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Evaluation of the Community Plant Health Regime

Terms of Reference

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1. Context of the assignment

1.1 Scope and evolution of the current Community plant health regime

The existing Community plant health regime (CPHR) aims to protect the 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 organisms[1] occurring elsewhere in the EU.

The plant health regime of the European Community (EC) is the product of decades of legislation. Initially, plant health was a national responsibility, secured through national control measures and border controls between Member States (MS). In 1969, two Council Directives[2] were adopted to harmonize the control measures for quarantine diseases of potato known to be established in several MS. In 1976, the Standing Committee for Plant Health (SCPH) was set up[3]. The basic structure of the current Community plant health regime was conceived in 1977 with Council Directive 77/93/EEC[4]. This Directive considered that systematic eradication of harmful organisms within 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 Community internal market in 1993, the concept of plant passports was introduced[5] 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.

Provisions for export to third countries have not been included in the CPHR, although the CPHR does specify the format of phytosanitary export certificates. The CPHR does not cover control measures with detailed eradication and management programmes in case of outbreaks, with the exception of some harmful organisms of potato. It includes invasive alien plant species in so far as they are directly harmful to plants and plant products. It does not cover organisms harmful to human or animal health.

It should be noted that food safety is not at stake in the CPHR, because plant pests and pathogens (harmful organisms) are generally not infectious to humans or animals and only

[1] 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.
[2] Council Directives 69/464/EEC and 69/465/EEC.
[3] Decision 76/894/EEC.
[4] Currently known as Council Directive 2000/29/EC.
[5] Council Directive 91/683/EEC.

exceptionally produce metabolites that are toxic to humans and animals[6]. Human health may be impacted indirectly, through increased pesticide application for controlling pests and diseases entering the Community in case of absence of quarantine legislation or failure of quarantine measure implementation. Possible consequences of pesticides to human health are as such covered in the plant protection (pesticides) regime and are not a part of this evaluation. Notwithstanding this, the CPHR and the Community plant protection regime share the objective to promote healthy and productive crops and to minimise environmental harm in achieving this objective.

Since its inception, various major changes and developments have taken place in relation to the CPHR which justify a comprehensive evaluation of the regime (Annex I). The main developments have been (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.

The Member States support the need for carrying out such an evaluation (Annex II). An internal working document providing a reconstruction of the CPHR at the time of its inception and the major modifications in the course of time is provided (Annex III).

1.2 Description of the policy area to be evaluated

The CPHR consists of the following main elements:

- *Preventive plant health measures on imports (plants and plant products)*
  Detailed legislation in the plant health field lays down conditions that Member States must apply to the imports of live plants and plant products from third countries. The provisions in part pertain to harmful organisms which are not allowed to enter the territory of the European Union, either in general or when linked to specific commodities. Other provisions specify plants and plant products of which import from third countries into the EU is prohibited, as well as specific import requirements for commodities (e.g. official guarantees that the material originates from a country, region, field or place of production that is free from the harmful organism involved, or official guarantees for appropriate treatment of commodities to kill any such harmful organisms[7]). In line with the WTO-SPS agreement, requirements for intra-Community trade equal the provisions for import from third countries, except when differences in provisions are technically justified.
  Regulated plants and plant products to be introduced into the EU must, as a general rule, be accompanied by an official plant health certificate as laid down in the EU legislation. The certificate must be signed officially. On arrival in the EU, consignments are to be placed under supervision of the responsible official bodies. The accompanying certificates must be officially verified and checked, either at an approved Point of Entry or after official transit to an inspection location within the territory of the Member State. Customs authorities shall not allow the importation of consignments of plants and plant

[6] For example mycotoxins; however, none of the fungi that produce them has been considered for quarantine listing since they are common worldwide.
[7] Example: coniferous wood and wood packaging material from third countries must be debarked and have undergone a heat treatment.

products, unless proof has been supplied that the relevant phytosanitary checks have been carried out with satisfactory results. Documentary checks must always be carried out at the border, while identity checks and physical checks for the presence of harmful organisms may be carried out at the final destination, but before customs clearing. For intra-Community movements between the point of entry and the final destination where the import inspections are carried out, the CPHR requires the use of an official plant health document that was developed for this purpose. A possibility of reduced frequency of checks is permitted under certain conditions. In case of risk of spread of harmful organisms, compulsory import inspection checks can be imposed on the relevant plants, plant products or other objects.

In case of derogation requests from existing import requirements or prohibitions, the Commission services evaluate whether the plant health situation, the official services, the legal provisions, the control systems and production standards of third countries involved meet the EU requirements. An on-the-spot inspection by the Commission services (Food and Veterinary Office – FVO) is often required before the derogation can be considered. A specific system has been established for the introduction or movement of harmful organisms, plants or plant products listed in the Annexes of Council Directive 2000/29/EC for trial or scientific purposes and for work on varietal selections (Directive 2008/61/EC).

- *Preventive plant health measures on intra-Community trade of seeds and plants for planting*

  The phytosanitary conditions for movements between the Member States for live plants and plant products are harmonised. Some seeds and plants for planting, and a limited number of end products for consumer use, must travel with a plant passport issued by growers authorised to do so. The plant passport specifies that the material originates from a registered and officially inspected place of production. Further non-discriminatory checks on plants and plant products may be carried out *en route* or at the final destination. These checks can be targeted where there is earlier evidence of non-compliance. Authorisation of growers is based on regular inspection of their premises for the presence of harmful organisms by or on behalf of the NPPO. No plant health certificate is issued.

- *Monitoring, eradication, containment and control of harmful organisms of plants and plant products and protected zones*

  Programmes for the monitoring and surveillance of harmful organisms not known to occur in the EU may be set up to ensure that the EU territory remains free of these harmful organisms. In case of EU emergency measures, legal provisions exist that require to carry out annual surveys. It is obligatory for Member States to notify findings of organisms listed in the Annexes of Council Directive 2000/29/EC as well as findings of non-listed harmful organisms that are found for the first time in the territory of a Member State. Provisions are in place for eradication of listed harmful organisms or, where not possible, to contain them; emergency measures may be in place for new harmful organisms that are not listed as yet in the Annexes of Council Directive 2000/29/EC.

  In the case of findings of new harmful organisms that are not listed in the Annexes of the basic Directive, Member States should carry out a pest risk assessment. Findings of new organisms which appear to be injurious require official measures to eliminate / eradicate the harmful organism, and both the finding itself and the measures taken should be notified by the Member State. The Commission shall discuss the national

emergency measures with the Member States in the SCPH, and a decision shall be taken concerning harmonised EU measures. The national measures have then to be rescinded or amended. EU emergency measures remain in place until they are rescinded (harmful organism eradicated or no longer controllable) or until the harmful organism is included in the Annexes of the basic Directive. New organisms which are not considered as being injurious do not require official measures, and the Commission does not expect such findings to be notified to the Commission and the Member States either.

In case eradication of a regulated harmful organism is not possible, the Member State shall take all necessary measures to contain it. Some Council Control Directives (for a number of soil-borne potato diseases[8]) are linked to the basic Council Directive 2000/29/EC since they regulate detailed control of harmful organisms of a crop (potato). The scope of Council Directive 2000/29/EC is confined to movements only and does not explicitly cover the eradication of naturally spreading harmful organisms[9].

For certain harmful organisms, protected zones are recognised within the EU in which these specific organisms do not occur. Seed and plants for planting of host plants coming from outside into these zones must fulfil the additional phytosanitary requirements (including the "ZP" plant passport for intra-Community movement). The protected zone status is lost in case eradication of outbreaks over two years proves unsuccessful. A two-year timeframe is required to declare a zone free of a specific harmful organism.

- *Export, transit and re-export*

  No Community plant health legislation exists concerning export. Third countries have requirements in place for imports from the EU into their territory[10], with lists of quarantine pests different from those of the Community. Member State authorities are required to provide guarantees to these third countries that consignments are free from the quarantine pests regulated by them and that the necessary requirements have been complied with. To this end, export inspections are in place, partly based on import inspections and plant passport inspections carried out earlier in the chain. Exporting companies are responsible for meeting the requirements of third countries, while Member State authorities are responsible for the reliability of the guarantees they provide to third country governments.

  Phytosanitary transit is governed by Council Directive 2000/29/EC, in line with the IPPC (ISPM No. 7 and No. 12) which provides that governments safeguard the phytosanitary integrity of consignments under transit through their territory. As a consequence of the free movement of consignments on the internal market, such safeguard provisions in practice need to also cover the transit through the territory of other Member States, until consignments leave the EU territory. For this reason, the Roosendaal Group in 2007 developed a voluntary intra-Community phytosanitary communication document for transit. Community legislation and implementation of ISPM No. 25 "Consignments in transit" has been advocated by some Member States.

[8] Council Directive 69/464/EEC, Council Directive 93/85/EEC, Council Directive 98/57/EC, Council Directive 2007/33/EC.

[9] A strict line is followed for Community financial support to MS expenditures to eradicate and contain harmful organisms. Financial support is not given for eradication of findings that probably resulted from natural spread; for example, eradication of the first findings of *Diabrotica virgifera* in specific Member States were not compensated by the Commission because the harmful organism already occurred in a neighbouring Member State.

[10] The Commission (SANCO) may be assisted in negotiating and managing SPS agreements with third countries by the Member States through the Roosendaal Group(s). These groups are kept informed, where relevant, of developments in the negotiations on export problems held in the framework of the WTO-SPS preparatory Committee and Market Access Advisory Committee. Market access and export issues are handled in the context of such agreements. In case no such agreement exists the market access and export issues are dealt with in the so-called market access working groups managed by DG TRADE. Furthermore market access and export issues are dealt with in the SPS Committee meetings.

Breeding, production, distribution and marketing of plants are often a very international business with incoming and outgoing flows of plant materials. An official movement document is not required in case of transit from a third country through Member States to another third country as long as the plant materials are not imported (i.e., Customs cleared for entry to the internal market) and in absence of phytosanitary risks linked to the transport. In the case of re-export, plant materials from third countries are imported by a Member State and re-exported either from that Member State or from another Member State.

- *Research and development*
  DG RTD supports the coordination of the commissioning of national plant health research budget of Member States, through the ERA-net EUPHRESCO and there are good chances for such an initiative to be strengthened and enlarged after 2010. National research budgets on plant health amount to roughly 90% of all such budgets available in the EU. The Community supports research on plant health through the successive multiannual Framework Programmes (FP). In the 7th FP (2007-2013) currently in force, plant health research in support to policies has been specifically mentioned and currently, at least one research project (of maximally 3 million euro) is financed annually. Research needs are identified by the Research Directorate General, taking into account the suggestions made by SANCO and others, including the Chief Plant Health Officers and EUPHRESCO, in a large consultation process. Funds for plant health complement research on e.g. pesticide use prevention, global warming, and other plant related issues.

- *Scientific advise*
  In its work, the Commission is assisted by EFSA, which since 2006 includes a scientific panel on Plant Health. The role of the panel is to deliver scientific opinions on the risks posed by harmful organisms. Similar advise can be provided from outside the Community institutions by the European and Mediterranean Plant Protection Organisation (EPPO) and by national bodies; Community risk assessments are covered by the Plant Health Panel of EFSA. External scientific advise may be also requested for the assessment of impacts of policy options under consideration for addressing the risks.

- *Diagnostic laboratories*
  Binding protocols for diagnostic methods do not exist, with the exception of some harmful organisms of potato for which Control Directives are in place which provide detailed requirements for detection and diagnosis. No network of Community and National Reference Laboratories exists in the plant health domain such as in the animal health and food safety domain, where legal obligations for such laboratories are in place. As for the advisory function of reference laboratories, the Commission draws upon the expertise of individual scientists and NPPO staff of Member States. For a range of organisms, EPPO and IPPC have issued standards for diagnostic methods and procedures.

- *EU financial instruments and contribution*
  Unlike in the animal health domain, no Community Plant Health Fund exists. Costs for growers whose plant material is destroyed are not compensated. Costs from public funds to implement eradication and containment measures may be supported financially by the Community on the basis of Articles 22 and 23 of Council Directive 2000/29/EC. Financial support may also be given for the border control infrastructure on the basis of

Article 13.c.5 of the same Directive. Characteristic for the current Community financial instrumentation of the regime is (i) its restriction to costs incurred by governments but not financial losses of growers (although a possibility to cover such costs has been inserted in the Directive but the legal framework to use it (implementing Regulation) has not been developed); (ii) its restriction to eradication and containment costs related to spreading of harmful organisms caused by movements of plants and plant products (but excluding natural spread); (iii) the relatively moderate annual budget that was spent in the past (except for Pine Wood Nematode)[11]. For a description of the financial instruments in use in MS (governmental compensations to growers, public and private insurance systems, etc.) see the report of the evaluation of the Financial Aspects of the CPHR (final report dated March 2008).

The Commission plays a key role in the management of plant health problems in the Community. It may adopt *ad hoc* additional protective measures (interim measures) and emergency measures. Updated information on the evolution of the plant health situation is exchanged in the Standing Committee on Plant Health (SCPH). The Commission is responsible for proposing legislation, for adopting appropriate implementation rules and for supervision (FVO) that these rules are correctly implemented by the Member States[12]. Before adoption, the implementing rules are discussed with and voted by the Member States' experts in the SCPH. All regulatory processes include the voting by Member States with qualified majority. In practice, most texts are voted with (quasi) unanimity.

A limited part of the CPHR has been brought under the scope of Regulation 882/2004/EC. This pertains to submission of multi-annual control plans and to inspection missions to Member States by the Food and Veterinary Office.

The CPHR touches upon many EU policies, e.g.:

- The environment policy (including policy on invasive alien species and on protection of EU forests and green areas from harmful impacts);
- The pesticides policy;
- The human health policy;
- The animal health policy;
- The seed and propagating material policy;
- The common agriculture policy;
- The enterprise and industry policy;
- The competition policy (i.e., Member States aid rules);
- The external relation, trade, enlargement and external aid policy (i.e., plant health conditions for import, pre-accession strategy and accession to developing countries);
- The customs policy (i.e., ensuring that customs requirements are fulfilled);
- The anti-fraud policy (i.e., illegal imports or trade);
- The research policy (i.e., development of plant health diagnostics methods, development of plant health economy and plant health risk assessment science, development of plant disease science).

The CPHR is strongly linked to the EU's obligations under the WTO Sanitary and Phytosanitary (SPS) Agreement adopted in 1994 (see also Chapter 1, paragraph 1.2). For

[11] In view of budget restrictions, the financial Community support in some years resulted in reimbursement of ± 10% of costs, rather than the expected 50%.

