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Report on

THE IMPACT ASSESSMENT FOR A REGULATION REPLACING DIRECTIVE 91/414/EEC ON PLANT PROTECTION PRODUCTS

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Lead DG: SANCO

Other involved services (Members of the Inter-Services Steering Group): SG, SJ, ECFIN, ENTR, COMP, AGRI, MARKT, EMPL, ENV, TRADE, and BUDG

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TABLE OF CONTENTS

1. EXECUTIVE SUMMARY

Council Directive 91/414/EEC ("the Directive") concerning the placing of plant protection products (PPP) on the market entered into force on 25th July 1993 and provides for harmonised rules governing plant protection products and the active substances contained in those products.

After 13 years of experience gained from the application of the Directive and recent scientific and technical developments, it appears that the basic structure and organization of the text is still acceptable but it is necessary to modify the Directive on certain aspects while maintaining the basic principle which is the high level of protection of human and animal health and of the environment.

Main objectives of the proposal are the following:

- Simplification, better definition and streamlining the procedures
- Increase the level of harmonisation throughout the EU
- Coherence of the text with the general EU policy in the same subject area

The measures to achieve the main objectives are divided into two main categories:

1. Major policy actions, which were subject to an Impact Assessment;
2. Policy actions which constitute refinement of existing policies, based on experience gained, where no separate Impact Assessment is needed.

Beside the "no action option", the following policy options have been identified within the five main policy actions and have been assessed:

1. National provisional authorisations

– Remove national provisional authorisations;

– *idem*, plus conduct evaluation of an active substance in parallel with the authorisation of PPPs;

– keep the system of national provisional authorisations after the dispatch of the Draft Assessment Report.

This policy action has to be seen in combination with applying binding timelines for the evaluation procedure also to new active substances. The assessment concludes to remove the option of national provisional authorisations before an active substance is approved.

2. Mutual recognition of PPP

– Zonal Evaluation on zonal and authorisation on national level;

– *idem*, plus opportunity for Member States to apply additional risk mitigation measures;

– central agency for evaluation and authorisation.

The assessment concludes to group the EU Member States intoin 3 zones. Mutual recognition becomes the norm and Member States within a zone could only amend the authorisations in accordance with already existing legislation on the protection of the health of distributors, users or workers.

3. Comparative assessment of PPP

– Comparative Assessment to be performed by Member States when granting authorisations for substances which have been identified as candidates at EU level, based on hazard criteria;

– *idem*, but application of the comparative assessment compulsory for all substances.

The assessment concludes that substance candidates for substitution should be identified at EU level and that a comparative assessment of plant protection products should be provided afterwards at national level. Criteria are also foreseen for the identification of substances candidates for substitution and for the application of comparative assessment.

4. Data protection and data sharing for the renewal of approval of an active substance

– 5 years of data protection starting six months after the renewal of approval. Compulsory data sharing with compensation and arbitration mechanism;

– *idem*, but protection period starts with date of dossier submission; data sharing not compulsory, but interested parties have to submit a joint dossier;

– no renewal of data protection for the period of renewal of approval.

The assessment concluded that there should be no renewal of data protection after the first 10 years at Member State level following the first authorisation. It is also proposed to remove all provisions on data protection at renewal of approval and studies on vertebrates may not be repeated.

5. Information on the use of PPP

– Active duty to inform neighbours on use of toxic PPP;

– passive duty to inform neighbours on use of toxic PPP.

The assessment concludes that professional users shall keep records on the use of PPP. It is also proposed that for certain categories of (toxic) substances the Member State may provide for an obligation to inform neighbours before use.

2. SECTION 1: PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

The main stakeholders concerned with the amending Directive 91/414/EEC were consulted and participated in meetings in 2002, 2004 and 2006 and in a written consultation in 2005. In addition to the Member State representatives, several other organisations were consulted (see Annex 3).

The Commission held a first stakeholder consultation on the amendment of Directive 91/414/EEC on 10–12 July 2002. The purpose of the consultation was to review the system and to discuss specific policy issues e.g. the scope of the Directive and its borderlines, its linkage to other legislation related to PPP such as the Water Framework Directive. Criteria for inclusion and exclusion of active substances were discussed, especially cut-off criteria, exposure factors and criteria concerning low-risk compounds.

On most issues, there was a reasonable amount of agreement with all stakeholders on the relevant key policy options. It was highlighted that the issue of data sharing and access mentioned in Article 13 of the Directive does not seem to be working well and should be simplified.

The Commission held a second stakeholder meeting on 30 January 2004 in order to refine the choice of policy options coming out of the consultation in 2002. At this meeting, an analysis of the current system was presented highlighting the issue of data protection, data sharing and public access. During the stakeholder consultation it was noted that the system of mutual recognition is not working well and that at present, de facto, very few products are authorised in all Member States. Therefore a non centralised decision making approach, including zonal authorisation, was discussed. Several further technical issues were discussed and on most issues, there was a reasonable amount of agreement among the stakeholders.

A third stakeholder consultation was held in April-May 2005; stakeholders were invited to comment on a Draft Proposal and a Draft Impact Assessment. A large number of comments were received especially on data protection and data sharing as well as on comparative assessment. The input from stakeholders was considered when preparing the final draft documentation.

From 10 March – 10 May 2005, the Commission carried out an Interactive Policy Making (IPM) online consultation with the general public. The purpose of the consultation was to consult European citizens, businesses and other interested parties including farmers on the proposed amendments made to Directive 91/414/EEC. 193 responses to the questionnaire were received. The outcome of this consultation is reported in Annex 4.

An Inter-Services Steering Group has been established in order to streamline the drafting process of the Impact Assessment. The Steering Group met 4 times, between 9 November 2005 and 23 February 2006 and the following Directorates-General were invited to participate: SG, SJ, ECFIN, ENTR, COMP, AGRI, MARKT, EMPL, ENV, TRADE, and BUDG.

In parallel, the Commission also contracted a study to a consultant (Food Chain Evaluation Consortium, FCEC) with the purpose to further contribute to an "Impact Assessment of options for a Regulation replacing Directive 91/414/EEC on plant protection products". That report presented the assessment of economic, environmental and social impacts of policy options in five focus areas, namely national provisions authorisation of PPP containing new active substances; mutual recognition and zoning; comparative assessment; data protection and data sharing; information duties. These options were identified on the basis of a review of the stakeholder comments from 2004 and 2005, in-depth interviews with various stakeholders and the Commission services and were agreed upon by the Inter-Services Steering Group set up to guide the assessment. The study performed by FCEC was based on data from the following sources: A review of existing studies and reports; comments by stakeholders from the consultation processes conducted by DG SANCO related to the revision of Directive 91/414/EEC; extensive consultation process with stakeholders conducted by the Contractor including a questionnaire survey of and in-depth interviews with competent authorities, industry, farmer organisations and other stakeholders.

In addition to the work performed by the consultant, in the period between December 2005 and March 2006, the Impact Assessment team has also carried out additional in-depth analysis of impact of the proposal on Administrative Burden on Member States' authorities as well as business operators. Authorities from 15 Member States, as well as 7 companies or group of companies have submitted their answers to detailed questionnaire and thus allowed estimation of Administrative costs resulting from the provisions of the proposal.

A fourth stakeholder consultation meeting took place on 25 January 2006. Stakeholders could contribute on the draft conclusions of the study and were offered a possibility to provide any further available data which could be relevant for the consultant. No additional data were submitted and the consultant concluded its study on 28 February 2006 (attached in Annex 2)

3. SECTION 2: PROBLEM DEFINITION

Plant protection products are used to protect plants or plant products against harmful organisms or prevent the action of such organisms, to influence the life processes of plants, to preserve plant products, to destroy undesired plants and to check or prevent undesired growth of plants.

Plant protection products contain substances that are deliberately released into the environment during use and lead to exposure of humans and the environment. Their use may involve risks and hazards for humans, animals and the environment, especially if placed on the market without having been officially tested and authorized and if incorrectly used. Therefore harmonized rules should be adopted on the placing on the market of plant protection products.

