







STUDY ON THE ESTABLISHMENT OF A EUROPEAN FUND FOR MINOR USES IN THE FIELD OF PLANT PROTECTION PRODUCTS

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FINAL REPORT

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The views expressed are those of the Consultant

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ABBREVIATIONS

a.s.	Active substance
CA	Competent authority
СОМ	European commission
COPA-COGECA	Farmers and cooperative union
EC	European commission
EU	European union
EWG	Experts working group
FCEC	Food chain evaluation consortium
IA	Impact assessment
MRL	Maximum residue level
MS	Member state
NCA	National competent authority
PPP	Plant protection product
SANCO	Directorate General for consumers and health
SC	Steering Committee
SOLA	Specific off-label approval
TS	Technical secretariat
ToR	Term of references
TWG	Technical working group
VDMC	Van Dijk Management Consultants
WG	Working group

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EXECUTIVE SUMMARY

This summary contains the main conclusions of the "Study on the establishment of a European fund for minor uses in the field of plant protection products". The research was conducted by the Food Chain Evaluation Consortium (FCEC) during the period January 2011 – July 2011.

The context of the study

The new Regulation (EC) No 1107/2009 on the placing on the market of plant protection products that has entered into force on the 14th of June 2011 is requiring in its Article 51(9) that "by 14 December 2011, the Commission shall present a report to the European Parliament and to the Council on the establishment of a European fund for minor uses by the end of 2011, accompanied, if appropriate, by a legislative proposal".

In support to the drafting of this report, the EU Directorate General for Health and Consumers launched an external study in January 2011. The consulting team was provided by the FCEC under the leadership of Arcadia International in narrow collaboration with Van Dijk Management Consultants (VDMC).

The objectives of this study are twofold and aim at:

- 1) Collecting information on minor uses in the EU to estimate the current and future economic importance of the issue; and more particularly on the following topics:
 - Current interpretation of "minor uses" and its application in MS;
 - List of crops and plant protection problems for which no PPPs are authorised (inventory of issues);
 - Quantitative and qualitative economic and agronomic information on minor uses in order to evaluate the importance of the potential problems (economic quantification of the issues);
 - Identification of the problems and obstacles faced by MS with the existing process;
 - National approaches and actions developed by MS including specific funding;
 - o Proposals for a EU-coordinated action on minor uses;
 - Expected impact of the new regulation for placing PPP on the market in relation to minor uses issues.
- 2) Identifying different options on the establishment of a European fund which could address the problem of minor uses. For each option, including the "status quo" option (i.e. leaving the resolution of minor uses problems to initiatives undertaken by MS with no action at EU level, including the opportunities offered by the new regulation), a general analysis of the costs and benefits and of the strengths and weaknesses of their implementation has to be completed.

In order to carry out this assignment, the FCEC developed a methodological framework which was based on the following key phases:

- An initial phase of desk research combined with a preliminary survey addressed to all national competent authorities (NCA) in order to identify all targets to be contacted during the study;
- A large scale consultative exercise with government representatives, industry,
 NGOs and other actors across the EU through a detailed questionnaire and indepth interviews;
- A data gathering consultation that provided evidence to support the analysis;
- A workshop with national competent authorities and EU stakeholders to discuss opportunities on setting-up a coordinated EU action supported by a EU fund;
- A second consultation exercise based on field visits in ten EU Member States to further analyse needs and current experiences and to gather views of NCAs and national stakeholders on the proposed options.

This final report explores the extent to which the issue related to the lack of PPPs is of significance for crop productivity in the EU and analyses how a coordinated EU action supported by an EU fund could operate and at which costs.

The current situation in the EU 27 MS

A modified EU regulatory framework regarding the placing on the market of PPPs

This study is placed in the context of regulatory changes that will impact the placing on the market and the use of PPPs. Within the new "pesticides package" which is entering into force in 2011, the Commission has introduced a proposal for a Regulation (Regulation (EC) No 1107/2009) revising the 1991 Directive (91/414/EEC) on the placing of plant protection products on the market, and a proposal for a Framework Directive on the sustainable use of pesticides (Directive 2009/128/EC). This comes in addition to the new Regulation addressing maximum residues limits which came into force on September 1st 2008 and requiring MRLs to be set at EU level before any PPP authorisation can be granted in a MS.

Minor uses issues: what are we talking about? Some confusions...

The current definition of a "minor use" as set out in the EU guidance document SANCO 7525/VI/95 has been specifically developed in support to the setting of maximum residue levels for minor crops. For a majority of the interviewees this definition does not fully address the problem of lack of PPP for certain uses and consider that a separate definition should be developed.

Firstly, any problems related to the lack of crop protection solutions for a given use should be considered as part of a coordinated EU action covered by a EU fund and not only the ones addressing minor crops as defined today at national level.

Secondly the term "minor use" may lead to the impression that the issue is economically also minor when in reality it concerns high value crops such as fruits and vegetables, ornamentals plants, and aromatic plants for which the EU 27 MS production is valued for at more than €70 billion per year on a total output value at producer price of the agricultural sector estimated at €317 billion.

Eventually, in the context of the new Regulation that introduces a zonal authorisation approach, it is considered by stakeholders that the list of minor uses should be defined at zonal level rather than at national level.

New provisions of Regulation (EC) No 1107/2009 are perceived as interesting instruments to partly solve minor uses issues but mutual recognition of existing PPPs is not expected to improve

Provisions of the new Regulation are assessed positively when related to Article 51 (application for an extension of use). More particularly, interviewees consider that extension of the data protection by three months for each minor use application is a significant incentive for the PPP industry. On the other hand, for growers, extension should remain an exception as they see a risk that the PPP industry will use this article to stop applying for minor uses authorisations and leave the burden and the liability to users as under this article the responsibility is being shifted to applicants, being growers or producers.

Provisions of Article 40 on mutual recognition are expected to be efficient within an authorisation zone (intra-zonal authorisation) for PPPs based on new active substances but not for existing PPPs as very few MS have drafted the assessment report required for any mutual recognition application and as the variability of assessment procedures between the different national agencies will make that data produced in one MS probably may not be acceptable by another MS.

Finally, all actors are expecting that more active substances will be withdrawn from Annex I of the PPP Regulation inducing new minor uses issues. A few limited studies have analysed that about 18 to 22 active substances may be lost in the coming years due to additional safety criteria (cut-off criteria).

The support for the creation of a EU fund is high

About 96% of the respondents to the general survey declare that they are in favour of the establishment of a European fund to coordinate activities that address minor uses issues within the EU, underlining the fact that Member States recognise the impact and comprehensiveness of issues caused by minor uses.

While most of the respondents have a clear view on the type of coordinated activities that should be financed by the fund, very few of them have estimated the level of funding necessary for the set-up and running of this fund.

The geographic distribution of minor use issues is not uniform at EU 27 MS level

Minor use issues are mostly observed on minor or speciality crops including most vegetables, fruits, nurseries and flowers which account for an EU production value of greater than €65 billion per year. The fruit and vegetable sector alone accounts for about €45 billion in the EU 27 MS for a total production of 70 million tons of vegetables and 40 million tons of fruits. The market value for ornamental plants is estimated at €27 billion.

Fruit production is mainly concentrated in the southern authorization zone, counting for about 80% of the total fruit cropping area, followed by the central zone (19%). The northern zone counts for less than 1% of the total EU fruit cropping area.

Vegetable production within the southern zone represents about 50% of the total EU acreage, while the acreage in the central zone reaches 45% of the total EU acreage. Less than 4% of vegetables are cultivated in the northern zone.

<u>Insufficient protection of crops is a problematic situation with various serious impacts on a large group of actors within the EU</u>

The lack of PPP solutions puts at stake the sustainable production of high quality, highly diverse and high value crops which is vital for both securing the future of the European continent's food supply at an affordable price to consumers as also for the EU economy (food sovereignty).

The number of uses that face issues regarding the protection of the crop due to a lack of PPP within the European Union is large; the list of issues collected through the general survey contains in total more than 1,400 cases. This collection must moreover be seen as far from complete since only 15 MS provided information on this part of the survey and most of the data that has been provided is of exemplary nature as comprehensive inventories of issues do not exist at MS.

Quantification of the economic impacts of these issues itself proves to be a time consuming and challenging exercise since impacts are often difficult to assess. These difficulties can be explained by the large number of factors that must be taken into account when assessing the economic damage caused by a lack of PPP and the high level of assumptions that need to be made in most cases. Quantification demands therefore a case-by-base in-depth economic analysis. National competent authorities have often no background and possibilities to conduct these assessments.

The research study leads to the conclusion that the relatively small amount of data does show the importance of minor uses issues from an economic point of view since the total amount of collected direct economic impacts accounts for more than €1 billion per year on in total over 9 million hectares.

Fifteen (15) MS have established national initiatives to respond to the problem

Most of the EU MS have initiated a national coordinated action that cover activities like the establishment and the management of technical working groups involving all actors (public authorities, technical institutes, producers, PPP industry, etc.) or campaigns of a coordinative nature.

Besides these mostly public funded activities some private initiatives exist. They are mostly collaborations between the producers (industry) and the users of PPP (growers) and contain for example a fund in support to the production of residue data within a country. These initiatives appear however very much on an ad hoc basis and meet in most cases specific local needs.

Some Member States (BU, CZ, EE, LV, LT, RO, SL, and FI) have indicated on the other hand that no initiatives addressing minor uses issues are in place. The reason for this absence of initiatives can be found mostly in the fact that there seems to be less or no demand for such activities, or simply in a lack of funding/capacities.

Total funding to support these activities is estimated at €9.8 million per year. This figure doesn't include partner's in-kind contribution of the level which can't be estimated at this stage.

A EU fund: what for?

Before proceeding with the analysis of the opinions of those consulted on the different options for greater support at the European level, it is important to summarise the key priorities for this support that came up during the various consultations. The funding is perceived as being a must in this approach, not only by bringing financial resources to the actors but also as it would be seen as a key commitment from the European Commission in supporting the issue of minor uses and it would ensure strong leadership to the coordinated EU action.

A first priority of support at the European level can be found in the need for better knowledge management, through the development of data sharing tools and communication between actors; as it has been largely highlighted by the respondents. Priorities relate to data sharing and information dissemination — interlinking existing networks and databases, establishing access to databases via a web portal, providing information on relevant policies and regulations, and collating needs. However, the approach should not only focus on the development of data sharing tools and databases,

thinking that actors will use the databases. Some efforts should also be devoted to secure that actors will fully use the tools and that communication between CA, risk assessment agencies and stakeholders is becoming efficient.

The second priority would be to fund EU projects leading to solving individual issues. When most policy makers consider that setting-up data sharing tools may be sufficient in solving most of the minor uses issues, both PPP industry and producers/growers are of the opinion that the EU should also fund individual projects leading to the solving of minor use issues of EU importance.

How to set-up this coordinated EU-action supported by a fund?

On the basis of these main priorities, four options related to the tasks to be financed by an EU fund are considered and two options are considered for the governance approach.

The following options were examined regarding tasks to be covered by the EU fund:

- Option 1 Status quo
 No EU financial support. Coordination and EU efforts continue on a voluntary basis.
- Option 2 "Limited" EU support
 EU budget is granted to facilitate meetings of the North and South Working Groups
 (back to the 2001-2009 situation).

- Option 3 - "Moderate" EU support

Encompassing option 2 plus EU funding for the strengthening of the development and management of the cooperation instruments (e.g. centralised databases) and the activities at the level of the TWGs + Steering Committee (SC) through the establishment of a Technical Secretariat.

- Option 4 - "Strong" EU support

Encompassing option 3 + EU financial support for project execution + TWG coordinators are part of the Technical Secretariat.

From the outset, it was considered that options 2 to 4 are not conflicting options but cumulative and that within each of these options a number of specific tasks should be developed and possibly assessed individually, which could lead to the partial redefinition or re-arrangement of certain options, in particular the preferred option.

Under option 3, the idea of setting-up a Technical Secretariat has been introduced as it has been highlighted by many stakeholders and NCAs that a centralised means for collecting and analysing data and for coordinating the organisation of the TWGs and SC meetings is required. This approach would allow a "one stop shop" and would bring visibility to the action.

This TS can be established in two different forms:

- Option a:

The Technical Secretariat is part of an existing organisation (COM, MS governmental body, research institution, technical institute, etc.) in which the organisation is responsible for the secretariat and should report to the Steering Committee;

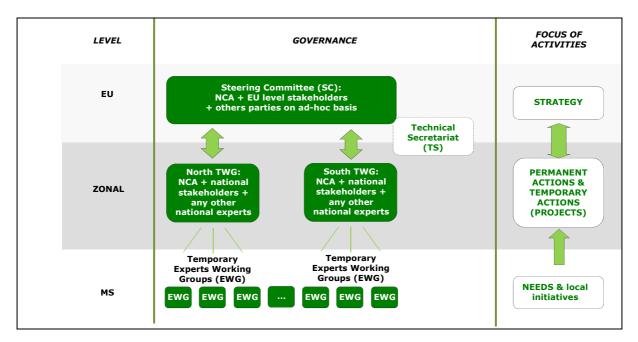
- Option b:

The Technical Secretariat, guided by the SC, is attached to a hosting organisation that provides housing and other services, but has no formal say over the work of the Technical Secretariat.

These two different options are not handled separately, but are integrated in the overall options definition according to the following approach:

	Option 1	Option 2	Option 3	Option 4
Option a	Not applicable	Not applicable	Option 3a	Not applicable
Option b	Not applicable	Not applicable	Option 3b	Option 4

The governance of the action will be as follows:



Overall preference on the proposed options

All interviewees were asked which of the four options concerning the creation of an EU fund they favoured. The results from the survey are presented in section 2. Additional results from field visits show:

- A very clear rejection of option 1 and option 2;
- Policy makers support in majority the option 3. When CAs from "large" MS recognise that the system should evolve mid to long term to option 4, CAs representatives from "small" MS do not see any added values in moving to option 4 as none of their projects would be considered as a priority by the EU fund;
- A clear preference for option 4 for a large majority of the producers and growers and for the PPP industry.

The views of the overwhelming majority of stakeholders and CA representatives were that a EU fund holds a significant potential, but that a radical step forward from the 2001-2009 period is needed.

The status quo option (option 1) is rejected by a large majority of actors

The research study demonstrated an overwhelming rejection of the « no action » scenario. A large majority of those consulted saw no advantages in taking no action, except that it would be easy and cheap for the Commission services. Under this option, difficulties faced by producers and growers in the field of crop protection would remain un-addressed if no action at national level were taken. The number of problems will further grow as the number of active substances (a.s.) will continue to decrease and that possible resistances may appear for uses for which only one a.s. is authorised. Taking no action would represent a step backwards in relation to the current situation in Europe as to date the majority of stakeholders and NCAs has the impression that the Commission has understood the emergency of the issue and is willing to act. By doing nothing the Commission will deliver the message that, after analysis of the situation, it has decided not to support any activity addressing the solving of the issue. Further, under option 1, the number of derogations will increase leading to a more negative perception of consumers towards PPP.

Coming back to the 2001-2009 situation (Option 2) is not seen as being sufficient

The consultation phase of the study revealed low support for the re-establishment of the 2001-2009 situation even if it was recognised by a majority of the interviewees that it would be a strong improvement compared to option 1. Meetings that took place during the 2001-2009 are considered by interviewees as largely cost-effective as they helped experts from all MS to exchange on the current situation in their country and on the difficulties to address the issues. Further strengths of option 2 are:

 A network of experts has developed and is today up and running and ready to take a step forward;

- Some improvements in data standardization have been achieved and presentations
 of existing initiatives have helped developing other national approaches;
- The approach of having a two-level structure (SC plus TWGs) allows a correct balancing of the EU and regional representation in the global governance;
- "Bottom-up" or "grass root" approach in identifying needs is facilitated.

The main critic of this approach is based on the fact that after a good set-up, these meetings became places for exchange of ideas and networking and not *fora* in which concrete actions were discussed and agreed. Participation to these meetings is voluntary, leading to the difficulty of formalising the activities of these committees. Networking is also largely based on personal relationship rather than on needs and leadership is not clearly established and the mandate of these committees remains rather vague. A large number of interviewees highlighted that very few concrete actions resulted from these discussions and that very few issues have been solved during that period. Additionally, data sharing tools have not been developed during that period.

<u>Option 3 (moderate EU support) is the preferred option of competent authorities and "small" EU MS</u>

Under option 3, the same governance structure as in option 2 will be re-established and will consist in one SC and two TWGs. In addition, a Technical Secretariat will be created to strengthen the governance of this structure. The TS would operate under the mandate and reporting line of the SC and would act as a support structure, offering project management capacities, responsible for the implementation of the functions of the SC with 2 to 4 staff (this doesn't include the coordinators who are paid by their respective authorities). This secretariat would be responsible for structuring the annual work programme to function as operational action plans for the given year, for the day-to-day implementation of the knowledge management tools, for the organisation of the meetings of the SC and the TWGs and in general liaising with institutions and stakeholders to address specific information needs.

Option 3 would profit from the networking efforts that have been established during the last 10 years. Most of interviewees consider that it is a *continuum* to what was in place in the last years. Establishment of such a platform with the addition of the TS will give credibility and more visibility to the action. It would facilitate to implement activities covered by the EU fund and in particular would help to build a strong reputation as a sound investment to solve minor uses issues and to secure stakeholders and NCAs effective engagement. Under this option, the data sharing tools would materialise as the TS would be in charge in leading the efforts in developing these tools.

For a large majority of the NCA representatives met during the field visits, option 3 is perceived as being largely sufficient to solve most of the current issues even if this option would not solve actual MS protectionism. Producers/growers and the PPP industry are not of

the same opinion as under option 3 projects leading to reducing minor use gaps are not EU funded or co-financed. For these interviewees, option 3 is not directly solving any problems but just putting in place the tools and the governance required for data sharing between MS. Under this scenario, individual projects will have to be initiated by NCAs or/and stakeholders as it is today. This is not being considered as sufficient as involvement of national experts is not guaranteed. Therefore, this option would lead to state-of-the-art data sharing tools with the risk that MS would not take full benefits of them. However, producers and the industry agree that option 3 is a good moving forward as long as option 4 is the long-term objective.

Option 4 that encompasses option 3 and co-finance individual projects is the preferred approach of the PPP industry and of the producers/growers

Under option 4, all tasks carried out under option 3 are implemented. Additionally individual projects with the objective of solving minor uses issues are co-financed and the two technical coordinators are integrated within the TS and paid by the fund.

Option 4 capitalises all advantages that have been listed under the previous options. In addition by having certain projects coordinated and EU funded, the EU fund takes a strategic dimension that did not exist under option 3 and an alignment to the EU PPP policy is possible as control over projects is taken (possibilities to find alternatives to chemical products in the form of non-chemical solutions such as agronomy (e.g. crop rotation) or/and resistant varieties, etc.). Projects will lead to re-enforced collaboration between MS and especially between national agencies in charge of risk assessment. By having the two technical coordinators attached and paid by the fund, the existing conflict of individual interest will disappear. The structure is clear and the governance reinforced. With clearer working procedures the TS will gain in neutrality and therefore in credibility.

Under option 4, the idea would be to copy the in the US existing "IR-4 type of approach" as done by the Canadian and Australian authorities, with the risk that the system becomes too bureaucratic. Another risk is that, due to the emergency of certain situations, all the funds would go directly to projects and knowledge management activities and that the implementation of a strong governance structure, intended to build the long-term roots of the system, would never be done properly. "Small" MS for which minor crops acreage is limited do not see any advantages in option 4 vs. option 3 as they consider that all funds will go to economically important projects only and therefore none of their projects will ever be funded. The question of prioritisation of projects seems also to be a rather difficult task. Who can decide? How to prioritise?

While option 3 seems rather easy to justify at political level, option 4 may be difficult to justify. This point is reinforced by the fact that this research is leading to a non-fully economic quantification of the minor use issues. Though lot of information has been gathered and analysed, the complete overall picture is not established yet.

Implementation costs of each option: What will it cost?

All analysed options show improvements in terms of effectiveness, efficiency, and consistency compared to the status quo (option 1).

As regards to effectiveness, the major difference between the options is the ability to solve structural global minor uses issues and to be aligned to the EU PPP policy strategy. This 'feature' can only be addressed by option 4 – strong EU support.

Regarding feasibility, option 4 must be seen as a rather difficult to implement option whose realisation will need a large amount of efforts and time to be successful. On the other hand is the level of transparency and governance that is ensured by this option rather high. Option 3 has proven to be the most realistic option when it comes to feasibility with an acceptable level of practicability, acceptability, governance and transparency.

As regards to efficiency, the implementation costs and the required budget for the implementation of the options ranges from €44,000 for option 2 to more than €6 million for option 4. Annual recurrent costs for running the TS, maintaining the databases and completing the meetings are estimated at €253,500. This is the total budget of the activity which is co-financed as discussed before.

1. Introduction

This document contains the final report submitted by the Food Chain Evaluation Consortium (FCEC) in respect of the assignment relating to the "study on the establishment of a European fund for minor uses in the field of plant protection products (PPP)".

The study was launched by the Directorate-General for Health and Consumers in January 2011. The consulting team was provided by the FCEC under the leadership of Arcadia International in narrow collaboration with Van Dijk Management Consultants (VDMC) and with inputs from Civic Consulting, both partners of the consortium in the framework contract (Lot 3: Food chain) through which this project was procured.

1.1 Description of the context of the assignment

"Minor use" pesticides are plant protection products (PPP) - fungicides, insecticides, and herbicides - most of time used on low acreage, high value crops (speciality crops), or where pest control is only needed on a small portion of the overall crop acreage. A minor use in one country may be a major use in another country: each MS is responsible for defining its minor uses. These pesticides are most of time used in such small volumes that manufacturers find the sales potential not sufficient for them to seek registration. Indeed, considering the high cost of developing new pesticides, firms invest as a priority in products for major crops like cereals, i.e. in more profitable markets, which secure faster return on investment.

All PPP are developed for major use; after approval of the active substance and authorisation of the product for major use development might continue for minor use. Each of these minor uses carries individual development and authorisation costs that are not covered by the extra sales of the already existing product for this specific use.

Crops grown on small areas include vegetables, fruits, seeds and plant propagating materials, herbs, spices, as well as nursery and landscape plants and flowers. These are often high-value, and are sometimes called "minor crops" because they are grown on significantly smaller areas of land compared to the large acreages of crops like e.g. maize, oilseeds, or wheat. Another term in use is speciality crops.

PPP are placed on the market following a two-step process. Firstly, active substances to be used as PPP are assessed and approved at EU level and secondly, individual PPP containing theses active substances are assessed and authorised by Member States under harmonised rules. Provisions for mutual recognition of PPP approvals are set out in the EU Regulation

(EC) No 1107/2009 to improve free marketing within the EU and especially within a zone¹. Mutual recognition is the process that allows for the harmonisation of product authorisations between MS, provided it can be shown that the agricultural, plant health and environmental (including climatic) conditions relating to the use of the product are comparable in the regions concerned.

The significant reduction of the number of active substances authorised at the EU level, the increased costs of developing new pesticides, and the past imperfect functioning of the mutual recognition principles have intensified the issue of lack of plant protection solutions available to farmers for minor uses for the last 15 years.

When crop protection solutions are lacking, growers may be tempted to use illegal products with potential negative effects on the health of users of PPP and consumers, as well as on the environment. Other negative effects may be the increased risk of development of pesticide resistances and an increasing risk to exceed the Maximum Residue Levels (MRLs) due to illegal and/or excessive use of a limited number of pesticides. Finally, competitiveness is at risk as production of minor crops may be shifted outside the EU as growers would not have proper plant production solutions. In some extreme cases even growing of specific crops outside the EU would deny the European consumer the benefit of use, since the EU MRL would ban access of the produce to the EU market.

Most Member States are concerned by minor uses issues and have for several years initiated actions to overcome them. Additionally, DG SANCO established a coordination platform (expert group on minor uses) in 2002 but these efforts have been suspended in 2009 due to lack of resources.

During the discussions on the revision of the PPP legislation², a large number of Competent Authorities and stakeholders representing the plant protection industry, growers associations, and food chain operators called for financial incentives in the form of a European fund to coordinate European actions to close the minor uses gaps.

The new Regulation (EC) No 1107/2009 on the placing on the market of plant protection products that has entered into force on the 14th of June 2011 has incorporated this demand as Article 51 (9) of this Regulation foresees that the Commission shall present a report to the European Parliament and to the Council on the establishment of a European fund for minor uses by the end of 2011, accompanied if appropriate, by a legislative proposal.

This study is a data collection exercise in support to the writing of this report by the Commission services.

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¹ An authorisation is only valid in the MS where it is given but its zonal evaluation may provide the base for authorisation elsewhere, if applied for.

² Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market

1.2 Objectives

According to the Terms of Reference (ToR), the purpose of the study is to provide the Commission with a comprehensive report on:

- The situation of minor uses in the EU; and
- The possibility to establish an EU minor uses fund.

The objective of this study aims first at collecting information on minor uses in the EU to estimate the current and future economic importance of the issue, and second at identifying different options on the establishment of an European fund which could address the problem of minor uses and including an analysis of the costs and benefits, strengths and weaknesses of each option.

The specific objectives of this study are more particularly:

- <u>Collection of information on minor uses in the European Union.</u> This includes the collection of data from all Member States and from stakeholders on the following topics:
 - o Current interpretation of minor uses and its application in MS;
 - List of crops and plant protection problems for which no PPPs are authorised (inventory of issues);
 - Quantitative and qualitative economic and agronomic information on minor uses in order to evaluate the importance of the potential problems (economic quantification of the issues);
 - Identification of the problems and obstacles faced by MS with the existing process;
 - National approaches and actions developed by MS including specific funding;
 - o Proposals for an EU-coordinated action on minor uses;
 - Expected impact of the new regulation for placing PPP on the market (Regulation (EC) No 1107/2009) in relation to minor uses issues.
- Identification of different options with analysis of the cost and benefit of each option. The identification of the needs and the analysis of experiences will help the contractor to identify options which could address the problem of minor uses, including the "status quo" option (i.e. leaving the resolution of minor uses problems to initiatives undertaken by MS with no action at EU level, including the opportunities offered by the new regulation). For each option, a general analysis of the strengths and weaknesses of their implementation should be completed.

The analysis will cover all EU 27 Member States. Member State information will be gathered mainly through desk research, supplemented by surveys addressed to all MS and stakeholders across MS, and specific enquiries in selected MS. The field visits will be done on a representative sample (10 MS) and will be balanced in terms of geographic coverage (i.e. north-south distribution, new vs. old MS, large specialty crop MS vs. small producer MS, segmented supply chain vs. integrated supply chain).

1.3 Description of the research method

This study involved a combination of data collection tools and included several phases:

- An initial phase of desk research combined to a preliminary survey addressed to all national competent authorities (NCA) in order to identify all targets to be contacted during the study;
- A first large scale consultative exercise with government representatives, industry, NGOs and others across the EU through a detailed questionnaire (see Annex I). The aim of this first questionnaire was to collect data related to the importance of the minor uses issues in each of the 27 MS as well as to make an inventory of existing national initiatives related to minor uses and to gather preliminary views on how the coordination activities supported by a EU fund should be structured;
- On the basis of the answers of this detailed questionnaire, the research team developed several options on how the coordination activities supported by a EU fund may be structured. This preliminary list of options was presented to NCAs and EU level stakeholders during a workshop organised by DG SANCO with the participation of key EU stakeholders³, Member State Competent Authorities and relevant MS experts in order to allow and support a free and open discussion on the preliminary identified policy options;
- After a discussion of the list of options with the Commission Services, follow-up interviews have taken place in the form of field visits carried out in 10 MS (DE, DK, ES, FR, HU, IT, NL, PL, SE, and the UK). Field visits have been a unique opportunity to discuss the options in great detail with representatives of the main types of stakeholders including, in particular, NCAs, growers, producers, and the PPP industry. Additional interviews with EU stakeholders (e.g. COPA-COGECA) helped in completing this data collection in support to the impact analysis of each of the considered options.

The project plan is presented in Annex III.

1.4 Purpose and structure of the Final report

The Final report presents the study conclusions and options to address the set-up of a EU fund and its related activities. It comprises:

- A presentation on the current situation of minor uses in the EU including:
 - The EU policy context including expected impacts of Regulation (EC) No 1107/2009 in regard to minor uses issues;
 - o The current interpretation of minor uses and its application in MS;

³ Minutes of the workshop can be found in Annex IX

- The geographic distribution and the economic importance of major and minor crops in the EU;
- The estimation of the economic impact related to the lack of PPP for crop production in the EU;
- The inventory of the national and European initiatives addressing minor uses issues already in place;
- The identification and description of policy options to address identified issues, and an assessment of each of the options;
- A set of annexes detailing the consultation tools, results and analysis that underlies the study results and options.

2 THE CURRENT SITUATION IN THE EU 27 MS

2.1 EU Policy context

The regulatory framework regarding plant protection products has been discussed during the last decade leading to the establishment of a new EU policy. In 2006, the Commission presented its proposal on the future European policy on the authorisation and use of plant protection products that was adopted in July 2006.

This strategy on the sustainable use of pesticides aims to address the threats posed by the use of pesticides to human health and the environment, whilst maintaining crop productivity. Its objectives are twofold in targeting both the issues at source with regards to PPPs producers on the one hand, and PPPs users on the other.

Within this "pesticides package" which is entering into force in 2011⁴, the Commission has introduced a proposal for a regulation revising the 1991 Directive on the placing of plant protection products on the market⁵, and a proposal for a framework directive on the sustainable use of pesticides⁶.

Finally, the new Regulation addressing maximum residues limits came into force on September 1^{st} 2008⁷ and requires MRL to be set at EU level before any PPP authorisation can be granted in a MS.

Therefore this study is placed in the context of these regulatory changes that will impact the placing on the market and the use of PPP. The Commission services have indicated us that the baseline scenario (option status quo) that should be considered in the assessment of the options of this study should be the new Regulation. Therefore we have addressed this question regarding the expected impacts of the new Regulation on minor uses issues during the field visits.

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⁴ The strategy is composed of four major pieces of legislations: 1) a new regulation to replace the Directive 91/414/EEC on placing of PPP on the market, 2) a framework directive on the sustainable use of pesticides, 3) a new statistics regulation, and 4) an amendment to the machinery directive.

⁵ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market entering into force on June 14, 2011, repealing Directive 91/414/EEC of 15 July 1991.

⁶ Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 14 December 2011.

⁷ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC.

2.1.1 Expected impacts of Regulation (EC) No 1107/2009 on minor uses issues

In its Recital 30, Regulation (EC) No 1107/2009 indicates that "the economic incentive for industry to apply for an authorisation is limited for certain uses. In order to ensure that diversification of agriculture and horticulture is not jeopardised by the lack of availability of plant protection products, specific rules should be established for minor uses".

It materialised in Article 51 of the Regulation which is addressing the extension of authorisation for minor uses.

Several other obligations address indirectly the availability and use of PPP for minor uses, as follows:

- The creation of zonal authorisation procedures for PPP is also expected to facilitate mutual recognition (Article 40) within a zone (intra-zonal authorisation);
- Derogation for active substances (a.s.): Article 4 of Regulation (EC) No 1107/2009 lists the requirements and conditions for approval of active substances. In its paragraph 7, it is mentioned that "by way of derogation from paragraph 1, where on the basis of documented evidence included in the application an active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, such active substance may be approved for a limited period necessary to control that serious danger but not exceeding five years [...], provided that the use of the active substance is subject to risk mitigation measures to ensure that exposure of humans and the environment is minimized". Therefore "Member States may authorise plant protection products containing active substances approved in accordance with this paragraph only when it is necessary to control that serious danger to plant health in their territory";
- Derogations exist also for the use of PPP in emergency situations in plant protection as defined in article 53 of Regulation (EC) 1107/2009 as follows: "in special circumstances a Member State may authorise, for a period not exceeding 120 days, the placing on the market of plant protection products, for limited and controlled use, where such a measure appears necessary because of a danger which cannot be contained by any other reasonable means".
- Data protection⁸ is extended by 3 months for each extension of authorisation for minor uses, except where the extension of authorisation is based on extrapolation, if the applications for such authorisations are made by the authorisation holder at the latest 5 years after the date of the first authorisation in that Member State. The total period of data protection may in no case exceed 13 years and 15 years for low-risk substances.

⁸ Data protection period is 10 years for normal substances and 13 years for low-risk substances.

As there is still some uncertainty over impacts of changes in the pesticides approvals legislation, we have asked interviewees about their views regarding these expected impacts. As an introduction most of them have indicated that impacts will not be observed before a minimum 5 years period. However it can be anticipated that:

More active substances to be withdrawn from Annex I.

Since the entry into force of the Directive 91/414/EEC, about 70% of active substances have been withdrawn from the Annex I. Several stakeholders and growers consider that more active substances will be delisted in the coming years based on hazard-based criteria for the placing of PPP on the market and based on substitution obligations. Under the new Regulation, there will be pesticide active substances that will not receive approval when their current approval is due for renewal. Discussions are still on-going on the criteria to be considered in risk assessment (e.g. definition of EU endocrine disrupting criteria) and therefore the number of a.s. to be lost is difficult to estimate. Figures provided by the interviewees are up to 50% of a.s. that could disappear in the coming years, but these figures are not supported by strong evidences.

ADAS⁹ in a study for the Department for Environment Food and Rural Affairs (DEFRA)¹⁰ indicates that the losses of pesticides will not be as severe as was once forecast but much will depend on the final implementation of the Regulation. According to ADAS, it would result in the loss of 23 active substances due to cut-off criteria¹¹.

Table 1 - Active substances expected to be lost due to changing approvals legislation in the UK

Active Substance	Action	Reason for revoking	Date current approval
		approval	expires
Bifenthrin	Insecticide	PBT/vPvB + endocrine ?	2018
Esfenvalerate	Insecticide	PBT	2011
Bitertanol	Fungicide	R2 + endocrine ?	2020
Carbendazim	Fungicide	M2/R2 + endocrine	2009
Flusilazole	Fungicide	R2 + endocrine ?	
Quinoxyfen	Fungicide	vPvP	2014
Cyproconazole	Fungicide	R3C3	2020
Epoxiconazole	Fungicide	R3 C3 endocrine	2018
Fenbuconazole	Fungicide	R3	2020
Mancozeb	Fungicide	R3 – endocrine	2016
Maneb	Fungicide	R3 – endocrine	2016

⁹ See www.adas.co.uk

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 $\frac{\text{http://randd.defra.gov.uk/Default.aspx?Menu=Menu\&Module=More\&Location=None\&ProjectID=17126\&FromSearch=Y\&Publisher=1\&SearchText=if01100\&SortString=ProjectCode\&SortOrder=As}{\text{Module=More\&Location=None\&ProjectID=17126\&FromSearch=Y\&Publisher=1\&SearchText=if01100\&SortString=ProjectCode\&SortOrder=As}{\text{Module=More\&Location=None\&ProjectID=17126\&FromSearch=Y\&Publisher=1\&SearchText=if01100\&SortString=ProjectCode\&SortOrder=As}{\text{Module=More\&Location=None\&ProjectID=17126\&FromSearch=Y\&Publisher=1\&SearchText=if01100\&SortString=ProjectCode\&SortOrder=As}{\text{Module=More\&Location=None\&ProjectID=17126\&FromSearch=Y\&Publisher=1\&SearchText=if01100\&SortString=ProjectCode\&SortOrder=As}{\text{Module=More\&Location=None\&ProjectID=17126\&FromSearch=Y\&Publisher=1\&SearchText=if01100\&SortString=ProjectCode\&SortOrder=As}{\text{Module=More\&Location=None\&ProjectID=17126\&FromSearch=Y\&Publisher=1\&Search=Y\&Publisher=1\&P$

¹¹ This figure has to be understood as being the number of a.s. that may be withdrawned based on additional safety criteria that have been included in the new Regulation (cut-off criteria). It does not consider possible a.s. withdrawn for other reasons and the ones not supported by the industry.

Active Substance	Action	Reason for revoking approval	Date current approval expires
Metconazole	Fungicide	R3 – endocrine	2017
Tebuconazole	Fungicide	R3 – endocrine	2019
Flumioxanine	Herbicide	R2	2012
Glufosinate am.	Herbicide	R2	2017
Linuron	Herbicide	R2 + endocrine	2013
Pendimethalin	Herbicide	PBT	2013
Amitrole	Herbicide	R3 – endocrine	2011
Ioxynil	Herbicide	R3 – endocrine	2015

Source: PSD report Dec 2008

Comment: PBT: Persistent bio-accumulating toxic, vPvB: very persistent, very bio-accumulating, M: mutagenic (category 2), R: reproductive (category 2 or 3), C: carcinogen (category 3)

In Germany, the Julius Kuhn Institute (JKI) analysed that four active substances would be rated as either mutagenic or carcinogenic or toxic in the categories 1 and 2 by the new criteria. In addition, up to eight other substances would be affected by the new criteria based on the assumption of the still uncertain evaluation of endocrine harmful substances and six other agents regarding their environmental impacts. Altogether a total of 18 active substances, about seven per cent of the currently approved in Germany, are potentially affected.

Regarding the impacts on crop production several aspects need to be considered. The criteria above will be in force in the medium term, when the current authorisation of active substances at EU level is reviewed. Therefore it may be assumed that the chemical industry can substitute at least some of the substances in the coming years.

Minor crops are in general using old a.s. which are the most subject to withdrawal. For example it may happen that based on the criteria retained to assess endocrine disrupting potency, most insecticides from the pyrethroid family that are widely used in vegetables may be withdrawn without any solution left against insects.

It should be noted that according to the law an authorisation is always given based on a crop, a plant protection product and often a pest. All non-authorised possible uses are forbidden. Minor crops rely on extensions of authorisations for major uses to minor uses which cannot be retained when the major use is withdrawn. The ways in which extensions have been established has varied between MS, and the requirements have differed as well.

In Nordic countries where agricultural acreages are rather limited, PPP industry is no longer interested in applying for major crops as burden has increased based on new requirements of the new Regulation and therefore the number of possibilities for minor use will decrease.

<u>Provisions of Article 40 (mutual recognition) of Regulation (EC) No 1107/2009: mutual recognition are expected to be efficient for PPPs based on new active substances but not for existing PPPs.</u>

Interviewees that have been met during the study have clearly made the difference between the future authorisation of new a.s. for which the applicants will base their strategy on the new Regulation and for which mutual recognition within a zone should be efficient, and already approved products for which the new authorisation process based on zones will not bring any significant improvements. The main arguments for this statement can be summarised as follows:

- Very few MS have drafted the "assessment report"¹² that is required for any authorisation process based on mutual recognition: only NL, UK, DE and FR would be able to provide this assessment/registration report for already assessed products;
- The variability of assessment procedures between the different agencies and the lack of trust will make that data produced in one MS are "not acceptable" by another MS. According to one CA this would be the case in more than 80% of the applications, at least for his country. Lack of trust between MS agencies has often been mentioned during the field visits and the new legislation would not help in overcoming this major blocking factor;
- A number of Member States accept simplified studies to support the granting of authorisations for minor uses and speciality crops at the national level but these studies are not accepted by other Member States. This is the case for off-labels authorisations in some MS in the north of the EU which are granted based on the assessment of a simplified data package which is not being seen as "acceptable" for a majority of MS in the south of the EU, and therefore any mutual recognition requests based on off-labels data packages will be rejected in these countries;
- Regarding the biological efficacy dossier, data from one MS can be used for authorisation procedure in another MS under the condition that these data have been produced in a "similar agronomic environment", a criteria which has not sufficiently defined in Annex VI of Directive 91/414/EEC¹³. This observed lack of acceptance of efficacy data across MS is being perceived as a blocking factor by the industry and by the producers.

For most of the stakeholders and NCA visited during the study, the situation will be different for new PPP based on new a.s. as the applicant will look for registration at the zonal level and therefore national authorities will have to develop a "core dossier" that would be acceptable for any authority in which an application is being filed. A zonal coordination is expected to happen in these cases.

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 $^{^{12}}$ For PPP for which registration has been granted less than 4 years ago

¹³ Annex VI: Uniform principles for evaluation and authorisation of chemical plant protection products

The number of mutual recognition dossiers is not expected to explode, but even if this would be the case and for the reasons that have been explained above, about 80% of these will be rejected according to several NCAs.

Expected impacts of Article 51 (extension of use) of Regulation (EC) No 1107/2009: A positive move forward

Article 51 of the new Regulation allows others beside the chemical industry to apply for an extension of use. This is being perceived as positive by the majority of interviewees. However, the majority of growers have indicated that it should be kept as an exception as there is a risk that PPP industry will use this article to stop applying for minor uses authorisations and leave the burden and the liability to users as under this article the responsibility is being shifted to applicants, being growers or producers.

