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

Annex 2, part 1

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Annex 2

Report from FCEC (Food Chain Evaluation Consortium)

European Commission
Directorate General for Health and Consumer Protection

Impact assessment of options for a Regulation replacing Directive 91/414/EEC on plant protection products

Final Report

Implementing framework contract for evaluation
impact assessment and related services; Lot 3 (Food Chain)
Contract ref. CS02/2005/D3/SI2.415759

Submitted by:

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Impact assessment of options for a Regulation replacing Directive 91/414/EEC on plant protection products

Final Report

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of the Food Chain Evaluation Consortium (FCEC)

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Contents

EXECUTIVE SUMMARY

The European Commission intends to replace Council Directive 91/414/EEC on the placing of Plant Protection Products (PPPs) on the market with a new Regulation. Due to the importance of the new legislative basis for the European PPP sector DG SANCO decided to commission a study to the Food Chain Evaluation Consortium to provide the basis for an Impact Assessment in line with the requirements laid down in the Communication on Impact Assessment and in the recently revised Impact Assessment Guidelines. This report presents 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 basis of a review of 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. This study is 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.

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 inclusion of the new active substance in Annex I 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 Annex I evaluation process 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 Annex I inclusion 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 Annex I inclusion of the new active substance (*option B2*);
- *Option C:* Keep national provisional authorisation after Draft Assessment Report.

Impact assessment of policy options

1.1.1.1. Impacts on administrative burden

Abolishing NPA (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 DAR (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 Annex I inclusion after national provisional authorisation is granted. None of the options are expected to have any direct impacts on the administrative burden of PPP users.

1.1.1.2. 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.

1.1.1.3. 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 11 months compared to the status quo (option A1). According to the results of the model the economics and attractiveness of new product (active substance) 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. Under this option, the economics and attractiveness of new product development is only slightly affected. 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 (for a detailed discussion of the assessment regarding policy action 1 see page 98 to 102).

1.1.1.4. 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.

1.1.1.5. 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.

1.1.1.6. Impact on information opportunities of citizens

No impact is expected under the different options.

1.1.1.7. Impact on the duplication of studies on vertebrate animals

No impact is expected under the different options.

1.1.1.8. 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 (see also below).

1.1.1.9. 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.

The results of the assessment are summarised in the following table:

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 - without binding time limits. No NPA after 2007		With 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
+ = Significant positive 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 inclusion in Annex I 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 Annex I inclusion procedure, including an independent review of the Annex I evaluation process to detect potential for speeding up the process and 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 Annex I inclusion process under this option. This will in itself lead to increased pressure on applicants and authorities to speed up the procedure.

Policy action 2: Mutual recognition of PPP containing an active substance already included in Annex I

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 only three Member States of the 22 responding to the survey 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 launched 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 evaluation and national authorisation of PPP with compulsory mutual recognition. No national risk mitigation measures;
- *Option C:* Zonal evaluation and national authorisation of PPP with compulsory mutual recognition. However, with national risk mitigation measures;
- *Option D:* Central agency for evaluation and authorisation of PPP with use of MS resources.

1.1.1.10. 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. 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 for industry is likely compared to the 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. None of the options are expected to have any direct impacts on the administrative burden of PPP users.

1.1.1.11. 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.

1.1.1.12. 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.

1.1.1.13. 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.

1.1.1.14. 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.

1.1.1.15. Impact on information opportunities of citizens

No impact is expected under the different options.

1.1.1.16. 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.

1.1.1.17. 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 included in Annex I. This reduces likely possible impacts on unauthorised cross-border sourcing of PPP under options B, C and D.

1.1.1.18. 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)[1].

The results of the assessment are summarised in the following table:

[1] 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.

Table 2: Summary of impacts of alternative options for mutual recognition of PPP containing an active substance already included in Annex I

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
+ = Significant positive 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 adequate 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.

Policy action 3: Comparative assessment of PPP

Current problems

An inclusion of an active substance in Annex I of Directive 91/414/EEC does not mean that the active substance is without risk to human health or the environment. An active substance can be included in Annex I of Directive 91/414/EEC if it can be demonstrated during the evaluation procedure that a specific use does not have "any unacceptable influence" on the environment. Acceptable environmental impacts may be expected with PPP use, and what precisely is an "unacceptable influence" can be subject to dispute. The inclusion in Annex I is therefore based on minimum criteria concerning environmental impacts, but does not provide a mechanism to minimise environmental impacts below these levels. 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, notably in Sweden and some other Nordic countries. 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)[2], and annual costs of the UK drinking water industry related to pesticide removal are estimated at around 120 million Pounds[3].

Policy options

The following policy options are included in the Impact Assessment:

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

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

- *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 (Annex ID). 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.

Impact assessment of policy options

1.1.1.19. 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). 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.

1.1.1.20. 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. However, 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 (see Annex B of this report). Comparative assessment may imply a shift from older, off-patent active substances to newer, patented active substances. This could theoretically 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. 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.

1.1.1.21. Impact on investment of PPP producers in R&D

With comparative assessment, the most significant factor affecting the economics of new product (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 included in Annex ID. 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.

1.1.1.22. 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.

1.1.1.23. 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.

1.1.1.24. Impact on information opportunities of citizens;

No impacts expected.

1.1.1.25. Impact on the duplication of studies on vertebrate animals

No impacts expected.

1.1.1.26. 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.

1.1.1.27. 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 included in Annex ID 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.

The results of the assessment are summarised in the following table:

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
+ = Significant positive 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 include active substances in a separate Annex ID 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 inclusion in Annex ID 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 criteria 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 active substances included in Annex I 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 may come with a cost for administrations, industry 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.

Policy action 4: Data sharing for the renewal of Annex I inclusion of an active substance

Current problems

Article 13 of Directive 91/414/EEC establishes rules on data protection and data sharing of active substances. Fifteen years after implementation of the Directive, Article 13 has caused 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. 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 Annex II data. 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. Annex I inclusion 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 Annex I inclusion. No provisions on compulsory data sharing;
- *Option B:* 5 years of data protection starting six month after the renewal of Annex I inclusion. Compulsory data sharing with compensation and an arbitration mechanism;
- *Option C:* No data protection period for renewal of inclusion in Annex I;
- *Option D:* 5 years of data protection starting with the time of dossier submission for the renewal of Annex I inclusion. 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.

Impact assessment of policy options

1.1.1.28. 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 included in Annex I. 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. 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.

1.1.1.29. 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.

1.1.1.30. Impact on investment of PPP producers studies for re-inclusion of an active substance

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 inclusion in Annex I (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 assessment regarding policy action 4 see page 145 to 148).

1.1.1.31. 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 included in Annex I. 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.

1.1.1.32. 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.

1.1.1.33. Impact on information opportunities of citizens

No impact expected.

1.1.1.34. Impact on animal welfare

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.

1.1.1.35. Impact on unauthorised cross-border sourcing of PPP

No impact expected.

1.1.1.36. Impact of active substances on the environment or human health

No impact expected.

The results of the assessment are summarised in the following table:

Table 4: Summary of impacts of options for data sharing for the renewal of Annex I inclusion

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
+ = Significant positive 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.

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 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."[4]

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.

Impact assessment of policy options

1.1.1.37. Impacts on administrative burden

Measures under policy action 5 could result in an administrative burden for PPP users and authorities, but this is not expected for PPP industry. 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

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

farmers, but significantly less than in option B. The most time-consuming requirement (record keeping of PPP use) is already required under other measures.

1.1.1.38. Impact on indirect costs for PPP users;

No impact expected.

1.1.1.39. Impact on investment of PPP producers in R&D;

No impact expected.

1.1.1.40. Impact on EU PPP industry competitiveness

No impact expected.

1.1.1.41. Impact on employment

No impact expected.

1.1.1.42. Impact on animal welfare

No impact expected.

1.1.1.43. 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.

1.1.1.44. Impact on unauthorised cross-border sourcing of PPP

No impact expected.

1.1.1.45. Impact of active substances on the environment or human health

It is questionable whether information provided to neighbours can have an impact 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.

The results of the assessment are summarised in the following table:

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
+ = Significant positive 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 of farmers a delay of spraying and 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 farmers‘ 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.

1.2. Aims of the study

The European Commission intends to revise Council Directive 91/414/EEC on the placing of Plant Protection Products (PPPs) on the market. It is planned that a new regulation replaces this directive as well as Council Directive 79/117/EEC on prohibiting the placing on the market and use of plant protection products containing certain active substances. In this process a Proposal for a Regulation of the European Parliament and of the Council concerning the placing of plant protection products and adjuvants on the market has been drafted. DG SANCO as responsible Directorate General has already conducted three stakeholder dialogues in 2002, 2004 and 2005 and an Internet Public Consultation. Due to the importance of the new regulation for the European PPP sector DG SANCO decided to additionally commission a study to the Food Chain Evaluation Consortium led by Civic Consulting to provide the basis for an Impact Assessment in line with the requirements laid down in the Communication on Impact Assessment[5] and in the recently revised Impact Assessment Guidelines[6]. An explicit aim of the study was to

- Clearly define the problems which will be addressed;
- Set out and assess economic, environmental and social impacts of key elements;
- Collect additional evidence with respect to impacts on the market structure, competitiveness, employment, investment, administrative burden etc.;
- If possible, provide more quantitative evidence.

This report presents the economic, environmental and social impacts of options related to the revision of Directive 91/414/EEC in five focus areas:

1. National provisions authorisation of PPP containing new active substances;
2. Mutual recognition and zoning;
3. Comparative Assessment;
4. Data protection and data sharing;
5. Information duties.

1.3. Approach and data sources

Throughout the process of the Impact Assessment, careful analysis of data has been based on the following resources:

- Literature review of existing studies and reports of the European Commission including recent studies and impact assessments;
- Review of existing studies and reports by government institutions, academic institutions and other independent experts;

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5 COM(2002) 276.

6 SEC(2005) 791.

- Comments by stakeholders from the consultation processes conducted by DG SANCO related to the revision of Directive 91/414/EEC;
- Expert and stakeholder interviews;
- Questionnaire survey of competent authorities and other stakeholders, supplemented by in-depth interviews with the competent authorities of 12 Member States.

The results presented in this report are mainly based on a qualitative analysis of the relevant impacts, based on the sources listed above, supplemented by a quantitative analysis of the impacts of the policy options on the economics of new product development (see description of methodology in Annex A of this report). Please note that quotes of comments by stakeholder organisations given without explicit source refer to the consultation questionnaires returned by these organisations.