[12] The Commission's Food and Veterinary Office plays and important role in this regard.

plant health, the SPS Agreement refers to the standards, guidelines and recommendations developed under the auspices of the International Plant Protection Convention (IPPC), which lays down requirements to Contracting Parties and their subordinate National Plant Protection Organisations. The IPPC has developed a large framework of so-called International Standards for Phytosanitary Measures (ISPMs). These are not legally binding, but Contracting Parties should base their phytosanitary policy upon them. All Member States are IPPC Contracting Parties. The Community acceded in 2004 to the IPPC. All Member States are also Member of the European and Mediterranean Plant Protection Organisation (EPPO), which has developed a large set of standards for phytosanitary measures (see the website of EPPO). The Commission attends some EPPO panels as well as the Phytosanitary Working Party as observer.

The CPHR links to the Convention on Biological Diversity (CBD) only through the IPPC, especially as concerns invasive alien species, which are covered by both the CBD and IPPC but currently only partly by the CPHR. On 3 December 2008, the Commission adopted a Communication on invasive alien species ("Towards an EU Strategy on Invasive Species")[13].

1.3 Objectives of the Community plant health regime

Global objectives[14]

The global objective of the CPHR is to protect the EU against the harm[15] caused by the introduction and spread of harmful organisms[16].

Issues of concern to society are the following:

- *Contribution to plant health protection through sustainable production*
  Citizens value an unspoilt and healthy environment. Entry and establishment of harmful organisms often results in increases of pesticide use and could thus impact negatively on the environment. 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.
- *Ensuring competitiveness of the agriculture complex, employment, and safeguarding rural development*
  EU citizens would expect their governments to stimulate and facilitate the agriculture system as a whole (growers, farmers and the associated supply and marketing chains), as this is a major employer and source of economic benefits for society. They would presumably be in favour of plant health measures, in so far as these would protect

[13] See http://ec.europa.eu/environment/nature/invasivealien/index_en.htm.

[14] The official term "global objectives" refers to the fundamental needs of society that are addressed by a legislative regime.

[15] The aim of the regime is often expressed as "safeguarding plant health". However, plant health by itself is usually not seen by citizens as an intrinsic value on its own (a public good), other than in the case of human health and animal health. While society considers that animal diseases need to be controlled because animals have a value of their own and, like human beings, should be treated with respect and should be ensured of welfare and health, no such notion exists for plants. Citizens tend to assume that growers should cope with diseases as part of good cultivation practice and entrepreneurship. Poor plant health will merely result in lower value of plant products. As for agriculture and horticulture, plant health measures should thus be evaluated in an economic perspective. For gardens, public green, forests and natural habitats, citizens' perceptions of plant health have changed significantly over the past decade, as a result of several serious pest outbreaks, so that plant health in forests and natural habitats is nowadays considered a public good. Especially tree diseases are the cause of public concern.

[16] The definition of harmful organisms in the CPHR is confined to plant, animal or pathogenic agents injurious to plants or plant products and thus includes invasive alien species, at least in so far as they are directly injurious to plants and plant products. Possible widening of the scope to invasive alien species that are indirectly injurious, through competition for food and niches, is addressed in the evaluation questions.

economic growth, employment and rural economies against harm inflicted by harmful organisms, unless the cost-benefit balance for society at large is negative or when measures are perceived as unfair to individual growers or private persons[17].

- *Ensuring food security*[18]
  EU citizens nowadays are again concerned about the availability of food supplies, in part as a consequence of the high food prices of 2007.
- *Protection of public and private green, forests, landscape (safeguarding the natural environment)*
  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 street trees, public and private green, recreational forests and to disruption and loss of natural ecosystems and habitats.
  It has recently become clear that in the context of energy policy and adaptation to climate change, increasing demands will be put on EU forests as a source of raw material, which means that it will become more important to protect forests against harmful impacts, including those of harmful organisms, whose spread moreover may be facilitated by global warming.

The CPHR aims at supporting environmental, social and economic sustainability. While the aims of ecology and economy can sometimes be combined, in many cases tension exists between these basic aims. Some citizens would be in favour of preventive measures aimed at long-term protection of the environment, while others would be against such measures because of the short-term costs and impacts. The policy domain of plant health moderates this dilemma. The functioning of the plant health regime within this context should be evaluated.

Specific objectives[19]

The specific aims of the CPHR in its current shape are as follows:

- To protect agriculture, horticulture, forests, public and private green and natural ecosystems (including aquatic ecosystems) against the harm following from 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;
- To ensure the availability and use of healthy plant material at the beginning of the chain of plant production, by preventing the spread of harmful organisms occurring in the EU with plants-for-planting and in particular propagating material;
- To control harmful organisms of still limited distribution which are so harmful that strict control on further spread is needed;
- To secure safe trade.

[17] Indeed, the WTO-SPS Agreement as well as ISPM No. 2 (Import regulations. Guidelines for pest risk analysis) and No. 11 (Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms) require that socio-economic impacts of phytosanitary measures must be taken into account in pest risk management additional to environmental impacts, and that costs and benefits must be assessed.

[18] Food safety is not at stake in the CPHR, because plant pests and pathogens (harmful organisms) are not infectious to humans or animals and only exceptionally produce metabolites toxic to humans and animals. Human health may be impacted indirectly, through pesticide application. The consequences of pesticides to human health are covered in the pesticides regime and are not a part of this evaluation.

[19] The official term "specific objectives" refers to specific aims of a legislative regime, at a lower level of abstraction that global objectives and relating to desired impacts rather than the underlying needs.

Operational objectives[20]

Using the considerations provided in the texts of the relevant Council Directives as a starting point, the operational objectives of the CPHR add up to the following:

- To protect against the introduction in the Community of organisms harmful to plants or plant products and against their spread within the Community (the basic Directive);
- To determine the distribution of potato wart disease (*Synchytrium endobioticum*), potato ring rot (*Clavibacter michiganensis* ssp. *sepedonicus*), potato brown rot (*Ralstonia solanacearum*), and potato cyst nematodes (*Globodera pallida* and *Globodera rostochiensis*), prevent their occurrence and if found, prevent their spread and eradicate or control them (a limited number of specific Control Directives);
- To provide a legal implementation framework.

Implementation

The operational objectives are implemented by the following Commission / Member States activities and interventions:

- Conducting risk assessments (EFSA / EPPO / MS) and risk management system appraisals (e.g. FVO missions to third countries), so as to verify whether specific organisms should be regulated and whether specific imports should be prohibited or can be allowed (COM / MS);
- Executing impact assessments for policy options (COM / MS);
- Developing plant health legislation to mitigate the risk of new harmful organisms and to eradicate, contain or control them (COM / MS);
- Performing import controls for compliance by importing companies with the legislation and presence of the necessary phytosanitary certificates[21] (MS);
- Inspection of growers producing seeds and plants for planting and supervision of companies allowed to issue plant passports for intra-Community trade (MS);
- Monitoring / surveying the territory of the EU for the absence of regulated harmful organisms (pest status determination) (MS);
- Containment and control of harmful organisms that cannot be eradicated (MS);
- Co-financing of eradication, containment and control activities (COM / MS);
- Enforcing compliance with the legislation, at industry (MS) and Member State level (COM);
- Issuance of appropriate derogations (COM / MS);
- Ensuring safe research on, movement of and use of regulated harmful organisms and regulated plants and plant products for which derogations are issued (MS);
- Resolution of trade barrier issues related to plant health (COM / MS);
- Communication with stakeholders and cizitens (COM / MS).

These interventions are supported at Member State level by national infrastructural actions such as:

- Development of quality assurance systems for plant health inspections (MS);
- Training of plant health inspectors (MS / COM[22]);

[20] The official term "operational objectives" refers to the concrete operational (practical) aims of a legislative regime, at a lower level of abstraction that global and specific objectives. Those given here were derived from the recitals of the basic Directives.
[21] Member States also perform export controls and issue phytosanitary export certificates, but this is outside the scope of the current plant health regime.
[22] At EC level: Better Training for Safer Food programme.

- Development of diagnostic protocols and quality assurance systems for plant health diagnostic laboratories (MS);
- Training of diagnosticians (MS);
- Support to plant health research on the biology and economy of harmful organisms, risk assessment and risk management (MS / COM);
- Support to the development, ring testing and implementation of rapid and reliable diagnostic methods (MS / COM);
- Support to the amelioration of the border control infrastructure (COM);
- Technical assistance (MS).

1.4 Scope of harmful organisms addressed under the objectives of the Community plant health regime

The scope of the CPHR includes in principle *all organisms that are harmful to plants or plant products*: not only classical pests such as viruses and virus-like organisms, bacteria, fungi, nematodes, mites, and insects, but also invasive alien plants that are harmful to plants and plant products. Approximately 250 harmful organisms have been listed as such in the Annexes of Council Directive 2000/29/EC; the other ones are covered in general terms in so far as their injury to plants be proven by pest risks analysis. Additionally, harmful organisms may be temporarily regulated under emergency measures. In so far as the CPHR requires that measures be taken against harmful organisms, such measures are imposed regardless of the number of findings (i.e., also for a single finding). The zero tolerance character of the CPHR characterises it as a *quarantine regime*. In the public domain, listed harmful organisms are often indicated as quarantine organisms. The term "Quarantine pest" is officially defined by the IPPC as "*a pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled*".

Questions arise on the coverage by the CPHR of:

a) harmful organisms of economic importance that are widely distributed in the EU and not under official control;
b) harmful organisms of economic importance that are present but not widely distributed in the EU;
c) so-called regulated non-quarantine pests (RNQPs) applicable to planting material where levels of tolerable pest presence may be set in legislation[23];
d) harmful organisms of limited economic importance which can be controlled under good plant protection practice with for instance crop rotation and pesticides (hundreds of thousands of these exist and it will not be feasible to regulate all[24]);
e) harmful organisms that are not directly injurious to plants and plant products, but are able to cause ecological damage through competition for niches or food.

It should be noted that the majority of pests and pathogens of economic importance (for instance *Botrytis cinerea*, *Myzus persicae*) is not regulated in any way. These harmful organisms are not being regulated because they occur Community-wide (sometimes world-

[23] The CPHR does not recognise RNQPs. The IPPC defines a RNQP as "*a non-quarantine pest whose presence in plants for planting affects the intended use of those plants with an economically unacceptable impact and which is therefore regulated within the territory of the importing contracting party*". Tolerances for RNQPs could be zero when technically justified.

[24] Member States are obliged to notify findings of non-listed harmful organisms found for the first time on their territory and take measures against these. In practice, a pragmatic approach is followed and non-listed harmful organisms are included in the CPHR only when pest risk assessment indicates that they are particularly injurious.

wide) or because a policy of prevention of the introduction and establishment is no longer adequate.

The questions on the coverage of harmful organisms by the CPHR are particularly evident in relation to the Community regime for Seed and Propagating Material, which overlaps with the CPHR as concerns plant health requirements and includes zero tolerance provisions for some harmful organisms (partly the same as in the CPHR, partly additional ones) as well as tolerance threshold levels for others[25]. At the introduction of the single market, this overlap with the quality standards for marketing of seed and propagating material was created because of the introduction of the plant passport. The objective was to avoid production inspection by two different authorities, those for plant health and those responsible for plant quality[26]. The evaluation of the Community regime for Seed and Propagating Material has shown that duplication exists between both regimes which should be considered in the CPHR evaluation.

In addition, the categorisation of harmful organisms in the Annexes of Council Directive 2000/29/EC is complex and possibly needs to be evaluated on the intervention logic and for proper prioritisation. The Council has stressed the importance of the evaluation of priority setting and of categorising phytosanitary risks. A summary of the current criteria for categorising harmful organisms as developed at the introduction of the single market (1993) is given in Annex IV.

The evaluation of the CPHR will need to address the scope and intervention logic of the regime vis-à-vis the criteria and categorisation of harmful organisms to be covered.

1.5 Legal basis, budget and duration

The Community plant health acquis is based on Article 37 of the Treaty establishing the European Community, and as such it makes part of Title II: Agriculture. It is also based on the IPPC, to which the European Community is a contracting party, and the WTO-SPS agreement.

Council Directive 2000/29/EC, Article 23 provides for expenditures for covering costs of Member States' Competent authorities incurred by imposing measures (however, so far not used for reimbursement of growers for losses of destroyed plant materials[27]); for amelioration of the border infrastructure, and for costs of training activities. According to Article 22, the Commission may in exceptional cases reimburse Member States to a higher level of costs. In the past years this has been the case for large-scale eradication and containment actions in Portugal against pinewood nematode. In total 8.4 million euro has been allocated for this purpose. Relevant budget lines (in part shared with animal health):

- 17 04 04 01 (Eradication of harmful organisms and amelioration of the border infrastructure): €1.0 million in 2009.
  As for plant health, over the past decade a total sum of €10.4 million was spent under this budget line to eradicate and contain pine wood nematode in Portugal.

[25] The Marketing Schemes generally require that plant material is "substantially free" from harmful organisms impairing the quality, with the exception of some harmful organisms for which zero tolerance is required. For specific pests of potato and vine, threshold levels have been defined.

[26] European Commission (1991), The regulatory bases for a plant health strategy to 1992, 1044/VI/91-EN.

[27] The eligibility criteria for the solidarity regime are not fully clear.

- 17 04 04 01 (Programmes of training events in the area of plant health): €1.0 million in 2009.
  Expenditures on animal and plant health.

The policy area is not subject to limitations in time.

1.6 Instruments

The phytosanitary acquis is summarised in Annex V. A list with the full acquis is available to the contractor from Commission services on request.

2. Description of the assignment

2.1 Purpose and objective of the evaluation

The first objective of the evaluation is to analyse, in an independent way, the results of the existing CPHR as compared to the acknowledged objectives that were set out by the Community when it was introduced. This ex-post part of the evaluation will ensure transparency and accountability in reporting results of the regime activities and impacts to European citizens.

The second objective of the evaluation is to clarify which aspects of the current regime need to be improved and to suggest potential options for amendment, including possible improvements to its structure and working practices. This aspect (interim evaluation) will have a strong focus on options and recommendations for the design of the future policy and the development by Commission services of a Community plant health strategy[28].

2.2 Evaluation issues to be addressed

The main focus of the evaluation questions is on the intervention logic, coherence, utility, and effectiveness of the CPHR. Furthermore, the question of a possible existence of a "dead weight" effect should be analysed (What if no Community financing is in place?).

Concerning the financial aspects of the CPHR, the contractors should build on the outcome of the recent evaluation of this specific domain.