Extension of data protection of 3 months for any minor use application is a strong incentive for the PPP industry

The extension of data protection of three months for each minor use application with a limit of 3 years is being perceived by the interviewees as a strong incentive for the PPP industry for registration of new PPPs. To be granted extension of data protection applications for minor uses have to be made within five years following the first registration in each MS, leading to the fact that this will apply primarily to submissions for new a.s. or new PPPs (article 59.1). This incentive does not apply for minor uses submitted for a renewal of approval as the application has to be made within this five years period.

2.1.2 Interpretation of minor uses and its application in MS

The new Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market defines in Article 3 (26) the criteria for classification of a minor use as follows: "Minor use means use of a plant protection product in a particular Member State on plants or plant products which are:

- Not widely grown in that Member State; or
- Widely grown, to meet an exceptional plant protection need."

The term "minor crop" is defined in the EU guidance document SANCO 7525/VI/95¹⁴ on comparability, extrapolation, group tolerances and data requirements for setting maximum residue levels.

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¹⁴ Last revision of March 2011 – Revision 9

In its Section 6.1.2 the criteria for classification of crops are as:

"The following criteria are used for classifying a crop or a product as major in a zone of the European Union:

- Daily dietary intake contribution > 0.125 g/Kg bw/day (mean daily consumption over the population) in GEMS Food Cluster Diet applicable to the concerned zone and relevant cultivation area (> 20 000 ha) and/or production (> 4000 000 tonnes per year) in the zone

Or

Cultivation area > 20 000 ha and production > 400 000 tonnes per year.

For the selection of major crops for the World zone (for import tolerances) the following criterion is used:

- Daily intake contribution > 0.125 g/kg bw/day (mean daily consumption over the population) in at least one of the 4 GEMS Food Cluster Diets or the crop is major in one of the EU residue zones.

These criteria are used equivalent for distribution of crops or products as being major or minor.

Based on those criteria the following crops have become "major" in revision 9 of this guidance document: for Northern Europe: cherries, beetroot, pepper, watermelons, sunflower seed, soya bean; for Southern Europe: plumbs; kiwi, courgettes, watermelons, cauliflowers, peas without pods, rape seed; and for the world: kiwi, pineapple, beetroot, courgettes, watermelons.

On the contrary, a number of crops have acquired the status of minor crops: for Northern Europe: Brussels sprout, hops; for Southern Europe: table olives and cucumber; and for the world: table olives and hops.

In some cases the dietary intake contribution and/or the cultivation area of a crop or a product is very small. In this case certain simplifications should be introduced.

The following criteria are used for classifying a crop or a product as 'very minor' in the European Community:

- Daily dietary intake contribution < 1.5 g (i.e. 1.5 g mean daily consumption over the population for a 60 kg person) and/or
- Cultivation area < 600 ha (less than 0.0035 % of the total cultivation area).

These criteria are used for classifying crops or products as being very minor with a preference on the dietary intake contribution meaning that a higher dietary intake contribution will exclude a crop or a product automatically from the classification as being very minor."

This definition has been specifically developed to support the setting of MRLs for minor crops, and a majority of stakeholders is of the opinion that when considering the issue of minor uses and minor crops, the current definitions and terminology used should be reviewed.

Any financial support to find crop protection solutions should not be limited to minor crops but should include any use for which lack of crop protection solutions is observed or can be foreseen in the coming years.

The French authorities have set up a national initiative called "Commission des usages orphelins "(Orphan uses Committee) which is aligned to the principle of solving any issues related to present and future lack of PPP solutions.

This approach is following the one that exists for about 10 years in the pharmaceutical sector in which different initiatives have been successfully taken to stimulate private companies to develop medicinal products for rare diseases.

Orphan medicinal products (OMPs)

Orphan medicinal products are intended for the diagnosis, prevention or treatment of life-threatening or serious conditions that are rare. Under normal market conditions, given the low prevalence for rare diseases, biopharmaceutical companies would not be attracted to develop treatment for orphan diseases. The EC implemented in 2000 Regulation (EC) No 121/2000 with the aim of providing incentives for the research, development and marketing of OMPs. In particular, a drug is to be designated orphan if:

- It is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than 5 in 10,000 persons in the EU when application is made, or
- It is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the EU and that without incentives it would be unlikely that it would generate sufficient return to justify the necessary investment, and
- There exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorised in the EU, or if such method exists, that the product will be of significant benefit to those affected by that condition.

Determining the epidemiological impact of rare diseases is a difficult task. It is estimated that between 5,000 and 8,000 distinct rare diseases exist today, affecting between 6% and 8% of the EU population in the course of their lives.

Following the political impetus provided by the OMP Regulation (EC) No 141/2000, there has been an important increase in the number of OMPs potentially available for patients in Europe compared to the situation before the Regulation. By the end of 2009, more than 5000 drugs have obtained orphan designation and 68 products with orphan drug status had been launched.

The pharmaceutical industry, like most stakeholders in the area of rare diseases, deems the EU OMP Regulation to have been a success as the incentives provided in the Regulation, mainly co-financing of R&D activities and market exclusivity, greatly fostered innovation, data sharing and improved relation between national initiatives and activities on rare diseases/orphan drugs.

A large majority of stakeholders have highlighted that the list of minor uses should be defined at zonal level rather than at national level. For example when considering obligation of Article 51(8) of Regulation (EC) No 1107/2009 for MS to establish and regularly update a list if minor uses, the obligation is too restrictive to consider the majority of cases of lack of PPPs.

The food chain representatives¹⁵ are proposing the following classification:

"All crops grown on less than 200 000 hectares (roughly equivalent to 0.2% of cropped area) should be considered as minor crops in the whole of the EU. Additionally, crops should also be classed as minor per zone when they are grown on a small percentage of the zonal land area (i.e. 0.5% of cropped land in that zone), and per individual MS when they are grown on a small percentage of the national land (i.e. 1.0% of cropped land in that MS)."

This proposal is based on the US situation in which a minor crop is a crop grown on less than 120 000 hectares (equivalent to 0.2% of the total US cropped area). Additionally, this proposal indicates that a separate definition of a minor use has also been developed in the US where it is linked to a major crop. This definition, which is also linked to a number of specific conditions¹⁶, is based on the pesticide use pattern being so limited that revenues from the expected annual sales will be less than the cost of registering the PPP. This situation may occur, for example, for a.s. used during cereals and oilseeds storage. In conclusions, this proposal mentions that such a provision could be helpful in dealing with specific situations, i.e. in plant breeding or seed production, or by the specific application of a PPP, e.g. as a seed treatment.

Several interviewees also stressed that EU funding should not only cover situations where knowledge exists on which PPP can be used to control a pest but when no knowledge exists and/or studies are lacking and therefore a financial support requires to fill the gap. It has been reported two other cases that would need to be considered within the fund:

- Where no knowledge exists on whether or how a pest for a specific plant/crop can be controlled via a PPP because this crop/plant represents a very small market and is then considered unimportant by both research and industry; and
- Where a decision is taken at EU level to ban or restrict an a.s. or a stringent MRL is set.

Therefore there is a clear demand for a European guidance to establish a common terminology which is fully addressing minor uses issues in regard to crop production and not only in regard of residues as it is the case today.

¹⁵ CELCAA, ECPA, COCERAL, FRESHFEL, AREFLH, ESA, PROFEL, COPA-COGECA – Position paper of Aril 26, 2011 These conditions are: 1) there are insufficient efficacious alternatives for the use, 2) alternatives pose greater risks, 3) the minor use is significant in managing pest resistance, or 4) the minor use plays a significant part in integrated pest management (www.pmac.net/minorcp.htm)

During the field visits several NCAs have agreed that this type of approach would be required.

2.1.3 Support for the creation of a EU Fund

A primary collection of views from Member States (CAs and stakeholders) on future options that could address minor uses issues has taken place within Section 5 of the survey questionnaire. In general this section has been completed by most participants to the survey (54 samples).

As stated in the below displayed table, 96% of the respondents declare that they are in favour of the establishment of a European fund to coordinate activities to address minor uses issues within the EU, underlining the fact that Member States recognise the impact and comprehensiveness of issues caused by minor uses. The preferred approach would be to base the coordination structure on the current 2 Technical Working Groups (North and South).

While most of respondents are in favour of the creation of a EU fund, very few of them have estimated the level of funding necessary for the set-up and running of this fund.

Table 2 - Political support of CAs and stakeholders to the establishment of a EU fund for minor uses

Ques	stion	Sample	Yes	No	Do not know
5.1	Are you in favour of the establishment of a European fund to coordinate activities to address minor uses issues?	56	<u>96%</u>	0%	4%
5.5	Are you in favour of maintaining the actual Expert Groups (North and South) on minor uses?	55	<u>80%</u>	7%	13%
5.6	Have you already estimated the level of the funding that is required for coordinating activities?	54	7%	<u>80%</u>	13%

Source: survey questionnaire

A comparable clear picture can be drawn out of the results on the potential activities of a European initiative as presented below:

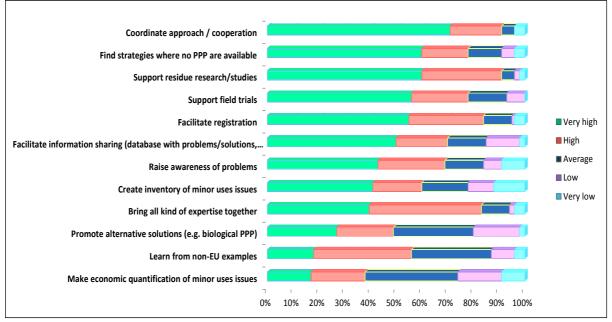


Table 3 - Activities to be coordinated by the EU fund

Source: survey questionnaire

As indicated in Figure 1, respondents assess coordination and cooperation as the task which is of most interest to them (71%). Other interventions of a fund that are marked as very interesting by a large number of respondents are the financial support for running field trials, support regarding conducting residue research/studies, finding strategies for uses that are characterised by the absence of authorised PPP, and the facilitation of a database to enable data sharing on authorisation granted per MS and on existing residues data.

Tasks/interventions that are characterised by less interest from respondents are for example the promotion of alternative solutions, the learning from non-EU examples and the economic quantification of minor uses issues. The lack of interest regarding especially this last intervention seems remarkable since preferred actions like support regarding residue research data or studies require a certain prioritisation of minor uses issues, for which an economic assessment is needed.

A considerable majority of respondents would like to see the coordination of the activities at European level and on zonal level. The high support for activities at EU level underlines the need for a European initiative.

Respondents describe the role of the European Commission in such an activity mostly as being a central player. Leadership regarding the gathering of information on problems or solutions from all Member States and the provisions of the required political support are examples of activities that could be part of the role of the COM. The financing role of the EU has not been clearly reported by the respondents. Most respondents see the contribution to a funding on European level as a task that needs to be fulfilled by more than one party being especially The European Commission, National governments and the PPP industry.. Farmers are also willing to contribute to the funding as long as the financial resources are not coming

from the actual CAP (pillar I or pillar II) as they consider that they already pay and finance R&D activities when buying products and therefore they do not want to pay twice.

Table 4 - Distribution of views on the source(s) of funding of a European initiative

Source of funding	Sample	Yes	No	Do not know
European Commission	55	<u>96%</u>	0%	4%
National government	51	<u>74%</u>	10%	16%
PPP Industry (producers and traders)	52	<u>73%</u>	17%	10%
Farmers and producers	47	47%	38%	15%
Supply chain actors: processors	43	42%	35%	23%
Customers	40	7%	<u>58%</u>	35%

Source: survey questionnaire

Most of the respondents do not wish a participation of end-consumers and are rather doubtful about a contribution from supply chain actors as food processors and retailers to a fund.

If such a fund would be established within the EU, 63% of the respondents expect that most of the problems caused by minor uses issues could be solved (see table below).

Table 5 - Distribution of views on the level problems that could be solved by a European initiative

All	Most	Few	None	Do not know	
2%	<u>63%</u>	23%	0%	12%	

Source: survey questionnaire

2.2 Geographic distribution of minor & speciality crops in the EU 27 MS & their economic importance

This section briefly presents the geographic distribution of the most important minor crops in the EU and in the context of the zonal authorisation system of the new Regulation (EC) No 1107/2009.

This presentation is followed by an introduction of the economic importance of fruits and vegetables crops (F&V) and the ornamental sector in the EU agriculture.

A more detailed inventory and a breakdown per crop and per MS are presented in Annex VII.

This presentation on the cropping areas is limited to F&V and does not include any data on medicinal and aromatic plants nor on ornamental plants as the acreage of these groups of plants is very low and highly fragmented¹⁷.

Geographic distribution of fruit crops in the EU

The fruit cropping area in the EU 27 MS is about 4.6 million ha. The distribution per type of crops is as follows:

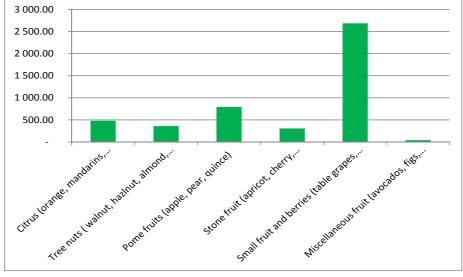
Table 6 - Fruit cropping area in the EU 27 MS

	Total	Autorisation zones			TWG	
	Total	North	Central	South	North	South
	in 1,000 ha		in%		ln	%
Citrus (orange, mandarins, clementins, lemons, grapefruits)	479.70	0.0	0.0	100.0	0.0	100.0
Tree nuts (walnut, hazlnut, almond, chesnut)	360.50	0.0	3.6	96.4	3.0	97.0
Pome fruits (apple, pear, quince)	791.66	4.1	55.2	40.7	45.9	54.1
Stone fruit (apricot, cherry, nectarines, peaches, plums)	304.06	1.3	33.0	65.6	30.1	69.9
Small fruit and berries (table grapes, wine grapes, strawberries, rapsberries, blackcurrant, redcurrant, gooseberies)	2 685.03	0.4	20.0	79.6	12.7	87.3
Miscellaneous fruit (avocados, figs, kiwis, olives)	41.10	0.0	0.0	100.0	0.0	100.0
Total	4 662.05	0.98	18.64	80.39	15.27	84.73

Source: Eurostat - 2008

Small fruit and berries, a group that includes table grapes, wine grapes, strawberries, raspberries, blackcurrant, redcurrant and gooseberries are grown on more than 2.5 million hectares representing about 55% of the total fruit cropping acreage.

Graph 1 - Distribution of fruit cropping area per type of crops



Source: Eurostat - 2008

http://www.aiph.org/site/index_en.cfm?act=teksten.tonen&parent=4685&varpag=3954

¹⁷ Statistics on ornamentals crops can be found in the AIPH/Union fleur statistical yearbook (International statistics flowers and plants) available at

Fruit production is mainly concentrated in the South authorization zone, counting for about 80% of the total fruit cropping area, followed by the Central zone (19%). The North zone counts for less than 1% of the total EU fruit cropping area.

North Central South

1%

19%

Graph 2 - Geographic distribution of fruit plants acreage per authorisation zone

Source: Eurostat - 2008

This concentration of the EU fruit production in the south is further highlighted when addressing the distribution of the fruit cropping area per coordination zone as follows:

North South

Graph 3 - Geographic distribution of fruit plants acreage per coordination zone (North and South)

Source: Eurostat – 2008

These two graphs suggest that Mediterranean countries (e.g. Greece, Italy, Spain, and Cyprus) have a much more important share of permanent crops than other countries. This can be explained by the favourable climatic conditions in these countries and the commercial importance of permanent crops such as citrus trees, vineyards or other fruit trees.

Pome fruits, and to a less extend stone fruits, are the only fruit plants that are cultivated significantly in the North zone, but still representing a rather small share, respectively 4.1% and 1.3%, of the total EU acreage .

Geographic distribution of vegetables crops in the EU

The distribution of vegetables crops is more equilibrated between the three authorisation zones as highlighted in the following table.

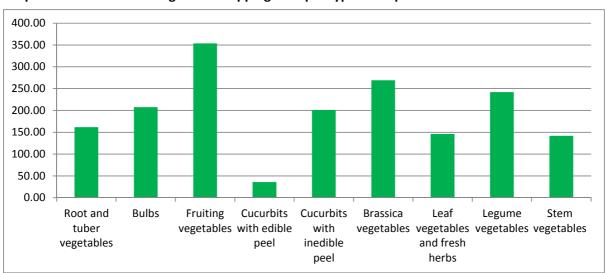
Table 7 - Vegetables cropping area in the EU 27 MS

	Total	Au	Autorisation zones			TWG	
		North	Central	South	North	South	
	in 1,000 ha		in %		in	%	
Root and tuber vegetables	161.53	10.17	67.88	21.96	71.23	28.77	
Bulbs	207.51	3.32	56.10	40.58	45.52	54.48	
Fruiting vegetables	353.43	6.98	22.03	70.99	17.94	82.06	
Cucurbits with edible peel	35.92	5.23	79.79	14.98	70.30	29.70	
Cucurbits with inedible peel	201.26	0.12	27.33	72.55	7.55	92.45	
Brassica vegetables	269.05	4.08	57.65	38.27	47.03	52.97	
Leaf vegetables and fresh herbs	146.22	1.56	23.46	74.98	24.50	75.50	
Legume vegetables	242.07	2.29	49.82	47.90	47.44	52.56	
Stem vegetables	141.79	0.11	17.55	82.33	17.67	82.33	
Total	1 758.78	3.76	44.62	51.61	38.80	61.20	

Source: Eurostat - 2008

The South zone represents about 50% of the total EU acreage, while the acreage in the Central zone reaches 45% of the total EU acreage. Less than 4% of vegetables are cultivated in the North zone (see also Graph 5 below).

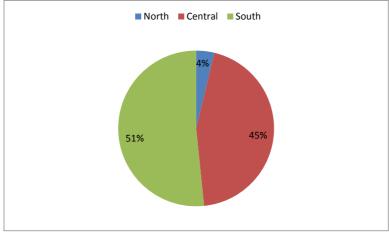
Graph 4 - Distribution of vegetable cropping area per type of crops



Source: Eurostat – 2008

The main vegetable crops are the fruiting vegetables (e.g. tomatoes, pepper and eggplant) and brassicas including mainly cauliflowers and all types of cabbages.

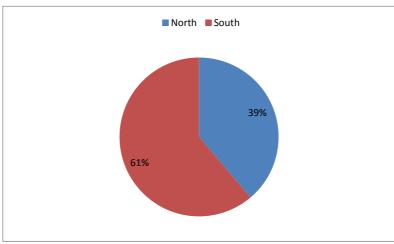
Graph 5 - Geographic distribution based on acreage of vegetables plants per authorisation zone



Source: Eurostat - 2008

The main acreages are equally distributed in the South and North authorization zones and on a ratio 60/40 for the South and North coordination zones as presented below.

Graph 6 – Geographic distribution of vegetables plants acreage per coordination zone (North and South)



Source: Eurostat – 2008

Economic importance of minor & specialty crops in the EU 27 MS

Specialty crops include most vegetables, fruits, nurseries and flowers (horticultural sector) which account for an EU production value of greater than €65 billion per year.

The EU horticultural sector in the EU is based on specialised, intensive cultivation of horticultural crops. It contributes an important share to European self-supply due to its products that complement agricultural food supply. Compared to main agricultural crops horticultural products are high in value.

The EU horticultural market is a leading one worldwide both in term of production and consumption. EU 27 MS vegetable growers produce about 14% of the worldwide production volume of vegetables. Europe has a leading position for cut flowers and pot plants adding 46% to worldwide production value. In terms of external trade, the EU is the world's leading importer for fruits and vegetables on the one hand and cut flowers and pot plants on the other hand.

The total EU horticultural sector represents about 20-22% of the value of EU total agricultural production¹⁸.

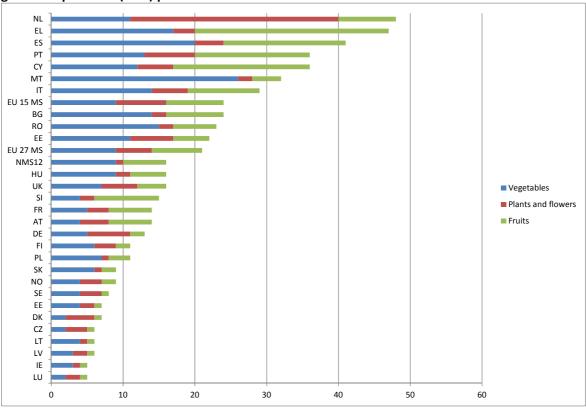
Table 8 - Crop output as share of agricultural goods output in 2008 (in %)

	EU 27 MS	
Cereals	14.8	_
Vegetables and horticultural products	14.8	21.6%
Fruits	6.8	21.07
Forage plants	6.5	_
Wine	4.8	
Industrial crops	4.4	
Potatoes	3.3	
Olive oil	1.4	
Other	0.8	

Source: COMEXT

The distribution of vegetables, horticultural products and fruit outputs as share of agricultural goods output is as follows.

¹⁸ Source: COPA-COGECA



Graph 7 - Distribution of vegetables, ornamental products and fruit outputs as share of agricultural goods output 2007 (in %) per MS

Source: COMEXT

The horticultural sector can be divided in two major sub-sectors being the fruits and vegetables sector (F&V) in one hand and the ornamental sector in the second hand.

A general introduction to the economics of these two sub-sectors is presented below.

The F&V EU economic sector

The F&V sector alone accounts for about €45 billion in the EU 27 MS for a total production of 70 million tons of vegetables and 40 million tons of fruits. The economic importance of that sector varies significantly across MS. In 15 MS, this sector represents more than 10% of the total production volumes as presented in the following graph. The EU 27 MS average is estimated at 16.9%.

EU 27 MS average: 16.9 %

Graph 8 - Significance of F&V in the agricultural sector (% of total production, average 2003-2005), MS with share above 10%

Source: Eurostat economic accounts of agriculture

The economic weight of the sector of fruit and vegetable products represents an average of 16.4% of total agricultural production of the EU-15 in the period 2001-2003 (for 2003, the share of the sector is 17.2% for the EU-15 and if we include the 10 new member countries 16.9%). The economic importance of the sector has increased steadily in the last few years (it has increased from 13.4% in 1995 to 17.2% in 2003), partly due to the decrease in market prices of the other products following the different CAP reforms.

The significance of the sector is particularly high in Greece (34.5% in 2001-2003), Spain (32.3%), Portugal (30.8%), Italy (25.0%), Malta (24.1%). It is also important in Belgium (16.7%), Hungary (15.1%), Poland (13.9%), the Netherlands (13.1%), Slovenia (11.3%) and France (11.1%). The major producing regions of the EU are Andalucía (with a share of fruit and vegetable production in total agricultural production of 28.3%), Murcia (36.1%), Provence Alpes Côte d'Azur (42.0%), Emilia-Romagna (24.2%), Campania (42.4%), Puglia (42.4%) and Sicilia (47.8%).

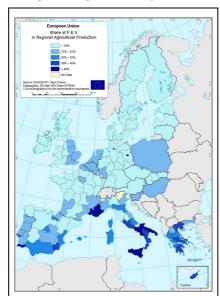


Figure 1 - Share of F&V in regional agricultural production in the EU 27 MS (2004)

The ornamental EU economic sector

The market value for ornamental plants is estimated at €27 billion and is distributed across MS as follows:

3500 3000 2500 Flowers and pot plants 2000 Bulbs ■ Tree nursery 1500 1000 500 DK FR DE EL HU IT NL PL

Graph 9 - Estimated EU 27 MS market value for cut flowers and pot plants in 2007 (in million €)

Source: Eurostat economic accounts of agriculture

About 6% of the agricultural production value of the EU is generated by the cultivation of ornamental plants and nursery products¹⁹. Production is characterised by its diversity as it is based on the cultivation of a large number of crop species including trees, bulbs, roots, tubers, flowers, and foliage and pot plants.

Based on available data four MS (NL, DE, IT, and FR) contributes to nearly 50% of the total EU production value (45%) and the Netherlands alone to 18% of the total.

2.3 Estimation of the impacts related to the lack of PPP solutions for crop production

Insufficient protection of crops against plant diseases is a problematic situation with various serious impacts on a large group of actors within the EU. Not having PPP solutions bears not only large potential negative effects on the health of consumers and the environment due to potential illegal use of PPP, but puts at stake the sustainable production of high quality, highly diverse and high value crops which is vital for both securing the future of the European continent's food supply at an affordable cost to consumers as also for the EU economy (food sovereignty).

¹⁹ Eurostat, 2009

As stated earlier in this report, speciality crops account for an EU production value greater than €65 billion per year representing about 22-25 % of the value of EU total agricultural production.

2.3.1 Economic information

Collection of information on the economic impact related to the lack of PPP solutions has taken place in the light of this study by means of a number of tools, being:

- A general survey that has been conducted among all relevant actors regarding minor uses within the European Union. Within this survey, information was collected on existing minor uses issues which have been described by:
 - Crop concerned;
 - o Pest concerned;
 - o The issue;
 - The economic damage caused by the issue (for users of PPP and food-supply-down-stream users).
- Interviews with experts on the economic impact caused by lack of PPP solutions in a large number of Member States and participation in workshops with representatives of producers and the PPP producing industry;
- Case studies, based on interviews with experts and in-depth research, on a number of existing issues like the lack of a PPP to protect rice in Italy against Rice Blast and or for weed control in artichokes in France (see Annex VI).

2.3.2 Objectives of the economic quantification

The objectives of the economic quantification within this study were to draw an overall global picture of the economic damages caused within the EU by the lack of PPP solutions. This aim proved to be very ambitious and not possible to be completely realised within the framework of this study due to a number of factors:

- The number of uses that face issues regarding the protection of the crop due to a lack of PPP within the European Union is large; the list of issues collected through the general survey contains in total more than 1,400 cases (see Annex VIII). This collection must moreover be seen as far from complete since only 15 MS provided information on this part of the survey and most of the data that has been provided is of exemplary nature;
- Comprehensive inventories of issues do not exist within (all) MS. This fact supports the assumption that the above mentioned collection is far from complete.
- Quantification of the economic impacts of these issues itself proves to be a time consuming and challenging exercise since impacts are often difficult to assess. These difficulties can be explained by the large number of factors that must be taken into account when assessing the economic damage caused by a lack of PPP and the high level of assumptions that need to be made in most cases. Quantification demands therefore a case-by-base in-depth economic analysis which is not part of (a standard) authorisation process. National competent authorities have often no background and possibilities to conduct these assessments. Annex VI (case studies on the

economic damage caused by minor uses issues) illustrates the data (and process) that is needed to complete an assessment of the economic damage caused by minor uses issues.

The issue was discussed with SANCO early on and it was decided jointly to collect and analyse whatever data could be found within the limitations of this study.

While recognising that this data set on minor uses issues is far from complete, it is interesting to point out the number of issues listed and collected in such a short period. A complete inventory has not been done to date but these statistics highlight the feasibility of the exercise to cover a minimum of 60-70% of the issues and in particular the ones of European importance.

Secondly, the case studies performed on e.g. rice and artichokes are interesting on several aspects. In particular they show that calculating economic impacts of any issues is a time-consuming, but feasible exercise. Individual cases presented by actors (mainly private) reinforce this impression of feasibility.

2.3.3 Economic impacts

The number of economic impacts caused by a lack of PPP solutions for crop production is very broad and not always unambiguous. Nevertheless two types of impacts can be identified: (1) direct economic impacts that are related to problems within the actual growing of the crop and (2) indirect economic impacts regarding long-term problems caused within the entire (relevant) food-supply-chain.

Direct economic impacts

As described above, direct economic impacts are economic damages created within the actual growing process of a certain crop due to a lack of PPP solutions. These impacts are, compared to the indirect ones, relatively easy to calculate and to trace since they can be expressed by a fluctuation of the selling price or productivity per hectare. The impact itself can however take place in number of ways.

For example, as described by the case study on issues related to the control of weed in the artichoke production in France, economic damage can be caused by higher labour requirements for weed cleaning manually artichoke fields that are needed to produce without adequate chemical weed control. In this case, this increase of labour requirements leads to an additional costs of €1,020/ha. Assuming that this problem would be applicable to the complete European artichoke production (i.e. including Spain and Italy), the economic impact of this lack of a PPP solution could cause €85 million extra costs to artichoke farmers in the EU (see details in Annex 6).

A second impact of insufficient protection can take place via direct effect on the growth of the crop, as described in the case study on damage caused by rice blast (*Pyricularia grisea*)

in rice production in Italy. In this case, without protection, total potential yield losses can amount to 60-80%, which could lead to a reduction of national production and value of an estimated 30%. This reduction of total produced quantities and value per area of cultivation could lead in a situation without adequate protection in Italy alone to a loss of an estimated €125 million (see details in Annex 6).

Extrapolation of these calculated impacts remains an even more difficult task since issues need to be addressed in a case-by-case approach due to the very different situations within MS regarding potential derogations, off-label-use, quality of control of illegal use, potential promotion of alternative solutions and in the end of course rather different meteorological circumstances and soil conditions in different areas.

Indirect socio-economic and environmental impacts

Indirect socio-economic and environmental impacts (which affect the entire food-supply chain) are, compared to the above described direct economic impacts, more difficult to calculate and trace since the identification of the actors and measures that might be affected is rather complicated. The extent of the indirect socio-economic and environmental impacts is nevertheless of importance to the EU economy.

Examples of indirect economic impacts, that have an effect on the production environment, are e.g. the fact that farming can become more sensitive to climatic risks due to insufficient availability of PPP solutions and the increasing difficulties to manage the crop production that can arise over several years. E.g. mechanical weed control is impossible during wet periods. Also, difficulties within the growing of one crop can affect the growing of other crops like described within the case study on artichoke growing in France. In this case, the production of cauliflowers is closely linked to the production of artichokes. Hence, increased costs within the production of artichokes create more difficult circumstances for the growing of cauliflower as labour is dedicated to cleaning artichokes filed when it is required for cauliflowers activities and can therefore lead to a situation in which an entire economy of a vegetable producing area could be compromised.

Examples of potential social impacts can be found in the vegetables and fruit processing sectors (canned and frozen activities). These sectors are largely dependent from sourcing of "local" raw material which is in this case fruits and vegetables. This raw material has to be geographically produced rather closely to the factories in order to avoid important logistics costs. Additionally this type of raw material has to be processed as soon as possible after harvest. Any issues regarding a sustainable and regular delivery of this raw material to the factories leads to additional processing and production costs and to the extent that processors may decide not to modernise their processing plants if supply of raw material is not guaranteed long-terms. Delocalisation may be anticipated with impacts on local employment.

If PPP solutions do not exist for crop production of certain minor crops, risks of delocalisation of certain crops exist. This has an employment impact but also can be considered as a safety issue as commodity products that will have to be EU imported may contain residues of PPP not authorised in the EU but authorised in the country of production.

Eventually, lack of PPPs in certain areas may lead to biodiversity losses in some areas as certain traditional regional crops production would no longer be possible (aromatic crops in South Europe).

These kind of problematic situations are difficult to assess but constitute nevertheless a serious potential risk for the complete EU agricultural sector and EU economy in general.

Quantification of economic impacts

The collection of minor uses issues has been initiated via the survey questionnaire. As stated earlier, this list must be seen as a primary collection which is far from complete (e.g. the information collected on economic impacts of the issues has been provided only in 14.9% of the cases).

However, this relatively small amount of data does show the importance of minor uses issues from an economic point of view since the total amount of collected direct economic impacts accounts for more than 1 billion EUR and the total amount of collected indirect economic impacts accounts for more than €100 million on in total over 9 million hectares.

Table 9 - Estimation of minor uses economic impacts - financial aspects

Affected area	Direct economic impacts	Indirect economic impacts	No of issues with figures
9,164,378 ha	1,020,188,654 EUR	111,974,000 EUR	14.9%

Source: FCEC calculations based on answers from the survey questionnaire

Additionally it can be extracted from the collected information is the fact that 61.7% of the issues suffer from a situation in which no authorised PPP solution is approved for crop protection. This figure underlines the fact that without emergency solutions like derogations or off-label-uses, specific crop productivity is at risk and that illegal use might take place in a large number of cases with potential serious effects on human health and the environment.

Table 10 - Estimation of minor uses economic impacts - Lack of a.s.

No PPP authorized	PPP originating from a unique a.s.	PPP with a.s. likely to be withdrawn	PPP with a.s. likely not to be supported for renewal in Annex I	Others
873	73	88	112	267
61.7%	5.2%	6.3%	7.9%	18.9%

Source: FCEC calculations based on answers from the survey questionnaire

Finally, the collection of information on the economic impact within this report reflects only an analysis of the status quo of the situation within the EU. It should however be taken into account that, based on research on possible future scenario's as presented above, the economic impact of minor uses issues will not decrease within the next years, but in the contrary, will gain importance affecting the entire EU economy.

2.4 Inventory of the existing initiatives addressing minor uses issues

Section 4 of the survey questionnaire focuses on the identification of national initiatives that are already in place in the Member States to address minor uses issues.

Sixty-one per cent (61%) of respondents indicated that at least one national initiative is in place within their country to address minor uses issues, being as follows:

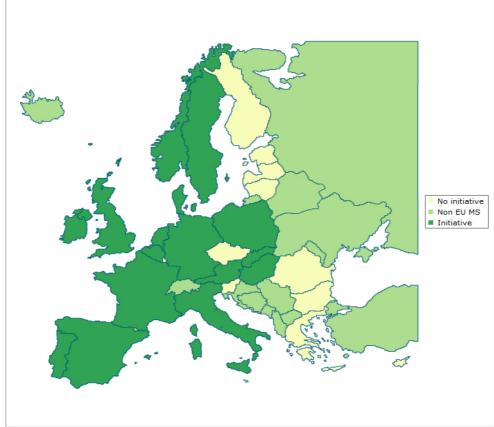


Figure 2 - MS (15) in which initiatives related to minor uses issues are in place

Source: compiled by the FCEC based on responses of the survey

Most Member States listed initiatives that cover activities like working groups or campaigns of a coordinative nature. Features that can be found within most initiatives are:

- Participation of a large number of stakeholders like grower or producer representatives and competent authorities and close cooperation between all parties;
- Regular meetings;
- Listing of problems and possible solutions that lead in some cases to common lists of priorities which can in turn lead to projects.

Initiatives that can also be found in a large number of Member States are those that cover technical working groups which have mostly the following features:

- Participation of national experts;
- Close cooperation with other cooperative initiatives like above mentioned working groups;
- Definition and implementation of technical measures that address minor uses issues;
- Prospective analysis of pest control aspects and provision of support regarding active substance authorisation to solve minor uses issues;
- Searching of alternative solutions and initiation of projects;
- Cooperation and communication on European level.

Besides these mostly public funded activities some private initiatives exist. They are mostly collaborations between the producers (industry) and the users of PPP (growers) and contain for example a fund in support to the production of residue data within a country. These initiatives appear however very much on an *ad hoc* basis and meet in most cases specific local needs.

Some Member States (BU, CZ, EE, LV, LT, RO, SL, and FI) have indicated on the other hand that no initiatives addressing minor uses issues are in place. The reason for this absence of initiatives can be found mostly in the fact that there seems to be less or no demand for such activities, or simply in a lack of funding/capacities.

The collection of national initiatives can be found in the Annex V.

Below, an overview of the initiatives in place within MS is given by grouping them into four categories of possible initiatives:

- Working groups, these initiatives cover a group of representatives from different sectors and industries, national competent authorities and other experts that deal with technical problems and the finding of solutions. Typical activities of these working groups cover coordination, prioritisation and exchange of data. The funding of these initiatives covers mainly FTEs and the organisation of meetings;
- Designated official experts, these initiatives cover a contact point/official expert
 within the national competent authority that is designated (fulltime/halftime) for
 minor uses topics. These experts are inter alia dealing with the day to day treatment
 of minor uses issues and are financed by public funding;
- *National funds*, initiatives that are listed in this category cover national funds that are specifically in place to finance efficacy and residue trials for minor uses. The funding of the budget fluctuates between initiatives;
- *Private initiatives,* within this group of initiatives, purely private activities that address minor uses without direct intervention of the NCA are grouped.

Table 11 - List of national initiatives

	TECHNICAL WORKING GROUP	OFFICIAL DEDICATED EXPERTS	NATIONAL FUND	PRIVATE INITIATIVE
SHORT DESCRIPTION	Group of representatives from different sectors and industries, national competent authorities and other experts that deals with technical problems and the finding of solutions.	Person/group of persons within the national competent authority that is responsible for minor uses issues.	Fund to finance efficacy/residue trials for minor uses.	Private initiatives that address minor uses issues (without intervention of the responsible national competent authority).
MAIN ACTIVITIES	Coordination, development of priority lists, exchange of information and data.	Day to day treatment of minor uses issues, international coordination and national representation, establishment of good working relations, development of legislative solutions.	Fund to finance efficacy and residue trials for minor uses with an advisory board in place (composition fluctuates according to the distribution of funding) that evaluates the research proposals.	Activities fluctuate between basic coordination and private funding of efficacy and residue trails.
INVOLVED PARTIES	Representatives from different sectors and industries, national competent authorities, experts (e.g. research institutes).	National competent authorities.	Representatives from different sectors and industries, national competent authorities.	Representatives from different sectors and industries.
ANNUAL BUDGET	-	100.000 - 1.000.000	40.000 – 2.000.000	20.000 – 200.000
USE OF FUNDING	Only FTE and organisation	Salary and overhead.	Efficacy and residue trials.	Various uses.
NATURE OF BUDGET	Mixed	Public	Mixed	Private
EXISTS IN	BE, DE, ES, FR, NL, AT, PL, PT, UK, SE, NO	BE, DE, IE, FR, LV, NL, PL, PT, SK, SE, UK, NO	BE, DK, DE, IE, ES, FR, NL, SE, UK, NO	BE, IE, FR, LV, NL, PL, UK, NO
TOTAL FUNDING IN PLACE WITHIN THE EU (Based on the data collected by the survey, interviews with experts and desk research)		€1.219.500	€8.173.000	€490.000

Food Chain Evaluation Consortium

3 POLICY OPTIONS TO ADDRESS MINOR USES ISSUES

3.1 Priorities for financial support at the EU level and rationale for the selection of the options

Before proceeding with the analysis of the opinions of those consulted on the different options for greater support at the European level, it is important to summarise the key priorities for this support that came up during the various consultations. A summary of these key priorities and the more broadly identified priorities is set out below.

3.1.1 Funding

It is clear that funding is the priority envisaged by the most respondents. More than 90% felt that a direct funding of co-operation would be useful. In aiming to identify where funding would be particularly useful, our initial questionnaire asked respondents to identify the need for more funding in two different categories — travel & expenses and development of collaborative tools and minor uses problem solving projects.

The funding is perceived as being a must in this approach and not only by bringing financial resources to the actors. It would be seen as a key commitment from the European Commission in supporting the issue of minor uses. Most of the actors met during the study consider that a non-regulatory approach could not be considered as the problems identified lie with EU legislation. Therefore, a non-regulatory approach is per definition not effective for solving the problem.

3.1.2 Knowledge management

The need for better knowledge management, through the development of data sharing tools and communication between actors, has been largely highlighted by the respondents. During the 2001-2009 period, several MS have initiated the set-up of some databases based on their own needs. These databases are fulfilling national needs and have shown added value but at regional level only. This is the case for the HDC and the Liaison databases in use in the UK, the field trial data management system developed by the German and the project management system under development by the French. This list, which is not complete, shows that needs exist but approaches have been taken nationally instead of European wide. A wider approach is required.

Priorities relate almost entirely to data sharing and information dissemination – interlinking existing networks and databases, establishing access to databases via a web portal, providing information on relevant policies and regulations, and collating needs.

Therefore the approach should not only be to develop data sharing tools and databases, thinking that actors will use the databases. Some efforts should also be devoted to secure that actors will fully use the tools and that communication between CA, risk assessment

agencies and stakeholders is becoming efficient. A win-win situation should be created in order to secure data entry in the tools and data flow (see governance option below).

3.1.3 Minor use problems solving projects

When most policy makers consider that setting-up data sharing tools may be sufficient in solving most of the minor uses issues, both PPP industry and producers/growers are of the opinion that the EU should also fund individual projects leading to the solving of minor use issues of EU importance. Their financial participation may not be guaranteed if the EU fund would not cover support for individual projects.

On the basis of these main priorities, four options related to the tasks to be financed by a EU fund are considered and two options are considered for the governance approach (the selection of the preferred option is out of the scope of the FCEC study).