1.4. Structure of Report

The report is structured as follows: Section 2 provides background information about PPP authorisation as well as the market as a whole in respect to its global competitive position, its recent growth and dynamics. Section 3 highlights perceived problems and circumstances involved with the current application of Directive 91/414/EEC. Problems that are dealt specifically with are: (1) problems related to the evaluation procedure for new active substances and national provisional authorisation; (2) problems related to the authorisation procedure for PPP containing active substances already including in Annex I; (3) problems related to environmental and health impacts of PPP; (4) problems related to data protection and sharing; (5) problems related to information availability on PPP authorisation and use. Section 4 defines policy objectives relevant for new legislation replacing Directive 91/414/EEC and determines related impact areas. Section 5 defines the different policy actions to address the previously defined problems of the current legislation. Section 6 is the impact assessment of policy actions and for each policy action different options are analysed according to their economic, social and environmental impacts. Finally, Section 7 discusses monitoring and evaluation. Following this is the Annex with details concerning the methodology applied for analysing the economics of new product development, the Swedish experience with comparative assessment, a list of stakeholders that provided an answer to the consultation questionnaire and finally, the questionnaire used during the consultation with stakeholders.

1.5. Acknowledgments

This study would not have been possible without the contribution and support from many sides. The expert team would like to use this opportunity to express their gratitude to all supporters: experts of national competent authorities and stakeholders participating in the interviews, who were willing with great patience to discuss the subject in depth. This is especially true for all organisations and individual persons that provided data related to the analysis of the current situation, which proved to be a very time consuming exercise. DG SANCO of the European Commission supported the authors through the provision of documents and background information. The Inter-Services Steering Group set up for the assessment provided valuable guidance. The authors are especially grateful to all respondents to the stakeholder surveys, in which they provided thoroughly and competently their data and expertise within a very short timeframe. The authors were

impressed and grateful for the detailed comments provided by competent authorities, industry, farmer organisations and other stakeholders, that were very helpful to understand the problems related to and consequences of possible policy actions.

2. BACKGROUND: THE EUROPEAN PPP SECTOR

2.1. Authorisation of PPP in the EU

The authorisation of PPP in the EU is currently done at Member State level. Active substances are evaluated at EU level leading to a decision on inclusion in Annex I of Directive 91/414/EEC. There are different procedures in place for existing active substances and for new active substances. New active substances are substances that were not authorised in any Member State of the European Community for plant protection before 25 July 1993[7], i.e. one day before the Directive 91/414 entered into force. Existing active substances are substances that were authorised in any Member State before that date.

The evaluation procedure for possible Annex I inclusion is lengthy and complex. Application for Annex I inclusion is done at one Member State, which from then on is the Rapporteur Member State (RMS). The first step of the evaluation procedure is that a completeness check of the dossiers is conducted. The next step for the RMS is to prepare and submit the Draft Assessment Report (DAR) to the European Food Safety Authority (EFSA) within 12 months after the completeness check. The DAR is a first assessment of the dossier, carrying a recommendation for the European Commission. There are four possible recommendations to be given[8]:

(i) Include the substance in Annex I;

(ii) Not include the substance in Annex I;

(iii) Suspend the substance from the market pending the provision of further data or;

(iv) Postpone taking a decision on the substance pending the provision of further data.

EFSA shall then confirm receipt of the DAR. In case the DAR clearly does not fulfill the requirements, the Commission shall then agree with EFSA and the RMS that the report needs to be resubmitted. When the DAR is accepted by EFSA a peer review is started. During the peer review the application dossier and the DAR are examined in a series of technical meetings by experts from several Member States, with the objective of confirming the assessments and the data gaps identified by the RMS and to evaluate whether the active substance may be expected to meet the requirements of Article 5(1) of the Directive. The peer review is concluded by the EFSA delivering its opinion to the European Commission. The EC then prepares a Draft Review Report and presents to the Standing Committee on the Food Chain and Animal Health (SCFCAH) in which all Member States are represented either a

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7 Website DG SANCO http://europa.eu.int/comm/food/plant/protection/evaluation/new_subs_faq_en.htm#q1

8 Working Document SANCO/2693/2001 of 25 July 2001. Technical Annex to Report from the Commission to the European Parliament and the Council on the Evaluation of the Active Substances of Plant Protection Products, p.7. Hereafter referred to as Working Document SANCO/2693/2001 of 25 July 2001.

- Draft Directive to include the active substance in Annex I of Directive 91/414/EEC or a;
- Draft Decision addressed to the Member States stating the reason for non-inclusion of the active substance in Annex I and requiring the Member States to withdraw the PPP containing this substance from the market.

2.2. The European PPP market

The PPP industry is the main component of the agro-chemicals industry, itself a sub-sector of the chemical industry. Its main products include herbicides, fungicides and insecticides. Some minor products such as growth regulators and non-crop products are also included.

Until 2004, the pesticide market had been fairly static for 20 years. In 2004, the global PPP market was valued at 24 734 million €; the European area[9] market share amounted to 6 769 million €, or 27.4%, of the total[10]. This was a 5.9% real increase in the European agro-chemical market from the year before, whereas the global real increase was only at 4.7%[11].

Although the volume of agrichemical sales has increased by a lesser extent than the total value, total volume made an increase of 3.9% in 2004[12]. Currently, about 350 active substances of commercial significance for crop protection are either accepted into Annex I of Directive 91/414/EEC or re-registration is pending[13], a significant percentage of them being off-patent.

The EU market for agrichemicals is in a transition phase because of legislative and structural changes due to the accession of new members in 2004, the reform of the Common Agricultural Policy (CAP), re-registration costs, the surging global interest in GMOs, and higher sales of lower-cost products.

Producers. There is a significant difference between the producers of agrichemicals on the global market. They can be segmented into three main groups:

- Multinational companies and their affiliates (e.g., formulators): Following a consolidation wave between 1984 and 2003, multinationals are currently represented by the "big six" companies[14];

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9 EU-25 and EFTA, of which € 6 668 million for the EU-25.

10 ECPA, Annual Report 2004-2005, p. 10. Please note that estimates of different sources may differ considerably due to definitions applied etc.

11 ECPA, Annual Report 2004-2005, p. 9.

12 Eurostat/ECPA Statistics, 2004 Summary.

13 Phillips McDougall, Keeping Europe attractive for Sustainable business development, Presentation at ECPA Annual Meeting, November 2005, p. 6.

14 Monsanto, Du Pont, Bayer, BASF, Dow, Syngenta.

- Coalition companies: A number of medium sized companies grouped themselves under the "coalition" flag[15];
- Generic manufacturers[16].

Table 6 indicates the significantly different market shares these segments benefit from.

Although the European companies belonging to the "big six" (Bayer, Syngenta, and BASF) have not experienced much growth within the EU, they have compensated for the stagnated market by expanding sales into GM crops and seeds.

Generics. Generics are non-patent protected products. As is indicated in the table, the market shares of the non-R&D group is growing at faster rate than the multinational companies and the market on the whole; it remains a niche market. Globally, patent protected PPP amount to roughly one third of sales, whereas non-patented protected products amount to two thirds. However, a large share of non-patent covered products is sold by multinational companies or their affiliates. In the case of Monsanto, 100% of their sales are from non-patent covered products.

Table 6: Sales per group of companies within the EU

	Sales 1999		**Sales 2004**		**Growth 1999-2004**
	Value (million €)	Market share (%)	Value (million €)	Market share (%)	Average annual growth (%)
Multinational companies and affiliated formulators	7 277	86.7	7 103	81.3	-0.5
Coalition companies	417	5	607	7	7.8
Major generics	699	8.3	1 017	11.7	7.8
Total	8 393	100	8 726	100	0.8

Source: Phillips McDougall, Market Position in EU 25 for Small and Medium sized Agrochemical companies involved with Research and Development, July 2005, p.5

Employment. According to ECPA, the European crop protection sector (excluding distribution) directly employed 29 885 people in 2003[17]. The 55 independent generic companies represented by ECCA, the Italian and the Spanish Generic Associations employed a total of 1 361 people in 2003[18].

R&D. Innovation remains an important growth mechanism in the agrichemical market. Only the multinational companies (i.e., the "big six") have a significant capacity to develop new active molecules, the cost of which currently estimated in the range of up to

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15 Isagro, Crompton, Gowan, ISK, Taminco, Luxan, IQV, Janssen, Stahler, Japan Agro S.

16 Main generics: Maktheshim-Agan Industries (MAI), Nufarm, Cheminova, United Phosphorus, Sipcam Oxon, Cerexagri. This group also includes numerous smaller companies, most of them not operating in the EU market. About 50 of them are grouped under ECCA.

17 ECPA, 2006, Impact Assessment of proposed changes to Directive 91/414/EEC, p. 22.

18 ECCA, 2004, Proposal for the New Directive to amend Directive 91/414 and for Re-registration guideline, p. 21.

200 million € per molecule, and to sustain a pipe-line of products at various development stages. Some other companies also maintain R&D activities, but not at the same level of development.

Table 7: Cost of R&D per Active Substance

R&D component	Cost: Million US $ (1995)	% (1995)	Cost: Million US $ (2000)	Cost: Million €[19] (2000)	% (2000)
Registration	13	8.4	11	12	7.0
Development	67	44.2	79	86	42.5
Research	72	47.4	94	102	50.5
Total	152	100	184	200	100

Source: Phillips McDougall, Keeping Europe attractive for Sustainable Business Development, Presentation at ECPA Annual Meeting, November 2005, p.21.

There has been a decreasing return and decline in R&D productivity, as is illustrated by the following facts: 1) The ratio of screened substances vs. put on the market has increased from approximately 1 to 50 000 to 1 to 140 000 between 1995 and 2000[20]; and 2) recently, there is a decline in the number of active ingredients receiving an ISO[21] name, as shown in the table below. This illustrates the declining rate of new chemical entities, which in the last decade decreased to 5-10 per year from an earlier average of 15-20 per year[22]. In 1976, moreover, 12 newly introduced products had annual sales larger than 50 million €, whereas only one made it in 2004[23].

Table 8: New ISO names

	1998	1999	2000	2001	2002
New ISO names	20	22	15	12	13

Source: Uttley, N., The EU Market for Generic Agrochemicals, Enigma Marketing Research 2004, p.28.

These results indicate that:

- Multinational companies with a large R&D capability still make a majority of the off-patent sales;
- The global generics market is steadily achieving growth. Large generic companies have many similarities with the multinational companies and significant opportunities in the future as an increasing number of active substances go off patent.

Price Competition. Both as an industry and as a market, the PPP sector is stable and mature in the EU, where it grows in line with inflation until 2004. Pressure on prices is reflected in the fast

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19 Converted from US$ sales at: 1€ = 0,92 US $ (2002).

20 Phillips McDougall, Keeping Europe attractive for Sustainable Business Development, Presentation at ECPA Annual Meeting, November 2005, p. 22.

21 International Standards Organisation.

22 Uttley, N., The EU Market for Generic Agrochemicals, Enigma Marketing Research 2004, p. 28.

23 Phillips McDougall, Keeping Europe attractive for Sustainable business development, Presentation at ECPA Annual Meeting, November 2005, p. 6.

growing penetration, if still limited in quantity, of imports from low-cost producing countries, as illustrated by the case of China, in Table 9.