Council Directive 91/414/EEC ("the Directive") concerning the placing of plant protection products on the market entered into force in 25th July 1993 and provides for harmonised rules governing plant protection products and the active substances contained in those products.

After 13 years of experience gained from the application of the Directive and recent scientific and technical developments, it appears that the basic approach of the Directive is still acceptable but the system is overloaded and efficiency is not satisfactory. Therefore, it is deemed necessary to put in place some corrective measures made to adjust the policy on PPP to existing EU policies in the area, to improve the efficiency or/and to introduce some new policy actions while maintaining the basic principle which is the high level of protection of human and animal health and of the environment.

The need for improvement has been confirmed by the European Parliament[1] and the Council[2] in their recommendation as well as by stakeholders during the consultation period.

The proposal is affecting a number of stakeholders namely:

- Farmers and users of plant protection products
- Pesticide industry
- Consumers
- Member States
- General public

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1 Report A5-0155/2002 of 25 April 2002.

2 Report 15046/01 of 6 December 2001.

The way these are affected varies considerably for each stakeholder between and within individual measures proposed. A more detailed analysis of the current situation and the problems arising for the different stakeholders was part of an analysis conducted by an outside contractor and can be found in chapter 2 and 3 of the report which can be found in Annex 2 of this document. The main findings of the aforementioned report are summarized and presented in Section 4 hereafter.

The Commission is of the opinion that there is a need for action to be taken because otherwise the problems identified would evolve in a way that they jeopardize the principles and intentions of the Directive.

The Commission is acting on the basis of the rights conferred to her by the Treaty establishing the European Community and in particular Articles 37 (2) and 152 (4)(b).

The proposal is not in conflict with the basic principles that should guide the EU intervention, especially:

- with the subsidiarity principle, since the action by Member States only could lead to different levels of protection for human and animal health and for the environment. Recommendations or self-regulations would not guarantee a sufficient level of protection of human health or the environment. It could also risk creating additional burden to industry when different requirements would apply. Competition conditions between farmers would be unequal if availability of plant protection products is very diverse;

- with the proportionality principles, since the proposal fully harmonises the approval of active substances but leaves it to Member States to authorise PPP taking into account specific conditions of use.

4. SECTION 3: OBJECTIVES

In view of the problems outlined above, the main objectives are the following:

- Extend and deepen the single market, to ensure open and competitive markets inside and outside Europe, in conformity to the Lisbon Strategy;

- increase the efficiency of the system through simplification, better definition and streamlining of the procedures;

- increase the level of harmonisation throughout the EU;

- Present a text reflecting existing EU policy in the same subject area developed since the entry into force of Directive 91/414/EEC, and also taking into account the ongoing consultation process on a Thematic Strategy on the sustainable use of pesticides.

To achieve the main objectives several policy options have been identified. The policy options have been divided into two main categories and have further been grouped together to policy actions. The two categories are:

1. Those that are required to bring the current provisions of Directive 91/414/EEC in coherence with more recent EU policies. In addition, the working experience that has been gained so far showed that some of measures foreseen in the Directive were not sufficient to fulfil the objectives. Therefore, those provisions are adjusted in the current proposal in order to optimise them. The impacts of these prospective measures are assumed to be minor and therefore do not require a detailed evaluation. A list of these measures is compiled in Annex 5.

2. Those that during the consultation period with various stakeholders have been identified as deserving an in-depth discussion. Therefore, a more detailed analysis of their impact to the various stakeholders was performed. These constitute the so called "major policy options" discussed in Section 4 below.

EU policies that have been taken into consideration were the following:

- Council Regulation No 396/2005 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

- Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes

- Council Directive 2000/60/EC of 23 October 2000 establishing a framework for Community action in the field of water policy

- Council Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC

- Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work

- Draft Commission proposal on a Thematic Strategy for the Sustainable Use of Pesticides

- Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents

5. SECTION 4: POLICY OPTIONS

A new Regulation on plant protection products would amend and replace provisions already in place under Directive 91/414/EEC. This means that for some problems identified, this option would meet the need to develop new policy, which did not exist when Directive 91/414/EEC has been drafted. For other issues corrective measures to simplify procedures and to increase the efficiency would also be proposed.

The policy options are structured by grouping closely related policy options to "policy actions".

Policy Action 1: Authorisation of PPP containing a new active substance/ national provisional authorisation

Current problems

At the time that Directive 91/414/EEC was adopted, it was recognised that the Community evaluation process for active substances was lengthy and complex. To avoid delays in the introduction of PPP containing new active substance to the market, it was decided that Member States could grant a national provisional authorisation before a decision was made about the approval of the new active substance (inclusion in Annex I to the Directive) once the Member State has concluded that the active substance and the plant protection products can be expected to satisfy the Community conditions.

The system of national provisional authorisation has, however, led to a duplication of administrative efforts of competent authorities and applicants. Furthermore, the duration of the national provisional authorisation procedure differs significantly between Member States.

Differences in the timing of national provisional authorisations for the same product contribute to differences of availability in PPP between Member States markets. This can distort competition between farmers in different Member States and provide an incentive for unauthorised cross-border trade in PPP. Another problem is that under the current regime of national provisional authorisations, a PPP containing a new active substance is usually already on the market while the Community evaluation is continuing. This reduces the incentives for the applicant to quickly provide additional information requested during the Community evaluation and finalise the evaluation process for an approval as soon as possible.

Policy options

The following policy options are included in the Impact Assessment:

- *Option A:* No EU action (Status Quo): Centralised procedure for evaluation of new AS without binding time limits (*option A1*). No national provisional authorisation (NPA) after 2007 (*option A2*);

- *Option B:* Centralised procedure for evaluation of new active substances with binding time limits. No national provisional authorisation. Two alternative approaches are possible; a sequential authorisation, in which national PPP authorisation follows only after the decision on approval of active substance (*option B1*); or a parallel authorisation, in which national PPP authorisation is conducted during the evaluation of the active substance. The PPP authorisation would only come into force after the decision on approval of the new active substance (*option B2*);

- *Option C:* Keep national provisional authorisation after Draft Assessment Report.

Policy action 2: Mutual recognition of PPP containing an active substance already approved

Current problems

Directive 91/414/EEC contains an optional provision for Member States to mutual recognise PPP authorisations from other Member States (Article 10). Most Member States agree that the application of mutual recognition would save resources at national level and speed up authorisation procedures. However, so far there appear to be only three Member States that apply mutual recognition to a significant extent. Many companies decide to apply separately for authorisation of the same PPP in each Member State where the PPP is to be placed on the market rather than to apply for mutual recognition. All Member States where an application for the authorisation of the same PPP has been made then start the national authorisation procedure, which means a significant duplication of work.

Furthermore, the market for PPP in Europe is currently fragmented. The fragmentation of the PPP market, which is partly caused by the lack of mutual recognition or a more centralised authorisation, has led together with significant differences in VAT for PPP to price differences between EU Member States that are sufficiently high to be an incentive for the unauthorised cross-border sourcing of PPP.

Policy options

The following policy options are included in the Impact Assessment:

- *Option A:* No EU action (Status Quo): National evaluation and authorisation of PPP with optional mutual recognition;
- *Option B:* Zonal[3] evaluation and national authorisation of PPP with compulsory mutual recognition within the zone. No national risk mitigation measures;
- *Option C:* Zonal evaluation and national authorisation of PPP with compulsory mutual recognition within the zone. However, with national risk mitigation measures;
- *Option D:* Central agency for evaluation and authorisation of PPP with use of MS resources.

Policy action 3: Comparative assessment of PPP

Current problems

An approval of an active substance does not mean that the active substance is without risk to human health or the environment. An active substance can be approved if it can be demonstrated during the evaluation procedure that a specific use does not have a harmful effect on human or animal health or any unacceptable influence on the environment. To minimise the hazards and risks to health and environment from the use of pesticides is an EC policy objective and national minimisation strategies are currently already applied in several Member States. An economic reasoning for this type of a minimisation strategy is that negative impacts of PPP on the environment can lead to significant externalities. For example, studies indicate that annual cost of the Dutch drinking water industry to meet the criteria for pesticides of the Drinking Water Directive are 30 million Euro (average 2001-2003)[4], and annual costs of the UK drinking water industry related to pesticide removal are estimated at around 120 million Pounds[5].