Policy options regarding the tasks to be covered by the EU fund

The following options were examined regarding tasks to be covered by the EU fund:

- Option 1 Status quo
 No EU financial support. Coordination and EU efforts continue on a voluntary basis.
- Option 2 "Limited" EU support
 EU budget is granted to facilitate meetings of the North and South Working Groups (back to the 2001-2009 situation).
- Option 3 "Moderate" EU support

Encompassing option 2 plus EU funding support for strengthening the development and management of the cooperation instruments (e.g. centralised databases) and the activities at the level of the TWGs + Steering Committee (SC) through the establishment of a Technical Secretariat.

Option 4 – "Strong" EU support
 Encompassing option 3 + EU financial support for projects execution + TWG coordinators are part of the Technical Secretariat.

From the outset, it was considered that options 2 to 4 are not conflicting options but cumulative and that within each of these options a number of specific tasks should be developed and possibly assessed individually, which could lead to the partial redefinition or re-arrangement of certain options, in particular the preferred option.

Policy options regarding the governance of the Technical Secretariat (TS)

Under option 3, we introduce the idea of setting-up a Technical Secretariat as it has been highlighted by many stakeholders and NCAs that a centralised means for collecting and analysing data and for coordinating the organisation of the TWGs and SC meetings was

required. This approach would allow a "one stop shop" and would bring visibility to the activities.

This TS can be established in two different forms:

- Option a:

The Technical Secretariat is part of an existing organisation (COM, MS governmental body, research institution, technical institute, etc.) in which the organisation is responsible for the secretariat and should report to the Steering Committee;

- Option b:

The Technical Secretariat, guided by the SC, is attached to a hosting organisation that provides housing and other services, but has no formal say over the work of the Technical Secretariat.

These two different options are not handled separately, but are integrated in the overall options definition according to the following approach:

Table 12 - Matching of options related to the tasks & options related to the governance of the TS

	Option 1	Option 2	Option 3	Option 4
Option a	Not applicable	Not applicable	Option 3a	Not applicable
Option b	Not applicable	Not applicable	Option 3b	Option 4

The following list of criteria has been developed for presenting the different options:

- Governance:
 - Structure (MS vs Zonal vs EU)
 - o Involvement of actors (CAs and stakeholders)
 - o Technical Secretariat
 - o Governance organisation
- Activities and Responsibilities:
 - Data management including data standardisation, database development, data entry and data QC, and data dissemination and sharing
 - Project management (individual projects)
 - Initiation
 - Execution
 - Prioritisation
 - Funding
- Resources:
 - o EU Level
 - Tools

- Staff
- o MS level
 - Tools
 - Staff
- Stakeholders level
 - Tools
 - Staff
- Funding:
 - Level of funding
 - Source of funding

The following definitions and roles apply to the description of the options:

- **Steering Committee (SC):** established to provide a high level discussion platform and a framework for strategic planning and implementation.

The objectives of the SC are:

- To define the global strategy of the activities covered by the EU fund. This strategy materialises in a yearly action plan;
- o To steer the cost-effective implementation of the annual plan;
- To foster European and national joint actions.

The SC is established at the European level and is chaired by the European Commission. Depending on the option, it can be supported with a secretariat (see Technical Secretariat). The SC is composed of NCAs representatives and of EU level stakeholders who are participating to the funding of the EU fund and may also invite other interested parties to participate to meetings on a case by case basis, including e.g. research community, international organisations.

- **Technical Working Groups (TWG):** established based on the current situation to:
 - o Implement the action plan defined at the SC level (top-down);
 - Compile needs by coordinating activities of the expert working groups (see Expert Working Group) (bottom-up);
 - Define projects and set-up priorities for the zone;
 - Manage projects from implementation to completion (in Options 1 to 3 TS manages projects in Option 4;
 - Report to the SC on completion of the actions.

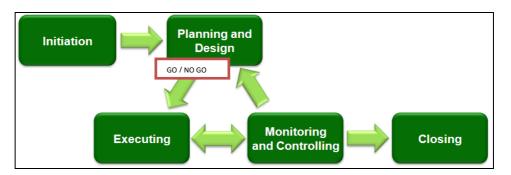
Two TWG are established (North and South zones). The chair and the secretariat of these TWG are option specific (see below). They include NCAs,

national/regional stakeholders and any national experts relevant for the activities of the TWG.

- Expert Working Group: Expert Working groups are defined on a case by case basis based on needs existing at a given time period. They can be created at any moment and can be dissolved when their objectives have been met. They target dedicated local, regional, crop, group of crops or sectorial issues. An Expert Working Group leader is appointed to chair and coordinate activities of this EWG.
- Project: A project is a temporary action to which a start and an end date as well as a budget are associated and for which deliverables might be defined. It is undertaken to meet unique goals and objectives. Due to their temporary nature, projects stand in contrast to business as usual which are repetitive, permanent functional work.

In the context of this study we consider that a project is an activity leading to the solving of (a) minor uses issues. Other activities can be organised in a project mode (e.g. setting-up of databases) and therefore the term activities will be used rather than project.

The different phases of a project are as follows:



<u>Project initiation</u> consists in planning and designing a project in terms of objectives, project plan, responsibilities, budget, deliverables and timing.

<u>Project execution</u> relates on activities for the implementation, monitoring, controlling and closing a project. Generally between project initiation and project execution a GO/NO GO decision is required.

 Technical secretariat (TS): Technical support to make the global general governance of the EU fund operational and cost-effective.

The TS is in charge of:

- Developing and maintaining data sharing tools (e.g. databases, extranet)²⁰;
- o Developing and implementing the governance organisation;
- Preparing the WG meetings at SC and TWG levels. Moderation id done by the coordinators;
- Monitoring the correct and cost-effective implementation of actions including project supervision when relevant;
- o Managing projects for which EU funding is granted.

Option 3a: The Technical Secretariat is part of a hosting organisation (COM, MS government, research institution) in which the hosting organisation is responsible for the secretariat and should report to the Steering Committee. The organisation is receiving the funds and is responsible. The Technical Secretariat is guided by the Steering Committee and by the hierarchy of the hosting organisation it is part of. The TS implements the annual plans that are defined by the SC and does the daily work. It may be mandated (or not) to spend money (e.g. on projects). The 2 TWG coordinators are not directly attached to this structure and remain governmental employees. They are supported by TS staff (1 coordinator + 0.5 secretary + 0.5 IT specialist).

Option 3b: The Technical Secretariat may be attached to a hosting organisation that provides housing and other services, but has no formal say over the work of the Technical Secretariat. The TS is only guided by the Steering Committee, does the daily work including self-management, and is mandated to spend money (e.g. on projects), receives any funding directly and is paid directly from the funds received. This construction demands legal steps. The 2 TWG coordinators are not directly attached to this structure and remain governmental employees. They are supported by TS staff (1 expert + 0.5 secretary + 0.5 IT specialist).

Option 4: The only difference in Option 4 vs. option 3b is based on the fact that under option 4, the 2 TWG coordinators are part of the TS and are fully paid by the EU fund. Under this option the TS staff will include 2 coordinators (one of them being the manager of the TS) + 1 secretary + 0.5 IT specialist.

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²⁰ Development and maintenance of databases can also be outsourced to competent organisations in this field (e.g. EPPO)

- Knowledge management: Knowledge management or data management would consist of several tasks as follows:
 - <u>Data standardisation</u>: any development of collaborative tools requires, as a pre-requisite, that data structuration is being agreed between actors that will use the collaborative tools (the database). This task includes, in particular, an agreement regarding grouping of crops, list of minor uses, crop codes (e.g. Bayer codes), extrapolation, etc. This activity should take advantages of the work being done by EPPO on standardisation and then be further developed till completion.
 - O <u>Development of the databases</u>: As mentioned earlier, several databases addressing national or regional needs have been developed. None of them has an European profile and therefore two approaches can be taken in developing these European databases:
 - Modification of the existing ones to fit to the needs of all actors (cheap approach but technical IT difficulties to be anticipated);
 - Re-writing of the databases (more expensive but state of the art databases would be available).

Interviewees have mentioned that several databases need to be created:

- A database including ALL PPP registered in the EU PER MS and PER use;
- A database listing all residues trials that have been performed on a given a.s. or a given PPP in the EU. The idea is not to include the trials data in the database but to list all trials that have been performed to produce residues data. Based on this information, any individual would be able to contact NCA or/and national agencies to see whether raw data are available or not and under which conditions (i.e. data confidentiality);
- A third database would be to develop an inventory of minor uses issues and possible solutions.

All these databases will be available via a web portal that has to be developed too. At this stage, interviewees do not consider that a EU database listing efficacy trials is required.

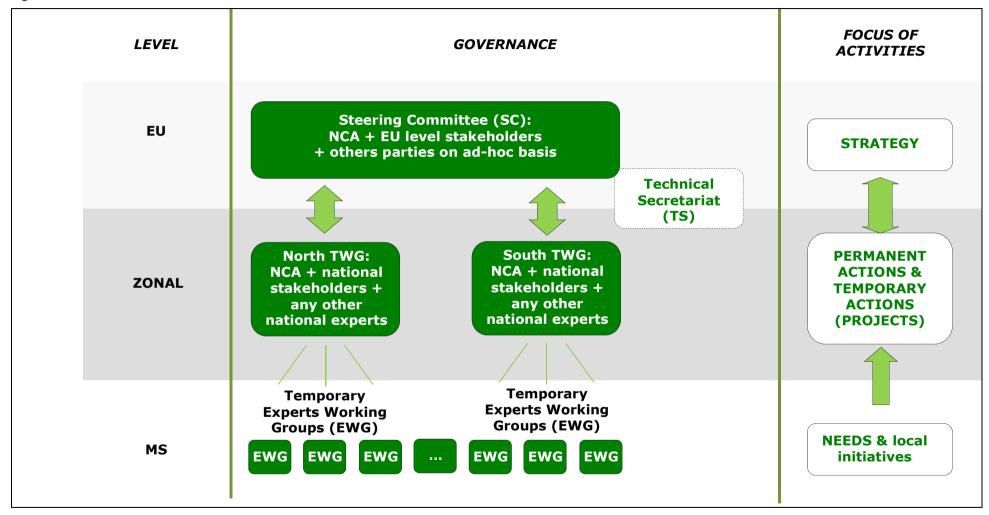
The development of these databases should be supported by national experts already engaged in the development and maintenance of the existing national tools.

 <u>Data entry:</u> when databases are created, data have to be entered in the databases with an important effort required for the first data entry as all data would have to be inserted in the databases. Based on discussions with interviewees during the field visits, it is estimated that initial data entry would require an effort of 0.3 FTE per MS. The alternative approach that would be to ask the TS to perform this task is not perceived as a viable option as the workload would be too important if the TS would have to perform data entry for 27 MS.

- Data quality control: When data are first entered in the databases, a QC would have to be performed in order to secure data uniformity. This task is perceived as being a task of the TS.
- Data ownership: Data ownership refers to both the possession of and responsibility for information. Ownership implies power as well as control. The control of information includes not only the ability to access, create, modify, package, derive benefit from, sell or remove data, but also the right to assign these access privileges to others. Data ownership is today a reason not to exchange data between MS. Applicants that have paid to produce residues data in a given MS do not always want these data to be used by a third party for free. Therefore these issues might be difficult to solve when attempting mutual recognition. In the context of this study, data ownership is discussed on a project by project basis (see option 4). For that reason, databases created under option are listing all possible sources of data BUT do not include data. A reference is made to data sources and a contact name is given.
- Governance organisation: this concept refers to the implementation of working principles, decision making process, voting rules, budget allocation rules, etc... to secure the cost-effective functioning of the mechanisms put in place for governance purposes. We do not intend to describe all organisational, operational and working procedures in this proposal as these aspects should be discussed within the SC when established. We limit ourselves to list the criteria of high relevance for the analysis of the impacts of each option.

The following scheme shows how the structures presented above articulate:

Figure 3 - Structure of the different committees



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3.2 Description of the options

Each option is presented in comparison to the previous one starting from the *Status Quo* (baseline option).

The activities supported by the EU fund are presented at maturity stage when the activities supported by the fund are up and running. These options have therefore to be seen as objectives to be reached.

Transitional actions (i.e.; action that may be required, before and after the establishment of the EU fund in the legislation) to reach that maturity stage are listed when assessing the options. This is particularly the case for the possible set-up of the Technical Secretariat by Research funding (e.g. COST or ERA-NET programs) before the entry into force of the EU fund.

The total costs are segmented between recurrent and one-off cost to highlight the importance of these transitional actions and their related costs.

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Table 13 - Description of each option

Specific	20772014 61 .		OPTION 3 - Moderate EU support		OPTION 4 - Strong EU support				
characteristics	OPTION 1- Status quo	OPTION 2 - Limited EU support	Option 3a	Option 3b	Option 4b				
GOVERNANCE	OVERNANCE								
Structure									
EU level	No	Steering Committee that meets twice a year	Steering Committee t	hat meets twice a year	Steering Committee that meets every 2 months				
Zonal level	2 TWG exist (as defined today: 1 for the North and 1 for the South)).								
MS level	Any EWG defined within the zon	e (at MS(s) , regional, local levels) are linked to the	TGW of that zone. In cases or in	nter-zonal EWG, the two TWG d	ecide to which TWG the EWG reports to.				
Involvement of sta	ikeholders								
In the SC	Not involved, only present as observers		Full members with defined status, role and responsibilities Only stakeholders participating financially to the fund are members		Full members with defined status, role and responsibilities. Only stakeholders participating financially to the fund are members				
In the TWG	Participate to the meeting of the WG but their status is not clearly defined. Stakeholders welcome on invitation, stakeholder platforms as regular members		Full members with defined status, role and responsibilities		Full members with defined status, role and responsibilities				
In the EWG	Participate to the meeting of the EWG as initiative may come from stakeholders.any EWG defines itself based on needs and will invite potential participants, mainly stakeholders.		on a case by case basis		On a case by case basis				

Specific			OPTION 3 - Mod	erate EU support	OPTION 4 - Strong EU support
characteristics	OPTION 1- Status quo	OPTION 2 - Limited EU support	Option 3a Option 3b		Option 4b
GOVERNANCE					
Technical secretar	iat				
	Not applicable	Not applicable	Option 3a: The Technical Secretariat is part of an organisation (COM, MS government, research institution,) in which the organisation is responsible for the secretariat and should report to the Steering Committee		Option 4b: The Technical Secretariat, mandated and guided by the SC, is attached to a hosting organisation that provides housing and other services, but has no formal say over the work of the Technical Secretariat (similar to Option 3b)
Governance organ	isation			•	
	Not clearly defined	Not clearly defined	The Technical Secretariat is guided by the Steering Committee and by the hierarchy of the organisation it is part of. It implements the annual plans that are defined by the SC and does the daily work. It does NOT receive funding directly but via a budget developed and approved by the SC. It may be mandated (or not) to spend money (e.g. on projects related to the improvement of the functioning of the system - horizontal projects). The 2 TWG coordinators are not directly attached to this structure and remain governmental employees. They are supported by additional TS staff (1 coordinator + 0.5 secretary + 0.5 IT specialist).	hierarchy of the organisation it is part of. It implements the annual plans that are defined by the SC and does the daily work. The TS is only guided by the Steering Committee, does the daily work including self-management, and is mandated to spend money (e.g. on projects), receives any funding directly and is paid directly from the funds received. This construction demands likely legal steps	It is mandated to spend money (e.g. on projects), receives any funding directly and is paid directly from the funds received. The two coordinators of the TWG are integrated in this structure. They are supported by additional staff (1 secretary + 0.5 IT specialist). 4 staff in total

Specific	OPTION A COLUMN	COTION 2. Living Ellipson	OPTION 3 - Mode	erate EU support	OPTION 4 - Strong EU support		
characteristics	OPTION 1- Status quo	OPTION 2 - Limited EU support	Option 3a	Option 3b	Option 4b		
ACTIVITIES COVE	RED BY THE EU FUND						
Data managemen	t						
Data standardisation	-			Data standardisation is orga	nised by the TS		
Data on needs and solutions	Data is collected on own initiative in MS	Data is collected on own initiative in MS	Data on needs and solutions are collected and inventorised within a structured database, based on inputs from any operators in the EU. Databases developed, managed and promoted by the TS are accessible to all operators. Data entry is performed directly by national operators via an extranet platform		structured database, based on inputs from any operators in the EU. Databases developed, managed and promoted by the TS are accessible to all operators. Data entry is performed directly by national operators via an extranet		Data on needs and solutions are collected and inventorised within a structured database, based on inputs from any operators in the EU. Databases developed, managed and promoted by the TS are accessible to all operators. Data entry is performed by the TS
Data on national authorisations	Data is collected on own initiative in MS	Exchange of data is coordinated within each WG but is on <i>a case by case</i> basis. Exchange of data between the WG might also happen	Compiled in the EU database		Compiled in the EU database		Compiled in the EU database.
Data on results of residue trials	Data is collected on own initiative in MS	Limited exchange of data on results and residue trials	Compiled in the EU database		Compiled in the EU database		Compiled in the EU database.
Data on results of efficacy trials	Data is collected on own initiative in MS	Data is collected on own initiative in MS	NOT compiled in the EU database				Not compiled in the EU database at short term. Databases are designed to possibly consider EU centralisation at medium to long term.

Specific characteristics	OPTION 1- Status quo	OPTION 2 - Limited EU support	OPTION 3 - Moderate EU support		OPTION 4 - Strong EU support					
			Option 3a	Option 3b	Option 4b					
	Project management (project to be understood as a group of actions leading to the solving of a or several minor use issues). Other activities can be organised in a project mode (e.g. setting-up of databases) and therefore the term "activities" will be used rather than "project"									
Project initiation	MS can set own priorities and private initiatives from industry can take place		Projects are initiated at EWG and TWG. The TWG are in charge of developing project proposals		Priorities are formulated at zonal level with the WG , then consolidated at EU level within the SC					
Project execution	No project at EU level, only at national level		Project execution by the TWG or EWG. Technical secretariat NOT on support to project execution.		Project execution by the Technical Secretariat for all projects funded by the EU fund only.					
Project prioritisation	MS can set own priorities and private initiatives from industry can take place		Prioritization at TWG level only		Projects that are defined at TWG level are submitted to the Technical Secretariat for prioritisation and then validated by the Steering Committee.					
Project funding	<i>ad-hoc</i> at MS, regior Funding by stakeholders o		Funding by stakeholders or through national fund.		EU financial support limited to projects for which a financial support has been requested via a proposal submitted by the TWG (based on inputs submitted to the TWG by the EWG) and accepted by the SC.					

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Specific characteristics	OPTION 1- Status quo	OPTION 2 - Limited EU support	OPTION 3 - Moderate EU support		OPTION 4 - Strong EU support	
			Option 3a	Option 3b	Option 4b	
RESOURCES						
Tools						
Database	No EU database. Any initiative takes place on a voluntary basis (public)		One centralised database is developed and managed by the TS			
Extranet	No	No		or data sharing)	Yes (necessary for data sharing)	
Staff (quantifiacta	ion of staff requirements is presented with ot	her costs in section 3.4: implementation cos	sst of each option)			
EU staff	No	Yes	N	0	No	
MS staff	Yes	Yes	Yes		Yes	
Stakeholders staff	Yes	Yes	Yes		Yes	
Technical secretariat	No	No	Y	es	Yes	

Specific characteristics	OPTION 1- Status quo	OPTION 2 - Limited EU support	OPTION 3 - Mod	lerate EU support	OPTION 4 - Strong EU support
			Option 3a	Option 3b	Option 4b
FUNDING OF THE	EU FUND (complementary to any zonal	, regional, national, local public and/or p	orivate funds)	•	
Source of funding					
Private funding (mainly PPP industry, producers)	No	No	Co-financing of governance, data management activities and possibly other activities defined on a need basis.		Co-financing of database, coordination and projects management
Public funding					
MS	No	Each MS contributes to the funding of its activities within and participation to the TWG as well as the funding of national initiatives, if any. Salary of civil servants are paid by national organisations. Stakeholders representatives costs are not reimbursed when participating to meetings.	Each MS contributes to the funding of its activities and participation within the TWG as well as the funding of national initiatives, if any. The two coordinators are paid by national governments.	The funding of the two coordinators is covered by the EU fund. For other WG members, each MS and stakeholder contribute to the funding of their activities within the EWG, TWG and/or SC	The funding of the two coordinators is covered by the EU fun For other WG members, each MS and stakeholder contribute to the funding of their activities within the EWG, TWG and/or SC
EC	No EU fund	EU funds to facilitate the meetings of the SC and the two TWGs (meeting rooms, travel expenses, etc)	EU funds to facilitate governance organisation, to develop and maintain tools and to accomodate the TS.	EU funds to facilitate governance organisation, to develop and maintain tools and to accomodate the TS.	EU funds to facilitate governance organisation, to develop an maintain tools and to accomodate the TS. Co-financing of the implementation of the individual projects
Eligible costs				•	
TWG coordinators travel expenses		Yes	Yes	Yes	Yes
TWG coordinators salaries and admin overheads costs	No EU fund	No	No	No	Yes
Civil servant travel expenses		Yes	Yes	Yes	Yes
Civil servant salaries and admin overheads costs		No	No	No	No
stakeholders travel expenses		No	No	No	Yes
Stakeholders salaries and admin overheads costs		No	No	No	No
Others (experts) travel expenses		No	No	No	Yes
Others (experts) salaries and admin overheads costs		No	No	No	No
Other costs for coordination of SC and TWG meetings		Yes	Yes	Yes	Yes
Development & management of data management tools		No	Yes	Yes	Yes
Data entry activities costs		No	No	No	Yes
Technical secretariat administrative costs (including salaries and admin overheads costs)		No	Yes	Yes	Yes
Project management costs		No	No	No	Yes

3.3 Assessment of the options

The study team was asked to evaluate the relative advantages (positive impacts) and disadvantages (negative impacts) of these four options on the tasks of the EU fund and on the two options of the governance related to the TS.

This chapter analyses the findings of the consultation phase of the study in relation to the views of stakeholders on the advantages and disadvantages of these four scenarios.

The analysis that follows is based on the results of the survey, interviews and workshop. In interpreting the results, it is important to bear in mind that the research team has been looking for comments and judgments of the four "types" of options rather than discussing any details on how the EU fund should be structured and how it should work. As such, participants were asked to make judgments on the basis of their own conception of what each of the four options implied in details.

As a general comment, the research team would like to highlight that very often during the interviews; participants were intended to discuss the details of the organisation and the functioning of the EU fund rather than to compare the different options.

As we didn't discuss the costs of implementing each option in details with the interviewees, we are presenting these costs in the next section.

3.3.1 Overall preference

All interviewees were asked which of the four options concerning the creation of a EU fund they favoured. The results from the survey are presented in section 2. Additional results from field visits show:

- A very clear rejection of option 1 and option 2;
- Policy makers support in majority the option 3. When CAs from "large" MS recognise that the system should evolve mid to long term to option 4, CAs representatives from "small" MS do not see any added values in moving to option 4 as none of their projects would be considered as a priority by the EU fund;
- A clear preference for option 4 for a large majority of the producers and growers and for the PPP industry.

The views of the overwhelming majority of stakeholders and CA representatives were that the EU fund held a significant potential, but needed a radical step forward from the 2001-2009 period.

After indicating their general preference, all interviewees were asked to provide their views on the relative advantages and disadvantages of the four proposed scenarios. This was also a subject of discussion during the workshop. The rest of this chapter analyses in turn the positive and negative aspects of each option, as expressed by the interviewees.

3.3.2 The Status quo (Option 1)

The survey, interviews and workshop demonstrated an overwhelming rejection of the « no action » scenario. A large majority of those consulted saw no advantages in taking no action, except that it would be easy and cheap for the Commission services. They also highlighted that there are numerous difficulties faced by producers and growers in the field of crop protection that would remain un-addressed if no action were taken. The large majority of interviewees indicated that the number of problems will continue to grow as the number of a.s. will continue to decrease and that possible resistances may appear for uses for which only one a.s. is authorised.

Furthermore, several of those consulted felt that taking no action would represent a step backwards in relation to the current situation in Europe as to date the majority of stakeholders and NCAs has the impression that the Commission has understood the emergency of the issue and is willing to act.

By doing nothing the Commission will deliver the message that, after analysis of the situation, it has decided not to support any activity addressing the solving of the issue.

A "do nothing" action from the Commission would also impact the nationally funded initiatives for which funding levels may be reduced. National government may consider that if the EU is not willing to overcome these issues, and not willing to help MS to solve problems, why should the national governments act?

This negative sign may consequently lead to the risk that farmers and producers do use illegal products. Unauthorised cross-border sourcing of PPP and the use of non-registered products may develop. In the IA for the proposal for a Regulation replacing Directive 91/414/EEC performed by the FCEC in 2006, 17 of the 22 MS who responded to the survey reported problems with unauthorized imports or use and agreed that the lack of availability of PPP on the national market provides an incentive for unauthorized sourcing of PPP. This is a major concern, as unauthorized use of PPP potentially carries a risk for human health and the environment. Under option 1, illegal use may significantly increase especially in MS in which derogations are not granted.

One may think that moving to the new Regulation (EC) No 1107/2009 would lead to solving issues via the mutual recognition obligations (article 40) that have been reviewed in the new legal text and that therefore the minor uses issues would be mainly solved by the application of these obligations. As presented in section 2, the interviewees consider that mutual recognition principles will not lead to an improved situation at least in the coming years. Mutual recognition may work on new a.s. and new PPP but not on the "old" ones and results would not be visible before a period of minimum five years.

Under option 1, the number of derogations will continue to increase leading to a more negative perception of consumers towards PPP, derogation should remain the exception.

Participants in the consultation felt that action is necessary for a range of fundamental and practical reasons that have already been highlighted in section 2 of this report. On a practical level, many of these issues were highlighted as justifications for action in order to close the minor uses gaps.

3.3.3 Limited EU support (Option 2)

Under option 2, the organisation that was in place during the 2001-2009 period is reestablished and funded by the COM. It would consist of:

- One Steering Committee including representatives of the EU 27 MS and stakeholders as observers;
- Two Technical Working Groups (North and South) coordinated by two national experts belonging to the CA (France and the Netherlands). TWGs are composed of NCAs representatives and stakeholders.

The EU fund consists in paying the travel expenses of NCAs for their participation to the SC and TWG meetings. Salaries and daily allowances are not reimbursed by the COM. Only coordinators received a daily allowance. Yearly COM budget ranged from €6,000 to €25,000 in that period.

The consultation phase of the study revealed low support for the re-establishment of the 2001-2009 situation even if it was recognised by a majority of interviewees that it would be a strong improvement compared to option 1, but not a sufficient one.

As minor uses issues are mainly due to lack of PPP authorised for a given use, one may think that the best approach would be to have 3 TWGs aligned to the zonal authorisation groups of the new Regulation (EC) No 1107/2009. However, nearly all respondents to the general survey (>90%) rejected this approach of three zones as they prefer to keep the established two coordination areas system.

The main argument presented by the respondents to the questionnaire to justify this position lies in the fact that an important blocking factor to facilitate mutual recognition is the lack of residues data flow between MS and therefore the zonal distribution should be aligned to the residues zones rather than the authorisation zones.

The research team sees some difficulties in this approach for the Nordic MS that have specific issues to solve and therefore we consider that a third TWG including these MS should be created. Another point of attention is the number of MS in the North coordination zone that may be seen as too important to be fully effective and operational.

Advantages

Meetings that took place during the 2001-2009 period are considered by a majority of interviewees as largely cost-effective as they helped experts from all MS to exchange on the current situation in their country and on the difficulties to address the issues. A network of experts has developed and is today up and running and ready to take a step forward.

Some improvements in data standardization have been achieved and presentations of national initiatives have helped developing national approaches.

The approach of having a two-level structure (SC plus TWGs) allows balancing EU and regional representation in the global governance. "Bottom-up" or "grass root" approach in identifying needs is facilitated. It is demand driven.

Disadvantages

The main critic of this approach as reported by the interviewees is based on the fact that after a good set-up and implementation of the SC and TWGs, these meetings became places for exchange of ideas and networking and not *fora* in which concrete actions were discussed and agreed.

Participation to these meetings is voluntary, leading to the difficulty of formalising the activities of these committees. Networking is also largely based on personal relationship rather than on needs. Leadership is not clearly established and the mandate of these committees remains rather vague.

A large number of interviewees highlighted that very few concrete actions resulted from these discussions and that very few issues have been solved during that period. Additionally, the data sharing tools have not been developed during that period.

These committees were composed of technical experts and communication to policy makers at MS and COM level to explain the importance of the minor use issues was missing. Certain interviewees consider that communication to citizens is also required to explain the risks and issues of lack of PPP for crop production and for the preservation of the environment and the crop biodiversity at EU and regional levels.

Under this option, resources would be dedicated to organise meetings that would not bring concrete results in filling the minor uses gaps as governance of these committees is not sufficiently adapted. While this approach was required in the early days to develop networks of experts, it is being seen today as not sufficient.

3.3.4 Moderate EU support (Option 3)

Under option 3, the same governance structure as in option 2 will be re-established and will consist in one SC and two TWGs. In addition, a Technical Secretariat will be created to strengthen the governance of this structure.

Most of the interviewees recognise that the governance of such a large structure, covering all MS and the majority of agricultural sectors, will be costly and complex and therefore consider that a secretariat is required. The study team has looked at a series of existing observatories and secretariats in the field, including EU and OECD secretariats, and has identified the following likely components of such a new structure.

It is anticipated that the Technical Secretariat would operate under the mandate and reporting line of the SC as presented above. This TS is a support structure, offering project management capacities, responsible for the implementation of the functions of the SC with 2 to 4 staff (this doesn't include the coordinators that are paid by their authorities they belongs to). This secretariat would be responsible for structuring the annual work programme to function as operational action plans for the given year, for the day-to-day implementation of the knowledge management tools, for the organisation of the meetings of the SC and the TWGs and in general liaising with institutions and stakeholders to address specific information needs. In its initial phase, the TS would be in charge of supporting the SC in establishing dedicated governance and decision making processes that are required within the SC and between the SC and each of the established TWG. A clear set of guidelines on the objectives, mandate, role, and operational procedures of the different bodies is required to secure delivery of concrete results in support to the global objective which is to reduce the minor uses gaps.

A large majority of interviewees consider that this Technical Secretariat should be seen as The European "One Stop Shop" for minor uses issues and that its staff should be managed by a senior expert in the field of PPP authorisation.

Advantages

Option 3 would profit from the networking efforts that have been established during the last 10 years. Most of interviewees consider that it is a *continuum* to what was in place in the last years. On the basis of the option 2, it will establish a robust platform for further networking and data exchange between MS as clear procedures and rules are defined. Participation will not be seen as on voluntary basis and therefore committees members will be further committed to the efforts and the results. Responsibility awareness would be strengthened.

Establishment of such a platform with the addition of the TS will give credibility and more visibility to the action. It would facilitate to implement activities covered by the EU fund and in particular would help:

- To build a strong reputation as a sound investment to solve minor uses issues;

- To secure stakeholders and NCAs effective engagement;
- To provide the correct framework in which the experts and NCAs representatives can cooperate in a transparent and efficient manner while extending trust between participants would lead to optimal data sharing;
- To establish a recognised democratic style of management and decision making process. Some interviewees have reported that the current situation and the lack of structured approach and governance leads to the situation where only a couple of MS seem to have a word;
- To help to build consensus and cooperation at a European level, generating an important sense of unity;
- To be the European representative at the international level (e.g. OECD, IPPC, GLOBALGAP, etc...) and to manage relations with non-members;

The Technical Secretariat would help to further connect leading experts, to accelerate actions and would be a gateway to solutions.

Under this option, the data sharing tools would materialise as the TS would be in charge in leading the efforts in developing these tools. A project team composed of national IT and specialists and experts (including EPPO) in the field should be created to agree on the exact needs and to build a systematic knowledge management structure to capture information on needs and minor uses gaps. In order to act quickly, development of the databases and the web portal, some of which may be outsourced.

The support of the TS to the existing EU network allows members to advocate for additional national resources at the national and sub-national government levels and to engage in programs tailored to their needs and local conditions based on European-wide knowledge platform. Some interviewees consider that under option 3, incentives are created leading to additional available resources for national initiatives. This argument has to be balanced with the comments made by other interviewees indicating that national funds may be transferred to the EU fund leading to a reduction of resources for local initiatives.

Additionally, the TS may serve to provide the following:

- Maximisation of potential synergies between MS in completing projects and in R&D by building dynamics and by avoiding duplication of work at MS level;
- Effective and efficient dissemination of the results to a wider, in particular local government and producers audience;
- Recommendations for future common EU activities.

Disadvantages

For a large majority of the NCA representatives met during the field visits, option 3 is perceived as being largely sufficient to solve most of the current issues even if this option would not solve actual MS protectionism.

Producers/growers and the PPP industry are not of the same opinion as under option 3 projects leading to reducing minor use gaps are not EU funded or co-financed. For these interviewees, option 3 is not directly solving any problems but just putting in place the tools and the governance required for data sharing between MS. Under this scenario, individual projects will have to be initiated by NCAs or/and stakeholders as it is today. This is not being considered as sufficient as involvement of national experts is not guaranteed. Therefore, this option would lead to state-of-the-art data sharing tools with the risk that MS would not take full benefits of them.

Additionally, stakeholders consider that minor use gaps will not be fully removed by "just" exchanging data between MS. More and more cases where no solution exists will appear and therefore European-wide approaches would be required to reach the critical mass necessary to engage R&D efforts.

However, producers and the industry agree that option 3 is a good moving forward as long as option 4 is the long-term objective.

The other disadvantages that have been mentioned by the interviewees relate to the governance of the Technical Secretariat. As we had anticipated this type of remarks it was decided to develop a specific option for the set-up of this Technical Secretariat in the form of option a, and option b, which have been described in the introduction of this section.

For the majority of the interviewees the past and current discussions between MS are "polluted" by national strategies and personal positions. The Technical Secretariat should be structured and set-up in a manner that it would be out of any national political influence. For that main reason, the preferred approach for structuring the Technical Secretariat is option b meaning a Technical Secretariat that is mandated by the SC and that is fully reporting to this SC and only to it.

Under option a, the TS would be attached administratively to an existing institution that could be a national agency, a research institution, or a technical institute. In the case it is attached to a national agency or a CA, confusion may exist between the national and EU strategy that could differ based on the national importance of the minor use issues. In the case, it is attached to a research, or technical institute, interviewees consider that it would not be operational enough and that its activities would consist in "research for research".

Also, the fact that a double reporting line exists may create management issues.

On the other hand, it is recognised that setting-up a TS under "option a" would be quick and rather easy.

Under option b, the main difficulties would be to define the legal structure of such body that could be time consuming.

For option a, interviewees have already listed several structures that could host this TS and two MSs being France and the Netherlands sent an offer regarding hosting of the TS at the structure of the Division Agriculture and Nature as part of the Ministry of Economic Affairs, Agriculture and Innovation for the NL and at FranceAgrimer for France.

Another disadvantage of option 3 is based on a tactical and practical consideration. If option 3 is recommended to the Council and EP, it would hardly be possible to move later on to option 4 when needed.

3.3.5 Strong EU support (Option 4)

Under option 4, all tasks carried out under option 3 are implemented and two main modifications are considered:

- Individual projects with the objective of solving minor uses issues are funded, and
- In order to manage the individual projects, the two technical coordinators are integrated within the TS and therefore no longer attached to their national government.

Advantages

Option 4 capitalises all advantages that have been listed under the previous options. Several key additional advantages can be listed as follows:

- By having certain projects coordinated and EU funded, the EU fund takes a strategic dimension that did not exist under option 3 and an alignment to the EU PPP policy is possible as control over projects is taken (possibilities to find alternatives to chemical products in the form of non-chemical solutions such as agronomy (e.g. crop rotation) or/and resistant varieties, etc.) One may also consider that such type of platform could be used to solve issues related to other EU policies (e.g. finding protection solutions for emerging and quarantine pests);
- Projects will lead to re-enforced collaboration between MS and especially between national agencies in charge of assessing the risks of the PPP and a.s. dossiers. This may lead to harmonisation of the assessment guidelines and of national RA strategies;
- Under option 4, stakeholders and producers, down to individual farmers, will recognise the value of the EU fund as concrete results will be delivered, potentially leading to an increase of stakeholders' financial participation to the fund resulting in a snow ball situation;

- By having the two technical coordinators attached and paid by the fund, the existing conflict of individual interest will disappear. The structure is clear and the governance reinforced. With clearer working procedures the TS will gain in neutrality and therefore in credibility;
- Difficult dossiers (e.g. uses for which research is required to find an economically sustainable protection solution) can be managed via projects that could be developed by associating the EU fund expertise to R&D expertise and collaborative EU platforms (ERA-NET or COST) and possibly international expertise;
- Option 3 does not motivate "large" MS collaboration; only option 4 does when projects are managed together. Under option 3, the fund limits itself to the development of a network and of a tool box that national actors may or may not use;
- Possible coordination of R&D funding with forward-looking analysis (Endure) may be sought;
- The Technical Secretariat would have the possibility to consider forward looking issues in order to anticipate future withdrawal of a.s.

Disadvantages

Under option 4, the idea would be to copy the "IR-4 type of approach". It should be noticed that this is the approach which has also been taken by the Canadian and Australian authorities, with the risk of creating a huge system (gas factory) that would be difficult to manage. The risks are that the system becomes too bureaucratic.

Another risk is that, due to the emergency of certain situations, all the funds would go directly to projects and knowledge management activities and that the implementation of a strong governance structure, intended to build the long-term roots of the system, would never be done properly.

"Small" MS for which minor crops acreage is limited do not see any advantages in option 4 vs. option 3 as they consider that all funds will go to economically important projects only and therefore none of their projects will ever be funded. So why to fund an activity if nothing is received back (not in win-win situation). Incentives for these "small" MS will decrease after the establishment of the knowledge management tools with the risk that they would not participate to the fund after that initial period. This argument goes to the benefit of the proposal to create 3 TWG and not only 2.

The question of prioritisation of projects seems also to be a rather difficult task. Who can decide? How to prioritise? Are concerns to be considered appropriately by defining clear criteria and guidelines? It would be the role of the TS to make proposals in this area and of the SC to validate the proposals.

While option 3 seems rather easy to justify at political level, option 4 may be difficult to justify. This point is reinforced by the fact that this research is leading to a non-fully

economic quantification of the minor use issues. Though lot of information has been gathered and analysed, the complete overall picture is not established yet. As highlighted before, the first set of data that is presented in this report constitutes a robust baseline but more data need to be compiled. As an example, this exercise has not permitted to fully quantify the socio-economic importance for the F&V processing industry (canned and frozen markets).

Finally, while the recurrent annual budget of the Fund for option 3 is about €0.5 million, required resources for option 4 are certainly over €5 million. Even if the approach is based on co-financing and therefore the budget shared with the PPP industry and other stakeholders, and based on the current EU budget restrictions, finding part of these resources at the COM level may be a difficult task.

3.4 Implementation costs of each option

When assessing the feasibility of the different options under consideration, the Commission services have also to take into account the availability of budgetary means within the EU budget.

Therefore, it is important to estimate the costs linked to the implementation of each of the options.

Making use of existing initiatives and existing resources is seen by many interviewees in the consultation as a way both to strengthen these organisations, while avoiding the need to spend (or "waste") money on creating new activities that may overlap with existing ones.

Although it is difficult to generalise, it is considered likely that establishing and running each of the four proposed options would cost in the range of €0.3 million (option 2) to €>6 million (option 4). These estimated costs have been calculated on the basis of the following elements:

- <u>Staff costs</u> which will vary according to the level of experienced of the selected staff to run the TS. Staff costs for one Category 1 staff (15+ years professional experience) to coordinate activities is in the range of €70,000 per annum and for one Category III staff (secretary, IT specialist) in the range of €35,000 per annum. National staff cost is lower as salaries are lower in a majority of NMS. For this exercise we consider that on average the unit cost is €25,000 per annum;
- Overhead costs: including rental of office space, telecommunication costs, IT equipment, etc. are estimated at about 30% of the staff costs;
- <u>Travel costs</u> for meetings of the SC and the TWGs are estimated based on average costs of organising and running a meeting with participation of individuals of the 27 MS in Brussels (e.g. standing committees). The average costs for running a regular Standing Committee meeting on PPP are estimated at €10,000 per meeting. As in Standing Committees, costs of two participants per MS are covered, we can consider

that in the context of the SC for minor use, costs will compensate expenses of one national representative only and therefore average costs can be estimated at €5,000 to €6,000 per meeting.