Table 9: Imports of pesticides from selected non-EU countries

EU imports from	Value of imports in 1999 (in 1000 €)	Value of imports in 2000 (in 1000 €)	Growth 1999-2000 (%)
Switzerland	402 020	364 933	(10)
USA	182 753	201 137	10
Israel	52 551	75 910	44
India	12 313	12 451	1
China	6 176	16 278	163
Others	114 885	130 260	13
Total	770 699	800 970	4

Source: Eurostat

Additional downward pressure on prices in the PPP market is influenced by the Common Agricultural Policy (CAP), which has a major influence on: 1) cultivated acreage, which depends on subsidies set aside; 2) farm income support which is becoming less dependent on crop price but more on direct single farm support; and 3) a decreasing trend of crop price, to reflect world market prices, with a pressure on costs. All these factors push the farmer towards the use of generics, although, as seen before, this substitution is limited.

PPP Market and Biotechnology. Globally, agri-biotechnology plays an important role in the classical PPP market: a) biotechnology is the fastest growing segment of the global crop protection market (see Table 10); b) as a response, some of the "big six" multinational companies are putting an increasing share of their R&D effort in this segment, correspondingly decreasing their contribution to classical PPP portfolio development; and c) biotechnology and classical PPP are complementary; BT corn requires less insecticide but RR soya or canola may require more herbicide. Such substitution plays a minor role in the EU, where biotech agriculture is only marginal. But it significantly impacts the global market, especially in high growth regions such as Latin America where, under the influence of biotech, farmers increasingly adopt low labour / high input practices such as low till agriculture.

Table 10: Global Crop Protection Market

	Sales in million € [24] (1999)	Market Share (%) (1999)	Sales in million € (2004)	Market Share (%) (2004)
Crop protection	25 536	82.0	25 604	76.6
Non-crop Agrochemicals	3 603	11.5	3 896	11.7
Agricultural Biotechnology	1 975	6.5	3 917	11.7
Total	31 114	100	33 417	100

Source: Phillips McDougall, Keeping Europe attractive for Sustainable business development, Presentation at ECPA Annual Meeting, November 2005, p.2. Note: Does not include conventional seed.

Users. Users are farmers and agri-business operators. Farmer numbers, which are declining in all EU 25 countries, are not a relevant way to look at market size, but rather by cultivated acreage, which increased by 2.8% in 2004[25]. Quantity values are determined by three factors: 1) nature of crop; 2) cultivated area; and 3) pesticide intensity.

PPP use by Member State. Between 2000 and 2003, nearly 1 million tones of active ingredients were applied in the European area; 70% of which was applied in four Member States: France; Italy; Spain; and Germany with France leading by 31% of the total volume[26]. Until the drought that affected Northern Europe in 2003, Central and Eastern Europe had been the fastest growing region of the global crop protection market, led by the Central European countries that have gained accession to the EU, but also with significant development in Russia and the Ukraine. Recovery from drought in the north and continuing increase in investment has lead to recent growth in these areas[27].

Intensity of use. Pesticide intensity may differ considerably between countries, depending on crop profile, farmer education and climatic conditions. In 1999, average PPP application rates varied from 1kg/ha (Sweden, Finland, Denmark) to 9 kg/ha (Portugal); the European area average was 4.5 kg/ha[28].

While all product sectors of agrochemical markets have recorded increases in the past few years, the fungicide sector recorded the highest growth[29]. Although herbicides have the largest market segment of value (see Table 11), fungicides are the largest segment in quantity of active substances.

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24 Converted from US$ sales figures at: 1 € = 1,1 US$ (1999), 1 € = 1,2 US$ (2004).

25 ECPA, Annual Review 2004-2005, p. 9.

26 ECPA and Eurostat Data.

27 ECPA, Annual Review 2004-2005, p. 10.

28 Eurostat, The use of Plant Protection Products in the European Union, 2002, p. 13.

29 ECPA, Annual Review 2004-2005, p. 9.

Table 11: Sales of pesticides in the EU, per main category

	Value 2003 (%)	Value 2004 (%)
Fungicides	36	38.6
Insecticides	16.2	15.4
Herbicides	43.3	41.8
Growth & other	4.5	4.5
Total	100	100

Source: ECPA, Annual Review 2004-2005, p. 9.

Although the agro-chemical market is not a major growth market within the EU, it competes for the world's largest market share and is a significant source of income. The EU industry competitiveness is primarily dependent on its ability to innovate and to push innovation through to market. Although R&D costs are rising, there generally is a downward pressure on prices; this is partially generated by a growing global market share for generics and off-patent products. The European market for PPP is large and stable but highly segmented among its Member States. Usage and intensity can vary significantly among the regions and the states themselves, as can the market share of generic products (see section 3.4.8).

3. PROBLEMS IN THE APPLICATION OF DIRECTIVE 91/414/EEC

3.1. Problems related to the evaluation procedure for new active substances / National Provisional Authorisation

3.1.1. Background

National provisional authorisation (NPA) applies to PPP containing a new active substance. 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 inclusion of the new active substance in Annex I[30].

A national provisional authorisation may be granted once the Member State has concluded that the active substance and the plant protection products can be expected to satisfy the Community conditions[31]. More specifically, Member States have to establish that the active substance can satisfy the requirements of Articles 5(1) and may be expected to meet the requirements of Articles 4(1)(b) to (f) of Directive 91/414/EEC before a national provisional authorisation is granted[32].

3.1.2. Duplication of administrative efforts

The current system of national provisional authorisation has led to a duplication of administrative efforts of competent authorities and applicants. Applications for national provisional authorisations of a PPP containing a new active substance are made (more or less simultaneously) to all Member States where the applicant intends to launch the product on the market. These Member States then all carry out an evaluation procedure to check whether the active substance and the product satisfy the above mentioned conditions. These parallel evaluations at the Member State level are a duplication of work, especially if the national provisional authorisation procedure starts well before the Rapporteur Member State (RMS) for the Annex I inclusion procedure (see section 2.1) has prepared the Draft Assessment Report (DAR), as is the case in several Member States.

Although national provisional authorisation can only be granted when the Member State has concluded that the new active substance of the PPP can be expected to satisfy the Community conditions, this assessment is based on national legislation and guidelines for the evaluation and authorisation procedure. In practice this leads to differing requirements of Member States with respect to the dossiers to be provided for national provisional authorisation (both in terms of structure and content), leading to additional administrative efforts (and costs) of applicants.

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30 Working Document SANCO/2693/2001 of 25 July 2001, p.15.

31 Directive 91/414/EEC, preambular paragraphs.

32 Working Document SANCO/2693/2001 of 25 July 2001, p.15.

3.1.3. Availability of PPP

The duration of the national provisional authorisation procedure differs significantly between Member States. Currently, according to industry sources it may take anywhere from less than 18 months to 40 months from submission of the dossier to the launch of the new PPP on the national market, depending on the Member State. This can partly be explained by differences in the national procedures; applications for national provisional authorisations of PPP are normally made after the application for the Annex I inclusion of an active substance. Member States can only issue national provisional authorisation after the completeness check of the Commission. Several competent authorities that responded to the survey questionnaire, issue the national provisional authorisation after the completeness check, others after the Draft Assessment Report. In some cases, the national provisional authorisation procedure for a PPP may even only start after the DAR is made available.

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 (see also section 3.2.3).

3.1.4. Duration of the evaluation process

Another problem is the duration of the Annex I inclusion process. The average time from dossier submission until the Commission Directive on Annex I inclusion is available is calculated by the Commission to be more than 6 years[33]:

- Under the present system, it takes an estimated 27 months before the Draft Assessment Report is available. This stage of the evaluation procedure includes the completeness check of the dossier, the Commission Decision on the completeness of the dossier, and the preparation of the Draft Assessment Report by the RMS;
- A Commission Directive is only available after a peer review of an additional 5-87 months with a mean time of 47 months. During the peer review additional information might be requested from industry[34].

Main reasons for the long duration of the Community evaluation procedure, especially in the first years after the introduction of Directive 91/414/EEC, can be summarised as follows:

- A lack of resources compared to the high workload. This refers both to the evaluation as such and the work to set up and develop the required infrastructure.

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[33] DG SANCO, Brussels, 24 June 2005 DDG/JPP/av D(2004)1291. FINAL DRAFT COMMISSION STAFF WORKING PAPER - REVISED VERSION: Impact Assessment on Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND THE COUNCIL concerning the placing of plant protection products and adjuvants on the market. Hereafter referred to as: DG SANCO 2005: Draft Impact Assessment .

[34] As this time period in some cases includes also provision for further data by the industry, it is according to the Commission not possible to determine with precision the duration of the Peer Review.

As the Commission stated in 2001, "In looking at the programme's achievements and the problems encountered, consideration has to be given first and foremost to the time it took to establish the required legislative, administrative, technical and informal structures, and to the arduous scientific and methodological learning curve that had to be climbed"[35];

- The complexity of the evaluation procedure, the depth of the evaluation as well as the breadth of the consultative process and the feedback procedures involved.

However, also the contributions of the applicant to the Community evaluation (e.g. with respect to provision of additional data required after the submission of the dossier) can have influence on the duration of the procedure and may, according to several competent authorities interviewed, lead to delays. 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[36]. This reduces the incentives for the applicant to quickly provide additional information requested during the Community evaluation and finalise the Annex I evaluation process as soon as possible, as the provisional national authorisation can be extended until the evaluation is complete.

Current data protection rules may even provide an unintended incentive for industry to delay the Annex I inclusion procedure. Data protection for new active substances (10 years for the first inclusion) only starts from the date of Annex I inclusion, even if the new active substance is already on the market based on a national provisional authorisation. This is under the condition that the application for national provisional authorisation was submitted later than the application for Annex I inclusion. It is current practice that the data is already protected during the evaluation procedure, i.e. before Annex I inclusion, when the 10 year data protection period formally starts. A long Community evaluation after national provisional authorisation can therefore be advantageous, as each month of delay of the Annex I inclusion provides an additional month of data protection. This is especially relevant in cases where the patent protection of the active substance expires before the end of the data protection period. In this case data protection can extend the time of exclusivity on the market, a crucial factor determining industry margins.

Independent from the causes for delay, a long duration of the Community evaluation procedure is a problem as it constitutes the main motivation for national provisional authorisation and the related duplication of administrative efforts and a longer duration can also be expected to lead to higher coordination efforts for competent authorities and applicants.

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35 COM(2001) 444: REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL Evaluation of the active substances of plant protection products.

36 In ECPA 2005: Data on the value of national provisional authorisations, which is based on an analysis of 13 AS application for national provisional authorisation, the average time from submission of the dossier until first launch on the market with NPA is given with 29 months, i.e less than half of the average duration of the Community evaluation procedure.

