplophora chinensis*) and the Red Palm Weevil (*Rhynchophorus ferrugineus*). Increased effectiveness of the regime will be essential to better protect the EU. The vulnerability of our crops, plants and forests to foreign pests, to which they often have little or no natural resistance, is exacerbated by the ongoing globalisation of trade and by climate change, resulting in increased risk of entry of harmful organisms, increased opportunities for their establishment and spread, and increased vulnerability of agricultural and natural ecosystems and forests.

Apart from considerations related to protecting the EU against harmful organisms, the governance model of the current regime needs to be reconsidered. In the context of the EU's Better Regulation agenda, the possibilities for reduction of administrative burden need to be considered. A need for modernisation of the regime is furthermore being felt in terms of incentives and resources, in relation to public and private responsibilities ("who is responsible for what?").

Evaluation of the EU plant health regime

In order to reinforce and modernise the regime, the Council in 2008 requested an evaluation of the plant health regime. In 2009, the European Commission commissioned a comprehensive evaluation study to the Food Chain Evaluation Consortium (FCEC), led by Dr. Maria Christodoulou and Mr Conrad Caspari of Agra CEAS. Apart from an analysis of the existing regime, the evaluation also addressed options for the future. Consultation of stakeholders and Member States was at the heart of the process. Five third countries have also been consulted. Two conferences have been organised to discuss the review, in February and in September 2010. The evaluation report was made public in July 2010. The evaluation report and related documents are available on the website of the European Commission (http://ec.europa.eu/food/plant/strategy/index_en.htm).

According to the evaluation report, the CPHR has so far contributed significantly to prevent the introduction and control the spread of pests affecting plant health in the EU. Despite this positive conclusion overall, the objectives of the CPHR, as defined in the EU legal basis (Council Directive 2000/29/EC and legislation on emergency and control measures), are considered to be only partially met. A number of shortcomings and weaknesses have been identified, and these point to the need for improvements to the system. Over the period under review, and particularly in more recent years, plant health risks have increased while the EU has expanded. New and increased risks are due both to globalisation (including the expansion of trade) and climate change. These challenges call for a review of the current system.

In the course of the evaluation, options for the future have been developed and a preliminary analysis of these options was undertaken. As a result, key recommendations are made, based on a preliminary analysis of the balance between advantages/disadvantages and anticipated impacts. At the core of the recommendations is the need to modernise the system through: more focus on prevention; better risk targeting (prioritisation); and, more solidarity (moving from an MS based to EU approach for more joint action to tackle risks of EU significance). In this context, the evaluation report recommends to:

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- Include in the scope of the future EU plant health regime Invasive Alien Species (IAS) plants with wider/environmental impacts (on habitats and ecosystems) and/or economic impacts on a wider range of stakeholders (*Recommendation 1*);
- Explicitly include natural spread in the regime, and – where deemed necessary on a case by case basis – cover by the solidarity regime (*Recommendation 2*);
- Adopt a zero tolerance regime (i.e. including Regulated Non Quarantine Pests with zero tolerance), and further explore potential synergies with S&PM regime (*Recommendation 3*);
- Take complementary measures on imports, in particular: for emerging risks, e.g. on new trade in plants for planting/propagating material (PM): commodity pathway analysis; strengthen measures for plants for planting/PM via official post entry inspections for latent harmful organisms (HOs) and, on the basis of commodity pathway analysis, proceed to import bans where necessary (*Recommendation 4*);
- Introduce mandatory general epidemio-surveillance at EC level for priority HOs, after exploring further the process and criteria to be used for the identification and selection of HOs, and scope and method of surveillance; develop common principles and guidelines for harmonized surveillance/reporting; and, introduce co-financing to improve surveillance (*Recommendation 5*);
- Step up emergency action, via: horizon scanning; compulsory development of contingency plans according to a harmonized framework; and speeding up the process for adoption and adaptation of both emergency and control/eradication measures (*Recommendation 6*);
- Improve the Plant Passport (PP) system, in particular by revising the scope of application and harmonising the PP document (*Recommendation 7*);
- Tighten the system of Protected Zones (PZ), in the short term by improving the status quo, and longer term by further examining the implications of applying the IPPC Pest Free Area (PFA) concept (ISPM 4) more widely (*Recommendation 8*);
- Improve incentives throughout the system by extending the current scope of solidarity to: cover the loss of destroyed material for producers/growers; enable co-financing of new measures e.g. surveillance, contingency planning. Carry out further analysis on the possibility of introducing cost-responsibility sharing schemes, in line with the ongoing development of this concept in the animal health field. (*Recommendation 9*);
- Improve support activities in terms of R&D and scientific advice: promote more sufficient and stable EU and MS resources for funding and coordinating research (e.g. structural budget within the CPHR in addition to the FP7); continue EUPHRESKO; identify the appropriate structures to address the economic impact of Pest Risk Assessment (e.g. PRATIQUE follow up; SANCO/EFSA and EPPO cooperation) (*Recommendation 10*). Enhance diagnostic capacity by completing the establishment of National Reference Laboratories in MS and establishing EU-Reference Laboratories for a limited number of priority HOs (*Recommendation 11*). Continue and strengthen training activity for inspectors and extend the training to experts in the diagnostics field (*Recommendation 12*);