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3 Zonal evaluation means, that the Member States with comparable agricultural and climatic conditions are grouped into one "zone", on the basis of expertise in Member States and the Commission.

4 Kiwa N.V Water Research 2004: Door drinkwaterbedrijven gemaakte kosten als gevolg van bestrijdingsmiddelgebruik, Nieuwegein, p. 3.

5 DEFRA 2003, Partial Regulatory Impact Assessment: Groundwater Proposals under Article 17 of the Water Framework Directive, p. 12.

Policy options

The following policy options are included in the Impact Assessment:

- *Option A:* No EU action (Status Quo): No provision for comparative assessment;
- *Option B:* Identification of candidates for substitution at the EU level based on hazard criteria. Comparative assessment of PPP at the national level;
- *Option C:* Comparative assessment for all PPP at national level when an application for the authorisation is made, independent from the hazard of the active substances.

Policy action 4: Data sharing for the renewal of approval of an active substance

Current Problems

Article 13 of Directive 91/414/EEC establishes rules on data protection and data sharing of active substances. Article 13 causes many problems, both for Member States and for the PPP industry.

One of the most problematic aspects of Article 13 for competent authorities is that despite the complexity of data protection issues, the provisions on data protection are very general. In addition to that, Article 13 is not supported by a recognised guidance document.

The combination of the ambiguity of Article 13 on the one hand and the lack of a clear, binding and recognised guidance document on the other hand, lead to various interpretations of data protection rules in different Member States. Currently, Article 13 leads to a high administrative burden for competent authorities. There are also lengthy discussions on which studies should be protected at renewal of approval (existing active substances).

Problems for companies involved in R&D on new active substances or defending existing active substances are not the same as for the generic industry. Problems for the R&D based industry are related to the lack of common practice at Member State level, lack of record keeping of authorities relevant for the determination of the protection status of studies, and a lack of clarity on protection status of new data on active substance level.

The major problem for generic producers in the EU is that data protection rules are working against generic competition and the market share of generic companies remains low in most EU countries. Approval of an active substance led in several Member States even to a reduction of generic competition because of data protection rules. However, available data on price trends on the European PPP market have up to now not given rise to concerns.

Policy options

The following policy options are included in the Impact Assessment:

- *Option A:* No EU action (Status Quo): 5 years of data protection starting with the renewal of approval. No provisions on compulsory data sharing;
- *Option B:* 5 years of data protection starting six month after the renewal of approval. Compulsory data sharing with compensation and an arbitration mechanism;
- *Option C:* No data protection period for renewal of approval;
- *Option D:* 5 years of data protection starting with the time of dossier submission for the renewal of approval. No provisions on compulsory data sharing. However, it would be compulsory for interested companies to cooperate to provide a joint dossier containing all additional data required to maintain an authorisation.

Policy Action 5: Informing neighbours on PPP use

Current Problems

Information availability on PPP use for neighbours and bystanders as well as for certain stakeholders (e.g. the drinking water industry) could be optimised and current evaluation and authorisation procedures are far from being transparent, according to the view of several stakeholders.

Neighbours and bystanders may perceive the application of PPP as a health risk, as they might come in contact with spray drift. A recent report by the Royal Commission on Environmental Pollution in the UK highlighted concerns in this respect to bystander protection. It recommends that records of PPP use should be available and residents living next to fields that are to be sprayed "be given prior notification of what substances are to be sprayed, where and when" [6].

[6] Royal Commission on Environmental Pollution 2005, Crop Spraying and the Health of Residence and Bystanders, p. 112.

Policy options

The following policy options are included in the Impact Assessment:

- *Option A:* No EU action (Status Quo): No duty to inform neighbours on use of toxic PPP.
- *Option B:* Active duty to inform neighbours on use of toxic PPP.
- *Option C:* Passive duty to inform neighbours on use of dangerous PPP.

None of the policy options examined under the policy actions above have been discarded at an early stage. Therefore, detailed analyses of economic, social and environmental impacts have been conducted and are presented in the following section.

6. SECTION 5: ANALYSIS OF IMPACTS

The analysis of impacts in this chapter is based on a questionnaire on Administrative Burden sent to Member States and industry (see Annex 1), an external report (see Annex 2), data delivered by key stakeholders (list of stakeholders consulted: see Annex 3) after the finalisation of the aforementioned report, information obtained in a public internet consultation (see Annex 4).

Policy Action 1: Authorisation of PPP containing a new active substance/ national provisional authorisation

Impacts on administrative burden

Abolishing National Provisional Authorisations (options A and B) reduces the duplication of administrative efforts for both industry and competent authorities, because the parallel evaluation of an active substance at national level during NPA would be prevented. Keeping NPA after the Draft Assessment Report (option C) would, to a significant extent, continue the current duplication of administrative efforts for applicants and authorities. This option could also lead to a continued lack of incentive for the applicant to finalise the approval procedure after national provisional authorisation is granted. It is predicted that main benefits fall with industry, with competent authorities affected to a lesser extent. None of the options are expected to have any direct impacts on the administrative burden of PPP users.

Impact on indirect costs for PPP users

The current situation (option A1) is not expected to lead to any negative or positive impact, while the abolition of NPA in 2007 (option A2) could have a negative impact on indirect costs for PPP users, if a very long authorisation procedure leads to a reduction of PPP – however, this concern is not undisputed. A sequential authorisation (option B1) could have a negative impact on similar grounds as option A2, but less significant. A parallel authorisation (option B2) does not affect the timeline of authorisation and is not expected to have any impact. Keeping NPA (option C) would be similar to A1 and is not expected to have any significant positive or negative impact, except a possible contribution to continuation of a fragmented European PPP market with related negative effects.

Impact on investment of PPP producers in R&D

The impacts on investment of PPP producers in R&D have been calculated with the help of a (discounted) cash flow model. With option A2 (no NPA after 2007 without binding time limits), product launch could be delayed by 5 years and 11 months compared to the status quo (option A1). According to the results of the model the economics and attractiveness of new product development would likely be severely negatively affected. With no NPA, binding timelines and sequential authorisation (option B1), time to product launch would be delayed by 1 year and 4 months compared to the status quo. However, with binding timelines and a parallel approach (option B2), time to product launch could be brought forward by 2 months compared to the status quo. This is similar to option C, which maintains the system of NPA after the Draft Assessment Report. Thus, under both options B2 and C the economics and attractiveness of new product (new active substance) development is not adversely affected.

Impact on EU PPP industry competitiveness

Option A2 would increase authorisation duration and would carry significant disadvantages for new product development. It would most certainly make many new ingredients' commercialisation unattractive. Option B would simplify the registration process. For option B to be competitiveness neutral, it is paramount that the proposed binding time limits are respected and the parallel approach is taken (option B2). Because the duration of the evaluation/authorisation process is dependent on the several institutions such as the Rapporteur Member State, EFSA and the Commission it is essential that the organisational feasibility and realistic character of the time limits be thoroughly verified. Option C would not involve any changes in competitiveness compared to the current situation, as the NPA system would be kept.

Impact on employment

Under option A2, the economics and attractiveness of new product development would likely be severely affected due to the delay in product launch. As a result, R&D based companies are likely to become more selective when deciding which active substances they should develop and this may have implications for employment in R&D. Option B1 was found to have a slightly negative impact on the economics and attractiveness of new product development. Consequently, some R&D based companies may become slightly more selective when deciding which active substances they should develop. This may have implications for employment in R&D, although to a lesser extent than option A2. It is likely that employment would remain relatively unaffected by options B2 and C.

Impact on information opportunities of citizens

No impact is expected under the different options.