3.2. Problems related to the authorisation procedure for PPP containing active substances already included in Annex I / Mutual Recognition

3.2.1. Difficulties to apply mutual recognition procedure

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 only three Member States of the 22 responding in the survey apply mutual recognition to a significant extent.

In the application of Article 10 of Directive 91/414/EEC three requirements have to be fulfilled, before mutual recognition of PPP authorised in another Member State can be applied:

- Mutual recognition can only be applied to products containing active substance that are included in Annex I;
- Mutual recognition can only be applied to PPP, which are authorised according to the uniform principles for the risk assessment of chemical plant protection products (contained in Annex VI of the Directive);
- Mutual recognition can only be applied if the "agricultural, plant health and environmental (including climatic) conditions relevant to the use of the product are comparable in the regions concerned"[37].

The first requirement is directly linked to Annex I inclusion of active substances. Because the number of active substances which are included in Annex I is currently around 120[38], this already reduces the number of PPP for which mutual recognition can be applied. Furthermore, mutual recognition is only to be applied to PPP, which are authorised according to the uniform principles. These principles have to be applied by all Member States, but only to PPP which contain active substances that are included in Annex I. Before Annex I inclusion of the active substance Member States optionally can authorise PPP according to the uniform principles, but only few do this in practice. In consequence currently only a minority of PPP are authorised according to the uniform principles and a majority of the PPP on the market are still authorised according to national principles for risk assessment.

For the third requirement, regarding comparability of environmental conditions, there are no EU guidelines available. Some Member States thus assess the comparability of environmental condition on a case-by-case basis. The issue of comparability of conditions is also rather complex, because already within one Member State one can find significant differences in environmental conditions, which lead to different risk mitigation measures. This increases the difficulty to assess the comparability of environmental conditions between different MS.

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37 Directive 91/414/EEC, Article 10(1).

38 According to a current overview by DG SANCO (3010 rev Nov2005.xls), 122 active substances have been included in Annex I, of which 66 are new active substances (for some of them the decision by the SCFA has not yet resulted in a Commission Directive).

Finally, there are also practical issues which impede the application of mutual recognition; after an active substance has been included in Annex I, PPP containing this active substance which have been previously authorised have to be re-registered. These re-registration reports are frequently not available in English, but only in the national language.

The problems resulting from different authorisation practices and a lack of coordination are highlighted by industry: "Both for new and for existing substances, an efficient use of mutual recognition is hampered by differences in risk assessment methodologies, models and additional data-requirements in the different Member States. In the current re-registration process after Annex I inclusion, coordination to facilitate the application of Mutual Recognition is lacking both in the industry and in the regulatory authorities"[39].

In consequence, many applicants decide to apply separately for authorisation of the same PPP in each Member State where the PPP is to be launched 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.

It should be noted, though, that a recent trend towards more application of mutual recognition can be detected. Although in most Member States this only relates to a few applications, the number seems to be increasing and some Member States have also started preparing English language re-registration reports to reduce practical obstacles to mutual recognition in the future.

3.2.2. A fragmented market for PPP

Currently, the market for PPP in Europe is rather fragmented, as is indicated by the number of PPP authorised, which vary from a few hundred in several Member States to approximately 4000 to 6000 in three Member States. This certainly is related to differences in environmental conditions and other factors, including market size and authorisation practices. However, several competent authorities expressed the view that the lack of applying for mutual recognition (which would lead to more homogenous markets) is also impeded by a lack of interest from industry. "Industry does not seem to be interested to launch Europe wide similar products," was a typical statement.

The fragmentation of PPP markets and related price differences are a well known (and hotly debated) phenomenon, which has led to a number of studies conducted internationally. For example, a 1993 study of the Prices Surveillance Authority of Australia found a

> "... dramatic variation in pricing of the same product in different countries. There were products where Australian farmers paid double that of farmers in other countries but, at the same time, prices elsewhere were sometimes recorded as being ten times higher than in Australia. Those are extremes, and a 30 to 40 per cent range of differences was more common. (...) An apparent reason for wide price variation [of farm chemicals] seems to relate to the fact that, for European farmers enjoying

[39] ECPA (76:3).

considerable production subsidies, ... it is not worth chasing low prices for products which represent only a small part of their costs.

The Authority, nevertheless, is concerned over the potential for excessive pricing of patented products and feels that some scope may exist for some lower prices. In the survey of supplying firms several common responses were made by major firms. First, they were unable to provide any information on the cost of manufacture of active ingredients, secondly they generally paid the world price of patented active and thirdly they priced patented product for Australian farmers according to 'what the market would bear'. The Authority interprets 'what the market will bear' to mean that the local subsidiary maximises longer term profits subject to the limitation imposed by the value of the product to the farmer and competition provided by other products"[40].

The issue of fragmented markets of PPP and resulting price differences is also discussed with respect to the US and Canadian markets. A 1999 report focusing on these price differences concluded that

"... there are differences in unit prices between North Dakota/Minnesota and Manitoba for some of the more frequently purchased pesticides. (...) There are many reasons why pesticide prices vary between the two regions and they include: differences in patent expiry dates; differences in market size and costs; differences in pesticide demand (e.g. farmer preferences, willingness to pay); and differences in the number of substitute products available. Several products, which are widely used in other crops and locations, tend to have many pesticide alternatives and non-chemical pest controls. Consequently these products have similar prices in both study locations. ... This is consistent with the notion of less pricing power by pesticide sellers when there are many substitute products or practices. From a manufacturer's perspective, the U.S. and Canada represent two distinct markets for pesticide sales"[41].

A study on the same issue in 2004, referring to the data of the previously quoted report and other studies, concluded, "it is in the pesticide manufacturers' interest to maintain segmented markets". It further stated:

"The existence of persistent price differentials for pesticides has been studied for some time ... It is shown here that price differentials for some pesticides are significantly different between Canada and the U.S. but there are no significant differences in pesticide prices in markets studied within each country. (…) Although several alternative hypotheses were considered, only price discrimination is consistent with the price patterns seen in these data. Given that price discrimination is a widely practiced pricing strategy, the conclusion

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40 PSA 1993: Inquiry into the prices of farm chemicals, Report No. 49, p. 152/153.

41 Carlson, G, Deal, J., McEwan, K and Deen, B. 1999: Pesticide Price Differential Between Canada and The U.S., prepared for the US Department of Agriculture and Agriculture and Agri-Food Canada. Not all prices were higher in one of the markets: Some prices were systematically higher in Canada than the U.S., others were lower, some roughly the same.

that price differentials are indeed a result of price discrimination is therefore warranted"[42].

This assessment is contested by industry and during a U.S. Senate Subcommittee on Production and Price Competitiveness hearing to examine proposed legislation permitting the Administrator of the Environmental Protection Agency to register Canadian pesticides, the representative of CropLife America stated in 2004:

> "American farmers are no longer at the disadvantage that was argued six years ago. In fact, according to a 2003 study conducted by North Dakota State University, North Dakota farmers experience a net benefit by purchasing their products in the U.S. It simply is not worth jeopardizing our steady efforts towards regulatory harmonization to solve a perceived pricing problem that no longer exists…"[43].

Also the European Crop Protection Association argues that prices tend to align when they state on the issue of price differences between EU Member States:

> "There have been significant price differences between Member States but prices tend to align in EU-25 since accession of 10 new MS (prices differed considerably in these new MSs). Trading in Euros also tends to lead to price alignment. The price differentials between Member States is determined by local market conditions and other factors such as the level of provision of support services to the farmers"[44].

It was not the aim of this study to perform an analysis of the European PPP market and pricing practices of European providers of PPP. However, as price differences could provide an incentive for unauthorised cross-border trade, competent authorities were asked to assess price differentials of PPP compared to markets in neighbouring countries and to identify possible reasons. Most authorities could not provide figures. Those who did reported differences of up to 30%, a figure also reported by ECCA[45].

Several authorities mention differences in VAT as a reason for existing price differences. In some Member States VAT on PPP is 20%, in others reportedly 3%. In spite of this, several competent authorities were of the opinion that tax differences and different distribution systems are not the only reasons: "There must be other factors involved", wrote a competent authority in a questionnaire. Possible reasons mentioned are "price policy and marketing strategies" and "different purchasing power of farmers". Even without a further analysis of this issue it may be concluded that the fragmentation of the

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42 Short, C., Freshwater, D. 2004: Canada – U.S. Pesticide Regulation: An Economic Analysis of Price Discrimination, p. vii/ix.

43 Vroom, J: Statement on June 23, 2004. http://www.croplifeamerica.org/media/testimony/6.23.04_vroom_prodprice.pdf, last accessed on 13.2.2006.

44 Questionnaire filled by ECPA.

45 The International Plant Protection Association (IPPA), a German based organisation of enterprises engaged in re- or parallel import of plant protection products from member states of the European Union (EU) or of the European Economic Area (EEA) into the Federal Republic of Germany, assessed in its questionnaire response that there are "still noticeable price differences in the EU" and even very significant price differences in comparison with non-EU-countries. No comprehensive data to independently verify this claim was available.

EU PPP market, partly caused by the lack of mutual recognition or a more centralised authorisation, has led in some cases to price differences between EU Member States that are sufficiently high to be an incentive for the unauthorised cross-border sourcing of PPP.

3.2.3. Illegal cross-border sourcing of PPP / Lack of availability of PPP

Unauthorised cross-border sourcing of PPP is a major problem for Member States: 17 of the 22 Member States who responded to the survey reported problems with unauthorised imports[46] or use, three had minor problems and only one country had no problems[47]. The main cause for buying PPP abroad are price differentials and – perhaps even more relevant – the lack of availability of certain PPP in some Member States that are available on the market in neighbouring countries. This can also be seen (at least partly) as a consequence of the non-application of mutual recognition. Especially small Member States face problems regarding availability of PPP, as products are not being placed on the market because the market is so small that industry is unwilling to bear the costs of authorisation. A typical situation described by a competent authority in a smaller Member State is that the "availability of products for regular uses is not sufficient, and also for minor uses".

Differences in availability are also due to differences in authorisation procedure for PPP, both for regular authorisations and for national provisional authorisations. Differences between authorisations could include differences in duration, differences in the timing of issuing the authorisation and the possible requirement for additional studies. When authorisations are issued at different times, products also enter the national market at a different time. This influences the availability of PPP on the markets of Member States.

Most stakeholders agree that the lack of availability of PPP on the national market provides an incentive for unauthorised sourcing of PPP. This is a major concern, as unauthorised use of PPP potentially carries a risk for human health and the environment. A statement provided by Eureau, the European Union of National Associations of Water Suppliers and Waste Water Services, illustrates this: "Especially countries with a more strict PPP policy feel the impact of unauthorised imports and use. Water operators regularly measure unauthorised substances in their monitoring programmes"[48].

