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**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND
THE COUNCIL**

**on the establishment of a European fund for minor uses in the field of plant protection
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EXECUTIVE SUMMARY

Regulation (EC) No 1107/2009 regulates the placing of plant protection products (PPP) on the market and contains special provisions for the application and authorisation of so called minor uses. These are uses of PPP that are economically not sustainable for the plant protection industry, but important for growers. The Regulation requires the Commission to present a report to the European Parliament and Council on the establishment of a European fund for minor uses, accompanied, if appropriate, by a legislative proposal. The aims of that report are:

- providing information regarding the situation on minor uses as reported by Member States and stakeholder organisations;
- presenting the strategy offered in Regulation (EC) No 1107/2009 as regards minor uses;
- presenting the options for action considered in the preliminary study funded by the Commission;
- informing the European Parliament and the Council about the Commission's conclusions on a possible legislative proposal for the establishment of a European minor uses fund.

Minor uses are mostly connected to minor crops that together are valued at about €70 billion per year, which is 22% of the total EU plant production value. It was estimated that direct impacts on the agricultural sector (i.e. crop production loss and additional growing costs for farmers) account for more than €1 billion per year. Furthermore most Member States consider minor uses to be so important that already today structural money and manpower amounting to approximately €8 millions are spent to address the issue.

The Commission notes that the main causes for the minor uses problem are:

- absence of economic incentives to apply for authorisation of PPP;
- inhomogeneous availability of PPP for minor uses as economic incentives and needs vary between MS;
- difficult access to and complicated use of regulatory pathways to obtain extensions of use for third parties;
- lack of information on existing initiatives in other MS.

Four options for action by the Commission have been considered:

- (1) No funding by the Commission.
- (2) Re-installation of the EU Minor Uses Expert Group.
- (3) Commission partly funding a coordination facility (Technical Secretariat) comprising of an independent central secretariat which coordinates the work between MS and stakeholders.

(4) Commission partly funding a coordination facility (Technical Secretariat) and specific projects.

The collection of views of Member States and stakeholders showed a clear demand for the establishment of a coordinated action at European level (96% of the respondents to the general survey launched by FCEC are in favour; 4 % did not know). No interest was expressed in either option 1 or 2. While policy makers supported in majority option 3, a clear preference for option 4 was indicated by growers and the plant protection industry.

Noting that coordination at the European level is essential to solve the minor use problem, noting that Member States have already national efforts in place, and noting that there are currently a number of grassroots stakeholder activities ongoing, the Commission proposes the establishment of a coordination group.

The Commission is of the opinion that, in the short and medium term, the creation of a coordination platform would be sufficient, to which the Commission is prepared to financially contribute based on Article 76(1) of Regulation (EC) No 1107/2009. Once the facility has been established and becomes operational, the Commission will assess its functioning as well as the results achieved and may propose further appropriate measures.

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1. INTRODUCTION

1.1. Background of the report and EU regulatory framework

The placing on the market of plant protection products in the European Union is regulated by Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009. This Regulation, which repealed Council Directive 91/414/EEC on 14 June 2011 provides for a comprehensive risk assessment and authorisation procedure for active substances and products containing these substances.

Active substances to be used as plant protection products are assessed and approved at EU level, while individual plant protection products containing these substances are assessed and authorised by Member States for specific crops and pests under harmonised rules.

Regulation (EC) No 1107/2009 places emphasis on the so-called "minor uses", which are uses of plant protection products on acreages too small for industry to invest in the application for a profitable authorisation of a product. Minor uses mainly concern minor or very minor crops (including most vegetables, fruit, nurseries and flowers) and it is estimated that they overall represent up to €70 billion per year, representing 22% of the entire EU plant production value.

Regulation (EC) No 1107/2009 defines in Article 3 (26) 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.”*

If there is no application by industry for a specific use of a product, there can be no evaluation and no authorisation, resulting in several cases in a lack of plant protection options. This lack of authorised plant protection products mainly affects minor crops, but it is also relevant for major crops for less common pests or diseases.

The problem of minor uses also affects organic production, as no plant protection products including those that can be used in organic farming, is exempt from evaluation and authorisation.