Apart from answering the evaluation questions, the contractor should develop a *reference model* for describing the current Community plant health regime including:

- Legal basis
- Objectives (including scope and positioning concerning related regimes)
- Responsibilities attribution (including aspects of subsidiarity and Community added value)
- Intervention logic
- Instrumentation of the policy and how instruments are integrated (including monitoring systems and reporting structure)
- Infrastructure (including official laboratories and science and methodological innovation (R&D))
- Management procedures and comitology
- Administrative burden to stakeholders
- Budget
- Community financing?

In support of the design of the future policy and the development by Commission services of a Community plant health strategy, the evaluator is required to present different *options*, including the "status quo" option and analyse their relevance and impact, and make recommendations on these options. For all recommendations, a judgment should be provided

[28] Including a strategy for engagement at the international level as well as for communication with actors (citizens and professionals).

concerning the choice for a certain recommendation in comparison with other options that were perhaps rejected or given a lower priority. This should be based on the:

- Relevance to the CPHR objectives and the problems identified;
- Costs / benefits analysis of different options;
- Coherence with wider economic, social and environmental objectives;
- Interaction with other existing and planned Community interventions;
- Pros and cons of the option;
- Support by stakeholders, Member State policy authorities and National Plant Protection Organisations of Member States.

Several evaluation questions and other aspects of the study require quantification of costs, benefits and impacts. In these cases, the contractor is to identify and assess the costs and benefits, and the impacts of policy options and measure these wherever possible. Where quantitative data are not available and cannot be reasonably generated as part of the study, the contractor is to focus efforts on the most likely costs, benefits and impacts, in the context of a proportionate approach, and use estimates based on credible hypotheses.

Throughout the study, account should be taken of the relevant FVO reports.

2.3 Scope of the evaluation

The evaluation study will concern the entire Community plant health acquis, its implementation in the Community and the infrastructural and budgetary support for the acquis. The evaluation will address phytosanitary obligations under the WTO-SPS Agreement, the IPPC, and the obligations for the EU linked to the Convention on Biodiversity (CBD) such as invasive alien plant species. It will not pertain to the CBD and environmental policy as such. The evaluation will address the relationship to related Community regimes, as indicated in this ToR.

The reference period for the evaluation will be 1993-2008, i.e., from the start of the internal market.

2.4 Evaluation questions

A. Objectives and scope of the CPHR

1. *In how far are the **objectives of the CPHR** as specified in paragraph 1.3 still met and are they still appropriate?*

2. *Is it desirable to include in the CPHR the **control of natural spread** (not only movement) of harmful organisms, in the light of the necessary efficacy of the regime?*
   Clarify to what extent the intervention logic of the CPHR is also suited for control (eradication and containment) of harmful organisms in public green[29], forests and natural habitats[30], like for agriculture and horticulture.

[29] Government-owned or owned by citizens and other legal persons who are not professionally involved in production or trade.
[30] Including Natura 2000 sites.

3. *To what extent would it be desirable / feasible to include **invasive alien species** which are not directly injurious to plants or plant products*[31] *in the scope of the CPHR?*

4. *Does the CPHR put appropriate emphasis on **prevention** in general and what type of additional provisions on prevention might be useful?*

B. Surveillance and categorisation of harmful organisms

5. *In how far does the **classification of harmful organisms** in Directive 2000/29/EC reflect the different objectives of the regime and the priorities as concerns phytosanitary risks, and in how far isreliable information available for appropriate risk assessment / risk management (including data on pest status and scientific data for impact and cost/benefit analysis)?*
   Please also clarify:
   (i) The views on appropriate positioning of Regulated Non-Quarantine Pests (RNQPs)
   (ii) To what extent it is possible for the inspection services of the Member States to effectively deal with 250 listed harmful organisms (often rare non-European organisms) and on which harmful organisms they are currently focussing

6. *What provisions exist in Member States for general **surveillance**[32] for the presence of listed organisms, non-listed organisms, and organisms for which emergency measures are in place, in relation to pest status, and how are they implemented?*
   Elements for study:
   (i) Implementation of Community provisions for surveillance / monitoring in relation to Protected Zones and Community emergency measures
   (ii) Existence of surveillance / monitoring programmes for harmful organisms other than under (i) and the need to introduce Community provisions to carry out such programmes
   (iii) Timely reporting on survey results in relation to protected zones and Community emergency measures
   (iv) Implementation of provisions for immediate notification of outbreaks and findings of new organisms on the territory of Member States
   (v) Availability of effective early warning / rapid alert systems and the need to involve persons / organisations not belonging to the Competent Authority in such systems

C. Import

7. *How is the implementation of the current **import regime** by Member States, how is its effectiveness and what are the critical success factors of the regime?*
   Elements for study[33]:

[31] The International Plant Protection Convention also considers the harm caused by invasive alien plant species to plant ecosystems. This aspect is currently not covered in the CPHR.
[32] Surveilance may include monitoring for harmful organisms in general, as well as surveys for specific harmful organisms or on specific crops / commodities.
[33] See also: *Council conclusions*, 2917th meeting of the Council Agriculture and Fisheries, 18-19 December 2008, 16916/08: Safety of imported agricultural and agri-food products and compliance with Community rules.

(i) Notifications of interception[34]
(ii) Efficacy of the system in dealing with non-compliance
(iii) Cooperation with Customs and consistency and connectedness of nomenclature and IT systems (see also Question 18)
(iv) Functioning of the reduced frequency checks system for imports of end products[35]
(v) Functioning of the system for derogating from existing import requirements / prohibitions, including derogations for scientific and breeding materials
(vi) Use + usefulness of the additional declaration on the phytosanitary certificate and of Annex VI (*Plants / plant products to which special arrangements may be applied*)
(vii) Functioning of possibility for identity and plant health checks and release at place of final destination instead of point of entry (see also Question 8 for Customs transit aspect)
(viii) Fulfilment of minimum requirements at Points of Entry
(ix) Need to further develop electronic certification
(x) Need for measures addressing passenger transport
(xi) Need to enforce capacity building in third countries
(xii) Effectiveness of emergency measures

D. Intra-Community movement

8. *How is the implementation of the **intra-Community movement regime** by Member States, how is its effectiveness and usefulness and what are its critical success factors?*
   Please address:
   (i) The functioning of the plant passporting system in general
   (ii) The following specific points: the need for harmonisation of the plant passport (reliability, legibility); the functioning of the producer registration system; the functioning of the authorisation system for registered nurseries to issue plant passports under NPPO supervision; the usefulness for traceability; the implementation of provisions for (a) small producers for the local market and (b) professional use versus final consumption use; the official plant health movement document (linked to inspection at final destination and re-export; Directive 2004/103/EC); and the intra-Community phytosanitary communication document for transit.

E. Protected zones and regionalisation

9. *How is the implementation of the **Protected Zones (PZ) regime** by Member States, how is its effectiveness and usefulness and what are its critical success factors?*
   Elements for study:
   (i) Evolution and effectiveness of the PZ in the Community in the reference period
   (ii) Need for alternative forms of regionalisation such as demarcated infested zones

[34] Take into account the frequency distribution of notifications of interception of the different harmful organisms over the reference period; the number and nature of harmful organisms that entered the EU and became established; the rate and speed of notification of interceptions by the Member States; and the use of notifications by the Member States for better preparedness to risk.

[35] An analysis should be provided of the total numbers of interceptions of harmful organisms (and which) made on imported end products since the regime was introduced in 2005 and what conclusion this allows on the safety of the system; the extent to which Member States have applied the reduced checks system; and the extent to which the introduction of the reduced checks system has met the needs of the stakeholders.

for emergency measures
(iii) Functioning of protected zone plant passports

F. Control measures for outbreaks and new findings

10. *How is the implementation of the provisions for **control and emergency measures** by Member States, how effective are they and what are their critical success factors?*
Elements for study:
(i) Implementation by the Member States (including difficulties experienced in implementing outbreak control measures) and effectiveness of the provisions for eradication and containment of outbreaks
(ii) Effectiveness of the CPHR to stop the natural spread of harmful organisms[36]
(iii) Emergency preparedness of Member States and Community
Elements for consideration: instruments available to Commission and MS for rapid intervention against outbreaks of new diseases; effectiveness of emergency interventions[37] in the reference period; availability of up-to-date MS contingency plans and for which organisms; possible new rapid intervention instruments; the possible development of an EU emergency team
(iv) Is there enough focus on prevention and early action?

G. Organisational issues

11. *How is the **Single Authority / Responsible Official Body** concept implemented by Member States and does it need to be improved (if so, how)?*

12. *What are the views on the appropriate **sharing of responsibilities** between national authorities and private sector in the implementation[38] of the CPHR?*
This relates to the balancing of governmental and private sector roles, taking into account:
(i) The need to stimulate companies to take professional responsibility for plant health through appropriate incentives (e.g. linkage of interests, risks[39] and liability[40] in the production and trade chain and making polluters pay)
(ii) The needs of governments to cope with decreasing resources and delegate tasks to other public/private legal persons
(iii) The need to guarantee quality, independence and impartiality of official plant health controls

13. *In how far do the **FVO** plant health activities ensure the harmonised implementation of Community provisions by Member States and third country compliance?*

14. *In how far does the **EUROPHYT** tool address the needs for rapid exchange of information on interceptions and provision of statistics? What are its critical success*

[36] Account should be taken of the existing impact assessment cases studies on Pine Wood Nematode and *Diabrotica virgifera*.
[37] As a follow-up to the recommendations of the Financial Aspects evaluation, clarification is required in how far eradication expertise that is built up during national eradication campaigns is shared and in how far the latest scientific information is used.
[38] The analysis should include inspections, sampling and laboratory analyses. See the relevant provisions in the General Food Law Regulation (EC) No. 178/2002/EC.
[39] This pertains to the sharing of risk within the production and trade chain, through public or private financial compensation systems for losses, building on the outcome of the evaluation of the Financial Aspects of the CPHR. It could include linking any compensations to incentives and requirements for Good Agricultural Practice and Integrated Pest Management as defined in the Common Agricultural Policy.
[40] See the provisions on liability in the General Food Law Regulation (EC) No. 178/2002/EC.

factors and are any changes needed?

15. *How effective is the functioning of the CPHR as for **communication and consultation?***
    (i) To what extent does the CPHR take into account the interests of stakeholders and sectors affected by the current regime?
    (ii) Is the information and communication between authorities responsible for plant health and to stakeholders and third countries concerning the CPHR and its legislation adequate?
    (iii) Are the requirements of the import regime clear to our trading partners, especially in the developing countries?

16. *To what extent is the CPHR supported by an appropriate **diagnostic infrastructure**, allowing for rapid and reliable diagnosis of all regulated harmful organisms?*
    Elements for consideration: availability of the necessary diagnostic expertise for all disciplines, as well as laboratory infrastructure and equipment, reference collections, ring-tested and validated diagnostic and detection methods for the identification and detection[41] of all listed harmful organisms[42], and resources.

17. *What would be the pros and cons of **Community Reference Laboratories** (CRL[43])?*
    Please clarify the pros and cons of CRLs in terms of ensuring quality, flexibility, and sustainability.

18. *In how far have the CPHR requirements for appropriate **training** of Member State plant health inspectors and diagnosticians been met and how can this be improved?*
    Please consider how the qualifications required are ensured and updated; the use of harmonised well-described inspection methods and inspection systems; resources available to Member States; how the Community can contribute in this respect and in how far the Better Training for Safer Food programme and EPPO fulfil such needs.
    Also: in how far do plant health inspectors co-operate to ensure effective risk targeting and harmonised application of the CPHR? What are the mechanisms for co-operation and the options for strengthening them?

H. Research and methodology development in support of the CPHR

19. *In how far is the CPHR adequately supported by **research and development**?*
    Elements for consideration:
    (i) Availability of *classical biological scientific expertise*[44] on harmful organisms and plant pathology[45] as is necessary for diagnostic laboratories, for education of scientific experts, and for provision of scientific advise on pest risks and their management

[41] Identification clarifies the identity (species) of a pest or pathogen (harmful organism) obtained from diseased plants. Detection clarifies whether or not a given pest or pathogen is present in a crop or commodity. See ISPM No. 27 (2006), Diagnostic protocols for regulated pests.

[42] How many of the 250 regulated harmful organisms can official laboratories detect / diagnose by themselves and how is outsourcing organised for the others?

[43] CRLs currently exist in the Community Animal Health and Food and Feed Safety regimes.

[44] See also the State of Emergency Declaration by EPPO on the erosion of the scientific expertise underpinning the CPHR: http://archives.eppo.org/MEETINGS/2004_meetings/council_presentations/state_emergency.htm

[45] Virology, bacteriology, mycology, nematology, entomology, acarology.

(ii) Availability of *innovative molecular identification and detection methods*, in the light of increased expectations for speed, reliability and transparency
(iii) Development of *plant health risk assessment science and impact (cost/benefit) assessment*, in particular economic and modelling expertise; as well as development of decision support tools for pest management
(iv) Adequate *scientific efforts in response to new challenges* in the context of a changing socio-economic and policy environment (climate change, globalization, …) and in anticipation of future needs (foresight so as to enable priority setting)
(v) Sufficient *support to scientific research programmes* at different levels (national, community-FP7, etc.) *and to the efforts to coordinate the commisioning of research projects* between Member States and with major trade partners outside Europe, to ensure adequate coverage of research needs, avoiding gaps and overlaps
(vi) Level of satisfaction with research projects commissioned by DG RESEARCH to support the CPHR, and with the ERA-net EUPHRESCO

I. Coherence with other Community regimes

20. *In how far is the CPHR appropriately connected and appropriately coordinated with **related Community regimes**?*
Please compare principles, and consider gaps and overlaps with the following regimes:
(i) Seed and propagating material (including forestry propagating material) (coverage of plant health issues; listing of harmful organisms compared to the CPHR and listing conflicts; instrumentation of plant health issues including delegation of tasks)
(ii) Control Regulation 882/2004/EC and the Food Hygiene Recast (Regulation (EC) No 178/2002 of the European Parliament and the Council; the *General Food Law*)
(iii) Environment (e.g. biodiversity, nature conservation, invasive alien species, forest protection)
(iv) Plant protection products
(v) The Common Agricultural Policy (e.g. cross-compliance requirements for good agricultural practice, use of resistant varieties, rotation provisions)
(vi) Community Customs provisions
(vii) Animal health strategy
(viii) Any other regimes that Member States or stakeholders would like to raise attention to in terms of coherence

J. Social, economic and environmental impacts in relation to the objectives of the regime

21. *In how far **has the CPHR successfully prevented the entry, establishment and spread of harmful organisms and what were the social, economic and environmental impacts?***
An analysis based on figures and case studies (examples of success and failure and reasons why) should be provided as well as critical success factors for achieving the respective objectives. Representative examples should be given of cases where the objectives of the CPHR were met or not met, for what reasons and with which impacts.