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- Improve organisational aspects: establish an EU/MS Emergency Team for Plant Health (within DG SANCO supported by an extended network of MS experts), as is practiced for animal health (*Recommendation 13*); developed and implement, both at EU and MS level, public awareness campaigns to improve awareness of plant health issues (*Recommendation 14*).

The evaluation of the CPHR performance to date, and in particular of the financial framework (solidarity regime) has extensively highlighted the mismatch between currently available resources and targeted objectives and this underpins many of the identified shortcomings and weaknesses. The analysis of options for the future has in all cases pointed to the need to increase resources and/or prioritise to meet the objectives set out in these options. The Commission will have to reflect on the best options to follow. The evaluation results have also confirmed the conclusions of the previous solidarity regime evaluation, according to which, a financial instrument is needed to ensure better preparedness in case of emergency. In this context, the evaluation report recommends to:

- Further examine the merits of developing a specific financial instrument in this sector, possibly in the form of a Plant Health Fund (drawing a parallel from the Animal Health Fund) (*Recommendation 15*).

Towards a new EU plant health law

The report of the evaluation of the CPHR was presented to and discussed with the stakeholders of the regime and the Member States in the conference "Towards a new EU plant health law" on 28 September 2010. The conference was part of the formal consultation of stakeholders and MS concerning the CPHR review and corresponding forthcoming impact assessment. The consultation concerned the Working Document for the conference (with a proposal on the issues to include in the forthcoming impact assessment) and the evaluation report itself, concerning which comments and opinions were welcomed.

In coordination with the Commission, the MS are further analysing and refining the options concerning the recommendations of FCEC on:

- Prioritisation; list of harmful organisms; RNQPs;
- Import regime and surveillance;
- Plant passporting and protected zones; and
- Emergency measures and solidarity.

Based on the evaluation report and the comments received from the stakeholders and the MS, a new EU plant health law will be developed in 2011. As part of the Commission's internal procedures, an impact assessment will be carried out for the major changes. A draft text for the new EU plant health law will be developed in parallel. Adoption by the Commission of a draft text for the new EU plant health law is scheduled in the Commission Work Programme³² for 2012. Once adopted by the Commission, the legal proposal by the Commission will be

³² Roadmap: http://ec.europa.eu/governance/impact/planned_ia/roadmaps_2010_en.htm#health, under EU Plant Health Strategy. The review of the EU plant health regime is listed in the Agenda Planning as 2013/SANCO/002 ("Common plant health strategy").

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sent to the Council and the European Parliament, which will discuss the proposal and adopt the new EU plant health law, as amended, under co-decision.

An Inter-Service Steering Group (ISSG) will be set up to provide guidance to the impact assessment. Meetings of the ISSG are foreseen for December 2010, April 2011 and September 2011. The following Directorates-General have been invited to participate:

- Secretariat General;
- Legal Service;
- DG Budget;
- DG Agriculture;
- DG Enterprise and Industry;
- DG Environment;
- DG Internal Market and Services;
- DG Research;
- DG Taxation and Customs Union;
- DG Trade.

Annex 2: Background information on issues to be addressed in this assignment

Focus on prevention

The evaluation report recommends horizon scanning for emerging risks, compulsory contingency planning, widening of the list of harmful organisms subjected to import controls, commodity pathway analysis, where necessary pre-export inspections or import bans, post-entry quarantine, introduction of mandatory EU-wide surveillance for priority pests and rapid emergency action.

Horizon scanning, contingency planning, widening of the list of harmful organisms subjected to import controls, commodity pathway analysis, import bans and rapid emergency action are already possible under the existing regime. The new elements which require impact analysis are the introduction of mandatory EU-wide surveillance for priority pests (co-financed by the EU) and post-entry quarantine. The introduction of mandatory surveillance potentially might have large impacts on MS and EU budget. Introduction of post-entry quarantine would impact, through the mandatory import fees or because of delayed entry of plant materials to the internal EU market, on the private operators.