- Costs related to the development of the databases and the web portal are difficult to estimate and can range from limited resources needed if the option to customize existing tools is preferred (about €10,000 per application) over the one of developing new tools from scratch (about €50,000 per application);
- Costs for running and completing individual ad hoc projects will depend on a large number of variables and especially on the number of projects that will have to be funded and/or co-funded. The number of EU funded projects will depend on the available annual budget. Estimation of this budget is hardly feasible at this stage. Based on ECPA inputs, for a minor use, where no extrapolation is possible and where the product is only for one specific use, the costs for a project could therefore be estimated at between €140,000 €250,000. Where extrapolation is possible, and where a particular study can be used for different uses in the same crop, the costs can be reduced substantially. In the cases where no solution is available R&D activities would have to carry out to develop a solution. Costs for such type of projects is hard to estimate and can easily be over €1 million.

On the basis of these estimates, the two tables below indicate costing for the different options. The aim is to provide a basis for comparison.

The required budget for the implementation of the options ranges from €44,000 for option 2 to more than €6 million for option 4.

Annual recurrent cost²¹ for running the TS, maintaining the databases and completing the meetings is estimated at €253,500. This is the total budget of the activity which is cofinanced as discussed before.

Table 14 - Summary of the estimated annual costs for the implementation of each of the three options (no funding in case of status quo)

				Option					
Cost center	Description	Unit cost	Type of cost (one-off vs recurrent)	2	3	4			
					Cost (in K€)				
Total (min-max)				44,000	518,500-678,500	1,180,000-> 6,000,000			
- Of which one-off costs (min-max)					265,000-425,000	265,000-425,000			
	- Of which	recurrent cos	ts (min-max)	44,000	253,500-253,500	914,000-> 5,500,00			

-

²¹ Recurrent costs: Regular costs incurred repeatedly, or for each item produced or each service performed. One-off costs: A cost that is paid once and not repeated.

Table 15 - Detailed indicative costing elements for the implementation of each of the three options (no funding in case of status quo)

				Option					
Cost center	Description	Unit cost	Type of cost (one-off vs recurrent)	2	3	4			
					Cost (in K€)				
Staff of the									
	Coordinator	70,000	recurrent	n.a.	70,000	140,000			
	Secretary	35,000	recurrent	n.a.	17,500	35,000			
	IT specialist	35,000	recurrent	n.a.	17,500	35,000			
COM Staff									
	Support to prepare meetings		recurrent	2,000					
	Monitoring costs		recurrent	n.a.	5,000	5,000			
MS Staff									
	Data entry (*)	25,000	one-off	n.a.	225,000	225,000			
	Data maintenance (**)	25,000	recurrent	n.a.	50,000	50,000			
Overhead co	osts (only applied to staff of the	TS not to not	ional staff)						
Overneau co	osts (only applied to stail of the	30% of total	Jonai Stair)						
			recurrent	n.a.	31,500	63,000			
						03,000			
ivieetings co	ordination (includes travel + e	•			•	20,000			
	SC meetings	6,000	recurrent	12,000	12,000	36,000			
	TWGs meetings	5,000	recurrent	30,000	30,000	30,000			
Knowledge	management								
	Development of databases								
	min.	10,000	one-off	n.a.	40,000	40,000			
	max.	50,000	one-off	n.a.	200,000	200,000			
	Maintenance of DB	20,000	recurrent	n.a.	20,000	20,000			
		•			·				
Project man	agement costs								
	min.	500,000	recurrent	n.a.	n.a.	500,000			
	max.	> 5,000,000	recurrent	n.a.	n.a.	> 5,000,000			
Total (min-r	max)			44,000	518,500-678,500	1,180,000-> 6,000,000			
,	•	one-off cost	s (min-max)	,.,-	265,000-425,000	265,000-425,000			
	•	ecurrent cost		44,000	253,500-253,500	914,000-> 5,500,00			

3.5 Comparing the options

While likely advantages and disadvantages of each option are presented above and in order to be able to weigh each of the options and their underlying tasks, a general comparison of the options which is based on the assessment of the following criteria is presented in this chapter:

- Effectiveness:

 Overall qualitative comparison of each of the options regarding their ability to attain the objectives of the EU fund.

- Feasibility:

 Overall qualitative comparison of each of the options regarding their ability to be actually implemented.

Efficiency:

- o Overall comparison of the implementation costs of each the options;
- Overall comparison of the impacts on administrative burden of each of the options.

3.5.1 Effectiveness

Within this section, the advantages and disadvantages of each of the options are described in regards to **effectiveness**, being: the ability of each of the options to attain the general objective of the EU fund which may be summarised as follows:

"To ensure that the range of authorised PPPs remains sufficiently wide to satisfy the needs of growers of most crops, including most of the minor crops".

Effectiveness of each option is assessed based on its:

Criteria	Description
Ability to close present minor uses gaps	Solving minor uses issues with the help of existing products/solutions that are authorised in other MS/zones or authorised for other uses by means of data-sharing and data-

²² Exchange of data between MS can take place on a number of levels and aims at inter-alia finding common solutions, being able to gain easier authorization for products that are already authorized in a MS and learning from experiences.

	exchange ²² .
Ability to solve structural global minor uses problems	Solving minor uses issues with the help of bridge studies, extrapolation studies, crop grouping studies or tests that are needed for new authorisations and that do not exist yet ²³ .
Harmonising the PPP approach	Solving minor uses issues by harmonising PPP authorisations procedures between MS in terms of building of trust and the establishment of regular coordination between competent authorities.
Alignment to PPP policy strategy	To be in line with other (EU) legislation/policy strategies that address PPP, e.g. sustainable use of pesticides.

The notation used to express the magnitude (compared to the baseline scenario) in the following table is the following:

- --- very negative impact
- - negative impact
- slightly negative impact
- 0 no impact
- + slightly positive impact
- + + positive impact
- +++ very positive impact

The following strengths and weaknesses per option have been identified regarding effectiveness:

-

²³ Bridge, extrapolation or crop grouping studies are studies that do not test efficacy or residue levels for a given product, but aim at streamlining PPP authorisation with potentially large effects on specific registrations.

Table 16 - Comparison of effectiveness of the options

	OPTION 1		OPTION 2		OPTION 3A & 3B		OPTION 4	
	STATUS QUO		LIMITED EU SUPPORT	г	MODERATE EU SUPPO	RT	STRONG EU SUPPORT	
	DESCRIPTION	SCORE	DESCRIPTION	Score	DESCRIPTION	SCORE	DESCRIPTION	Score
CLOSING PRESENT GAPS	None, no structural knowledge sharing takes place.	0	Only a few gaps will be closed since realisation of actions remains to be, despite the fact that working groups create possibilities to establish knowledge sharing, on ad-hoc basis.	+	A large number of gaps will be closed due the high level of knowledge sharing among MS which will be ensured by working groups and the developed tools (incl. a secretariat).	+++	A large number of gaps will be closed due the high level of knowledge sharing among MS which will be ensured by working groups and the tools developed (incl. a secretariat).	+++
SOLVING GLOBAL STRUCTURAL PROBLEMS	No global structural problems on EU or zonal level are being solved since project-management remains responsibility of MS/industry and since no standardization effort takes place.	0	Limited structural problems on EU or zonal level are being solved since project-management remains responsibility of MS/industry even if standardization efforts takes places but in a not enough structured approach.	0	Moderate structural problems on EU or zonal level are being solved since project-management remains responsibility of MS/industry even if standardization efforts takes places but in a not enough structured approach.	0	The global structural problems on EU or zonal level can be addressed since (limited) budget for project execution is available. The level of the budget will determine the number of solved issues.	++
HARMONISING THE PPP APPROACH	No improved harmonisation of PPP approaches between MS takes place.	0	Moderate improved harmonisation of PPP approaches between MS takes place due to	++	Moderate improved harmonisation of PPP approaches between MS takes place due the	++	High improved harmonisation of PPP approaches between MS takes place due to	+++

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			networking improvements as a result of the meetings		establishment of trust and working procedures via working group meetings and the secretariat.		improved networking between NCAs, the establishment of working procedures and the management of EU funded projects.	
COHERENCE WITH OTHER STRATEGIES	No improved coherence with other (EU) legislation/strategies is ensured.	0	No improved coherence with other (EU) legislation/strategies is ensured.	0	No improved coherence with other (EU) legislation/strategies is ensured.	0	Coherence with other policies and alignment to PPP policy strategy can be addressed as projects are executed at the EU level or zonal level; projects can therefore e.g. promote sustainable use of PPP.	+++
TOTAL		<u>0</u>		<u>+</u>		<u>++</u>		<u>+++</u>

3.5.2 Feasibility

Within this section, the advantages and disadvantages of each of the options are described in regards to **feasibility**, being: the strengths and weaknesses of each of the options regarding its actual implementation.

Each option is compared based on its:

Criteria	Description
Practicability	Ability to realise the activities, tools and goals that are part of each option based on opportunities and risks encountered.
Duration of realisation	Ability to realise the activities, tools and goals that are part of each option in a prompt time frame.
Transparency	Ability to solve issues in a clear and understandable way and to provide information/solutions that are publically accessible.
Acceptability	Ability to rely on the political will of actors which is needed to attain the objectives of the EU fund.
Governance	Ability to ensure consistent management, cohesive policies, guidance, processes and decision-rights.

The notation used to express the magnitude (compared to the baseline scenario) in the following table is the following:

- --- very negative impact
- - negative impact
- slightly negative impact
- 0 no impact
- + slightly positive impact
- ++ positive impact
- +++ very positive impact

The following strengths and weaknesses per option have been identified regarding feasibility:

Table 17 - Comparison of feasibility of the options

	OPTION 1		OPTION 2		OPTION 3A		OPTION 3B		Option 4	
	STATUS QUO		LIMITED EU SUPPORT		MODERATE EU SUP	MODERATE EU SUPPORT		ORT	STRONG EU SUPPORT	
	DESCRIPTION	SCORE	DESCRIPTION	SCORE	DESCRIPTION	SCORE	DESCRIPTION	SCORE	DESCRIPTION	SCORE
PRACTICABILITY	Not applicable since no actions take place.	0	Execution demands only a small level of efforts.	-	Execution demands a rather high level of efforts especially at the initial phase.		Execution demands a rather high level of efforts especially at the initial phase.		Execution demands a high level of efforts and strong dedication among all actors.	
DURATION OF REALISATION	Not applicable since no actions take place.	0	Realisation can be achieved in a relatively prompt time frame.	-	Realisation can be achieved in a relatively prompt time frame.		Realisation can be achieved in a relatively prompt time frame.		Realisation can be high time-consuming and hard to schedule.	
Transparency	Coordination remains bilateral and on ad-hoc basis with no overall overview.	0	Coordination remains mainly bilateral and on ad-hoc basis, despite the existence of the working groups.	+	Transparent and clear procedures are ensured by the secretariat and the working groups, but complete information sharing is not guaranteed.	++	Transparent and clear procedures are ensured by the secretariat and the working groups, but complete information sharing is not guaranteed.	++	Transparent and clear procedures are ensured by the secretariat and the working groups, information sharing will improve over time	+++
ACCEPTABILITY	Clear rejection from all actors.	0	Clear rejection from all actors.	0	Preferred option for NCAs	++	Preferred option for NCAs	++	Preferred option for a large majority of the producers and the PPP industry.	+++

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Governance	No EU coordination regarding policies, guidance, processes and decision-rights takes place.	0	Weak governance since costs for coordination have to be financed by the MS.	0	Limited effective governance due to a fixed budget which is available for coordination, despite the close MS-link.	+	Effective governance due to a fixed budget which is available for (partial) coordination and a clear independent position.	++	Strong governance due to a fixed budget which is available for coordination and a clear independent position.	+++
TOTAL		<u>o</u>		<u>o</u>		<u>++</u>		<u>++</u>		±

3.5.3 Efficiency

Within this section, the advantages and disadvantages of each of the options are described in regards to comparison of the costs related to the options and the **efficiency**, being: the extent to which time, efforts or investments are being used to attain the objectives.

Each option is compared regarding efficiency based on its:

Criteria	Description
Costs related to the implementation of the options	Efforts that need to be made to improve the system that is linked to an option that can be accounted directly to the system itself.
Impacts on the administrative burden	Efforts that need to be made to improve the system that is linked to an option that can be accounted directly as administrative cost for (N)CAs and stakeholders

The comparison of implementation costs is based on the analysis as presented in section 3.4 (*Implementation costs of each option*).

The notation used to express the magnitude (compared to the baseline scenario) of the efficiency in the below presented table is the following:

- --- high cost
- -- moderate cost
- low cost
- 0 no cost / benefit
- + low benefit
- ++ moderate benefit
- +++ high benefit

The following strengths and weaknesses per option have been identified regarding efficiency:

Table 18 - Comparison of efficiency of the options

	OPTION 1 STATUS QUO		OPTION 2 LIMITED EU SUPPORT		OPTION 3	А	OPTION 3	В	OPTION 4	
					MODERATE EU SUPPORT		MODERATE EU SUPPORT		STRONG EU SUPPORT	
	DESCRIPTION	SCORE	DESCRIPTION	SCORE	DESCRIPTION	SCORE	DESCRIPTION	SCORE	DESCRIPTION	SCORE
IMPLEMENTATION COSTS	Not applicable since no actions take place.	NONE	Implementation costs (one-off and recurrent) are rather low since only travel + expenses costs of meetings (meeting coordination) and databases for knowledge management are being covered.	LOW	Implementation costs (one-off and recurrent) are of average level since the fund covers, on top of meeting coordination and databases for knowledge management, a technical secretariat.	AVERAGE	Implementation costs (one-off and recurrent) are of average level since the fund covers, on top of meeting coordination and databases for knowledge management, a technical secretariat.	AVERAGE	Implementation costs (one-off and recurrent) are rather high since the fund covers on top of meeting coordination, databases for knowledge management and a comprehensive technical secretariat, large budget to carry out projects.	HIGH

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					The technical		The technical		The technical	
			Limited work-		secretariat and		secretariat and		secretariat and	
	No offect on		sharing takes		the working-		the working-		the working-	
No effect on administrative		place between		groups ensure a		groups ensure a		groups ensure a		
EFFECT ON	burden, since no		MS but is		high level of		high level of		high level of	
ADMINISTRATIVE	work-sharing	0	compensated by	0	work-sharing	++	work-sharing and	++	work-sharing	++
BURDEN			the workload		and reduce		reduce		and reduce	
	takes place between actors.		caused by		administrative		administrative		administrative	
	between actors.		participation in		burden for a		burden for a		burden for a	
			the meetings.		large number of		large number of		large number of	
					actors.		actors.		actors.	

3.5.4 Overall comparison of the options

All analysed options show improvements in terms of effectiveness, efficiency, and consistency compared to the status quo.

As regards to effectiveness, the major difference between the options is the ability to solve structural global minor uses issues and to be aligned to the EU PPP policy strategy. This 'feature' can only be addressed by option 4 – strong EU support.

Regarding feasibility, option 4 must be seen as a rather difficult to implement option whose realisation will need a large amount of efforts and time to be successful. On the other hand is the level of transparency and governance that is ensured by this option rather high. Option 3 has proven to be the most realistic option when it comes to feasibility with an acceptable level of practicability, acceptability (see section 3.3.1 – overall preference), governance and transparency.

As regards to efficiency, the implementation costs of any of the options (excluding costs of projects) are rather low to moderate. The option 4 is, by far, the most expensive option (see section 3.4 − implementation costs of each option) as the costs of running projects are funded. In that case, the budget is correlated to the number of projects that are co-financed (more project-higher budget). Recurrent costs for maintaining the knowledge management platform, managing the different meetings, and running the TS is less than €0.4 million.

The impacts on administrative burden for options 1 and 2 can be seen as neutral and for options 3a, 3b and 4 as equal positive.

Below a summary of the overall comparison, including all main-criteria can be found.

Table 19 - Overall comparison of the options

	Option 1 Status quo	Option 2 Limited EU support	Option 3a Moderate EU support	Option 3b Moderate EU support	Option 4 Strong EU support
Effectiveness	0	+	++	++	+++
Feasibility	0	0	++	++	+
Efficiency (cost)	None	Low	Average	Average	High
Efficiency (Admin. Burden)	0	0	++	++	++

ANNEX I: THE DETAILED QUESTIONNAIRE

GENERAL SURVEY by the Food Chain Evaluation Consortium (FCEC)

Introduction

This general survey takes place in the framework of a study related to the establishment of a European fund for minor uses in the field of plant protection products (PPP), which is undertaken by the Food Chain Evaluation Consortium (FCEC) for the European Commission Directorate General for Health and Consumers (DG SANCO).

The first objective of this study aims at collecting information on minor uses of PPP in the European Union in order to assess the current and potential economic importance of this issue. The second objective of the study is to identify options on how to set up a European fund which could address issues related to minor uses of PPP.

This general survey aims at collecting as much detailed information as possible on PPP uses, minor crops and speciality crops, minor uses and the issues related to minor uses of PPP. The survey also aims at identifying detailed information on existing initiatives in the Member States addressing minor uses issues and at collecting your views on options on how to set-up a European Fund that could address the minor uses issues. The survey is part of an overall data collection process that also includes analysis of literature and stakeholder interviews.

The confidentiality of your responses and statements is guaranteed in the sense that your organisation will be identified as having responded to the survey but none of your statements included in the study report will be related to its author.

If you have questions, do not hesitate to contact:

Mr. Jan Bruschke – Van Dijk Management Consultants (jbr@bvdmc.com) or

Mr. Daniel Traon – Arcadia International (daniel.traon@arcardia-international.net)

If you are not the right person to answer this questionnaire, please forward this e-mail to the relevant person or send us his/her identification data.

Please return this questionnaire by e-mail to minoruses@bvdmc.com. Please do not answer later than 30.03.2011.

Identification data

-	Title of the person completing the questionnaire:
-	Name of the person completing the questionnaire:
-	Position:
-	Department in the organisation:
-	Phone number:
-	E-mail:
-	Name of the organisation:
-	Country:
-	Type of organisation: Tick the appropriate box.
	☐ European organisation ☐ National organisation
	☐ International organisation ☐ Scientific/research body
	☐ NGO ☐ Competent Authority
	Other, please detail:
-	Representative of: Tick the appropriate box(es).
	PPP Manufacturers Traders
	☐ Importers ☐ Agro-food-chain processors
	Consumers PPP Users (producers and farmers)
	Other, please detail:
-	Representative of (a) specific agricultural sector(s): Tick the appropriate box(es).
	Agricultural crops Horticultural & ornamental crops
	☐ Vegetable crops ☐ Fruit crops
	Aromatic and medicinal crops Seed
	Other, please detail:

Instructions for filling in the questionnaire

The following questionnaire covers the various areas of minor uses of plant protection products (PPP), with questions grouped into six main parts in accordance with the Terms of Reference for the study, to which you are referred for background information.

Not all sections and questions may be relevant to your organisation: when filling in the questionnaire, please focus on the relevant sections and leave level of details or sections that are not relevant for you open.

All questions include a box for comments, and it is important in most cases to detail your answer in the box.

The questionnaire should preferably be completed in English. Replying in French or German is also possible.

For any questions within these sections that are not relevant to your organisation, please tick the "do not know" box.

The survey questionnaire is structured as follows:

General Situation (to be completed by NCA only)

Section 1: Definition of PPP uses and of minor crops

Detailed inventory of major and minor crops

Section 2: Detailed inventory of major and minor crops with their cultivation areas

Detailed inventory and quantification of minor uses issues

Section 3: Detailed inventory of minor uses issues and assessment of their agronomic and economic importance

European and national initiatives

Section 4: Initiatives

Policy options for setting-up a EU fund to coordinate minor uses activities

Section 5: Preliminary reflexion on the possible options

Section 6: Alternative policy options (The IR-4 system)

Additional information

GENERAL SITUATION

This section of the survey focuses on the identification of the different definitions in use in the national legislation in your country. It distinguishes between 1) plant protection product uses, 2) major crops, minor crops and very minor crops as well as 3) minor uses. It is of key importance to the success of the study that description of definitions and the national legislation takes place as detailed and exhaustive as possible.

<u>Please note that the questions of Section 1 are addressed to National Competent</u>

<u>Authorities. We kindly ask other stakeholders to continue at Section 2 of this questionnaire.</u>

SECTION 1. DEFINITIONS OF PLANT PROTECTION PRODUCTS USES AND OF MINOR CROPS

PLANT PROTECTION PRODUCT USES

1.1. Are "PPP uses" officially defined for other reasons than residues in your country?			
Tick the appropriate box:			
☐ Yes	☐ No	Do not know	
If the answer is 'Yes',	please provide the defi	nition and criteria being used:	
1.2. Is there a definitive I		nich PPPs are or can be registered in your co	ountry?
☐ Yes	□ No	☐ Do not know	
If the answer is 'Yes',	please provide referend	es to the list (website, attached file, etc):	

MAJOR CROPS, MINOR CROPS AND VERY MINOR CROPS

There is no valid EU document that defines the criteria for classification of all crops. The EU guidance document SANCO 7525/VI/95²⁴ on comparability, extrapolation, group tolerances and data requirements for setting maximum residue levels (MRLs) however defines in Section 6.1.2 the criteria for classification of crops as follow:

"The following criteria are used for classifying a crop or a product as <u>major</u> in the European Community:

- Daily dietary intake contribution > 7.5 g (i.e 7.5. g mean daily consumption over the population for a 60kg person) and/or
- Cultivation area > 10.000 ha; and
- Production > 200.000 tonnes per year

The following criteria are used for classifying a crop or a product as <u>very minor</u> in the European Community:

- Daily dietary intake contribution < 1.5 g (i.e. 1.5. g mean daily consumption over the population for a 60kg person) and/or

Cultivation area < 600 ha (less than 0.0035% of the total cultivation area)"

All crops in between the two above-mentioned classes can be considered as minor crops.

1.3. Do you follow the definition of EU guidance document 7525/VI/95 for classifying crops for other reasons than residues in your country? Tick the appropriate box:			
Yes	☐ No	Do not know	
Please detail your	answer:		

²⁴ http://ec.europa.eu/food/plant/protection/resources/app-d.pdf

Yes	☐ No	☐ Do not know	
If the answer is 'Y	es', please provide the list	(or a relevant link) and refer to Section 2:	
MINOR USES			
-		erning the placing of plant protection products of a signification of a minor use as follows:	on the
'Minor use' means u roducts which are:	se of a plant protection p	oduct in a particular Member State on plants or	plan
- Not widely gro	own in that Member State	or	
	own in that Member State , to meet an exceptional p		
- Widely grown 5. Do you already foountry? Tick the app	, to meet an exceptional pollow the definition of Repropriate box:	ant protection need." gulation (EC) No 1107/2009 on minor uses in yo	our
- Widely grown	, to meet an exceptional p	ant protection need."	our
- Widely grown 5. Do you already foountry? Tick the app	, to meet an exceptional pollow the definition of Repropriate box:	ant protection need." gulation (EC) No 1107/2009 on minor uses in yo	our
- Widely grown 5. Do you already foountry? Tick the app Yes Please detail your 5.1 If the answer is	to meet an exceptional pollow the definition of Repropriate box: No answer:	gulation (EC) No 1107/2009 on minor uses in yo Do not know r definition or/and other criteria on minor uses	
- Widely grown .5. Do you already foountry? Tick the app Yes Please detail your .5.1 If the answer is	ollow the definition of Repropriate box: \text{\tiny{\text{\tinit}\text{\text{\text{\text{\text{\text{\text{\text{\text{\texi\text{\tinit}\text{\text{\text{\text{\text{\text{\text{\text{\texi\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\te\tint{\text{\texit{\texi\texit{\texi\texi{\text{\texit{\texit{\tex{\texi\texit{\text{\texi{\texi{\texi{\texi{\texi{\texit{\texi{\	gulation (EC) No 1107/2009 on minor uses in yo Do not know r definition or/and other criteria on minor uses	

http://www.eppo.org/PPPRODUCTS/information/2009_1107_EU-e.pdf

If the answer is 'No all:	o', please describe how mi	inor uses are regulated in your country, if regulated	at
1.6. Is there a definitiv	ve list of minor uses in yo	ur country? Tick the appropriate box:	
Yes	☐ No	☐ Do not know	
If the answer is 'Ye	es', please provide the list	(or a relevant link):	

DETAILLED INVENTORY OF MAJOR AND MINOR CROPS

This section of the survey aims at listing the (groups of) crops cultivated in each Member State and the size of the national corresponding cultivation areas. The identification of the minor crops will then allow assessing the relative part of these crops in the total agricultural landscape and making comparisons between countries and aggregations at EU level.

SECTION 2. DETAILED INVENTORY OF MAJOR AND MINOR CROPS WITH THEIR CULTIVATION AREAS

Excel file Table 1 (MinorUsesSurvey_Table1_CropClassification.xls) which is attached to this survey questionnaire, is a table based on research from 2008 coordinated by Mr Dr. Mario Wick for the Technical Working Group North and by Mr Jean-Claude Malet for the Technical Working Group South on minor uses. This table is divided into two sections/sheets for each of the above-mentioned zones (South and North):

- 1. A detailed inventory of the cultivation areas in hectares (ha) for outside grow and protected grow for the majority of all crops;
- 2. A detailed inventory of the characterisation according to EU definitions or your national definitions in terms of major crop, minor crop or very minor crop for the majority of all crops.

Please use this table to:

$\boldsymbol{A}.$ Check if the indicated data is	still up to date	for your country;
--	------------------	-------------------

or

B. Provide the data in case there is no data indicated for your country yet.

Please detail for each crop cultivated in your country as much data as possible.

If needed, please explain the data provided in the table:

DETAILLED INVENTORY AND ASSESMENT OF MINOR USES ISSUES

This section of the survey aims at identifying and listing specific and relevant examples of minor uses issues in each Member State and the size of the cultivation areas concerned by each issue, as well as assessing the economic damage caused by the issue. Those data will then allow assessing the agronomic and economic impacts of the issues by making comparisons between countries and aggregations at EU level.

SECTION 3. DETAILED INVENTORY OF MINOR USES ISSUES AND ASSESSMENT OF THEIR AGRONOMIC AND ECONOMIC IMPORTANCE

This section of the survey aims at identifying and listing <u>specific</u> and <u>relevant</u> examples of minor uses issues in each Member State. These examples issues should be documented in the Excel file Table 2 (MinorUsesSurvey_Table2_UsesIdentification.xls), which is attached to this survey questionnaire.

Please detail for each example of minor use issue the following data:

- 1. The crop concerned;
- 2. The pest concerned by:
 - Selecting a pest group in the drop-down list;
 - Providing the common English name of the pest; and/or
 - Providing the scientific Latin name of the pest; and/or
 - Providing the BAYER / EPPO code of the pest.
- 3. The issue by:
 - Selecting a type of issue in the drop-down list;
 - Describing the nature of the issue in qualitative way;
 - Estimating the affected total cultivated area in your country (agronomic importance).
- 4. The YEARLY economic damage of the issue by:

- Estimating the economic damage for users of PPP (e.g. famers) caused by the issue.
 Please note that in case no detailed figures are available, any rough estimation is accepted (if needed expressed in terms of a range or by the use of symbols as ±, >,
 ⟨);
- Estimating the economic damage food-supply-down-stream users (e.g. supermarkets or final customers) caused by the issue. Please note that in case no detailed figures are available, any rough estimation is accepted (if needed expressed in terms of a range or by the use of symbols as ±, >, <).
- 5. All links to documents or information that would help us to better understand your examples.

EUROPEAN AND NATIONAL INITIATIVES

This section of the survey focuses on the identification of national initiatives that are already in place in the Member States to address minor uses issues. It is of big importance to the success of the study that description of the initiatives takes place as detailed and exhaustive as possible.

SECTION 4	I. INITIATIVES			
4.1. Are there any national initiatives addressing minor uses issues in your country? <i>Tick</i> the appropriate box:				
	⁄es	☐ No	t	Do not know
If the a	nswer is 'No', p	please detail your ans	swer:	
If the answ	wer is 'Yes':			
4.1.1 Pleas	se list all thes	e national initiativ	es that addres	s minor uses issues and describe
their relat	ive scope:			
Name of th	e initiative	Scope (e.g. industry for speciality crops,	•	Further description
1.				
2.				
3.				
4.				
5.				
4.1.2 Pleas	se describe fo	or each initiative lis	sted under poi	nt 4.1.1 your level of collaboration:
Initiative	Level of colla	boration	Further descri	ption
1.				
2.				
3.				
4.				
5.				

4.1.3 Please describe for each initiative listed under point 4.1.1 the date of establishment and the parties involved:

Initiative	Date of establishment	Involved parties (e.g. industry, authority)
1.		
2.		
3.		
4.		
5.		

4.1.4 Please describe for each initiative listed under point 4.1.1 the governance applied:

Initiative	Governance (e.g. leadership, management, decision making process, working rules etc.)
1.	
2.	
3.	
4.	
5.	

4.1.5 Please describe for each initiative listed under point 4.1.1 the mission and objectives:

Initiative	Mission and objectives (e.g. planning of research/field trials, exchange of data)
1.	
2.	
3.	
4.	
5.	

4.1.6 Please describe for each initiative listed under point 4.1.1 if there is any collaboration with any other initiative in a different sector or region/country (also international):

Initiative	Description of external (also international) collaborations
1.	
2.	
3.	
4.	
5.	

4.1.7 P	lease describe	for each initiati	ve listed und	ler point 4.1.1	the main a	ctivities/t	ools
used:							

Initiative	Description of the main activities/tools (e.g. database, extranet, workshops, meetings)
1.	
2.	
3.	
4.	
5.	

4.1.8 Please estimate for each initiative listed under point 4.1.1 the annual budget and describe the nature of the funding:

Initiative	Annual budget	Nature of funding	Description
1.		Public Private Mix	
2.		Public Private Mix	
3.		Public Private Mix	
4.		Public Private Mix	
5.		Public Private Mix	

4.1.9 Please list for each initiative listed under point 4.1.1 the achievements completed to date:

Initiative	Achievements completed to date (including not direct results, e.g. agreement on working procedures)
1.	
2.	
3.	
4.	
5.	

4.1.10 Are you aware of any EUROPEAN private initiatives regarding coordination activities
to address the issues of minor uses beside the existing technical working groups?

Yes	☐ No	
If the answer is coordinators.	'Yes', please provide the description	n of the EU initiative(s) and coordinates of

FUTURE OPTIONS							
This section of the survey focuses on the future options that could address minor uses issues. It is of key importance to the success of the study that description of your view regarding the set-up of a possible European fund and possible alternative options takes place as detailed and exhaustive as possible.							
section 5. preliminary reflexion on the possible options							
5.1. Are you in favour of the establishment of a European fund to coordinate activities to address minor uses issues? <i>Tick the appropriate box:</i>							
☐ Yes ☐ No ☐ Do not k	now						
If the answer is 'No', please detail your answer: If the answer is 'Yes': 5.2. Please detail in the following table the degree of interest you see in the following possible interventions of the fund (score from 1 to 5 corresponding to very low – low –							
average – high – very high):	J	,					
Possible interventions of the fund		Score of interest					
r ossione interventions of the fund		2	3	4	5		
Create inventory of minor uses issues							
Make economic quantification of minor uses issues (for prioritization purposes)							
Raise awareness of problems							
Coordinate approach / cooperation							
Bring all kind of expertise together							
Facilitate registration							
Support field trials							
Support residue research/studies							
Facilitate information sharing (database with problems/solutions	, 🗌						

-4-4:-4:4- \		<u> </u>	
statistics etc.)			
Find strategies where no PPP are available			
Promote alternative solutions (e.g. biological PPP)			
Learn from non-EU examples			
5.3. Please indicate at which level coordination box:	on should be orga	nised. <i>Tick th</i>	ne appropriate
	Yes	No	Do not know
EU level			
Zonal level (North vs. Central vs. South			
Others, please detail:			
			<u>'</u>
5.5. Are you in favour of maintaining the actu	al Expert Groups	(North and S	outh) on minor
uses? Tick the appropriate box:			
☐ Yes ☐ No	☐ Do not k	now	
Please detail your answer:			
,			
5.5.1. If the answer is 'No', please indicate ho structured (in terms of the governance of the			
Please detail your answer:			

ctivities? <i>Tick the ap</i>	_		_		
Yes	☐ No		Do not ki	now	
If the answer is 'Yes	s', please provide <u>j</u>	your estimati	ion and detail you	ur answer:	
If the answer is 'No	or 'Do not know'	', please deta	iil your answer:		
7. Who should conto	tribute to the fu	nding of the	ese coordinatio	n activities	? Tick the
opropriate boxes:	tribute to the fu	nding of the	ese coordinatio	n activities	? Tick the Do not know
propriate boxes:	tribute to the fu	nding of the			1
propriate boxes: ropean Commission ational government		nding of the			1
propriate boxes: propean Commission ational government P Industry (producer	s and traders)	nding of the			1
propriate boxes: propean Commission ational government P Industry (producers armers and producers	s and traders)	nding of the			1
	s and traders)	nding of the			1
propriate boxes: propean Commission pational government P Industry (producer rmers and producers pply chain actors: prosess	s and traders)	nding of the			1
ppropriate boxes: propean Commission ational government PP Industry (producers armers and producers	s and traders)	nding of the			1
propriate boxes: propean Commission ational government P Industry (producers rmers and producers pply chain actors: pro estomers whers, please detail: B. In which proport and? Tick the appro	s and traders) cocessors tion would natio	onal problen	Yes	No	Do not know
ropean Commission tional government P Industry (producer mers and producers oply chain actors: pro stomers hers, please detail:	es and traders) cocessors tion would natio		Yes	No	Do not know
ropean Commission tional government P Industry (producers and producers apply chain actors: prostomers hers, please detail: 3. In which proport and? Tick the appropriate the second producers and producers and producers and producers are second producers.	tion would nation priate box:	onal problen	Yes	No	Do not know

5.9. To your opinion, would it be more appropriate to address most national problems with a national fund or with a European fund?			
National fund	European fund	Mixed fund	
Other, please detail:			
Please detail your answer:			
5.10. In your opinion, what ar European fund?	e the actual major blocki	ng factors for the establishmen	t of a
	e the actual major blocki	ng factors for the establishmen	t of a
European fund? Please detail your answer:	icipate with the entry int	ng factors for the establishmen o force of the Regulation (EC) N	

section 6. Alternative options

This section needs to be filled in case you are familiar to the IR4 System.

For over 35 years, the US IR-4 program has worked successfully to fill the gap in providing pest management tools (pesticides and biopesticides) for minor crop growers. IR-4 conducts field trials and residue analyses under Good Laboratory Practices to develop food safety data on minor crops that result in the clearance of effective pest management agents by EPA. More information to be found at: http://www.ir4.rutgers.edu/

esult in the clearance of effective pest management agents by EPA. More information to be found at http://www.ir4.rutgers.edu/				
6.1. Please provide your opinion regarding the extent to which the IR4 system is a suitable system for the EU. <i>Please list advantages and disadvantages of the IR4 system in the EU context:</i>				
Please detail your answer:				
6.2. Please provide your opinion regarding the alternative solutions to the EU Fund:				
Please detail your answer:				
FURTHER INFORMATION				
section 7. Additional information				
7.1. Please make reference here to any available data/documents that support your answers, or indicate sources where such data/documents can be found.				
Please detail per question number:				

We thank you very much for your valuable contribution!

ANNEX II: ANALYSIS OF THE RESPONSES TO THE DETAILED QUESTIONNAIRE

The survey questionnaire (see Annex I) was launched on 3 March 2011 and addressed to 164 targets with a deadline for completion on 30 March (being 4 weeks).

In total 58 completed survey questionnaires have been received. 25 of these questionnaires derive from National Competent authorities, 33 questionnaires derive from Stakeholders.

Table 1 - Responses to the survey questionnaire

Completed Survey Questionnaires	58
National Competent Authorities	25
Stakeholders	33

The 25 survey questionnaires from National Competent Authorities represent answers from 23 Member States and Norway, being:

Belgium, Bulgaria, Czech Republic, Denmark, Germany, Estonia, Ireland, Spain, France, Italy, Latvia, Lithuania, Hungary, Netherlands, Austria, Poland, Portugal, Romania, Slovenia, Slovakia, Finland, Sweden, United Kingdom and Norway.

No completed survey questionnaires have been received from:

Greece, Cyprus, Luxembourg, and Malta.

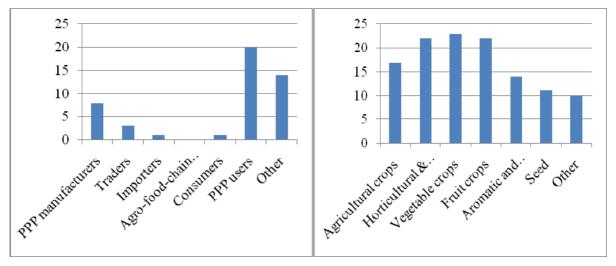
The 33 survey questionnaires from Stakeholders contain answers from 4 global or EU stakeholders being: ECPA, COPA-COGECA, IBMA and GLOBALG.A.P, and 29 stakeholders who represent an expertise, a certain industry or group of consumers from one of the following Member States:

Belgium, Germany, Spain, France, Italy, Latvia, Hungary, Netherlands, Austria, Poland, Portugal, Finland and United Kingdom.

Geographic coverage can be considered as sufficient as answers from 23 MS have been received with a correct distribution between old and new MS and between North and South MS. The completed survey questionnaires represent the following groups of stakeholders (PPP manufacturers, traders, importers, agro-food-chain processors, consumers, PPP users and others) and sectors (agricultural crops, horticultural & ornamental crops, vegetable crops, fruit crops, aromatic and medicinal crops, seed and other crops). The distribution of this representation is as follows:

Figure 1 - Representation by group of stakeholders (no of answers)

Figure 2 - Representation by sector (no of answers)



1.1 Identification of the different definitions in use in the national legislations

Section 1 of the survey questionnaire focuses on the identification of the different definitions in use within the national legislation of Member States. These questions were addressed to National Competent Authorities and have therefore only been answered on average by 30 people.

The distribution of the answers on the questions within Section 1 is as follows:

Table 2 - Distribution of answers on questions from Section 1

Question		Sample	Yes	No	Do not know
1.1	Are PPP uses officially defined for other reasons than residues purposes in your country?	29	69%	31%	0%
1.2	Is there a definitive list of PPP uses for which PPPs are or can be registered in your country?	29	76%	24%	0%
1.3	Do you follow the definition of EU guidance document 7525/VI/95 for classifying crops for other reasons than residues in your country?	30	33%	60%	7%
1.4	Is there a definitive list of major crops, minor crops and very minor crops for other reasons than residues in your country?	30	53%	40%	7%
1.5	Do you already follow the definition of Regulation (EC) No 1107/2009 on minor uses in your country?	33	45%	45%	10%

1.5.1	Do you have another definition and/or criteria on minor uses in the legislation of your country?	19	53%	42%	5%
1.6	Is there a definitive list of minor uses in your country?	30	50%	50%	0%

As stated in the above displayed table, 69% of the respondents declare the existence of a definition of PPP uses for other reasons than residues purposes in their country. The correctness of these 69% needs to be checked however since a number of comments on this declaration show a given uncertainty regarding this question.

A large number of Member States have defined global criteria on the definition of "use of PPP", like for example the Netherlands or France that provides exhaustive online databases on authorised PPPs and their corresponding uses. These databases are based on Member State specific criteria and can be used for other reasons than only residues purposes. A large number of Member States declare moreover the use of the EU-residues criteria on agronomic efficacy or effects on human health and/or the environment to classify the use of a PPP.

It should be highlighted here that a high percentage of Member States does not follow the criteria stated within the Guidance document (SANCO 7525/VI/95 on comparability, extrapolation, group tolerances and data requirements for setting maximum residues levels) for classification of crops for other reasons than residues in their country. Even if some Member States (E.g. Latvia) use the definitions to classify crops regarding the determination of the number of trials that is needed to access agronomic efficacy or crop safety, or have their own criteria in place to classify crops (E.g. Slovakia²⁶), there is still a majority of MS in which no clear criteria to classify crops for other reasons than residues exist. This situation is partly caused by a general uncertainty that is also described within the comments.

A comparable trend is also documented within the answers on question 1.4. Some Member States indicate to maintain an official list on crops and their corresponding classification, but the content of these lists are in many cases mainly dependent on the understanding of experts. National lists therefore do not present an exhaustive picture of the national situation, mainly because they concentrate mostly on minor or very minor crops.

Daily intake is not taken into account.

Major crops: cultivation area > 10 000 ha

Minor crops: cultivation area \leq 10 000 ha (0,75% of total cultivation area)

Very minor crops: cultivation area ≤ 0,0035% of the total cultivation area

.

²⁶ Slovakian Classification of crops: major, minor and very minor according to cultivation area and production.

Furthermore it has to be noticed that even the more comprehensive initiatives, such as the off- label authorisation scheme which is in place in several MS to improve availability of pesticides for minor crops, make use of very rough definitions (minor crops are defined as all crops other than a small list of major arable crops).