22. *What are the **costs and benefits** of the CPHR?*
    (i) What administrative costs and other operational costs[46] are incurred by companies, public authorities and Commission in meeting legal obligations of the CPHR? Are there opportunities to reduce these costs? Which costs are charged to companies in the current fee system and what impacts does this have on stakeholders and Competent Authorities? Does the retribution of costs provide incentives to support the objectives of the regime?
    (ii) What direct and indirect losses are incurred by operators because of mandatory destruction of plant materials? To what extent are such costs borne by stakeholders individually, by stakeholders in a public or private risk-sharing system[47], by MS governments, and by the Community?[48] What is the level of satisfaction with the repartition of financial risks?
    (iii) How could the cost-benefit balance of the CPHR be improved[49]?

K. Strengths, weaknesses, opportunities and threats

23. *What are the major **strengths and weaknesses, opportunities and threats** of the CPHR, based on the conclusions of all previous questions, and which areas of improvement can be identified?*

24. *In how far is the CPHR suitable to mitigate risks of future challenges, in particular the control of new harmful organisms reaching or spreading in the Community as a consequence of **climate change**?*

25. *Which **IPPC guidelines and WTO-SPS rules** should be better taken into account in the CPHR?*

26. *What economic impacts do any **differences in standards between EU producers and key international trading partners** have on Community trade, and is there a need that EU societal concerns and legitimate factors would be better reflected in the implementation of international and bilateral rules?*

27. *How many **financial resources** should be mobilised and are the necessary **financial instruments** for the CPHR in place?**Is Community financing of the CPHR justified?***

L. Forward-looking issues

28. ***What options exist to strengthen and modernise the CPHR, so as to better reach its objectives and serve the needs of society?** Where is simplification possible, which areas need more harmonisation, and how can this be achieved?*
    Provide options and recommendations for a future strategy and suggestions for an

[46] Please provide a quantitative analysis of administrative costs under the current regime, using the Standard Cost Model (Administrative cost of obligations under EU legislation) and providing at least an average of the costs for (a) public authorities and (b) companies. Please also provide a quantitative analysis of authorisation, supervision and inspection costs incurred for the CPHR, as well as an overview of the repartition of these costs between operators and government, for the MS and for the Community. The analyses may include a number of assumptions and extrapolations but shall be based on discussions with stakeholder representative organisations and public authorities.

[47] For instance: compensations by government; appropriations by a fund filled by operators and/or government; mandatory or voluntary mutual insurance systems.

[48] Please make use of the recent Financial Aspects Evaluation of the CPHR.

[49] Please use the insights gained from the impact analysis case studies on *Diabrotica virgifera* and pine wood nematode.

amended reference model[50], along with a qualitative and quantitative description of their economic, social and environmental impacts[51].

2.5 Other specific tasks to be carried out under the assignment

Information shall be collected through among others desk studies, questionnaires[52] and in-depth interviews. The issues and questions will need to be analysed and discussed with the stakeholders impacted by the CPHR (see Annexes) as well as with the MS Competent Authorities (responsible persons in plant health policy units, National Plant Protection Organisations, and official laboratories)[53]. Interviews shall also be held with WTO, IPPC and EPPO secretariats; with FVO, EFSA, ISTA, IOBC and experts from phytosanitary science (biology and diagnosis of harmful organisms; economy of risks and risk management). Interviews shall also be conducted with (the Brussels delegation of) 3 major trading partners (like US, Canada, Argentina, Thailand, Israel). See Annexes VI and VIII for relevant contact persons.

As a minimum, all key stakeholders at EU level and their member organizations in MS should receive the questionnaires, as well as all MS. As for the stakeholders, in-depth interviews shall be held with all EU-level organizations. Visits shall be made to as a minimum 12 Member States for in-depth interviews / case studies with (i) authorities and (ii) national stakeholders' organisations[54].

As for the stakeholders, a meeting shall be organized with representatives of private sector stakeholders (growers, traders, logistic companies, foresters, …) and representatives of NGOs. Aim of the meeting shall be to provide information of the evaluation, test the basic assumptions of the CPHR and discuss the questions and policy dilemmas of the regime.

A desk study comparison shall be made of the CPHR and the plant health regimes of selected trade partners (US, Canada, Argentina, Thailand, Israel) by analyzing their websites and studying the relevant mission reports of the FVO. Additionally, this topic shall also be covered in the interview with EPPO.

Wherever possible, performance indicators (in accordance with Commission criteria and "SMART") should be proposed to monitor the relevance, utility, coherence, sustainability, effectiveness and efficiency of the CPHR in future, and for assessment whether Community financial support can be given to Member States for eradication and containment dossiers[55].

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[50] The reference model should also consider the roles and responsibilities of the Member States and of the European Community and its institutions and bodies (DG SANCO, FVO, EFSA), the SCPH, the Council Working Parties on Plant Health, and how they connect to and interact with non-Community organisations (e.g. WTO, IPPC, EPPO, CBD).

[51] See Impact Assessment Guidelines under References (Useful Web-links).

[52] During the use of the questionnaire, the contractor should give specific attention to gathering data on costs. The contractor may wish to draft a separate questionnaire on cost aspects.

[53] Note that, within a MS, the views of responsible officers in policy units, NPPOs and official laboratories may differ.

[54] The minimum number is interviews will be 58: 27 interviews with EU-level stakeholders' organisations (Annex VI), 12 interviews with the selected MS Competent Authorities, 12 interviews with the joint stakeholders' organisations in the selected MS; and 7 with international and scientific organisations (Annex VIII; note that EUPHRESCO and PRATIQUE may be combined in a single interview).

[55] Indicators should be proposed to test whether eradication and containment have been achieved to the extent that Community financial support is justified.

A clear distinction shall be made in the report between facts and opinions, and as for opinions, between those of private sector stakeholders, NGO stakeholders, Member State policy units, National Plant Protection Organisations, and laboratories.

The contractor should be available for presenting the conclusions of the report at a conference and at internal meetings of SANCO (e.g. advisory committees).

2.6 Reporting and deliverables

The evaluators will deliver different reports at various key stages of the evaluation process: inception report, intermediate report, draft final report and final report. Each report should be written in English and addressed to the Commission.

a) Inception report

This report will describe the evaluators' understanding of the evaluation objectives, issues and questions. This document will present in detail how the method proposed by the evaluator is going to be implemented and in particular how the method will answer each evaluation question and provide a judgement. It will include the draft questionnaires which the evaluators will use to obtain information from the different stakeholders for approval by the Steering Group, and include a draft list of interviews and visits planned. This document will provide the Steering Group with the opportunity to make a final check of the feasibility of the method proposed and the extent to which it corresponds with the information needs outlined in the Terms of Reference and its Annexes.

The inception report will be submitted at the latest 6 weeks after the signature of the contract.

b) Interim report

This report will provide information about initial analyses of data collected. The evaluator may already be in a position to provide preliminary answers to some of the evaluation questions. This report will provide the Steering Group with the opportunity to check whether the evaluation is on schedule and whether the evaluation has actually focused on the specified information needs.

The interim report will be submitted at the latest 5 months after the inception report.

c) Draft final report

This document will provide the conclusions of the evaluator in respect to the evaluation questions, and the other issues and tasks described in the Terms of Reference and its Annexes. These conclusions will be clearly based on evidence generated through the evaluation. Judgements provided should be clear and explicit. The draft final report will also contain the draft options and recommendations for the design of the future policy and the development by Commission services (SANCO E1) of a Community plant health strategy. For all recommendations, a judgment should be provided concerning the choice for a certain recommendation in comparison with other options that were perhaps rejected or given a lower priority, as described in Chapter 2.2.

The structure of the draft final report will respect the structure set up by common Evaluation Standards and include an executive summary (synthesis of main analyses and conclusions,

added value of the proposals including cost/benefits), main report (presenting in full the results of the analyses, conclusions and recommendations), technical annexes (one of which will be the Task Specification), and a draft one-page summary on the Key Messages of the evaluation.

The draft final report will be submitted at the latest 10 months after the signature of the contract.

d) Final report

It will take into account the results of quality assessment and discussions with the Steering Group about the draft final report insofar as they do not interfere with the autonomy of the evaluators in respect to their conclusions. The final executive summary and Key Messages page will be part of it.

2.7 Quality criteria

The contents of the report have to be relevant (rigorous analysis, obeying to quality standards and delivered in a timely manner). The report has to be structured and comprehensible. It should mention its sources and the information collected should be compatible with the tools used. Hypotheses and structure of reasoning should be logical and interpretation of results should be explicitly made clear. Conclusions and recommendations shall not be influenced by personal or partial opinion. Conclusions and recommendations shall be understandable, useful and sufficiently detailed.

The quality of the evaluation report will be evaluated by the Steering Group according to the following criteria (see also standard quality checklist of SANCO):

- Relevance of the content
- Adequacy of the methodology
- Reliability of the data
- Solidity of the analysis
- Credibility of the results
- Validity of the conclusions
- Usefulness of the recommendations
- Clarity

2.8 Organisation and timetable

Organisation

The evaluation shall be carried out and completed within 12 calendar months.

The management of the project is under the responsibility of the Deputy Director-General of the Directorate-General for Health and Consumers.

A Steering Group is created to advise the Deputy Director-General on the execution of the evaluation project. It is composed of members of the Commission services and

representatives of the Chief Plant Health Officers from, but not participating on behalf of, five Member States. The Steering Group will supervise the evaluation process in order to ensure that it will be conducted in line with the Terms of Reference. The Steering Group will take any decision required to ensure the effectiveness of the evaluation process in that respect and will provide guidelines to the evaluation team as and when required. The Steering group will advise the Deputy Director-General to approve the inception, intermediate and final reports delivered by the evaluators.

The role of the Steering Group will be:

- To approve the selected evaluation team;
- To monitor the structuring phase of the evaluation which will, through the inception report, propose to the Steering Group how to carry out the evaluation in operational terms;
- To facilitate the access to the data and information needed by the evaluators;
- To validate the methodology, the assessment tools and techniques to be utilised;
- To monitor compliance to the time frame set for the evaluation;
- To control the quality of the work and reports delivered by the evaluators.

The Steering Group meetings are scheduled to take place after the reception of the Steering Group launch note, the inception note, the interim report and the draft final report. The evaluation consortium team leader will participate to these meetings. Prior to each meeting, the notes and reports will be circulated to the Steering Group members for comments. If during the evaluation process, the Steering Group is unable to resolve any issues, it will promptly seek guidance from the Deputy Director-General of the Directorate General for Health and Consumers.

The dissemination of the evaluation results and the implementation of recommendations fall under the responsibility of the Deputy Director-General.

Access to data

Access to data and information will be broadly given to the contractor, who will also gather opinions of interested parties (European Commission, stakeholders and other relevant persons and organisations) through interviews.
Key stakeholders include inter alia Member States' national policy units, National Plant Protection Organisations, official laboratories, international institutions, and relevant interest groups (consumers, manufacturers, retailers, farmers, foresters, traders, logistic companies, industrial companies, insurance companies, …).

The contractor will propose other tools for data collection and analysis as they may see fit including desk research, questionnaires, workshops, etc.

Timetable

- Evaluation by contractor
  June 2009 – May 2010
- Presentation of evaluation outcome to the Commission
  September – October 2010

- Presentation of evaluation outcome to the stakeholders
  Conference with stakeholders, organised by Presidency, with speech by Commissioner (with involvement of the Contractor consortium)
  September – October 2010

2.9 Budget

A budget of maximally …… euro is available for the evaluation.
Budget line: BA 17.010401.

2.10 Special requirements

Given the very specialised nature of the subject matter that has to be evaluated, the evaluation team is expected to comprise at least the following members:

- One senior member and one junior member with specific expertise in plant health (regulated harmful organisms) policy and its implementation;
- One senior member with scientific expertise on the biology and risk management of plant pests and pathogens;
- One senior member and one junior member with economic expertise in relation to cost-benefit analysis and analysis of administrative costs;
- One senior member with expertise in modern public governance.

In the context of the assignment, data will have to be collected of a confidential nature, 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.

3 References

3.1. Annexes to the Task Specification

I. Justification of the assignment
II. Revision of the EU Plant Health Regime (Council Conclusions)
III. Categorisation of harmful organisms in the CPHR
IV. Reconstruction of the intervention logic of the Community Plant Health Regime
V. Summary of the phytosanitary acquis
VI. List of stakeholders (not exhaustive)
VII. List of Chief Plant Health Officers
VIII. Contact persons in relevant international organisations
IX. List of Steering Group members

Available on request in Commission services:

X. List of Commission and MS representatives in the Council Working Party (Plant Health – Harmful Organisms) and the Standing Committee on Plant Health
Chairman SCPH: Mr. Harry Arijs (Tel: +3222987645; harry.arijs@ec.europa.eu)
XI. List of Commission and MS representatives in Standing Committee on Seeds and Propagating Material
Chairperson: Ms. Päivi Mannerkorpi (Tel: +3222993724; päivi.mannerkorpi@ec.europa.eu)
XII. List of Commission and MS representatives in Standing Committee on Seeds - Forestry
Chairman: Mr. Bruno Foletto (Tel: +3222950515; bruno.foletto@ec.europa.eu)

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

Available in Commission services for the purpose of this assignment are:

- Commission on Phytosanitary Measures (CPM). Independent evaluation of the workings of the IPPC and its institutional arrangements. Agenda item 10.8.1 of the Agenda of the second session of the CPM, 26-30 March 2007.
- Council of the European Union. Safety of imported agricultural and agri-food products and compliance with Community rules – *Council conclusions*. Press release, 2917th meeting of the Council Agriculture and Fisheries, 18-19 December 2008, 16916/08 (Presse 361).
- Council of the European Union. Better regulation in the plant variety and seed sectors – *Council conclusions*. Press release, 2917th meeting of the Council Agriculture and Fisheries, 18-19 December 2008, 16916/08 (Presse 361).
- D.L. Ebbels, Principles of plant health and quarantine, CAB International, 2003.
- European Commission. A new strategy in the field of plant health (harmful organisms). COM(87) final, 10 March 1987.