Most Member States are concerned by minor uses issues and during the discussions prior to the adoption of Regulation (EC) No 1107/2009, a large number of them and some stakeholders called for incentives in the form of a European fund to coordinate European actions to address the minor uses issue. The European Commission funded in 2011 a preliminary study for this report¹ that is available on its website².

¹ The study was conducted by the Food Chain Evaluation Consortium (hereinafter FCEC).

² http://ec.europa.eu/food/plant/protection/evaluation/study_establishment_eu_fund.pdf.

1.2. Objective of the report

The report aims at:

- providing information regarding the situation on minor uses as reported by Member States and stakeholder organisations;
- presenting the strategy offered in Regulation (EC) No 1107/2009 as regards minor uses;
- presenting the options for action considered in the preliminary study funded by the Commission;
- informing the European Parliament and the Council about the Commission's conclusions on a possible legislative proposal for the establishment of a European minor uses fund.

2. PLANT PROTECTION PRODUCTS AND MINOR USES

2.1. The problem

The lack of plant protection options for minor uses was already known before 1991, when the first EU regulatory framework on plant protection products was laid down in Directive 91/414/EEC. This Directive already established two main provisions to increase availability of plant protection products to farmers and to enhance harmonisation across the EU. Those provisions related to the possibility a) to mutually recognise in a Member State the authorisations granted in another Member State and b) to extend the existing authorisations to minor uses, by way of a reduced dossier.

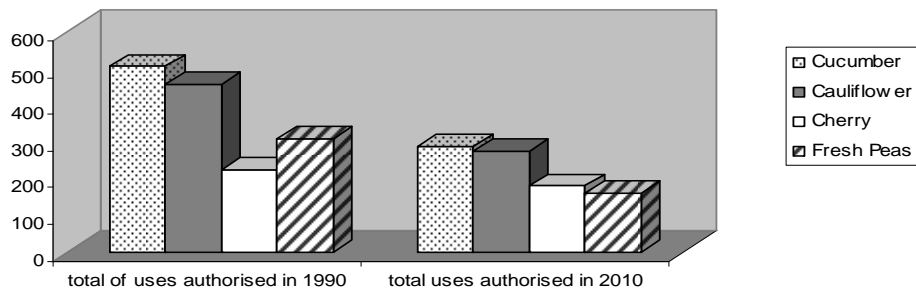
However, despite the provisions of Directive 91/414/EEC, the situation with minor uses did not improve. This was due in particular to:

- the significant reduction of active substances approved at EU level, resulting from e.g. the review programme of existing active substances carried out between 1993 and 2009. This programme led to the withdrawal of approximately 70% of the active substances that were on the market before 1993;
- the very limited use of the simplification tools for minor uses provided by Directive 91/414/EEC (i.e. mutual recognition and extension of minor uses);
- the lack of incentives for industry to submit a dossier for minor uses authorisation³.

As authorisations are granted by the Member States and there is no EU-wide overview on minor uses, it is difficult to provide estimates on the total number of uses lacking crop protection solutions. FCEC identified over 1400 cases (crop x pest) without any authorised plant protection product and this list is not complete. Furthermore, the Commission collected data on 4 crops from 4 Member States, and their analysis clearly shows a substantial decrease in the number of available efficacious crop protection authorisations for minor crops in the period 1990-2010, as illustrated in graph 1.

³ The data generation and data evaluation of a minor use may cost over €200,000.

Graph 1: Number of authorised use 1990-2010 for DE, FR, NL and UK in cucumber, cauliflower, cherry and fresh peas.



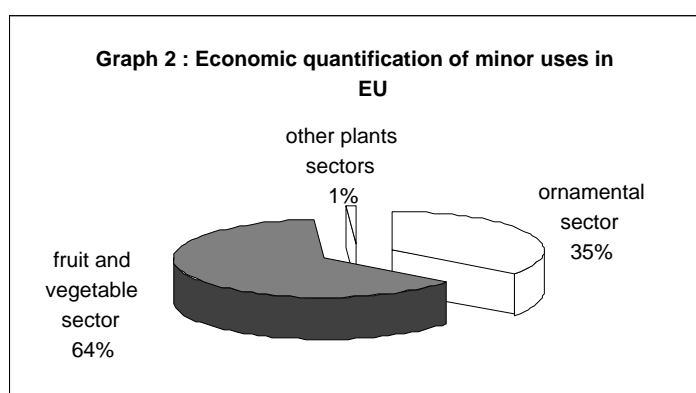
For 30 out of the 209 pests and diseases identified on the four crops used for this study, no plant protection products were available to control them. Moreover, 161 harmful organisms had no authorised plant protection products available in at least one of the four MS studied. These figures illustrate the problem of minor uses and the need for a solution. However they confirm as well that the Member States did not always take full advantage of the possibility offered by Directive 91/414/EEC when solutions existed in other Member States, or when they were available for other crops.