The definitions on minor uses that are stated within the Regulation (EC) No 1107/2009 on minor uses are already followed by half of the Member States. In general however a majority of Member States, even if they have already implemented them nationally, sees the definitions as too general or too wide and they see the need of development of more detailed criteria that are considering Member State specificities in order to increase flexibility. Contrary to criteria regarding the classification of crops more criteria exist among Member States on minor uses. These criteria differ between Member States and are mostly based on local needs.

In line with this is the fact that half of the Member States maintain lists of minor uses. These lists are in most cases not mandatory but cover urgent needs that represent for example public interest.

The definitions in use on PPP uses for other reasons than residues and minor uses within MS that have been collected by the survey questionnaire are as follows:

Table 3 - Definition of PPP uses within MS

Member State	Definition of PPP uses for other reasons than residues
Belgium	Major/Minor uses are defined for residue purposes (Lundehn). The major/minor concept is also used for efficacy evaluations in case of third party extensions and for applying for financial support from the Fund of raw materials. For the last two cases there is no formal definition. The authorisation board can decide case by case. Of course a list is existing for practical use.
Bulgaria	PPP uses not officially defined for other reasons than residues
Czech Republic	Residues, but also agronomic differences and historic nomenclature
Denmark	Efficacy, human and environmental effects
Germany	What means "officially defined for reasons"? An authorised use is not defined for residue reasons. Uses are the basis for evaluation and management decisions in all areas concerned (e.g. ecotox, tox, residues, efficacy, fate and behaviour, physical-chemical properties etc.). When everything in the evaluation process ends positive the use will be authorised. An "official definition" is e.g. a defined crop and pest.
Estonia	Plant protection products shall mean active substances and preparations containing one or more active substances, put into the form in which they are supplied to the user, intended to: protect plants or plant products against all harmful organisms or prevent the action of such organisms; influence the life processes of plants, other than as a nutrient, (e.g. growth

	regulators); preserve plant products, in so far as such substances or products are not subject to special provisions of other Acts; destroy undesired plants, or destroy parts of plants, check or prevent the undesired growth of plants.
Ireland	PPP uses not officially defined for other reasons than residues
Spain	Uses are defined for authorization of PPP. List is based on statistical yearbook classification
France	In ornamental sectors are plants are not eaten, residues data are not required during the autorisation process.
Italy	If it mean the kind of valuation, in our country "PPP uses" is considered also for "efficacy"
Latvia	The PPP uses are defined in Article 39.1 of Cabinet Regulation No 156 "Registration Procedures for Plant Protection Product" on registration of PPP in Latvia. The PPP uses include: 39.1.1. The combinations "kultūraugs/kaitīgais organisms" [crop/harmful organism] or "lietošanas mērķis/vieta" [target/place of use] pursuant to the intended use; 39.1.2. Dose; 39.1.3. The time interval from the treatment of plants until harvesting, the waiting period until the utilisation of the treated plants (plant products) for food or feeding stuff, admittance of domestic animals into treated areas, resumption of crop farming work, sowing or planting of successive crops (if necessary); 39.1.4. The method of application; 39.1.5. Restrictions upon use, also protection measures for bodies of water and groundwater, if necessary; 39.1.6. Maximum permissible number of treatments during a season; 39.1.7. Useful life, taking into account the stage of development of the crop or harmful organism.
Lithuania	PPP uses not officially defined for other reasons than residues
Hungary	PPP uses not officially defined for other reasons than residues
Netherlands	Currently uses are according to the Dutch PPP and biocides legislation defined as follows: Plant protection product: Active substance or compound containing one or more active substances, designated or being used to: 1. Protect plants or plant products against all harmful organisms or prevent their effect; 2. Influence life processes of plants, as long as nutrients are not concerned; 3. Preserve plant products; 4. Destroy weeds, or; 5. Destroy parts of plants or undesirable growth.
Austria	Decree § 2 (3) of the Austrian Federal Act on Plant Protection Products 1997: "Indication" shall be a description of the purpose of application, in particular with the following specifications: 1. plant species or plant products or groups thereof, if necessary, in their respective

	stages of development, 2. harmful organisms or groups thereof, if appropriate, in their respective stages of development or the kind of influence on the life processes of plants and plant products or the destruction of undesired plants or parts of plants, 3. place of application (e.g. outdoors, greenhouse, storage building).
Poland	"PPPs uses" in minor uses are defined not only for residues but also for toxicology, fate & behaviour and ecotoxicology. Efficacy data are not required.
Portugal	PPP uses are not officially defined but there is a definition currently used by our services. The definition considers the combination pesticide / crop / pest (disease, pest, weed or effect to be obtained-plant growth regulator) and the conditions of use. So, besides residues, efficacy, toxicology and environment and ecotoxicology are also being considered.
Romania	PPP uses not officially defined for other reasons than residues
Slovenia	PPP uses not officially defined for other reasons than residues
Slovakia	 List of registered PPPs is created according to PPP- crop - pest, separate part of this list is dedicated to "off labels" - minor uses of registered PPPs Separate list of minor uses was published in official journal of the Ministry of Agriculture and Rural Development in the past.
Finland	I don't know if I understood the question right. In Finland the authorities exactly define those uses where a certain specific PPP is allowed to use, when they approve PPPs to the markets. There is often restrictions for the use, for example the use is forbidden in ground water areas, near waterways etc.
Sweden	PPP uses not officially defined for other reasons than residues
United Kingdom	What constitutes a PPP use is effectively defined by the definition of what constitutes a 'PPP' in Directive 91/414/EEC
Norway	List of all crops for which PPP is registered. More crops can be added if necessary. Target pests are not included in the list

Table 4 - Definition minor uses within MS

Member State	Definition of minor uses
Belgium	Follows already the definition on Minor Uses of Regulation (EC) No 1107/2009
Bulgaria	According to plant protection law in Bulgaria, minor use is use of PPP in three situations: minor pest on major crop, major pest on minor crop or minor pest on minor crop.
Czech Republic	Follows already the definition on Minor Uses of Regulation (EC) No 1107/2009; we are working on the guidance specifying more detailed criteria for the Czech condition in compliance with the definition of 1107/2009
Denmark	Follows already the definition on Minor Uses of Regulation (EC) No 1107/2009

Germany	Follows already the definition on Minor Uses of Regulation (EC) No 1107/2009, but only partly
	Yes, but only partly. Germany has the additional possibility to have a minor use 'in all cases of minor extend'. This must be proven during an authorisation. It is not restricted to 'an exceptional plant protection need'. So we go beyond this definition by more flexibility. Finally we think the wording "to meet an exceptional plant protection need" is wrong and the wording listed here 1.5.1 d) "in other cases solely in small quantities" was intended.
	citation from the national plant protection act, § 18: a) for plants cultivated only on a minor scale or whose cultivation is of minor importance,
	b) for plant products whose production is of minor importance,
	c) against harmful organisms which only occasionally cause serious damage or in specific areas or
	d) in other cases solely in small quantities.
Estonia	Plant protection Act § 71. Extension of field of application of plant protection product (1) Persons and scientific or research bodies involved in agricultural activities may request that the field of application of a plant protection product that has already been authorised be extended to purposes other than those covered by this authorisation when it is in the public interest, if:
	1) the requirements prescribed in clauses 63 (5) 3) - 5) of this Act are satisfied; 2) the intended field of application of the plant protection product is minor or the plant protection product is to be used on a crop with a limited growing area; 3) the users of the plant protection product are informed as to instructions for the extended field of application of the plant protection product.
	(2) For the extension of the field of application of a plant protection product, the person or agency specified in subsection (1) of this section shall submit a standard format application to the Plant Production Inspectorate and pay the state fee.
Ireland	Minor uses are determined based on the area of the crop grown. PPPs can only be used on minor crops where the product approval permits the use, either by an "on label" or an "off label" approval
Spain	It is defined by a National rule (OM 20 June 2001): Annex III includes a list of minor uses. The inclusion of this list was based on surface and ingestion criteria.
France	PPP uses not officially defined
Italy	Follows already the definition on Minor Uses of Regulation (EC) No 1107/2009
Cyprus	-
Latvia	-
Lithuania	The minor crops are defined as not widely grown. The minor uses are defined as not

	widely spread harmful organisms and for which there are no authorised PPP.
Hungary	There is only a national list of minor crops in the mentioned ministerial decree.
Netherlands	Not yet, but of course from June 14 the definition will be used, with the following parameters: not widely grown: Arable crops < 5000 ha.; other filed crops < 1000 ha and glasshouse crops < 500 ha. Exceptional plant protection need: the area of the crop compares to a crop group, to which the crop belongs, is less than 5% of the area of the crop. This in more or less the same approach as described in 1.4 but the acreage is increased.
Austria	-
Poland	Minor uses means uses of a plant protection product: on plants cultivated on a small area (less than 1% of the cultivation area) or against harmful organisms causing losses only on specific areas
Portugal	Criteria considered to define a minor use in our country: - Use in a minor crop - area and dietary use to define a minor crop; - Minor use in a major crop (see 1.5.1). In relation to the Regulation N. 1107/2009, we may refer the following: "Not widely grown in that Member State" - We follow this definition, as area is one criteria used, but dietary is also another important criteria we use. -"Widely grown, to meet an exceptional plant protection need" - this definition is dubious, it should be more precise. Please see point 1.5.1. concerning the criteria used to define a minor use in a major crop.
Romania	The main crops are established in national legislation in force
Slovenia	Definition in Regulation has wide meaning. Based on this definition the national definition with specificities should be created.
Slovakia	Definition mentioned above is implemented into draft of national legislation concerning PPPs – special part of provision is dedicated to minor uses. But principles stated in 1.3 and 1.4 have been used for several years. List of minor uses has been developed but has not been updated regularly.
Finland	Not yet regulated.
Sweden	Not yet regulated.
United Kingdom	There is no definition of minor uses in UK legislation. However, for the purpose of the Specific Off-label (SOLA) Approval Scheme a definition very close to that in 1107/2009 does apply. Minor uses are considered to include all uses on minor crops or situations that are relatively small in area or uses on major crops where a particular problem is small or sporadic. The need for each SOLA has to be justified and the key basis for this is invariably that there are no 'on-label' approvals to deal with the particular pest, disease or weed problem. A list of SOLAs is available on the CRD website so potential applicants can judge the type of application that would fall within the scheme. Since

	new crops are always being introduced and new pest problems developing the [scope of] uses covered by SOLAs will change over time.
Norway	Follows already the definition on Minor Uses of Regulation (EC) No 1107/2009

1.2 Detailed inventory of major and minor crops

Part 2 of the survey questionnaire aims at listing crops cultivated in each Member State, the size of the national corresponding cultivation areas and the characterisation according to EU or national definitions. The following map lists MS that have provided data on this section.

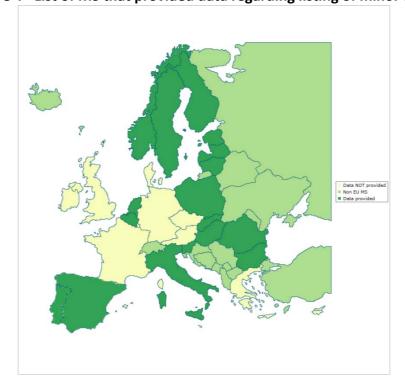


Figure 4 - List of MS that provided data regarding listing of minor crops

The complete data sets on crops cultivated in each Members State, corresponding cultivation areas and characterisation based on collection by way of the survey questionnaire and preliminary collection are as follows:

Table 5 - Overview of data collected within Section 2

	Data on cultivation area			Data on crop classification		
	No data available	Previous collected data available	New data available	No data available	Previous collected data available	New data available
Belgium		X	X		X	X
Bulgaria			X		X	X
Czech Republic		x			x	
Denmark		X			X	
Germany		X			X	
Estonia		X	X		X	X
Ireland		Χ			X	
Greece	X				X	
Spain	X				X	
France	X				X	
Italy			X		Χ	X
Cyprus	X				X	
Latvia		Χ	X		X	X
Lithuania		X	X		X	X
Luxembourg		Χ			X	
Hungary		X	X		X	X
Malta	X				X	
Netherlands		X	X		X	X
Austria		Χ			X	
Poland		X	X		X	Х
Portugal	X				X	
Romania			X		Х	X
Slovenia			X		X	X
Slovakia		Х	X		X	X
Finland		X	X		X	X
Sweden		X	X		X	X
United Kingdom		x			x	
Norway			X			X

Non-provision of data by some Member States can be explained by the fact that such data might not exist in every Member State.

1.3 Detailed inventory and quantification of minor uses issues

A collection of minor uses issues within the different Member States has taken place in the section 3 of the survey questionnaire. This collection covers in total 1415 issues among 15 Member States and should be considered far from complete.

The initiatives are described with help of the following criteria:

- The crop concerned;
- The pest concerned, by:
 - Pest group;
 - Pest name (common English name and scientific Latin name);
 - Pest code (BAYER/EPPO code).
- The issue concerned, by:
 - Type of issue;
 - Description of the issue;
 - The estimated total affected cultivated area.
- Economic damage caused by the issue, for:
 - Users of PPP;
 - Food-supply-down-stream users.

The database with all consolidated cases is presented in Annex VIII.

ANNEX III: THE PROJECT PLAN

Tasks	Description	Methodological tools	Related deliverable
Main ta	sk 1: Inception phase		
1.1	Kick-off meeting	Presentation and discussion of the methodology	
1.2	Introduction to the study and sending of a first questionnaire to CAs to identify all relevant stakeholders and experts	Introductory email & preliminary survey	
1.3	Preliminary desk research		
1.4	Stakeholders analysis (mapping of the actors)		
1.5	Exploratory interviews with SANCO and stakeholders at EU level	Mainly face-to-face meetings (about 10)	
1.6	Development of a draft survey questionnaire and testing		
1.7	Inception note: Outcome and conclusions on elements 1.1 to 1.6	Meeting with Commission	Inception note
Main ta	sk 2: Data Collection phase		
2.1	Launching of the survey	Survey	
2.2	Primary analysis of survey responses		
2.3	Third Country investigation	Phone interviews with key experts in selected countries (Australia, Canada, USA)	
2.4	Phone consultation for filling data gaps and validating results	Phone interviews	
2.5	Secondary analysis (including analysis of Third Country investigation)		
2.6	Draft interim note: update on progress of elements 2.1 to 2.5 and preliminary formulation of options	Meeting with DG SANCO	Draft interim note
Main ta	sk 3: Definition of the options		
3.1	Preparation of workshop and discussion of preliminary options with stakeholders including MS Competent Authorities and relevant experts, and DG SANCO	Workshop	
3.2.	Debriefing/conclusions of workshop and revised selection/definition of options	Meeting with DG SANCO	Report on workshop
3.3	Finalise interim note: final validation of options	Meeting with Commission services	Final interim note
Main ta	sk 4: Impact analysis of the options		
4.1	Field visits to MS and complementary EU interviews	Field visits to 10 MS (DE, DK, ES, FR, HU, IT, NL, PL, SE, UK)	
4.2	Analysis of the impacts of each option (including Cost/Benefit analysis)		Draft final report
Main ta	sk 5: Final reporting		тероп
	Draft final report: presentation of the methodology used, analysis of the results of the data collection, systematic comparison of the options, executive summary and key messages		
	Finalise report on the basis of quality assessment and discussion with the Commission		Final report

ANNEX IV: PRESENTATION OF THIRD COUNTRY APPROACHES (ESPECIALLY THE US – IR4 SCHEME)

This section of the report presents major initiatives that have been implemented by Third Countries in order to address minor uses issues.

We have particularly focused on 3 countries:

- The USA (IR4 system),
- Canada,
- Australia.

1.1. USA (IR 4 system)

1.1.1. Mission

In the USA, the "Interregional Research Project No. 4", commonly known as IR-4, addressed minor use issues. The mission of the IR-4 program is:

"to facilitate registration of sustainable pest management technology for specialty crops and minor uses".

The principal task of the IR-4 program is to assist in the cooperative registration process of pesticides and other pest management technology for specialty and minor crop growers. This task is mainly fulfilled by means of providing field trials and laboratory residue data, including identification of certain food crops which are representative for a group of crops ("crop grouping"). These data are used for the clearance of minor crop tolerances and approval of new uses for pesticides by the U.S. Environmental Protection Agency (U.S. EPA), which is responsible for regulating pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Food Quality Protection Act (FQPA).

"Minor uses" are defined under American legislation as "any crop grown on 300,000 acres or less" 27.

Further similar assistance is provided by the IR-4 program on minor uses of major crops, ornamental horticulture, bio-pesticides, and public health pesticides. Additional tasks of IR-4 include namely advocating of international harmonization of Maximum Residue Levels (MRL) in order to facilitate international trade.

1.1.2. History and development

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²⁷ Which roughly corresponds to 120,000 hectares.

The IR-4 program was launched in 1963 in answer to an identified shortcoming in the area of minor uses by the Directors of State Agricultural Experiment Stations (SAES), in co-operation with two units of the U.S. Department of Agriculture (USDA):

- The Agricultural Research Service (ARS), and
- The Cooperative State Research, Education, and Extension Service (CRSEES).

From the very beginning, the U.S. land grant university system, which foresees publicly funded educational applied science institutions in the area of agriculture and engineering in each state of the U.S., was involved in the IR-4 program.

The program itself started with a

- A coordinating Technical Committee,
- State Liaison Representatives who convey needs and supply information on clearances needed as well as use and residue data at State level,
- Administrative Advisers, and
- A National Project Leader with the USDA covering the expenses of the project.

The IR-4 program has evolved its structure and more tasks (such as bio-pesticides uses) have been added, still some of the elements can be recognised in today's structure (see below 0)

Since its establishment, the IR-4 project has achieved over 11,000 pest control clearances on food crops (including bio-pesticides uses) and over 10,000 clearances on ornamental crops.

1.1.3. Current resources

Currently, in total 25 field research centres are established under IR-4 at strategic locations throughout the United States, representing different geographical and climate conditions. In addition, IR-4 has a network of four regional, three ARS and seven private contracted satellite analytical laboratories that determine the amount of chemical remaining on the crop.

IR-4 conducts about 100 studies annually, supported by approximately 650 field trials. This activity leads to approximately 1,000 tolerances for crop and chemical combinations on food crops and registrations that impact 3,000 plus ornamental crops annually. (Figures taken from the documents National Research Support Project-4 IR-4, External Peer Review, 2009, available at http://ir4.rutgers.edu/Other/IR-4PeerReviewFinalReportAugust%202009.pdf, and National Economic Impact of the IR-4 Project, 2007, available at http://ir4.rutgers.edu/Other/IR4EconomicImpact.pdf; additional information provided by Dr Jerry Baron of IR-4 program).

It should be noted that for every research project which is funded by the IR-4 program, there are approximately five projects delayed pending additional resources. Consequently, the question of prioritisation requires major attention (see below).

1.1.4. Organisation and governance

The IR-4 program is a cooperative government and industry effort by

- The USDA's Agricultural Research Service (USDA-ARS);
- The National Institute of Food and Agriculture (USDA-NIFA), a federal body under the USDA which has replaced the CSREES;
- SAES;
- The land grant university system, the US EPA, the agrochemical industry, commodity groups and growers.

IR-4 is not a legal person itself. The program is closely linked to the institutions that are in charge of its support.

It is a distinctive aim of the entire IR-4 program to have an open door relationship with industry, and the regulatory community, as well as with foreign administrative bodies.

1.1.5. Internal structure

The IR-4 program has evolved, integrated diverse interests and administrative bodies.

The following major organisational entities are sometimes referred to as the IR-4 program itself:

- IR-4 Project Management Committee,
- IR-4 Headquarters (HQ) at Rutgers University (New Jersey),
- Four Regional Offices (each with a Regional Director responsible for the staff and programs in their region), and
- USDA-ARS Office on Minor Use pesticides.

The Management Committee is in charge with policy development, funding distribution and strategic decisions, composed of the HQ Executive Director, Associate Director of Administration, four Regional Directors, Coordinators from the USDA units, and the chair of the Commodity Liaison Committee (CLC). It meets four times a year. Day-to-day-activities are managed by the HQ, the four regional offices and the USDA-ARS Office of Minor Use pesticides.

Analytical laboratories, offices, research farms, infrastructure, administrative support, and scientific expertise are run through in-kind support by **SAES**. Fieldwork for food use and ornamental horticulture is coordinated by Regional Field Coordinators under the four Regional Offices, as well as by **USDA-ARS** directly, for various sites in 31 states throughout the United States.

Protocol development, data assimilation, petition writing, and registration processing are coordinated through HQ, and/or crop protection industry and food processors.

The HQ, the ARS Office of Minor Use Pesticides, the four regional offices, and related analytical laboratories and field research centres employ about 125 full-time staff.

Further important coordination work with important stakeholders is provided by:

- The CLC which represents crop growers and commodities' interests provides advice and is in charge with fund raising,
- Administrative Advisory Committee, which provides liaison between SAES Directors, USDA-ARS and NIFA representatives,
- State Liaison Representatives through which the IR-4 program has a presence within almost every state of the United States.

1.1.6. Procedure

The most important task when fulfilling the primary mission of IR-4 program to support growers of minor crops with pest management solutions is to provide field trial and laboratory residue data necessary for the clearance of minor crop tolerances and approval of new uses for pesticide labels.

The ways IR-4 proceeds are identical in all mission areas and outlined in the figure below.

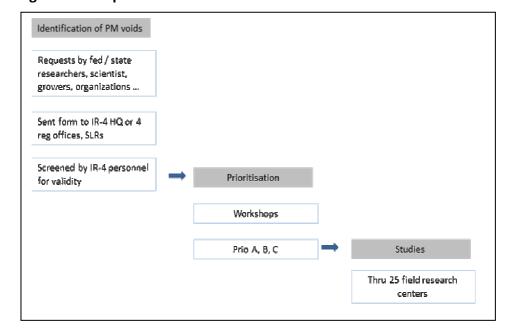


Figure 1: IR -4 procedures in schematic matter

The IR-4 procedure is launched by requests for assistance, often from federal and state researchers or extension scientists involved in minor crop pest management. IR-4 also receives requests directly from growers or organisations representing a commodity. Agricultural chemical companies are not allowed to submit requests.

A request for assistance consists of the completion and submission of a concise inquiry, which is also possible via internet. Some basic information needs to be provided, such as the crop, the proposed pest management tactic, the target pest in question, the proposed use of the pest management tool including the application rate and timing, the interval from last

treatment to harvest and why the pest control material is needed. Inquiries may be sent directly to HQ, to one of the four regional offices, or to the local State Liaison Representatives.

Upon receipt of the inquiry, the proposed use is screened by IR-4 personnel for validity. It is checked whether the proposed use is already registered, whether the agricultural chemical company which holds the U.S. registrations for the chemical be willing to cooperate with IR-4, and whether there are any regulatory impediments known that may delay or result in denial of the registration.

1.1.7. Prioritisation of projects at workshop

The projects that passed the test to this point are subject to prioritisation decisions, following the restricted IR-4 budget. These decisions are - for Food Crops and Ornamental Horticulture - taken at the "Food Use and Ornamentals Workshops", following extensive discussions of the participants.

The workshops are held once a year; over 200 minor crop growers, commodity organisation representatives, agricultural chemical company representatives, and federal and state research scientists attend and participate.

At the workshops, every potential project is discussed in detail. Factors such as

- Economic need for solutions,
- The availability and efficacy of alternatives,
- Pest damage potential,
- Performance of the proposed chemical, and integrated pest management compatibility are all regarded.

Factors to be considered are discussed at the workshop; however, there is no fixed set of criteria with a related evaluation for each project, and a written justification of the ranking result is not foreseen.

The projects are grouped in three priority categories (A, B, and C). Usually,

- all "A" ranked projects are executed,
- "B" ranked projects only conducted in case all "A" ranked projects have been executed and financial means are still available,
- "C" ranked projects are not executed.

The decisions are taken by agreement of all participants.

A minor share of the IR-4 funding may be used for projects for which a special need can be demonstrated even if the project received a low ranking at the workshops.

1.1.8. Conduction of studies and obtaining regulatory clearance

After prioritisation, the studies themselves are conducted at the field research centers and the analytical laboratories. The identified data are submitted to EPA as part of the clearance process. If the data show that clearance of the use would not expose consumers or the environment to unreasonable adverse effects, the EPA publishes a MRL tolerance as a Final Rule in the Federal Register.

For non-food crops, a tolerance is not required. The cooperating company can add the ornamental crops to their registration once it feels comfortable that the use is safe to the crop and effective on the pest.

1.1.9. Funding

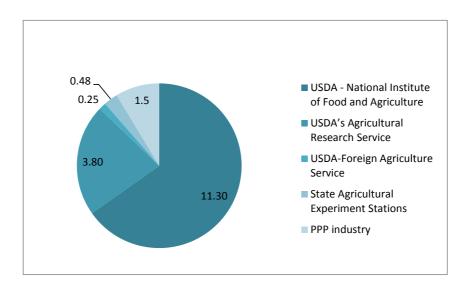
The IR-4 Project is funded by USDA in partnership with the SAES. The total direct funding was around 15 Million USD in 2008 (which is around 10.5 million EUR). It should be highlighted that the direct funding is supplemented by in-kind support from the State Agricultural Experiment Stations which is conservatively estimated to be equal to the amount of direct federal support.

Out of the direct funding in 2008, 12.9 Million USD (around 85 %) applied to the food crop mission area, whereas the funding in the area of ornamental mission area is around 1 Million USD.

The project is funded by the following sources:

- The majority of USDA funding for the IR-4 Project comes through NIFA (11.3 million USD);
- Further USDA funds are provided
 - o by ARS (3.8 million USD) and to a lesser extent –
 - by USDA-Foreign Agriculture Service FAS (around 250,000 USD in 2009) in order to facilitate on international activities to support specialty crop exports;
- SAES contributes financial resources through Multi-State Research Funds (around 480,000 USD annually) and a significant amount of in-kind contributions by housing IR-4 Field Research Centres, Analytical Laboratories and management offices throughout the United States.
- The crop protection industry also contributes direct financial resources (1.5 million USD).

Figure 2: IR-4 (in USD) funding distribution



This support is supplemented by in-kind support from the State Agricultural Experiment Stations which is conservatively estimated to be equal to the amount of direct federal support.

Figure 3: detailed Funding of IR-4 program

	C	urrent Fundi	ng (FY 200	8)	Proposed Funding for FY 2009 to 2			2014
	CSREES	ARS	OTHER ¹	<u>Total</u>	CSREES	ARS	OTHER	<u>Tot</u>
Food								
Comparative Product Performance (Step 1)					\$900,000			\$9
Research/Regulatory Support (Step 2)	\$9,400,000	\$3,300,000		\$12,700,000	\$10,400,000	\$3,800,000		\$14,2
Remove Pesticides as a Trade Barrier (Step 3)			\$250,000	\$250,000			\$1,500,000	\$1,5
SUBTOTAL	\$9,400,000	\$3,330,000	\$250,000	\$12,950,000	\$11,300,000	\$3,800,000	\$1,500,000	\$16,6
Ornamental								
Research/Regulatory Support	\$500,000	\$500,000		\$1,000,000	\$950,000	\$750,000		\$1,7
Invasive Species					\$500,000			\$5
SUBTOTAL	\$500,000	\$500,000		\$1,000,000	\$1,450,000	\$750,000		\$2,2
Biopesticide								
Biopesticide Grants/Regulatory Support	\$650,000		\$100,000	\$750,000	\$750,000		\$100,000	\$8
Organic Support					\$250,000			\$2
SUBTOTAL	\$650,000			\$750,000	\$1,000,000			\$1,1
Cooperative Program - Public Health								
Regulatory Support			<u>\$260,000</u>	<u>\$260,000</u>			\$260,000	<u>\$2</u>
NET FUNDING	\$10,550,000	\$3,800,000	\$610,000	\$14,960,000	\$13,750,000	\$4,550.000	\$1,860,000	\$20,0
USDA Holdback	\$750,000			\$750,000	\$900,000			\$9
Total	\$11,300,000	\$3,800,000	\$610,000	\$15,710,000	\$14,650,000	\$4,550,000	\$1,860,000	\$21,06

source: The IR-4 program, A Strategic Plan for the IR-4 project (2009-2014), available at http://ir4.rutgers.edu/Other/AnnualReports/StrategicPlanFinal.pdf

1.1.10. Success factors, strengths and weaknesses

The following success factors were recognised by Mr. Jerry Baron of IR-4 program during a telephone interview:

- The "grass roots" approach of the project. Need for solutions in the area of minor uses is demonstrated/identified by growers and scientists, and communicated bottom-up,
- The nation-wide integration, providing the possibility to categorize and assess needs for minor uses from agriculturally and geographically diverse areas,
- The excellent networking, serving as a facilitator between interested parties, taking into account (and involve) different stakeholder's interests,
- IR-4's strategy to serve as a facilitator between interested parties, and to involve stakeholders with different perspectives as much as possible, has proven to be successful,
- IR-4 system and IR-4 staff has gained a long-year reputation for acting in grower' interests, and for taking reasonable decisions backed by scientific expertise, in the entire pest management community.

Weaknesses according to IR-4 representatives:

- The structure of IR-4 is rather complex,
- Funding / supporting institutions have sometimes competing interests with which the IR-4 program has to cope,
- Currently, too many projects are foreseen. It is intended to reduce the time for project execution.

1.2. Canada

1.2.1. Mission

The Minor Use Pesticide Program in Canada is modelled to some extent after the U.S. IR-4 program. Similarly to the IR-4 program,

- Pest problems are identified "bottom-up", channelling the communication of grower's needs for minor use solutions at one national headquarters,
- Priorities are established, and
- Field trials are coordinated and conducted to generate necessary data needed to support registering minor use pest-control products in co-operation with relevant authorities and stakeholders.

Namely, the process of prioritisation of projects is analogous to the IR-4 procedure of holding workshops.

Note that the key institution, the Pest Management Center (PMC) uses the U.S. definition for minor use. It is however interpreted as the pesticide use in high-value, low-acreage crops. This includes all horticultural, ornamental, fruit (including berries), and greenhouse and forage crops. It excludes grains, canola, field corn and soybeans.

1.2.2. History and development

The Canadian Minor Use Pesticide Program (MUPP) was launched in June 2002 as a joint initiative between AAFC (Agriculture and Agri-Food Canada Department under the Federal Minister of Agriculture and Agri-Food Canada) and Canada's Pest Management Regulatory Agency (PMRA). Its establishment was laid down in the Agricultural Policy Framework (APF) Implementation Agreements of the Federal Government with provinces and territories. After its expiration in March 2008, the APF was replaced by the "Growing Forward" multilateral framework agreement, concluded on for the duration of five years. It is envisaged to continue the program under the successor agreement "Growing Forward II".

From the beginning, the Canadian initiative was orientated to (and in many ways, cooperated with) the U.S. IR-4 program, yet with a more stringent structure.

The competence for the implementation of the MUPP is consigned mainly to the PMC which was established under the responsibility of AAFC in 2003, however, similarly to the IR-4 program, the diverse competent administrative bodies in the area of agriculture and pesticides as well as important stakeholders such as growers and grower's associations and manufacturers of pesticides, were involved in the decision procedures.

Since 2003 until July 2010, 683 projects have been conducted; 275 submissions to PMRA were made, 165 registrations were achieved, and more than 540 new labelled uses were established. In 2010, data and information were for 65 pesticide minor use regulatory submissions.

1.2.3. Current resources

The MUPP disposes of nine Research Centers, managed by the AAFC, which does most of the trials itself. The number of staff within the MUPP is 38. [All figures taken from: North American Success Model, presentation by Dr Manjeed Sethi, Executive Director PMC, 2010, available at http://ir4.rutgers.edu/GMUS/IUPAC2010/Manjeet%20Australia%20final%20draft%20.pdf; additional information provided by a telephone interview with Ms Shirley Archambault of PMC].

1.2.4. Organisation and governance

A key player for the implementation of the MUPP is the PMC, the headquarters are located in Ottawa. In the area of minor uses, the PMC receives advice from two advisory and technical committees:

- The PMC Advisory Committee that includes representatives from farm and commodity groups, the pest control industry and other groups;
- The Minor Use Pesticides Technical Working Group where representatives from growers, pesticide manufacturers and provincial minor use coordinators are present, which provides advice on a variety of issues, such as the process used for identifying minor use priorities, protocol development, the drafting of registration

submissions, submission mechanics, as well as collaborative projects with companies and with the U.S. IR-4 Minor Use program.

The PMC channels and compiles inquiries for minor use solutions needs, brought up by growers, grower's associations, authorities at provinces/territories, and scientific researchers. The minor use solution needs are in the first place allocated at province level, by so-called Provincial Minor Use Coordinators (PMUC).

After prioritisation by means of a workshop (see below), field trials and laboratory analysis are conducted in research centers, mostly at **AAFC** properties at different locations in the country (additionally by private contractors or Universities), to obtain the analyses to collect the required data, including efficacy and residue information, before drafting regulatory submissions to PMRA for the registration of new minor uses.

1.2.5. Launching of procedure and establishment of national list

Grower's requests for minor use solutions at regional level are communicated to territories/provinces at regular meetings where the information is collated. These pest problems are then matched with potential pesticide solutions, using input from pesticide manufacturers, to produce provincial lists of pest priorities and possible solutions in three categories - weed, disease, and insect. Non-chemical solutions are also considered and included. The PMC allocates all information into one national list.

1.2.6. Prioritisation of projects at workshops

The prioritisation of all the projects listed on the national list is taken by a workshop which is held annually. Representatives from a broad range of stakeholder groups - including provincial minor use coordinators, producers, the pesticide industry, crop specialists, as well as representatives from the U.S. IR-4 program and provincial and federal governments - attend the workshop. The participants shall reach a consensus on the top national priorities in each pest category (weeds, insects, and diseases), and additional priorities are determined to address regional needs.

The basic rationale behind the prioritisation process is which crop/pest combination needs a solution most crucially, taking grower's perspective. The categorisation into "A", "B", and "C" projects is identical to the one applied at the IR-4 program.

In 2010, 37 "A" priorities projects were determined, divided among the three disciplines (weeds and growth regulators, entomology and pathology). In addition, five regional priorities and two organic priorities were selected.

1.2.7. Conduction of studies and obtaining regulatory clearance

Once the priorities are established, the PMC, in consultation with industry and other administrative institutions, conducts field trials to generate the data needed to support submissions to the PMRA for registering minor use pest-control products.

The PMC reviews the data resulting from field trials and laboratory analyses, and prepares a submission to the PMRA to support the registration of the minor use pesticide.

The interaction of AAFC and PMCA is outlined in the figure below.

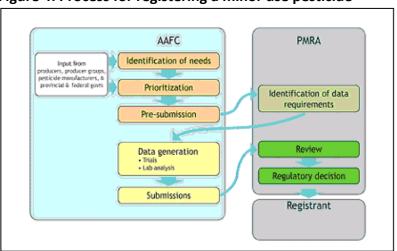


Figure 4: Process for registering a minor use pesticide

Source: http://www4.aqr.qc.ca/AAFC-AAC/display-afficher.do?id=1286197216280&lang=eng#l1

1.2.8. Funding

The minor use project started with a funding commitment of 54.5 million CAD over six years provided by the Federal Government (which equates to an annual funding of around 6.7 million EUR).

Under the Growing Forward Agreement, the Federal Government provides funding in the amount of 52.2 million CAD (around 38 million EUR²⁸) through two departments:

- The major part of the funding is made available by AAFC which provides funding of 36.2 million CAD over the Growing Forward running time; with the budget in 2010-2011 being 9.1 million CAD (around 6.6 million EUR). The costs per AAFC project are estimated in a range of 60,000 CAD (around 45,000 EUR)
- Additional funding amounting to 16 million CAD (around 11.6 million EUR) over the Growing Forward running time is provided by the Canadian Health department; the budget in 2010/2011 was 4 million CAD (around 2.9 million EUR). [Sources: Manjee presentation, and information available at http://www4.agr.gc.ca]

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²⁸ 1 CAD = 0.72 EUR

1.2.9. Collaboration between the United States and Canada

Not only is the Minor Use Program in Canada modelled after the IR-4 system, the two systems are cooperating together, sharing information, consult on program content, and build relationships. This collaboration provides the opportunity to work together on field trials and improve ways to support registrations, so that more registered minor use pesticides are available to producers in both countries.

In 2010, 18 new cooperative projects, consisting of numerous field trials, were initiated between IR-4 and PMC. These trials will result in harmonized MRLs for new products, and new reduced risk tools for growers.

Additionally, PMC personnel are active participants in IR-4 prioritization workshops, meetings with registrants, other meetings and vice versa. Both agencies establish MRLs at the same level and at the same time, thus preventing trade irritants.

1.2.10. Success factors, strengths and weaknesses

- The orientation towards and co-operation with IR-4 system, with similar approach and similar mechanisms, has led to taking advantage of the "good name" of the IR-4 program and good acceptance with all actors in the area of pest management, thus, strengths are similar to those identified for U.S. IR-4 program,
- Yet the Canadian system is organized in a more simplified system than IR-4, mainly with only one main funding body, and provided with planning reliability for the duration of the agreements.

1.3. Australia

In Australia, no overall co-ordinated specific public funding program for minor uses is in place. However, assistance and support for industry struggling with minor uses issues is done in the framework of general R&D programs under the umbrella of specific statuary institutions (i.e. non-profit bodies created by legislative act) set up for groups of commodities. Yet the programs identified have a much smaller budget than the programs in the U.S. and Canada.

1.3.1. Administrative structure and framework for minor uses approach

Minor uses are defined by Australian legislation as:

'A use of the product or constituent that would not produce sufficient economic return to an applicant for registration of the product to meet the cost of registration of the product, or the cost of registration of the product for that use, as the case requires (including, in particular, the cost of providing the data required for that purpose)'.

The competent authority for evaluation and registering agricultural and veterinary chemicals in Australia is the Australian Pesticides and Veterinary Medicines Authority (APVMA). Users

of agricultural chemical products in Australia must comply with the *control-of-use* legislation that applies in their particular state. This legislation can vary between states, particularly with respect to what constitutes off-label use, but as a general rule only products registered by the APVMA can be used. Product registration for novel compounds or new use patterns must be submitted to the APVMA by the registrant, chemical users cannot seek registration for new uses (crops and pests) for existing product labels.

For minor uses, APVMA may issue temporary permits

- To allow the use of registered products contrary to the approved label (Off-Label Permits).
- To allow the use of unregistered products (Supply/Use Permits), or
- To conduct a trial (Research Permits).

Permits are generally issued in response to an application which is evaluated against APVMA's risk assessment criteria, i.e. to the same 'core legislative requirements' as apply to registrations.

APVMA receives and assesses approximately 1,000 permit applications every year. Of the 1,000 permit applications received, more than 600 are for agricultural minor uses.

1.3.2. Minor use funding programs

As pointed out, a coordinated national funding program in Australia does not exist. However, in the framework of agricultural R&D conducted by statutory corporations, namely Horticulture Australia Limited (HAL) and the Grains Research & Development Corporation (GRDC), minor use projects are in place.

Statutory corporations exist for different groups of commodities in Australia. Their R&D activities are partly financed through compulsory levies for specific commodities, and on a 50/50 basis supplemented by direct federal government funding.

Note that not all commodities are subject to levies. For commodities for which no levies are imposed (which is the case for many minor use commodities), there is no possibility to directly profit from the R&D activities of the statutory corporations; regarding minor uses, this means that it generally remains to the growers to fund all data generation and regulatory costs for minor use permits.

1.3.3. HAL Minor Use Project

Note: following information and figures, if not specifically indicated, were provided by Mr. Alan Norden of APVMA.

HAL is a statutory corporation covering 39 commodities (such as fruits, nuts, vegetables ...). In the framework of their R&D activities, HAL has set up a minor use project in 1997 Minor use investment by HAL has been around 300,000 AUD (around 210,000 EUR) in 2010, thus representing a share of 0.3 % of the total R&D budget of around 90 million AUD (around 65

million EUR, see the envisaged budget of HAL in the document "HAL Operating Plan 2010/2011"), available at

http://www.horticulture.com.au/librarymanager/libs/160/HAL%20Annual%20Operating%20 Plan%202010-11.PDF).

The funding in the framework of the HAL minor use project includes

- The overall management of the project
- Efficacy and residue generation and
- The submission of minor use permit's applications.

HAL does not dispose of in-house capacities to conduct tests themselves for data generation. After prioritisation of minor use applications by the project team, a tendering process is launched for which external laboratories may apply. The awarded laboratory is subsequently contracted, and the final report taken as the basis for the permitting procedure.