The tasks related to prevention are Tasks 1 and 2 (see Chapter 3.4).

Focus on major risks

The evaluation report recommends better risk targeting and prioritisation (resources / objectives). The regime should move to a truly EU (rather than MS interest) approach for more joint action to tackle risks of EU significance. This is a matter of improved implementation, which does not require impact assessment. No tasks for the contractor are foreseen in this area.

Incentives

For a better functioning of the regime in relation to its objectives, the evaluation report recommends the introduction of EU co-financing for losses of producers/growers from destroyed material. The perverse incentive to hide outbreaks needs to be removed. The evaluation report also recommends to expand the EU co-financing for eradication actions of MS authorities to also include measures against natural spread³³ (on a case by case basis, depending on feasibility of such measures).

The tasks related to incentives are Tasks 3 and 4 (see Chapter 3.4).

³³ When developed in 1993, the CPHR targeted only movements of plants and plant products as sources of infestation. The future regime is supposed to also address control measures, both in agriculture and in relation to forestry, the landscape, amenity and street trees and public and private gardens. This requires inclusion of natural spread in the solidarity regime.

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Resources

The evaluation report highlights that virtually all current shortcomings and weaknesses of the regime can be attributed to a general lack of resources for plant health. In essence, the lack of resources is an awareness problem (lack of recognised justification of the regime's benefits. Since the CPHR is a prevention regime, its benefits can only be expressed in terms of monetised avoidable risks. The range of magnitude of these risks, which the CPHR serves to mitigate, can be estimated among others from cases where the CPHR so far successfully prevented entry and establishment and from cases of missed opportunities:

- Costs incurred by the EU or by third countries because of avoidable quarantine pests where measures to prevent entry and establishment failed;
- Costs incurred outside the EU for pests endemic in third countries which pose a threat to the EU;
- Financial impact calculations for the EU or third countries for specific quarantine pests.

The task for the contractor related to resources is Task 5 (see chapter 3.4).

Need for substantial upgrade of the plant passport and protected zone systems

At the regime's major review of 1993, when the internal EU market was introduced, a balance was struck between enabling the free movement of plants and plant products within the EU versus protection of pest free zones within the EU. The instruments introduced to enable this were the plant passport and the protected zone systems. Jointly, they define the balance between free movement of plants and plant products on the internal market, versus protection. Both instruments are interlinked: plants and plant products that are moved into protected zones require a special "protected zones plant passport" that should guarantee that the commodities are free from the pests against which the zone is protected.

The evaluation report clarifies that the plant passport system as well as the protected zones system require upgrading:

- For the plant passport system, the report recommends to revise the scope of application (lot or individual plant; source; species; stages in marketing to which plant passports should apply) and to harmonise the plant passport document;
- For the protected zones system, the report recommends to tighten the system by improving the status quo (improval of surveillance targets; involvement of stakeholders; harmonised eradication programmes; ending PZ status on time) and in longer term by further examining the implications of applying the IPPC Pest Free Area (PFA) concept more widely.

Revision of the plant passport and protected zones systems links in to the overlapping remit for plant health controls of the EU plant health regime and the EU seed & propagating material (S&PM) regime. In so far as plant passports are issued for propagating material under the CPHR, they in part duplicate the health certificates issued under the S&PM regime. The provisions for health certification under the S&PM regime are generally tighter than under the CPHR, but allow a more direct involvement of private operators. This follows from the objective of the S&PM regime in relation to plant health: regulatory protection against

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market failure from information asymmetry (ensuring healthy propagative material to protect growers from buying plant material with invisible infestations).

In comparison, the EU plant health regime serves public good (sustainability; protection of the environment, forests, landscape, gardens) along with private good objectives (competitiveness of plant production; healthy starting material; eradication, containment and control of agricultural pests).

Amendment to the scope of the two regimes thus requires consideration of the public/private responsibilities and cost/responsibility sharing: an issue that is important and sensitive to private operators and MS authorities.

The tasks in this domain cover the coherence of the CPHR and S&PM regimes (including the issue of public/private responsibilities and cost/responsibility sharing), improvements to the plant passport system and improvements to the protected zones system are Tasks 6, 7 and 8 (see Chapter 3.4).

Insufficient stable support for the regime from R&D and diagnostic infrastructures

The evaluation report points out that the necessary support for the EU plant health regime needs improvement. The recommendations made are to improve capacities, organisational structures (including setting up of EU reference laboratories) and resources. This will require additional EU resources, but not to the extent that this requires inclusion in the impact assessment. The current assignment therefore does not contain tasks related to R&D and diagnostic laboratories.