Impact on the duplication of studies on vertebrate animals

No impact is expected under the different options.

Impact on unauthorised cross-border sourcing of PPP

The system of NPA is one of the factors contributing to the fragmentation of the EU PPP market. This fragmentation may lead to unauthorised cross-border sourcing of PPP, intensified by the differences in the duration of the national provisional authorisation procedure in different Member States. Therefore, slightly positive impacts under option B (and under option A2) are possible.

Impact of active substances on the environment or human health

Only minor impacts seem possible under all options. Under option A2 (without time limits, no NPA after 2007) the time to market could be delayed for new active substances that may have fewer impacts on the environment. A significantly longer authorisation procedure could also theoretically lead to incentives for unauthorised imports from non-EU countries, which are by definition a potential risk to environment and human health. This is under the condition that the respective new PPP would be available in third countries at an earlier stage. On the other hand, abolition of NPA could contribute to more homogenous national markets for PPP, which would reduce incentives for unauthorised import/use from other MS (options A and B). Binding time limits without NPA (option B) and keeping NPA after Draft Assessment Report (option C) would lead to a shorter duration of the evaluation procedure compared to option A2. This would reduce the time to market for new active substances that may have fewer impacts on the environment (especially option B2 and C). However, keeping NPA (option C) would continue to contribute to diverse national markets that could be an incentive for unauthorised import/use.

Policy action 2: Mutual recognition of PPP containing an active substance already approved

Impacts on administrative burden

The continuation of the status quo (option A) would mean the continuation of the current duplication of administrative efforts for competent authorities and industry, if the low rate of mutual recognition continues. However, there seems to be a (limited) trend towards more application of mutual recognition. Zonal authorisation of PPP without national risk mitigation measures (option B), can be expected to lead to a significant reduction of administrative burden for national authorities, provided that burden of dossiers' assessment is shared equally among all authorities within a zone. Also, some dossier costs for industry could be reduced compared to the status quo. Zonal authorisation of PPP with national risk mitigation measures (option C), could still be expected to lead to a significant reduction of administrative burden for national authorities, however less than in options B and D. Also a reduction of dossier costs expected for industry is likely compared to status quo (however less than in options B and D, as additional national requirements may have to be addressed). A central agency for evaluation and authorisation (option D) would most likely lead to a significant reduction of administrative burden for national authorities and a significant reduction of dossier costs for industry, as only one dossier for authorisation would have to be provided and a separate mutual recognition procedure would not be required. In this case however, one-off costs of setting up of an agency would have to be borne. None of the options are expected to have any direct impacts on the administrative burden of PPP users.

Impact on indirect costs for PPP users

The current situation in which PPP are authorised at the national level (option A) is not expected to lead to any negative or positive impact on availability of PPP, especially for minor uses, and consequently on indirect costs to farmers. Option B and C can be expected to increase availability of PPP for minor uses especially in smaller markets, depending on the willingness of the PPP industry to apply for mutual recognition. Farmers see an increased availability of PPP for minor uses as beneficial, e.g. in terms of being able to cultivate minor crops or even starting the cultivation of these crops. A larger availability of PPP could in some areas also lead to increased competition, implying a reduction of product prices. Option D can also be expected to increase availability of PPP for minor uses especially in smaller markets, without the need that PPP industry applies for mutual recognition. However, the actual number of authorisations would depend on the financial and staff resources provided to a central agency for PPP authorisation as well as the approach taken for authorisation.

Impact on investment of PPP producers in R&D

With mutual recognition, the most significant factor affecting the economics of new product (active substance) development would likely be the potential impact it would have on the date of product launch. As the survey among competent authorities indicated, there are diverging views on whether the duration of authorisation will decrease or increase for each of the individual options. However, the experience of Member States that currently apply mutual recognition to a significant extent does not indicate a risk for major delays. All three Member States having this experience did not expect a longer duration of the authorisation with options B and C. However, given the uncertainty surrounding the impact that mutual recognition would have on the duration of authorisation, conclusive statements concerning the impact of each option on the economics and attractiveness of new product (active substance) development cannot be made. Any delay would adversely affect the economics and attractiveness of new product development.

Impact on EU PPP industry competitiveness

National evaluation and authorisation (option A) is costly and complex, but flexible. It minimises risks for market size reduction through uniform application rates. Zonal authorisation – no national risk mitigation measures (option B) is a rather simple approach and lowers barriers to entry, as administrative efforts are reduced for applicants that want to reach an authorisation in several Member States. A market size reduction is likely if lower application rate is applied throughout entire zone. Zonal authorisation – with national risk mitigation measures (option C) may also lead to a market size reduction, but less so than under option B. A central agency for evaluation and authorisation (option D) requires significant resources at EU level. It can be expected to have the same impacts as option B, but on a larger scale.

Impact on employment

The results of the discounted cash flow model found that if mutual recognition would lead to a delay in authorisation this would adversely affect the economics and attractiveness of new product development with a possibility that employment in R&D may also theoretically be affected. The extent of this impact would be directly dependent on the length of the delay. However, as has been outlined above, the experience of Member States that currently apply mutual recognition to a significant extent does not indicate a risk for major delays.

Impact on information opportunities of citizens

No impact is expected under the different options.

Impact on the duplication of studies on vertebrate animals

Under Directive 91/414/EEC data sharing of vertebrate studies may be required by the Member States (Art. 13). This provision has led to different rules in Member States, which makes it difficult to assess the extent to which a duplication of vertebrate studies is actually taking place at present. The assessment is therefore provisional in character. It is estimated that options B, C, D have the potential to reduce the number of duplicated studies involving testing on vertebrate animals depending on the degree to which national legislation does not prevent this to happen currently and industry actually duplicates such tests – an issue on which no reliable data exists.

Impact on unauthorised cross-border sourcing of PPP

Both zonal authorisation with compulsory mutual recognition (options B and C) and central authorisation (option D) will by definition lead the more homogenous national markets. This is valid for the respective zones to the degree that industry uses this possibility and applies for mutual recognition in all member states of a zone. A centralised system will clearly lead to more homogenous national markets. A more homogenous market will reduce incentives for unauthorised cross-border sourcing of PPP, but only to the extent that price differences are also reduced. As the existing differences in VAT are one of the relevant factors, this is far from being definitive. Also, illegal imports from third countries may still be a problem especially for active substances that are not approved. This reduces likely possible impacts on unauthorised cross-border sourcing of PPP under options B, C and D.

Impact of active substances on the environment or human health

National evaluation and authorisation (option A) makes it much easier to take into account varying environmental conditions. However, the status quo will contribute to continuing incentives for unauthorised cross-border sourcing of PPP with the related potential risks. With the zonal approach without national risk mitigation measures (option B) some negative impacts may be expected because of the difficulty for one authority to take into account all environmental/climatic conditions in a zone. The risk of "zonal averaging" that does not take into account vulnerable hydrological and soil conditions cannot be ruled out. However, more homogenous markets in a zone would lead to fewer incentives for unauthorised cross-border sourcing of PPP with the related potential risks (option B and C). Zonal approach with national risk mitigation measures (option C) will make it easier to take into account variations in environmental conditions. With the central agency for evaluation and authorisation (option D) some negative impacts may be expected because of the difficulty for the agency to take into account all environmental/climatic conditions in a zone. However, more homogenous markets in a zone would lead to fewer incentives for unauthorised cross-border sourcing of PPP with the related potential risks (even more than in options B and C)[7].

Policy action 3: Comparative assessment of PPP

Impacts on administrative burden

The status quo - no provision for comparative assessment (option A) does not imply a change in administrative burden. At least in the short to mid-term it is expected that comparative assessment will mean an additional step in the authorisation procedure requiring additional staff input. In the long term, industry could be expected to place PPP on the market without risk of substitution, therefore requiring less administrative input by authorities. Identification of candidates for substitution at the EU level based on hazard criteria (option B) is expected to imply a significant increase of administrative burden for competent authorities, even more so comparative assessment at the national level independent from the hazard of the active substances (option C). This cost increase could only partially be mitigated by reduced number of applications for evaluation / authorisation resulting from decreased number of products on the market. However, comparative assessment may also provide the basis for functioning of compulsory mutual recognition and related gains in administrative burden. It is not expected that any of the options increase the costs of dossier submission for industry, if absolute and predictable criteria are used for comparative assessment. No increase of administrative burden is also expected for PPP users.