HAL is administering approximately 50% of minor use applications originating from the horticultural sector. The remainder of horticultural submissions are lodged independently by individual growers or industry peak bodies at their own cost. Taking into account that horticultural crops represent approximately half of all minor use permit applications, the HAL project is administering around one quarter of all minor use permits lodged with the APVMA.

1.3.4. GRDC's Pesticides for Minor Uses in Grain project

The Grains Research & Development Corporation (GRDC) is responsible for planning, investing and overseeing R&D, delivering improvements in production, sustainability and profitability across the Australian grains industry. Levies are collected on 25 crops, spanning temperate and tropical cereals, oilseeds and pulses; these commodities represent approximately 12% of all minor use submissions.

In the framework of GRDC's "Pesticides for Minor Uses in Grain" project, unlike under the HAL project, no data are generated; field trials are neither directly conducted nor arranged within the framework of this project. Instead, the program aims at supporting industry by identifying suitable pesticides, co-operating with State departments of agriculture, independent advisers and the chemical industry to obtain the information necessary for registration or use permits for nominated chemicals in co-operation with APVMA. The program engages with industry bodies and provides regulatory assistance to those organisations in the development and submission of minor use permits.

The annual budget of GRDC's minor use project is around 120,000 AUD (around 85,000 EUR), which represents around 0.1 % of the annual spending of GRDC on R&D which is around 130 million AUD (around 93 million EUR). This low figure in comparison to the share of HAL's minor use project can partly be explained with the relevance of minor uses for the affected commodities.

ANNEX V: LIST OF EXISTING NATIONAL INITIATIVES

This annex presents the existing different initiatives that are in place at national level in the EU. This information has been collected via the general questionnaire and a summary of these initiatives is presented in Section 2.

Sixty-one per cent (61%) of respondents indicated that at least one national initiative is in place within their country to address minor uses issues, being as follows:



Figure 1 - List of MS (15) in which initiatives related to minor uses issues are in place

Below, a comprehensive overview of all national initiatives collected by the survey questionnaire to address minor uses issues can be found.

No initiative
Non EU MS
Initiative

MS: **Belgium**

	Initiative 1	Initiative 2	Initiative 3	Initiative 4	Initiative 5	Initiative 6
Name of the initiative:	Working groups 'minor uses'	Single contact point for minor uses within the competent authority	Fund of raw materials	Kern minor use	Applications for minor use extensions of MRLs for minor uses are free of charges	Meetings of quality managers and fyto companies
Scope:	4 working groups dealing with availability of PPPs in: - ornamentals; - small fruits; - vegetables under protection; - vegetables grown in open air.	One person is responsible for all minor uses issues (problems, extension, funding,) within the national competent authority	Fund finances efficacy/residue trials to gain/support minor use extension	Meeting with the third party representative every six weeks		Meeting with quality managers of the auctions and yearly meeting with all fyto companies every six weeks
Description of the Scope:	Each working group consists of representatives of the growers sector, authorities and research institutes. Each year a list is made of the problems/possible solutions in the working		The fund is based on levies of PPPs, the levies are depending on the toxicity and the volumes sold of a PPP. A part of this budget is used to pay studies to support/gain minor	During this meeting an update is made of the current situation of minor use issues (future of ai's, ongoing applications, EU initiatives) New initiatives are		Auctions: to be informed of problems and possible solutions in different cultures and update of extensions. Phyto companies: to discuss bottlenecks in

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	field. These lists are used during the next year to apply for third parties extensions and/or to apply for financial support for residue trials through the Fund.		use extension (budget ± 500 000 EUR/year)	coordinated so that double work is avoided		different dossiers.
Level of collaboration:	Participation in the meetings	Single contact point for minor uses topics	Secretary of the fund	President of the meeting	As single point of contact for the applications	Participations and preparation of meeting documents
Description of level of coll.:	as the person responsible for minor uses I participate in each meeting				I 'm the dossier manager for all these applications	Update of problems and possible solutions
Date of establishment:	2003	1996	1998	2006	1996	2004
Involved parties:	Growers assosiations, authorities, research centers	Authority	Authority, industry	Growers associations, authority	Authority	Growers associations, industry.
Governance:	A representative from the regional authority (responsible for agriculture) presides the meeting, the secretary is a representative of the growers. The meeting takes place once a year.	not applicable	The Fund for raw materials has an advisory board to evaluate the research proposals. For minor use projects, the board leans on the priority lists and the advice of	During this meeting minor use issues (applications, meetings, initiatives, etc) are discussed with the third party applicants.		The priority lists are the guidelines for this meeting.

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	A priority list of minor use problems is made (consensus)		the Authorisation board. The Minister responsible for the Funds takes the final decision.			
Mission and objectives:	Priority lists for minor use problems per working group	Day to day treatment of minor use issues, planning field trials, exchange of data, representation of Belgium at the EU level, establish a good working relation with the 'field'	One of the objectives of the Fund is funding minor use trials	Assuring the correct and smooth treatment of minor use extensions. Coordination of minor use initiatives	Encourage third parties to apply for minor use extensions.	Quick detection of problems with minor uses and find a good solution.
External collaborations:	The different working groups share information. The priority lists are taken into consideration when exchanging data with other countries or other parties. The priority lists are a valuable tool when participating in working groups on EU level.	Participation in meetings on a regional, national and international level	The fund uses the priority list to take a decision about funding the proposed projects. The data are exchanged with other MS.	Information is gathered in different meetings and is shared, international collaboration is being prepared.		Participation in meetings on a regional, national and international level.
Main activities/tools:	Workshops, excel tables, email exchanges,	Meetings, excel tables, email exchanges,	Meetings	Meetings, excel tables, dbases, email		Excel tables, email exchange, exchange of data, workshops,

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	exchange of data	exchange of data		exchanges		meetings
Annual budget:		100.000 EUR	500.000 EUR			20.000 EUR
Nature of funding:	Mixed funding	Public funding	Public funding	Public funding		Private funding
Description of the funding:	Public: 14 % FTE Private: organisation of the meetings, lunch, meeting room, etc.	Salary and overheads for the management of minor uses (this budget is also used for initiative 1 and 4)	The fund is based on levies of PPPs, depending on their toxicity and the volumes sold. The advisory board advises the Minister	7 % FTE	120 000 EUR (this is an estimation based on the cost for an extension of use by a company). The extension for third party is free of charges. This amount is what they would have to pay if it were not free	
Achievements completed to date:	- Awareness of het growers/researchers of the authorisations procedures and the different ways they can follow to get authorisations for minor uses. Research institutes can organise a part of their research in such a way that the trials are usable in an authorisation dossier. - Networking - Collaboration residue trials (protocols)	- Satisfactory collaboration with third parties - Work sharing with third countries for residu trials - Exchange of data with other countries - Good working relations with the phytopharmaceutical industry	Each year a dozen residue trials lead to an extension of use (includes MRL setting if necessary)	Minor use problems are dealt with as soon as possible. Good working relation with the growers associations	The number of minor use extension is growing each year. In 2010 around 150 extensions were granted.	Good working relation between the grower association and fyto industry.

MS: Denmark	
	Initiative 1
Name of the initiative:	Grøn Vækst
Scope:	Governmental initiative
Description of the Scope:	Increased registration of alternative pesticides
Level of collaboration:	
Description of level of coll.:	
Date of establishment:	2010
Involved parties:	Authority, industry, extension, growers organisations +++
Governance:	All
Mission and objectives:	
External collaborations:	
Main activities/tools:	Increased number of approved alternative pesticides (most targeted for minor uses)
Annual budget:	DKK 3 mill (ca. 575.054 EUR)
Nature of funding:	Public funding
Description of the funding:	
Achievements completed to date:	Approved applications, more pesticides available to minor crops

MS: Germany				
	Initiative 1	Initiative 2	Initiative 3	Initiative 4
Name of the initiative:	Working Group 'Minor Uses' at Federal Ministry of Food, Agriculture and Consumer Protection	Working Groups 'Minor Uses' of the Federal States	Working Group Minor Uses of the Julius Kühn-Institute	Round Table Talks
Scope:	national expert group consisting of Ministries, Competent Authorities, Federal States working groups minor uses, growers associations (NGOs) and companies	plant protection experts and advisers of the Federal States, representatives of: the competent authorities, growers associations, other EU member state	to accompany and assist all workings in the field of minor uses in Germany	Working Groups 'Minor Uses' of the Federal States and companies
Description of the Scope:	annual meetings on general problems and further development of minor uses in Germany and internationally	annual meetings to report and plan efficacy and residue trials, to discuss developments and to agree on national and international co-oparation and working plan	participation in all other initiatives listed here, representative of EU TG Minor Uses, responsible for the evaluation of the public interest of a minor use application in Germany	annual meetings to discuss the working plan and to intruduce new products by companies
Level of collaboration:	very close co-operation of all parties for many years, annual discussion	very close co-operation of all parties for many years	very close co-operation of all parties for many years	very close co-operation of all parties for many years, direct contact to companies
Description of level of coll.:				
Date of establishment:	1991	1993	1993	1993

Involved parties:	Ministries, Competent Authorities, Federal States working groups minor uses, growers associations (NGOs) and companies	plant protection experts and advisers of the Federal States, representatives of: the competent authorities, growers associations, other EU member states	members of the working group	Working Groups 'Minor Uses' of the Federal States and companies
Governance:	leadership at national level, steering, establishing framework conditions, EU Steering Group Minor Uses	leadership at expert level, working plan for trials, application of authorisations for minor uses, co-operation at EU expert level	participation in all other initiatives listed here, representative of EU TG Minor Uses, responsible for the evaluation of the public interest of a minor use application in Germany	minor uses problem discussions and finding of solutions, working plans
Mission and objectives:				
External collaborations:	All initiatives in Germany are an essential national component to close minor use gaps. All partners act in close contact and cooperation to each other on minor use problems. Germany is member of the Steering Group, Technical Group and Expert Group of the EU and collaborates with other countries bi- and multilaterally. It is a cooperation system which can't be described with single descriptions of collaborations.	Austria, Switzerland and Belgium join the annual meetings of the Federal States Working Group Minor Uses in January in Braunschweig		
Main activities/tools:	conferences, meetings	meetings, workshops, co-operation, databases	conferences, meetings, workshops, co-operation, databases	meetings, co-operation
Annual budget:	No budget	600000 - 800000 €/year; about 150.000 €/year for residue trials	No budget	No budget

Nature of funding:		Mixed funding		
Description of the funding:	members get payment from their institutions	annual budget for residue trials vegetables members get payment from their institutions	members get payment from their institutions	members get payment from their institutions
Achievements completed to date:	Steering Group decides the framework for all other groups	well working national minor use procedure, 4058 applied uses, more than 6000 trials for efficacy/toxicity and residues, different databases as tools; this is an achievement of the good co-operation of all persons involved	exchange of information and data for finding minor uses solutions	exchange of information and data for finding minor uses solutions

MS: Ireland		
	Initiative 1	Initiative 2
Name of the initiative:	Bord Bia activities	Pesticide Registration and Control Division activities
Scope:		
Description of the Scope:		
Level of collaboration:	Purchase access to residue data	Pesticide Registration and Control Division liaison with PPP companies
Description of level of coll.:		
Date of establishment:	2000-2003 period	2000
Involved parties:	Bord Bia, a state agency responsible for development of the Irish horticulture industry & owners of residue data in other EU countries	Pesticide Registration and Control Division & companies
Governance:	Access to data purchased based on grower demand	
Mission and objectives:	Purchase access to residue data to gain approval on minor crops	Extend PPP registrations to minor crops where possible

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External collaborations:	No formal collaboration	No formal collaboration
Main activities/tools:	Priorities re. purchase of data decided based on informal communications with growers of minor crops and advisory/extension service staff	Meetings
Annual budget:	40000 EUR	
Nature of funding:	Private funding	
Description of the funding:	Grower levy	Undertaken as part of PPP registration process
Achievements completed to date:	Minor use registrations granted on the basis of residue data purchased from grower levy	Minor use registrations granted on the basis of extrapolation from major crops.

MS: Spain		
	Initiative 1	Initiative 2
Name of the initiative:	Minor uses (finished in 2007)	Table of orphan crops
Scope:	Producer and exporter organization	Ministry of Environment and Regional Government
Description of the Scope:	Pilot project in order to establish a procedure facilitating that farmer's organizations promote new PPP uses. The project finished in 2007.	Description of pest problems and crops with no authorized PPP
Level of collaboration:	40%	25%
Description of level of coll.:	Coordination and funding	Initiative and Coordinators. Input from regional authorities and private organisations of farmers, exporters and industry
Date of establishment:	2006	Aug. 2010
Involved parties:	FEPEX, AEPLA (producers and exporters organitation)	Ministry, regional government
Governance:	leadership and funding	Leadership
Mission and objectives:	Develop a system for authorisation for minor uses applied by producers	To have an official list of orphan uses to have a legal support in order to make administrative decisions to improve the current situation
External collaborations:	Producer and exporter organization	Regional governments, main stakeholders on use of PPP

Main activities/tools:	Funding trials in order to support the authorisation	Database
Annual budget:	1.480.000 EUR	0 EUR
Nature of funding:	Mixed funding	
Description of the funding:		
Achievements completed to date:	33 new authorisations (20 substances)	Provisional list of orphan uses

MS: France			
	Initiative 1	Initiative 2	Initiative 2
Name of the initiative:	Orphan Uses Committee	CTIFL – regional experimental stations	ForumPhyto
Submitted by:	NCA	AREFLH	AREFLH
Scope:	All crops concerned by means of protection particulary speciality crops	Expertise and trials	Exchange of general information from growers and cooperatives perspective
Description of the Scope:	The orphan uses committee valids a National action plan elaborated by the thechnical expert group. This action plan presents differents parts - experimental program - administrative and regulatory measures (e.g. review of catalog of uses, biological extrapolation) - European cooperation - prospective analysis of phytosanitary aspects - support to active substances to solve orphan uses	Potential solutions: interest and feasibilty, doing trials (GPE)	Internet site and newsletter, prioritisation of the needs, economic impact assessment, judicial coordination between cooperatives.

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	- communication and work platform Find attached details of the action plan 2011		
Level of collaboration:	3 levels of collaboration - technical field - expert technical group -Orphan uses committee		Management
Description of level of coll.:			
Date of establishment:	June 2008		01.01.2007
Involved parties:	All partners concerned by plant protection aspects (Agency of evaluation, Ministry of agriculture, Professional organisation, Industry)	Authorities, growers, and cooperative trade unions etc.	Fruit, vegetables and potato food chain, PPP industry.
Governance:			AOPs (cooperatives) have the leadership. Non-profit association.
Mission and objectives:			Providing general information towards all stakeholders. Coordination between cooperatives.
External collaborations:	Point 8 of the action plan provides active cooperation at the European level, particulary in the southern zone		COPA-COGECA, AREFLH, FRESHFEL, CPWG GlobalGap
Main activities/tools:	The orphan uses committee valids a		Newsletters, meetings

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	National action plan elaborated by the thechnical expert group. This action plan presents differents parts: - experimental programme - administrative and regulatory measures (e.g. review of catalog of uses, biological extrapolation) - European cooperation - prospective analysis of phytosanitary aspects - support to active substances to solve orphan uses - communication and work platform	
Annual budget:	1.000.000 EUR	
Nature of funding:	Mixed funding	Private funding
Description of the funding:		Member's fees. Only a small part on minor uses and speciality crops.
Achievements completed to date:	Permanent action	Awareness of the fruit and vegetables industry and stakeholders (impact assessment, priorisation of growers needs). Coordination between cooperatives for relationships with growers. Coordination in the frame of quality management schemes.

MS: Latvia

	Initiative 1
Name of the initiative:	PPP off-label use for minor crops
Submitted by:	Latvijas darwnieks
Scope:	Growers association
Description of the Scope:	According to national legislation it is possible to get off-label use for some crops.
Level of collaboration:	Experts of vegetables growers association
Description of level of coll.:	Collaboration with national plant protection authority in drawing up documents for off-label use.
Date of establishment:	2004
Involved parties:	Agriculture ministry, Plant protection authority, PPP traders association, growers association.
Governance:	Working rules
Mission and objectives:	Exchange of data
External collaborations:	
Main activities/tools:	Database, working parties
Annual budget:	Approx. 1500 EUR
Nature of funding:	Private funding
Description of the funding:	Taxies for procedure
Achievements completed to date:	Vegetables growers' associations has got 6 off-label PPPs in 2009 and 2 permissions for limited use of unregistered (in Latvia) PPPs in 2009 and 2010, and hope to get it also in 2011.

MS: Netherlands (1/2)					
	Initiative 1	Initiative 2	Initiative 3	Initiative 4	
Name of the initiative:	International Co-ordination Minor Uses	National Co-ordination Minor Uses	NL fund minor uses	Trustee foundation	
Scope:	International coordination/EU Expert Group on Minor Uses	National & international coordination and cooperation with MS national coordinators	Joint government & stakeholders initiative	Crop protection industry, trade organisations of PPP and Dutch farmers union	
Description of the Scope:	Facilitation and stimulation of cooperation between Member States, aimed at solving minor use gaps. Identification of legal and procedural problems in this process, addressing this to the Expert Group on Minor Uses	Cooperate with the NL Fund and Helpdesk Minor Uses in finding solutions for Dutch growers by means of - facilitating voluntary mutual recognition - obtaining relevant data (approval) from other MS through e.g exchange - facilitating joint studies with international partners - searching for alternative solutions and initiation of pilots Facilitating solutions in other MS by stimulating the exchange of NL data	The Fund offers support for the costs of authorising plant protection products and biological control agents in the Netherlands. These costs comprise application and assessment fees or research expenses. To qualify for support from the Fund, applications must be submitted to the Secretariat of the Adjudication Committee. The Plant Health Division of the new Food and Consumer Product Safety Authority holds the secretariat of this Fund. All applications are reviewed by the Adjudication Committee, which comprises Agrodis and LTO Nederland	Establish to cover liability issues related to third part extensions	

Lovel of	Coordination 9 Cooperation at	Identification of legal and procedural obstacles in these processes and advising the Ministry.		
Level of collaboration:	Coordination & Cooperation at international level	Coordination & Cooperation at national level	Secretariat of Fund	Cooperation
Description of level of coll.:	Facilitate and encourage cooperation among MS to find solutions for minor use gaps. Moreover identify problems faced and have it discussed in the EU Expert Group on Minor Uses	Seeking solutions for minor use gaps, through facilitating (voluntary) mutual recognition; working together with national coordinators of MS. Encouraging exchange of data	Coordination of applications; international exchange of data obtained through the Fund; cooperation with the ECMPS etc. Studies financed by the Fund are used in the process of international cooperation/exchange of data	Coordination of third part extensions; arrangements for liability; finding solutions for minor use gaps Assisting enterprises who are not familiar with the process of third part extensions
Date of establishment:	2002	2002	2000	2000
Involved parties:	Government	Government	Government and growers associations	Industry, being growers associations, associations representing the chemical industry
Governance:	Coordination and initiation	Coordination and initiation	Decision making	Decision making
Mission and objectives:	Stimulation and facilitation of the cooperation among MS and finding solutions for minor use gaps; identification of obstacles in these processes and address these to the Steering Group. Furthermore develop and	Technical cooperation and coordination with other national coordinators; identification of common projects leading to national authorizations and aiming at enhancing harmonisation among EU MS	The Foundation manages funds to provide support for authorisation costs of plant protection products and biological control agents (e.g. mites and parasitoids) in the Netherlands. The Fund offers the opportunity to expand the number of authorised uses of protection products or biological control agents	Taking over the liability issue for third part extensions

	maintain contacts with similar organisations outside EU		amongst other speciality crops.	
External collaborations:	Collaboration with TG South; OECD/EGMU;IR-4; Collaboration with the NL Trustee, Fund, Helpdesks and DG SANCO; ECPA and COPA COGECA	Collaboration with CEMPS, Dutch Farmer Union, Nefyto as well as with national coordinators of MS; NL Fund & Trustee	Collaboration with industry, farmers associations and colleagues from MS; exchange of data	Collaboration with industry, competent authority and minor use helpdesk
Main activities/tools:	Meetings, workshops	Meetings, workshops, database	Meetings (Adjudication Committee), database (data from Fund into Liaison dbase)	Meetings
Annual budget:			600.000 EUR	
Nature of funding:	Public funding	Public funding	Mixed funding	Private funding
Description of the funding:	Full time equivalent	Full time equivalent at NPPO and CA	50% contribution Government, 50% contribution Growers Association	
Achievements completed to date:	Collaboration & co-operation between Member States and building trust between Member States; insight in procedures and processes	Exchange of data and co-operation in projects; mainly with regard to residue trials	39 authorizations realized for products for minor uses; many application in progress; 500k€ spent on applications and research for minor use authorisations	Trustee regularly used when liability is an obstacle in realising authorisations for minor uses; achievements see 1.6

MS: Netherla r	MS: Netherlands (2/2)					
	Initiative 5	Initiative 6	Initiative 7	Initiative 8		
Name of the initiative:	Co-ordinator Effective Crop Protection Measures (ECPM)	Helpdesk Minor Use NPPO	Helpdesk Authorizations of Ctgb	Expert Centre Speciality Crops		
Scope:	Experts of Dutch Organisation for Agriculture and Horticulture (LTO)	Government initiated helpdesk	Helpdesk of Competent Authority, Ctgb	Joint Government (Ministry of Economic Affairs, Agriculture and Innovation & CA), Industry (Nefyto, LTO, Plantum-NL) and Wageningen University		
Description of the Scope:	The Coordinators (in Dutch abbreviated as CEMPs) focus on the availability of plant protection products. The main role of the Coordinators consists of making inventories of existing and future bottlenecks in crop protection. Subsequently they consult crop advisors, researchers and industry to find out which plant protection product is preferred and if it's likely that an authorisation can be finalized. After the desired solution is identified, the Coordinator will support the application or will submit the application. The Coordinators are directed by the agricultural organizations. All Dutch growers can indicate gaps in their crop	The aim of the Helpdesk Minor Uses, which will help to solve problems involving specialty crops within the system of integrated crop protection, is to provide recommendations to businesses and the government. The Helpdesk points out the quickest and most economical way of formulating an authorisation request, including the most favourable way of gaining authorisation. The Helpdesk also makes active use of the new Food and Consumer Product Safety Authority's international contacts in the area of minor uses, thus facilitating the exchange of research data between the Netherlands and other countries. When	The Helpdesk Authorisations has been set up to give (potential) applicants for new authorisations and (simplified) extensions of crop protection products adequate support regarding dossier requirements, the application procedure to be followed, cost estimates, and completeness assessment of the dossier that is to be submitted. This means that the Helpdesk is only available for questions about authorisations or (simplified) extensions in the stage prior to application. Further information can be found on the website of the Ctgb.	www.specialitycrops.eu		

	protection management to the Coordinators.	seeking solutions the Helpdesk also identifies favourable non-chemical options.		
Level of collaboration:	Coordination	Coordination	Coordination	Coordination
Description of level of coll.:	Regular meetings to assist ECMP with process of application, from identifying a mu gap towards finding a solution.	Industry and the government work together to ensure that an effective package of measures is available for the sector. Assisting in finding solutions and guidance in relation to procedural aspects.		Activities mentioned are taken on board in this new network, aimed at gaining efficiency in order to improve/speed up the process from research towards authorisation
Date of establishment:	1998	2003	2004	2010
Involved parties:	Industry, being growers associations	Government	Competent Authority	Government, Competent Authority, Industry, Growers associations and University
Governance:	Guidance/assistance	Guidance/assistance	Guidance/assistance	Guidance and working rules
Mission and objectives:	The main role of the Coordinators consists of making inventories of existing and future bottlenecks in crop protection. Subsequently they consult crop advisors, researchers and industry to find out which plant protection product is preferred and if it is likely that an authorisation can be finalized. After the desired solution is identified, the Coordinator will support the application	The aim of the Helpdesk Minor Uses, which will help to solve problems involving speciality crops within the system of integrated crop protection, is to provide recommendations to businesses and the government. The Helpdesk points out the quickest and most economical way of formulating an authorisation request, including the most favourable way of gaining authorisation. The	The Helpdesk Authorisations has been set up to give (potential) applicants for new authorisations and (simplified) extensions of crop protection products adequate support regarding dossier requirements, the application procedure to be followed, cost estimates, and completeness assessment of the dossier that is to be submitted. This means that the Helpdesk is only	Provide more insight into the various procedures via the digital portal of the Expert Centre. Also be working towards a better coherence of the "behind the screen" procedures. This will enable a faster and easier coordination between research, advice, financing and authorisation so that innovations

	or will submit the application.	Helpdesk also makes active use of the new Food and Consumer Product Safety Authority's international contacts in the area of minor uses, thus facilitating the exchange of research data between the Netherlands and other countries. When seeking solutions the Helpdesk also identifies favourable non-chemical options	available for questions about authorisations or (simplified) extensions in the stage prior to application	that are based on Dutch expertise are (more) rapidly reaching the market via authorisations.
External collaborations:	Collaboration among the colleague CEMPs, Trustee, Industry, Competent Authority with national coordinators of MS as well as with technical staff of various institutes in MS. Requesting research institutes to carry out trials etc.	Cooperation with ECMPs, industry, farmers associations, Fund and policy makers; not only national but also international	Collaboration with NPPO, industry and Trustee	Initiative just started
Main activities/tools:	Meetings	Meetings	Meetings, procedures to list minor uses	Meetings; internet
Annual budget:				
Nature of funding:	Private funding	Public funding	Public funding	Mixed funding
Description of the funding:		Full time equivalent		
Achievements completed to date:	Preparation of dossiers (see 4) and identification of minor uses and discussion with industry for possible solutions.	Contributing to reasonable application to Fund; finding concrete solutions and also advising in correct routing; currently discussing 300 applications with the agri/horti sector. Contribution to international cooperation	Knowledge regarding the dossier requirements, procedures & costs related, resulting in a smooth routing of an application	

MS: Austria			
	Initiative 1		
Name of the initiative:	ÖAIP (Austrian Working Group for Integrated Plant Protection)		
Scope:	farmers association		
Description of the Scope:			
Level of collaboration:	High		
Description of level of coll.:			
Date of establishment:	1997		
Involved parties:	farmer, industry, competent authorities		
Governance:	Leadership		
Mission and objectives:	application and coordination, field trials, data exchange		
External collaborations:	AK Lück Germany, Industry in Austria		
Main activities/tools:	Meetings		
Annual budget:			
Nature of funding:	Mixed funding		
Description of the funding:			
Achievements completed to date:	extensions of authorisations achieved, awareness raised for the problem, sensibilisaton		

Agriculture.

MS: Poland					
	Initiative 1	Initiative 2	Initiative 3	Initiative 4	
Name of the initiative:	Reduced registration fee	Simplified registration procedure	Minor Crop producers initiative	Minor uses Committee	
Submitted by:	NCA	NCA	PCPA	PCPA	
Scope:			Communication pattern between growers and particular PPP producers	Polish Academy of Science and Advisory chamber to minister of Agriculture	
Description of the Scope:			Necessary application format is prepared by ministry of agriculture	Know how support for Minor Crops growers	
Level of collaboration:			Communication support	Co-initiator	
Description of level of coll.:			Matching request with potential solution supplier	Guidance within administrative and communication procedures	
Date of establishment:	01.05.2003	01.05.2003	2004	2010	
Involved parties:	Authority	Authority	Growers associations, industry, industry associations	PP committee of Polish academy of Science PP committee of Advisory chamber to minister of	

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Decision making process

Decision making

process

Governance:

Leadership depends, shared by growers and

industry, decisions lay in authorities hands,

followed by application. Work sharing adapted

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	case by case	
Mission and objectives:	Joint work is a key to right solutions	Guidance can support very minor uses and applications.
External collaborations:	Collaboration within industry across Europe	Learning from French initiative on Minor Uses
Main activities/tools:	Workshops, meetings	Workshops, meetings
Annual budget:		
Nature of funding:	Private funding	Private funding
Description of the funding:	Industry collects data, research is very limited	Industry collects data, research is very limited
Achievements completed to date:	Better communication among growers associations and interested parties	Better communication among growers associations and interested parties

MS: Portugal	MS: Portugal				
	Initiative 1	Initiative 2			
Name of the initiative:	Minor Uses off-labels	National Action Plans to get solutions for gaps			
Scope:	Third parties (Growers and Organizations)	Firms and growers			
Description of the Scope:	Minor use off-label is only applied by third parties; - it is only applied for a product already authorized for a major use; the use is not included on the label, but is available in an official publication. The efficacy and crop safety is the user's responsibility.	Promotion of meetings and contacts with growers in order to get information about existing problems. Awareness of firms for getting solutions for these problems. Writing some documentation and internal procedures, in this framework.			
Level of collaboration:	Responsibility for granting the off-label.	Firms awareness about the gaps existing in Portugal; Guidance documents related to the problems identified			
Description of level of coll.:	The authority examines and evaluates the application following a simplified procedure. Extrapolations and registrations from outside of Portugal are used . However, communitary MRL has to be stablished or the firm may support with residues data.	Authority promotes meetings with growers and/or firms. Authority makes some contacts (oral or written) in order to inform and sensibilize the firms for some problems. Authority makes some specific procedures, in order to to have tools to get solutions to some gaps existing in the country			
Date of establishment:	2001	2004			

Involved parties:	Industry is also involved working with the growers, sending the comparative documents about registrations in others Member states, or sending some data (residue or others), if requested. Authority manages the entire process and decides about the authorization of the off-label.	Authorities (including regional services), growers and firms (see 4.1.1)
Governance:	Decision making process and working rules (see our document "Critérios para definição de usos menores", on our website)	Leadership, working rules (see our documents "PPA(H/C)-05/05 for problems without solutions, 2/DG/ 2008 for fruit fly on pomes and citrus, DSPF (H/C)-12/2006 for rice seed tretment.
Mission and objectives:	To get solutions for the problems the companies do not invest in.	Exchange of data in order to promote some actions to get solutions for new problems or problems existing due to the withdrawal of active substances or lack of efficacy.
External collaborations:	There is no official contact with others Member States, but there is official website consultation	
Main activities/tools:	Meetings with growers; Official lists of authorized PPPs and extensions of uses in Portugal and others Members states; PPP labels and other authorization comparative documents; Communitary MRL Lists, Sanco guidance documents about extrapolations.	Meetings with growers and firms.
Annual budget:		
Nature of funding:	Mixed funding	
Description of the funding:	Authority- evaluation costs	Private- applications payment
Achievements completed to date:	Lists of minor uses authorized	Lists of gaps existing in Portugal (to be updated this year)

MS: Slovakia					
	Initiative 1	Initiative 2	Initiative 3	Initiative 4	Initiative 5
Name of the initiative:	Reduced regulatory data requirements	Reduced number of efficacy trials (1/2)	Reduced fees	Shortened time for minor uses authorisation process	Off labels
Scope:	State administration/registration authority	State administration/registration authority	State administration/registration authority	State administration/registration authority	State administration/registration authority
Description of the Scope:					
Level of collaboration:	management/preparation of legislation	management/preparation of legislation	management/preparation of legislation	management/preparation of legislation	management/preparation of legislation
Description of level of coll.:	manual (GD) for applicants/national legislation	manual (GD) for applicants/national legislation			
Date of establishment:	before 2008	before 2008	before 2008	before 2008	before 2008
Involved parties:	state administration/registration authority	state administration/registration authority	state administration/registration authority	state administration/registration authority	state administration/registration authority
Governance:	working rules, management	decision making,	working rules, management	working rules, management	management, decision

		management			making process
Mission and objectives:	Exchange of data	planning of field trials			manual (GD) for applicants/national legislation
External collaborations:	Meetings of representatives from expert institutions involved into registration process, extrapolation tables	extrapolation tables			meetings and discussions with farmers
Main activities/tools:	Meetings of representatives from expert institutions involved into registration process, workshops (at EU or OECD level), extrapolation tables	list of minor crops and minor uses	manual (GD) for applicants/national legislation	manual (GD) for applicants/national legislation	consultations with farmers (associations)
Annual budget:	I do not know	I do not know	I do not know	I do not know	I do not know
Nature of funding:					
Description of the funding:					
Achievements completed to date:	the rules for the process have been established, in some cases residual data missing	the rules for the process have been established	the rules for the process have been established	the rules for the process have been established	off labels - the rules for the process have been established, but there are no data in relation to biological efficacy

MS: Sweden				
	Initiative 1			
Name of the initiative:	Increase the supply of pesticides for crops grown on small areas and for minor use			
Scope:	Project aimed to find out what is needed to make registrations possible for products used in small amounts			
Description of the Scope:	Financing and coordination of field trials, strategy trials and residue studies and other studies needed for PPP registrations.			
Level of collaboration:	The Swedish Board of Agriculture takes part in a reference group			
Description of level of coll.:	The Swedish Board of Agriculture is funding the project. The Federation of Swedish Farmers is head of the project.			
Date of establishment:	2008			
Involved parties:	Industry, authorities, growers association (Federation of Swedish Farmers)			
Governance:	Field trials for example residue studies, strategy studies, phytotoxic studies both indoor and outdoor use.			
Mission and objectives:	Planning and implementation (performance) of field trials, exchange of data			
External collaborations:	Contacts with other countries, for example UK and the Nordic countries, with initiatives to facilitate registration of pesticides for minor use			
Main activities/tools:	Field trials, applications for off label registrations			
Annual budget:	28.000 EUR			
Nature of funding:	Public funding			
Description of the funding:	Public funding			
Achievements completed to date:	8 off labels allowed			

MS: United Kingdom					
	Initiative 1	Initiative 2	Initiative 3	Initiative 4	
Name of the initiative:	SOLA scheme	"SCEPTRE" and similar research project	Pesticide Availability and Alternatives group	Department for Environment, Food and Rural Affairs (Defra) pesticide research programme	
Scope:	Run by CRD (Chemicals regulation Directorate) and available to grower groups and similar organisations	Government and wide range of agriculture and food industry organisations participate	Government/agricultural industry/other stakeholders	Part of the programme looks for alternatives to "conventional" pesticides, some of which could potentially help protect minor crops	
Description of the Scope:	A scheme to extend the availability of existing approved products to minor crops and minor uses.	Research to improve the availability of pesticides and IPM approaches for fruit and vegetables	Liaison group	There are projects looking at the potential use of simple salts, biopesticides and the use of atheta beetle to control pests on brassicas. Many of these also include IPM approaches.	
Level of collaboration:	High	Medium	High	High	
Description of level of coll.:	Scheme operated by CRD	Research led by Horticultural Development Company (HDC) with funding from Department for Environment, Food and Rural Affairs (DEFRA)	Stakeholder Group	Research programme managed by CRD on behalf of Defra	
Date of establishment:	1980s	2010	2006	Before 2000	

Involved parties:	CRD, agricultural organisations, research bodies	Defra, CRD, agricultural and food organisations	CRD, agricultural organisations, NGO	CRD, Defra, research contractors, stakeholders
Governance:	Scheme run by CRD	Project consortium chaired by Horticultural Development Company (HDC)	Group chaired by CRD	Research programme managed by CRD on behalf of Defra
Mission and objectives:	To improve availability of pesticides for minor uses	To improve availability of pest control measures and IPM approaches relevant to minor uses	To consider the impact of EU policies on pesticide availability for minor uses and discuss means by which impacts can be minimised (consistent with protection of people and the environment)	To find and develop alternatives to "conventional" pesticides
External collaborations:	No	No	Group links with EU minor uses groups through CRD and HDC	Other parts of Defra and some projects involve working with international partners
Main activities/tools:	Part of statutory approvals process.	Project consortium meetings and research reports	Twice yearly meetings, informal liaison	Project consortium meetings and research reports
Annual budget:	Not quantified	£2 million	Not quantified but small	£1million
Nature of funding:	Private funding	Mixed funding	Mixed funding	Public funding
Description of the funding:	Costs of approval process recovered from applicants through fees. Costs of generating data also fall to applicants	Defra contribution to funding £760,000		Part of £4m pesticides research budget funded by Defra
Achievements completed to date:	90-100 SOLAs issued a year	Research at a very early stage (Duration 1 October 2010 - 30 September 2014)	Group's views fed into UK position during negotiation of 1107/2009 particularly on extended data protection for minor uses and zonal authorisation system.	Research is on-going

Norway			
	Initiative 1	Initiative 2	Initiative 3
Name of the initiative:	Funding from Action Plan/Food safety authority	Farmers agreement/SLF	Funding from Action Plan/Ministry of Agriculture
Scope:	support efficacy and residue trials in minor crop	funding for efficacy and residue trials in vegetables	support efficacy and residue trials in minor crops
Description of the Scope:	year: 2003-2009. Trials run by research institute in cooperation with extension groups	2010. Cooperation between extension groups and research instititute	2011. Cooperation between extension groups and research institute
Level of collaboration:	administrator, others are principal researchers	others are principal researchers	others are principal researchers
Description of level of coll.:			
Date of establishment:	2004-2009	2010	2011
Involved parties:	Norwegian Food Safety Authority, Research Institute, extension groups	Extension groups, Research Institute	Extension groups, Research Institute
Governance:	needs of PPP in minor uses given by extension groups/farmers organisations. Research institute makes suggestion for trials and this was approved by Food Safety Authority	Cooperation between extension groups and research institute	Cooperation between extension groups and research institute
Mission and objectives:	planning and conducting field trials to support registration/off-label of PPP in Minor uses	planning and conducting field trials to support registration/off-label of PPP in Minor uses	planning and conducting field trials to support registration/off-label of PPP in Minor

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			uses
External collaborations:	No	No	No
Main activities/tools:	e-mail, phone, meetings	e-mail, phone, meetings	e-mail, phone, meetings
Annual budget:	800.000 NOK (ca 150.000 EUR)	600.000 NOK (ca 100.000 EUR)	1.500.000 NOK (ca 275.000 EUR)
Nature of funding:	Public funding	Public funding	Public funding
Description of the funding:			
Achievements completed to date:	Off-label of PPP	Off-label of PPP	No results yet

ANNEX VI: CASE STUDIES ON THE ECONOMIC DAMAGE CAUSED BY MINOR USES ISSUES

1.1. Economic damage caused by the lack of plant protection products for weed control in the artichoke production in France

1.1.a. Artichoke production in France

In France, artichoke production represents nearly 50,000 tons a year, corresponding with an acreage of about 9,000 ha. The artichoke production has come down from 83,000 tonnes in 1998.

Artichoke is mainly grown in the Brittany region, which produces 80% of the national tonnage.

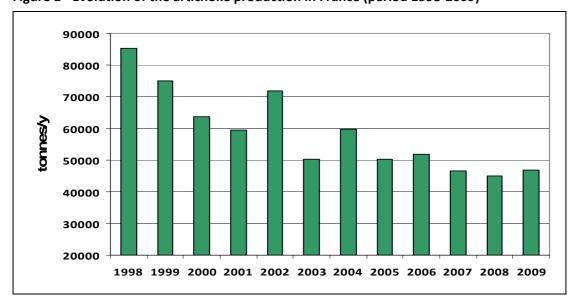


Figure 1 - Evolution of the artichoke production in France (period 1998-2009)

In Europe, the main artichoke producing countries are Italy and Spain, with respectively a yearly production in 2009 of 486, 600 tonnes and 198, 900 tonnes.

1.1.b. Issue: weed control in artichoke production

Currently, the artichoke production is suffering from the lack of approval of an herbicide especially effective against broadleaf weeds. Most of the authorised a.s. are active against grasses which do not constitute a particular problem for the artichoke producers.

Until 2007, the commercial product Patoran, effective against broadleaf weeds was authorised in France. Since then, derogations for emergency use for 120 days allow to overcome the lack of approved products, but with all problems related to the provisional

character of these derogations. For example, in 2009 the product Emir had obtained a derogation of 120 days, but its effectiveness was not entirely satisfactory. A demand for authorisation for a PPP (Defi) containing the a.s. Prosulfocarbe has been submitted in 2010. Without this authorisation, artichoke production is in jeopardy in France.

Prosulfocarbe is not registered for use on the artichoke in any other Member State, but other products are registered Spain and Italy (oxyfluorfen, linuron, pendimethalin and aclonifen).

1.1.c Economic damage caused by protection problems of artichoke crop against weeds

To illustrate the economic damage caused by the lack of plant protection products for weed control in artichoke production in France, we took the specific case study of a farm in the Brittany region. The direct cost and indirect impact of the implementation of an alternative weed control solution, i.e. mechanically weed control accompanied by a manual hoeing, is summarised.

Through extrapolation of the farm scale data, the economic impact at the scale of the entire artichoke production sector in France is estimated.