3.3. Problems related to environment and health impacts of PPP

An inclusion of an active substance in Annex I of Directive 91/414/EEC does not mean that the active substance is without risk to human health or the environment. Rather, as Article 5(1)(a) of the Directive states, an active substance shall be included in Annex I if it may be expected that plant protection products containing the active substance will fulfil the conditions that their residues and use, "consequent on application consistent with good plant protection practice, do not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment". This implies that for active substances included in Annex I the following is valid:

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46 The term "import" here refers to both PPP originating from other Member States and from third countries. It is later referred to as "unauthorised cross-border sourcing of PPP".

47 Survey to competent authorities.

48 Questionnaire EUREAU, question 6.

a. A PPP including the active substance may be harmful to human or animal health or to groundwater, if application is not consistent with good plant protection practice;

b. And even when applied consistent with good plant protection practice it might have an "acceptable influence" on the environment, i.e. a negative impact that is deemed to be acceptable during the authorisation procedure based on the studies supplied.

In conclusion this means that criteria for the evaluation and authorisation of active substances / PPP with respect to health impacts are formulated significantly more strictly ("not have any harmful effects") than the criteria for environmental impacts ("not have ... any unacceptable influence"). Acceptable environmental impacts may be expected with PPP use, and what precisely is an "unacceptable influence" can be subject to dispute.

3.3.1. Minimisation of environmental externalities

The inclusion in Annex I of Directive 91/414/EEC is therefore based on minimum criteria concerning environmental impacts, but does not provide a mechanism to minimise environmental impacts below these levels. To minimise the hazards and risks to health and environment from the use of pesticides is an EC policy objective[49] and national minimisation strategies are currently already applied in several Member States, notably in Sweden and some other Nordic countries. An economic reasoning for this type of a minimisation strategy is that negative impacts on the environment could lead to significant externalities.

Traditionally, a cost and benefit analysis is used to estimate the net worth of plant protection products (PPP) by weighing profits (e.g., increased crop yields, increased income) against expenses (e.g., labour costs, increased administrative costs). Generally, society accepts the use of pesticides because of the potential for large economic gains. A significant majority of the available literature recognizes that pesticides contribute to economic welfare but there is also some concern that pesticide use may exceed the socially optimal level.

Certain expenses, or externalities, are not quantifiable or immaterial and therefore, cannot easily be calculated into the cost and benefit analysis. Immeasurable positive externalities can be anything from increased income security for farmers, additional incentive to develop more active substances by industry, increased competitiveness of the sector, increased availability for minor crops, and decreased demand for land. Conversely, negative externalities can be anything from damage to ground and drinking water, decreased biodiversity, decreased soil fertility, health risks for users of PPPs, and health risks for those who consume the final product. These potential negative externalities are partly addressed by setting regulatory standards and demanding extensive research on possible impacts during the evaluation procedure. However, not all costs to society are calculated when evaluating the net impact of any particular active substance.

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[49] COM(2002) 349 - TOWARDS A THEMATIC STRATEGY ON THE SUSTAINABLE USE OF PESTICIDES, Brussels, 1.7.2002.

Finding a solution that satisfies these qualifications may be difficult because contradicting data and literature often reach vastly different conclusions about pesticides' impact on economic welfare versus its impact on environment and human health. This is indicative of the inherent immeasurability of externalities. Further data gaps complicate these calculations; for example, it is difficult to calculate the effects of negative externalities in the long term, whether damage is from excessive use or use at all, and any unanticipated effects that have thus far, not been correlated with the use of PPP. The European Commission therefore concluded in 2002: "In practice, it is extremely difficult to quantify many of the actual adverse effects resulting from the use of pesticides and even more difficult to attribute monetary values to them, in particular as there are no agreed values for many of the so called 'externalities' such as effects on the environment. Therefore, like for benefits, it is not possible to give a figure of the overall costs of the use of pesticides in the EU"[50].

However, in some areas incidental evidence is available that externalities caused by PPP use involve substantial costs. For example, a study provided by Eureau, the European Union of National Associations of Water Suppliers and Waste Water Services, indicates 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), up 25% compared to the average yearly costs of approximately 24 million Euro calculated for the period 1991-2000[51]. Annual costs of the UK drinking water industry related to pesticide removal are estimated at around 120 million Pounds[52].

3.3.2. Lack of mechanism to remove some active substances already included in Annex I

In its current form Directive 91/414/EEC does not contain a simple provision for removing active substances from Annex I, even if exclusion would minimize possible environmental impacts without reducing the availability of similar active substances. An example of this is the inclusion of several active substances that contain high level of non-active isomers (e.g. Mecoprop), while also a similar active substance not containing high levels of non-active isomers is included in Annex I (in this case Mecoprop-P). When Mecoprop is used instead of Mecoprop-P, this increases the amount of substances released to the environment. This may directly or indirectly through their metabolites lead to (unnecessary) negative environmental effects.

3.3.3. Difficulty to apply national minimisation strategy

The current system established by Directive 91/414/EEC does not foresee the possibility to deny authorisation of a PPP (where the active substance is included in Annex I) on the grounds that alternative PPP or non-chemical alternatives for a given use are available that are more environmentally friendly. Some Member States have adopted more stringent measures than the Directive provides for, which is possible due to transitional measures

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50 COM(2002) 349, p. 13.

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

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

and derogations. The Directive itself "does not allow for residual rights for Member States to keep or adopt more stringent measures such as a ban on a particular PPP or a particular PPP usage"[53]. Therefore at present there are in practice two regulatory systems in many Member States in operation, namely the national system for PPP containing active substances not yet included in Annex I, and the system established by Directive 91/414/EEC for PPP containing active substances that are already included in Annex I as new active substances or in the framework of the review procedure for existing active substances. With more active substances included in Annex I, the room for national governments to prioritise the minimisation of environmental impacts of agriculture and the reduction of reliance on chemical plant protection products gets more limited.

Sweden, for example, has employed a system of comparative assessment with substitution since 1990 (see Annex B: Comparative Assessment – the Swedish experience). As a consequence, a significant number of products seen as environmentally less advantageous were either banned or withdrawn by industry based on national risk assessment. However, some of the banned substances were later included in Annex I during the Community evaluation process. If a company were to apply for authorisation of a PPP with an active ingredient included in Annex I but previously banned in Sweden, national authorities would have to authorise the product, which would not be in line with the national policy on chemicals and pesticides and could also be seen as being in conflict with the general EU objective of minimisation of hazards and risks to health and environment from PPP use.

3.4. Problems related to data protection and sharing

Article 13 of Directive 91/414/EEC establishes rules on data protection and data sharing of active substances. At the time when the Directive was established, there was no previous experience on an EU wide data protection system. As such, there was no previous knowledge how to establish an efficient system. Fifteen years after implementation of the Directive, Article 13 has caused many problems, both for Member States and for the PPP industry.

Problems of competent authorities in Member States

3.4.1. Lack of guidance documents

One of the most problematic aspects of Article 13 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, lead to various interpretations on data protection issues between different Member States[54]. Already in 2001 the Commission concluded: "The

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53 Milieu Environmental Law and Policy. April 22, 2004. Integration of the objectives of the pending Thematic Strategy on sustainable use of pesticides into Directive 91/414/EEC, p. 8.

54 ECPA, 2004. View on the revision of Directive 91/414/EEC Contribution to the stakeholder workshop to be held on 30 January, p. 4.

current rules are very complicated to apply for Member States and are also contested by industry"[55].

One competent authority gave an example for the resulting lack of clarity by referring to Article 13(3)(c). This paragraph states that: "Member States shall not make use of the information referred to in Annex II for the benefit of other applicants: [...] for periods not exceeding 10 years from the date of the decision in each Member State and provided for in existing national rules, concerning an active substance on the market two years after the date of notification of this Directive"[56]. In this provision it is not clarified what 'the decision' is referring to. As a result, this Member State presumes that this refers to a decision on inclusion of an active substance in Annex I[57] .

3.4.2. Lack of clarity with respect to which data is protected

Several competent authorities reported problems distinguishing which data should be protected and which data should not. When an active substance is included in Annex I, competent authorities receive the Annex I review report, which contains lists of data that needs to be protected. Data in need of protection is described as new studies, with new studies being defined as previously unused studies. A problematic aspect is that some of the data listed as protected data might have previously been used by other Member States.

If this had happened, it would mean some studies could obtain unjustified data protection. In order to prevent this, lists have to be cross-checked by all Member States. The review report therefore typically contains a disclaimer that the list of protected studies "is based on the best information available to the Commission services at the time this review report was prepared; but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC neither does it commit the Commission." This means that the list provided in the review report is legally not binding. Member States are experiencing significant problems to carry out the verification efficiently. There is a need for national databases on previously used studies, which are not existing in all Member States. Consequently, competent authorities experience a high administrative effort due to complicated investigation procedures, especially when other Member States have to be contacted to verify the protection status.

3.4.3. Possible duplication of vertebrate testing

Directive 91/414/EEC currently contains a provision in Article 13(7)(b) that encourages applicants for authorisation to "take all reasonable steps to reach agreement on the sharing of information so as to avoid the duplication of testing on vertebrate animals." Duplicate vertebrate testing refers to testing which takes place either because a company does not know that another company has already carried out the animal tests in question or because it cannot access the data. Despite this encouragement to share data, and national legislation in some Member States that bans the duplication of vertebrate testing, it still

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55 DG SANCO, 2001. Working Document of the Commission Services Technical Annex to Report from the Commission to the European Parliament and the Council on the Evaluation of the Active Substances of Plant Protection Products, p. 49.

56 Directive 91/414/EEC.

57 Questionnaire Competent Authority.

can occur in practise. However, there is no reliable data available regarding the extent to which this is the case.

Duplication of testing might partially be explained as a reluctance to share data between companies who fear that their competitive position will weaken after sharing data. Currently "… there is an inherent conflict of interest between the multinational R&D-based companies and the smaller generic producers. Even within the group of multinationals there is much suspicion and reluctance to share data defined as confidential"[58]. Reluctance in data sharing between companies might unintentionally lead to duplication of vertebrate testing.

Problems of PPP industry

Not only for competent authorities, but also for industry there are problems with the data protection regime of Directive 91/414/EEC. ECPA notices, "the principle issues arising from the existing Directive relate to the extent to which the provisions in themselves are not sufficiently explicit"[59]. Problems regarding data protection are different for companies involved in R&D on new active substances or defending existing active substances on the one hand and the generic industry on the other.

Companies involved in R&D on new active substances or defending existing active substances

3.4.4. Lack of common practice at Member State level

After an active substance is included in Annex I, all producers of PPP containing this active substance have 6 months to demonstrate that they have access to the relevant studies. If a producer does not have access to the relevant data, Member States have to amend or withdraw existing authorisation for PPP containing the included active substance. A problem occurs when Member States do not apply this rule. Several cases were reported where companies were allowed to stay on the market without the provision of necessary data. ECPA provided the example of a Member State in which 20 registrations existed for Isoproturon (IPU) before Annex I listing. "After Annex I inclusion 3 were withdrawn, 3 were supported by access to protected studies, but 14 remained on the market with no access to protected studies"[60].