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- European Commission. The EC single market – A new strategy in the field of animal and plant health. VI/B/II, February 1982.
- European Commission. Green paper on bio-preparedness. COM (2007) 399 final. 11 July 2007.
- European Commission. Evaluation of the Community Animal Health Policy (CAHP) 1995-2004 and alternatives for the future. Final report by the Food Chain Evaluation Consortium, Part I: Main report; and Part II: Pre-feasibility study on options for harmonised cost-sharing schemes for epidemic livestock diseases. 25 July 2006.
- European Commission. A new Animal Health Strategy for the European Union (2007-2013) where "Prevention is better than cure". COM 539 (2007) final, adopted on 19 September 2007.
- European Commission. Interim evaluation Phytosanitary: Harmful Organisms – Financial Aspects. Final Report by the Food Chain Evaluation Consortium. 13 March 2008.
- European Commission. Evaluation of the Community *acquis* on the marketing of seed and plant propagating material (S&PM). Final Report by the Food Chain Evaluation Consortium. 10 October 2008.
- European Commission. Organisation of training courses on plant health controls. Final report by TrainSaferFood. 27 November 2008.
- European Commission. Towards an EU Strategy on Invasive Species. Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions. SEC(2008)2887 et SEC(2008)2886, 3 December 2008.

3.3. Useful web-links

- DG SANCO plant health website: http://ec.europa.eu/food/plant/organisms/index_en.htm
- Food and Veterinary Office (FVO): http://ec.europa.eu/food/fvo/index_en.htm
- EFSA: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_home.htm
- EPPO: http://www.eppo.org
- IPPC: https://www.ippc.int/IPP/En/default.jsp
- WTO-SPS: http://www.wto.org and http://www.wto.org/English/res_e/booksp_e/agrmntseries4_sps_08_e.pdf
- CBD: http://www.cbd.int
- European Commission impact assessment guidelines (SEC(2005) 791): http://ec.europa.eu/governance/impact/docs/SEC2005_791_IA%20guidelines_annexes.pdf

- DG AGRI, on the Common Agriculture Policy: http://ec.europa.eu/agriculture/publi/capleaflet/cap_en.htm
- DG ENTR, administrative cost of obligations under EU legislation: http://ec.europa.eu/enterprise/admin-burdens-reduction/action_program_en.htm#ee
- DG SG, second strategic review on Better Regulation: http://ec.europa.eu/governance/better_regulation/documents/com_2008_0032_en.pdf
- UK Department of Forestry and Rural Affairs (DEFRA): The rationale for public sector plant health policies https://statistics.defra.gov.uk/esg/evaluation/planth/chapter5.pdf

Annex I: Justification of the assignment

Developments to be considered

The plant health regime of the European Community (EC) is the product of decades of legislation (see paragraph 1.1). Since its inception in 1977, various major changes and developments have taken place in relation to the CPHR. For the purposes of this Terms of Reference (ToR) and without prejudice to the outcome of the evaluation they are tentatively summarised as follows:

a. GLOBALISATION AND CHANGED EXPECTATIONS FROM SOCIETY
   - ✓ In the past decades, agricultural production has changed from a supply economy for primary food production by growers, to a demand-driven economy for food, plants for planting, bio-energy, non-food products such as flowers, and other plant products (including wood). An agricultural system evolved with interdependencies between growers, trade, logistic companies and industry. Plant production increases in the past decades were possible in part because of the globalisation of trade, which has increased considerably in volume and diversity[56] (for plants and plant products, a hundreds of billion euro market is impacted). Plant health policy stakeholders have changed and so have their expectations. Interests of producers and traders have diverged, leading to costs for one stakeholder and benefits for another. The EU is expected to protect the interest and competitiveness of the agricultural system as a whole (growers, farmers and the associated supply and marketing chains);
   - ✓ As a consequence of trade globalisation, natural borders that once were effective barriers to the introduction and spread of harmful organisms no longer offer effective protection. The EU is expected to protect its territory against the increased threat of incursion of such harmful organisms. Facilitating safe agricultural trade is a necessity;
   - ✓ A rapid increase in forestry pest incursions into the EU necessitates the establishment of closer links between plant health and environmental policy. Additional to the protection of agriculture and horticulture, the EU is expected to safeguard the health of ecosystems, natural habitats, forests and the European landscape against foreign harmful organisms[57];
   - ✓ Global warming might allow for foreign harmful organisms to spread into the EU and allows regulated harmful organisms thus far restricted to Mediterranean MS to more northern MS. Mitigating climate change and its consequences has become a political priority;
   - ✓ Biosecurity has become important in view of the threats of terrorism;

[56] World trade in agricultural products has increased in value by 42% over the period 2000-2004, reaching almost US $800 billion. Over the period 1980-2000, the share of fruit, vegetables and cut flowers in agricultural exports has grown from 13.7% to 18.9%. More and more countries are involved in exports and plants and plant products often move around the globe several times before the end product reaches the consumer. Moreover, consumers' expectations are diversifying: consumption of exotic products, fruit and vegetables all year round. Consumer demands over price are leading to product purchases in countries where production costs are lower due to multiple factors, possibly including plant health.

[57] At the same time, government nature conservation policies often question whether measures should be taken against harmful organisms because pests are part of the ecosystem anyhow and dead trees can offer added value to an ecosystem. Eradication campaigns can moreover be very damaging. On the other hand, invasive harmful organisms have shown to be able to eliminate entire ecosystems; for instance, the vast *Castanea* (edible chestnut) forest of eastern North America have been completely eliminated by invasion of the fungus *Cryphonectria parasitica*.

- ✓ Specific phytosanitary provisions (e.g. for wood packaging material) have huge impacts on world trade in general (not only on agricultural trade). The Community plant health policy needs to take into account its impacts on society at large, and to strike an appropriate balance between social, economic and environmental impacts.

b. ENLARGEMENT OF THE EUROPEAN COMMUNITY
   - ✓ The introduction of the Community internal market and subsequent enlargements of the EU territory have resulted in the inclusion of a wider range of geo-climatic agricultural conditions that need to be accommodated;
   - ✓ For a number of harmful organisms, the enlargement of the EU territory resulted in a change in pest status of the EU. Harmful organisms foreign to some MS but established in other MS can result in tensions as concerns the Community measures to be adopted (EU internal market disruption risks);
   - ✓ It would seem that in addition to existing provisions concerning movement of plants and plant products and eradication of outbreaks, further attention for control provisions may be required for confining regulated harmful organisms to infested regions of the Community, where eradication is no longer possible. The advantages and disadvantages of different types of regionalisation could be examined.

c. DEVELOPMENTS CONCERNING INTERNATIONAL TREATIES
   - ✓ The establishment of the WTO - SPS Agreement and the accession of the European Community to the International Plant Protection Convention (IPPC)[58] have brought along obligations concerning pest risk analysis as foundation for phytosanitary measures, for introduction of economic impact and cost-benefit analyses in pest risk management decisions[59], for minimising negative impact of phytosanitary measures to trade and for support to the necessary scientific research on plant health. A large framework of obligations and of international plant health standards needs to be taken into account;
   - ✓ A large framework of conceptual international standards for phytosanitary measures has been developed under the IPPC;
   - ✓ The inclusion of invasive alien species (IAS) in the scope of the IPPC, including exotic plants harmful to natural ecosystems, necessitates to consider the advantages and disadvantages of widening the scope of the CPHR to environmental issues (ecosystem and biodiversity protection)[60].

[58] The IPPC is an essential instrument facilitating the continuously expanding international trade in plants, plant products and other regulated articles. It provides the global forum to exchange views on how to best address phytosanitary issues. The Convention, in addition to the OIE and Codex Alimentarius, is one of the three standards setting bodies recognised under the WTO-SPS Agreement.

[59] From the scientific perspective, assessing the risk of pests (harmful organisms) and choosing appropriate levels of prevention and control are as much economic questions as they are ecological ones. Making decisions solely on the basis of natural science can lead to incorrect estimations of true risk and to costly policies with no gain in environmental quality. It is necessary to ensure that expected returns of each intervention exceed its costs. This needs to be determined on a case-by-case basis, examining the costs and benefits of available policy options. Some scientists argue that the geometric progression of the biological growth function implies that prevention measures will likely have greater cost effectiveness than control expenditures once the harmful organism is introduced; other scientists have shown that preventative measures such as trade bans can actually be welfare reducing. In spite of WTO-SPS and IPPC obligations, most plant health policies world-wide have escaped a rigorous economic evaluation (and even technical scientific evaluations are lacking).

[60] Both the IPPC and WTO-SPS make reference to protecting wild plants and the environment, but these agreements are generally considered largely to concern trade. The Convention on Biodiversity (CBD) (UNEP, 1992) has the objective of the 'conservation of biological diversity and the sustainable use of its components' (Article 1). It recognizes that one of the major threats to diversity is the spread of 'alien species which threaten ecosystems, habitats and species' and requires contracting parties to prevent their introduction or control and eradicate them (Article 8h). To help governments meet their obligations, two

d. INCREASED POLITICAL IMPORTANCE OF EXPORT

- ✓ In 2007, the Council of Ministers concluded that the European Community has the exclusive competence on export policy, including negotiations with third countries on sanitary and phytosanitary trade related matters, in line with Article 133 of the Treaty[61]. For pragmatic reasons, negotiations on certification requirements are largely left to the MS, provided that these certification requirements are not counter to the WTO agreement, a bilateral agreement between the EU and the country concerned and do not disrupt the internal market. The Council conclusions reconfirm role of the Commission in export policy.
- ✓ The EU approach of phytosanitary issues, in which imports from third countries into the Community are subject to fully harmonised phytosanitary provisions while export to these countries traditionally was left to the MS, has been increasingly challenged by third countries. Several large third countries have expressed the wish to negotiate with the European Commission rather than the MS about both imports to and exports from the EU. Council in 2004 agreed on the Roosendaal Group arrangement to support the Commission in such negotiations;
- ✓ EU agriculture and food industries increasingly depend on open and accessible markets. Non-tariff barriers risk to become more prominent as a potential impediment for exporters to access these markets. The WTO plays an important role for preventing disproportionate or not scientifically justified phytosanitary measures to become new trade barriers[62].

e. ESTABLISHMENT OF EFSA

In response to food safety crises, the European Food Safety Authority (EFSA) was created in 2002 as an independent source of scientific advise and communication on risk associated with the food and feed chain and with a Panel on Plant Health. At the heart of this decision was the need to separate risk assessment from risk management. The creation of EFSA and the activities of its Panel on Plant Health for phytosanitary risk assessment have led to adjustment of the role and responsibility of the Commission and the SCPH in relation to EFSA in the field of pest risk assessment and management.

f. EROSION OF THE SCIENTIFIC EXPERTISE UNDERPINNING FOR THE CPHR

The Lisbon Strategy identifies science and innovation as key drivers of EU economic competitiveness. The agri-food sector is being encouraged to invest more in research, development and innovation. On the contrary, a rapid erosion has taken place of the scientific expertise in plant health in all MS in the past decade. This led to a state-of-

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protocols have been established under the CBD, the *Cartagena Protocol on Biosafety* (UNEP, 2000) and the *Guiding Principles for the Prevention, Introduction and Mitigation of Impacts of Alien Species* (UNEP, 2002). Many aspects of the CBD, its Guiding Principles and the Biosafety Protocol have far-reaching implications for plant health policy. An alien species that is a plant pest (such as a pathogen or invasive weed) and threatens ecosystems, habitats or species is considered a quarantine pest under the IPPC and requires import controls and precautionary measures. Neither the IPPC nor the CBD takes precedence over the other, and there is an obligation on contracting parties to respect both conventions.

[61] Paragraph 1 of Article 133 reads "*The common commercial policy shall be based on uniform principles, particularly in regard to changes in tariff rates, the conclusion of tariff and trade agreements, the achievement of uniformity in measures of liberalisation, export policy and measures to protect trade such as those to be taken in the event of dumping or subsidies.*"

[62] As tariffs and other trade barriers are reduced under the WTO agreements, governments might be seduced to protect domestic production from foreign economic competition by using measures ostensibly designed to protect plants from harmful organisms, but which actually go beyond what is necessary or reasonable for this purpose and constitute a barrier to trade. Such measures can deceptively exercise very effective covert control on trade, while being very difficult to challenge because of their highly technical nature. The main aim of the SPS Agreement is therefore to prevent the abuse of health protection measures for trade protectionist purposes, while maintaining the right of governments to take necessary and justifiable measures to maintain the level of health protection it considers to be appropriate. However, technical justification for restriction of market access to third countries is often lacking and a Pest Risk analysis (PRA) has to be carried out on a case by case basis. This may take years or decades, thus discouraging potential exporters due to the uncertainty of the results.

emergency declaration by EPPO[63] in 2004 and some first steps by Council to revive phytosanitary science, including actions for better cooperation and funding of phytosanitary research and for creation of a Community system of reference laboratories. The rapid technological developments and necessary innovation in plant health diagnostics can however no longer be accommodated by MS individually and coordination and harmonisation are needed, taking into account standards developed for this purpose by IPPC and EPPO.

g. DECREASING RESOURCES FOR PUBLIC SERVICES

The staff and financial resources of public services in MS are gradually decreasing, while the number of controls to be carried out increases. The number of regulated harmful organisms under the CPHR is increasing continually, while delisting occurs only exceptionally. A possible lack of balance between tasks and resources of public services might result in qualitatively and quantitatively inadequate controls, and if so, potentially jeopardize the efficacy of the entire CPHR and resulting in increasing incursion of new harmful organisms. No mechanisms seem to be in place for either increasing resources of public services, or restricting the aims of and demands posed by the CPHR.

h. EVOLUTION OF RELATED COMMUNITY REGIMES

- ✓ The regime of the Marketing Directives for seeds and propagating material concerns harmful organisms for which a tolerance level is accepted, while the CPHR includes regulated quarantine pests, for which a zero tolerance is applied. The overlap of the two regimes is being experienced by MS as confusing;
- ✓ The inclusion of plant health in the Directorate-General for Health and Consumers (SANCO), along with animal health and food safety and the partial inclusion of plant health along with these in Council Regulation 882/2004/EC. The advantages and disadvantages of further aligning certain aspects of plant health, animal health and food safety controls could be considered;
- ✓ Cross-compliance is an important element of the Common Agricultural Policy (CAP) of the European Community. EU policies to help agriculture provide financial incentives to farm in a better way for the environment, e.g. by insisting that farmers must respect environmental laws and laws on public, animal and plant health if they wish to qualify for direct income payments. Obligations to farmers among others include mandatory crop rotation, which is crucial for eradication and management of harmful organisms;
- ✓ The development of a Community Strategy on Invasive Alien Species, overlapping in part with the CPHR, necessitates further reflection on the proper positioning and implementation of such Strategy in relation to the CPHR.