Need to align the scope of the regime with the revised International Plant Protection Convention as concerns Invasive Alien Species (IAS)

The International Plant Protection Convention³⁴ (IPPC) covers not only harmful pests and pathogens but also harmful plants (a subset of Invasive Alien Species in general). The current regime does not address such harmful plants. The evaluation report recommends that the future EU plant quarantine provisions, apart from pests and diseases, should include invasive plant species – as in the IPPC. The common ground is the quarantine logic.

The Directorate General for the Environment is currently investigating the possibilities for setting up a future EU legislative framework for IAS, either separate or complementary to the legislative frameworks on plant and animal health in DG SANCO. To this end, DG ENV has published several studies on the impacts of IAS.

In the context of the current assignment, the implementation costs should be estimated for the options in which certain IAS are included in the CPHR.

The task relating to IAS is Task 9 (see chapter 3.4).

³⁴ The EU and its MS are contracting parties to the revised IPPC (1997).

Annex 3: Contact details of the Chief Officers for Plant Health

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The voice of the European seed industry, representing the interests of those active in research, breeding, production and marketing of seeds of agricultural, horticultural and ornamental plant species.

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Annex 5: List of 20 important harmful organisms regulated by the Community Plant Health Regime

Organisms to be included in Task 1 are in bold.

1. <i>Anoplophora chinensis</i>	Citrus longhorned beetle
2. <i>Anoplophora glabripennis</i>	Asian longhorned beetle
3. <i>Bursaphelenchus xylophilus</i>	Pine wood nematode
4. <i>Clavibacter michiganensis</i> ssp. <i>sepedonicus</i>	Potato ring rot
5. <i>Diabrotica virgifera virgifera</i>	Western corn rootworm
6. <i>Dryocosmus kuriphilus</i>	Oriental chestnut gall wasp
7. <i>Erwinia amylovora</i>	Fire blight
8. <i>Gibberella circinata</i>	Pitch canker
9. <i>Globodera rostochiensis</i> and <i>G. pallida</i>	Potato cyst nematodes
10. <i>Guignardia citricarpa</i>	Citrus black spot
11. <i>Liriomyza</i> spp.	Leaf miners
12. Pepino Mosaic Virus	PepMV
13. <i>Phytophthora ramorum</i>	Sudden oak death
14. Potato Spindle Tuber Viroid	PSTVd
15. <i>Ralstonia solanacearum</i>	Potato brown rot
16. <i>Rhynchophorus ferrugineus</i>	Red palm weevil
17. <i>Synchytrium endobioticum</i>	Potato wart disease
18. <i>Thrips palmi</i>	Melon trips
19. <i>Tilletia indica</i>	Karnal bunt
20. <i>Xanthomonas axonopodis</i>	Citrus canker

Source: Council Directive 2000/29/EC, Control Directives, Provisional Emergency Measures (Commission Decisions) and EUROPHYT interception data

Annex 6: List of harmful organisms considered in 1991 as candidates for transfer from Directive 77/93/EEC to the certification schemes

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01.07.1992(72)

List of harmful organisms to be transferred from
Directive 77/93/EEC to certification schemes

From Annex (I.A.II subsections a) to d), the following organisms:

(a) Insects, mites and nematodes, at all stages of their development

Species

1. Agallenechoides boiseyi Christie
2. Ditylenchus destructor Thoenes
4. Ditylenchus dipsaci (Kühn) Filipjev

(b) Bacteria

Species

7. Corynebacter michiganensis ssp. michiganensis (Smith) Davis et al.
9. Erwinia chrysanthemi pv. dianthicola (Hellmers) Dickey
5. Pseudomonas caryophylli (Berkholder) Steci et Evckindler
8. Xanthomonas campestris pv. phaseoli (Smith) Dye
10. Xanthomonas campestris pv. vesicatoria (Doidge) Dye
11. Xanthomonas fragariae Kennedy et King
12. Xylephiala ampelina (Panasopoulos) Williams et al.

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(c) Fungi

Species

2. Colletotrichum acutatum Slenzenda
4. Didymella (Lodolgia) (Baker, Dimock et Davis) v. Arx
5. Phialophora dispersedens (Wollenweber) van Beyma
7. Phytophthora fragariae Nicolson var. fragariae
8. Plasmopara halstedii (Passow) Berl. et de Toni
9. Fusicladium rosariae Hennings

(d) Viroses and virus-like organisms.

Species

1. Arabis mosaic virus
3. Crysanthemum stunt viroid
5. Raspberry ringspot virus
11. Strawberry crinkle virus
12. Strawberry latent ringspot virus
13. Strawberry mild yellow edge virus
14. Tomato black ring virus
15. Tomato spotted wilt virus