3.4.5. Lack of record keeping of authorities

According to Article 13(4) of the Directive, the authorisation of a PPP in a Member State leads to a 10 year protection period of its Annex III data. The data protection period starts from the date of the first authorisation in any Member State[61]. For industry this is a problematic aspect as it is not always clear where a PPP has been authorised for the first

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58 Working Document SANCO/2693/2001 of 25 July 2001, p. 55.

59 ECPA 2004, ECPA view on the revision of Directive 91/414/EEC, Contribution to the stakeholder workshop to be held on 30 January, p. 4.

60 ECPA Questionnaire.

61 Directive 91/414/EEC, Article 13(4).

time. ECPA notes a lack of record keeping by competent authorities and states that "it is not known on what the data packages the decisions were made a few years ago"[62].

3.4.6. Lack of clarity on protection status of new Annex II data

Another problem which occurs in respect to data protection is related to Annex II data. It might happen that an applicant has to provide additional Annex II data regarding the active substance to achieve re-registration of PPP at MS level not used to support Annex I inclusion (e.g., because it is not available at that time). ECPA states, "91/414 Article 13 does not provide explicit protection, which is therefore left to MS' prerogative"[63].

Generic industry

3.4.7. Lack of list of unprotected data

To obtain a registration for a PPP, the generic industry has to provide a registration dossier as any applicant. Generic companies typically have little resources and experience data requirements as entry barrier, especially because there are no lists available of studies which are necessary and sufficient to obtain a registration. Furthermore, both protected and unprotected data of the first applicant for the registration of a PPP are confidential to second applicants, so it is difficult for generic companies itself to find out which data is required. Directive 91/414 does not specify who should create such a list, neither does it oblige authorities to indicate what studies are unprotected and therefore available to producers of generics[64]. A comment from the Asociación Española de Fitosanitarios y Sanidad Ambiental (AEFISA) illustrates the problems faced by generic companies to obtain access to data:

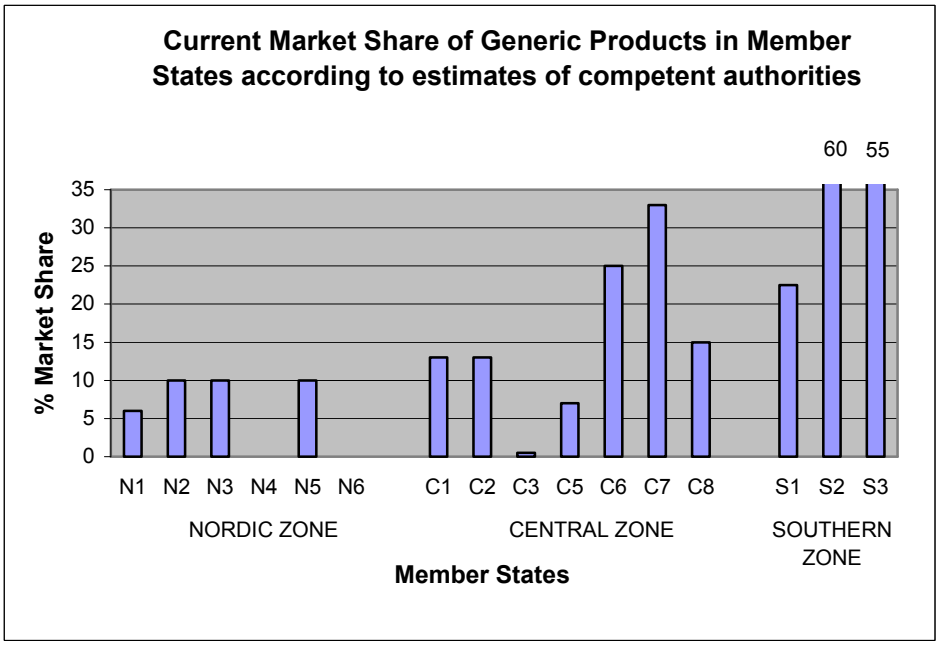
- "Difficulties to know the notifiers of an existing active ingredient just after the inclusion and the uncertainty to know as a formulator if you can be able to keep your authorization;
- Once the notifier is know[n], difficulties to obtain letter of access and obviously supply from notifiers, mainly with the very reduced periods of time given to demonstrate the interest in continue defending your authorizations;
- Normally, abusive conditions are established by notifiers to give a letter of access and supply the active substances to formulators;
- It is also normal that notifiers den[y] meetings to negotiate to formulators"[65].

3.4.8. Reduced competition after Annex I inclusion

Views on the current market share of generic products in EU Member States are differing. Definition for "generic products" varies significantly, and for the survey conducted in the

62 Questionnaire ECPA.
63 Questionnaire ECPA.
64 ECCA (15:2).
65 Questionnaire AEFISA, p. 8.

framework of this impact assessment the following definition was used: A generic PPP is an off-patent product not produced by the former patent holder. According to ECPA, the European organisation of major multinational companies active in R&D on new active substances, the sales of generic companies were around 1 200 million Euro in 2004, or 17% of the EU market. At the same time the European Crop Care Association (ECCA), which represents generic companies, argues that independent generic producers represent only 5% to 10% of the EU market[66]. The market share of generics differs significantly by Member State, as is illustrated in the graph below. The median market share of the estimates by competent authorities is 10%, varying between 0% and 60% in different Member States. The market share of generics is highest in the Southern zone and lowest in the Nordic zone:

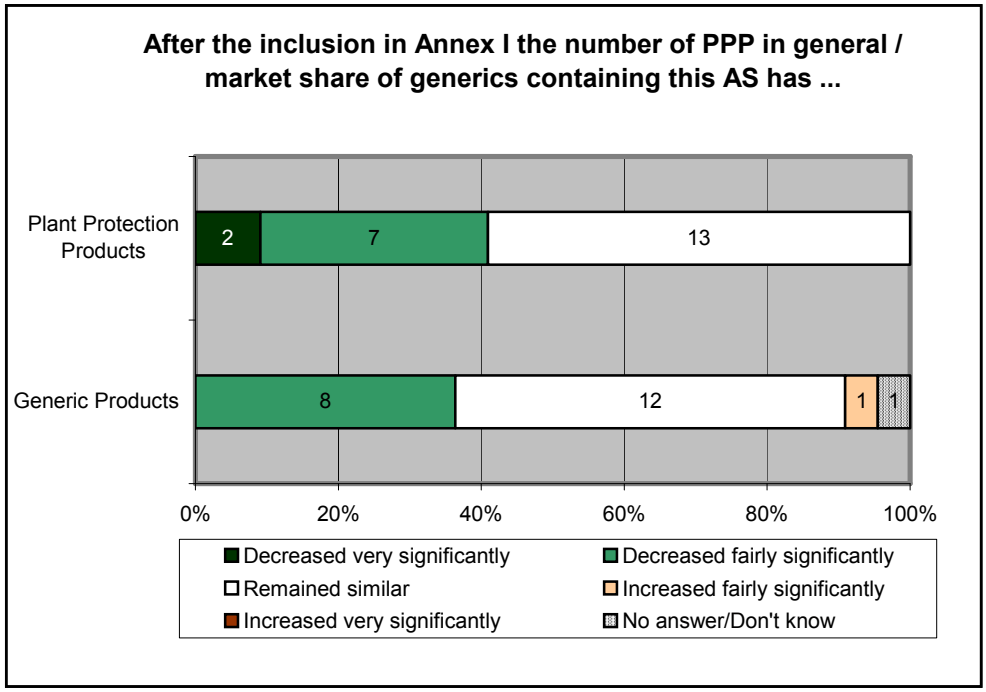


Source: Survey of competent authorities. Please note that in all graphs in this impact assessment Member States are represented by a code relating to the zone to which the Member State belongs.

According to ECCA the number of competitors on the EU market has been reduced due to the data protection rules of Directive 91/414/EEC[67]. In fact, the research done for this impact assessment indicates that data protection rules have contributed to a reduction of the market share of generic PPP in the EU, at least in several Member States. Competent authorities were asked to assess whether after the inclusion in Annex I the number of PPP in general and the market share of generics products containing this active substance has increased or decreased. Authorities from 9 Member States reported that the number of PPP has decreased by at least 10% to 25 % after Annex I inclusion of the active substance. In 8 MS the market share of generic PPP has decreased to a similar degree after Annex I inclusion of the active substance. This is illustrated in the following graph:

66 Email Brito Correia, 2.2.2006.

67 Questionnaire ECCA.



Source: Survey of competent authorities

As is indicated in the graph, the majority of competent authorities reported that both the number of PPP and the market share of generic products remained similar, meaning a change of less than 10%. However, during the interviews with competent authorities it became clear that also in some of these countries the tendency was rather a decrease than an increase (be it to a lesser degree), and several countries did not report a decrease because generic products were not on the market at all before Annex I inclusion. It was also reported from several Member States that even if after Annex I inclusion generic producers remained on the market, they often had to change the provider of the active substance and source it from the former patent-holder to obtain access to data, thereby ceasing to be a competitor and becoming basically a part of the distribution network of the former patent holder.

The reduction of generic competition because of data protection rules has given rise to competition concerns. In a statement provided to the Contractor DG Competition these concerns were voiced as follows: "[I]n general, the largest agrochemical companies either hold the data required for the inclusion of a given active substance in Annex I of Directive 91/414 or the necessary financial resources for compiling such data. This position confers on them the possibility to exclusively commercialise such active substance even after the expiry of patent protection. Furthermore, this position may oblige companies, which have been active in the downstream markets for years and cannot access or collect the relevant data, to cease their activity and leave the market, thus reducing or eliminating competition in the market concerned. [...] Currently, there is a general risk that data protection legislation may be exploited in order to eliminate competition from both upstream markets – active substances- and downstream market – formulated products"[68].

So far, price trends on the European PPP market have not given rise to concerns. Most competent authorities did not have data on price developments available. Those few that

[68] Statement - Email DG Competition, 17.11.2005.

provided an assessment did mostly not report any or only little price increases because of the reduction of number of PPP or the reduction of market share of generic products. Other stakeholders only rarely report price increases after Annex I inclusion (e.g. from AEFISA, Spain and IPPA, Germany). The main price effects reported from other stakeholders are those caused by the need to change products after an active substance was not included in Annex I and withdrawn from the market. The Eurostat price index for agrochemicals is given in Table 12.