Need for modernization of the policy instruments

Apart from addressing the developments described in the previous paragraph, the evaluation of the CPHR should also investigate the possibilities for modernization of its instrumentation. The CPHR currently consists of technical official requirements to farmers and traders (so-called 1st generation policy instruments). Such obligations and prohibitions have been traditionally perceived to be more effective in the area of plant health than a system in which

[63] http://archives.eppo.org/MEETINGS/2004_meetings/council_presentations/state_emergency.htm

plant health authorities delegate part of the responsibilities to the operators. However, the success of 1st generation policy instruments depends on the enforcement mechanisms available and the prevailing incentives to operators. As a general rule for all legislation, obligations and prohibitions usually invoke resistance of stakeholders, and escape behaviour, rather than responsibility sharing. In the case of plant health, counterproductive behaviour of stakeholders is especially undesirable as it would undermine the objectives of the CPHR. An issue to consider is therefore if and where other instrumentation that also gives responsibility to the stakeholders, such as accreditation systems, voluntary certification schemes, supervision, liability systems, insurance systems, incentives, consultative policy making, agreements and memoranda (so-called 2nd and 3rd generation instruments), could be appropriate and acceptable. The Directorate-General for Health and Consumers is open to using both binding legal instruments and other policy tools that bring effective results (*Mission statement*[64]). Three aspects in particular require investigation.

Incentives versus prohibitions

A major issue to explore is the creation of incentives to stimulate stakeholders to take responsibility for the plant health chain as a whole. Consideration should also be given to fostering risk-sharing institutions that explicitly address the nature of transferable risk and to liability issues. At present companies may profit financially from risky behaviour, while the burden of harmful organism outbreaks will be borne by others. The incentives and punitive elements of the regime should where possible link the interests of actors in such a way that incentives exist for responsible behaviour, remaining risks are shared, and polluters pay. In absence of such mechanisms the CPHR may be perceived as unfair, particularly when measures are imposed at the expense of private companies, without financial compensation, while the operator considers himself to be a victim of rather than responsible for the entry of the quarantine pest. At Community level, similar dilemmas exist since costly eradication measures are taken by one MS to safeguard the Community as a whole. Although governments are partially reimbursed for costs of measures, affected growers are not. This negatively influences the willingness of MS to take the necessary measures against harmful organisms and it possibly reduces the efficacy of the CPHR.

The recent evaluation of the financial aspects of the CPHR creates opportunities to introduce incentives. For example, requirements for potential polluters to obtain full insurance against any damages they may generate would cause the insurance industry to require appropriate safety measures on the part of the potential polluters and to charge insurance premiums according to the risk classification of companies involved. Similarly, payments to growers from a plant health fund might be made conditional to compliance with safety and quality assurance requirements.

Payments to growers under the CAP are currently not conditional to cross-compliance with plant health legislation but they do relate to good agricultural practice including crop rotation obligations. Under the pesticides regime, Community-wide standards of Integrated Pest Management will become mandatory as from 2014. The facts concerning these related policy domains require further investigation when considering the creation of incentives in the instrumentation of the CPHR.

[64] See http://intranet.sanco.cec.eu.int/intranet/we-do/mission-statement/Document.2005-04-06.1831/?searchterm=mission%20statement.

Role of government versus private industry
In many Member States, an evolution has taken place of the concept of the role of the State and the stakeholders. Modernisation may be considered as concerns the role of the government as sole responsible for plant health controls. While the government should be responsible for any plant health status guarantees it provides, this does not by itself imply that government should carry out or pay for the plant health controls executed under its responsibility. An issue to be considered is whether or not more responsibility should be given to stakeholders for the plant health quality of plants and plant products that are produced and traded. Developing a political position will require critical point analysis, exploration of the views of stakeholders (industry as well as environmental NGOs) on the issue, and alignment with the Community position in general on positioning of official controls. Factors to be taken into account are the increasing trade volume and numbers of inspections that must be carried out, and the growing pressure on MS competent authorities to review their organisational structures to cope with limited or reduced financial and human resources.

Under the Marketing Directives for Seed and Propagative Materials, growers may perform specific official functions provided that they are supervised by the Competent Authority. In the CPHR, this is possible for issuing plant passports but not for official controls. A regime, different from the CPHR and the aforementioned Marketing Directives, for delegation of controls involving registration and approval of companies exists in Regulation No. 882/2004/EC of the European Parliament and the Council, which covers food and feed controls control and eradication of animal diseases with a public health impact, as well as includes multiannual plant health control programme obligations and plant health inspection missions by the Food and Veterinary Office (FVO).

In the Council Working Party of Chief Plant Health Officers (COPHs), an approach was recently discussed with different levels of compliance, such as registration and approval of companies for carrying out delegated plant health control tasks relying on a systems approach, in which the management of the phytosanitary risks by companies is checked *a priori* and *a posteriori* by official inspection.

Better regulation and reduction of administrative burden
In the context of the renewed Lisbon Strategy, refocused on growth and jobs, the Commission has launched a comprehensive strategy on better regulation to ensure that the regulatory framework in the EU contributes to achieving growth and jobs, while continuing to take into account the social and environmental objectives and the benefits for citizens and national administrations. The EU's Better Regulation policy aims at simplifying and improving existing regulation, to better design new regulation and to reinforce the respect and the effectiveness of the rules, all this in line with the EU proportionality principle. Better Regulation strategy is based on three key action lines:

- Promoting the design and application of better regulation tools at the EU level, notably simplification, reduction of administrative burdens and impact assessment;
- Working more closely with Member States to ensure that better regulation principles are applied consistently throughout the EU by all regulators;
- Reinforcing the constructive dialogue between stakeholders and all regulators at the EU and national levels.

The Better Regulation principles constitutes the framework in which the CPHR evaluation takes place and should be at the core of the CPHR evaluation. These should be fully taken

into account when designing options for the future (especially simplification and reduction of administrative burden).

Previous evaluations

Since its inception, the CPHR as such has not been evaluated[65]. Given the impact of the regime on stakeholders, an evaluation is advisable.

Conclusion

The CPHR has been developed over the past decades. Since its inception, major changes have taken place as concerns stakeholders involved, expectations from society, institutions and international treaties, the functioning of markets and the need for and availability of scientific support as well as in the EU itself. The CPHR needs to be evaluated for the possible need for amendments to address these changes. Modernization of the CPHR instrumentation should also be considered.

Support from the Council of Ministers

On 21 November 2008, the Council of Ministers adopted Conclusions on the aims and importance of the CPHR and the necessity of updating it (see Annexes), and invited the Commission:

- To proceed to an evaluation of the current Community plant health regime and to consider possible modifications to the existing legal framework and the impact of such modifications, taking into account the issues underlined in paragraphs 4 to 19 of the Conclusions;
- To present, based on the outcome of such evaluations, a proposal for a Community plant health strategy, putting prevention at the core of the Community plant health system;
- To inform the Council regularly of the progress achieved.

[65] An interim evaluation on a subdomain (Phytosanitary: Harmful Organisms – Financial Aspects) has recently been carried out.

Annex II: Revision of the EU Plant Health Regime (Council Conclusions)

COUNCIL OF
THE EUROPEAN UNION

EN

Council Conclusions on the Review of the EU Plant Health Regime

2906th ECONOMIC and FINANCIAL AFFAIRS/BUDGET
Brussels, 21 November 2008

"THE COUNCIL OF THE EUROPEAN UNION

RECOGNISING

1. that the Community legislation relating to phytosanitary requirements for plants, plant products and other objects ensures the protection of the European Community territory and a phytosanitary secure trade of plants and plants products,

2. the necessity of taking into account the increase in international trade and the continuing enlargement of the European Union,

3. the necessity of updating, in the light of experience and of new requirements linked to sustainable development, the existing regime to develop a regime dealing with imports, movements within the Community, measures on the territory of the Community, global concepts for exports and the necessity of providing the means to implement the regime.

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UNDERLINES

4. the importance of reasserting that the global aim of the Community plant health regime is to protect plant resources, food security, sustainable production, environment and to contribute to the protection of human health, taking into account trade concerns ;

5. the importance of defining priorities and of categorizing phytosanitary risks, by choosing management measures in accordance with defined priorities and adapting the level of control to phytosanitary risks ;

6. the importance of having global monitoring of the phytosanitary status of the EC territory, for example via plant health monitoring networks, phytosanitary precautionary surveillance,… ;

7. the importance of having a robust and effective network of scientific expertise and facilities to underpin phytosanitary activities ;

8. the importance of ensuring the efficacy of controls to prevent the entry of harmful organisms into the EC territory, for example via qualification of inspectors, facilities at points of entry, harmonized management of emerging risks, cooperation with the customs authorities,… ;

9. the importance of ensuring collective control to prevent the spread and establishment of harmful organisms within the EC territory, for example via Community phytosanitary control measures on the territory, effective measures against outbreaks, including emergency measures, phytosanitary risks covered by the International Plant Protection Convention which includes inter alia invasive alien species,… ;

10. the importance of putting prevention at the core of the Community plant health regime by involving professional stakeholders, for example via systems of prevention and management of phytosanitary risks within companies, phytosanitary security at different levels (approvals, phytosanitary documents),… ;

11. the importance of considering financial participation in risk management relating to outbreaks, taking into account the relevant outcomes of the current Health Check of the Common Agricultural Policy ;

12. the importance of continuously adapting phytosanitary legislation in order to reflect the real phytosanitary situation in the European Union, for example via harmonized monitoring analysis, alert systems, pest risk analyses,… ;

13. the importance of ensuring commonly accepted and effective control practices, for example via comparative inspection practices, training of inspectors, updated inspection reference, qualified and validated diagnostic protocols, research and development programmes,… ;

14. the importance of having a simple legislative framework by exploring the links with other Community regimes, such as that for marketing seeds and propagating material, elements from food law,… ;

15. the importance of having a Community strategy for involvement at international level ;

16. the importance of ensuring communication and transparency between authorities responsible for plant health, for example via Community performance indicators for critical points of activity and results, harmonization of phytosanitary documents, sharing of information within a Community IT network,… ;

17. the importance of communicating with the stakeholders, whether the citizens or the professionals, in order to prevent risky behaviour ;

18. the importance of ensuring phytosanitary protection while taking into account administrative burdens and costs involved ;

19. the importance of considering, in the implementation of the Community plant health regime, the roles and responsibilities of the Member States and of the European Community and its institutions and bodies, such as the European Commission (DG Sanco, FVO), the Standing Committee on Plant Health, EFSA and how they connect to and interact with non-Community organisations (e.g. IPPC, EPPO, CBD,…) ;

The Council therefore INVITES

20. the Commission to proceed to an evaluation of the current Community plant health regime and to consider possible modifications to the existing legal framework and the impact of such modifications, taking into account the issues underlined in paragraphs 4 to 19 ;

21. the Commission to present, based on the outcome of such evaluations, a proposal for a Community plant health strategy, putting prevention at the core of the Community plant health system ;

22. the Commission to inform the Council regularly of the progress achieved."

Annex III: Reconstruction of the intervention logic of the Community Plant Health Regime

The following is a reconstruction[66] of the original intervention logic of the Community Plant Health Regime (CPHR), based on documents issued by the Commission in the preparatory period (1987-1992) for the introduction of the single internal market.

Part of this annex pertains to the Commission strategy in the field of plant health of 1987. The reader should be aware that the CPHR in part developed in a different manner than was foreseen at that time. This is particularly the case for the integrated approach presented in the Commission strategy, in which the Community regime for Seed and Propagating material was considered to be a part of the Community plant health regime. The Marketing Directives for Seed and Propogating Materials nowadays are considered a separate regime. Existing confusion on the scope of both regimes as concerns harmful organisms may be attributed to the original overlap and subsequent independent evolution of the two regimes.

Documents used:

- A new strategy in the field of plant health (harmful organisms), COM(87) final, 10 March 1987
- The implications of the EC plant health regime post 1992 (by M. Vereecke), 921/VI/90-EN, 1990
- Developments in Community legislation on plant health in the context of the completion of the internal market (by Dieter Obst), 3005/VI/90-EN, 9 March 1990
- The regulatory bases for a plant health strategy to 1992 (by J. Gennatas), 1044/VI/91-EN, 11 April 1991
- Le passeport phytosanitaire communautaire (propositions – réflexions), PVNA/FR/0148, Novembre 1991
- The EC single market – A new strategy in the field of animal and plant health, VI/B/II, February 1982

Situation before a Community Plant Health Regime was put into place

Under the Treaty of Rome, in 1957, some fields were not directly included in the programme of economic and political integration of the Member States (MS) of EEC, but left entirely to national policies. The protection of "health and life of humans, animals or plants", mentioned in article 36 of the Treaty of Rome was the most important of such fields left to MS.

The result was that the individual MS had set up and applied different plant quarantine instruments, with quite distinct prohibitions and restrictions to imports of plants/plant products to prevent the introduction or spread of organisms harmful to plants / plant products. There was considerable variation between MS (except the three BENELUX countries). It is obvious that trade in plants and plant products between MS was greatly affected by this divergence of national requirements.

The goal of a free internal market was already mentioned in the opening lines of the Treaty of Rome: "*The Community shall have as its task, by establishing a common market and*

[66] The help of Mr Jacques Gennatas, DG SANCO, to prepare this reconstruction is gratefully acknowledged.

progressively approximating the economic policies of Member States, to promote throughout the Community a harmonious development of economic activities…". Through the Common Agricultural Policy, a free internal market was indeed established for most agricultural products as far back as 1962. The plant health sector, however, was one of the remaining barriers to free intra-Community trade.

Start of the Community Plant Health Regime

In order to improve this situation, EEC undertook to work out, through harmonization, a uniform EEC plant quarantine instrument, applicable in all MS.

In 1969, two Council Directives[67] had already been adopted to harmonize the control measures for quarantine diseases of potato known to be established in several MS (potato wart disease and potato cyst nematodes).

The main harmonization instrument was Council Directive 77/93/EEC of 21 December 1976 on protective measures against the introduction into the MS of harmful organisms of plants or plant products[68]. This Directive considered that systematic eradication of harmful organisms within 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. A uniform quarantine system with standardized requirements was introduced, covering intra-Community trade in plants and plant products as well as their imports from outside the Community. The system did not cover exports from the Community into areas outside the Community or trade within one MS.