[7] It should be noted that in theory option D could also be combined with national risk mitigation measures, which would lead to a similar assessment as in option C.

Impact on indirect costs for PPP users

Comparative assessment (both options B and C) is expected to lead to a reduction of availability of PPP by a majority of competent authorities. A majority of other stakeholders share this view. Although this is not the experience of Sweden in applying comparative assessment, where the number of pesticide products was reduced at first but has since increased again to the previous level (for more details see Annex 2 of this report), comparative assessment may imply a shift from older, off-patent active substances to newer, patented active substances. This could increase the average price of PPP, as usually patented products are more expensive due to the lack of generic competition. There is no comprehensive price data available from Sweden. However, no major price increases are reported from Swedish stakeholders. In conclusion it can be said that comparative assessment (both options B and C) may reduce the market share of generic products and "older" products leading possibly to a price increase of PPP. However the extent to which this takes place in practice depends on the way comparative assessment is applied at the national level.

Impact on investment of PPP producers in R&D

With comparative assessment, the most significant factor affecting the economics of new product (meaning here: active substance) development would likely be attitude to risk. Any increase in perceived risk would be reflected in the use of higher discount rates to appraise potential investment in research and development. The extent to which comparative assessment affects a company's attitude to risk is likely to vary considerably between companies and even within companies. It is therefore difficult to make conclusive statements concerning the impact of each policy option on the economics and attractiveness of new product development. One factor that is likely to have significant influence on the attitude to risk is the number of active substances potentially affected by comparative assessment. Option A would not affect any active substance. Option B would only affect active substances that have been identified as candidate for substitution. Option C could potentially have impact on all active substances. Given that Option C is likely to be perceived as being more risky than Option B, which is likely to be perceived as being more risky than Option A, the greatest potential impact on investment of PPP producers in R&D are likely to be associated with Option C.

Impact on EU PPP industry competitiveness

The status quo, in which there is no provision for comparative assessment, is the most competitiveness friendly option. Option B may reduce the number of commercialised active substances and could reduce the market size. However, it drives innovation efforts towards hazard free substances. It may act in favour of some companies at the expense of others, depending of profile of their active substances. Option C can be expected to have the same effects as in Option B, but with a larger span of uncertainty for the industry.

Impact on employment

As noted above, the significant factor affecting the economics of new product development with comparative assessment would likely be attitude to risk. Given that option C is likely to be perceived as being more risky than option B, which is likely to be perceived as being more risky than option A, the greatest potential impact on (R&D) employment levels are likely to be associated with option C with the lowest impact associated with option A. No assessment can be made on the absolute size of these effects, as this would depend on the implementation of comparative assessment at the Member State level.

Impact on information opportunities of citizens

No impacts expected.

Impact on the duplication of studies on vertebrate animals

No impacts expected.

Impact on unauthorised cross-border sourcing of PPP

Comparative assessment can become a factor contributing to fragmented markets for PPP in Europe, depending on the national implementation. If comparative assessment were to be implemented very differently in neighbouring Member States, differences in availability of PPP could provide additional incentives for the unauthorised cross-border sourcing of PPP. It has, however, to be stressed that comparative assessment is only one of the factors affecting availability of PPP and cross-border sourcing of PPP. The impact of option B and C on unauthorised cross-border sourcing can be expected to be rather limited in nature compared to the other factors involved.

Impact of active substances on the environment or human health

Option A implies a continuation of the situation described in the problem analysis, i.e. the lack of flexibility in the legislative framework to implement PPP minimisation strategies. Option B provides a possibility for national minimisation strategies. A reduction of environmental impacts of active substance and an increase in safety margins for the protection of human health can be expected. The size of the impact depends on which active substances are identified as candidate for substitution and how comparative assessment is implemented in Member States. Option C can be expected to have similar impacts as option B, with an increased flexibility of Member States.

Policy action 4: Data sharing for the renewal of approval of an active substance

Impacts on administrative burden

The current data protection rules cause a very significant administrative burden for authorities. The status quo (option A) would not lead to the reduction of the current high administrative burden and may even increase as more active substances are approved. Data protection, with compulsory data sharing (option B), would lead to a reduction of burden for authorities, if authorities are not involved in arbitration process. The arbitration process may become an administrative burden for PPP industry, which is difficult to verify, as the procedure is untested. No data protection (option C) would lead to a significant reduction of administrative burden for both authorities and PPP industry; however, it may reduce the willingness of companies to defend active substances in the re-inclusion process. There is however also a small risk, that both option B and C, could lead to increased number of applications for evaluation / authorisation, thus creating additional burden on competent authorities. Data protection, with compulsory joint dossier of interested companies (option D) would lead to a reduction of the administrative burden for authorities, if authorities are not significantly involved in the mechanism for setting up the joint task force of companies.

Impact on indirect costs for PPP users

The status quo (option A) would not lead to increased numbers of PPP and a reduced market share of generic companies could in the mid to long term cause higher costs to PPP users. Data protection, with compulsory data sharing (option B) would lead to an increase in the market share of generic products and resulting lower prices for users, but may also imply a lower number of active substances on the market and possible resulting costs for users. No data protection (option C) can be expected to lead to a significant increase in the market share of generic products and resulting lower prices for users, but may also imply a significantly lower number of active substances on the market and possible resulting costs for users. With both option B and C it is not possible to assess the net effect of these two potentially contradictory trends at this stage. Data protection, with compulsory joint dossier of interested companies (option D), can be expected to lead to some increase in the market share of generic products or at least the continuation of the status quo, making price increases less likely, while at the same time safeguarding defence of active substances on the market. This makes increased costs for users unlikely.

Impact on investment of PPP producers in R&D

Under this policy action, the most significant factor affecting the economics of investing in studies for re-registration of active substances would be the potential loss of market share during periods where there is no data protection. Under all policy options, it remains according to the results of the discounted cash flow model profitable for a PPP producer to invest in studies for re-inclusion of an active substance. Under the assumptions of the model, the impact of data protection, with compulsory data sharing (option B) and no data protection period for renewal of approval (option C) on the economics and attractiveness of defending an active substance during re-inclusion are similar. The impact of a compulsory joint dossier (option D) was found to be most like the status quo (option A). However, the results are highly sensitive to the assumptions of the cost quantification model. This is because of the unpredictable nature of the marketing environment during the periods where there is no market exclusivity, compared to policy actions 1, 2 and 3 where the active substance is assumed to be protected by patent (for a detailed discussion of the limitations of the assessment regarding policy action 4 see Annex 2).

Impact on EU PPP industry competitiveness

The status quo (option A) gives high protection to owner of studies and keeps high entry barriers to generic manufacturers or new entrants, even more so as more active substances are approved. Option B reduces the protection enjoyed by initial registering companies, reduces the entry barrier for generic manufacturers and will lead to a more competitive market. It may, however reduce the profitability of some active substances, depending on the actual duration of data protection. Option C can be assessed similar to option B, with even stronger impact on reduction of entry barriers for generics and a resulting more competitive market. It may, however reduce the profitability of some active substances. Option D gives high protection to the owner of the studies but lowers the entry barriers for generic manufacturers or new entrants. Impact on competition depends on the details of the arrangements for joint task force and cost-sharing. According to industry, with implementation of option D a higher number of active substances would be defended compared to options B and C.

Impact on employment

Under all policy options, the discounted cash flow model suggests that it remains profitable for a PPP producer to invest in studies for re-registration for a ‘typical’ active substance. However, for those companies specialising in active substances for niche markets, option B and option C are more likely to adversely affect employment levels. In contrast, it is likely that employment would remain relatively unaffected with option D as, based on the assumptions used in the model, this option was found to be most like the status quo option A (no EU action). However, this policy action may generate significant positive effects on employment levels for generic companies, particularly small and medium sized enterprises. In this respect, reduced market exclusivity offered by policy options B and policy option C offer the greatest potential.