1.1.d Economic impact at farm level: example of a farm in Brittany

The farm considered in this specific example is situated in the Brittany region. Of the total cultivation area (20 to 30 ha), 10 ha is used for artichoke production. The farm only cultivates vegetable field crops with no usage of irrigation. The artichoke variety planted is Camus, and the planting density is 10,000 plants/ha. The total duration of cultivation of the plants is 3 years, yielding on the average 10 t/ha.

Direct costs

The data provided, allowing to calculate the cost impact of the mechanical and manual weed control practices applied, compared to a standard practice using herbicides, are summarized in the below table. The additional direct cost is estimated at 1,020 €/ha.

		Standard Practice	Without chemical treatments registered for weed control in artichoke production	Evolution
	Planting	30 h	30 h	0 %
Working	Mechanical and manual weeding	10 h	80 h	+ 700 %
time	Obuting	80 h	80 h	0 %
time	Other maintenance	10 h	10 h	0 %
	Harvest for one year	67 h	67 h	0 %
	TOTAL	264 h/ha	334 h/ha	+ 27 %
	Plants at 0,05 €/plant	500 €	500€	0 %
Operational	Fertilisation	450€	450 €	0 %
charges	Chemical herbicides	30 €	0€	- 100 %
(cost of	Other Pesticides	61€	61€	0 %
labour : 15 €/h)	Labour	3 960 €	5 010 €	+ 27 %
	TOTAL	- 5 001 €/ha	- 6 021 €/ha	+ 20 %
	Selling price*	0,56 €/kg	0,56 €/kg	0 %
Products	Price per head (1 year)	0,13 €/head	0,13 €/head	+ 17 %
Froducts	Price per head (2 or 3 years)	0,12 €/head	0,12 €/head	0 %
	Turnover for one year	+ 5 600 €/ha	+ 5 600 €/ha	0 %
Gross margin over the total duration of cultivation, being 3 years		6 199 €/ha	5 179 €/ha	- 16 %
Presentation of the results	Net margin over the total duration of cultivation, being 3 years	2 999 €/ha	1 979 €/ha	- 34 %
	Selling price	0,56 €/kg	?0,66 €/kg	+ 18 %

^{*} The selling price (farm gate) has been considered stable over the 3 years of cultivation. In reality, it fluctuates depending on the market conditions.

Indirect cost

The total absence of the availability of a registered herbicide for the treatment of weeds, and as a consequence the implementation of alternative solutions such as mechanical weed control, has also a number of indirect impacts on the organization of the farming practices and makes the operations more vulnerable to climate conditions. The main direct impacts, for which costs are more difficult to quantify, are:

- Drudgery of manual weeding (not quantifiable);
- Lack of availability of manpower: the mechanical weed and hand weeding control comes at the same time as the manual harvesting of the artichoke heads of the third cultivation year. The workforce, employed with this harvest, is not available to do the weeding of the first year crops. Chemical weed control poses no such problem since it is faster and only mobilizes one person;

^{**}Earnings before interest, taxes, and depreciation

- Farms are more sensitive to climatic risks: The climate strongly influences the success of mechanical weed control which is essential to obtain good yields. In Brittany, such weeding practice can be risky in view of the wet conditions of early spring and the risk of pulling plants;
- Difficulty in management over several years: The mechanical technique used against
 weeds is less effective, especially in wet conditions, resulting in a possible fouling of
 the plots. If not done properly and under good weather conditions, the stock of weed
 seeds in the soil may increase, and therefore the weed population as well, making
 weed control more difficult over time.

1.1.e Economic impact at the level of the entire artichoke production sector in France

At farm level, the lack of registered plant protection products for weed control of artichoke caused a decrease in the net margin of $1,020 \in /$ ha for a culture of artichoke for 3 years. As in France artichokes are grown on 9,000 ha, at the scale of the total artichoke production sector, the direct loss of profit amounts to slightly less than $10,000,000 \in .$

In the long term, farms may not be economically viable because the net margin is too low $(1,979 \ \ \ \)$ ha for 3 years, or $660 \ \ \ \ \)$ ha for one year) to allow profitable production from one year to another. Therefore, some farms may disappear due to the lack of profitability. This will affect employment in production, but also in all the downstream activities (packaging, marketing, shipping ...).

For example, in northern Brittany, 900 growers produce artichoke as principal crop. Most of these producers employ the equivalent of 2.7 FTE (Full Time Equivalent). The absence of chemical herbicides allowed on artichoke therefore threatens the equivalent of 2,430 FTE in this region, without counting jobs indirectly linked to production. Moreover, a majority of producers performs crop rotation associating artichokes to cauliflowers. The difficulty of growing artichoke crops will affect the production of cauliflower. The entire economy of this vegetable producing area could be compromised.

1.2. ECONOMIC DAMAGE CAUSED BY LACK OF PLANT PROTECTION PRODUCTS AGAINST RICE BLAST (PYRICULARIA GRISEA) IN RICE IN ITALY

Rice production in the EU and Italy

Rice can be seen as the most important staple food for the human population and is, after maize, the grain with the highest worldwide production¹². The traditional method for cultivating rice is a water seeded system in which the rice seeds are broadcasted in a flooded field. This method reduces the growth of weeds because most species cannot survive flooding; however some others are specialised for this habitat. Water seeded systems represent 70-75% of the Italian surface. Dry seeded systems on the other hand, ensure best plant establishment conditions in sandy soils and represent 25-30% of Italian rice¹¹.

In 2009, the total surface area planted with rice in the EU was more than 461.000 hectares (ha) producing over 3 million tons of rice. Rice is grown in 8 EU MS and around half of the European production takes place in Italy. It must however be mentioned that the EU rice production is representing less than 3% of the total world rough rice production.

Table 1: Rice Production in the EU 14, 16

<u>2009</u>	Area Harvested (ha)	Yield (tonnes/ha)	Production (tonnes)	% of total cereal production	Classification
Spain	119,300	7.54	899,400	2.00	Major
France	24,200	5.71	138,100	0.25	Minor
Italy	238,500	6.29	1,500,000	5.50	Major

The production of rice in Italy takes place in several rice growing areas such as Sardinia, Veneto, Emilia Romagna but Piedmont and Lombardy represent 93% of the total surface cultivated. These areas are characterised by large amounts of water and a particular climate. A large amount of varieties are being cultivated in those areas being mainly *Japonica* varieties, essential to both risotto and paella.

Control of Rice Blast in Italian rice production

Protection of Rice crops is more complicated than protection of other crops due to the sector's specific characteristics like small leaf surface areas and flooded cultivation. Without protection potential losses due to pests can amount 60 to 80% yield losses. The actual average yield losses are estimated at around 20-30%, due the fact that around 50% of the crops can actually be correctly protected against pest diseases.

The Rice Blast fungus *Pyricularia Grisea* can be seen as the most destructive pathogen of rice worldwide as the disease is extremely difficult to control and can cause complete yield losses. Chemicals are somewhat effective against Rice Blast and a number of PPP manufacturers market commercial pesticides targeted at the diseases. Breeding work has resulted in varieties that proved to be resistant for 2 or 3 years. Neither ways of protection provide however a total effective approach. This is mainly due to the pathogen's ability to rapidly adapt.

Producers of rice are therefore bound to use chemicals to protect their crops from Rice Blast. The most common used solutions is Azoxystrobin (trademark: Amistar) and Flutriafol (trademark: Impact 250 SC). Fungicides represent about 6-50% of the total crop protection costs.

<u>Issues regarding the protection of rice crops against Rice blast</u>

To preserve the availability of clean and environmentally safe water, contamination of surface and groundwater by all agricultural and industrial chemicals must be prevented and is therefore on the European level regulated in the form of Directive 91/414/EEC. Annex I of this Directive (a list of active substances that are authorized for incorporation of Plant Protection Products) is under constant revision which has led to an estimated removal of 74% of all pesticides¹².

The placing on the market of new active substances and the authorisation of accepted active substances for a certain use, have become highly expensive:

- Authorisation of a new active substance takes over 9 years and costs an estimated €184 million;
- First product authorisation of a PPP which includes 2-3 uses on the label costs an estimated €3million;
- Authorisation for each new crop use costs between €140.000 and €250.000. 13

The only (legal) available active substances are AZOXYSTROBIN and FLUTRIAFOL. AZOXYSTROBIN is a fungicide whose application reduces disease development and inoculation and increases grain and milling yields. FLUTRIAFOL is also a preventive PPP but can also be used as curative solution. The most effective pesticide to control Rice Blast however is TRICYCLAZOLE; which has the status of 'not included' in the EU approval system.

Last year, Italian authorities authorised TRICYCLAZOLE (trademark: Beam) through emergency use for a period of 120 days (Article 53 of Regulation 1107/2009). Ente Nazionale Risi and other farmer associations requested for 2011 a new derogation period of 120 days (starting from mid of April) to the Italian competent Authority (Ministry of Health).

It is important to notice that Rice blast is a disease in which resistance to pesticides easily evolves and that the present pesticides in use belong to classes at considerable risk.

Minimizing resistance risks demands therefore a sound strategy involving all possible non-chemical methods in combination with at least 3 or 4 different fungicides.

Table 2 – Surface protected and unprotected ^{5, 6}

<u>2010</u>	Area Not-Treated	Area treated with TRICYCLAZOLE	Area treated with AZOXYSTROBIN	Area treated with TRICYCLAZOLE and AZOXYSTROBIN	Total
Surface (ha)	56,691	88,002	11,211	72,514	228,419
%	25%	39%	5%	32%	100%

Economic damage caused by protection problems of rice crops against Rice Blast

The crop value of the Italian rice is relatively high.

Table 3 - Produced amount and value of Italian Rice 5, 14, 16

<u>2010</u>	per ha	Total
Production (tonnes)	6.1	1.396.000
Value (EUR)	1,823	416.000.000
Crop Protection Costs (EUR)	68	15.676.000

Direct effects - Lower yield and loss of value

In 2010, Italian farmers were able to protect their crops against Rice Blast (see table 3). This protection could however only take place due to emergency derogation from the Italian competent authorities. This exemption has (to date) not been granted yet for 2011.

Without any protection against Rice Blast at all, a reduction of production and value of an estimated 29.8% can take place.

Table 4 - Reduction of value and produced amounts without protection 3, 5, 6, 10

<u>2010</u>		rop protection t rice blast		equate crop ainst rice blast	
	per ha	Total	per ha	Total	Reduction
Production (tonnes)	6.1	1,396,000	4.3	979,700	-29.8 %
Value (EUR)	1,823	416,000,000	1,276	292,000,000	-29.8 %
Costs (EUR)	68	15,676,000	0	0	

This reduction of total produced quantities and value per area of cultivated rice leads to a total loss of 125,000,000 EUR.

They will spray with the authorised products, even if they don't provide sufficient efficacy, until they have completely lost efficacy everywhere.....

Table 5 – Total loss of value and produced amount without protection 3, 5, 6, 10

<u>2010</u>	Loss per ha	Total Loss
Production (tonnes)	-1.8	-416,000
Value (EUR)	-546	-125,000,000
Costs (EUR)	68.6	15,676,000

Indirect effects

Although a not-controlled situation of Rice Blast has no direct effect on human health, there are a certain amount of indirect effects caused by a lack of efficient products to control Rice Blast in rice production in Italy like contractual problems of farmers towards other food-chain-processors and a loss of quality within the rice-quality-chain in general.

Also important to note is the fact that AZOXYSTROBIN, the momentary only real legal available solution, is a strobilurin which can lead to problems regarding the development of resistance to this chemical class like encountered in other crops. Finally, due to the fact that no Rice-Blast-resistant cultivars and only few varieties with genes to control blast have been developed so far⁶; national producers consider that without efficient crop protection solutions, rice production in Italy will no longer be possible within a few years.

NB tricyclazole is an azole and classified as risk-prone.

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- 13. ECPA.

<u>Databases:</u>

- 14. http://faostat.fao.org;
- 15. http://www.knowledgebank.irri.org/rice.htm;
- 16. http://epp.eurostat.ec.europa.eu;

17. http://ec.europa.eu/sanco_pesticides/public/index.cfm.

Legislation:

18. Directive 91/414/EEC.

1.3 ECONOMIC DAMAGE CAUSED BY THE LACK OF PLANT PROTECTION PRODUCTS AGAINST ROOT MAGGOTS IN RADISH PRODUCTION IN FRANCE

1. Radish production in France

France is the second largest European producer, behind Germany, of radish for human consumption. Each year, 48 000 tons of radish are produced, on an acreage of about 2 700 ha. The department Loire-Atlantique is the most important contributor (~1100 ha). In 2006, radish production represented a turnover of almost 80 M€ for this department alone²⁹.

2. Issue: protection of the radish crop against root maggots

On radish, two types of vegetable flies can cause damage on the roots, one of which, root maggots, is largely present. Radishes need protection against the fly during their entire cropping cycle (which can take up to 120 days), with the most important treatment to be done at the beginning³⁰. Production of radishes without protection against root maggots is inconceivable if one wants to avoid poor radish quality and disruption of the crop ³¹.

Insecticide treatment is the most effective solution to protect the crops against the pest. The alternative solution, physical protection of the crop using a net, has been proven inefficient and costly. But, since 2007, no plant protection product is registered in France for use against root maggots in radish production. Derogations for emergency use for 120 days have been granted for seed and soil treatment, but these treatments do not guarantee an efficient solution and keep the producers in a climate of uncertainty about the future.

There is thus an urgent need in France to develop/register new PPPs authorised for use on radish. Effective a.s. are included in Annex I and are currently used in other European countries.

Food Chain Evaluation Consortium

²⁹ Personal communication from forumphyto (www.forumphyto.fr)

Ecophyto, le bulletin de liaison No4-2008 : http://www.forumphyto.fr/images/pdf/bulletin-liaison/forumphytobl0804.doc

³¹ Etude Réglementation sur les pesticides : Impasses techniques & distorsions de concurrence, 2010, Note d'étude réalisée par le Collectif Sauvons les Fruits et Légumes : http://www.forumphyto.fr/images/pdf/DocusPublics/2010/100428etudecsfl2010.pdf

3. Economic damages

3.1. Economic impact at farm level: example of a farm in the Loire-Atlantique (France)

To illustrate the economic consequences for radish growers caused by the lack of a viable crop protection solution, we took the example of a farm in the Loire-Atlantique department. To guarantee good quality produce, the farm manually sorts the radishes at harvest.

Direct costs

A detailed calculation comparing the cost of the manual operations involved in sorting the plants at harvest to a standard pesticide treatment has been made and the summary is presented is the below table. The additional labour cost related to the manual operations substantially reduces the farm's productivity. The reduction of the gross margins is calculated at 6,905 €/ha.

_		Standard practice	Without chemical treatments registered against seed flies (sorting at harvest)	Evolution
Working time	Harvest and sorting	448 h	917 h	+ 105 %
	TOTAL	538 h/ha	1 007 h/ha	+ 87 %
Total of o	perational charges	11 608 €/ha	18 513 €/ha	+ 59 %
Gr	oss margins	15 893 €/ha	8 988 €/ha	- 43 %
Presentation	EBITDA*	8 143 €/ha	1 238 €/ha	- 85 %
of the results	Selling price	0.50 €/bunch	0.63 €/bu,ch	+ 25 %

^{*}Earnings Before Interest, Taxes, Depreciation and Amortisation

Indirect cost

The absence of an efficient solution to protect radish from the damage of insects also has a number of indirect impacts. These impacts, which cannot be easily quantified, are related to the increased importance of manual labour involved during harvest. They can be summarized as follows:

- Drudgery of the manual harvesting practice.
- Problem of sorting when harvesting is done mechanically: machinery involved in harvesting the radishes is not suitable for sorting.

Availability of labour and profitability of working hours: the labour is used on a
permanent basis (no seasonality), so if the employees are involved in harvesting, less
time will be available for other operations. Moreover, it will be difficult or impossible to
find the additional labour.

3.2. Economic impact at the level of the entire radish production sector in France

As demonstrated in the example, the additional cost caused to replace a chemical treatment by a manual operation (manual sorting at harvest) is calculated at 6,905 €/ha. At the sector level, the lack of availability of a registered PPP against vegetable flies would thus lead to a direct loss of 18 600 000 €. This loss in profitability seriously impacts the viability of the radish production sector in France and puts at the stake the employment directly and indirectly involved in this sector. To give an indication, in Loire-Atlantique this sector has significant weight representing 2 500 FTEs (Full Time Equivalent).

The increase in staff cost due to manual sorting may cause a non-negligible increase of the selling price (estimated at € 0.20 / bunch). In addition, manual sorting is never perfect. Some bunches of radishes of poor quality cannot be detected. A decline in quality is detrimental for the product image in the eyes of the consumer. Taken this into consideration, the risk of distortion of competition in the French radish production sector is real vis-à-vis other European countries where pressure of the vegetable flies is less.

4 ANNEX VII: GEOGRAPHIC DISTRIBUTION OF MAJOR AND MINOR CROPS IN THE EU 27 MS (IN DETAIL)

This annex presents the detailed statistics regarding cropping in EU 27 MS based on Eurostat data from 2007.

For each crop national grown areas and production volumes have been considered.

Data are classified by:

- ✓ Crops: The crop classification list is taken from the Annex 1 of the Regulation (EC) No 396/2005
- ✓ Member States:
 - Distribution by authorisation zone with³²:
 - 1. <u>Northern zone</u> 6 MS: Denmark, Estonia, Finland, Latvia, Lithuania, Sweden
 - Central zone 13 MS: Austria, Belgium, Czech Republic, Germany, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United-Kingdom
 - 3. <u>Southern zone</u> 8: Bulgaria, Cyprus, France, Greece, Italy, Malta, Portugal, Spain.
 - Distribution by *Technical working group (TWG)*³³:
 - Northern Europe group 17 MS: Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, Germany, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Netherlands, Poland, Slovakia, Sweden, United-Kingdom.
 - 2. <u>Southern Europe group</u> -10 MS: Bulgaria, Cyprus, France, Greece, Italy, Malta, Portugal, Romania, Slovenia, Spain.

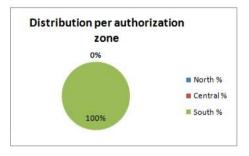
³² The distribution in 3 zones has been established in Regulation (EC) No 1107/2009.

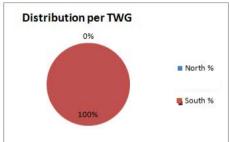
³³ Distribution in the « minor uses » European working group

CITRUS

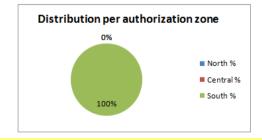
Surface (1000ha)

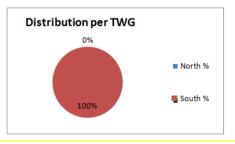
	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
CITRUS	0.00	0.00	0.00	0.00	5.81	0.00	206.62	0.00	0.00	1.83	70.04	0.00	0.00	168.91	0.00	0.00	0.00	0.12	0.00	0.00	26.37	0.00	0.00	0.00	0.00	0.00	0.00	479.70
Oranges					2.010		153.700			0.050	64.400			105.060				0.090			20.480							345.790
Mandarins					1.340						0.730			10.330							4.870							17.270
Clémentins					0.890					1.540	2.330			22.880				0.003										27.643
Lemons					0.960		52.920				2.270			30.340				0.030			1.000							87.520
Grapefruits					0.610				j.	0.240	0.310			0.300				0.000			0.020							1.480





	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
CITRUS	0.000	0.000	0.000	0.000	129.160	0.000	3191.100	0.000	0.00	24.45	1080.90	0.00	0.00	3488.89	0.00	0.00	0.00	1.97	0.00	0.00	282.72	0.00	0.00	0.00	0.00	0.00	0.00	8199.19
Oranges					27.030		2294.600			0.650	962.000			2261.400				1.340			209.990							5757.010
Mandarins					21.230						11.200			183.510							60.820							276.760
Clémentins					42.420					19.360	61.500			433.530				0.080										556.890
Lemons					18.430		896.500				38.500			603.390				0.540			11.700							1569.060
Grapefruits					20.050					4.440	7.700			7.060				0.010			0.210							39.470

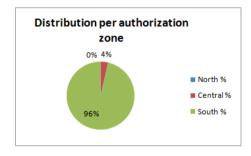


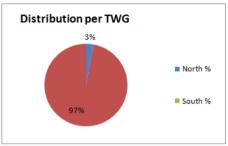


Tree nuts

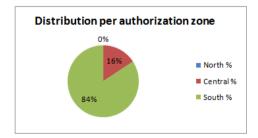
Surface (1000ha)

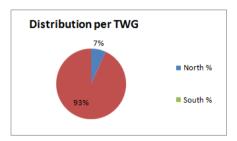
	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Tree nuts	0.00	0.07	0.00	10.38	5.42	0.01	0.00	0.00	0.00	27.74	79.93	5.50	0.00	152.19	0.00	0.00	0.08	0.00	0.00	4.97	71.98	0.00	2.10	0.00	0.03	0.10	0.00	360.50
Walnut		0.07		8.53	0.30					15.97	4.65	4.40					0.08			2.33	3.17	0.00	2.06		0.02	0.06		41.64
Hazelnut				0.26	0.09	0.01				2.99	2.49	0.12		68.87						2.64	0.59		0.01			0.03		78.10
Almond				1.59	5.03					1.49	64.91	0.37		83.32							38.05							194.76
Chesnut				0.00						7.29	7.88	0.61									30.17		0.03		0.01	0.01		46.00





	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Tree nuts	0.00	17.03	0.00	2.90	1.06	0.01	0.00	0.00	0.00	49.44	82.90	4.14	0.00	206.22	0.00	0.00	0.14	0.00	0.00	8.90	40.74	0.13	38.25	0.00	0.00	2.80	0.00	454.66
Walnut		17.03		2.64	0.27					33.19	21.50	3.34					0.14			5.84	4.17	0.13	38.17		0.00	2.69		129.11
Hazelnut				0.02	0.04	0.01				4.45	2.10	0.09		87.88						3.06	0.38		0.01			0.10		98.14
Almond				0.24	0.75					2.28	47.00	0.32		118.34							13.96							182.89
Chesnut				0.00						9.52	12.30	0.39									22.23		0.07		0.00	0.01		44.52

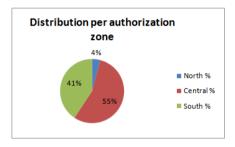


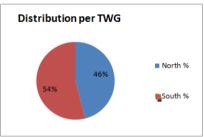


Pome fruits

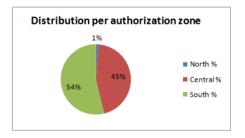
Surface (1000ha)

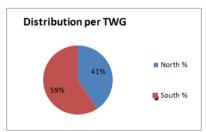
	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Pome fruits	33.24	6.47	16.65	5.81	1.41	2.08	91.86	1.43	0.65	67.07	17.54	45.39	0.00	104.44	9.60	17.30	1.15	0.01	16.43	182.22	34.01	9.38	102.43	16.71	3.35	3.38	1.64	791.66
Apple	31.15	6.06	8.87	5.39	1.27	1.62	43.49	1.43	0.65	57.72	13.95	42.02		61.70	8.52	16.25	1.02	0.00	9.74	169.65	20.85	9.08	95.64	15.01	3.20	3.10	1.44	628.82
Pear	2.09	0.41	7.78	0.33	0.13	0.46	48.37			9.15	3.59	3.23		42.66	0.83	0.90	0.13	0.01	6.69	12.57	12.88	0.30	6.07	1.70	0.15	0.28	0.20	160.91
Quince				0.09	0.01					0.20		0.14		0.08	0.25	0.15					0.28		0.72					1.92





	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Pome fruits	888.92	5 7 0.95	546.36	26.97	11.90	45.93	1421.90	4.29	3.61	2474.54	295.50	530.24	0.00	3117.99	39.78	65.90	4.92	0.29	554.00	2134.26	381.83	137.38	693.81	237.58	36.63	114.41	19.37	14359.26
Apple	852.60	452.61	317.21	26.13	10.78	35.31	769.90	4.29	3.61	2246.35	247.00	510.36		2192.00	37.52	64.02	3.82	0.07	359.00	2074.95	251.47	134.09	611.20	213.73	36.26	106.20	17.68	11578.16
Pear	36.32	118.34	229.15	0.75	1.11	10.62	652.00			227.99	48.50	19.74		925.91	2.01	1.73	1.10	0.22	195.00	59.31	130.08	3.29	81.89	23.85	0.37	8.21	1.69	2779.18
Quince				0.09	0.01					0.20		0.14		0.08	0.25	0.15					0.28		0.72					1.92

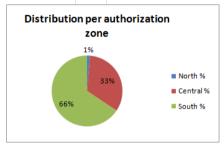


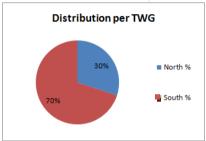


Stone fruits

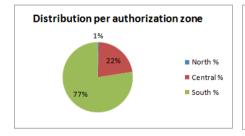
Surface (1000ha)

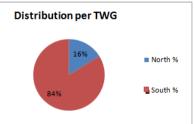
	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Stone fruits	9.63	0.60	1.22	20.88	0.76	1.78	35.78	0.01	0.00	34.74	19.02	24.60	0.00	81.51	0.90	1.23	0.12	0.01	0.61	45.45	6.85	4.30	12.90	0.38	0.44	0.20	0.14	304.06
Apricots	0.05	0.46		7.34	0.23		15.78			14.86	6.70	5.82		19.27				0.01		1.47	0.57	1.70	4.15		0.23	0.03		78.67
Cherry																												
(including	9.58	0.14	1.22	13.54	0.24	1.78	20.00	0.01		12.13	6.70	18.78		29.30	0.90	1.23	0.12		0.61	43.98	6.28	2.60	8.70	0.38	0.21	0.17	0.14	178.74
Nectarines					0.29					7.75	5.62			32.94				0.00					0.05					46.65
Peaches	0.10	0.24		5.99	0.43		107.98			10.88	61.37	8.24		62.00				0.07		3.29	6.19	1.26	2.64		0.68	0.64		272.00
Peaches & neo	0.10	0.24		5.99	0.71		107.98			18.63	66.99	8.24		94.93				0.08		3.29	6.19	1.26	2.69		0.68	0.64		318.64
Plums	4.99	0.35	0.09	15.06	0.31	0.09	26.92	0.05		19.00	0.42	9.01		14.46	0.98	0.96	0.80	0.04	0.30	20.82	1.92	0.77	93.87	1.05	0.55	0.04	0.09	212.94





	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Stone fruits	51.39	43.31	6.80	32.02	3.61	9.04	229.10	0.00	0.00	443.83	177.00	79.90	0.00	951.82	1.86	0.76	0.16	0.17	0.00	180.52	20.32	12.29	148.52	1.04	0.53	3.92	0.14	2398.05
Apricots	0.22	13.09		10.62	1.73		136.60			181.61	58.00	25.66		232.88				0.04		3.16	4.71	2.37	43.15		0.15	0.37		714.36
Cherry																												
(including	51.17	30.22	6.80	21.40	0.59	9.04	92.50			69.02	31.00	54.24		101.30	1.86	0.76	0.16			177.36	15.61	9.92	104.68	1.04	0.38	3.55	0.14	782.74
Nectarines					1.29					193.20	88.00			617.64				0.13					0.69					900.95
Peaches	0.76	8.23		14.83	2.74		1198.30			237.42	681.00	48.39		1075.52				0.75		9.59	49.04	2.91	28.03		2.48	13.34		3373.33
Peaches & nec	0.76	8.23		14.83	2.74		1198.30			430.62	769.00	48.39		1693.15				0.88		9.59	49.04	2.91	28.72		2.48	13.34		4272.98
Plums	44.51	61.57	0.40	17.95	0.83	0.31	190.80	0.04		214.34	3.00	35.96		185.40	2.44	1.35	0.53	0.31		91.39	16.20	4.46	572.86	14.97	1.33	4.33	0.31	1465.59

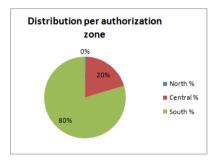


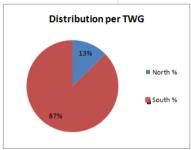


Small fruits and berries

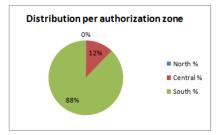
Surface (1000ha)

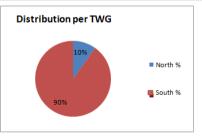
	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Small fruits																												
and berries	112.32	46.80	1.14	128.00	11.96	0.70	37.69	0.46	3.53	85 7.7 6	84.90	94.06	0.06	794.73	0.70	2.97	1.31	0.02	1.67	55.14	222.52	0.49	190.02	3.78	13.10	16.80	2.40	2685.03
Table grapes				9.14	0.78		30.09			7.92	12.40	2.17		73.91							6.02		11.17			0.27		153.87
Wine grapes	98.88	45.73		117.71	11.08					846.00	72.50	91.22		714.99			1.30		0.07		216.50		176.63		12.86	16.43		2421.90
Strawberries	13.44	1.07	1.14	1.15	0.10	0.70	7.60	0.46	3.53	3.84		0.67	0.06	5.83	0.70	2.97	0.01	0.02	1.60	55.14		0.49	2.22	3.78	0.24	0.10	2.40	109.26
Raspberries	0.87	0.15	0.03	2.02		0.04		0.17	0.47	1.31		1.72	0.03	0.19	0.18	0.69			0.04	17.76		0.03		1.43	0.06		0.16	27.35
Blackcurrant	8.77	0.21		0.06		1.60		0.26	2.11	2.63		1.87			0.64	5.53			0.53	36.50		0.43	0.01	2.97	0.54		0.51	65.17
Redcurrant	30.40	0.07	0.06			0.35		0.13	0.21	0.37		2.16			0.25	0.59			0.27	10.61		1.26		0.00	0.28			47.01
Black +red curra	39.17	0.28	0.07	0.07		1.94		0.39	2.33	3.00		4.02	0.01		0.89	6.11			0.80	47.11		1.69	0.01	2.97	0.82		0.51	112.19
Gooseberries	10.95	0.00	0.01			0.02		0.00	0.03			0.45			0.09	0.18				3.13		0.01	0.06	0.00	0.03			14.96





	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
all fruits and ber	1376.50	318.07	42.00	272.75	51.57	5. 7 8	6374.80	1.16	10.05	6841.60	0.00	539.69	0.00	8700.34	4.01	10.18	18.80	0.38	39.00	184.63	989.20	1.55	477.47	0.06	54.68	123.05	12.14	26449.46
Table grapes				20.65	13.85		309.20			56.58		9.43		1661.23							49.03		43.75		0.52			2164.24
Wine grapes	1230.00	301.87		245.54	35.87		5757.60			6727.38		526.33		6892.34			18.76				940.17		415.70		53.58	120.87		23266.01
Strawberries	146.50	16.20	42.00	6.56	1.85	5.78	308.00	1.16	10.05	57.64		3.93		146.77	4.01	10.18	0.04	0.38	39.00	184.63		1.55	18.02	0.06	0.58	2.18	12.14	1019.21
Raspberries	12.48	1.23	0.32	3.90		0.06		0.22	0.61	6.14		6.72		1.42	0.46	0.47				65.48		0.05		11.30	0.03		0.25	111.14
Blackcurrant	23.82	6.57				9.33		0.18	1.78	10.83		4.08			2.80	6.46				138.93		0.21	0.02	20.19	0.16		0.49	225.85
Redcurrant	80.84	12.88				1.92		0.10	0.27	2.15		8.01			2.39	0.73				47.88		2.51			0.12			159.80
Black +red curra	104.66	19.44				11.25		0.28	2.06	12.98		12.10			5.19	7.19				186.81		2.72	0.02	20.19	0.28		0.49	385.66
Gooseberries	66.62	1.66	0.10			0.12			0.03			1.31		0.02	0.83	0.21				16.72		0.09			0.02			87.73

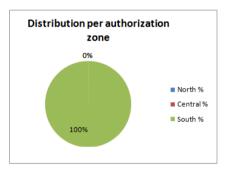


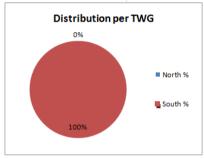


Miscellaneous fruits

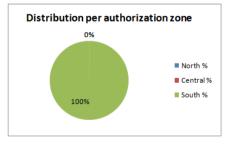
Surface (1000ha)

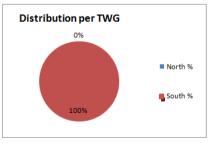
	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Miscellaneous																												
fruits	0.00	0.00	0.00	0.05	0.55	0.00	0.00	0.00	0.00	4.88	0.00	0.00	0.00	27.20	0.00	0.00	0.00	0.06	0.00	0.00	8.34	0.00	0.00	0.00	0.00	0.02	0.00	41.10
Avocados					0.10					0.01																		0.11
Figs					0.43					0.47				3.52				0.06			7.13					0.01		11.62
Kiwis				0.05	0.02					4.40				23.68							1.21					0.01		29.37
Total olives					14.83		2672.80			18.34				1168.62				0.12			376.52					0.78		4252.01





	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Miscellaneous																												
fruits	0.00	0.00	0.00	0.41	5.28	0.00	0.00	0.00	0.00	80.21	0.00	0.00	0.00	435.14	0.00	0.00	0.00	0.39	0.00	0.00	32.79	0.00	0.00	0.00	0.00	0.27	0.00	554.49
Avocados					1.16					0.07																		1.23
Figs				0.01	3.96					3.32				20.09				0.39			21.50					0.03		49.30
Kiwis				0.40	0.16					76.82				415.05							11.29					0.24		503.96
Total olives					16.22		3919.80			17.97				3774.81				0.17			211.87					2.91		7943.75

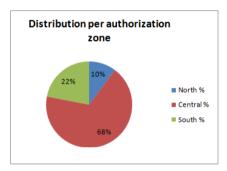


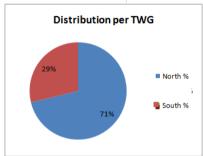


Root and tuber vegetables

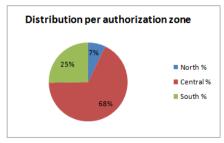
Surface (1000ha)

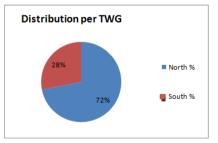
	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Root and tuber																												
vegetables	12.46	1.82	4.84	0.36	0.10	1.80	0.00	0.58	2.19	18.94	2.12	2.58	0.71	13.91	4.57	5.26	0.01	0.04	9.50	54.06	0.00	1.00	10.77	11.15	0.50	0.24	2.02	161.53
Beetroot	1.27	0.18		0.02	0.04	0.20		0.24	0.42	2.58	0.97	0.21	0.02	0.46	1.76	2.41		0.01	0.31	14.92			0.16	1.64	0.04	0.12	0.29	28.27
Carrots	9.86	1.37	3.99	0.34	0.06	1.44		0.34	1.73	14.67	1.15	2.37	0.69	13.45	2.81	2.83	0.01	0.03	7.98	33.22		0.71	10.38	9.51	0.44	0.12	1.73	121.23
Celeriac	1.33	0.27	0.85			0.16			0.04	1.69						0.02			1.21	5.92		0.29	0.23		0.02			12.03
Radishes	3.11	0.32	0.02	0.02	0.05					2.90	0.20	0.30		1.11		0.06			0.13				0.06		0.06			8.34
Salsify			0.43							0.81									0.87						0.33			2.44
Turnips			0.37	0.01					0.51	2.86		1.85	0.49	2.46		0.02				·				3.06				11.63





	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Root and tuber																												
vegetables	620.95	99.78	281.90	4.37	3.79	72.23	0.00	14.28	81.88	825.4 5	<i>59.70</i>	84.26	0.00	611.60	58.34	91.49	0.28	1.29	562.00	1399.58	0.00	31.32	157.78	769.46	12.56	5. 7 6	108.93	5958.98
Beetroot	54.10	8.67		0.19	1.90	6.39		4.32	14.01	114.10	23.20	4.40		9.16	23.61	40.77		0.25	22.00	356.04			2.38	50.96	1.02	3.01	12.70	753.18
Carrots	516.33	79.45	239.40	4.18	1.89	62.82		9.96	67.03	659.31	36.50	79.86		602.44	34.73	50.37	0.28	1.04	487.00	929.01		25.18	152.89	718.50	11.28	2.75	96.23	4868.43
Celeriac	50.52	11.66	42.50			3.02			0.84	52.04						0.35			53.00	114.53		6.14	2.51		0.26			337.37
Radishes	98.38	7.16	0.30	0.18	0.58					43.40	2.30	4.20		26.40		0.14		0.02	28.00				0.55		0.55			212.16
Salsify			10.75							23.78									17.00						3.56			55.09
Turnips			14.60	0.15				, and the second	141.94	67.64		30.21		53.49		0.10							, and the second	114.05				422.18

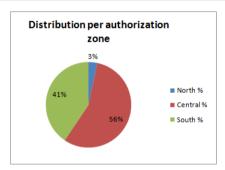


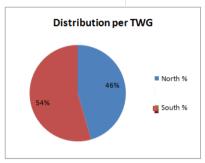


Bulbs

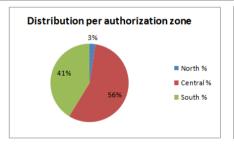
Surface (1000ha)

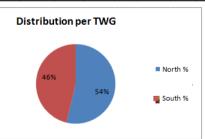
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Bulbs	7.91	2.39	1.00	2.15	0.18	1.47	40.60	0.06	0.95	14.58	10.95	4.20	0.22	15.44	1.96	1.55	0.00	0.30	22.52	36.03	0.00	1.89	28.53	10.63	0.77	0.33	0.90	207.51
Garlic		0.02		0.62			18.00	0.02	0.02	3.38	1.85	1.30		3.16	0.23	0.27		0.07		1.37		0.05	8.29		0.05	0.04		38.74
Onions	7.91	2.37	1.00	1.53	0.18	1.47	22.60	0.04	0.93	8.91	9.10	2.90	0.15	12.28	1.73	1.28	0.00	0.23	22.52	34.66		1.84	20.24	10.63	0.72	0.29	0.90	166.41
Shallots										2.29			0.07															2.36





		DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
	Bulbs	364.51	103.22	53.02	18.00	6.98	53.01	1258.80	0.29	21.23	420.38	214.20	101.87	0.00	388.53	16.44	16.65	0.13	7.00	1060.00	729.06	0.00	47.76	273.05	404.49	12.69	7.45	28.61	5607.37
0	Garlic		0.23		3.70			145.30	0.09	0.03	26.13	12.20	9.68		29.60	0.54	1.50		0.51		14.99		0.17	47.01		0.16	0.24		292.08
(Onions	364.51	102.99	53.02	14.30	6.98	53.01	1113.50	0.20	21.20	347.67	202.00	92.19		358.93	15.90	15.15	0.13	6.49	1060.00	714.07		47.59	226.04	404.49	12.53	7.21	28.61	5268.71
5	hallots										46.58																		46.58

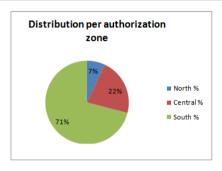


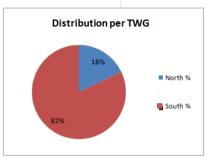


Fruiting vegetables

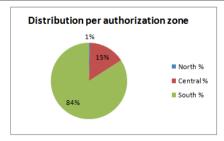
Surface (1000ha)

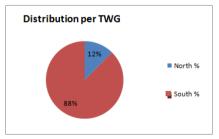
	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Fruiting																												
vegetables	0.35	0.35	0.66	10.99	0.44	23.54	71.90	0.01	0.72	9.20	7.36	3.59	13.82	150.93	0.10	0.25	0.00	0.08	2.70	14.77	0.00	0.48	38.78	0.25	1.75	0.36	0.05	353.43
Tomatoes	0.32	0.18	0.55	5.39	0.38	0.04	71.90		0.12	4.98		3.56	0.03	138.76	0.10	0.25		0.08	1.40	13.19		0.48	22.59	0.19	1.15	0.16	0.05	265.85
Peppers & chilli																												
peppers	0.03	0.16	0.10	5.13	0.00	23.50		0.01	0.60	3.79	4.35		13.79						1.28	1.49			9.31	0.06	0.60	0.20		64.40
Aubergines		0.01	0.01	0.47	0.06					0.43	3.01	0.03		12.17					0.02	0.09			6.88					23.18