The new EEC plant health system depended mainly on the international system of provision of phytosanitary certificates by exporting MS, to give the importing MS the assurance that plants or plant products had been properly inspected and that the pre-export requirements were complied with. A long list of these requirements was set out to ensure that certain plant pests and diseases, which were prohibited for entry to any MS, were not passed between MS, or did not enter the Community. For intra-Community trade, plant health inspections were in place prior to shipment, on the basis of which phytosanitary certificates were issued in the forwarding MS, and on import checks in the MS of entrance / destination.

Council Directive 77/93/EEC did not fundamentally change the previously existing structures. The provisions were restricted to trans-border movements and trade within a MS was not covered. The main progress achieved can be summarized as follows:

- Standardization, in principle, for all MS of the various lists (prohibited commodities; commodities subjected to plant health certification; harmful organisms; special requirements);
- Reduction of the list of prohibited commodities of Community origin;
- Abolition of systematic phytosanitary checks on imports in intra-Community trade;
- Community control over plant health measures taken by individual MS and not provided for in the CPHR (safeguard measures) and derogations (temporary authorization of prohibited imports).

[67] Council Directives 69/464/EEC and 69/465/EEC.

[68] In 1976, the Standing Committee on Plant Health was also installed.

In its form of before 1993, the deficiencies of the CPHR under Council Directive 77/93/EEC in relation to the free circulation of goods were:

- Absence of provisions uniformly applicable to both national and intra-Community trade; products qualified for domestic trade did not automatically qualify for intra-Community trade; for export to other MS, additional rules had to be observed;
- Plant health certification was required in trans-border movement; the related additional procedures were not free of charge;
- For EC products, documentary checks and possible identity checks took place also at the internal border or elsewhere in the importing MS;
- For third country products, possible phytosanitary checks (by sample checking) on import, either at the border or elsewhere in the importing MS.

The deficiencies of the CPHR under Council Directive 77/93/EEC in relation to the objective of preventing the introduction or the spread of harmful organisms were:

- No regular control on movements within MS; therefore risk of uncontrolled spread of harmful organisms from one possible source of infection throughout the country;
- Difficulties in satisfying the special requirements concerning official growing season inspections at the place of production, since it might not be known if the product was to be exported;
- Prior-to-export phytosanitary inspections could in practice only be done by visual examination of samples of the harvested product and were usually carried out when the product was already packed;
- Inspectors carrying out prior-to-export phytosanitary inspections were officials of the exporting country; there were suggestions that the required certificates were more likely to be issued than refused;
- Phytosanitary checks on import could only be spot checks and were often conducted when the product was still packed or loaded.

Evolution of the regime in the period 1977 - 1992

After the introduction of the CPHR, further steps were taken towards the achievement of an internal market:

- Prohibition of systematic phytosanitary inspections, in respect of all products;
- Relocation of phytosanitary inspections from the border to inside the MS of destination;
- Restriction in respect of identity checks;
- Deletion of "one-third"-rule practice (of that time, i.e., before Schengen) for "occasional" phytosanitary inspections;
- Phasing out of all documentary and identity checks between MS, starting with Schengen countries.

Amendment of the regime at the 1993 introduction of the single internal market

The CPHR in its original shape needed major amendment so as to line up with the unanimously adopted concept of the Single Market, which was to be established by 1993. This concept basically included the idea of assimilating, for movement of goods, the entire Community territory to that of a single country. It was at that time believed that frontier customs posts would not be maintained solely for plant health reasons.

Re-assessment of the balance between free trade and prevention

The major changes needed necessitated to review the philosophy of the CPHR. It had long been recognized that *the CPHR needs to strike a balance between the commercial need for unhindered trade in plants and plant products, and the necessity of preventing the introduction of harmful organisms into, and their spread within areas where they are not established*. Historically, this balance had been achieved in EC by consensus where possible and elsewhere by permitting MS to retain their own high(er) level of plant health protection. The Commission developed a new strategy, which was set out in various documents such as the Commission's White Paper "Completing the Internal Market" of 1985 (COM(85) 310 final), the Commission's Communication on the new strategy in the field of plant health of 1987 (COM(87) 97 final) and finally its proposals amending the Community main plant health Directive (COM(89) 646 final). The development of a new strategy involved a re-negotiation of the above-mentioned arrangement and required re-assessment of the balance.

Main elements of the new strategy

According to the official communication of the Commission, the objective of the new strategy in the field of plant health (harmful organisms) was *to reconcile the interest of free circulation of plants/plant products within the Community with a minimum of prohibitions, restrictions and other formalities, with the prevention of the introduction or the spread of harmful organisms into areas where they are not established and where they would present a risk to plants planted or otherwise growing there*.

The essential elements of the new strategy and philosophy were as follows:

- The establishment of common plant health standards for domestic and intra-Community trade;
- The transfer of checks from internal borders to places of production and for third country products, to eternal Community frontiers;
- The issue of a "plant passport" for all movements within EEC, replacing phytosanitary certificates for intra-Community trade;
- The definition of protected zones at particular risk;
- The establishment of a system of official checks during marketing;
- The establishment of a Community plant health inspectorate to oversee the regime;
- The establishment of a system of Community financial assistance and of certain rules of liability in respect of plant health[69].

The result of the new strategy would be the free movement of plants, plant products or other objects throughout the Community, of course subject to the rules of protected zones.

Community production

Scope

The new standards to be introduced by 1993 for EC production would be restricted to "Community quarantine organisms", i.e. harmful organisms which are known to occur in

[69] The system of Community financial assistance aimed to share at Community level the burden of possible risks which might remain in trade under the new regime. It provided for adequate contributions to certain expenses for specific measures which MS had adopted to control infections my harmful organisms introduced from another MS. It was linked to the concept f financial liability, in which a consignor MS shall refund any Community financial contribution and, in certain cases, part also of the expenditure of control or eradication incurred by the infected MS, in case where it is established that the required inspections or examinations were carried out inadequately in that MS.

certain parts of the Community, but which are neither widespread in the whole Community not otherwise out of control.

The standards to be introduced by 1993 for EC production would not concern "extra-Community quarantine organisms" not known to occur in the Community[70], and neither "quality organisms" (harmful organisms widespread or otherwise out of control and therefore reducing the quality or usefulness of infected plants/plant products, but not representing by virtue of such infection a particular risk for other plants).

The list of harmful organisms subject to control should be reduced to those of genuine quarantine concern[71], and the list of products subject to control should be limited to carriers of these quarantine organisms which represent a serious threat of their establishment at the place of destination. The standards would therefore apply solely to material intended for planting, and selected material for consumption of particular plant health concern, such as wood, potatoes and citrus, as well as ornamentals (cut flowers, branches) of certain species[72].

Introduction of the plant passport
Material meeting the standards would receive a so-called "plant passport", permitting the free circulation of material once certified free of disease at the place of production. This would be a conventional marking system adapted to the type of product and attached to the product, or to the packaging or to the vehicles transporting them and replacing the phytosanitary certificate in intra-Community trade. The plant passport could take the form of a certificate, a label, a band/stamp or a seal (details as then yet to be established).

Material which would not comply with the Community standards would not receive the plant passport and would be subjected to official measures (appropriate treatment, destruction, permit for movement under official control to designated places or areas where they do not represent an additional risk). The listing of the producer in the official register was to be suspended until it would be established that the risk of spreading harmful organisms was eliminated.

The official authorities responsible for issuance of the plant passport were allowed to be:
- The official plant protection service of a MS;
- Any other public authority established at national or regional level, or
- Any legal person, public or private, exclusively charged with specific public tasks, or created on behalf of the official services.

The plant passport could be produced, printed and stored by the authorities or by the producers, under official supervision. The producer would himself affix the plant passport to the commodity.

[70] Nowadays “extra-Community quarantine organisms are included in the standards for Community production provided by the CPHR and the Marketing Directives.
[71] The only criteria to be used were the latest scientific assessments of the health risk posed by these organisms.
[72] In an EC without MS border controls of any sort, it would not in theory be possible for MS to have varying plant health standards and requirements. These consequently had to be harmonized and supplemented by specific standards, agreed at Community level, relating to climatic and geographic factors and the distribution of pests and diseases. The Commission suggested that this should be achieved by reducing the amount of material to which standards would be applied to planting material and certain finished products, such as wood, potatoes, citrus fruit, where the pest and disease risk is greatest. To keep the system practical without causing significant plant health problems, various plants and plant products that at that time were being controlled would have to be excluded from the system (some fruit, most pot plants, finished plants for final use, vegetables, cut flowers).

A logic for replacement passports was developed, with a shared responsibility of industry and authorities.

Outline of new requirements for inspection and testing
MS were supposed to organize official checks on compliance with the provisions of the new CPHR at random, without any discrimination in respect of the origin of the material. These checks might be regular or targeted if facts had come to light to suggest non-compliance. The checks would take place at any place where plants are moved, grown, produced, stored or offered for sale, as well as on the premises of purchasers.

Compliance with the standards and requirements would be checked at the most appropriate places, i.e. at the place of production, and at the most appropriate times, i.e. during the growing season and where appropriate, after harvest. These checks would be mandatory at these places, and would not be made on a consignment base, but on a producer base. This would require a producer registration system[73]. No distinction would be made any longer in checks for domestic of for intra-Community trade purposes. Official examinations would have to be made regularly at appropriate times, at least twice a year. They would have to be made at least by visual observations; in case of doubt or when there are specific requirements to be fulfilled, the specific examinations would have to be made by appropriate testing on samples.

Establishment of regionalisation principle
The new philosophy foresaw special arrangements to take account of differing pest and disease situations and differing crop and growing conditions within the Community. The Commission suggested the establishment of "ecological regions" exposed to a relatively uniform plant health risk as determined by similar ecological and agricultural conditions and the presence of potential host plants and vectors or harmful organisms, or "isolated zones" (later called "protected zones") which are areas where particular harmful organisms established elsewhere in the Community are not known to occur. Checks at boundaries of ecological regions or isolated zones would be possible on a systematic base, provided that these boundaries are properly marked with appropriate traffic signs.

The regionalization principle[74] would also apply to outbreaks. It was expected that third countries would accept the regionalization principle on a reciprocal basis and that this concept offers sufficient guarantees for trade to continue from the remaining areas of the Community.

MS might exempt the local movement (restricted to the territory of the local administratibe area where the premises of the procedures are located and of the adjoining local administrative areas) of material from official examination and registration.

Establishment of Community plant health rules for marketing of propagating material
The Community acts laid down certain plant health standards for the marketing of young plants and propagating materials of various plant types such as fruit plants, ornamentals and vegetables. These only applied to trade between MS, not to MS' domestic production. This

[73] This would also allow for tracking and tracing of findings of harmful organism.

[74] The Commission noted in 1992 that in the veterinary field, regionalisation is considered to mean the application of strict controls to a part of the Community to control and eradicate a disease while preventing spread to other areas, thus permitting free movement of animals and products outside the affected area. In the plant health field, "protected zones" are zones where particular harmful organisms established elsewhere in the Community are not endemic or established (or: zones in which there is a danger that certain harmful organisms will establish themselves, given favourable ecological conditions, despite the fatc that these organisms are not endemic or established in the Community).

phenomenon had led in many MS to the introduction of national rules intended to guarantee the quality and health of such materials, which were thus accorded different treatments in different MS. Barriers to trade and free movement of these goods within the Community might arise.

This problem was solved by introducing new marketing schemes. In summary:

- The standards would be applicable to material marketed in intra-Community trade and in the domestic trade of MS;
- To ensure that material subject to the scheme was properly produced and stored, suppliers had to comply with certain requirements such as registration, they had to permit inspections, they had to keep records of specific treatments and methods of cultivation as well as of all occurrences of designated harmful organisms and all measures taken in consequence;
- The material had to comply with among others quality conditions and all plant health conditions;
- MS had to ensure compliance with the requirements mentioned above by carrying out official check inspections, but there had to be systematic official inspections of the material to ensure compliance with the plant health conditions;
- Compliance with the Community standards would be attested by official certification (*in the sense of the Seed Marketing Directives*), following official examination of the material concerned;
- Material which complied with the requirements and conditions of the plant quarantine and seed marketing regulation(s) might move freely throughout the Community.

The certification and marketing standards were to include plant health requirements for issuance of the plant passport, so as to avoid production inspection by two different authorities, those for plant health and those responsible for plant quality.

Third country production

Additionally, a uniform and strengthened control would be put in place at external borders for imports from third countries, since once within the Community products could circulate freely. The import controls aimed at preventing the introduction into the Community of harmful quarantine organisms not known to occur there, through systematic checks or formalities at the external borders of the Community. It would also cover "Community quarantine organisms". The compliance with the requirements would as before be certified on an international (IPPC model) phytosanitary certificate, issued by the third country involved.

In the case of satisfactory checks, these products would be subsequently assimilated to Community production, in respect of the plant passport system. The Commission would monitor or carry out this control together with the MS and envisaged stationing inspectors in third countries in order to streamline and facilitate the inspection.

Arrangements between the Community and certain third countries may be made with a view to transferring import checks from the external border of the Community to the third country of production (preclearance inspections).

Collection and distribution of scientific and technical information

All parts of the Community were to be brought to the highest possible scientific and technical level in the field of plant health. Information available must be made accessible to others. Where information is lacking, it should be sought.

The Commission launched a programme of coordinating and financing scientific / technical activities with a view to developing appropriate tools (e.g. diagnosis, identification and detection methods) and harmonizing these. A legislative basis was to be prepared for this programme, to ensure its continuity and permanence.

Manpower implications of the 1993 regime for inspection and certification

Significant manpower implications were foreseen by the Commission from the introduction of the amended CPHR for inspecting and certifying all propagating material produced in the Community, checking that no uncertified material is on sale, making investigations and checking at the borders for imports from third countries.

The Commission provided in this respect two kinds of actions:

- The establishment of a Community plant health inspectorate[75];
- The creation of the possibility for MS to use for the purpose of plant health checks available official manpower other than that of MS' official plant protection organizations.

The Commission would also coordinate at Community level the training of persons employed as "qualified agents". Within the limits of the appropriations available for that purpose in the Community budget, the Commission would support financially the training of those agents.

Amendment of the regime since 1993

Since 1993, the CPHR has been amended several times. The major amendments have been:

- The codification of Council Directive 77/93/EEC, resulting in the new Council Directive 2000/29/EC;
- The revision of the import regime and introduction of reduced frequency checks in 2002, to be implemented from 1 January 2005;
- The replacement of Council Directive 69/465/EEC on the control of potato cyst nematodes by Council Directive 2007/33/EC;
- The accession of the twelve new Member States in 2004 and 2008, with transitional plant health arrangements.