Insufficient protection of crops against harmful organisms may have impacts at various levels. It endangers the sustainable production of high quality, highly diverse and high value food crops within the EU. The lack of plant protection solutions can carry potential negative effects on human health and the environment, due to possible illegal use of plant protection products. In addition, the absence of plant protection uses could, amongst other factors, affect the competitiveness of EU agriculture.

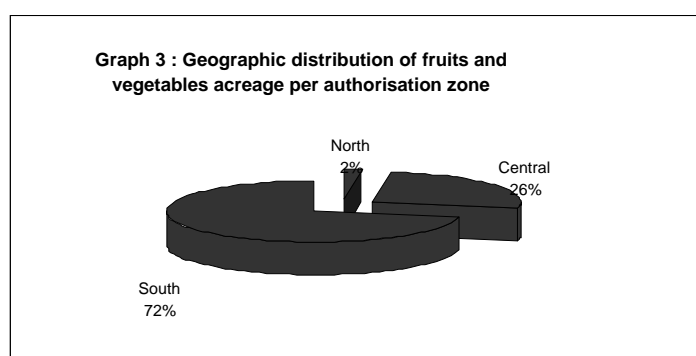
Despite the small amount of economic data available at stakeholder level, the FCEC study gives an indication about the economic impact due to the lack of plant protection solutions for minor uses. It was estimated that direct impacts (i.e. crop production loss and additional growing costs to farmers) account for more than €1 billion. Indirect socio-economic and environmental impacts were estimated to be in the range of €100 million. Those impacts include local unemployment and biodiversity losses (e.g. in areas like Southern Europe, where certain traditional productions like that for aromatic crops would no longer be possible). Those figures refer to a total area of over 9 million hectares.

2.2. Economic significance of minor uses

The term “minor use” may give the impression that their economic dimension is also minor, but is the contrary. Minor uses concern in reality high-value speciality crops, such as fruits and vegetables, ornamentals, nursery crops (plants for planting), and aromatic plants. For the purpose of this report all these crops are taken as minor, though some are major in some Member States. These speciality crops are valued at about €70 billion per year, representing 22% of the total output value of the agricultural sector⁴. The fruit and vegetable sector alone accounts for about €45 billion in EU-27⁵ for a total production of 70 million tons of vegetables and 40 million tons of fruits per year. The market value for ornamental plants is estimated at €7 billion per year. The economic quantification of minor uses in the EU is represented in graph 2.



The fruit and vegetables cropping areas in EU-27 from which the zonal breakdown is shown in graph 3, are respectively about 4.6 million ha and 1.8 million ha, which collectively represent approximately 17% of the EU total production volumes.



⁴ The values presented are estimates derived from Eurostat data that does not differentiate between minor and major crops. Some fruit or vegetable crops, such as apples are major in most Member States, and some arable crops such as rice are considered minor in most rice growing Member States.

⁵ The study was carried out prior to the accession of Croatia.

2.3. Existing initiatives at EU level and in Member States

Most Member States are concerned by the minor uses issue and have been working on solutions for several years, both at national level and in the framework of the EU Expert Groups on Minor Uses.

2.3.1. National funds

National funds are often in place to support minor uses extension and to finance efficacy and residue trials for minor uses. The annual budget devoted by Member States fluctuates from €40.000 to €1.000.000 based on public, private or mixed funding, excluding hidden contributions in staff and services. The total annual funding in place in all Member States can be estimated at about €8 million spent in research projects. This funding is devoted to specific national projects without any coordination of the different actions carried out in the EU.

During the survey carried out by FCEC, 15 Member States indicated that minor uses are considered to be so important that structural money and manpower are spent to address the issue. But no one considers that the resources available are sufficient to solve the problem at national level. Moreover, 10 Member States have no resources available.