Table 12: Nominal agricultural input prices of plant protection products and pesticides for the EU 25 (base year: 2000=100)

	2000	2001	2002	2003	2004
Fungicides	100	101.0	100.7	99.9	100.5
Insecticides	100	101.8	105.2	105.1	107.1
Herbicides	100	100.4	100.5	101.1	100.9
Other PPP	100	101.6	104.2	104.4	105.2
TOTAL PPP	100	100.7	101.4	101.4	102.2

Source: Eurostat

According to this data the price index for plant protection products and pesticides shows a slight increase in nominal input prices for the EU 25 from 2000 (100) to 2004 (102.2). However the 'deflated' index, in which the effect of inflation has been deducted, indicates for the same period an overall decline in prices from 2000 (100) to 2004 (92.8).

Some competent authorities expect price effects in the future when more decisions on Annex I inclusion (or non-inclusion) will have been taken. Also, no detailed and recent data was available on the level of prices of plant protection products in the EU compared to third country markets, which would provide additional insight on whether possible monopoly situations in some relevant product markets are harming competition and consumer welfare.

3.5. Problems related to information availability on PPP authorisation and use

3.5.1. Transparency of evaluation procedure

Currently, the Commission employs two websites on the status of the evaluation process on Annex I inclusion. The first website has restricted access and contains confidential data provided by the Commission to the Member States. The second website is publicly available on the EUROPA server of the Commission. This site contains public information on the evaluation of PPP at the Commission and provides links to Member States[69]. According to some stakeholders, the information availability on PPP use for stakeholders could be optimised and the evaluation and authorisation procedures are far from being transparent. "The actual authorization process is still not transparent and input

[69] Working Document SANCO/2693/2001 of 25 July 2001, p. 4, 5.

from public interest groups is very restricted"[70]. Information which is currently only available on the website with restricted access can be protected due to commercial confidentiality. Because there is no clear definition for the term 'commercial confidentiality', this may cause a concern that it is used "as excuse for … excessive restriction" of access to dossiers.

3.5.2. Information availability for neighbours and bystanders

Currently, especially the UK is engaged in a discussion on the effects of PPP usage on the health of neighbours and bystanders. Neighbours and bystanders may perceive the application of PPP as a health risk, as they might come in contact with spray drift. According to some stakeholders, there is currently a lack of information availability for neighbours and bystanders. A recent report by the Royal Commission on Environmental Pollution in the UK highlighted concerns with respect to bystander protection. It states that "we are concerned that the toxicological testing currently undertaken within the pesticides approval and assessment process, whilst taking into account a wide range of health problems, does not encompass the full range of conditions that have been described to us by members of the public and attributed by them to exposure to pesticides."

The Royal Commission recommends that "records of which pesticides, and when and where they have been used, should be directly available from the persons responsible for crop spraying upon request to any resident and bystander and to researchers investigating the health effects of resident and bystander exposure. We recommend that the residents living next to fields that are to be sprayed be given prior notification of what substances are to be sprayed, where and when" [71].

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70 PAN Europe 2001, PAN Europa position on EU pesticides authorisation p. 5.

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

4. POLICY OBJECTIVES AND RELATED IMPACT AREAS

4.1. General policy objectives

It is intended to amend or replace Directive 91/414/EEC with new legislation to address current problems (see section 3) and to meet several political objectives. In general, these can be divided in economic, social and environmental objectives.

4.1.1. Economic objectives

In order to create a more dynamic, innovative and attractive Europe, new legislation has to be in line with the Lisbon Strategy. The Strategy states, "the Union must become the most competitive and dynamic knowledge-based economy in the world"[72]. New legislation should stimulate competitiveness and openness so that European companies are able to increase their efficiency and innovative potential. Vigorous competition in a supportive business environment, research and innovation are key elements for productivity growth and competitiveness[73]. Related to an improved regulative environment is the reduction of administrative costs. Administrative costs imposed by legislation should be reduced as much as possible[74]. It has therefore been decided to include the following impacts into the scope of the assessment:

⇒ Impact on the administrative burden of competent authorities of Member States, PPP industry, PPP users;

⇒ Impact on indirect costs for PPP users arising from a change in the availability of PPPs on the market;

⇒ Impact on investment of PPP producers in R&D activities and in supporting existing products through re-registration, through changed authorisation procedures and data protection/sharing rules;

⇒ Impact on EU PPP industry competitiveness.

4.1.2. Social objectives

Competitiveness is a measure of an economy's ability to create valuable goods and services productively in a globalising world so as to raise the standard of living and secure high employment, as the Commission has reinforced various times[75]. Any new measure has therefore to be scrutinised with respect to its competitiveness and employment effects.

A general objective of the Community is improved access to environmental information and the promotion of better understanding of and participation in environmental issues

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72 European Council, March 2000, Lisbon: europa.eu.int/comm/education/policies/2010/et_2010_en.html

73 COM(2004) 293 - A pro-active Competition Policy for a Competitive Europe, Brussels, 20.4.2004, p. 3,4.

74 EC 2005, Annex to the Communication on better Regulation for Growth and Jobs in the European Union. Minimising Administrative Costs Imposed by Legislation. Detailed outline of a possible EU Net Administrative Cost Model, p. 2

75 E.g. COM(2004) 293, p. 3.

amongst European citizens[76]. Also, avoiding the duplication of tests on animals, particularly vertebrate animals, is a declared objective of the EU chemicals policy[77].

It has therefore been decided to include the following impacts into the scope of the assessment:

⇒ Impact on employment in producer sector arising from changed authorisation procedures and data protection/sharing rules

⇒ Impact on information opportunities of citizens in terms of the availability of information on PPP use for neighbours of agricultural areas

⇒ Impact on animal welfare in terms of the reduction of the number of duplicated studies on vertebrate animals conducted for PPP authorisation

4.1.3. Environmental objectives

A priority action of the Sixth Community Environment Action Programme is a thematic strategy on the sustainable use of pesticides that addresses, among others (i) minimising the hazards and risks to health and environment from the use of pesticides; (ii) improved controls on the use and distribution of

Pesticides; and (iii) reducing the levels of harmful active substances including through substituting the most dangerous with safer, including non-chemical, alternatives[78].

It has therefore been decided to include the following impacts into the scope of the assessment:

⇒ Impact on controls on use and distribution in terms of reduction of unauthorised cross-border sourcing of PPPs

⇒ Impact of active substances on the environment or human health - potential for reduction through comparative assessment

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[76] E.g. in DECISION No 1600/2002/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 July 2002 laying down the Sixth Community Environment Action Programme, Article 3.

[77] COM(2001) 88 - Commission White Paper of 27 February 2001 on the strategy for a future chemicals policy.

[78] Sixth Community Environment Action Programme, Article 7.

5. POLICY OPTIONS AVAILABLE TO REACH OBJECTIVES

5.1. Policy action 1: Authorisation of PPP containing a new active substance / national provisional authorisation

5.1.1. Overview

Based on exploratory interviews with DG SANCO, competent authorities, industry, farmers and other stakeholders the following options for assessment were selected and agreed by the Inter-Services Steering Group of the Impact Assessment:

- Option A: No EU action (Status Quo): Centralised procedure for evaluation of new AS without binding time limits. No national provisional authorisation (NPA) after 2007;
- Option B: Centralised procedure for evaluation of new active substances with binding time limits. No national provisional authorisation;
- Option C: Keep national provisional authorisation after Draft Assessment Report and continue to foresee provisional national MRLs after 2007.

These options are described in more detail below.

5.1.2. Description of options

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

This option describes the continuation of the Status Quo (No EU action). The current Community evaluation procedure for a new active substance according to Directive 91/414/EEC would continue, without introducing new binding time limits, to speed up the evaluation process. The Status Quo scenario takes into account a modification of Art. 4.1. (f) of Directive 91/414/EEC by Art. 48 of Regulation 396/2005, which is expected to be applicable around 2007. With this legislative change Member States can no longer set provisional national MRL, which in turn will lead to the abolishment of national provisional authorisation, according to the legal interpretation of DG SANCO. This option therefore consists of different authorisation timelines for the current situation (reference scenario) and the situation after the abolishment of national provisional authorisation. These two options are later referred to as *option A1* (reference scenario) and *option A2* (after 2007). It has to be noted that strictly speaking only option A2 is of relevance, as a possible new regulation replacing Directive 91/414/EEC is not to be expected to be applicable before 2008. However, to be able to compare the impacts of different options with the current situation it was decided to also include option A1.

5.1.2.2. Option B: Centralised procedure for evaluation of new AS with binding time limits. No national provisional authorisation.

The current Community evaluation procedure for a new active substance according to Directive 91/414/EEC would continue, however, the authorisation procedure would be

subjected to time limits for each step, leading to a maximum duration of 25 months. The foreseen time limits are: Validity Check of Dossier (1 months); Draft Assessment Report by RMS (12 months); EFSA Conclusion (6 months); Commission Directive (6 months).

5.1.2.3. Option C: Keep national provisional authorisation after Draft Assessment Report and continue to foresee provisional national MRLs after 2007.

With option C national provisional authorisation would be kept as a possibility after the Draft Assessment Report is available (i.e., at a later stage compared to the current situation, where a NPA is in principle possible after the Commission Decision on the completeness of the dossier). According to the legal interpretation of DG SANCO this would require a change in the new MRL Regulation (396/2005), which is expected to be applicable around 2007.

5.1.3. Fine-tuning of options during the impact assessment

During the consultation process performed in the framework of this impact assessment one of the stakeholder organisations challenged the legal interpretation of DG SANCO that with a modification of Art. 4.1. (f) of Directive 91/414/EEC by Art. 48 of Regulation 396/2005, which is expected to be applicable around 2007, national provisional authorisation would be abolished[79]. As a legal analysis of the new MRL regulation was not part of the mandate for this study, it was decided not to address this issue in depth. The question also seems to be only of limited relevance to this study, as both an option with NPA and an option without NPA are considered in the assessment. The question of whether a change of Regulation 396/2005 would be required to keep national provisional authorisation or not would therefore not significantly affect the outcome of the impact assessment with respect to the related impacts.

A more detailed definition of option B, however, seemed appropriate during the assessment, as it became clear that in fact this option could be interpreted in two different ways that would significantly alter the outcome. One interpretation of this option would be to assume that keeping the current Community evaluation procedure for a new active substance with binding time limits and abolishing NPA would imply that PPP authorisation could only start after Annex I inclusion, leading therefore to a extension of the timeline compared to the Status Quo. This approach later is referred to as "sequential approach" or *option B1*. Alternatively, however, PPP authorisation could already start after the DAR is available. With this approach the PPP authorisation process would be ongoing in parallel to the peer review of the Community evaluation of the active substance, later referred to as "parallel approach" (*option B2*). The PPP authorisation would only come into force after the decision on Annex I inclusion of the new active substance, this being the major difference to the present system of national provisional authorisations.