[75] The system involved experts acting as Community plant health inspectors, being employees of the Commission or employees of MS put at the disposal of the Commission on a temporary or ad-hoc basis. They would monitor examinations carried out by consignor MS, monitor or carry out import inspections from third countries, set up a Community information and warning network, examine cases which involve safeguard measures, and establish guidelines for a Community inspection manual.

Annex IV: Categorisation of harmful organisms in the Community Plant Health Regime

Current categorisation of harmful organisms

The CPHR defines harmful organisms as "any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products" (Council Directive 2000/29/EC, Article 2(1)(e)).

In its current form, the CPHR distinguishes between harmful organisms whose introduction into, and spread within, all Member States shall be banned, either in all cases (those listed in Annex I of Council Directive 2000/29/EC) or only if present on certain plants and plant products (those listed in Annex II). The rationale for this distinction is that the probability of entry and establishment of the latter group of harmful organisms depends on the commodity involved. A zero tolerance is applied for all listed harmful organisms. The zero tolerance is applied for harmful organisms listed in Annex II only when the harmful organism is encountered on listed commodities / host species, but not when it is found on other commodities / host species.

Distinction is made between on the one hand harmful organisms not known to occur in any part of the Community and relevant for the entire Community (Section I of Annex I and Section I of Annex II), and on the other hand harmful organisms known to occur in the Community and relevant for the entire Community (Section II of Anex I and Section II of Annex II).

In the case of protected zones (PZ), provisions also depend on the location where findings of harmful organisms are made (provisions for PZ are given in Annex I, Part B and in Annex II, Part B). Such PZ are considered free from specific harmful organisms and findings of these harmful organisms within the PZ and its buffer zone must be eradicated. Findings of the same harmful organisms outside the PZ and its buffer zone do not require measures, except when the harmful organism is also listed in Part A (for instance: *Erwinia amylovora*).

Original 1993 categorisation criteria (based on historic Commission documents)

At the time that the CPHR was revised to accommodate for the 1993 introduction of the single internal market, the following intervention logic was developed for the categorisation of harmful organisms[76]:

- For Community production, the CPHR standards[77] would be restricted to "Community quarantine organisms" known to occur in certain parts of the Community, but neither widespread in the whole Community nor otherwise out of control. The standards

[76] A new strategy in the field of plant health (harmful organisms), COM(87) final, 10 March 1987; The implications of the EC plant health regime post 1992 (by M. Vereecke), 921/VI/90-EN, 1990; Developments in Community legislation on plant health in the context of the completion of the internal market (by Dieter Obst), 3005/VI/90-EN, 9 March 1990; The regulatory bases for a plant health strategy to 1992 (by J. Gennatas), 1044/VI/91-EN, 11 April 1991; Le passeport phytosanitaire communautaire (propositions – réflexions), PVNA/FR/0148, Novembre 1991; The EC single market – A new strategy in the field of animal and plant health, VI/B/II, February 1982.

[77] The standards for "Community quarantine organisms" would apply solely to material intended for planting, and selected material for consumption of particular plant health concern, such as wood, potatoes and citrus, as well as ornamentals (cut flowers, branches) of certain species.

would not concern "extra-Community quarantine organisms" (quarantine organisms which are not known to occur in the Community) and "quality organisms" (harmful organisms which are widespread or otherwise out of control and therefore reduce the quality or usefulness of infected plants/plant products, but do not represent, by virtue of such infection, a particular risk for other plants);

- For import (third country production), the CPHR standards[78] would require freedom from "extra-Community quarantine organisms" and also cover "Community quarantine organisms".

The criteria applied were apparently:

- Presence or absence of harmful organisms in the Community;
- Extent of spread of harmful organisms within the Community;
- Whether or not harmful organisms were out of control in the Community;
- Whether or not quality-affecting harmful organisms present a particular risk to other plants.

In addition, Community rules were established for the marketing of various plant types (plants and planting materials of fruit plants, ornamentals and vegetables). This was done because existing Community acts at that time applied only to trade between Member States, not to domestic production, resulting in diverse national rules for the quality and health of such material and barriers to free movement of such goods within the Community. The new marketing schemes included certain plant health provisions and combined plant health and quality aspects in one text. Compliance with the Community standards would be attested by official certification, following official examination of the material concerned[79]. The quality standards for marketing would include health requirements for issue of the plant passport, so as to avoid production inspection by two different authorities, those for plant health and those responsible for plant quality[80].

The current Community regime for Seed and Propagating Material thus overlaps with the CPHR as concerns plant health requirements. It includes zero tolerance provisions for some harmful organisms (partly the same as in the CPHR, partly additional ones) as well as tolerances / threshold levels for others[81].

[78] The standards for "extra-Community quarantine organisms" would apply to specified plants/plant products from third countries.

[79] European Commission (1990), The implications of the EC plant health regime post 1992, 921/VI/90-EN; European Commission (199), Developments in Community legislation on plant health in the context of the completion of the internal market, 3005/VI/90-EN.

[80] European Commission (1991), The regulatory bases for a plant health strategy to 1992, 1044/VI/91-EN.

[81] The Marketing Schemes generally require that plant material is "substantially free" from harmful organisms, with the exception of harmful organisms listed in the Annexes of the Marketing Schemes, for which zero tolerance is required. Only for specific pests of potato and vine, threshold levels have been defined.

Annex V: Summary of the phytosanitary acquis

The acquis consists of a single basic Council Directive, four additional Council Directives concerning specific harmful organisms of potato, part of them being consolidations of earlier Directives; a Council Regulation on food and feed controls, and the IPPC convention and the WTO-SPS agreement:

- 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 against their spread within the Community
- Council Directive 69/464/EEC of 8 December 1969 on control of Potato Wart Disease
- Council Directive 2007/33/EC of 11 June 2007 on the control of potato cyst nematodes and repealing Directive 69/465/EEC
- Council Directive 93/85/EEC of 4 October 1993 on the control of potato ring rot
- Council Directive 98/57/EC of 20 July 1998 on the control of *Ralstonia solanacearum* (Smith) Yabuuchi et al.
- Regulation (EC) No. 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
- Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reach in the Uruguay Round multilateral negotiations (1986-1994)
- Council Decision 2004/597/EC of 19 July 2004 approving the accession of the European Community to the International Plant Protection Convention, as revised and approved by Resolution 12/97 of the 29th Session of the FAO Conference in November 1997

Some Council Directives have been amended or replaced:

- Council Directive 2002/89/EC of 28 November 2002 amending Directive 2000/29/EC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community
- Council Directive 2005/15/EC of 28 February 2005 amending Annex IV to Directive 2000/29/EC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community
- Commission Directive 2006/56/EC of 12 June 2006 amending the annexes to Council Directive 93/85/EEC on the control of potato ring rot
- Commission Directive 2006/63/CE of 14 July 2006 amending Annexes II to VII of Council Directive 98/57/EC on the control of Ralstonia solanacearum (smith) Yabuuchi et al.
- Council Directive 2007/33/EC of 11 June 2007 on the control of potato cyst nematodes and repealing Directive 69/465/EEC

Two Commission Regulations exists and one Commission Recommendation:

- Commission Regulation (EC) No. 1756/2004 of 11 October 2004 specifying the detailed conditions for the evidence required and the criteria for the type and level of the reduction of the plant health checks of certain plants, plant products or other objects listed in Part B of Annex V to Council Directive 2000/29/EC

- Commission Regulation (EC) No 690/2008 of 4 July 2008 recognising protected zones exposed to particular plant health risks in the Community
- Commission Recommendation 2006/565/EC of 11 August 2006 on containment programmes to limit the further spread of *Diabrotica virgifera* Le Conte in Community areas where its presence is confirmed

The acquis also contains a number of (implementing) Commission Directives and Regulations and is completed by Decisions and Recommendations (Council and Commission). Particularly important are the Decisions on derogations and emergency measures as well as four Directives that provide basic elements of the phytosanitary acquis:

- Commission Directive 92/90/EEC of 3 November 1992 establishing obligations to which producers and importers of plants, plant products or other objects are subject and establishing details for their registration
- Commission Directive 92/105/EEC of 3 December 1992 establishing a degree of standardization for plant passports to be used for the movement of certain plants, plant products or other objects within the Community, and establishing the detailed procedures related to the issuing of such plant passports and the conditions and detailed procedures for their replacement
- Commission Directive 93/51/EEC of 24 June 1993 establishing rules for movements of certain plants, plant products or other objects through a protected zone, and for movements of such plants, plant products or other objects originating in and moving within such a protected zone
- Commission Directive 94/3/EC of 21 January 1994 establishing a procedure for the notification of interception of a consignment or a harmful organism from third countries and presenting an imminent phytosanitary danger
- Commission Directive 2008/61/EC of 17 June 2008 establishing the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V to Council Directive 2000/29/EC may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections (Codified version of Commission Directive 95/44/EC)

The acquis as it existed in 2007, but excepting derogations for third countries and Community financial support to MS decisions, can be found in Appendix 2 of Commission Decision 2008/86/EC (=Decision No. 1/2008 of the Joint Committee on Agriculture set up by the Agreement between the European Community and the Swiss Confederation on Trade in Agricultural Products).

A list of the acquis will be provided on request.

Annex VI: List of key stakeholders (*not exhaustive*)

Growers

- COPA-COGECA
  Pekka Pesonen, Secretary General
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  Contact persons:
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  E-mail: pekka.pesonen@copa-cogeca.eu
  -- Roxane Feller, Senior Policy Advisor, Phytosanitary Affairs
  E-mail: roxane.feller@copa-cogeca.eu

- International Association of Horticultural Producers (AIPH)
  Committee for Environment & Plant Health
  Mr. George Franke, Secretary
  P.O. Box 1000, 1430 BA Aalsmeer, The Netherlands
  Tel: +31297395007 / Fax: +31297395012
  E-mail: g.franke@vbn.nl
  www.aiph.org

- The Global Partnership for Safe and Sustainable Agriculture (GLOBALGAP; formerly EurepGap)
  GLOBALGAP Secretariat
  c/o FoodPLUS GmbH
  P.O. Box 190209, 50499 Cologne, Germany
  Tel: +492215799325 / Fax: +492215799389
  www.globalgap.org

Breeders

- CIOPORA
  Dr. Edgar Krieger, Secretary General
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  Tel: +494055563702 / Fax: +494055563703
  E-mail: info@ciopora.org / edgar.krieger@ciopora.org
  http://www.ciopora.org
  International community of breeders of asexually reproduced ornamental and fruit varieties

- EUROPEAN SEED ASSOCIATION (ESA)
  Garlich Von Essen, Secretary General
  Rue du Luxembourg 23/15, 1000 Brussels, Belgium
  Tel : +3227432860 / Fax: +3227432869
  E-mail: vonessen@euroseeds.org
  www.euroseeds.org
  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.

Traders

- Comité du Commerce des céréales, aliments du bétail, oléagineux, huile d'olive, huiles et graisses et agrofournitures (COCERAL)
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- UNION FLEURS
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Forest and wood packaging industry

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  Tel: +31135944802 / Fax: +31135944749
  E-mail fefpeb@wispa.nl
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- CEI-Bois
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  www.cei-bois.org

Logistic companies

- European Association for forwarding, transport, logistics and customs services (CLECAT)
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  Tel: +32 2503 4705 / Fax: +32 2503 4752
  E-mail: info@clecat.org
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- International Roadtransport Union (IRU)
  Mr. Martin Marmy, Secretary General
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  1040 Brussels, Belgium
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  E-mail:brussels@iru.org
  www.iru.org

- European Shippers' Council (ESC)
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Pesticide companies

- European Crop Protection Association (ECPA)
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  Tel: +3226631550 / Fax: +3226631560
  E-mail: friedhelm.schmider@ecpa.eu
  www.ecpa.be
  The European Crop Protection Association (ECPA) is the pan-European voice of the crop protection industry. Its members include both national associations and companies throughout Europe, including Central and Eastern Europe.

Insurance companies

- Comite Europeen des Assurances (CEA)
  Michaela Koller, Director General
  Square de Meeûs 29, B-1000 Brussels, Belgium
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  E-mail: koller@cea.eu
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Non Governmental Organisations (NGOs)

- European Initiative for Sustainable Development in Agriculture (EISA)
  Mr Robby Schreiber, EISA c/o gani-med
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  E-mail: gani-med@skynet.be
  www.sustainable-agriculture.org

- IFOAM EU Group (IFOAM)
  Objective: to promote within the EU the principles and practices of organic agriculture and food production as set out in the IFOAM Standards
  Rue du Commerce 124, BE - 1000 Brussels, Belgium
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  E-Mail: info@ifoam-eu.org
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- Forests and the European Union Resource Network (Fern)
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  Tel: +3227330814 / Fax: +3227368054
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- European Environmental Bureau (EEB)
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- World Wildlife Fund (WWF)
  WWF European Policy Office
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Annex VII: List of Member State delegates to the Council Working Party of Chief Plant Health Officers

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International Plant Protection Convention
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European and Mediterranean Plant Protection Organisation
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Contact persons:

- Mr. Nico van Opstal, Director General
- Ms. Francoise Petter, Deputy Director General

Many relevant activities and panels, among others on phytosanitary measures, on laboratories, on quarantine pests for forestry, on pesticides etc.

European Food Safety Authority
Largo N. Palli 5/A (on the Viale Mentana), I-43100 Parma, Italy
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Contact persons:

- Ms. Rita Majala, Director Risk Assessment
- Ms. Elzbieta Ceglarska, Head of Unit, Plant Health

Note that the expertise of EFSA not only covers plant health, but also pesticides safety and approval.

International Organisation for Biological and Integrated Control of Noxious Animals and Plants, West-Palaearctic Regional Section (IOBC-WPRS)
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International Seed Testing Association (ISTA)
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Zürichstrasse 50, 8303 Bassersdorf, CH - Switzerland
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E-mail ista.office(at)ista.ch
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Plant health science support initiatives

- ERA-net EUPHRESCO
  Framework Programme 7 project for coordination of MS funding for plant health research
  Mr. Alan Inman (project coordinator), Central Science Laboratory, Sand Hutton,
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- PRATIQUE
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Further information might also be obtained from the Standing Committee on Agricultural Research (SCAR). See http://ec.europa.eu/research/agriculture/scar/index_en.cfm.

Annex IX: List of Steering Group members

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- Mr. José María Cobos Suarez (ES)
- Mr. Martin Ward (UK)
- Ms. Laure Le Bourgeois (FR)
- Ms. Tiina-Mari Martimo (FI)