2.3.2. EU Expert Groups

The EU Expert Group on Minor Uses, organised by the Commission between 2002 and 2009, was composed of:

- 1) A Steering Committee consisting of policy representatives of selected Member States, two co-ordinators and the Commission. The Steering Committee was in charge of the general policies and management of the work of the Technical Groups.
- 2) Two Technical Groups for Southern and Northern Europe, each led by a coordinator (one from France, one from the Netherlands) and contained representatives of all Member States. Also stakeholders (representatives of producers, farmers, NGOs, pesticide industry) were invited to attend the Technical Groups. The task of these groups was to find technical solutions for minor uses by identifying problems, sharing information, setting common priorities and organising work-sharing. These activities led to the development of projects on data exchange, voluntary mutual recognition, and data generation.

Through the Expert Groups initiative, Member States developed bilateral and multilateral collaboration.

The Expert Groups, although considered to be a good platform for exchange of ideas and for work-sharing, did not attain sufficient implementation of solutions to minor uses. For this reason and for the very limited role played by the Commission in national authorisations, the Commission decided to discontinue the initiative in 2009. Thereafter, some Member States continued developing national or regional initiatives such as technical working groups of a

coordinative nature among national authorities and stakeholders such as growers, industry, research stations and extension services.

2.4. Minor uses in non-EU countries

Minor uses are today internationally recognized as priority topic requiring solutions.

The OECD Pesticide programme established in 2007 the Expert Group on Minor Uses (EGMU) where its members⁶ try to develop international cooperation and technical guidance with a view to facilitate registration of pesticides for minor uses.

Some countries have put in place national initiatives for minor uses, in particular the USA, Australia and Canada.

In the United States, the so-called IR 4 program (Interregional Research Project No.4) has been established in 1963 by the USDA Cooperative State Research, Education and Extension Service in coordination with the Environmental Protection Agency to assist in the collection of residue and efficacy data⁷ in support of the registration or re-registration of minor use pesticides and the determination of tolerances for residues of minor use chemicals in or on raw agricultural commodities.

The IR-4 program is a cooperative government and industry effort and has a federal budget of about €8 million per year. To this are added stakeholder funding and contribution, amounting to an estimated doubling of the budget. IR4 reported over 550 authorisations realised between 2008 and mid- 2011.

3. STRATEGY FOR MINOR USES UNDER REGULATION (EC) NO 1107/2009

Regulation (EC) No 1107/2009 on the placing of plant protection products on the market lays down several provisions to ensure that diversification of agriculture and horticulture is not jeopardised by the lack of availability of plant protection products.

Overall, these provisions combine into an integrated strategy, whose correct and full application is expected to gradually reduce the minor uses problem.

3.1. Harmonised availability of plant protection products

In order to simplify the procedures, harmonise availability of plant protection products and reduce the workload for the evaluation of plant protection products by Member States, thus speeding up the authorisation process, Regulation (EC) No 1107/2009 introduced a system of zonal evaluation of plant protection products by dividing the European Union into three zones

⁶ *Australia (Chair), Austria, Belgium, Canada, Czech Republic, France, Germany, Greece, Hungary, Ireland, Italy, Japan, Netherlands, New Zealand, Slovak Republic, Slovenia, UK, US, European Commission, FAO, EPPO, IBMA, US IR-4 and industry.*

⁷ *25 field research centres are established under IR-4 throughout the United States and involved in 100 studies annually supported by approximately 650 field trials.*

(northern, central and southern zone), where Member States have to mutually recognise the evaluation and authorisation of a plant protection product granted by one Member State within the zone. For certain uses, including very important minor uses applications in greenhouses, seed treatments or post-harvest treatments, the authorisation granted by one Member State can be used in any other Member State irrespective of the zone to which it belongs.

Provided that the agricultural practices are comparable, the mutual recognition of authorisations is obligatory within short fixed deadlines, in order to ensure quicker access to the market and a more harmonised availability of plant protection products, especially for minor uses. This system, also known as "Zonal system" (Article 40) will strongly promote harmonisation because it requires Member States to carry out one single assessment within one zone (or the entire EU for applications in greenhouses, seed treatments or post-harvest treatments).