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[79] The European Crop Protection Association (ECPA) stated that "the removal of provisional national MRLs does not exclude the possibility of National provisional authorisations. Provisional EU MRLs … will be possible for NPA authorisations – ensuring early market access if the binding MRL time limits are applied. Provisional EU MRLs will be set by the new EFSA/COMM procedure and will thus not [be] given by the country evaluating the NPA, but instead by EFSA".

5.2. Policy action 2: Mutual recognition of PPP containing an active substance already included in Annex I

5.2.1. Overview

Based on exploratory interviews with DG SANCO, competent authorities, industry, farmers and other stakeholders the following options for assessment were selected and agreed by the Inter-Services Steering Group of the Impact Assessment:

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

These options are described in more detail below.

5.2.2. Description of options

5.2.2.1. Option A: No EU action (Status Quo): National evaluation and authorisation of PPP with optional mutual recognition.

The current situation with respect to the authorisation of a PPP containing an active substance already included in Annex I is described in sections 2.1 and 3.2.

5.2.2.2. Option B: Zonal evaluation and national authorisation of PPP with compulsory mutual recognition. No national risk mitigation measures.

The application for the authorisation of a PPP containing an active substance already included in Annex I shall be examined by one Member State proposed by the applicant in each of three zones that are defined in a Commission proposal, unless another Member State in the same zone agrees to examine the application. The zones foreseen are[80]:

Zone A – North. The following Member States are belonging to this zone: Denmark, Estonia, Latvia, Lithuania, Finland, Sweden;

Zone B – Center. The following Member States are belonging to this zone: Austria, Belgium, Czech Republic, Germany, Hungary, Ireland, Luxemburg, Netherlands, Poland, Slovakia, Slovenia, United Kingdom;

[80] Commission draft of a new Regulation concerning the placing of plant protection products and adjuvants on the market, October 2005.

Zone C – South. The following Member States are belonging to this zone: Cyprus, France, Greece, Italy, Malta, Portugal, Spain.

When this designated Member State authorises the PPP, all other Member States in the same zone must authorise the PPP too, if an application is made. A conciliation procedure is foreseen in case of disagreement between Member States. Member States may refuse mutual recognition of authorizations granted for plant protection products containing an active substance, which are included in the new Annex ID to be introduced under Policy Action 3 (comparative assessment, option B), i.e. the list of active substances that are candidates for substitution.

Under this option it is assumed that Member States would not have the possibility to introduce national risk mitigation measures when applying compulsory mutual recognition.

5.2.2.3. Option C: Zonal evaluation and national authorisation of PPP with compulsory mutual recognition. However, national risk mitigation measures.

This option would be similar to option B, however with the possibility to require national risk mitigation measures when applying compulsory mutual recognition.

5.2.2.4. Option D: Central agency for evaluation and authorisation of PPP with use of MS resources.

Such a system would have some similarities to the centralised procedure of the European Medicines Agency (EMEA). EMEA is a decentralised body of the European Union with headquarters in London. EMEA coordinates the evaluation and supervision of medicinal products throughout the European Union. The Agency brings together the scientific resources of the 25 EU Member States in a network of more than 40 national competent authorities. In the centralised procedure companies submit one single marketing authorisation application to the EMEA. A single evaluation is carried out through the Committee for Medicinal Products for Human Use or the Committee for Medicinal Products for Veterinary Use. If the relevant Committee concludes that quality, safety and efficacy of the medicinal product is sufficiently proven, it adopts a positive opinion. This is sent to the Commission to be transformed into a single market authorisation valid for the whole of the European Union. A network of some 3 500 European experts underpins the scientific work of the EMEA and its committees[81].

5.2.3. Fine-tuning of options during the impact assessment

During the consultation process performed in the framework of this impact assessment hardly any of the stakeholders proposed changes to the options selected under this policy action. Only ECPA claimed that an "Option E is missing, which would consist of a flexible, voluntary work sharing system". However, such a system would not change the legal basis and associated problems with mutual recognition and would not comprise a very significantly different approach compared to option A (Status Quo). For this reason, it was decided to not consider this option separately.

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[81] http://www.emea.eu.int/htms/aboutus/emeaoverview.htm, last accessed 14.2.2006.

5.3. Policy action 3: Comparative assessment of PPP

5.3.1. Overview

Based on exploratory interviews with DG SANCO, competent authorities, industry, farmers and other stakeholders the following options for assessment were selected and agreed by the Inter-Services Steering Group of 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 (Annex ID). 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.

These options are described in more detail below.

5.3.2. Description of options

5.3.2.1. Option A: No EU action (Status Quo): No provision for comparative assessment.

The current situation with respect to comparative assessment is described in section 3.3.

5.3.2.2. Option B: Identification of candidates for substitution at the EU level based on hazard criteria (Annex ID). Comparative assessment of PPP at the national level.

With option B an assessment has to be done when an application for authorization of a plant protection product is made that contains an active substance included in Annex ID. An active substance is included in Annex ID when certain criteria are fulfilled. The Commission provided draft criteria for the inclusion of an active substance in Annex ID for discussion:

"An active substance will be listed in Annex ID if it meets the criteria for inclusion into Annex IA but where:

- its ADI, ARfD or AOEL are very low compared to the active substances included in Annex IA
- it meets [one] [two] of the criteria to be considered as a PBT substance
- there are reasons for concern linked to the nature of the critical effects (such as sensitisation, corrosivity, neurotoxicity, carcinogenicity, mutagenicity and reproductive toxicity, high toxicity to environmental organisms and bioaccumulation), which, in combination with the use/exposure patterns, imply use situations that could still cause concern. This is the case when its conditions of use are such that only with very restrictive risk management options (such as very extensive personal protective equipment or very large buffer zones) it can be achieved that its use is not harmful for human or animal health or not unacceptable for the environment

- the active substance contains an important proportion of non-active isomers."

In the draft Regulation provided to the Contractor[82], the principles for applying comparative assessment at the Member State level are defined as follows:

"When an application for authorization of a plant protection product containing an active substance included in Annex ID is made, Member States shall evaluate in an independent, objective and transparent manner (…) whether for the uses of the plant protection product there are efficient alternatives or non-chemical control methods which, in the light of scientific or technical knowledge, are significantly safer for human or animal health or the environment. When performing such evaluations Member States shall take into account the balance between the risks and the benefits of the use of the plant protection product, and in particular the following principles:

- the chemical diversity of the active substances should be adequate to minimise occurrence of resistance in the target organism;
- the principle of comparative assessment should be applied only to active substances which, when used under normal conditions in authorised plant protection products, present a significantly different level of risk;
- the principle of comparative assessment should be applied only after allowing the possibility, where necessary, of acquiring experience from use in practice, if it is not already available."

5.3.2.3. 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 (i.e. for all active substances).

Option C is similar to option B with respect to the principles of comparative assessment and substitution. However it would be relevant for all active substances, i.e. there would not be a separate Annex ID with candidates for substitution.

5.3.3. Fine-tuning of options during the impact assessment

No fine-tuning of options was necessary during the impact assessment.

[82] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the placing of plant protection products and adjuvants on the market, October 2005.

5.4. Policy action 4: Data sharing for the renewal of Annex I inclusion of an active substance

5.4.1. Overview

Based on exploratory interviews with DG SANCO, competent authorities, industry, farmers and other stakeholders the following options for assessment were selected and agreed by the Inter-Services Steering Group of the Impact Assessment:

- Option A: No EU action (Status Quo): 5 years of data protection starting with the renewal of Annex I inclusion. No provisions on compulsory data sharing;
- Option B: 5 years of data protection starting six month after the renewal of Annex I inclusion. Compulsory data sharing with compensation and an arbitration mechanism;
- Option C: No data protection period for renewal of inclusion in Annex I;
- Option D: 5 years of data protection starting with the time of dossier submission for the renewal of Annex I inclusion. 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.

5.4.2. Description of options

All options refer to the renewal of Annex I inclusion of an active substance. Data protection provisions apply, however, for other cases as well. The duration of data protection for the first inclusion of a new active substance and the first authorisation of a PPP will remain 10 years of exclusivity without compulsory data sharing. However, the principles of data sharing with compensation and an arbitration mechanism also apply for the renewal of authorisation of a PPP. Tests and studies involving vertebrate animals may not be repeated for the purpose of an application for the inclusion or renewal of inclusion of an active substance in Annex I or for the authorization of a PPP. With all options data protection only applies to new, i.e. previously unused studies submitted with the dossier.

5.4.2.1. Option A: No EU action (Status Quo): 5 years of data protection starting with the renewal of Annex I inclusion. No provisions on compulsory data sharing;

The current situation with respect to data protection is described in section 3.4.

5.4.2.2. Option B: 5 years of data protection starting six month after the renewal of Annex I inclusion. Compulsory data sharing with compensation and an arbitration mechanism.

If the applicant and holders of previous authorizations can not reach an agreement on the sharing of test and study reports, the matter may be submitted for binding arbitration to an arbitration organisation unless the applicant decides to withdraw his application or to generate the data himself.

5.4.2.3. Option C: No data protection period for renewal of inclusion in Annex I;

This option would not foresee any form of data protection for studies submitted for renewal of inclusion of an active substance in Annex I.

5.4.2.4. Option D: 5 years of data protection starting with the time of dossier submission for the renewal of Annex I inclusion. No provisions on compulsory data sharing, however a compulsory joint task-force.

It would be compulsory for interested companies to cooperate to provide a joint dossier containing all additional data required to maintain an authorisation of an active substance. Non-cooperating companies, that either had not declared their interest to participate in the joint task-force or decided to enter the market at a later stage would only be allowed onto the market during the data protection period if they generate their own data or negotiate access with the cooperating parties.

5.4.3. Fine-tuning of options during the impact assessment

No fine-tuning of options was necessary during the impact assessment.

5.5. Policy action 5: Informing neighbours on PPP use

5.5.1. Overview

Based on a exploratory interviews with DG SANCO, competent authorities, industry, farmers and other stakeholders the following options for assessment were selected and agreed by the Inter-Services Steering Group of 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.

5.5.2. Description of options

5.5.2.1. Option A: No EU action (Status Quo): No duty to inform neighbours on use of toxic PPP.

The current situation would continue and informing neighbours on use of PPP would be a voluntary measure by farmers or subject to national rules.

5.5.2.2. Option B: Active duty to inform neighbours on use of toxic PPP.

For PPP classified under Directive 1999/45/EC as very toxic or toxic applied by spraying, the authorisation of the PPP by the competent authority can stipulate the obligation to inform neighbours who could be exposed to the spray drift before the product is used.

5.5.2.3. Option C: Passive duty to inform neighbours on use of dangerous PPP

This would imply a duty to provide information to neighbours on demand. Application at least for similar PPP as under Option B (classified under Directive 1999/45/EC as very toxic or toxic applied by spraying).

5.5.3. Fine-tuning of options during the impact assessment

No fine-tuning of options was necessary during the impact assessment.

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