	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Fruiting																												
vegetables	57.46	45.04	253.21	209.61	36.93	19.70	5693.10	1.22	38.99	831.94	157.40	303.82	0.00	7888.80	0.31	1.49	0.15	13.40	1046.00	251.92	0.00	15.01	595.34	95.58	41.17	16.86	17.28	17631.73
Tomatoes	57.46	35.32	229.61	126.46	34.11	19.70	4651.00	1.22	38.00	790.05		188.42		7187.01	0.31	1.49	0.15	12.68	660.00	232.38		15.01	379.82	79.81	32.44	6.63	17.28	14796.36
Peppers & chilli																												
peppers		9.45	19.40	72.16			1042.10		0.99	23.66	80.30	114.72		362.99					345.00	19.54			117.62	15.77	8.73	10.23		2242.66
Aubergines		0.27	4.20	10.99	2.82					18.23	77.10	0.68		338.80				0.72	41.00				97.90					592.71

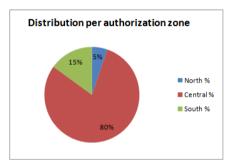


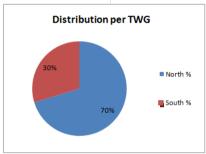


Cucurbits with edible peel

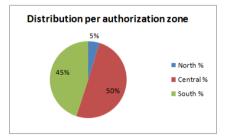
Surface (1000ha)

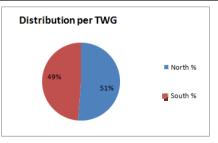
	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Cucurbits																												
with edible																												
peel	4.29	0.53	0.54	0.95	0.24	0.14	0.00	0.07	0.45	3.52	5.98	0.98	0.01	19.07	1.28	0.65	0.00	0.13	0.80	20.57	0.00	0.44	5.35	0.12	0.51	0.13	0.29	35.92
Cucumbers	0.60	0.16	0.07	0.61	0.24	0.04		0.07	0.08	0.59	1.95	0.98	0.01	1.98	1.07	0.56		0.01	0.63	20.57		0.12	5.16	0.12	0.11	0.13	0.06	5.04
Gherkins	2.67	0.27		0.17		0.08			0.33	0.14	0.12			0.35								0.32			0.36		0.23	5.04
Courgettes	1.02	0.10	0.47	0.17		0.02			0.04	2.79	3.91			16.74	0.21	0.09		0.12	0.17				0.19		0.04			26.08





	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Cucurbits																												
with edible	219.51	42.07	52.66	47.96	16.63	18.99	0.00	5.46	45.51	255.53	240.25	70.91	0.00	565.55	8.19	5.02	0.02	3.86	452.00	257.46	0.00	10.65	91.73	54.49	10.7 5	3.71	35.79	2514.70
Cucumbers	75.59	25.29	22.86	42.13	16.63	16.46		5.46	32.37	132.88	157.50	70.91		72.57	5.59	4.21		0.70	440.00	257.46		4.54	88.93	54.49	5.15	3.71	24.29	1559.72
Gherkins	143.92	12.90		2.62		2.21			12.04	1.73	2.25			4.93								6.11			4.44		11.50	204.65
Courgettes		3.88	29.80	3.21		0.32			1.10	120.92	80.50			488.05	2.60	0.81	0.02	3.16	12.00				2.80		1.16			750.33

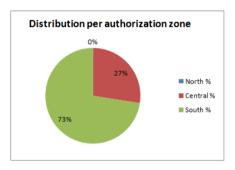


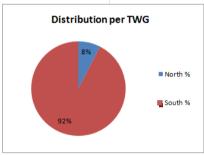


Cucurbits with inedible peel

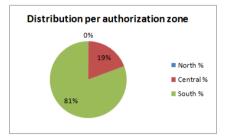
Surface (1000ha)

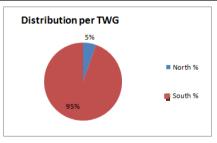
	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Cucurbits																												
with inedible																												
peel	1.24	0.24	0.10	7.29	0.78	0.00	54.30	0.00	0.04	16.79	24.41	11.80	0.02	42.01	0.17	0.02	0.01	0.44	0.00	0.00	0.00	0.00	40.04	0.00	1.55	0.00	0.01	201.26
Melons		0.01		2.27	0.24		38.50			14.89	8.41	1.05		27.82				0.23					4.49		0.14		0.01	98.06
Squashes	1.24	0.23	0.10	0.22					0.04	1.73		0.58	0.02		0.17	0.02	0.01	0.08					2.85		0.83			8.12
Watermelons				4.80	0.54		15.80			0.17	16.00	10.17		14.19				0.13					32.70		0.58			95.08





	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Cucurbits																												
with inedible	0.00	11.30	4.50	101.03	46.09	0.00	1841.40	0.00	1.09	348.28	808.50	243.32	0.00	1130.96	2.42	0.31	0.22	11.77	0.00	0.00	0.00	0.00	740.98	0.00	22.07	0.00	0.08	5314.32
Melons		0.50		22.31	10.14		1118.30			294.87	166.50	15.11		611.50				5.16					63.43		1.61		0.08	2309.51
Squashes		10.80	4.50	3.71					1.09	46.09		14.02			2.42	0.31	0.22	1.65					49.22		11.06			145.09
Watermelons				75.01	35.95		723.10			7.32	642.00	214.19		519.46				4.96					628.33		9.40			2859.72

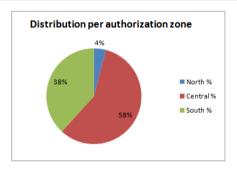


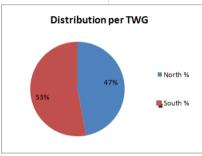


Brassica vegetables

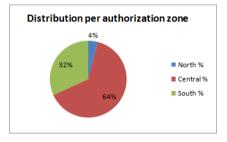
Surface (1000ha)

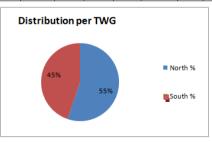
	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Brassica																												
vegetables	14.10	1.08	7.46	3.52	0.23	1.06	25.40	0.55	1.22	29.54	11.76	5.58	2.13	32.04	3.26	3.96	0.01	0.48	8.68	51.11	0.00	1.63	38.7 5	22.71	1.06	0.80	0.93	269.05
Cauliflowers	7.18	0.25	4.46	0.16	0.09	0.62	25.40	0.07	0.62	27.31	3.89	1.64	0.93	27.18	0.13	0.25		0.38	3.95	14.06		0.49	1.80	18.65	0.25	0.10	0.56	140.42
Brussels	0.81	0.01	2.70	0.06		0.07			0.02	1.13		0.02	0.28	0.33		0.01		0.00	3.22	2.08		0.14		4.06				14.94
Head cabbage	6.11	0.82	0.30	3.30	0.14	0.37		0.48	0.58	1.10	7.87	3.92	0.92	4.53	3.13	3.70	0.01	0.10	1.51	34.97		1.00	36.95		0.81	0.70	0.37	113.69
Kohirabi	2.25	0.12	0.10	0.00					0.01			0.27				0.02		0.04				0.12			0.08		0.16	3.17





	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Brassica																												
vegetables	614.48	58.37	152.81	71.93	6.68	22.93	438.40	12.29	24.35	481.03	264.90	136.66	0.00	678.28	65.86	97.83	0.12	9.69	246.00	1588.17	0.00	60.40	769.20	264.99	23.87	26.77	22.95	6138.96
Cauliflowers	176.55	7.69	86.21	1.83	2.29	6.12	438.40	0.62	4.93	375.50	75.90	24.55		569.22	1.51	2.04		6.53	56.00	238.84		7.78	24.12	219.45	2.71	1.76	7.39	2337.94
Brussels																												
sprouts	12.56	0.20	48.60	0.79		0.48			0.08	20.53		0.42		5.67		0.10		0.01	62.00	29.33		3.13		45.54	0.03			229.47
Head cabbage	425.37	50.48	18.00	69.31	4.39	16.33		11.67	19.34	85.00	189.00	111.69		103.39	64.35	95.69	0.12	3.15	128.00	1320.00		49.49	745.08		21.13	25.01	15.56	3571.55
Kohirabi	66.91	3.69	10.00						0.09			8.67				0.12		1.05				1.69			1.41		4.89	98.52

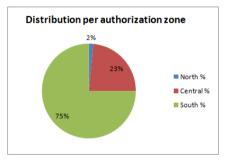


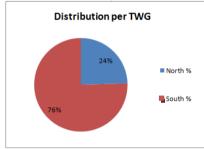


Leaf vegetables and fresh herbs

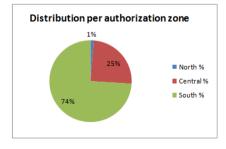
Surface (1000ha)

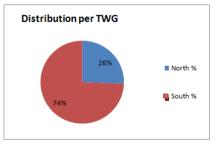
		DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Leaf ve	egetables																												
and fr	esh herbs	11.63	1.75	6.50	0.22	0.16	0.51	36.20	0.00	0.43	22.97	9.70	0.44	0.18	40.25	0.04	0.09	0.02	0.13	5.67	1.46	0.00	0.00	0.23	5.86	0.03	0.54	1.21	146.22
Lettuce		7.65	1.18	1.95	0.17	0.06	0.47	36.20		0.36	13.25	4.05	0.32	0.15	21.83	0.04	0.08	0.02	0.10	2.60	1.46			0.11	5.86	0.03	0.35	1.21	99.50
Scarole	?	0.43	0.13	0.19							4.09	2.31			11.05			0.00	0.01	0.81							0.16		19.18
Spinaci	h	3.55	0.44	4.36	0.05	0.10	0.04			0.07	5.63	3.34	0.12	0.03	7.37		0.01		0.02	2.26				0.12			0.03		27.54
Witlof		0.33	0.00	3.60							14.77				17.13			0.00		3.35							0.22		39.40





	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Leaf vegetables																												
and fresh herbs	303.33	60.75	181.24	4.60	5.91	10.79	1026.70	0.00	5.95	587.80	158.80	10.23	0.00	828.61	0.13	0.25	0.19	3.26	145.00	19.91	0.00	0.00	1.57	139.58	0.28	11.08	27.20	3533.16
Lettuce	222.51	46.12	76.30	3.96	3.73	10.79	1026.70		5.33	362.30	80.00	8.53		499.91	0.13	0.23	0.15	2.83	74.00	19.91			0.74	139.58	0.28	7.43	27.20	2618.66
Scarole	12.12	4.73	9.20							108.09	38.70			229.33			0.04	0.17	28.00							3.24		433.62
Spinach	68.70	9.90	95.74	0.64	2.18				0.62	117.41	40.10	1.70		99.37		0.02		0.26	43.00				0.83		0.00	0.41		480.88
Witlof		0.00	54.00							255.86				281.23			0.01		67.00							3.48		661.58

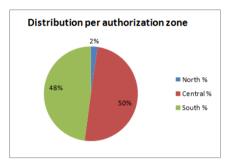


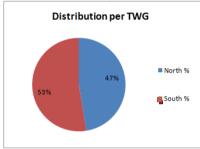


Legume vegetables (fresh)

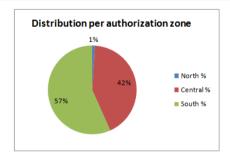
Surface (1000ha)

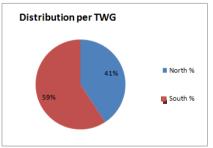
	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Legume																												
vegetables																												
(fresh)	9.21	1.53	19.44	1.33	0.36	3.03	10.96	0.01	2.01	58.80	9.25	16.18	0.00	34.79	0.10	0.39	0.00	0.45	12.15	15.70	0.00	0.98	10.75	33.05	1.06	0.54	0.00	242.07
Green beans	4.07	0.47	9.81	0.99	0.28	0.01			0.01	30.64	7.10	2.43		23.15		0.26		0.42	7.06	7.27			6.60	2.02	0.03	0.49		103.11
Peas	5.14	1.06	9.63	0.32	0.08	3.02	9.70	0.01	2.00	28.16	1.25	13.75		11.64	0.10	0.13	0.00	0.03	5.09	7.09		0.98	4.15	31.03	1.03	0.05		135.44
Broad bean				0.02			1.26				0.90									1.34								3.52





	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Legume																												
vegetables																												
(fresh)	71.85	10.43	164.43	5.60	3.16	11.96	68.16	0.01	4.24	564.67	83.49	106.74	0.00	290.17	0.36	0.74	0.02	3.63	100.50	106.26	0.00	5.05	43.28	148.01	2.63	3.34	0.00	1798.73
Green beans	43.12	5.62	106.62	4.09	2.36	0.03			0.04	359.61	71.20	21.76		218.76		0.51		3.45	70.50	64.89			34.40	20.75	0.13	3.11		1030.95
Peas	28.73	4.81	57.81	1.37	0.80	11.93	66.50	0.01	4.20	205.06	8.80	84.98		71.41	0.36	0.23	0.02	0.18	30.00	38.03		5.05	8.88	127.26	2.50	0.23		759.15
Broad bean				0.14			1.66				3.49									3.34								8.63

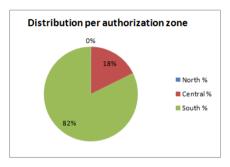


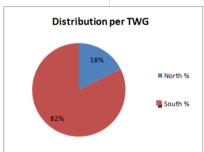


Stem vegetables

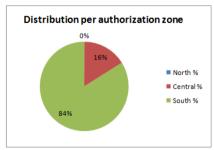
Surface (1000ha)

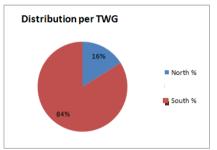
	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Stem vegetables	18.12	0.47	0.66	0.01	0.23	0.10	30.60	0.00	0.02	16.84	8.65	1.39	0.05	60.30	0.00	0.04	0.00	0.11	2.06	0.24	0.00	0.00	0.00	1.6 5	0.25	0.00	0.00	141.79
Asparagus	18.12	0.47	0.16			0.05	12.00		0.01	6.03	6.00	1.16		6.44		0.01			2.06					0.79	0.25			53.55
Celery			0.50	0.01	0.05	0.03			0.01	0.63		0.23	0.05	3.73		0.03	0.00	0.01		0.24				0.86				6.38
Artichoke					0.18	0.02	18.60			10.18	2.65			50.13				0.10										81.86
Leek	2.30	0.14	4.50	0.17		0.36			0.04	6.42	1.64	0.11	0.07	0.60	0.08	0.08	0.01	0.01	2.73	5.68			0.05	1.70	0.01	0.03	0.13	26.86





	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Stem vegetables	82.76	2.17	28.29	0.05	5.02	0.77	236.50	0.00	0.12	95.30	50.30	9.59	0.00	613.96	0.00	0.19	0.02	1.44	15.00	2.60	0.00	0.00	0.00	49.05	1.41	0.00	0.00	1194.54
Asparagus	82.76	2.17	0.96			0.06	47.60		0.00	20.39	24.30	4.53		43.50		0.01			15.00					2.30	1.41			244.99
Celery			27.33	0.05	2.28	0.55			0.12	24.76		5.06		100.48		0.18	0.02	0.46		2.60				46.75				210.64
Artichoke					2.74	0.16	188.90			50.15	26.00			469.98				0.98										738.91
Leek	76.08	5.80	168.60	2.80		5.63			0.63	182.91	37.00	1.39		15.48	0.63	0.54	0.13	0.22	82.00	99.56			0.79	49.79	0.07	0.71	3.42	734.18

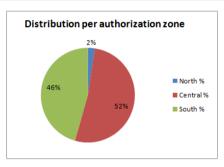


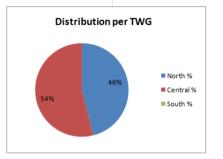


Pulses

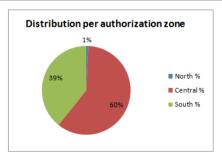
Surface (1000ha)

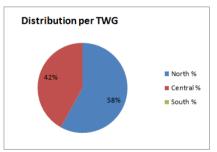
		DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Puls	ses	54.30	3.90	0.81	10.63	0.77	0.00	110.61	0.10	0.30	120.68	12.70	2.25	0.00	59.05	0.51	8.80	0.13	0.00	1.55	56.61	8.44	0.00	58.74	187.00	2.77	0.46	7.14	708.25
Beans		15.70	3.55	0.81	8.57	0.64		64.71	0.10	0.30	103.70	11.20	1.52		57.26	0.50	3.90	0.12		1.54	27.71	8.44		58.74	187.00	1.68	0.46	7.14	565.29
Lentils					2.06	0.13		32			9.84	1.40	0.52		1.79											1.00			48.74
Lupins		38.60	0.35					13.90			7.14	0.10	0.21			0.01	4.90	0.01		0.01	28.90					0.09			94.22
Peas		110.30	36.04	1.34	2.00	0.15	16.33	209.70	4.30	3.80	316.93	4.31	19.96		11.14	1.60	12.30	0.33		2.32	19.53		29.12	22.01	43.00	12.24	1.51	24.16	904.42





	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Pulses	59.60	11.27	2.70	12.36	1.53	0.00	55.09	0.00	0.00	414.50	24.14	3.85	0.00	107.06	0.84	10.70	0.39	0.00	6.80	97.84	3.02	0.00	41.73	716.21	3.26	0.97	0.00	1573.86
Beans	59.60	10.23	2.70	10.06	1.52		42.78			381.40	22.17	2.89		105.83	0.80	5.80	0.38		6.80	56.93	3.02		41.73	716.21	2.00	0.97		1473.82
Lentils				2.30	0.01		5.97			15.54	1.82	0.57		1.23											1.26			28.70
Lupins		1.04					6.34			17.56	0.15	0.39			0.04	4.90	0.01			40.91								71.34
Peas	346.30	90.26	4.60	2.92		53.05	142.20	5.70	8.10	1332.54	7.13	50.24		34.54	2.50	21.10	1.09		9.82	41.77		78.80	39.10	161.00	28.21	4.58	65.40	2530.95

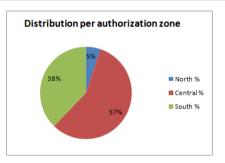


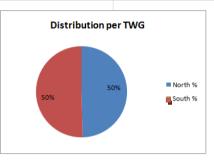


<u>Oilseeds</u>

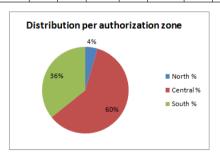
Surface (1000ha)

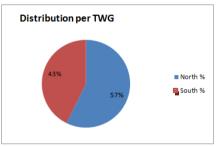
	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Oilseeds	1385.40	70.80	24.93	645.99	0.00	111.70	522.77	46.80	5.80	1885.87	4.56	633.38	3.73	133.40	73.00	112.10	4.06	0.00	7.21	555.55	7.07	314.06	1058.81	565.22	201.91	2.30	83.33	8459.75
Linseed	14.40	5.37	19.29				0.67	0.20	1.80	11.65		2.01			1.60	2.70			4.73	1.02		7.30	0.08	45.22	2.70		9.85	130.59
Sunflower seed	27.10	30.18		635.00			517.3		0.10	643.53	4.56	511.14		129.87					0.38	4.33	7.07	39.60	970.95	1.00	91.81	0.04		3613.96
Rape seed	1343.90	35.25	5.64	10.99		111.70	4.80	46.60	3.90	1230.69		120.23	3.73	3.53	71.40	109.40	4.06		2.10	550.20		267.16	87.78	519.00	107.40	2.26	73.48	4715.20
Soya bean		21.43		0.27			1.00			55.99		33.64		152.33						0.30		9.30	143.09	1.00	10.66	0.17		429.18





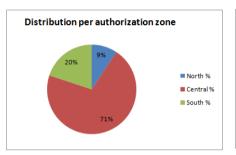
	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Oilseeds	5144.17	191.52	38.40	956.64	0.00	342.22	366.86	83.30	5.70	6060.63	5.70	1388.71	14.19	295.45	146.30	203.20	14.70	0.00	11.38	1458.87	2.40	873.10	1488.61	1783.52	433.05	5.44	201.50	21515.56
Linseed	25.37	6.44	14.40				0.56	0.20		24.68		2.82			0.60	2.00			3.64	1.69		8.90	0.10	75.52	2.67		15.70	185.29
Sunflower seed	67.10	80.78		934.86			360.9			1502.11	5.70	1107.91		289.37						7.42	2.4	94.80	1340.94	2.00	195.31	0.09		5991.69
Rape seed	5051.70	104.30	24.00	21.78		342.22	5.40	83.10	5.70	4533.84		277.98	14.19	6.08	145.70	201.20	14.70		7.74	1449.76		769.40	147.57	1706.00	235.07	5.35	185.80	15338.58
Soya bean		60.57		0.60			2.70			139.92		77.96		553.00						0.33		18.90	312.78	4.00	18.97	0.33		1190.06

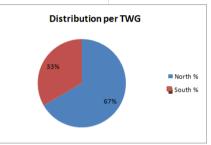




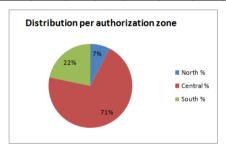
Potatoes

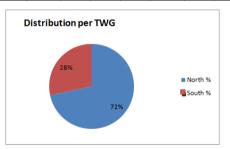
(1000ha) Surface DE CY EE RO Potatoes 292.20 33.83 75.94 24.00 5.38 40.01 117.80 14.00 28.90 171.14 35.50 27.28 11.79 88.64 45.60 68.30 0.61 0.95 155.78 588.18 41.39 38.27 319.64 149.89 20.93 6.97 30.45 276.90 22.19 64.95 24.00 5.38 40.01 100.60 14.00 28.90 158.13 35.50 25.38 1.90 11.79 69.91 45.10 64.80 0.61 0.95 155.78 588.18 41.39 36.07 284.91 137.38 19.42 6.31 30.45 Ware potatoes 13.01 34.73 Early potatoes 15.30 11.64 10.99 17.2 18.73 0.50 3.50 2.20 12.51





	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE
Potatoes	12101.20	1103.87	3177.50	375.46	150.00	1576.43	3013.20	209.80	742.70	7043.43	849.90	702.32	409.18	2213.55	665.30	830.50	19.33	25.00	6776.86	10369.25	569.53	1055.40	4208.58	6004.47	325.18	155.82	947.30
Ware potatoes	11624.30	763.17	2780.80	375.46	150.00	1576.43	2604.00	209.80	742.70	6680.82	849.90	656.72	409.18	1753.53	658.20	785.70	19.33	25.00	6776.86	10369.25	569.53	1013.00	3738.59	5815.38	301.17	144.71	947.30
Early potatoes	476.90	340.70	396.70				409.2			362.61		45.60		460.02	7.10	44.80						42.40	469.99	189.09	24.01	11.11	

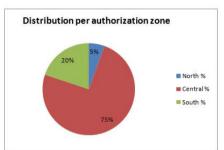


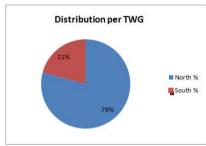


<u>Cereals</u>

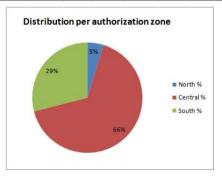
Surface (1000ha)

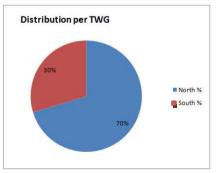
	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Cereals	549.10	42.85	0.00	13.28	0.00	27.31	209.50	7.40	14.30	49.16	33.20	44.49	0.00	223.58	39.30	50.90	0.92	0.00	2.54	1415.34	47.30	46.90	24.57	5.86	24.49	1.32	21.30	2894.91
Rice				4.50			119.00			17.85	23.10	2.67		220.93							21.94		3.92					413.91
Rye	549.10	42.85		8.78		27.31	90.5	7.40	14.30	31.31	10.10	41.82		2.65	39.30	50.90	0.92		2.54	1415.34	25.36	46.90	20.65	5.86	24.49	1.32	21.30	2481.00
Sorghum				1.59			7.00	111		52.15		4.05		31.58					0.11				1.47					97.95
Triticale	480.80	39.45	8.36	9.32		31.28	39	6.20		330.47	j	156.99			13.30	75.20	3.41		3.68	1194.54	20.49	64.81	33.89	12.60	17.16	1.99	50.12	2593.06
Wheat	3173.70	288.96	213.81	1101.81	6.24	675.64	2249.80	85.40	215.10	5272.49	845.50	1130.72	95.23	2122.90	187.50	369.50	11.93		135.70	2218.09	122.73	820.44	2475.97	1869.00	375.80	30.06	354.12	26448.14





	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU I	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Cereals	2793.50	163.65	0.00	33.78	0.00	132.05	965.20	20.40	32.40	250.78	197.77	116.75	0.00	1420.84	87.30	108.30	5.72	0.00	10.89	3404.31	139.93	196.80	63.21	39.51	68.59	4.09	112.30	10368.07
Rice				20.16			838.70			102.31	180.60	9.44		1412.96							120.18		14.25					2698.60
Rye	2793.50	163.65		13.62		132.05	126.5	20.40	32.40	148.47	17.17	107.31		7.88	87.30	108.30	5.72		10.89	3404.31	19.75	196.80	48.96	39.51	68.59	4.09	112.30	7669.47
Sorghum				3.24			26.80			271.75	11111	12.42		184.92									1.91					501.04
Triticale	2675.90	198.47	48.80	22.64		151.56	55.5	15.00		1793.97		567.74			31.80	201.10	18.53		19.90	3902.92	8.25	255.20	94.14	52.88	52.37	7.85	271.50	10446.02
Wheat	23692.70	1453.07	1799.40	3478.07	9.27	4887.22	3814.90	263.40	801.20	36840.81	1761.00	5088.22	801.72	7717.13	676.50	1379.40	71.15	1	1174.69	8771.43	81.55	4145.00	7340.67	14877.00	1607.87	141.29	2246.80	134921.46

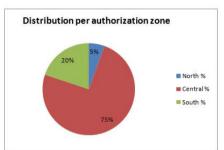


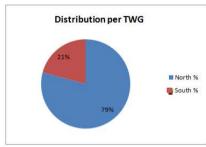


<u>Cereals</u>

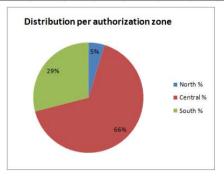
Surface (1000ha)

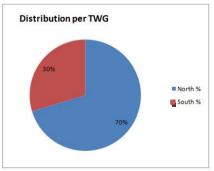
-	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Cereals	549.10	42.85	0.00	13.28	0.00	27.31	209.50	7.40	14.30	49.16	33.20	44.49	0.00	223.58	39.30	50.90	0.92	0.00	2.54	1415.34	47.30	46.90	24.57	5.86	24.49	1.32	21.30	2894.91
Rice				4.50			119.00			17.85	23.10	2.67		220.93							21.94		3.92					413.91
Rye	549.10	42.85		8.78		27.31	90.5	7.40	14.30	31.31	10.10	41.82		2.65	39.30	50.90	0.92		2.54	1415.34	25.36	46.90	20.65	5.86	24.49	1.32	21.30	2481.00
Sorghum				1.59			7.00	111		52.15		4.05		31.58					0.11				1.47					97.95
Triticale	480.80	39.45	8.36	9.32		31.28	39	6.20		330.47		156.99			13.30	75.20	3.41		3.68	1194.54	20.49	64.81	33.89	12.60	17.16	1.99	50.12	2593.06
Wheat	3173.70	288.96	213.81	1101.81	6.24	675.64	2249.80	85.40	215.10	5272.49	845.50	1130.72	95.23	2122.90	187.50	369.50	11.93		135.70	2218.09	122.73	820.44	2475.97	1869.00	375.80	30.06	354.12	26448.14





	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU I	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Cereals	2793.50	163.65	0.00	33.78	0.00	132.05	965.20	20.40	32.40	250.78	197.77	116.75	0.00	1420.84	87.30	108.30	5.72	0.00	10.89	3404.31	139.93	196.80	63.21	39.51	68.59	4.09	112.30	10368.07
Rice				20.16			838.70			102.31	180.60	9.44		1412.96							120.18		14.25					2698.60
Rye	2793.50	163.65		13.62		132.05	126.5	20.40	32.40	148.47	17.17	107.31		7.88	87.30	108.30	5.72		10.89	3404.31	19.75	196.80	48.96	39.51	68.59	4.09	112.30	7669.47
Sorghum				3.24			26.80			271.75	11111	12.42		184.92									1.91					501.04
Triticale	2675.90	198.47	48.80	22.64		151.56	55.5	15.00		1793.97		567.74			31.80	201.10	18.53		19.90	3902.92	8.25	255.20	94.14	52.88	52.37	7.85	271.50	10446.02
Wheat	23692.70	1453.07	1799.40	3478.07	9.27	4887.22	3814.90	263.40	801.20	36840.81	1761.00	5088.22	801.72	7717.13	676.50	1379.40	71.15	1	1174.69	8771.43	81.55	4145.00	7340.67	14877.00	1607.87	141.29	2246.80	134921.46

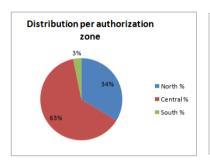


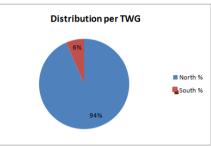


Miscellaneous products

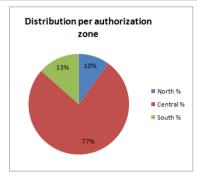
Surface (1000ha)

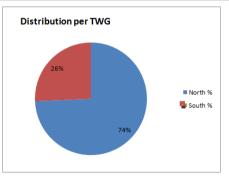
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Miscellaneous																												
products	17.30	0.20	0.20	0.23	0.00	0.00	0.64	0.00	13.30	0.81	0.00	0.00	4.00	0.00	0.90	3.60	0.00	0.00	0.09	2.29	0.02	5.70	0.28	1.40	0.48	1.45	0.00	52.89
Hops	17.30	0.20	0.20	0.23			0.64			0.81		0.00	4.00							2.29	0.02	5.70	0.28	1.40	0.31	1.45		34.83
Cumin seed									13.30						0.90	3.60			0.09						0.17			18.06
Sugar beet	420.10	44.21	85.53	1.29		47.02	102.00		31.30	379.52	42.50	61.64	31.00	253.04	13.50	21.00			91.31	286.18	8.62	65.57	25.22	148.30	33.05	5.06	49.18	2246.14
Medicinal,																												
aromatic and																												
condiment	6.30	3.87	0.19	39.14			5.6	0.30	13.50	36.32	2.40	2.13			0.90	4.20			0.09	20.33		8.40	4.57		1.35	0.02		149.61





	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Miscellaneous	;																											
products	0.00	0.31	0.40	0.22	0.00	0.00	1.35	0.00	0.00	1.37	0.00	0.05	0.00	0.00	0.30	1.90	0.00	0.00	0.16	3.41	0.03	7.80	0.19	1.53	0.50	2.50	0.00	22.02
Hops		0.31	0.40	0.22			1.35			1.37		0.05								3.41	0.03	7.80	0.19	1.53	0.43	2.50		19.59
Cumin seed															0.30	1.90			0.16						0.07			2.43
Sugar beet	25284.70	3132.60	5983.17	24.73		2762.58	7275.70		1181.30	31242.51	2800.00	3515.87	1394.96	14155.68	519.90	798.50			5930.98	11912.44	604.88	3495.60	729.66	8500.00	1732.61	260.10	2381.20	135619.67
Medicinal,																												
aromatic and																												
condiment				41.94			16.88					3.22			0.30	1.90			0.16	15.89		7.70	3.30		0.77	0.02		92.08

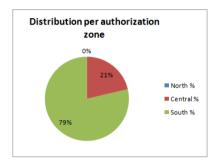


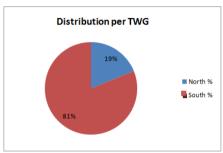


Tobacco

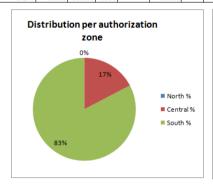
Surface (1000ha)

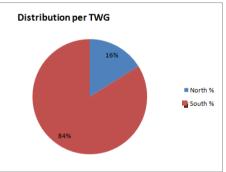
	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total
Tobacco	4.60	0.10	0.33	40.87	0.08	0.00	13.15	0.00	0.00	8.37	50.10	6.55	0.00	0.00	0.00	0.00	0.00	0.00	0.00	14.88	1.62	0.00	3.57	0.00	0.96	0.00	0.00	145.16
Tobacco	4.600	0.098	0.325	40.869	0.078		13.150			8.367	50.100	6.553								14.875	1.618		3.565		0.957			145.155





	DE	AT	BE	BG	CY	DK	ES	EE	FI	FR	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	CZ	RO	UK	SK	SI	SE	Total	
Tobacco	0.00	0.25	0.80	58.34	0.35	0.00	40.60	0.00	0.00	25.57	112.00	11.39	0.00	0.00	0.00	0.00	0.00	0.00	0.00	33.48	4.75	0.00	3.68	0.00	1.04	0.00	0.00	292.23	
Tobacco		0.247	0.800	58,336	0.350		40,596			25,568	112,000	11.385								33,483	4.749		3.682		1.038			292,23	





Annex VIII: Databases on crop classification & inventory of needs





Annex IX: Minutes of the workshop of 5 of May 2011

The European conference entitled "Analysing the needs for a European fund for minor uses in the field of plant protection products" took place in Brussels on May 5th, 2011.

The significant reduction of the number of active substances authorised at the EU level, the increased costs of developing new pesticides, and the imperfect functioning of the mutual recognition principles have intensified the issue of lack of plant protection solutions available to farmers for minor uses for the last 15 years.

When crop protection solutions are lacking, growers may be tempted to use illegal products with potential negative effects on the health of users of PPP and consumers, as well as on the environment. Other negative effects may be the increased risk of development of pesticides resistances and an increasing risk to exceed the Maximum Residue Levels (MRLs) due to illegal and/or excessive use of a limited number of pesticides. Finally, competitiveness is at risk as production of minor crops may be shifted outside the EU as growers would not have proper plant production solutions. In some extreme cases even growing of specific crops outside the EU would deny the European consumer the benefit of use, since the EU MRL would ban access of the produce to the EU market.

Most Member States are concerned by minor uses issues and have initiated actions to overcome them for several years. Additionally, DG SANCO established a coordination platform (expert group on minor uses) in 2002 but these efforts have been suspended in 2009 due to lack of resources.

A large number of Competent Authorities and stakeholders representing the plant protection industry, growers associations, and food chain operators called for financial incentives in the form of a European fund to coordinate European actions to close the minor uses gaps.

Therefore the main objective of this workshop was to collect participants' preliminary views on options that have been developed by the Food Chain Evaluation Consortium (FCEC) as well as to invite stakeholders to provide their views and inputs (data) concerning the impact of the options under review.

The agenda of the workshop that has been drafted conjointly by the Commission services and the FCEC aimed at, first, setting-up the scene before, secondly, discussing the approach to a EU coordinated action supported by a EU fund.

The agenda of the workshop was as follows:

9.15	Welcome and opening of the Workshop
	The minor uses and the Regulation (EC) no 1107/2009 on plant protection
	products
	Mr. Michael Flueh, Head of Unit E3 – DG SANCO
9.30	Experiences of the technical WG North on minor uses
	Mr. Johan Roman – Coordinator TWG North
9.50	Experiences of the technical WG South on minor uses
	Mr. Johan Roman – Coordinator TWG South
10.10	OECD approach to minor uses
	M.Béatrice Grenier– OECD
10.30	Objectives of the study on the establishment of a European fund for minor uses
	M. Roselyne Roy - Unit E – DG SANCO
10.40	Coffee Break
11.00	Introduction to and organisation of the study
	FCEC – Daniel Traon
11.15	Presentation of the interim results (discussion)
	FCEC – Jan Bruscke
11.30	Presentation of the Third Country analysis: Management of minor uses issues in
	the USA, Canada and Australia
	FCEC – Ferdinand Zoltz
11.50	Reflections on options for the future minor uses policy
	FCEC – Laurence Van Nieuwenhuysse
12.30	Lunch break
14.00	Discussions with the participants on options for the future minor uses policy
	FCEC – Laurence Van Nieuwenhuysse & Daniel Traon
15.30	Coffe break
16.00	Discussions with the participants on options for the future minor uses policy
	(Con't)
	FCEC - Laurence Van Nieuwenhuysse & Daniel Traon
17.00	Concluding remarks
	Anton Rotteveel - DG SANCO

This report presents the main conclusions of the workshop.

The workshop was opened by Michael Flueh who was chairing the workshop during the morning session.

About 60 persons registered for the workshop, representing national PPP competent authorities and EU level stakeholders (including PPP industry and producers associations) were present.

As an introduction to the workshop, Michael Flueh presented the general context related to the minor uses issues in the transition phase of 2011 where Directive 91/414/EEC has been replaced by the Regulation (EC) No 1107/2009. He insisted on the fact that tools already existed in the past Directive to address minor uses issues which have been reinforced in the Regulation.

In the following, Jean Claude Malet and Johan Roman presented the past and current activities of the two coordination groups. Both speakers indicated that though what has been achieved during the last 10 years have positively impacted the situation, it is key to further boost cooperation and data exchange between MS in order to fill minor uses gaps that are observed in all MS, the number of which is increasing. What has been achieved to date has been presented as effective but a new enlarged dimension has to be given to the initiative.

Béatrice Grenier briefly presented the OECD approach to minor uses. She highlighted that lack of PPP solutions for minor crops is a global problem that exist in all crop production areas and not only in the EU and that global coordination is also required to secure global trade of safe products.

Then, Roselyne Roy introduced the study that has been mandated to the FCEC by presenting its main objectives as follows:

- <u>Collection of information on minor uses in the European Union.</u> This will include the collection of data from all Member States and from stakeholders on the following topics:
 - Current interpretation of minor uses and its application in MS;
 - List of crops and plant protection problems for which no PPPs are authorised (inventory of issues);
 - Quantitative and qualitative economic and agronomic information on minor uses in order to evaluate the importance of the potential problems (economic quantification of the issues);
 - National approaches and actions developed by MS including specific funding;
 - Proposals for an EU-coordinated action on minor uses;
 - Expected impact of the new regulation for placing PPP on the market.
- o <u>Identification of different options with analysis of the cost and benefit of each option.</u> The identification of the needs and the analysis of experiences will help the contractor to identify options which could address the problem of minor uses, including the "status quo" option (i.e. leaving the resolution of minor uses

problems to initiative undertaken by MS with no action at EU level, including the opportunities offered by the new regulation).

After these different presentations the floor was given to the FCEC team that briefly reintroduced the study methodology and presented the main interim results of the study to date.

The last presentation of the session of the morning aimed at presenting to the audience the drafted options as defined by the FCEC team related to the set-up of a EU coordinated action supported by a EU fund and in preparation of the discussion to come in the afternoon.

The FCEC team presented 4 different options as follows:

Option 1 - Status quo No EU financial support

Option 2 - Limited EU support

To facilitate meetings of the North and South WG (back to the 2001-2009 situation)

- Option 3 - Moderate EU support

Idem 2 but three zonal WG + EU support for the development and management of data sharing tools (e.g. centralised database) and the coordination of the actions at the level of the WGs + Steering Committee

- Option 4 - Strong EU support

Idem 3 + EU support for management of projects

After the lunch break, the session of the afternoon was dedicated to a general discussion with the participants. This session was moderated by the FCEC and conclusions drafted by Anton Rotteveel from DG SANCO.

The main general conclusions of the discussions can be summarised as follows:

Participants in the workshop indicated their satisfaction and expressed their appreciation for the European Commission's initiative to organise this workshop. The quality of the presentations and the discussion that did follow-up was highly appreciated by most of participants.

In global terms, there is a general interest in (further) building a EU coordination in support to solving minor uses issues. Participants indicated that what has been achieved to date via the two coordination groups is highly valuable but that a new dimension should be defined in order to materialize actual activities in true results. Further coordination is required at both EU and zonal/national/regional level. A bottom-up approach at grass root level is considered by the majority of the participants as a key success factor and therefore a "must" in any approach.

Independency and transparency are also considered mandatory in order to correctly use available means. This should be materialised by the implementation of a Technical Secretariat in support to a multi-layer governance composed of a EU Steering Committee and two coordination groups (one in the North and one in t South – based on current structure).

Several participants indicated that the European Plant Protection Organisation (EPPO) should be considered as a possible coordinating body as EPPO expertise in this field is large and fully recognized by the large majority of actors (NCA and stakeholders) in this area.

Participants also highlighted the necessity to organize a coordination platform on short tracks in order to fix urgent problems. The approach presented by the COM may take a couple of years before it materialized as legal considerations and changes have to be considered. Large problems are currently being faced now and coordination is required immediately. In order to overcome this timing issue, several participants proposed different approaches to set-up a coordination in short terms. These approaches are mainly related to financial support by DG RESEARCH via the existing ERA-Net and COST platforms. However no concrete action plan was decided on how to approach DG RESEACH.

Growers and producers (COPA-COGECA) highlighted their interest for Option 4 meaning that EU resources should be dedicated to solve minor uses issues via EU funded projects.