The only derogation foreseen in mutual recognition is the possibility for a Member State to refuse authorisation of the plant protection product if, due to its specific environmental or agricultural circumstances, it has substantiated reasons to consider that the product in question poses an unacceptable risk to human or animal health or the environment.

Coordination activities within the zones and at EU level are already ongoing and new ones are planned to ensure that the new provisions are fully implemented. It is expected that the full and correct implementation of the zonal system will have a strong and positive influence on minor uses.

In the framework of this activity, the exchange of information on authorisations for plant protection products, which are under evaluation or have already been granted, is crucial. For this reason the Commission is developing an EU database to enhance the information sharing among the Commission, Member States and third parties in order to help the Commission, Member States and applicants from industry to comply with their legal obligations and in addition to inform the general public.

3.2. Incentives for industry

Regulation (EC) No 1107/2009 contains also two main provisions that constitute an incentive for industry to develop solutions for minor uses.

- Simplified procedure for the setting of maximum residue levels (MRLs)

In the context of the approval procedure industry is encouraged to apply for all intended MRLs, including not only major uses but also minor uses (Art 11(2) and 12(6) of Regulation (EC) No 1107/2009).

MRL applications will be evaluated in parallel to the approval of the active substance to save time and resources at all levels. The objective is that, at the time of approval of the active substance, as many MRLs as possible can be set to ease and speed up the authorisation process of the relevant uses at Member State level.

- Extended data protection

Data protection (Art 59) is extended by 3 months for each extension of authorisation for minor uses up to a maximum of three years extra, except when the extension of authorisation does not imply the submission of new residue data. This provision should have positive effects on the number of minor uses applications.

3.3. Extensions of authorisations

Article 51 defines simplified rules for third parties, authorisation holders, official or scientific bodies, professional agriculture organisations or users, to ask for an extension of existing authorisations to minor uses not yet covered by that authorisation. Similar provisions operated already under Directive 91/414/EEC.

In addition, this article allows Member States to take measures facilitating or encouraging the submission of such applications. The Regulation does not specify further what these measures could be and therefore leaves a substantial degree of freedom and initiative to Member States.

Regulation (EC) 1107/2009 kept the simplification rules laid down in Directive 91/414/EEC and strengthened the flexibility offered to Member States to make the best and more effective use of the extension rules. That increased flexibility allows now Member States to take measures facilitating or encouraging the submission of applications to extend existing authorisations to minor uses. This can for example concern a reduced fees regime, accelerated procedures for the evaluation of applications, awareness-raising schemes for interested parties, disincentives to the use of other measures and notably the Emergency measures provided for in Article 53 of Regulation (EC) 1107/2009.

3.4. Improved clarity

One of the major hurdles when estimating the extent of the minor uses problem, is the lack of an agreed list of minor uses to be used for the search of common solutions.

Regulation (EC) No 1107/2009 provides for improved transparency in this sense, by obliging the Member States to establish a list of minor uses at national level.

3.5. European fund for minor uses

The need and possibilities for the establishment of a fund is to be explored by the Commission (see next paragraph 4) pursuant to Article 51(9) of Regulation (EC) No 1107/2009.

4. Policy options considered

The study conducted by FCEC identified four options that emerged from the contributions of Member States and stakeholders. They range from no funding by the Commission to substantial funding through a structured and recognised European fund.

(1) No funding by the Commission

In this option the Commission does not take part directly in minor uses activities. The provisions of Regulation (EC) No 1107/2009 as described in paragraph 3 of this Report are expected to have beneficial effects and should be fully implemented before considering any further action.

(2) EU Minor Uses Expert Group

This option consists of the re-installation of the former EU Expert Groups as described in paragraph 2.3.2 of this Report. Twice a year the Commission provides the meeting room, reimburses the travelling costs of one delegate per Member State and the daily allowance for the co-ordinators.

The direct costs are estimated in the range of €44,000/year at the expense of the Commission, not including the resources needed in the Commission to attend and follow-up the meetings.

(Activities: sharing of information and experience gained at national level and launching of bilateral projects between Member States)

(3) Commission partly funding a coordination facility (Technical Secretariat)

This option consists of option 2, to which are added 2 full time equivalents within a technical secretariat outside the Commission. The Commission is partly subsidizing the system. The secretariat has a legal identity and reports to a steering committee, consisting of Member States, co-financing stakeholders and the Commission.