Impact on the duplication of studies on vertebrate animals

An overwhelming majority of competent authorities expects a significant reduction of the number of duplicated tests involving vertebrate animals with option B and C. As such, options B and C have the largest potential to reduce the number of duplicated studies involving testing on vertebrate animals, followed by option D. The degree to which a reduction of duplicated studies would take place in reality depends on the extent to which national legislation does not prevent this to happen currently and industry actually duplicates such tests – an issue on which no reliable data exists. The assessment is therefore provisional in character.

There is no impact expected on information opportunities to citizens, unauthorised cross-border sourcing of PPP, or on the environment and human health.

Policy Action 5: Informing neighbours on PPP use

Impacts on administrative burden

Measures under policy action 5 could result in an administrative burden for PPP users and authorities, but not for PPP industry. The extent of burden is however expected to remain insignificant. The main administrative burden of the measures under an active or a passive duty to inform neighbours on demand (respectively options B and C) would result for farmers that would have to apply the rules. Option B leads to an increased administrative burden for authorities and farmers, depending on the definition of "neighbour", "spray drift" and the actual application of the provision during national authorisation. Option C would lead to an increased administrative burden for authorities and farmers, but significantly less than in option B. The most time-consuming requirement (record keeping of PPP use) is already required under other measures.

Impact on information opportunities of citizens

By definition both options B and C will improve information opportunities of citizens. This is reflected in the assessment of most competent authorities. Option B was seen as being significantly more effective as option C. However, it has to be pointed out that this assessment refers to the impact on information opportunities. It cannot be assessed at this stage how the information provided would affect the awareness of neighbours on PPP use.

Impact of active substances on the environment or human health

The status quo, with no duty to inform neighbours (option A) does not lead to a reduction of impacts on the environment or human health. However, under an active duty to inform neighbours a reduction of negative impacts of active substances on environment or health is possible under two main scenarios, namely through a preference of farmers for less toxic products and through activities of bystanders to avoid exposure to spray drift after prior notification. The extent to which this actually would happen cannot be assessed at this stage. A passive duty to inform neighbours (option C) could lead to a reduction of negative impacts of active substances on environment or human health, depending on whether farmers would change type and application of PPP and adhere (more) to good agricultural practices because of increased accountability and enforcement. The extent to which this actually would happen cannot be assessed at this stage.

There is no impact expected on indirect costs for PPP users, investment of PPP producers in R&D, EU PPP industry competitiveness, employment, on animal welfare, or on unauthorised cross-border sourcing of PPP.

7. SECTION 6: COMPARING THE OPTIONS

This section sets out, how the current situation can be improved by making a legal proposal by the Commission which refelects the most favourable policy option, respectively.

Policy Action 1: Authorisation of PPP containing a new active substance /national provisional authorisation

The results of the assessment are summarised in table 1.

Table 1: Summary of impacts of alternative options for evaluation of new active substance / national provisional authorisation of PPP containing a new active substance

Type of impacts	**Option A**		**Option B**		**Option C**
Description of option	Status quo - <u>without</u> binding time limits. No NPA after 2007		<u>With</u> binding time limits. * * No NPA		Keep NPA after DAR
	A1 current	**A2** after 2007	**B1** sequential	**B2** parallel	
Economic impacts					
Impact on administrative burden	o	+ (may increase coord. efforts)	++	++	o
Impact on indirect costs for PPP users	o	(–) *	(o) * (minor negative impacts possible)	o	o (may contribute to fragmented market)
Impact on investment of producers in R&D	o	– –	–	o	o
Impact on PPP Industry competitiveness	o	– –	–	o	o
Social impacts					
Impact on employment	o	–	o	o	o
Impact on information opportunities	o	o	o	o	o
Impact on animal welfare	o	o	o	o	o
Environmental impacts					
Impact on unauthorised cross-border sourcing of PPP	o	o	o (slight reduction possible)	o (slight reduction possible)	o
Impact of AS on environment or human health	o	o (minor impacts possible)	o (minor impacts possible)	o (minor impacts possible)	o (minor impacts possible)

++ = Very significant positive impacts
−− = Very significant negative impacts
+ = Significant positive impacts
− = Significant negative impacts
o = No change from the present situation
Notes: * No final assessment possible at this stage. Negative impact only to be expected if increased time to market would lead to significant reduction of PPP
** All assessments are based on the timelines as implied by the binding time limits. Delays in the evaluation procedure could affect results of the assessment.

Potential for optimisation of options

The main means of optimisation conceived during the impact assessment is the introduction of a new option B2, which foresees a national authorisation procedure for a new PPP after the Draft Assessment Report in parallel with the peer review. This could imply that the authorisation comes into force directly after decision on approval and would therefore not increase the time to market for a new PPP, a crucial factor that determines the profitability of an investment in R&D. To reach the rather short binding time limits in some countries, increased staff capacities may be needed, according to competent authorities. However, in the long run the administrative burden is expected to be reduced.

An important question that was especially raised by industry is how to safeguard that the binding time limits foreseen under option B are respected in practice. During interviews and also in the survey to competent authorities the question was raised what sanctions or mechanisms could safeguard that time limits in the authorisation procedure are adhered to. Although most authorities did not think sanctions are a workable tool a number of proposals to safeguard the binding time limits was received, including a more streamlined procedure, clear data requirements for applicants, and fee reduction in case of delays. Other parties generally thought sanctions not workable, but proposed additional measures to streamline the approval procedure, including an independent review of the approval process to detect potential for speeding up the process an the introduction of an online tracking system for the applicant to be able to follow the status of the evaluation process. It can also be expected that a major factor for keeping binding time limits is the increased significance of the approval process under this option. This will in itself lead to increased pressure on applicants and authorities to speed up the procedure.

Analysis of current situation and justification of the proposal

The current system provides that provisional authorizations can be granted for products containing new active substances after the Commission has adopted a formal Decision that the dossier is complete, based on a report of the rapporteur Member State.

The draft Regulation would remove provisional authorizations because it is not compatible with zonal mutual recognition of authorisations. Also, it is no longer possible with the new Regulation on maximum residue levels (MRLs) to set provisional MRLs at Member State level before approval. On the other hand, provisions are introduced to speed up decision making on active substances and plant protection products and by setting deadlines for the various steps of the procedure.

The Impact Assessment (IA) confirms that there would be a major reduction on the administrative burden. There would be no negative impact on R&D industry provided there are binding timelines for the evaluation and that Member States can already start to evaluate plant protection products in parallel to the peer review. Both recommendations are included in the draft Regulation and it is foreseen a considerable simplification, an increase in the efficiency of the system and a better harmonisation throughout the EU.

Proposal: It is proposed to remove the option of national provisional authorisations.

Policy action 2: Mutual recognition of PPP containing an active substance already approved

The results of the assessment are summarised in table 2.

Table 2: Summary of impacts of alternative options for mutual recognition of PPP containing an active substance already approved

Type of impacts	Option A	Option B	Option C	Option D
Description of option	Status quo - National evaluation and authorisation	Zonal authorisation – no national risk mitigation measures	Zonal authorisation – with national risk mitigation measures	Central agency for evaluation and authorisation*
Economic impacts				
Impact on administrative burden	o	++	+	++
Impact on indirect costs for PPP users	o	+ (increased availability of PPP)	+ (increased availability of PPP)	+ (increased availability of PPP, depending on approach of agency)
Impact on investment of PPP producers in R&D	o	o (negative impact, if unclear procedures lead to delays)	o (negative impact, if unclear procedures lead to delays)	o
Impact on PPP industry competitiveness	o	o (minor impacts possible)	o (minor impacts possible)	+ (lower barriers to entry)
Social impacts				
Impact on employment	o	o	o	o
Impact on information opportunities	o	o	o	o
Impact on animal welfare	o	(+)**	(+)**	(+)**
Environmental impacts				
Impact on unauthorised cross-border sourcing of PPP	o	+ (more homogenous markets)	+ (more homogenous markets)	+ (more homogenous markets)
Impact of AS on environment or human health	o	– (difficulty to take into account all environ-mental conditions)	o	– (difficulty to take into account all environ-mental conditions)

++ = Very significant positive impacts
−− = Very significant negative impacts
+ = Significant positive impacts
− = Significant negative impacts
o = No change from the present situation
Notes: * Staff and financial resources provided to a central agency affects the assessment significantly. For this assessment it has been assumed that the agency would have access to adequately financial and staff resources.
** Assessment only provisional, as no reliable data exists on the extent to which vertebrate studies are duplicated at present.

Potential for optimisation of options

In the framework of this impact assessment the following measures could be identified to optimise the options:

- The diverging views on the possible impacts of a zonal approach on the duration of the authorisation indicates the need to clarify procedural details for compulsory mutual recognition and related procedures, including the withdrawal of authorisation (relevant for options B and C);

- Under options B and C as much parallel authorisation activities as possible could be done to speed up authorisation, similar to the parallel approach discussed in the context of policy action 1. For example, national authorities could already decide on national risk mitigation measures after the designated Member State provides a draft registration report, i.e. before the first authorisation of the product in the designated Member State;

- One of the factors providing incentives for unauthorised cross-border sourcing of PPP are differences in VAT among Member States, reportedly of up to 17%. This is especially significant, as in some Member States not all farmers are required to apply formal financial bookkeeping but can deduct costs on a fixed rate basis, which means that the difference in taxes is net saving for a farmer involved in unauthorised cross-border sourcing of PPP. It is strongly recommended to harmonise VAT in the area of PPP to reduce incentives, as unauthorised cross-border sourcing of PPP constitutes a potential risk for the environment and human health.

Analysis of current situation and justification of the proposal

In the current system, mutual recognition is obligatory if agricultural, environmental and plant health conditions are comparable. With the agreement of the applicant, non-comparable conditions can lead to modifications of the authorisations.

Member States accept zonal evaluation but want to keep national authorisations. Industry is not in favour. NGOs and some Member States want that particular environmental conditions can be taken into account and excluded fro mutual recognition. Farmers want a further harmonisation and support the zonal system, which they welcome as a step towards a completely centralised authorisation.

The IA indicates that zonal mutual recognition reduces trans-border movement of non authorised products. The option preferred by most Member States would leave still the possibility for Member States to impose specific risk mitigation measures at national level. It is expected that proposed measure will contribute to a great extend to the simplification of the system, increased efficiency and harmonisation throughout the EU.

Finally, an interesting point that was identified from the impact assessment was the harmonisation of VAT for plant protection products sold in different Member States. The same issue was examined under the "Thematic Strategy for Sustainable Use of Pesticides". Therefore, it was decided not to take that on board since it will be addressed by another EU policy.

Proposal: It is proposed that mutual recognition becomes the norm and that Member States within a zone could only amend the authorisations in accordance with already existing legislation on the protection of the health of distributors, users or workers. The recommendations from the IA in relation to information of neighbours (see below) have also been taken on board.

Policy action 3: Comparative assessment of PPP

The results of the assessment are summarised in table 3.

Table 3: Summary of impacts of alternative options for comparative assessment of PPP

Type of impacts	Option A	Option B	Option C
Description of option	Status Quo - No provision for comparative assessment	Identification of candidates for substitution at the EU level based on hazard criteria.	Comparative assessment at national level independent from the hazard of the AS
Economic impacts			
Impact on administrative burden	o	– (depending on implementation)	–/– – (depending on implementation)
Impact on indirect costs for PPP users	o	o / – (depending on implementation)	o / – (depending on implementation)
Impact on investment of PPP producers in R&D	o	(o / –)* (depending on implementation)	(o / –)* (depending on implementation)
Impact on PPP industry competitiveness	o	+ / – (depending on implementation, positive impacts on innovation possible)	o / – (depending on implementation, positive impacts on innovation possible)
Social impacts			
Impact on employment	o	(o / –)* (depending on implementation)	(o / –)* (depending on implementation)
Impact on information opportunities	o	o	o
Impact on animal welfare	o	o	o
Environmental impacts			
Impact on unauthorised cross-border sourcing of PPP	o	o (minor negative impacts possible)	o (minor negative impacts possible)
Impact of AS on environment or human health	o/– (In some MS negative impacts possible compared to current situation)	+/++ (depending on implementation)	+/++ (depending on implementation)

++	=	Very significant positive impacts
−−	=	Very significant negative impacts
+	=	Significant positive impacts
−	=	Significant negative impacts
o	=	No change from the present situation

Note: * Depending on subjective factors such as risk perception of PPP companies. May therefore also differ between companies and cannot finally be assessed at this stage.

Potential for optimisation of options

The more comparative assessment is based on predictable criteria, the more it gets in line with the very idea of European PPP policy – the idea of a positive list of active substances, which has been accepted from all parties involved. On the other hand, if comparative assessment was to be implemented in a way that a new product in the pipeline could be made worthless because of a product with a better environmental profile under development at the same time by a competitor, this would constitute an obvious horror scenario for industry. Such a system would by definition not be predictable and could constitute a risk for R&D investment which is very difficult to quantify. Defining criteria to identify active substances as candidates for substitution (option B) is therefore an element of safeguarding predictability. If option B was chosen, negative impacts on R&D for new active substances could be minimised by applying criteria for identification as candidate for substitution that are:

- Science based – so the regulatory action is legitimised by addressing external effects, including by applying the precautionary principle;
- Predictable – so that perceived investment risk decreases;
- Measurable – so that they can be assessed during the R&D phase;
- Early identifiable – the earlier in the R&D phase that criteria can be assessed the better;
- Absolute – criteria should not refer to relative disadvantages of other (individual) active substances, but rather to fixed threshold values or average values of all approved active substances that can be easily calculated and are not subject to short or medium term change (< 5-10 years).

Additionally, predictability could be increased by providing detailed guidance for Member States how to implement comparative assessment, which would also minimise the risk of unintended incentives for unauthorised cross-border sourcing of PPP.

Finally, as comparative assessment and national minimisation strategies come with a cost for administrations, users and farmers, possible gains for society from these measures have to be documented. A beneficial consequence of comparative assessment should preferably be documented by models or measurements pointing to a reduction of relevant PPP residues, e.g. in drinking water resources, a reduction of human exposure or health risks. On the other hand, possible negative impacts of comparative assessment that are reasons for concern for several stakeholders, e.g. in the area of resistance management, should be monitored to adapt criteria and/or implementation guidelines, if necessary.

Analysis of current situation and justification of the proposal

There are no provisions on comparative assessment in the current system.

The draft Regulation provides comparative assessment for substances which would be identified at EU level as candidates for substitution. There would be an obligation to do comparative assessment and substitution at Member State level on products containing such substances.

The IA indicates that there would be negative impact on administrative burden, on indirect costs for users, on industry, on employment depending on implementation, but very positive impact on human health and the environment. The IA identifies that the negative effects can be mitigated if the system is predictable. This can be achieved by foreseeing clear criteria for identification of such substances, which have included in the proposal. With the proposed measure it is expected a better definition and streamlining of the procedures.

Proposal: Identification at EU level of substances candidates for substitution and comparative assessment of plant protection products at national level. Clear criteria are also foreseen for identification of substances candidates for substitution.

Policy action 4: Data sharing for the renewal of approval of an active substance

The results of the assessment are summarised in table 4.

Table 4: Summary of impacts of options for data sharing for the renewal of approval

Type of impacts	***Option A***	***Option B***	***Option C***	***Option D***
Description of option	Status quo	Compulsory data sharing	No data protection	Compulsory joint dossier
Economic impacts				
Impact on administrative burden	–	+ (depending on implementation)	++	+ (depending on implementation)
Impact on indirect costs for PPP users	–	+ / o (lower prices, may also lead to lower number of AS)	+ / – (lower prices, but may also lead to significantly lower number of AS)	o
Impact on investment in studies for re-registration of an AS	o	(–)* (however: remains profitable to invest)	(–)* (however: remains profitable to invest)	(o)*
Impact on PPP industry competitiveness	– (high entry barriers)	+ / – (lower entry barriers, less profitability)	+ / – (lower entry barriers, less profitability)	+ / o (lower entry barriers, depending on implementation)
Social impacts				
Impact on employment (R&D based companies)	o	o /– (depending on reduction in profitability)	o /– (depending on reduction in profitability)	o
Impact on employ-ment (generics)	–	+	+	o
Impact on inform. opportunities	o	o	o	o
Impact on animal welfare	o	(++)**	(++)**	(+)**
Environmental impacts				
Impact on unauthor. cross-border trade	o	o	o	o
Impact of AS on environment / health	o	o	o	o

++	=	Very significant positive impacts
––	=	Very significant negative impacts
+	=	Significant positive impacts
–	=	Significant negative impacts
o	=	No change from the present situation
Note:	*	Results are highly sensitive to model assumptions.
	**	Assessment only provisional, as no reliable data exists on the extent to which vertebrate studies are duplicated at present.

Potential for optimisation of options

The main criteria for setting up a new framework for data protection should be to reduce the administrative burden for authorities and industry, create legal clarity and lower entry barriers for generic companies and new entrants. For this aim, the legal provisions would have to be accompanied by detailed guidelines for either arbitration procedures or setting up compulsory joint task forces, if option B or D was to be chosen. Some other measures could be taken to ease the administrative burden related to data protection. A significant concern related to data protection is the date when exactly the initial authorisations of PPP were given and which studies were used. This could be addressed by a central database at EU level, in which new studies would have to be registered by the applicant and receive an identification code for the study. After a transition period data protection would only apply to registered studies. During the authorisation procedure, Member States would communicate the identification code together with the date of authorisation of the related PPP to the central database at EU level, which would remove any difficulty to identify the first use of the study at a later stage.

Analysis of current situation and justification of the proposal

The current system provides for 10 years data protection for new active substances and 5 years for existing substances for data necessary for their approval (inclusion in Annex I to the Directive) or renewal of this approval. There is no obligation for data sharing, but companies may share data. Member States may impose sharing of data on vertebrates, but only a few Member States apply this provision.

The IA examined the effects of amendments for the data protection at renewal of approval, because that is the contested part of the data protection. The main impact is not due to the actual costs of the studies, but to the dominant position that data protection gives to those companies which are owners of the initial dossier. Option C is the most favourable option since it still allows a profitable investment, but at the same time maximises the positive impacts on administrative burden for national authorities and the industry, industrial competitiveness and employment as well as animal welfare.

The option of no data sharing shows also a reduction of administrative burden compared to the option with compulsory data sharing. Although a decrease in the number of active substances might occur, due to a lower NPV for the developer of an active substance, the number of formulated products will probably increase due to a higher incentive to develop improved formulations after the first renewal of approval.

Proposal: It is proposed to simplify the system. Data protection for 10 years after the first authorisation is maintained. This will mean 10 years exclusivity for new substances (as is the case today) and 10 years exclusivity for new authorizations (new formulation or new use, as is already the case now).

All provisions on data protection at renewal of approval are removed.

Also, studies on vertebrates may not be repeated.

Companies can agree between themselves on the sharing of vertebrate data and the cost thereof. If they do not agree, Member States use the data anyhow for a second applicant and companies have to go to national courts if they want to be compensated.

Policy Action 5: Informing neighbours on PPP use

The results of the assessment are summarised in table 5.

Table 5: Summary of impacts of alternative options for informing neighbours on PPP use

Type of impacts	*Option A*	*Option B*	*Option C*
Description of option	Status quo – No duty to inform neighbours	Active duty to inform neighbours	Passive duty to inform neighbours
Economic impacts			
Impact on administrative burden	o	– (depending on implementation)	o (minor negative impacts possible)
Impact on indirect costs for PPP users	o	o	o
Impact on investment of PPP producers in R&D	o	o	o
Impact on PPP industry competitiveness	o	o	o
Social impacts			
Impact on employment	o	o	o
Impact on information opportunities	o	+	+
Impact on animal welfare	o	o	o
Environmental impacts			
Impact on unauthorised cross-border sourcing of PPP	o	o	o
Impact of AS on environment or human health	o	(+) (positive impacts possible, extent not possible to assess)	(+) (positive impacts possible, extent not possible to assess)

++ = Very significant positive impacts
–– = Very significant negative impacts
\+ = Significant positive impacts
– = Significant negative impacts
o = No change from the present situation

Potential for optimisation of options

Policy action 5 raises concerns with respect to the objectives of the intervention:

- If the aim is to raise public awareness for use of toxic PPP, then option B might be the most effective. However, questions have been raised as to what the public will do with this information, what mechanisms for action are possible, and if it is possible to request farmers to delay spraying and to use of alternative PPP;

- If the aim is to reduce the use of toxic PPP, comparative assessment and substitution performed during the authorisation process (policy action 3) may be a better tool;

- If the aim is to increase the transparency of PPP use and accountability of farmers in general, option C seems to be adequate. Implementation details will need to be determined as to who should have access to farmer's records.

To optimise the options it is recommended to clarify the objectives and the related concerns raised above. This discussion could take place in a general discussion on the transparency of PPP authorisation and use. A general approach on transparency in PPP authorisation and use should be considered, including a more transparent evaluation process, a structured inclusion of stakeholder comments in the process, record keeping for all PPP used and possibly a duty to inform neighbours and relevant third parties, depending on the objectives of the intervention.

Analysis of current situation and justification of the proposal

There are no provisions on information of neighbours in the current system.

The IA identified negative impacts on the administrative burden but possible positive impact on human health and the environment and on transparency. The suggestions made to improve the provision by combining a passive obligation for information (record keeping of products used and availability of this to interested parties) with the active obligation to inform neighbours who express an interest to be informed before spraying.

Proposal: It is proposed that the authorisation may provide for an obligation to inform neighbours who notified their interest to be informed. Moreover records have to be kept by farmers on all plant protection products used and to be made available on request to neighbours and the drinking water industry.

8. SECTION 7: MONITORING AND EVALUATION

The effective monitoring of the new legislation on PPP authorisation requires an evaluation at regular intervals. For this purpose, it is necessary to put a system in place to carry out regulatory monitoring.

It is proposed to use the following indicators for monitoring and evaluation of the future system:

Problem	Potential Indicator	Data Source	Rationale
Duration of evaluation procedure	Average time for evaluation of new active substance / re-inclusion of active substance	EC	Approval evaluation process should speed up with the new legislation / Binding timelines need to be monitored
	Average time for granting authorisations at Member State level	Member States	Aim is to monitor the respect of the deadlines introduced
Duplication of administrative efforts for PPP authorisation	Number of PPP of similar composition authorised in different MS within the same zone and between different zones	Member States	It is giving an overview of the effectiveness of the new measures proposed for zonal authorisation of PPP's
Availability of PPP	Availability of PPP and alternative methods of pest control for minor uses and resistance management in Member States	Member States/ Farmers' organisations	Aim is to provide a sufficient number of PPP and alternative methods of pest control for minor uses and resistance management in Member States
Reduction of health risks	Availability of low risk PPP's	Member States	Aim is to monitor the effectiveness of the new measures introduced
	Number of PPP's for which comparative assessment provisions have been applied	Member States	Aim is to monitor the effectiveness of the new measures introduced
Influence on competition and innovation	Number of available products containing the same active substance for similar crops/uses	Member States	Aim is to safeguard sufficient level of competition as a requirement for a competitive industry and low prices for PPP users.
	Number of new substances approved and plant protection products authorised containing new substances	Member States/EU	Aim to monitor innovation in the EU following the introduction of new provisions on data protection.