The required budget for the implementation of option 3 has been estimated in the range of €0.5 to €0.7 millions/year to be shared between the Commission and MS. The co-funding by the Commission, on the basis of Article 76(1) of Regulation (EC) No 1107/2009, could be implemented in the form of a grant according to Title VI of the Financial Regulation (Regulation (EU, Euratom) No 966/2012).

(Activities: In addition to the activities under (2), coordination of minor use work between Member States and stakeholders, creation and maintenance of a data base on minor uses, stimulation of harmonisation (e.g. crop group and pest group definitions, development of guidance))

(4) Commission partly funding a coordination facility (Technical Secretariat) and specific projects

Option 4 encompasses option 3 and in addition provides for limited EU financial support for projects on data generation for efficacy and safety, dossier evaluation and authorisation of individual minor uses.

A budget estimated at €1.2- €6 million/year would be necessary depending on the number of projects funded. In this option the costs should be shared between the three stakeholder groups (industry, growers and the Commission/MS).

(Activities: as under (3) and in addition minor uses data generation for dossier submission at zonal level, with an expected EU-wide impact)

5. Conclusions

The collection of views from Member States and stakeholders showed a clear demand for the establishment of European coordinated action (96% of the respondents to the general survey launched by FCEC are in favour; 4 % did not know). No interest was expressed in either option 1 or 2. While policy makers supported in majority option 3, a clear preference for option 4 was indicated by growers and by the plant protection industry as they favoured the establishment of a fund, which would be added to the already substantial financial support that is provided across the EU at national level (estimated €8 Million).

Besides the Commission is of the opinion that option 4 goes beyond the scope of Article 76(1) of Regulation (EC) No 1107/2009 and would require a modification of the existing legal base, which is not an option for the short and medium term.

The main urgency expressed by Member States was the need for coordination and information sharing within a common platform of EU experts on minor uses. Stakeholders indicated a preference for adding additional funding to the already existing sources for data generation.

The Commission acknowledges that such a coordination facility would be beneficial to promote synergies and to avoid duplicating the efforts, but also to ensure that national funds are efficiently invested.

The Commission is ready to assist and to financially contribute in the short and medium term to the creation of this independent coordination facility (option 3 of the policy options considered), based on Article 76(1) of Regulation (EC) No 1107/2009. A first analysis indicates that a funding of 350,000€year would be sufficient to carry out the necessary measures considered under option 3.

Therefore the Commission is of the opinion that a specific legislative proposal to the European Parliament and to the Council for a minor uses fund is not needed at this stage. However, the Commission will monitor the progress made in the coming years and may propose appropriate measures depending on the experiences gained so far from the coordination facility as outlined above.

The Commission is convinced that the establishment of a coordination facility, combined with the full and correct implementation of the new provisions offered by Regulation (EC) No 1107/2009 and described in paragraph 3 of this report, will substantially contribute to ease the minor uses problem.

In addition to the proposed coordination facility on minor uses the Commission, under the last call for proposals in the seventh research framework programme⁸, will support an ERANET

⁸ FP7 Cooperation Work Programme: Food, Agriculture and Fisheries, and Biotechnologies, topic KBBE.2013.1.4-02: Integrated Pest Management (IPM) – ERANET, Call: FP7-ERANET-2013-RTD).

on Integrated Pest Management with specific reference to minor uses (IPM ERANET). ERANETs are research coordination instruments whereby Member States can coordinate their National research activities and ultimately fund joint projects. They provide important opportunities for Member and Associated States to exchange information, pool resources and agree on common research approaches in specific areas. The IPM ERANET will begin in the first months of 2014 with the objective of creating synergies and ensuring a higher level of IPM implementation on minor use crops amongst European farmers. Coordination between this ERANET and the proposed coordination facility will be imperative and ultimately beneficial to resolving future minor use crop issues.

The Commission also calls for the full involvement of relevant stakeholders to successfully implement Regulation (EC) No 1107/2009 and to find EU-wide viable solutions for minor crop pest problems. Special attention should be given to the implementation of integrated pest management practices and to low-risk active substances, bio-pesticides and basic substances, in line with the principles of Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides.