



COMMISSION OF THE EUROPEAN COMMUNITIES

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COMMISSION STAFF WORKING PAPER

Report on

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

Annexes 1-5

EN

Lead DG: SANCO

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

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Annex 1

Refined Assessment on Administrative burden

A) Questionnaire



IMPACT ASSESSMENT
REVISION OF DIRECTIVE 91/414/EEC
ASSESSMENT OF POTENTIAL ADMINISTRATIVE BURDEN
*
DG HEALTH AND CONSUMER PROTECTION
EUROPEAN COMMISSION
BRUSSELS

Please return questionnaire by email to SANCO-QUESTIONNAIRE-02@cec.eu.int or by fax to +32-2-296 48 75 before **10.02.2006**

We also offer to jointly fill in the questionnaire and discuss your comments during a phone interview,
should you prefer this (see contact details below)

IDENTIFICATION DATA

Name and country of organisation:

Please specify

Questionnaire completed by (Name of person, position, contact details):

Please specify

INTRODUCTION

The European Commission intends to revise Directive 91/414/EEC on the placing of Plant Protection Products (PPP) on the market. 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 already been drafted. Impact Assessment of the new Regulation replacing Directive 91/414/EEC on plant protection products is being developed simultaneously. The impact assessment team considers the experience and perspective of Member State authorities as crucial inputs into the impact assessment process.

There has been already one detailed questionnaire addressed to Member States and prepared by external consultants (Food Chain Evaluation Consortium), which supports the European Commission in drafting of the Impact Assessment. However, this survey only briefly touched

upon the impact of the new Regulation on so-called Administrative Burden that is all costs incurred by enterprises, the voluntary sector, public authorities and citizens in meeting legal obligations to provide information on their action or production, either to public authorities or to private parties.

The recent conclusions of the European Council that took place in Brussels, 15-16 of December, stressed the importance "...of reducing unnecessary burdens for business and citizens", as well as it invited "...the Commission to start measuring administrative burdens, on a consistent basis and in line with transparent criteria, as part of integrated impact assessments launched as of January 2006."

Having in mind this clear message from the European highest authority, DG Health and Consumer Protection has decided to prepare more detailed analysis of Administrative Costs of new legislation of plant protection products. This survey goes beyond the analysis that will be carried out by Food Chain Evaluation Consortium, therefore we would like endorse for your consideration this additional questionnaire.

Questions in the following sections relate to the current application of Directive 91/414/EEC and alternative policy actions for the future. The detailedness of the questionnaire is driven by underlying effort to quantify the potential costs / benefits with the best possible accuracy.

We would like to apologize for submitting the questionnaire only in English, as due to time constraints we have decided to proceed only with one language version. Thank you for your comprehension.

Similarly as in previous questionnaire, **please note that the point of reference for all questions related to your assessment of impacts is the current situation in your country.** The answers you will give are assumed to reflect your expertise in authorisation of PPP and are not considered to be the official position of your country. Results will be presented in aggregated form only.

We would like to thank you in advance for your contribution, as it is highly valuable to us and is crucial in process of assessment of the feasibility of different options.

In case you have any further questions, do not hesitate to contact us:

- On questionnaire related matters:

Mr. Wojciech Dziworski (Policy Officer, DG Health and Consumer Protection)

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- On new regulation related matters:

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**I. CURRENT APPLICATION OF DIRECTIVE 91/414/EEC
DURATION AND COSTS OF AUTHORISATION/EVALUATION PROCEDURE**

1. Please estimate the annual average number of submitted applications for the authorisation/evaluation ...

a) ... of a new active substance that supported by a full data package (in case your country is RMS)?

Please specify

b) ... of a new PPP containing an active substance already included in Annex I where the type of use is similar to those previously considered for the active substance?

Please specify

c) ... of a new PPP containing an active substance already included in Annex I where the type of use is very different to those previously considered for the active substance?

Please specify

2. What is the average time (in calendar months) for the authorisation/evaluation procedure (from day of receiving the application) ...

! Question asked in previous questionnaire – no answer is needed !

3. If possible, please give an estimate of the average cost* (in EUR) of the authorisation / evaluation procedure

a) ... of a new active substance that supported by a full data package (in case your country is RMS)?

Please specify

b) ... of a new PPP containing an active substance already included in Annex I where the type of use is similar to those previously considered for the active substance?

Please specify

c) ... of a new PPP containing an active substance already included in Annex I where the type of use is very different to those previously considered for the active substance?

Please specify

* Cost – the figure should include all variable costs related to authorisation / evaluation procedure as well as proportion of related fixed costs (i.e. overheads, salaries)

4. Please give an estimate in % how much of the total cost of the authorisation / evaluation procedure is generated internally, by external bodies (done by other public authorities or public institutes / institutions) or by outsourcing companies (to private institutes or companies).

a) ... of a new active substance that supported by a full data package (in case your country is RMS)?

<i>Internal</i>	%	<i>External</i>	%	<i>Internal</i>	%
-----------------	---	-----------------	---	-----------------	---

b) ... of a new PPP containing an active substance already included in Annex I where the type of use is similar to those previously considered for the active substance?

<i>Internal</i>	%	<i>External</i>	%	<i>Internal</i>	%
-----------------	---	-----------------	---	-----------------	---

c) ... of a new PPP containing an active substance already included in Annex I where the type of use is very different to those previously considered for the active substance?

<i>Internal</i>	%	<i>External</i>	%	<i>Internal</i>	%
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5. Please estimate the average staff time (in full time equivalent working days*) for the authorisation/evaluation procedure ...

! Question asked in previous questionnaire – no answer is needed !

* Example: If one staff would work full time for 600 working days and a second staff 50% of the time for the same period, this would amount in total to 900 full time equivalent working days.

6. Please estimate what % of average total staff time (referred to in point 5 or in point 11 of previous questionnaire) for the authorisation/evaluation procedure is dedicated by yourself as competent authority to each of the actions listed below:

	Type of action	New active substance	New PPP containing Annex I active substance but with use very different	New PPP containing Annex I active substance but with use similar
1	Familiarising with the application	%	%	%
2	Check of completeness and quality of the application	%	%	%
3	Analysis of available studies	%	%	%
4	Consultation with the applicant on data / info gaps to be filled	%	%	%
5	Holding meetings (internal an external)	%	%	%
6	Co-ordination of work of external bodies and outsourcing companies	%	%	%
7	Preparation and compilation of the decision paper	%	%	%
8	Sending of the decision paper to the applicant	%	%	%

9	Follow – up activities	%	%	%
10	Other	%	%	%
		%	%	%
		%	%	%
		%	%	%
		100%	100%	100%

7. Please estimate for each of actions listed below (similarly as in question 6) what % of working hours is done outside the competent authority, that is externalized (done by other public authorities or public institutes / institutions) and outsourced (to private institutes or companies):

	Type of action	New active substance	New PPP containing Annex I active substance but with use very different	New PPP containing Annex I active substance but with use similar
1	Familiarising with the application	%	%	%
2	Check of completeness and quality of the application	%	%	%
3	Analysis of available studies	%	%	%
4	Consultation with the applicant on data / info gaps to be filled	%	%	%
5	Holding meetings (internal and external)	%	%	%
6	Co-ordination of work of external bodies and outsourcing companies	%	%	%
7	Preparation and compilation of the decision paper	%	%	%
8	Sending of the decision paper to the applicant	%	%	%
9	Follow – up activities	%	%	%
10	Other	%	%	%
		%	%	%
		%	%	%
		%	%	%

II. POLICY ACTIONS RELATED TO THE REVISION OF DIRECTIVE 91/414/EEC

POLICY ACTION 1: AUTHORISATION OF PPP CONTAINING A NEW ACTIVE SUBSTANCE / NATIONAL PROVISIONAL AUTHORISATION

Please compare the following options:

- ❑ **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.** Due to a change to Directive 91/414/EEC introduced by new MRL regulation (which will be applicable +/- 2007) provisional national MRL can no longer be set by Member States (Art. 4.1. f of Directive 91/414/EEC as modified by Art. 48 of Regulation 396/2005).
- ❑ **Option B: Centralised procedure for evaluation of new AS with binding time limits. No national provisional authorisation.** The authorisation procedure for AS is subjected to time limits for each steps, leading to a foreseen maximum duration of 25 months.
- ❑ **Option C: Keep national provisional authorisation after Draft Assessment Report and continue to foresee provisional national MRLs after 2007.** This would require a change in the new MRL regulation.

8. How do you assess the impact of the different policy options on yourself as competent authority in terms of the annual average number of applications for the authorisation / evaluation of a new active substance (supported by full data package, in case your country is RMS)?

! If possible please give an estimate of increase/decrease in number of applications (column 1) !

	1	2	3	4	5	6
Number of applications for the authorisation / evaluation would...	Increase (+) / decrease (-) by number of applications	as % change compared to current situation (only if column 1 not filled in)				
		decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	increase very significantly (>25%)
<i>Option A: Status quo - without binding time limits. No NPA after 2007</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: With binding time limits. No NPA</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: Keep NPA after Draft Assessment Report</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

Comments

9. How do you assess the impact of the different policy options on yourself as competent authority in terms of the number of staff days needed per application

for a new active substance (supported by full data package, in case your country is RMS)?

! In addition to previous questionnaire, if possible, please give an estimate of increase/decrease in number of days !

Number of staff days per application would ...	Increase (+) / decrease (-) by number of days
<i>Option A: Status quo - <u>without</u> binding time limits. No NPA after 2007</i>	
<i>Option B: <u>With</u> binding time limits. No NPA</i>	
<i>Option C: Keep NPA after Draft Assessment Report</i>	

Not marked = Don't know

Comments

10. How do you assess the impact of the different policy options on the duration (in days) of the evaluation procedure?

! In addition to previous questionnaire, if possible, please give an estimate of increase/decrease in number of days !

Duration of the evaluation procedure would ...	Increase (+) / decrease (-) by number of days
<i>Option A: Status quo - <u>without</u> binding time limits. No NPA after 2007</i>	
<i>Option B: <u>With</u> binding time limits. No NPA</i>	
<i>Option C: Keep NPA after Draft Assessment Report</i>	

Not marked = Don't know

Comments

11. How do you assess the impact of the different policy options in terms of increase or decrease (in %) of cost of work done internally (competent authority), by external bodies (other public authorities or public institutes / institutions) or by outsourcing companies (private companies)?

		1	2	3	4	5
Cost of work done internally, externally or outsourced would...		decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	increase very significantly (>25%)
% change compared to current situation						
<i>Option A: Status quo - without binding time limits. No NPA after 2007</i>	Internal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	External	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Outsourced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: With binding time limits. No NPA</i>	Internal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	External	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Outsourced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: Keep NPA after Draft Assessment Report</i>	Internal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	External	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Outsourced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

<i>Comments</i>

12. How do you assess the impact of the different policy options in terms of relative increase or decrease (in %) of average staff time (meant as in question 5 & 6) for the authorisation/evaluation procedure dedicated to each of the actions listed below:

	Type of action	<i>Option A: Status quo - <u>without</u> binding time limits. No NPA after 2007</i>	<i>Option B: <u>With</u> binding time limits. No NPA</i>	<i>Option C: Keep NPA after Draft Assessment Report</i>
1	Familiarising with the application	%	%	%
2	Check of completeness and quality of the application	%	%	%
3	Analysis of available studies	%	%	%
4	Consultation with the applicant on data / info gaps to be filled	%	%	%
5	Holding meetings (internal an external)	%	%	%
6	Co-ordination of work of external bodies and outsourcing companies	%	%	%
7	Preparation and compilation of the decision paper	%	%	%
8	Sending of the decision paper to the applicant	%	%	%
9	Follow – up activities	%	%	%
10	Other	%	%	%
		%	%	%
		%	%	%
		%	%	%

Not marked = Don't know

Comments

POLICY ACTION 2: MUTUAL RECOGNITION OF PLANT PROTECTION PRODUCTS CONTAINING AN ACTIVE SUBSTANCE ALREADY INCLUDED IN ANNEX I

Please compare the following options:

- ❑ **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.** The application shall be examined in each of the three zones by one Member State proposed by the applicant, unless another Member State in the same zone agrees to examine the application. When this MS authorises, all other MSs in the same zone must authorise the PPP too, if an application is made. Conciliation procedure in case of disagreement between MS.
- ❑ **Option C: Zonal evaluation and national authorisation of PPP with compulsory mutual recognition. However, national risk mitigation measures.** As Option B, however with the possibility to require national risk mitigation measures during the authorisation process.
- ❑ **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 (EMA), that consists of a single application which, when approved, grants authorisation for all markets within the European Union.

13. How do you assess the impact of the different policy options on yourself as competent authority in terms of the annual average number of applications for a PPP containing an active substance already included in Annex I?

! If possible please give an estimate of increase/decrease in number of applications (column 1)!

	1	2	3	4	5	6
Number of applications for a PPP would...	Increase (+) / decrease (-) by number of applications	as % change compared to current situation (only if column 1 not filled in)				
		decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	increase very significantly (>25%)
<i>Option A: Status quo - National evaluation and authorisation</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: Zonal evaluation and national authorisation – <u>no</u> national risk mitigation measures</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: Zonal evaluation and national authorisation – <u>with</u> national risk mitigation measures</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option D: Central agency for evaluation and authorisation</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

<i>Comments</i>

14. How do you assess the impact of the different policy options on yourself as competent authority in terms of the average number of staff days needed per application for a PPP containing an active substance already included in Annex I?

! In addition to previous questionnaire, if possible, please give an estimate of increase/decrease in number of days !

Number of staff days per application for a PPP would ...	Increase (+) / decrease (-) by number of days
<i>Option A: Status quo - National evaluation and authorisation</i>	
<i>Option B: Zonal evaluation and national authorisation – <u>no</u> national risk mitigation measures</i>	
<i>Option C: Zonal evaluation and national authorisation – <u>with</u> national risk mitigation measures</i>	
<i>Option D: Central agency for evaluation and authorisation</i>	

Not marked = Don't know

<i>Comments</i>

15. How do you assess the impact of the different policy options on the duration of the authorisation procedure?

! In addition to previous questionnaire, if possible, please give an estimate of increase/decrease in number of days !

Duration of the authorisation procedure would ...	Increase (+) / decrease (-) by number of days
<i>Option A: Status quo - National evaluation and authorisation</i>	
<i>Option B: Zonal evaluation and national authorisation – <u>no</u> national risk mitigation measures</i>	
<i>Option C: Zonal evaluation and national authorisation – <u>with</u> national risk mitigation measures</i>	
<i>Option D: Central agency for evaluation and authorisation</i>	

Not marked = Don't know

Comments

16. How do you assess the impact of the different policy options in terms of increase or decrease (in %) of cost of work done internally (competent authority), by external bodies (other public authorities or public institutes / institutions) or by outsourcing companies (private companies)?

Cost of work done internally, externally or outsourced would...		1	2	3	4	5
% change compared to current situation		decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	increase very significantly (>25%)
<i>Option A: Status quo - National evaluation and authorisation</i>	Internal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	External	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Outsourced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: Zonal evaluation and national authorisation – <u>no</u> national risk mitigation measure</i>	Internal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	External	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Outsourced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: Zonal evaluation and national authorisation – <u>with</u> national risk mitigation measures</i>	Internal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	External	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Outsourced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option D: Central agency for evaluation and authorisation</i>	Internal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	External	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Outsourced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

Comments

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17. How do you assess the impact of the different policy options in terms of relative increase or decrease (in %) of average staff time (meant as in question 5 & 6) needed per application for a PPP containing an active substance already included in Annex I, dedicated to each of the actions listed below:

	Type of action	<i>Option A: Status quo - National evaluation and authorisation</i>	<i>Option B: Zonal evaluation and national authorisation – no national risk mitigation measures</i>	<i>Option C: Zonal evaluation and national authorisation – with national risk mitigation measures</i>	<i>Option D: Central agency for evaluation and authorisation</i>
1	Familiarising with the application	%	%	%	%
2	Check of completeness and quality of the application	%	%	%	%
3	Analysis of available studies	%	%	%	%
4	Consultation with the applicant on data / info gaps to be filled	%	%	%	%
5	Holding meetings (internal and external)	%	%	%	%
6	Co-ordination of work of external bodies and outsourcing companies	%	%	%	%
7	Preparation and compilation of the decision paper	%	%	%	%
8	Sending of the decision paper to the applicant	%	%	%	%
9	Follow – up activities	%	%	%	%
10	Other	%	%	%	%
		%	%	%	%
		%	%	%	%
		%	%	%	%

Not marked = Don't know

<i>Comments</i>

POLICY ACTION 3: COMPARATIVE ASSESSMENT OF PPP

Please compare the following options:

- ❑ **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.** The assessment has to be done when an application for authorization of a plant protection product containing an active substance included in Annex ID is made. *A draft of possible criteria for comparative assessment is given in the Annex of this questionnaire.*
- ❑ **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).**

18. How do you assess the impact of the different policy options on yourself as competent authority in terms of the annual average number of applications for a PPP?

! If possible please give an estimate of increase/decrease in number of applications (column 1) !

	1	2	3	4	5	6
Number of applications for a PPP would...	Increase (+) / decrease (-) by number of applications	as % change compared to current situation (only if column 1 not filled in)				
		decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	increase very significantly (>25%)
<i>Option A: Status Quo - No provision for comparative assessment</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: Identification of candidates for substitution at the EU level based on hazard criteria</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: Comparative assessment at the national level independent from the hazard of the active substances</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

Comments

19. How do you assess the impact of the different policy options on yourself as competent authority in terms of the average number of staff days needed per application for a PPP?

! In addition to previous questionnaire, if possible, please give an estimate of increase/decrease in number of days !

Number of staff days per application for a PPP would ...	Increase (+) / decrease (-) by number of days
<i>Option A: Status Quo - No provision for comparative assessment</i>	
<i>Option B: Identification of candidates for substitution at the EU level based on hazard criteria</i>	
<i>Option C: Comparative assessment at the national level independent from the hazard of the active substances</i>	

Not marked = Don't know

<i>Comments</i>

20. How do you assess the impact of the policy options on the duration of the authorisation procedure?

! In addition to previous questionnaire, if possible, please give an estimate of increase/decrease in number of days !

Duration of the authorisation procedure would ...	Increase (+) / decrease (-) by number of days
<i>Option A: Status Quo - No provision for comparative assessment</i>	
<i>Option B: Identification of candidates for substitution at the EU level based on hazard criteria</i>	
<i>Option C: Comparative assessment at the national level independent from the hazard of the active substances</i>	

Not marked = Don't know

<i>Comments</i>

21. How do you assess the impact of the different policy options in terms of increase or decrease (in %) of cost of work done internally (competent authority), by external bodies (other public authorities or public institutes / institutions) or by outsourcing companies (private companies)?

		1	2	3	4	5
Cost of work done internally, externally or outsourced would...		decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	increase very significantly (>25%)
% change compared to current situation						
<i>Option A: Status Quo - No provision for comparative assessment</i>	Internal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	External	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Outsourced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: Identification of candidates for substitution at the EU level based on hazard criteria</i>	Internal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	External	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Outsourced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: Comparative assessment at the national level independent from the hazard of the active substances</i>	Internal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	External	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Outsourced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

<i>Comments</i>

22. How do you assess the impact of the different policy options in terms of relative increase or decrease (in %) of average staff time (meant as in question 5 & 6) needed per application for a PPP, dedicated to each of the actions listed below:

	Type of action	<i>Option A: Status Quo - No provision for comparative assessment</i>	<i>Option B: Identification of candidates for substitution at the EU level based on hazard criteria</i>	<i>Option C: Comparative assessment at the national level independent from the hazard of the active substances</i>
1	Familiarising with the application	%	%	%
2	Check of completeness and quality of the application	%	%	%
3	Analysis of available studies	%	%	%
4	Consultation with the applicant on data / info gaps to be filled	%	%	%
5	Holding meetings (internal an external)	%	%	%
6	Co-ordination of work of external bodies and outsourcing companies	%	%	%
7	Preparation and compilation of the decision paper	%	%	%
8	Sending of the decision paper to the applicant	%	%	%
9	Follow – up activities	%	%	%
10	Other	%	%	%
		%	%	%
		%	%	%
		%	%	%

Not marked = Don't know

Comments

POLICY ACTION 4: DATA SHARING FOR THE RENEWAL OF ANNEX I INCLUSION OF AN ACTIVE SUBSTANCE

Please compare the following options:

- ❑ **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.** 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. Tests and studies involving vertebrate animals may not be repeated.
- ❑ **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. Non-cooperating companies would only be allowed onto the market if they generate their own data or negotiate access with the cooperating parties.

Note: The duration of data protection for the *first inclusion* of a new active substance and the *first authorisation* of a PPP is not foreseen to change under the draft Regulation and 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.

23. How do you assess the impact of the different policy options on yourself as competent authority in terms of the annual average number of applications that you would expect for a renewal of inclusion of an active substance in Annex I? Please use Option A as reference.

! If possible please give an estimate of increase/decrease in number of applications (column 1)!

	1	2	3	4	5	6
Number of applications would...	Increase (+) / decrease (-) by number of applications	as % change compared to current situation (only if column 1 not filled in)				
		decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	increase very significantly (>25%)
<i>Option A: Status quo - Data protection, no compulsory data sharing</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: Data protection, with compulsory data sharing</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: No data protection period for renewal of inclusion in Annex I</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option D: Two stage data protection starting with the time of dossier submission</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

<i>Comments</i>

24. How do you assess the impact of the different policy options on yourself as competent authority in terms of the average number of staff days needed per application that you would expect for a renewal of inclusion of an active substance in Annex I? Please use Option A as reference.

! In addition to previous questionnaire, if possible, please give an estimate of increase/decrease in number of days !

Number of staff days per application would ...	Increase (+) / decrease (-) by number of days
<i>Option A: Status quo - Data protection, no compulsory data sharing</i>	
<i>Option B: Data protection, with compulsory data sharing</i>	
<i>Option C: No data protection period for renewal of inclusion in Annex I</i>	
<i>Option D: Two stage data protection starting with the time of dossier submission</i>	

Not marked = Don't know

<i>Comments</i>

25. How do you assess the impact of the different policy options on the duration of the authorisation procedure?

! In addition to previous questionnaire, if possible, please give an estimate of increase/decrease in number of days !

Duration of the authorisation procedure would ...	Increase (+) / decrease (-) by number of days
<i>Option A: Status quo - Data protection, no compulsory data sharing</i>	
<i>Option B: Data protection, with compulsory data sharing</i>	
<i>Option C: No data protection period for renewal of inclusion in Annex I</i>	
<i>Option D: Two stage data protection starting with the time of dossier submission</i>	

Not marked = Don't know

<i>Comments</i>

26. How do you assess the impact of the different policy options in terms of increase or decrease (in %) of cost of work done internally (competent authority), by external bodies (other public authorities or public institutes / institutions) or by outsourcing companies (private companies)?

Cost of work done internally, externally or outsourced would...		1	2	3	4	5
% change compared to current situation		decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	increase very significantly (>25%)
<i>Option A: Status quo - Data protection, no compulsory data sharing</i>	Internal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	External	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Outsourced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: Data protection, with compulsory data sharing</i>	Internal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	External	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Outsourced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: No data protection period for renewal of inclusion in Annex I</i>	Internal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	External	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Outsourced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option D: Two stage data protection starting with the time of dossier submission</i>	Internal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	External	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Outsourced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

<i>Comments</i>

27. How do you assess the impact of the different policy options in terms of relative increase or decrease (in %) of average staff time (meant as in question 5 & 6) needed per application that you would expect for a renewal of inclusion of an active substance in Annex I (please use Option A as reference), dedicated to each of the actions listed below:

	Type of action	<i>Option A: Status quo - Data protection, no compulsory data sharing</i>	<i>Option B: Data protection, with compulsory data sharing</i>	<i>Option C: No data protection period for renewal of inclusion in Annex I</i>	<i>Option D: Two stage data protection starting with the time of dossier submission</i>
1	Familiarising with the application	%	%	%	%
2	Check of completeness and quality of the application	%	%	%	%
3	Analysis of available studies	%	%	%	%
4	Consultation with the applicant on data / info gaps to be filled	%	%	%	%
5	Holding meetings (internal and external)	%	%	%	%
6	Co-ordination of work of external bodies and outsourcing companies	%	%	%	%
7	Preparation and compilation of the decision paper	%	%	%	%
8	Sending of the decision paper to the applicant	%	%	%	%
9	Follow – up activities	%	%	%	%
10	Other	%	%	%	%
		%	%	%	%
		%	%	%	%
		%	%	%	%

Not marked = Don't know

Comments

POLICY ACTION 5: INFORMING NEIGHBOURS ON PPP USE

Please compare the following options:

- 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.** For plant protection products classified under Directive 1999/45/EC as very toxic or toxic applied by spraying, the authorisation can stipulate the obligation to inform neighbours who could be exposed to the spray drift before the product is used.
- Option C: Passive duty to inform neighbours on use of dangerous PPP (i.e. providing information to neighbours on demand).** Application for similar PPP as under Option B (classified under Directive 1999/45/EC as very toxic or toxic applied by spraying).

28. How do you assess the impact of the different policy options on the responsible authority in terms of the number of staff days needed for enforcement of rules related to the use of PPP?

! In addition to previous questionnaire, if possible, please give an estimate of increase/decrease in number of days !

Number of staff days per application would ...	Increase (+) / decrease (-) by number of days
<i>Option A: Status quo – No duty to inform neighbours</i>	
<i>Option B: Active duty to inform neighbours</i>	
<i>Option C: Passive duty to inform neighbours</i>	

Not marked = Don't know

<i>Comments</i>

B) Report on Administrative Burden

Introduction

During the stakeholder consultations in 2004 and 2005, some participants highlighted the importance of assessment of impact of the proposal on so-called Administrative Burden. This term covers all costs incurred by enterprises, the voluntary sector, public authorities and citizens in meeting legal obligations to provide information on their action or production, either to public authorities or to private parties.

The Administrative Burden was already considered and assessed by the European Commission in the early drafts of the Impact Assessment, however assessment remained only qualitative. In a similar manner, the administrative costs resulting from the proposal were also analysed by the consultant (FCEC) in its report (see Annex 2).

However, conclusion of work on the impact assessment came at the time of extensive work within the European Commission on methodologies for assessment and quantification of the Administrative Burden. The European Council which took place in Brussels on 15-16 of December, stressed the importance "...of reducing unnecessary burdens for business and citizens", as well as inviting "...the Commission to start measuring administrative burdens, on a consistent basis and in line with transparent criteria, as part of integrated impact assessments launched as of January 2006.". Having this in mind, The European Commission adopted in October 2005, the Communication 1 on an EU common methodology for assessing administrative costs imposed by legislation along with detailed Staff Working Paper² outlining the proposed EU common methodology and presenting Report on the Pilot Phase (April– September 2005) This process eventually concluded with revision of Impact Assessment Guidelines³ in March 2006 and addition of Annex on Administrative Burden's quantification methodologies.

Even though, accordingly to the Communication, only impact assessments which were started to be drafted in 2006 are subject to the obligation to quantify Administrative Burden in case of assessment of impacts of major proposals, DG Health and Consumer Protection has decided to prepare a more detailed analysis of Administrative Costs of new legislation of plant protection products, attempting to apply the new methodology.

Data limitations

The administrative processes which were to be assessed proved to be very complex, hence any attempt for quantification required estimation of numerous variables. Only few of the variables were available from public sources (i.e. Eurostat), therefore the significant data gaps had to be filled in with help of detailed questionnaires sent in to both Member States and business operators in the market.

Due to the relative novelty of this process and unfamiliarity with the concept of Administrative Burden within the European Union, the quality of data collected through questionnaires is very poor. Thus the accuracy of the assessment decreased. In addition, detailed verification of all the data collected due to their sheer volume was not feasible, therefore in case of frequent consistencies or remaining gaps, extra assumptions had to be made, diminishing further the exactness of the calculations. Based on aforementioned, even though the results presented below give a good idea of the scale of costs involved,

¹ COM(2005) 518

² SEC(2005) 1329

³ SEC(2005) 791

they should be treated with a degree of reservation, as a quantification of Member States' authorities predictions / wishes rather than thorough forecasting.

Methodology

The core equation of the model for assessment of the Administrative Burden agreed by the European Commission is based on the Dutch Standard Cost Model. Administrative costs is assessed on the basis of the average cost of the required action (Price) multiplied by the total number of actions performed per year (Quantity). For the purpose of this exercise (Administrative Burden in public authorities) the equation is the following

$$\Sigma \text{ Price x Quantity}$$

- Price = Tariff x Time;
 - Tariff = labour cost per day in public administration
 - Time = number of working days needed for evaluation / authorisation
- Quantity = Number of actions x Frequency
 - Number of entities actions = annual number of submitted applications for evaluation / authorisation
 - Frequency = 1 (one-year)

The data were collected through questionnaires and analysis of general statistics. The questionnaires were sent to all 25 Member States and main industry organisation for distribution among their members. There were 15 responses from the Member States authorities and only 8 answers from business operators. The response rate from Member States, even though the quality of the answers varies substantially, is sufficient to perform basic estimation. The results from 15 Member States were then used for extrapolation for EU-25 on the basis GDP at market prices generated by agricultural sector in each of the countries.

As far as analysis of Administrative Burden on business operators is concerned, very low number of received responses makes even indicative estimation too unreliable, therefore quantitative analysis was not be carried out.

The data collected through questionnaires were then combined with publicly available data from Eurostat (i.e. labour costs) for estimation of impact of each policy option in each of the 5 policy actions. Both the data from the questionnaires as well as from Eurostat depict significant differences, or rather gaps, between some Member States i.e. labour costs per hour in public administration in Denmark exceed 31 euros, while in Latvia reach only 3,5 euros.

The assessment methodology proposed by the European Commission however could not be fully applied. Due to poor quality and low volume of data collected, a breakdown into types of obligations linked with Administrative Burden and their further division into specific actions was not possible.

Analysis of the results

The results will be presented below following the division into 5 policy actions.

In one of the questions, the Member States authorities were asked to give an estimate of the cost of the authorisation / evaluation of one dossier. The responses varied significantly:

	The average cost (in EUR) of the authorisation / evaluation procedure of 1 dossier
New active substance that supported by a full data package (in case your country is RMS)	50.000 – 360.000, with majority of responses > 100.000
New PPP containing an active substance already included in Annex I where the type of use is <u>similar</u> to those previously considered for the active substance	10.000 – 240.000, with majority of responses < 50.000
New PPP containing an active substance already included in Annex I where the type of use is <u>very different</u> to those previously considered for the active substance	10.000 – 2400.000, with majority of responses < 50.000

As the analysis below proves that reality is less costly.

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

	Annual Administrative Burden ('000 eur) for EU-25	average % change in number of days needed for revision of a dossier	average % change in number of applications for evaluation / authorisation
2005	22.775,67	-	-
Option A: Status quo - without binding time limits. No NPA after 2007	21.832,68	0,00%	-1,97%
Option B: With binding time limits. No NPA	24.688,78	1,65%	-0,72%
Option C: Keep NPA after Draft Assessment Report	24.220,66	1,65%	0,18%

By abolishing National Provisional Authorisations (options A and B) the number of applications for evaluation / authorisations reduces. However, the Member States authorities suggest that binding limits (option B) can surprisingly result in increase of labour costs as shortened time limits might create a demand for additional staff.

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

	Annual Administrative Burden ('000 eur) for EU-25	average % change in number of days needed for revision of a dossier	average % change in number of applications for evaluation / authorisation
2005	22.775,67	-	-
Option A: Status quo - National evaluation and authorisation	22.775,67	0,00%	0,00%
Option B: Zonal evaluation and national authorisation - no national risk mitigation measures	25.349,77	-3,87%	17,22%
Option C: Zonal evaluation and national authorisation - with national risk mitigation measures	25.221,80	-3,73%	17,24%
Option D: Central agency for evaluation and authorisation	21.200,32	-4,63%	-15,06%

The Member States authorities predict that zonal system with mutual recognition will reduce the number of days needed for revision of a dossier, however at the same time each of them situate itself as the one that will carry the burden of zonal authorisation / evaluations the most (number of applications) i.e. UK. The option D (Central Agency) is certainly the best option from the point of view of Member States' authorities since they do not take into account all the costs linked with establishment of such an agency.

- *Policy action 3: Comparative assessment of PPP*

	Annual Administrative Burden ('000 eur) for EU-25	average % change in number of days needed for revision of a dossier	average % change in number of applications for evaluation / authorisation
2005	22.775,67	-	-
Option A: Status Quo - No provision for comparative assessment	22.775,67	0,00%	0,00%
Option B: Identification of candidates for substitution at the EU level based on hazard criteria	22.354,50	2,53%	-12,61%
Option C: Comparative assessment at the national level independent from the hazard of the active substances	23.104,78	6,06%	-12,26%

The Member States' authorities accentuate the risk of increased staff needs resulting from the implementation of the comparative assessment. However, as at the same time, comparative assessment should lead to reduction in the number of active substance / PPPs (number of applications for evaluation / authorisation), the overall costs should decrease in option B and slightly increase as for option C.

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

	Annual Administrative Burden ('000 eur) for EU-25	average % change in number of days needed for revision of a dossier	average % change in number of applications for evaluation / authorisation
2005	22.775,67	-	-
Option A: Status quo - Data protection, no compulsory data sharing	22.775,67	0,00%	0,00%
Option B: Data protection, with compulsory data sharing	26.023,79	-0,40%	11,07%
Option C: No data protection period for renewal of inclusion in Annex I	27.128,28	-0,71%	15,41%
Option D: Two stage data protection starting with the time of dossier submission	23.257,38	-0,16%	0,04%

The Member States' authorities predict that data sharing should directly result in increased number of applications / evaluations thus increasing the Administrative Burden. Rather surprisingly the same authorities see no impact of data sharing on quality of the dossier and subsequently the time required for their revision.

- *Policy Action 5: Informing neighbours on PPP use*

	Annual Administrative Burden (‘000 eur) for EU-25
Option A: Status quo - No duty to inform neighbours	0,00
Option B: Active duty to inform neighbours	690,90
Option C: Passive duty to inform neighbours	525,88

The Administrative Burden linked with obligation to inform neighbours is rather negligible as this cost annually for EU-25 is not expected to exceed 1 million euro in both active and passive duty approach.

Conclusion

Administrative Burden is only one of the impacts that were evaluated in the course of the impact assessment drafting. The analysis proved that Administrative Burden on Member States’ authorities resulting from Plant Protection Products authorisation / evaluation procedures will not change significantly following the proposed revision of the new Regulation replacing the currently functioning Directive. The effect of the provisions depends largely on their implementation. The most of the Member States’ authorities still remains unsure about how both mutual recognition and data sharing will work in practice, therefore predict increased numbers of applications for authorisations / evaluation in coming years, thus adversely affecting the calculations.

However, as Report FCEC (Annex 2) presents the large part of the benefits of proposed policy options in terms of Administrative Burden lies with business operators. The two parts should be therefore analysed together, despite the fact that due to low response rate, the impact of the proposal on Administrative Burden on business operators could not be quantified.

List of received answers:

- Member States' authorities:
 1. Austria – Federal Office for Food Safety
 2. Denmark - Environmental Protection Agency
 3. Estonia – Plant Protection Inspectorate
 4. Finland - Plant Production Inspection Centre
 5. Germany - Federal Office of Consumer Protection and Food Safety
 6. Greece - Ministry of Rural Development & Food, Directorate General for Plant Production, Dept. of Pesticides
 7. Ireland - Pesticide Control Service, Department of Agriculture Laboratories
 8. Italy – Ministero della Salute, Dipartimento della Sanita' Pubblica Veterinaria, La Nutrizione e la Sicurezza degli Alimenti
 9. Latvia - State Plant Protection Service
 10. Lithuania – State Plant Protection Service
 11. The Netherlands - Ministry of Agriculture, Nature and Food Quality
 12. Slovak Republic - Ministry of Agriculture
 13. Slovenia - Phytosanitary Administration
 14. Sweden - Swedish Chemicals Inspectorate
 15. United Kingdom - Pesticides Safety Directorate

- Business operators or industry organisations:
 1. AgriChem b.v. – The Netherlands
 2. Bayer CropScience – Germany
 3. Herbex – Portugal
 4. Coalition of smaller research-based PPP companies (Chemtura , Gowan, ISK, Japan Agro Services, Stahler, Taminco, Isagro) – international
 5. Syngenta – Switzerland
 6. Rokita-Agro Spółka Akcyjna – Poland
 7. Asociación Española de Fitosanitarios y Sanidad Ambiental AEFISA – Spain
 8. European Seed Association – Belgium

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/SI.415759

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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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Impact assessment of options for a Regulation replacing Directive 91/414/EEC: Final Report

DG SANCO Evaluation Framework Contract Lot 3 (Food Chain)

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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:

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- *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

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.

Impact on indirect costs for PPP users

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

Impact on investment of PPP producers in R&D

The impacts on investment of PPP producers in R&D have been calculated with the help of a (discounted) cash flow model. With option A2 (no NPA after 2007 without binding time limits), product launch could be delayed by 5 years 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).

Impact on EU PPP industry competitiveness

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

Impact on employment

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

Impact on information opportunities of citizens

No impact is expected under the different options.

Impact on the duplication of studies on vertebrate animals

No impact is expected under the different options.

Impact on unauthorised cross-border sourcing of PPP

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

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

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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
	A1 current	A2 after 2007	B1 sequential	B2 parallel	Keep NPA after DAR
Description of option	Status quo - <u>without</u> binding time limits. No NPA after 2007		<u>With</u> binding time limits. ** No NPA		
Economic impacts					
Impact on administrative burden	0	+	++	++	0
		(may increase coord. efforts)			
Impact on indirect costs for PPP users	0	(-)*	(0)*	0	0
			(minor negative impacts possible)		(may contribute to fragmented market)
Impact on investment of producers in R&D	0	--	-	0	0
Impact on PPP Industry competitiveness	0	--	-	0	0
Social impacts					
Impact on employment	0	-	0	0	0
Impact on information opportunities	0	0	0	0	0
Impact on animal welfare	0	0	0	0	0
Environmental impacts					
Impact on unauthorised cross-border sourcing of PPP	0	0	0	0	0
			(slight reduction possible)	(slight reduction possible)	
Impact of AS on environment or human health	0	0	0	0	0
		(minor impacts possible)	(minor impacts possible)	(minor impacts possible)	(minor impacts possible)

++ = Very significant positive impacts
 -- = Very significant negative impacts
 + = Significant positive impacts
 - = Significant negative impacts
 0 = No change from the present situation

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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.

Impact assessment of policy options

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.

Impact on indirect costs for PPP users

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

Impact on investment of PPP producers in R&D

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

Impact on EU PPP industry competitiveness

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

Impact on employment

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

Impact on information opportunities of citizens

No impact is expected under the different options.

Impact on the duplication of studies on vertebrate animals

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

Impact on unauthorised cross-border sourcing of PPP

Both zonal authorisation with compulsory mutual recognition (options B and C) and central authorisation (option D) will by definition lead to 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.

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).⁴

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

⁴ 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.

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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 – <u>no</u> national risk mitigation measures	Zonal authorisation – <u>with</u> 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 environmental conditions)	O	- (difficulty to take into account all environmental conditions)

++ = Very significant positive impacts
 -- = Very significant negative impacts
 + = Significant positive impacts
 - = Significant negative impacts
 O = No change from the present situation

Notes: * Staff and financial resources provided to a central agency affects the assessment significantly. For this assessment it has been assumed that the agency would have access to 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);

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- 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)⁵, and annual costs of the UK drinking water industry related to pesticide removal are estimated at around 120 million Pounds.⁶

Policy options

The following policy options are included in the Impact Assessment:

- *Option A*: No EU action (Status Quo): No provision for comparative assessment;

⁵ Kiwa N.V Water Research 2004: Door drinkwaterbedrijven gemaakte kosten als gevolg van bestrijdingsmiddelgebruik, Nieuwegein, p 3

⁶ DEFRA 2003, Partial Regulatory Impact Assessment: Groundwater Proposals under Article 17 of the Water Framework Directive, p12

- *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

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.

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.

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.

Impact on EU PPP industry competitiveness

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

Impact on employment

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

Impact on information opportunities of citizens;

No impacts expected.

Impact on the duplication of studies on vertebrate animals

No impacts expected.

Impact on unauthorised cross-border sourcing of PPP

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

Impact of active substances on the environment or human health

Option A implies a continuation of the situation described in the problem analysis, i.e. the lack of flexibility in the legislative framework to implement PPP minimisation strategies. Option B provides a possibility for national minimisation strategies. A reduction of environmental impacts of active substance and an increase in safety margins for the protection of human health can be expected. The size of the impact depends on which active substances are 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.

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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
<i>Economic impacts</i>			
Impact on administrative burden	○	– (depending on implementation)	–/–– (depending on implementation)
Impact on indirect costs for PPP users	○	○ / – (depending on implementation)	○ / – (depending on implementation)
Impact on investment of PPP producers in R&D	○	(○ / –)* (depending on implementation)	(○ / –)* (depending on implementation)
Impact on PPP industry competitiveness	○	+ / – (depending on implementation, positive impacts on innovation possible)	○ / – (depending on implementation, positive impacts on innovation possible)
<i>Social impacts</i>			
Impact on employment	○	(○ / –)* (depending on implementation)	(○ / –)* (depending on implementation)
Impact on information opportunities	○	○	○
Impact on animal welfare	○	○	○
<i>Environmental impacts</i>			
Impact on unauthorised cross-border sourcing of PPP	○	○ (minor negative impacts possible)	○ (minor negative impacts possible)
Impact of AS on environment or human health	○/– (In some MS negative impacts possible compared to current situation)	+ / ++ (depending on implementation)	+ / ++ (depending on implementation)

++ = Very significant positive impacts
 -- = Very significant negative impacts
 + = Significant positive impacts
 – = Significant negative impacts
 ○ = 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

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.

Impact on indirect costs for PPP users

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

products or at least the continuation of the status quo, making price increases less likely, while at the same time safeguarding defence of active substances on the market. This makes increased costs for users unlikely.

Impact on investment of PPP producers 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).

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.

Impact on employment

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

Impact on information opportunities of citizens

No impact expected.

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.

Impact on unauthorised cross-border sourcing of PPP

No impact expected.

Impact of active substances on the environment or human health

No impact expected.

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

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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	–	+ / 0	+ / –	0
		(lower prices, may also lead to lower number of AS)	(lower prices, but may also lead to significantly lower number of AS)	
Impact on investment in studies for re-registration of an AS	0	(–)*	(–)*	(0)*
		(however: remains profitable to invest)	(however: remains profitable to invest)	
Impact on PPP industry competitiveness	– (high entry barriers)	+ / –	+ / –	+ / 0
		(lower entry barriers, less profitability)	(lower entry barriers, less profitability)	(lower entry barriers, depending on implementation)
Social impacts				
Impact on employment (R&D based companies)	0	0 / –	0 / –	0
		(depending on reduction in profitability)	(depending on reduction in profitability)	
Impact on employment (generics)	–	+	+	0
Impact on inform. opportunities	0	0	0	0
Impact on animal welfare	0	(++)**	(++)**	(+)**
Environmental impacts				
Impact on unauthor. cross-border trade	0	0	0	0
Impact of AS on environment / health	0	0	0	0

++ = Very significant positive impacts
 -- = Very significant negative impacts
 + = Significant positive impacts
 – = Significant negative impacts
 0 = 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.”⁷

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

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

⁷ Royal Commission on Environmental Pollution 2005, Crop Spraying and the Health of Residence and Bystanders, p.112

Impact on indirect costs for PPP users;

No impact expected.

Impact on investment of PPP producers in R&D;

No impact expected.

Impact on EU PPP industry competitiveness

No impact expected.

Impact on employment

No impact expected.

Impact on animal welfare

No impact expected.

Impact on information opportunities of citizens

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

Impact on unauthorised cross-border sourcing of PPP

No impact expected.

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:

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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	0	– (depending on implementation)	0 (minor negative impacts possible)
Impact on indirect costs for PPP users	0	0	0
Impact on investment of PPP producers in R&D	0	0	0
Impact on PPP industry competitiveness	0	0	0
Social impacts			
Impact on employment	0	0	0
Impact on information opportunities	0	+	+
Impact on animal welfare	0	0	0
Environmental impacts			
Impact on unauthorised cross-border sourcing of PPP	0	0	0
Impact of AS on environment or human health	0	(+) (positive impacts possible, extent not possible to assess)	(+) (positive impacts possible, extent not possible to assess)

++ = Very significant positive impacts
 -- = Very significant negative impacts
 + = Significant positive impacts
 - = Significant negative impacts
 0 = 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

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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. Introduction

1.1. 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 Assessment⁸ and in the recently revised Impact Assessment Guidelines⁹. 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.

1.2. 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;
- Comments by stakeholders from the consultation processes conducted by DG SANCO related to the revision of Directive 91/414/EEC;
- Expert and stakeholder interviews;

⁸ COM (2002) 276

⁹ SEC (2005) 791

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- 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.

1.3. 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.

1.4. 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 1993¹⁰, 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 given¹¹:

- (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

- 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.

¹⁰ Website DG SANCO

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

¹¹ 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

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 area¹² market share amounted to 6 769 million € or 27.4%, of the total.¹³ 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%.¹⁴

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 2004.¹⁵ 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 pending¹⁶, 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” companies¹⁷;
- Coalition companies: A number of medium sized companies grouped themselves under the “coalition” flag¹⁸;
- Generic manufacturers.¹⁹

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

¹² EU25 and EFTA, of which €6 668 million for the EU 25

¹³ ECPA, Annual Report 2004-2005, p. 10. Please note that estimates of different sources may differ considerably due to definitions applied etc.

¹⁴ ECPA, Annual Report 2004-2005, p. 9

¹⁵ Eurostat/ECPA Statistics, 2004 Summary

¹⁶ Phillips McDougall, Keeping Europe attractive for Sustainable business development, Presentation at ECPA Annual Meeting, November 2005, p. 6

¹⁷ Monsanto, Du Pont, Bayer, BASF, Dow, Syngenta

¹⁸ Isagro, Crompton, Gowan, ISK, Taminco, Luxan, IQV, Janssen, Stahler, Japan Agro S.

¹⁹ 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.

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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 2003.²⁰ The 55 independent generic companies represented by ECCA, the Italian and the Spanish Generic Associations employed a total of 1 361 people in 2003.²¹

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 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 € ²² (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

²⁰ ECPA, 2006, Impact Assessment of proposed changes to Directive 91/414/EEC, p.22

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

²² Converted from US\$ sales at: 1€= 0,92 US \$ (2002)

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increased from approximately 1 to 50 000 to 1 to 140 000 between 1995 and 2000²³; and 2) recently, there is a decline in the number of active ingredients receiving an ISO²⁴ 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 year²⁵. In 1976, moreover, 12 newly introduced products had annual sales larger than 50 million € whereas only one made it in 2004²⁶.

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 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

²³ Phillips McDougall, Keeping Europe attractive for Sustainable Business Development, Presentation at ECPA Annual Meeting, November 2005, p.22

²⁴ International Standards Organisation

²⁵ Uttley, N., The EU Market for Generic Agrochemicals, Enigma Marketing Research 2004, p.28

²⁶ Phillips McDougall, Keeping Europe attractive for Sustainable business development, Presentation at ECPA Annual Meeting, November 2005, p.6

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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 € ²⁷ (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 2004.²⁸ 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.²⁹ 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 led to recent growth in these areas.³⁰

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.³¹

²⁷ Converted from US\$ sales figures at: 1 €= 1,1 US\$ (1999), 1 €= 1,2 US\$ (2004)

²⁸ ECPA, Annual Review 2004-2005, p. 9

²⁹ ECPA and Eurostat Data

³⁰ ECPA, Annual Review 2004-2005, p. 10

³¹ Eurostat, The use of Plant Protection Products in the European Union, 2002, p. 13

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While all product sectors of agrochemical markets have recorded increases in the past few years, the fungicide sector recorded the highest growth.³² Although herbicides have the largest market segment of value (see Table 11), fungicides are the largest segment in quantity of active substances.

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).

³² ECPA, Annual Review 2004-2005, p. 9

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.³³ 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.³⁴ 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.³⁵

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.

³³ Working Document SANCO/2693/2001 of 25 July 2001, p.15

³⁴ Directive 91/414/EEC, preambular paragraphs

³⁵ 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:³⁶

- 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.³⁷

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. 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”;³⁸

³⁶ 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

³⁷ 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.

³⁸ COM(2001) 444 final: REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL Evaluation of the active substances of plant protection products

- 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.³⁹ 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.

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;

³⁹ 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

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- 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.”⁴⁰

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 120⁴¹, 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.

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.”⁴² 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

⁴⁰ Directive 91/414/EEC, Art 10(1)

⁴¹ 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).

⁴² ECPA (76:3)

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 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.”⁴³

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

⁴³ PSA 1993: Inquiry into the prices of farm chemicals, Report No. 49, p 152/153

substitute products or practices. From a manufacturer's perspective, the U.S. and Canada represent two distinct markets for pesticide sales."⁴⁴

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 that price differentials are indeed a result of price discrimination is therefore warranted."⁴⁵

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..."⁴⁶

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."⁴⁷

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.⁴⁸

⁴⁴ 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.

⁴⁵ Short, C., Freshwater, D. 2004: Canada – U.S. Pesticide Regulation: An Economic Analysis of Price Discrimination, p. vii/ix

⁴⁶ Vroom, J: Statement on June 23, 2004.

http://www.croplifeamerica.org/media/testimony/6.23.04_vroom_prodprice.pdf, last accessed on 13.02.2006.

⁴⁷ Questionnaire filled by ECPA

⁴⁸ 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

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 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 imports⁴⁹ or use, three had minor problems and only one country had no problems.⁵⁰ 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.”⁵¹

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

price differences in comparison with non-EU-countries. No comprehensive data to independently verify this claim was available.

⁴⁹ 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”

⁵⁰ Survey to competent authorities

⁵¹ Questionnaire EUREAU, question 6

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:

- 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 objective⁵² 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.

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

⁵² COM(2002) 349 final, TOWARDS A THEMATIC STRATEGY ON THE SUSTAINABLE USE OF PESTICIDES, Brussels, 1.7.2002

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.”⁵³

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 1991-2000⁵⁴. Annual costs of the UK drinking water industry related to pesticide removal are estimated at around 120 million Pounds.⁵⁵

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 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”⁵⁶. 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

⁵³ COM(2002) 349 final, p. 13

⁵⁴ Kiwa N.V Water Research 2004: Door drinkwaterbedrijven gemaakte kosten als gevolg van bestrijdingsmiddelgebruik, Nieuwegein, p 3

⁵⁵ DEFRA 2003, Partial Regulatory Impact Assessment: Groundwater Proposals under Article 17 of the Water Framework Directive, p12.

⁵⁶ 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

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.⁵⁷ Already in 2001 the Commission concluded: “The current rules are very complicated to apply for Member States and are also contested by industry.”⁵⁸

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”⁵⁹. 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.⁶⁰

⁵⁷ ECPA, 2004. View on the revision of Directive 91/414/EEC Contribution to the stakeholder workshop to be held on 30 January, p.4

⁵⁸ 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

⁵⁹ Directive 91/414/EEC

⁶⁰ Questionnaire Competent Authority

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 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.”⁶¹ 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.”⁶² 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.

⁶¹ Working Document SANCO/2693/2001 of 25 July 2001, p.55

⁶² 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

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.”⁶³

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.⁶⁴ For industry this is a problematic aspect as it is not always clear where a PPP has been authorised for the first 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.”⁶⁵

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.”⁶⁶

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.⁶⁷ A comment from the Asociación Española de Fitosanitarios y

⁶³ ECPA Questionnaire

⁶⁴ Directive 91/414/EEC, Article 13(4)

⁶⁵ Questionnaire ECPA

⁶⁶ Questionnaire ECPA

⁶⁷ ECCA (15:2)

Sanidad Ambiental (AEFISA) illustrates the problems faced by generic companies to obtain access to data:

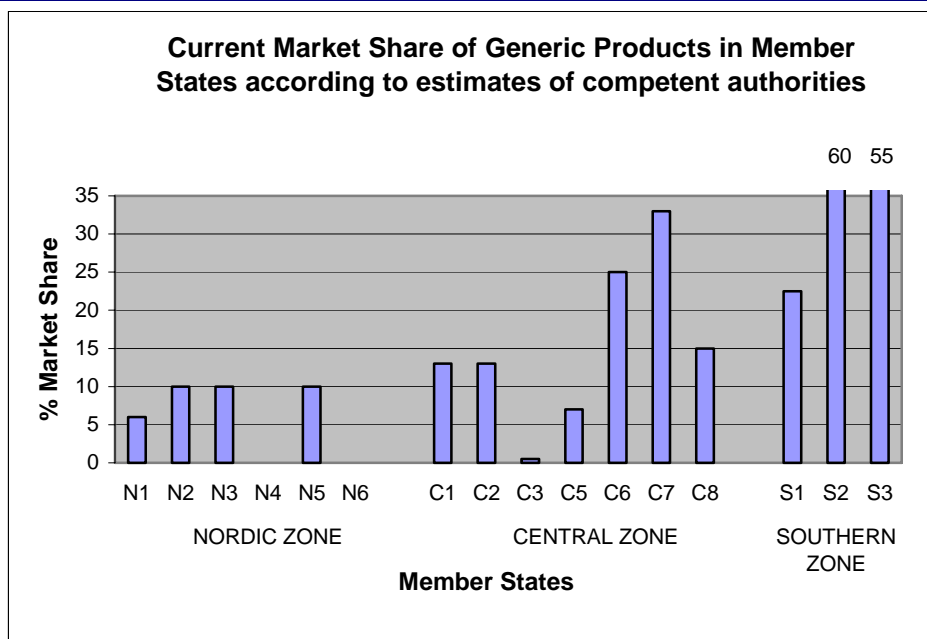
- “Difficulties to know the notifiers of an existing active ingredient just after the inclusion and the uncertainty to know as a formulator if you can be able to keep your authorization;
- Once the notifier is know[n], difficulties to obtain letter of access and obviously supply from notifiers, mainly 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.”⁶⁸

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 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 market⁶⁹. 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:

⁶⁸ Questionnaire AEFISA, q.8

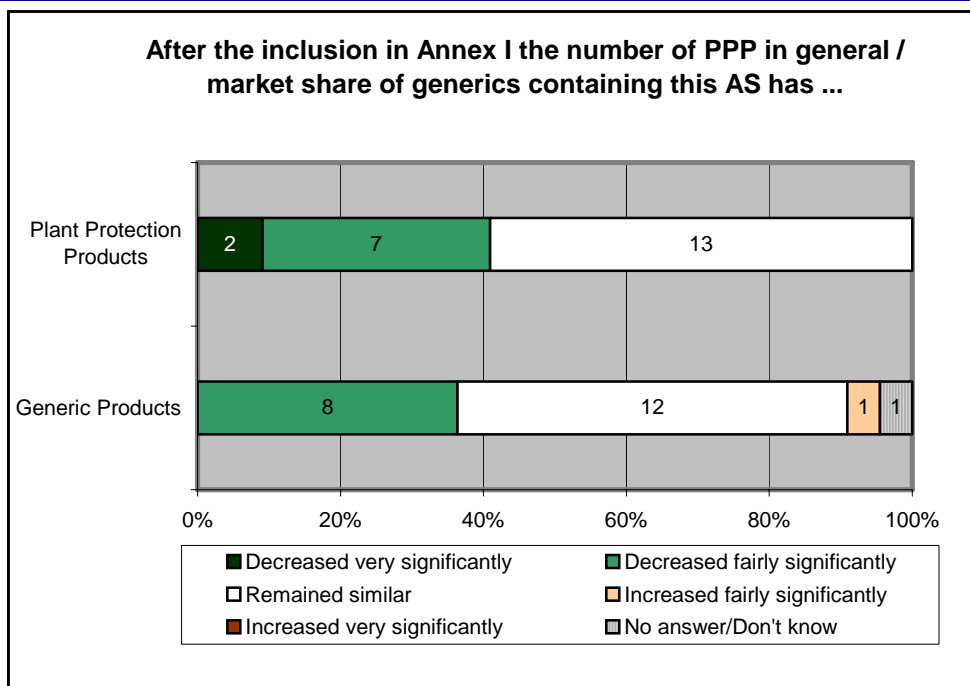
⁶⁹ Email Brito Correia, 2.2.2006



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.⁷⁰ 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:

⁷⁰ 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.”⁷¹

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 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

⁷¹ Statement - Email DG Competition, 17.11.2005

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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.⁷² 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 from public interest groups is very restricted.”⁷³ 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.

⁷² Working Document SANCO/2693/2001 of 25 July 2001, p.4, 5

⁷³ PAN Europe 2001, PAN Europa position on EU pesticides authorisation p.5

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.”⁷⁴

⁷⁴ 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”.⁷⁵ 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 competitiveness⁷⁶. Related to an improved regulative environment is the reduction of administrative costs. Administrative costs imposed by legislation should be reduced as much as possible.⁷⁷ 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 times⁷⁸. 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 amongst European citizens.⁷⁹ Also, avoiding the duplication of tests on animals, particularly vertebrate animals, is a declared objective of the EU chemicals policy.⁸⁰

⁷⁵ European Council, March 2000, Lisbon: europa.eu.int/comm/education/policies/2010/et_2010_en.html

⁷⁶ COM(2004) 293 final, A pro-active Competition Policy for a Competitive Europe, Brussels, 20.4.2004, p.3,4

⁷⁷ 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

⁷⁸ E.g. COM(2004) 293 final, p3

⁷⁹ 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

⁸⁰ COM(2001) 88 final, Commission White Paper of 27 February 2001 on the strategy for a future chemicals policy

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, alternatives⁸¹.

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

⁸¹ 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

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.

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).

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.⁸² 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 an 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.

⁸² 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

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.

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 are⁸³:

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;

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

⁸³ Commission draft of a new Regulation concerning the placing of plant protection products and adjuvants on the market, Oct. 2005

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.

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.

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 (EMA). EMA is a decentralised body of the European Union with headquarters in London. EMA 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 EMA. 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 EMA and its committees.⁸⁴

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.

⁸⁴ <http://www.emea.eu.int/hmts/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

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.

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 Contractor⁸⁵, 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.”

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.

⁸⁵ 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.

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.

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.

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.

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

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.

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.

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.

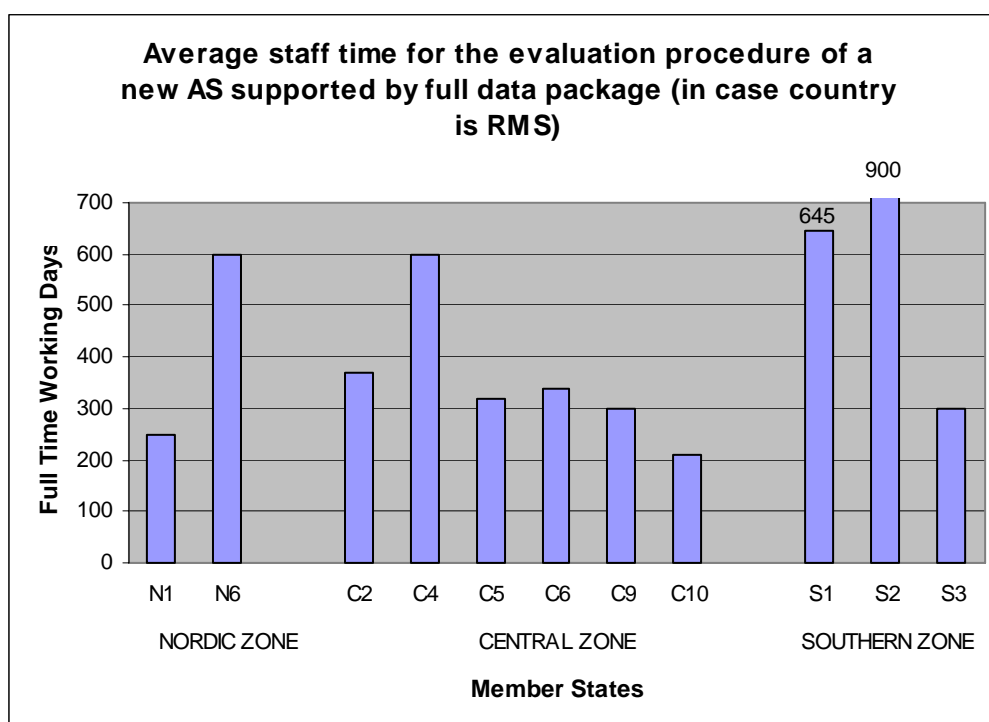
6. Impact assessment of policy options

6.1. Assessment of policy action 1: Evaluation of new active substance / national provisional authorisation of PPP containing a new active substance

6.1.1. Economic impacts

Impacts on administrative burden

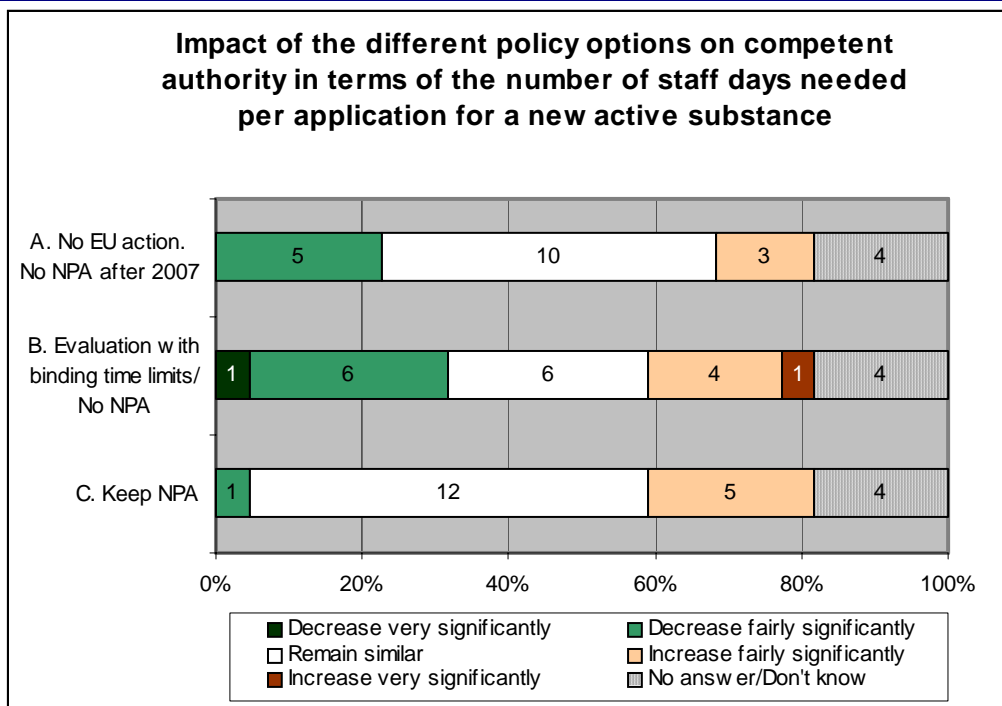
The administrative burden related to the options described in section 5.1 mainly results from the number of authorisation procedures performed for launching a PPP with a new active substance in different Member States and the size and degree of similarity of the dossiers to be delivered by the applicant and to be evaluated by the competent authorities. The evaluation of a new active substance requires a significant input of staff resources of the competent authority of the Rapporteur Member State (RMS), which differs by Member State with the median being 340 full time working days. 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.⁸⁶ An overview is given in the graph below:



Source: Survey of competent authorities. Not all authorities provided data

As has been described in the problem analysis, the current system of national provisional authorisations leads to a duplication of administrative efforts for both authorities and the applicant. Several competent authorities therefore expect the different options to have a significant impact on the administrative burden. This is illustrated in the following graph:

⁸⁶ The survey of competent authorities in Member States was performed to reflect the expertise of the responsible staff in the authorisation of PPP. Answers were not considered to be the official position of the Member State. It was therefore decided to present results only in a form that could not lead to a misunderstanding in this respect.



Source: Survey of competent authorities

The Status Quo option (option A) would imply the continuation of the current Community evaluation of new active substances without binding time limits. However, no national provisional authorisation would be possible after 2007. A minority of 5 competent authorities expects this option to lead to a fairly significant decrease of the staff input (by 10% to 25%). A slightly higher number of 7 authorities expect option B with binding time limits and also no NPA to lead to a decrease of the staff input, with one authority even expecting a very significant reduction of staff input (more than 25%). However, due to the binding time limits some authorities expect an increase of staff input. In the interviews with authorities this assessment was explained with the need to employ additional staff to be able to keep the deadlines. Hardly any competent authority expects option C (Keeping NPA after Draft Assessment Report) to lead to a reduction of staff input. With both options A and C, a majority of the competent authorities that have an opinion expect no significant change compared to the current situation.

From an analytical point of view it can be expected that 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 situation of a significant duplication of the administrative burden 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.

It has to be noted that the duplication of administrative efforts with NPA and the related costs are conceded by industry sources. For example, Japan Agro Services considers option C as “very costly but allowing for faster entry into the market”. The negative effect of an extended timeline for authorisation without NPA is an overwhelming concern for industry. The impact of the options on the timeline of authorisation will be discussed below.

None of the options are expected to have any direct impacts on the administrative burden of PPP users.

Impact on indirect costs for PPP users

An impact of the options on indirect costs for PPP users could theoretically result from a number of factors:

- a. Delays in launching of PPP with new active substances that could possibly provide advantages compared to PPP already available (depending on time to market);
- b. Reduced interest of PPP industry to develop new active substances depending on (possibly increased) time to market (possibly) leading in the long run to a reduction of the overall number of PPP available on the market, especially for minor uses;
- c. Influence on the number of PPP available on different national markets that possibly leads to a distortion of competition;
- d. Number of generic products on the market that would compete with the new product.

Several stakeholders argued that one or more of these factors would affect farmers. For example, COCERAL stated that “most of the traders support option B as it would increase the number of PPPs available”. The Central Union of Agricultural Producers and Forest Owners, Finland expressed a similar position: “Option B would be best and time limits for the evaluation process would make the process faster than nowadays. (...) Option C [Keeping NPA] reduces the number of PPP available on the market. This is a problem especially in small market areas and for minor uses. National provisional authorisation is difficult because the process takes time and the national authorities make the decisions on a different basis in each country. It is not democratic for farmers in different countries.” On the other hand, the Agricultural Industries Confederation, UK, opposed this view and stated that “Option C would have least effect on reducing the number of PPPs available, whereas options A and B could reduce the number of [active substances] available and uses of these [active substances] due to higher cost.” Industry associations such as IBMA and ECPA also suggested that abolishing NPA would lead to a reduction of availability of PPP.

The stakeholder statements quoted above indicate that a significant degree of vagueness exists regarding possible impacts on availability of PPP and other factors that could lead to indirect costs for PPP users. This is not surprising as all factors listed above depend on a chain of interrelated impacts such as the impact of an option on the *time to market* for a new PPP which may (or may not) influence the willingness of industry to develop new products which then could (or could not) have an impact on the *number of PPP* to address some minor uses.

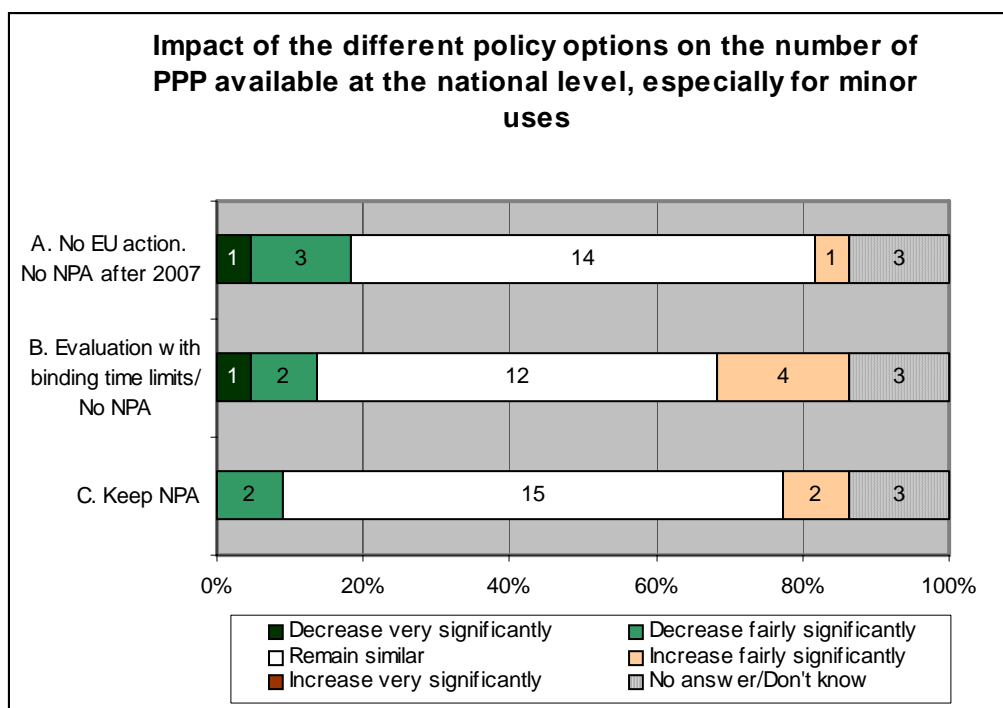
An analytical view on this chain of impacts leads to the following observations:

Impact on time to market: The first two factors influencing indirect costs for farmers mentioned above are highly speculative in nature. Although a delay in launching of a PPP with a new active substances that could possibly provide advantages compared to PPP already available (factor a) could theoretically lead to indirect costs for farmers, this is far from being definite and cannot reasonably be assessed at this stage. A reduced interest of PPP industry to develop new active substances depending on (possibly increased) time to market (possibly) leading in the long run to a reduction of the overall number of PPP available on the market, especially for minor uses (factor b) seems more likely; although it could be expected that industry would bring a new product on the market whenever it expects a profitable market fairly independent from the duration of the authorisation procedure. Obviously there are limits to this statement, which will be explored in the next

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section (Impact on investment of PPP producers in R&D). It is far from certain that an increased time to market would automatically have a negative influence on the number of PPP (factor c). This assessment is shared by the large majority of competent authorities. Twelve to 15 authorities do not expect any significant change in the availability of PPP, especially for minor uses, independent from which option was to be implemented:



However, even when one shares the view that an increased time to market would affect new product development so significantly that the number of PPP would be reduced, this would lead to the conclusion that any option not affecting the current timeline would not be expected to have significant influence on availability of PPP and would therefore have the least impact in this respect (see discussion of timelines of different options in the next section).

Some stakeholders suggest that the system of NPA contributes to fragmented national markets that may lead to a distortion of competition for farmers with related indirect costs in countries where PPP are less available, especially for minor uses. This seems to be plausible, however a certain fragmentation of the market is unavoidable with national authorisation of PPP, which is not affected by any of the options. The system of NPA is therefore only one of several factors influencing the fragmentation of the European PPP market, which also depends on the authorisation practices of national authorities and on marketing strategies of the PPP industry.

Finally, no impact of any of the options on the number of generic products could be expected (factor d). The policy action refers to new active substances only, that are usually protected by patent. In the rare case that the new active substance would not be protected by patent, other mechanisms (such as data protection) would most likely lead to a period of market exclusivity of at least ten years.

Based on this analysis several conclusions can be drawn:

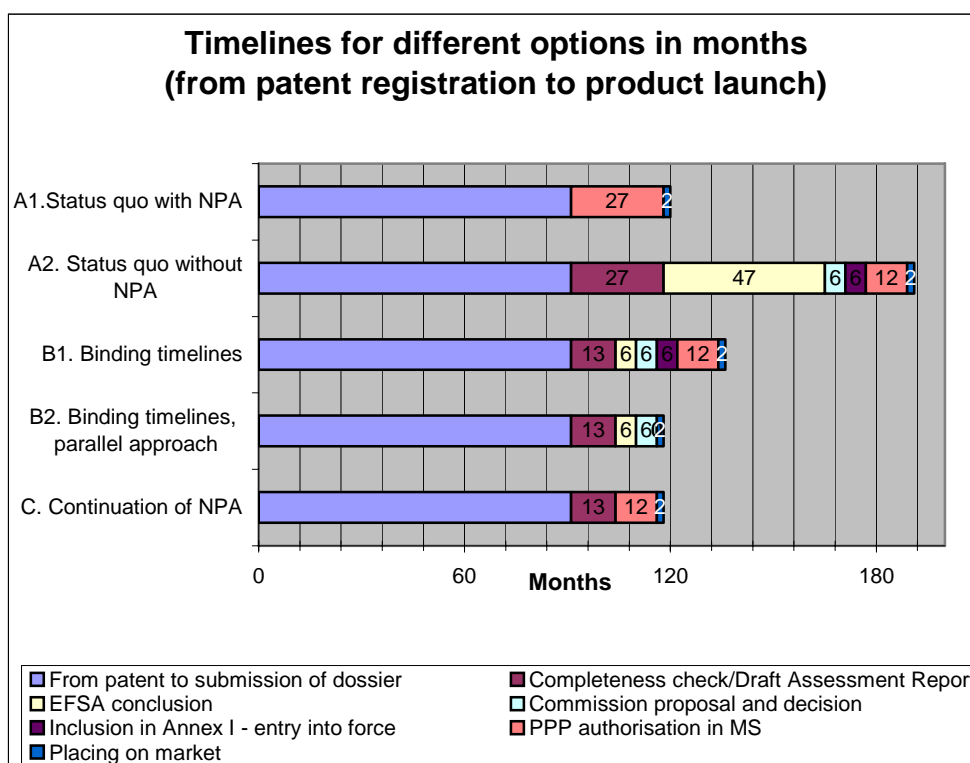
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- Option A1 (the current situation, reference scenario) is not expected to lead to any negative or positive impact;⁸⁷
- Option A2 (abolition of NPA after 2007) could have a negative impact on indirect costs for PPP users, if a very long authorisation procedure leads to a reduction of PPP – however, this view is not undisputed;
- Option B1 (sequential authorisation) could have a negative impact on similar grounds as option A2, but less significant;
- Option B2 (parallel authorisation) does not affect the timeline of authorisation and is not expected to have any impact;
- Option C (Keep NPA) would be similar to A1 and is not expected to have any significant positive or negative impact, except a possible contribution to continuation of a fragmented European PPP market with related negative effects.

Impact on investment of PPP producers in R&D

Based on the definition of options detailed in section 5.1 and an analysis of the current average duration of the different steps of the Community evaluation process, the following timelines of the different options under consideration can be derived:



Source: FCEC

The application of the cost quantification model for new product development (see Annex A of this report) leads to the following conclusions: Under option A (No NPA after 2007 without binding time limits), time to product launch would be delayed by 5 years 11 months with a system without NPAs. In addition, the model assumes that peak sales will

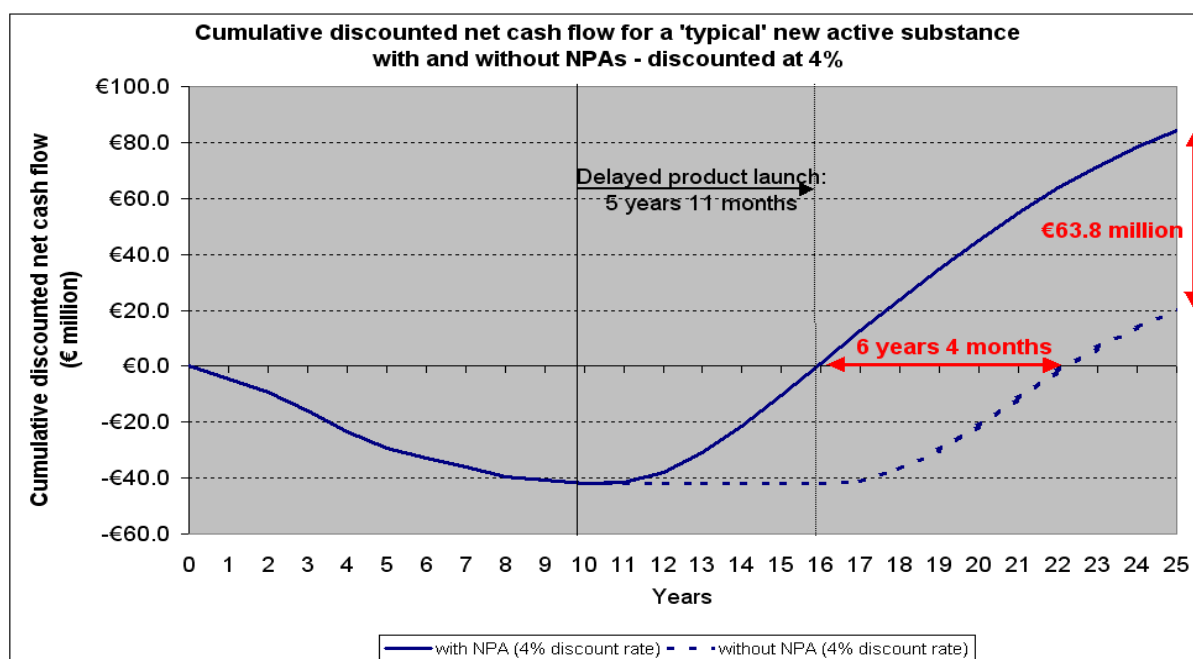
⁸⁷ Possible price effects caused by the reduction of the market share of generic PPP after Annex I inclusion of the active substance are discussed in the context of policy action 4 (data protection)

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be achieved two years earlier following market launch (i.e., in the 6th marketing year), than under a system with NPA (which assumes peak sales in the 8th marketing year). This assumption is in line with industry expectations.⁸⁸

The impact of this delay in product launch is presented graphically in the graph below and summarised in Table 13:



Source: FCEC

Table 13: Model results: Policy action 1, option A - status quo compared to a system without binding time limits and no NPA after 2007 – discounted at 4%

	Status quo With NPA	Status quo Without NPA
NPV (€million)	€84.2	€20.4
IRR (%)	12.7%	6.4%
Payback period (years from product discovery)	15.9	22.2
Payback period (years from product launch under status quo)	5.9	12.2
Discount rate	4%	4%

In essence, for a 'typical' active substance over a 25 year investment period, if there was no NPA after 2007 and no binding time limits, then under the assumptions of the model:

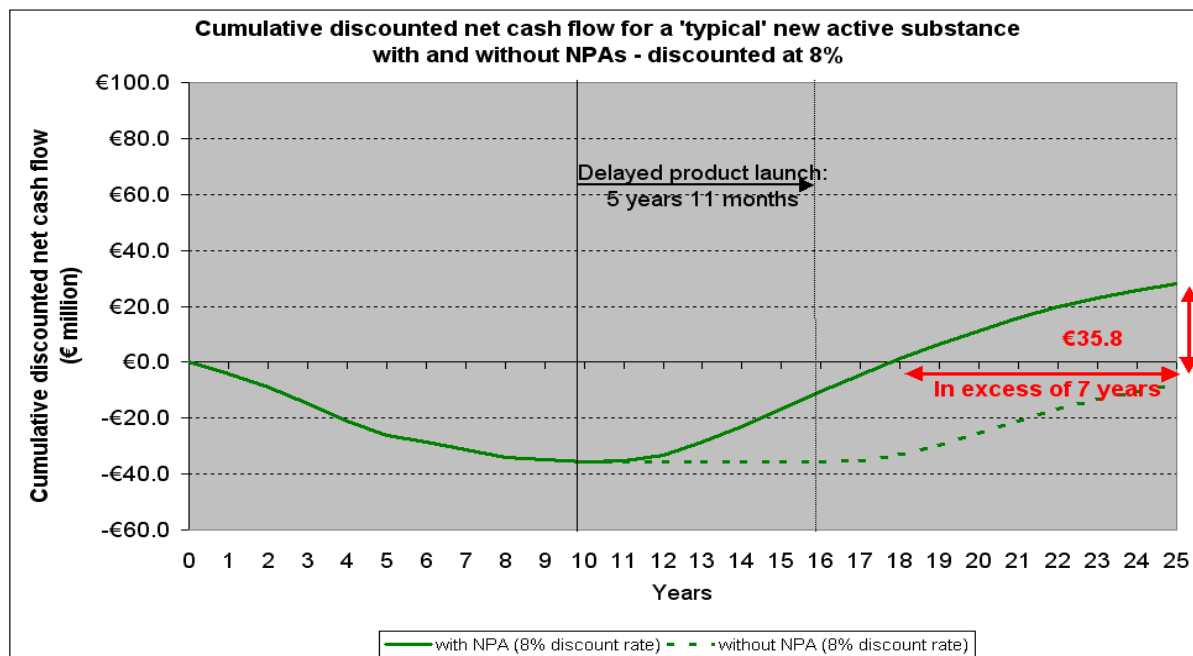
- The NPV of the cumulative net cash flow falls by €63.8 million (76%) from €84.2 million to €20.4 million;
- Payback period more than doubles, increasing by 6.3 years (6 years, 4 months), from 5.9 years to 12.2 years;
- IRR falls by a half from 12.7% to 6.4%.

⁸⁸ Based on interviews with leading agrochemical companies and as reported in the ECPA evaluation on 'Data on the value of National Provisional Authorisation', November 2005, page 6.

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Under this option, the economics and attractiveness of new product (active substance) development is severely affected. This impact is compounded when using higher discount rates. When using an 8% discount rate, for example, the investment fails to break-even within the 25 year investment period (graph below and Table 14):



Source: FCEC

Table 14: Model results: Policy action 1, option A - status quo compared to a system without binding time limits and no NPA after 2007 – discounted at 8%

	Status quo With NPA	Status quo Without NPA
NPV (€million)	€7.9	-€7.9
IRR (%)	12.7%	6.4%
Payback period (years from product discovery)	17.79	>25 years
Payback period (years from product launch under status quo)	7.79	>15 years
Discount rate	8%	8%

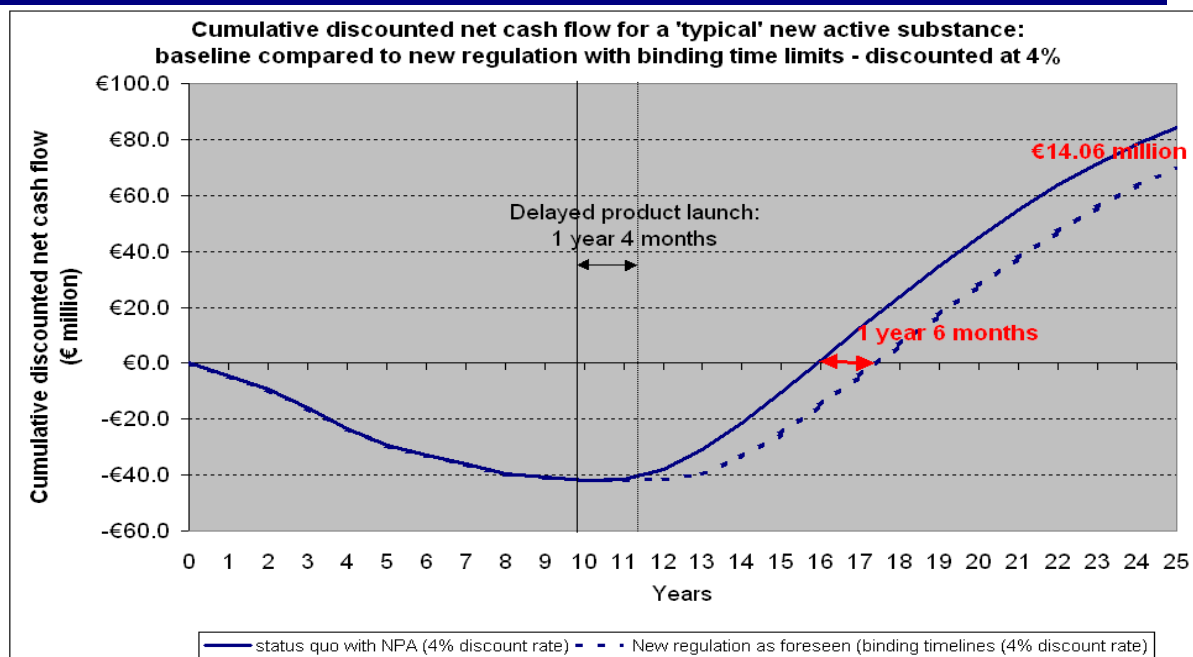
Furthermore, the results are highly sensitive to the average peak sales level. For those active substances that generally have a lower average peak sales value such as those active substances that are specifically targeted at niche markets (e.g., biologicals or active substances used on a smaller scale for specific crops, e.g. fruit and vegetables), the economics and attractiveness of research and development will be seriously affected. As a result, R&D based companies are likely to become more selective when deciding which active substances they should develop.

Under option B: (No NPA after 2007, but *with* binding time limits,) time to product launch would be delayed by a lesser extent. Under option B1, with binding timelines time to product launch would be delayed by 1 year and 4 months compared to the status quo (baseline scenario).

The impact of this more marginal delay in product launch (compared to option A) is presented graphically below and summarised in Table 15:

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Source: FCEC

Table 15: Model results: Policy action 1, options B 1, B2 and C - status quo compared to a system with binding time limits and continuation of NPA – discounted at 4%

	Status quo with NPA	New Reg. as foreseen (B1)	Parallel approach (B2) / Continuation of NPA (C)
NPV (€million)	€84.2	€70.1	€86.1
IRR (%)	12.7%	11.2%	13.0%
Payback period (years from product discovery)	15.9	17.4	15.7
Payback period (years from product launch under status quo)	5.9	7.4	5.7
Discount rate	4%	4%	4%

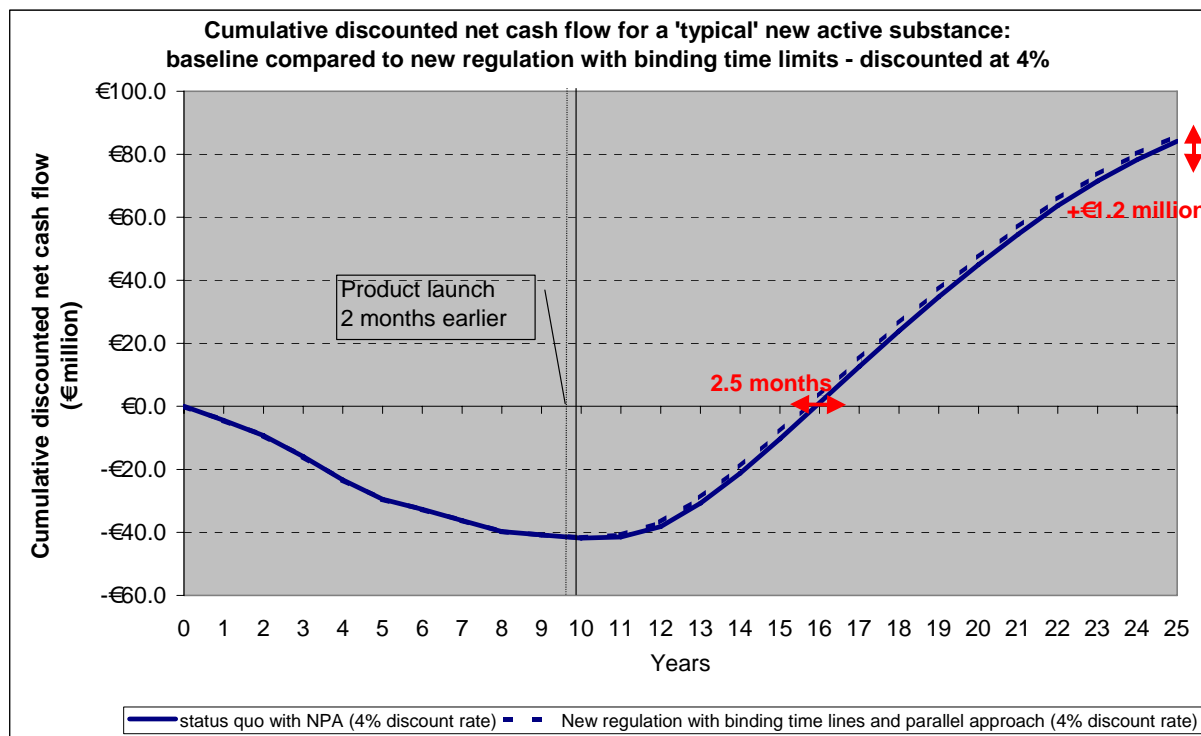
In essence, for a ‘typical’ active substance over a 25 year investment period, if there was no NPA after 2007 but *with* binding time limits, then under the assumptions of the model:

- The NPV of the cumulative net cash flow falls by €14.1 million (17%) from €84.2 million to €70.1 million;
- Payback period increases by 1.5 years (27%), from 5.9 years to 7.4 years;
- IRR falls by 1.5% from 12.7% to 11.2%.

Under this option, the economics and attractiveness of new product (active substance) development is only slightly affected. With possible amendments to the new Regulation, these negative impacts on the economics of new product development could be mitigated. With binding timelines and a parallel approach (option B2), time to product launch could be brought forward by 2 months⁸⁹ compared to the status quo (baseline scenario).

⁸⁹ Time limits as foreseen, product launch after Annex I inclusion

The impact of this earlier product launch date is presented graphically below and summarised in Table 15.



Source: FCEC

In essence, for a 'typical' active substance over a 25 year investment period, if there was no NPA after 2007 but *with* binding time limits *and* a parallel approach, then under the assumptions of the model:

- The NPV of the cumulative net cash flow would increase slightly by €1.9 million (2%) from €4.2 million to €6.1 million;
- Payback period would decrease marginally, falling by 0.2 year (2.5 months), from 5.9 years to 5.7 years;
- IRR increases marginally (0.3%) from 12.7% to 13.0%.

Under this option, the economics and attractiveness of new product (active substance) development is not adversely affected (even when using higher discount rates).

Under option C: which maintains the system of NPA after the Draft Assessment Report, time to product launch could be brought forward by 2 months compared to the status quo (baseline scenario). The impact of this earlier product launch date would therefore be similar to that of option B2 which was presented graphically before. Thus, under this option the economics and attractiveness of new product (active substance) development is not adversely affected (even when using higher discount rates).

Impact on EU PPP industry competitiveness

The main competitiveness issue from abolishing NPA appears to be linked to the influence of the options on the timing in delivering an authorisation for PPPs containing a new active substance. This timing has a bearing on the time to market and therefore on the length of time that an active substance can be sold during its patented life. This impact has been explored in detail in the previous section. As has been shown, any delay in delivering an authorisation would result in delayed sales and reduced profitability, on a

Net Present Value (NPV) basis. Therefore, the system of national provisional authorisation has, in the industry perspective, a double effect:

- Reducing the timing for placing a PPP with a new active substance on the market, thereby increasing the NPV. This is a profitability argument;
- Increase, or protect, the patent covered period. This is both a profitability and a competitiveness argument of companies who create and introduce new active ingredients, the rationale of which being that a non patent protected product would easily be attacked by generics manufacturers. This is far from evident, as illustrated by the section on the profile of the PPP industry, which suggests that entry barriers to the generics manufacturers are multiple and complex. A non-patent covered active substance will not automatically become part of the generics manufacturers portfolio.

Also, national provisional authorisations necessarily reflect individual MS views, and are not necessarily conducted across the EU according to the same standards. This may create uncertainty.

Replacing national provisional authorisations by a fast Community evaluation system would, in principle, alleviate these disadvantages without penalising sales timing, provided that the duration of the authorisation is not increased significantly. So, for any option that foresees to abolish national provisional authorisations to be competitiveness neutral, it is essential to ensure that a shortened centralised procedure can actually be managed. On the other hand, it is not certain that even with a delayed procedure sales would be reduced over the product life cycle, which extends after the patented life, since the penetration rate of the market by generic companies is not very high in general. In conclusion, effective timing is key in assessing the impact of the options on industry competitiveness.

- Option A would increase authorisation duration from 125 to 198 months 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 RMS, 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. It would be neutral with respect to Net Present Value and new launch attractiveness.

6.1.2. Social impacts

Impact on employment

Based on the results of the discounted cash flow model (impact on investment of PPP producers in R&D), the following conclusions can be made:

- Under option A2 (no NPA after 2007, without binding time limits), the economics and attractiveness of new product development would likely be severely affected due to the 5 years and 11 months delay in product launch. This is because under

the assumptions of the model, this option would result in significant negative impacts on NPV, payback period and IRR, particularly for those active substances that tend to have lower average annual sales values such as those active substances that are specifically targeted at smaller or niche markets (e.g. biologicals or active substances used on a smaller scale for specific crops, such as fruit and vegetables). 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 (binding time limits and no NPA after 2007) 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. Consequently, 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 given that their impact on NPV, payback and IRR is relatively marginal.

Impact on information opportunities of citizens

No impact is expected under the different options.

Impact on the duplication of studies on vertebrate animals

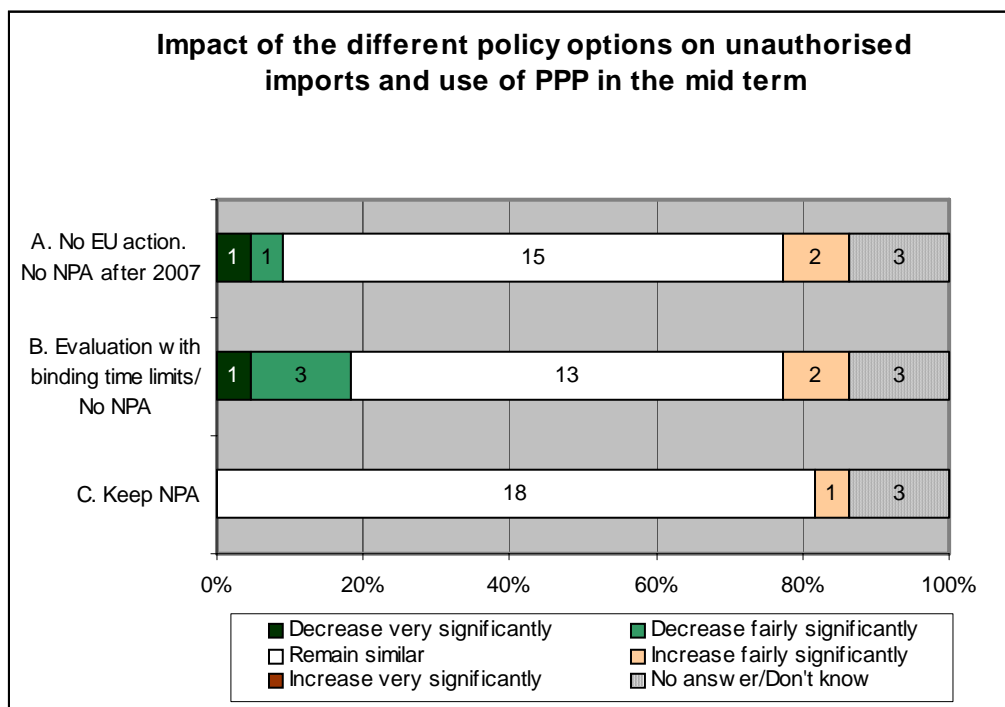
No impact is expected under the options compared to the status quo. All options refer to PPP containing new active substances, for which usually only one applicant submits dossiers, so that a duplication of vertebrate testing is not expected. The extent of vertebrate testing for the production of the dossier of the main applicant has not been analysed in this impact assessment, as no changes in the evaluation procedure are foreseen. It should be mentioned, however, that animal welfare groups such as the European Coalition to End Animal Experiments (ECEAE) and Eurogroup for Animal Welfare, UK and Belgium have general concerns not related to the specific policy actions discussed in this impact assessment. Both groups communicated to the Contractor their position that “alternative test methods should be included in the Annexes with a view to replacing the animal test method with the alternative, as would be the case in REACH. This should be a continuous process. In terms of scope, the term ‘vertebrate testing’ should be amended to read ‘animal testing’ in light of the proposed review of Directive 86/609 and broadening of the scope of concern beyond vertebrates. There is an increasing scientific body of work that supports our claims that animal testing is far less reliable (in addition to ethical concerns) than non-animal alternatives.”

6.1.3. Environmental impacts

Impact on unauthorised cross-border sourcing of PPP

As has been pointed out before, 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 A after 2007) are possible. However, as many factors contribute to the fragmentation (industry marketing policy, degree of application of mutual recognition) and unauthorised trade (price differences and

differences in availability) the abolition of NPA alone cannot be expected to lead to significant change. This is confirmed by the assessment of the competent authorities:



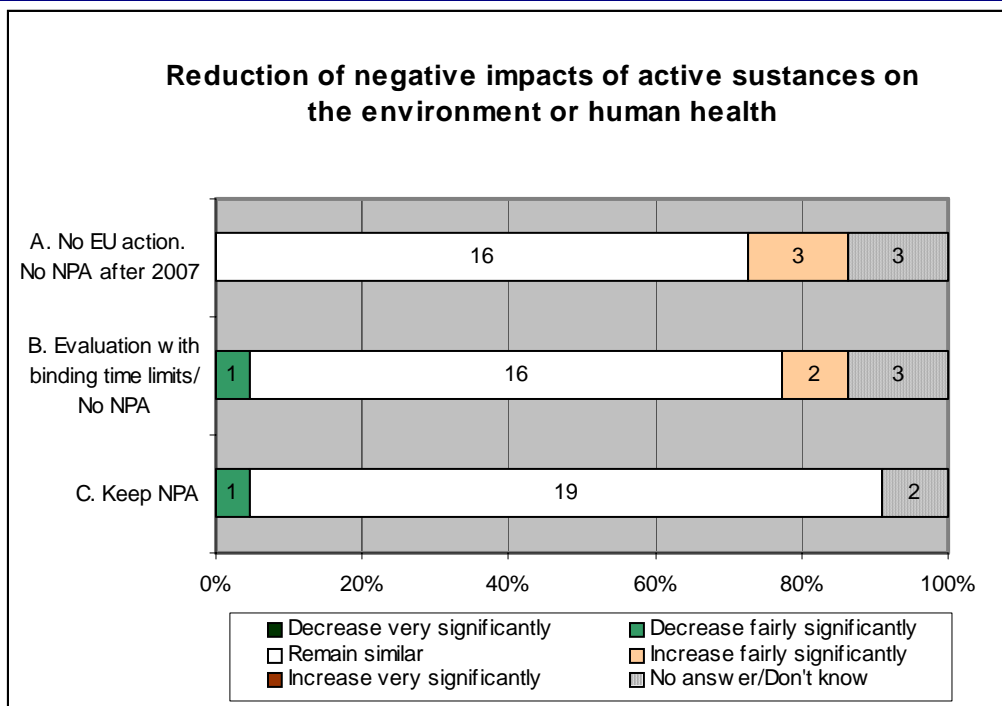
Source: Survey of competent authorities

Impact of active substances on the environment or human health

In this section only possible impacts of active substances on the environment or human health are analysed that *may be caused by the implementation of one of the options discussed*. It was not the mandate of the contractor to assess impact of pesticide use and the criteria for evaluation of active substances at a more general level.⁹⁰

The great majority of competent authorities does not expect any impact on the environment or health of any of the options described in section 5.1 (mainly relating to binding time limits for the evaluation process and to national provisional authorisation). This is clearly shown in the following graph:

⁹⁰ During the consultation with stakeholders it became clear that some environmental organisations have principle concerns regarding the *criteria for the evaluation of active substances*. This concern was most clearly voiced by the Pesticides Action Network Europe in demanding that „stringent and consequent cut-off criteria need to be defined and used as first step in the authorisation process“ and requesting to *quantify external environmental impacts* of PPP use. Other stakeholders propose to draw attention on *mixing and application* of PPP. However, this impact assessment only covers impacts of proposed changes to Directive 91/414/EEC. As the Community evaluation procedure for new active substances is not planned to be changed these concerns fall out of the scope of the assessment and will have to be addressed when and if a change of the Community evaluation procedure for active substances is considered.



However, several minor impacts seem possible:

- Option A (Status quo - without time limits, no NPA after 2007) could delay the time to market 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 (see previous section);
- Option B (With binding time limits, no NPA) 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). Abolition of NPA could contribute to more homogenous national markets for PPP, which would contribute to reducing incentives for unauthorised import/use from other MS;
- Option C (Keep NPA after Draft Assessment Report) would lead to a shorter duration of the evaluation procedure compared to option A2 and would reduce the time to market for new active substances that may have less impacts on the environment (similar to B2). However, NPA would continue to contribute to diverse national markets that are an incentive for unauthorised import/use.

6.1.4. Summary

The results of the impact assessment of *policy action 1: Evaluation of new active substance / national provisional authorisation of PPP containing a new active substance* are presented in the table below:

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Table 16: 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
	A1 current	A2 after 2007	B1 sequential	B2 parallel	
Description of option	Status quo - <u>without</u> binding time limits. No NPA after 2007		<u>With</u> binding time limits. ** No NPA		Keep NPA after DAR
Economic impacts					
Impact on administrative burden	O	+	++	++	O
		(may increase coordination efforts)			
Impact on indirect costs for PPP users	O	(-)*	(O)*	O	O
			(minor negative impacts possible)		(may contribute to fragmented market)
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	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	O	O
			(slight reduction possible)	(slight reduction possible)	
Impact of AS on environment or human health	O	O	O	O	O
		(minor impacts possible)	(minor impacts possible)	(minor impacts possible)	(minor impacts possible)

++ = Very significant positive impacts
 -- = Very significant negative impacts
 + = Significant positive impacts
 - = Significant negative impacts
 O = No change from the present situation

Notes: * No final assessment possible at this stage. Negative impact only to be expected if increased time to market would lead to significant reduction of PPP ** All assessments are based on the timelines as implied by the binding time limits. Delays in the evaluation procedure could affect results of the assessment.

6.1.5. Proportionality and added value of EU action

Table 17: Proportionality and added value of alternative options for evaluation of new active substance / national provisional authorisation of PPP containing a new active substance

	Option A	Option B	Option C
Description of option	Status quo - <u>without</u> binding time limits. No NPA after 2007	<u>With</u> binding time limits. No NPA	Keep NPA after Draft Assessment Report
Proportionality	<ul style="list-style-type: none"> • A change of the evaluation/authorisation procedure that would increase the time to market by nearly 6 years would harm industry significantly • This would not be outweighed by reduction of administrative efforts 	<ul style="list-style-type: none"> • A streamlined evaluation procedure with reduced administrative burden would benefit both authorities and industry • Significant differences exist between options B1 and B2. B2 is clearly more favourable, as any increase in the duration of the evaluation procedure (as implied by option B1) would not be in line with objectives regarding R&D and competitiveness 	<ul style="list-style-type: none"> • The current time to market for new PPP would not be increased, which is in line with objectives regarding R&D and competitiveness • However, administrative burden would not be reduced
Added value of EU action	<ul style="list-style-type: none"> • Abolition of NPA can only be introduced at EU level • However, no added value of EU action, rather a recipe to reduce R&D spending and industry competitiveness 	<ul style="list-style-type: none"> • Abolition of NPA can only be introduced at EU level • Leads to a significant reduction in administrative efforts without negative impacts on R&D, if option B2 is chosen and time limits are respected 	<ul style="list-style-type: none"> • Limited added value of EU action, as current duplication of administrative efforts continues

6.1.6. 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:

- Streamlined procedure: “Improved organisation of review programs as individual projects between the Commission, EFSA and MS.” - “More emphasis on the introduction of the basic elements of project and quality management. If deadlines and quality standards of parties involved in the procedures are not met, this should become more transparent.”- “Reporting about completing every step.”;

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- Procedures for submission of data: “Clear data requirements for applicants.” - “Rejection of application, if data requirements are not fulfilled. If possible, prevent subsequent deliveries, at the most one delivery at a given time. Evaluation and decision on the basis of the application made. Generally, no subsequent changes of procedure or subsequent introduction of new data requirements, evaluation directives or evaluation models. The procedure must be and stay predictable and transparent.”;
- Financial sanctions: “The payment of fees could be made subject to meeting certain standards. High quality work done in due time should be rewarded.”- “Fee reduction”;
- Changing Rapporteur Member State: “Introducing mechanisms for the Commission to substitute one member state for another, if necessary. Industry would stop applying to a particular member state as RMS if problems had been encountered.”

Other parties generally thought sanctions not workable, but proposed additional measures to streamline the Annex I inclusion procedure, including:

- Evaluation of Community evaluation process: An independent review of the evaluation process to detect potential for speeding up the process;
- Online tracking: An online tracking system for the applicant to be able to follow the status of the evaluation process.

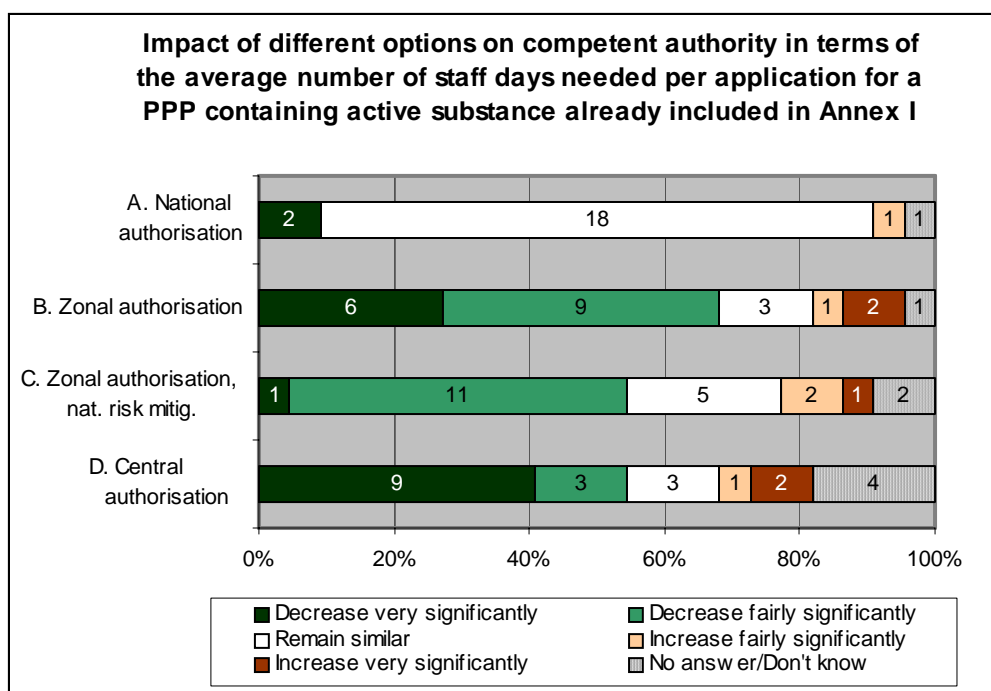
This list from both Member States’ competent authorities and other stakeholders indicates that there are several steps that can be taken to optimise the Community evaluation process for Annex I inclusion, which is relevant for all options, but especially with option B. It can also be expected that a 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.

6.2. Assessment of policy action 2: Mutual recognition of PPP containing an active substance already included in Annex I

6.2.1. Economic impacts

Impacts on administrative burden

The options described in section 5.2 are aimed at reducing the duplication of efforts for authorising similar PPP in different Member States. According to a large majority of competent authorities all options other than the Status Quo would imply a reduction of at least 10% to 25% in terms of the *average* number of staff days needed per application for a PPP containing active substance already included in Annex I (see graph below). The term “average” implies for options B and C a mixture of authorisation processes in a Member State, where a part of PPP would be authorised through mutual recognition and some of the PPP through a full authorisation procedure (in case the relevant country would be designated to conduct the initial authorisation for the zone).



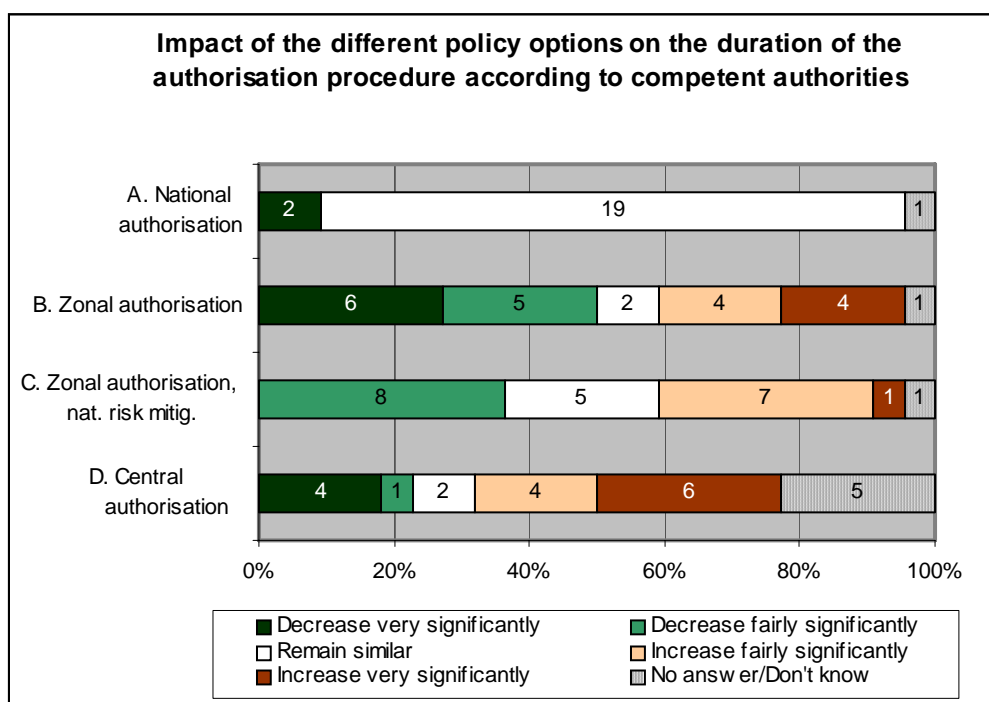
Source: Survey of competent authorities

The largest number of competent authorities expecting a reduction of administrative effort was registered with option B, where 15 authorities expected a reduction of at least 10-25% of staff input. This figure was slightly lower with option C. This option means a higher workload for national authorities than option B because of national risk mitigation measures. During the interviews with the authorities, however, it was confirmed that even a mutual recognition of a PPP with national risk mitigation measures would imply a significant reduction of administrative effort compared to evaluating a full dossier for a PPP. With option D, the central authorisation of PPP through a central agency for evaluation and authorisation of PPP with use of MS resources, 9 competent authorities would expect a reduction of staff input of more than 25%, a very significant decrease. No consensus was found among competent authorities, however, whether or not the options would lead to a significant reduction in the duration of the authorisation procedure compared to the status quo. Eleven of the competent authorities expect a reduction of the

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duration with option B, whereas 8 expect an increase. With option C opinion is nearly evenly split, and with option D (central authorisation) most but not all authorities expect a longer duration of the PPP authorisation procedure. This is illustrated in the graph below:



Source: Survey of competent authorities

The diverging views of authorities on the impact of the options on the duration of PPP authorisation procedures could be interpreted that making a well founded prognosis is difficult and a system of zonal authorisation with compulsory mutual recognition is perceived as carrying a risk of delays, and even more so with central authorisation. ECPA voiced strong concerns in this respect, bringing forward the following view: “Compulsory mutual recognition is a recipe for failure and will lead to blockage within zones. (...) Option A will likely be the fastest. Options B, C and D will likely result in blocking authorizations in other MS than [the designated Member State] because they are based on compulsory mutual recognition (B and C) or a likely poorly resourced central system (D).”⁹¹ Does this argument hold? Currently three Member States apply mutual recognition to a significant extent, one country even to hundred percent. An interview with one of these states did not indicate any significant problems with respect to the duration of the mutual recognition procedure. Also, all three Member States having this experience did not expect a longer duration of the authorisation with options B and C. Rather, they expected these options to lead to a similar duration or even a reduction of the duration of the authorisation procedure compared to the current situation. It may also be noted that the assessment of industry associations other than ECPA differed significantly, with ECCA expecting lower costs under option D, and the Coalition of smaller research-based PPP companies⁹² assessing options C or D as the “quickest option”. This leads to the following conclusions:

- Option A, the continuation of the status quo would mean the continuation of the current duplication of administrative efforts for competent authorities and industry (dossier has to be translated, re-formatted and partly extended), if the low rate of

⁹¹ ECPA questionnaire

⁹² Consisting of Chemtura, Gowan, ISK, Japan Agro Services, Stahler, Taminco, Isagro

mutual recognition continues. However, there seems to be a (limited) trend towards more application of mutual recognition;

- Option B, the zonal authorisation of PPP without national risk mitigation measures 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;
- Option C, the zonal authorisation of PPP with national risk mitigation measures, could still be expected to lead to a significant reduction of administrative burden for national authorities, however less than in options B and D. Also a reduction of dossier costs expected for industry is likely compared to status quo (however less than in options B and D, as additional national requirements may have to be addressed);
- Option D, a central agency for evaluation and authorisation 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.

Impact on indirect costs for PPP users

An impact of the options on indirect costs for PPP users could theoretically result from a number of factors:

- a. Reduction of the number of PPP available, especially for minor uses, which could also lead to a reduction of competition and related increase of prices;
- b. Number of generic products on the market that tend to affect price levels of PPP.

Stakeholders are divided on the possible impacts of policy action 2 on the number of PPP available, especially for minor uses. In general, two contradictory arguments were brought forward:

According to the first argument a zonal system would lead to a reduction of availability of PPP, especially for minor uses, because industry would focus more on major uses/crops (shared by ECPA, LTO Nederland).

However, according to the second argument precisely the opposite would be the case, with optional mutual recognition (options B and C) leading to an increased availability of PPP, especially for minor uses. This view was shared, for example, by the Central Union of Agricultural Producers and Forest Owners (Finland), the Agricultural Industries Confederation (UK), APCA and FNSEA (France), and Coordinadora de Organizaciones de Agricultores y Ganaderos – Iniciativa Rural (Spain). The Coalition of smaller research-based PPP companies also argued: “A rationalised system with mutual recognition and adapted fees for national registration would be beneficial for minor uses in general.

However it should also be taken into account that some minor uses are country specific and in that case there would be no difference. If only relevant for one country, the investment could be too big, unless facilities would be granted like a reduced number of efficacy and residue trials (minor crops already have a lower number of residue trials than major crops, but more extrapolation possibilities etc.). It seems more difficult for a centralised system to recognise (local) minor uses.”

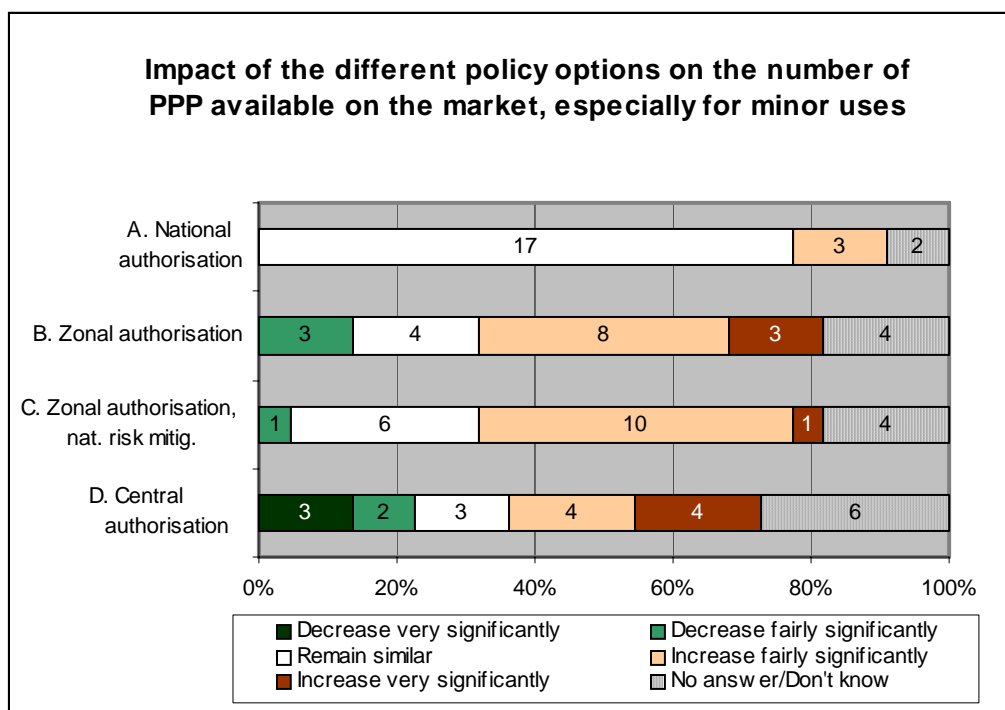
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Several organisations argued that option D (centralised authorisation) would increase most the number of PPP/active substances available (Coceral, Agricultural Industries Confederation (UK)).

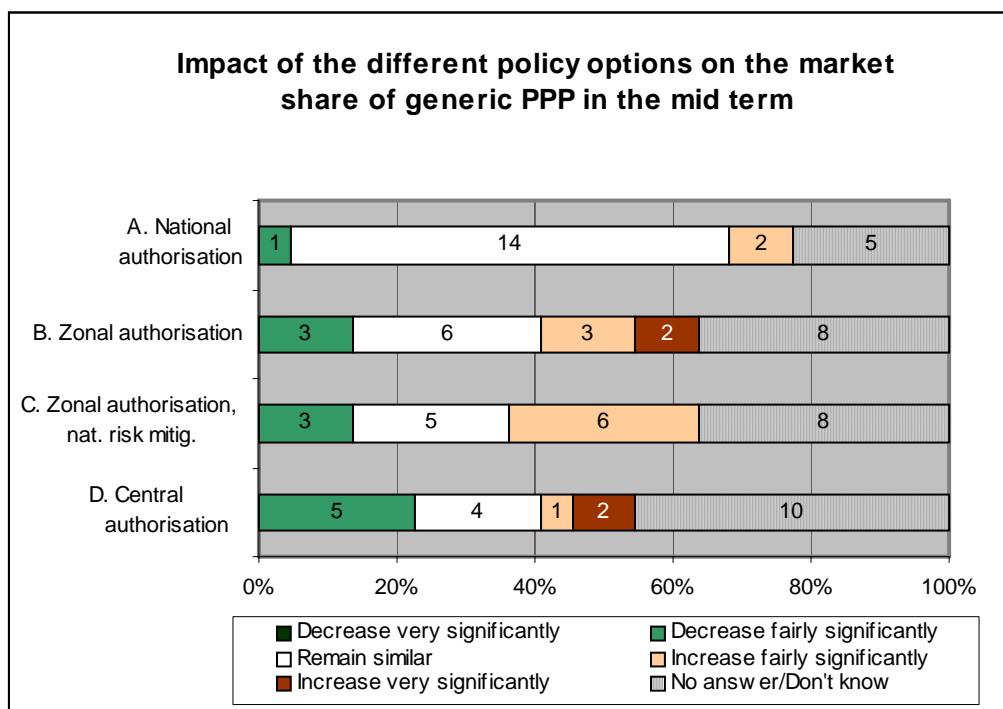
From an analytical point of view it can be expected that compulsory mutual recognition as foreseen in options B and C will increase the number of PPP on the market compared to the current situation, *at least in the smaller markets*. Presently the markets in a zone are not homogenous and larger markets tend to have a higher number of PPP authorised. However, it has to be pointed out that for options B and C to have this effect industry would have to apply for mutual recognition in the smaller markets. Although this seems likely to be the case if the mutual recognition procedure is easy and fees are low, there is, however, no guarantee that companies will actually apply for mutual recognition, especially in very small markets.

According to the experience of countries having significant experience with mutual recognition this approach has led to an increase of PPP available and this is also what a clear majority of competent authorities expects to happen under options B and C. Eleven of the 18 authorities that had an opinion on this issue expect the number of PPP on the national market to increase at least by 10% to 25% compared to the current situation. This view is also dominant with respect to option D, however, there are also 5 authorities that expect a reduction of PPP with central authorisation, possibly because of the expectation that a centralised authorisation would not have the capacity to authorise PPP in similar numbers as the present decentralised system. The perspective of competent authorities is illustrated in the following graph:



Source: Survey of competent authorities

A less clear picture was given on the second factor that could influence indirect costs for PPP users. No consensus was found among competent authorities whether mutual recognition would lead to an increased share of generic products, with only 5 to 6 authorities expecting this to be the case with the zonal approach, and even less with a centralised authorisation. This is illustrated in the next graph. It also indicated the relatively high number of authorities not having an opinion on this issue:



Source: Survey of competent authorities

A significant number of other stakeholders expected only a moderate or no impact on the share of generic PPP on the market, a notable exception being the organisation of generic producers ECCA, which is strongly in favour of central authorisation and opposed to a “very cumbersome national registration”. The Asociación Española de Fitosanitarios y Sanidad Ambiental (AEFISA) expects mutual recognition not to have advantages for generic PPP producers or formulators and the loss of market share of producers and formulators of generic PPP (described in section 0) would continue. Although the impact of policy action 2 on the market share of generic PPP seems to be a matter of discussion, there are, however, few arguments that point to a significant or even very significant reduction of market share of generic PPP compared to the status quo as a result of one of the options B, C or D.

Several conclusions can be drawn:

- Option A (the current situation, national authorisation) 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 farmers⁹³;
- 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;

⁹³ Possible price effects caused by the reduction of the market share of generic PPP after Annex I inclusion of the active substance are discussed in the context of policy action 4 (data protection)

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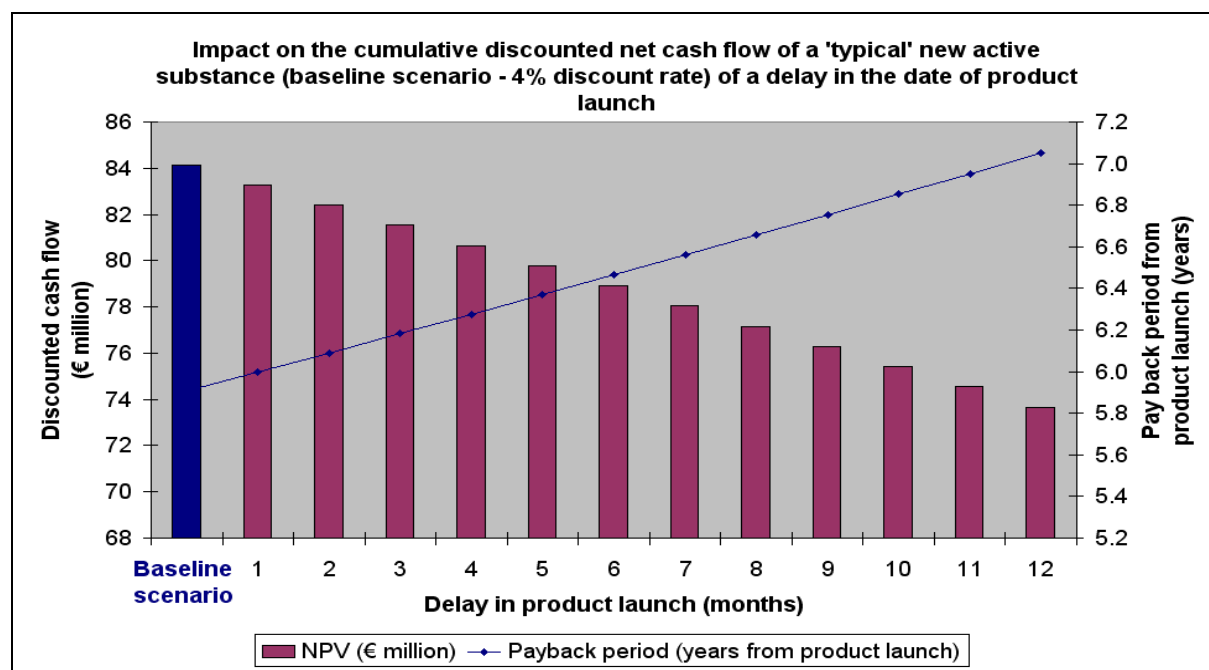
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- Option D can also be expected to increase availability of PPP for minor uses especially in smaller markets, without the need that PPP industry applies for mutual recognition. However, the actual number of authorisations would depend on the financial and staff resources provided to a central agency for PPP authorisation as well as the approach taken for authorisation.

Impact on investment of PPP producers in R&D

With mutual recognition, the most significant factor affecting the economics of new product (active substance) development would likely be the potential impact it would have on the date of product launch. As our survey among competent authorities found (see above), there are diverging views on whether the duration of authorisation will decrease or increase for each of the individual options.

The impact of an earlier product launch date is presented graphically in the figure below and summarised in Table 18:



Source: FCEC

Table 18: Model results: Policy action 2 – sensitivity analysis – discounted at 4%

	Impact of delay on product launch							
	0	1	2	4	6	8	10	12
NPV (€million)	84	83	82	81	79	77	75	74
IRR (%)	12.7	12.6	12.5	12.4	12.2	12.0	11.8	11.6
Payback period (years from product discovery)	15.9	16.0	16.1	16.3	16.5	16.7	16.9	17.1
Payback period (years from product launch under status quo)	5.9	6.0	6.1	6.3	6.5	6.7	6.9	7.1
Discount rate	4%	4%	4%	4%	4%	4%	4%	4%

In essence, for every month delay to product launch for a ‘typical’ active substance, then under the assumptions of the model regression analysis found that:

- The NPV of the cumulative net cash flow would be reduced by €874 000 over the 25 year investment period;
- IRR would fall by 0.1%;
- Payback period would be extended by approx. 1 month.

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, although shorter delays would minimise the likely impact on NPV, pay back period and IRR. That said, if mutual recognition results in decreasing the duration of authorisation and products can be marketed earlier, then the likely impact on NPV, pay back period and IRR would be positive.

Impact on EU PPP industry competitiveness

Mutual recognition is intended to reduce and to simplify authorisation procedures and costs, while promoting the application of uniform evaluation standards and preserving existing protection standards. In principle, this should have positive effects on industry competitiveness, as it would:

1. Reduce the cost and the complexity of new substances’ authorisations;
2. Reduce the uncertainty created by possible differences of approaches to authorisation by selected MS;
3. Contribute to uniform market entry conditions, and therefore increased competition and competitiveness.

A combination of zonal evaluation and compulsory recognition (options B and C) is in principle designed to bring these positive effects. A centralised authorisation agency (option D) would even more simplify the complexity of the authorisation procedure and reduce the uncertainty faced by the companies who want to introduce a new substance on the market. This aspect is especially pointed out by the generic industry. One should however be careful that the proposed zone based evaluation can have various spurious effects, depending how it is practically implemented. Possible issues for industry concerns are:

- Zonal authorisations may reflect only the minimal application rate requirements of the most environmentally vulnerable country in the zone. If mutual recognition will be based on these minimal requirements being applied across the board, which may result in zonal sales significantly lower than if authorisation was granted in each country on the basis of local conditions, without this being justified by valid environmental concerns. This impact could be not uniform across PPP categories, since it will depend on the agriculture profile of the zone. Depending on the country, average use rates might differ significantly. This may then impact selectively on some producers, depending on their product portfolio. Differences in PPP use are accounted for in part by local agriculture conditions, practices and profiles, but also, to some extent, by national authorisation.
- A concern rather specific to generics manufacturers is that zone wide authorisations and mutual recognition are not sufficient conditions to open the PPP

market, as the administrative burden will still be much higher than with a central authorisation.

National risk mitigation measures (option C) would in principle counterbalance the risk of a uniform application rate for a zone by making country level application flexible on a case by case basis. However, one should remain careful that the complexity of requiring and of managing local mitigation measures does not offset the simplification of the zonal authorisation procedure.

This leads to the following conclusions:

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

6.2.2. Social impacts

Impact on employment

Given the uncertainty surrounding the impact that mutual recognition would have on the duration of the authorisation process, conclusive statements concerning the impact of each policy option on the economics and attractiveness of new product (active substance) development cannot be made. The results of the discounted cash flow model (impact on investment of PPP producers in R&D) found that a delay in authorisation would adversely affect the economics and attractiveness of new product development, although the extent of this impact would be directly dependent on the length of the delay. It can therefore be hypothesised that there is a possibility that employment in R&D may be affected with increased delays as R&D based companies become slightly more selective when deciding which active substances they should develop. However, as has been outlined above, the experience of Member States that currently apply mutual recognition to a significant extent does not indicate a risk for major delays.

Impact on information opportunities of citizens

No impact is expected under the different options.

Impact on the duplication of studies on vertebrate animals

Under Directive 91/414 data sharing of vertebrate studies may be required by the Member States (Art. 13). Several Member States have introduced legislation in this effect, other

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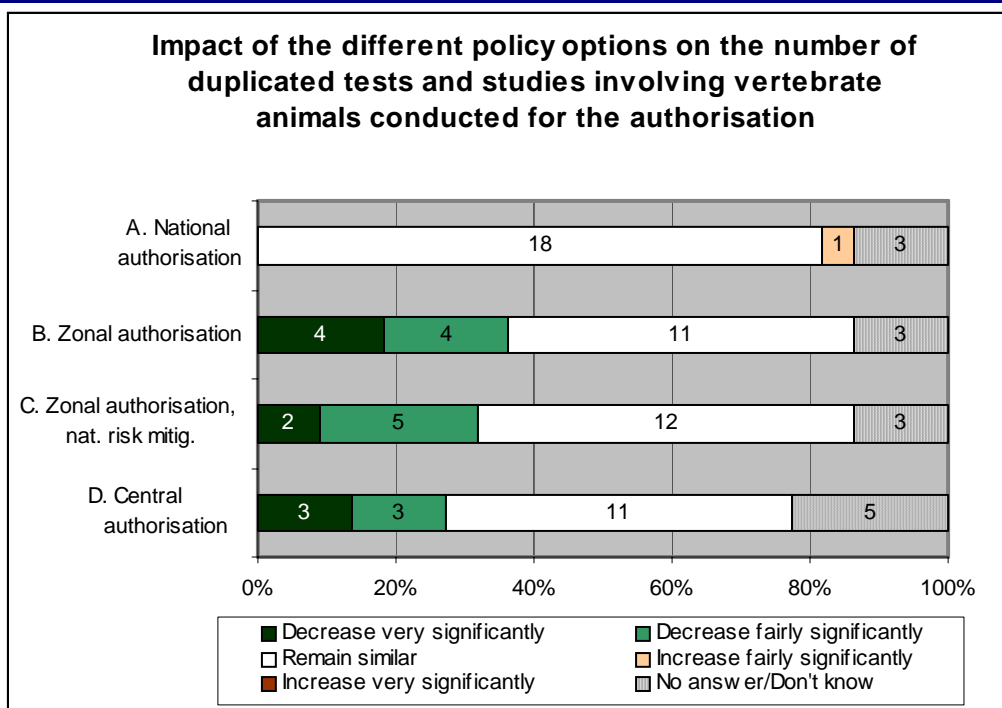
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Member States have not. This provision has led to different rules in Member States, which makes it difficult to assess the extent to which a duplication of vertebrate studies is actually taking place at present. Two cases have to be differentiated: a) The same company registers a similar product in different Member States. Then the company normally would use the same studies for all national dossiers, except in cases where differences in the national authorisation requirements would lead to the need to produce additional studies involving vertebrate animals; b) A generic company registers a product that has already been registered by another company. In this case the application of the national data protection/sharing rules would decide whether or not a duplication of a study involving vertebrate animals might occur.

Industry stakeholders differ in their assessment of whether the option would have an influence on duplication of vertebrate animal testing. ECPA does not expect any impact, whereas the Coalition of smaller research-based PPP companies states: “Duplication of tests on vertebrates may occur in the course of national registrations, but it is not so frequent. It is more likely to occur if there is more than one notifier, i.e. if generics want to register their product, and this is not dependent on the policy options. With regard to the policy options, the best case would be option D (completely central), where duplication of tests (by the same registrant) is almost automatically ruled out. Mutual recognition would also be efficient.”

The European Coalition to End Animal Experiments (ECEAE) and Eurogroup for Animal Welfare (UK and Belgium) also preferred in a joint statement option D, as it should be the task of a central agency “to ensure data sharing and prevent animal testing from being carried out, (...) to develop strategies to replace animal testing and to ensure integration of the development and use of alternative test methods”. No data on the extent of possible duplication of animal testing during national registration was presented by any of the stakeholders.

National competent authorities have a rather similar view on the issue for all “new” options: A majority does not expect a change of the current situation. However, a strong minority of 6 to 8 authorities expects a significant reduction of the number of duplicated tests involving vertebrate animals with either option B, C and D (see following graph):



Source: Survey of competent authorities

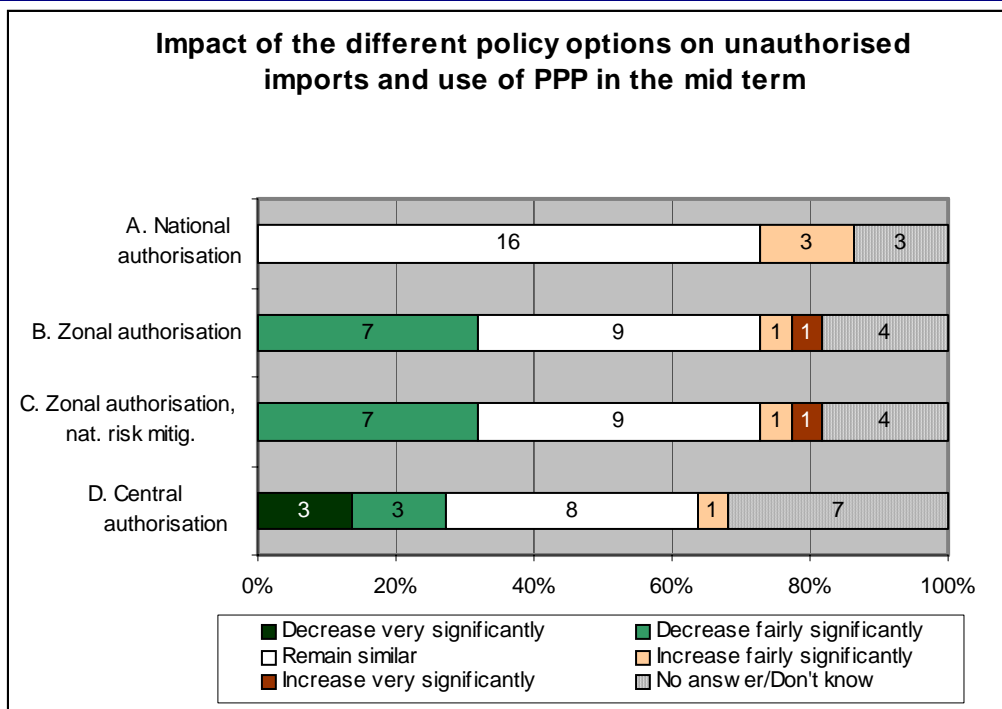
This leads to the following conclusion: Options B, C, D have the potential to reduce the number of duplicated studies involving testing on vertebrate animals depending on the degree to which national legislation does not prevent this to happen currently and industry actually duplicates such tests – an issue on which no reliable data exists. The assessment is therefore provisional in character.

6.2.3. Environmental impacts

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 (see also discussion in section *Impact on indirect costs for PPP users*, above).

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. The assessment of the competent authorities is presented in the following graph. A majority of authorities does not expect a change, however a strong minority of 6 to 7 authorities is of the opinion that all “new” options will indeed reduce unauthorised cross-border sourcing of PPP.



Source: Survey of competent authorities

Impact of active substances on the environment or human health

Three factors relate to the impact of active substances on the environment or human health:

- The impact the options have on unauthorised cross-border sourcing of PPP, which is a potential risk to environment and human health;
- The impact the options have on the time to market for new active substances that may have fewer impacts on the environment;
- The impact the options have on the way national (or regional) environmental conditions are taken into account during the authorisation.

The first factor has been discussed in the previous section. The second factor depends on the timeline for applying mutual recognition, which is a matter of controversy (see above) and will mainly depend on the technical details of the implementation. In any case, any related impact is rather speculative in nature. This assessment will therefore focus on the third factor that has been subject to several comments by stakeholders: Industry and farmers/trade mainly argued that a reduction in negative impacts would not be expected under any of the options as the current approval process already minimises the risks to humans and the environment. Two organisations, however, the Pesticides Action Network-Europe and Eureau (the European Union of National Associations of Water Suppliers and Waste Water Services) voiced significant concerns regarding zonal authorisation. Eureau stated: “The assumption on which zonal evaluation is based (that ‘agricultural, plant health and environmental/climatological conditions are comparable in the regions concerned’) does not hold. At least not for the environmental conditions groundwater, surface water and soil. Precisely these conditions vary greatly within one zone, and it's these conditions, which are most determinative for e.g. leaching tot groundwater or the intensity of emissions to surface water. So any form of 'zonal' averaging is not in the interest of protection of drinking water resources.” And PAN, after arguing along the same line added: “Analysing the current situation in different countries

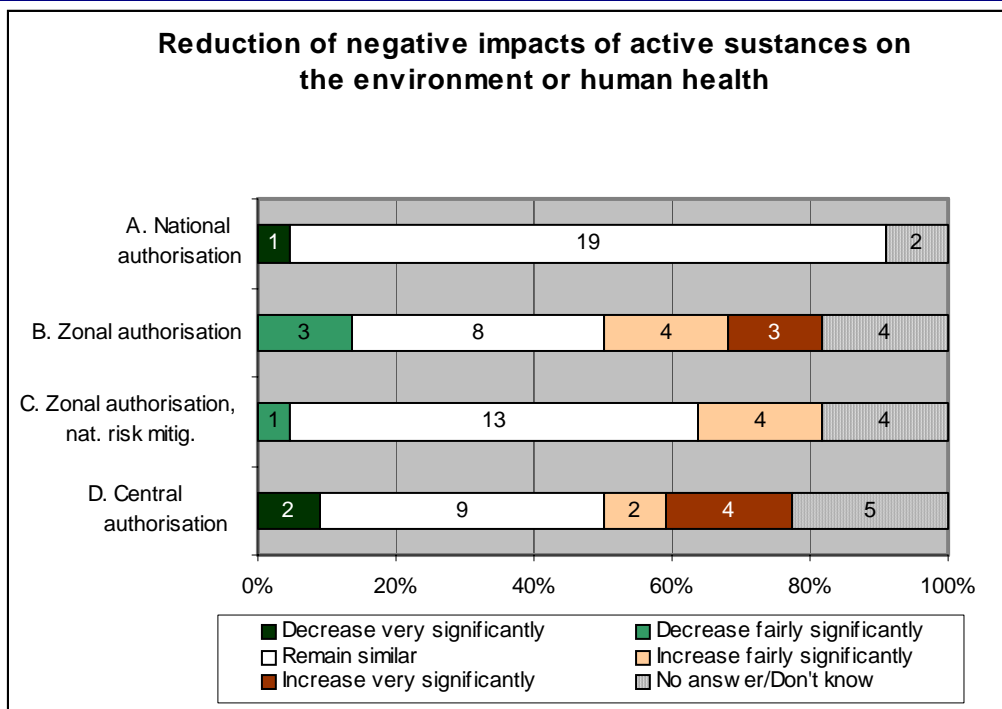
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regarding the number of active substances in the market can provide us with an insight into a future were a zonal registration is in place. If we compare a country in the proposed Northern Region (UK) and Scandinavian Region (Denmark), we can state that the number of active substances for agricultural use is much higher in UK (204 against 84). Many active substances were rejected in the Danish market following stricter rules for the protection on human health and environment, in particular water resources. The zonal registration will increase the number of hazardous substances in the environment and the human exposure to pesticides in countries that, up until now, have decided to have stricter rules for the approval of PPPs.”

Although the latter argument mainly applies to central authorisation (the UK and Denmark are in two different zones), the concern is reasonable and was also brought forward by competent authorities from the northern zone. They argued that compulsory mutual recognition would only be acceptable if comparative assessment (policy action 3) was to be introduced, allowing to continue the national minimisation strategies regarding the use of PPP and preventing a situation described by PAN. This issue will be further discussed in the context of policy action 3 (see section 6.3).

The risk of “zonal averaging” seems to be relevant to a certain degree, although environmental conditions vary significantly inside larger and even inside some smaller Member States, so that authorisation already has to take these differences into account. This means that zonal or central authorisation is not confronted with a new problem, but rather with the same problem to a larger extent. On the other hand, it is a fact that Member State authorities have significant experience in applying risk mitigation measures adapted to the environmental conditions in their country. For this reason an authorisation procedure that would draw on this experience can be expected to be more sensitive to national conditions and concerns than an approach relying fully on an outside institution (be it another Member State in the zone or a central agency). This is also reflected in the view of a minority of 6 to 7 competent authorities that assess option B and D (both without national risk mitigation measures) as leading to an increase of negative impacts of active substances on the environment or human health, half of them expecting even a very significant increase.



Source: Survey of competent authorities

Option C (Zonal authorisation with national risk mitigation measures) is seen by a clear majority as having a similar impact as the status quo option. The continuation of national authorisation is the option seen by the largest number of authorities as having no increased negative impacts on environment or health, a view shared by both Eureau and PAN. This leads to the following conclusions:

- Option A (National evaluation and authorisation) 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 option B (the zonal approach without national risk mitigation measures) 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 C (the zonal approach with national risk mitigation measures) will make it easier to take into account variations in environmental conditions. At the same time, more homogenous markets in a zone would lead to fewer incentives for unauthorised cross-border sourcing of PPP with the related potential risks;
- With option D (the central agency for evaluation and authorisation) 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

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cross-border sourcing of PPP with the related potential risks (even more than in options B and C).⁹⁴

⁹⁴ 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.

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6.2.4. Summary

The results of the impact assessment of *policy action 2: Mutual recognition of PPP containing an active substance already included in Annex I* are presented in the table below:

Table 19: 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 – <u>no</u> national risk mitigation measures	Zonal authorisation – <u>with</u> 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 environmental conditions)	O	– (difficulty to take into account all environmental conditions)

++ = Very significant positive impacts
 -- = Very significant negative impacts
 + = Significant positive impacts
 – = Significant negative impacts
 O = No change from the present situation

Notes: * Staff and financial resources provided to a central agency affects the assessment significantly. For this assessment it has been assumed that the agency would have access to adequate financial and staff resources.

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** Assessment only provisional, as no reliable data exists on the extent to which vertebrate studies are duplicated at present.

6.2.5. Proportionality and added value of EU action

Table 20: Proportionality and added value of alternative options for evaluation of new active substance / national provisional authorisation of PPP containing a new active substance

	Option A	Option B	Option C	Option D
Description of option	Status quo - National evaluation and authorisation	Zonal authorisation – <u>no</u> national risk mitigation measures	Zonal authorisation – <u>with</u> national risk mitigation measures	Central agency for evaluation and authorisation*
Proportionality	<ul style="list-style-type: none"> This approach leaves the most room for national policies on PPP use However, also implies significant duplication of administrative efforts Leads also to high entry barriers, especially for small PPP companies 	<ul style="list-style-type: none"> A zonal approach leaves existing infrastructure in place (national competent authorities remain at the core of the PPP evaluation process) Reduces administrative burden and entry barriers, depending on implementation May lead to negative environmental impacts, if “zonal averaging” would result 	<ul style="list-style-type: none"> A zonal approach leaves existing infrastructure in place (national competent authorities remain at the core of the PPP evaluation process) Reduces administrative burden and entry barriers, depending on implementation Prevents risk of “zonal averaging” 	<ul style="list-style-type: none"> A central agency would require substantial resources and would take over some functions of the existing infrastructure for PPP authorisation, similar to EMEA Reduces administrative burden and entry barriers significantly May lead to negative environmental impacts, if “EU averaging” would result
Added value of EU action	<ul style="list-style-type: none"> No EU action 	<ul style="list-style-type: none"> Zonal system is only workable with EU coordination (and intervention, e.g. to reconcile diverging views of MS) 	<ul style="list-style-type: none"> Zonal system is only workable with EU coordination (and intervention, e.g. to reconcile diverging views of MS) 	<ul style="list-style-type: none"> In the long run the simplest solution, transparent with lower entry barriers

* Staff and financial resources provided to a central agency affects the assessment significantly. For this assessment it has been assumed that the agency would have access to adequately financial and staff resources.

6.2.6. Potential for optimisation of options

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

1. 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);
2. 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;

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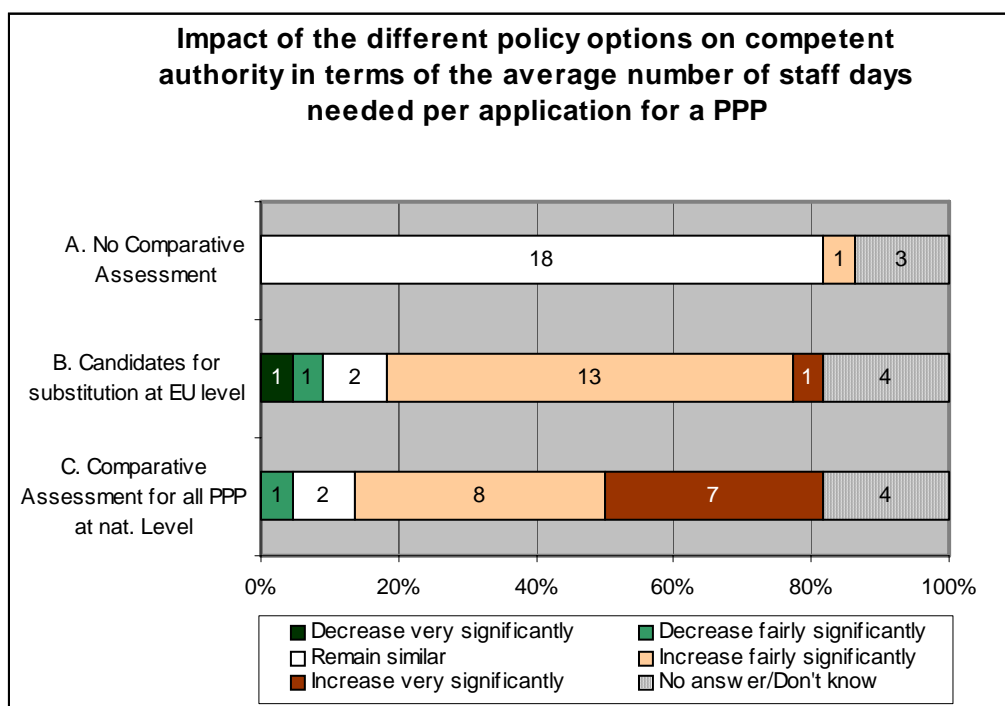
3. One of the factors providing incentives for unauthorised cross-border sourcing of PPP are differences in VAT among Member States, reportedly of up to 17%. This is especially significant, as in some Member States not all farmers are required to apply formal financial bookkeeping but can deduct costs 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.

6.3. Assessment of policy action 3: Comparative assessment of PPP

6.3.1. Economic impacts

Impacts on administrative burden

Two thirds of competent authorities are of the opinion that comparative assessment will bring an additional administrative burden. Most authorities (13) expect that the average number of staff days needed per application will increase by 10% - 25% with option B, a significant minority of 7 authorities even expect the increase to be more than 25% with option C.



Source: Survey of competent authorities

Although this general assessment is not in line with the Swedish experience (see Annex B), it seems reasonable to assume that at least in the short to mid-term comparative assessment will mean an additional step in the authorisation procedure requiring additional staff input, even more so with option C. 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 (depending on the type of criteria to be finally selected, see below in section *potential for optimisation*). This is again in line with the Swedish experience, where substitution was mainly relevant for existing active substances. It also has to be noted that there is some interrelationship between policy action 2 (compulsory mutual recognition) and policy action 3 (comparative assessment). For some competent authorities comparative assessment with option B is a condition to accept mutual recognition, because according to the current lines of discussion a Member State could deny mutual recognition of a PPP if the active substance it contains is included in Annex ID. This would prevent that comparative assessment and compulsory mutual recognition lead to contradictory results and give priority to national minimisation strategies. An additional administrative burden caused by comparative assessment could therefore partly be compensated by the application of compulsory mutual recognition in a

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zone, which would be less likely to happen without comparative assessment. This leads to the following conclusions:

- Option A (Status Quo - No provision for comparative assessment) does not imply a change in administrative burden;
- Option B (Identification of candidates for substitution at the EU level based on hazard criteria) is expected to imply a significant increase of administrative burden for competent authorities, however it may also provide the basis for functioning of compulsory mutual recognition and related gains in administrative burden;
- Option C (Comparative assessment at the national level independent from the hazard of the active substances) implies a significant increase of administrative burden for competent authorities (possibly more than option B), however it may also provide the basis for functioning of compulsory mutual recognition and related gains in administrative burden.

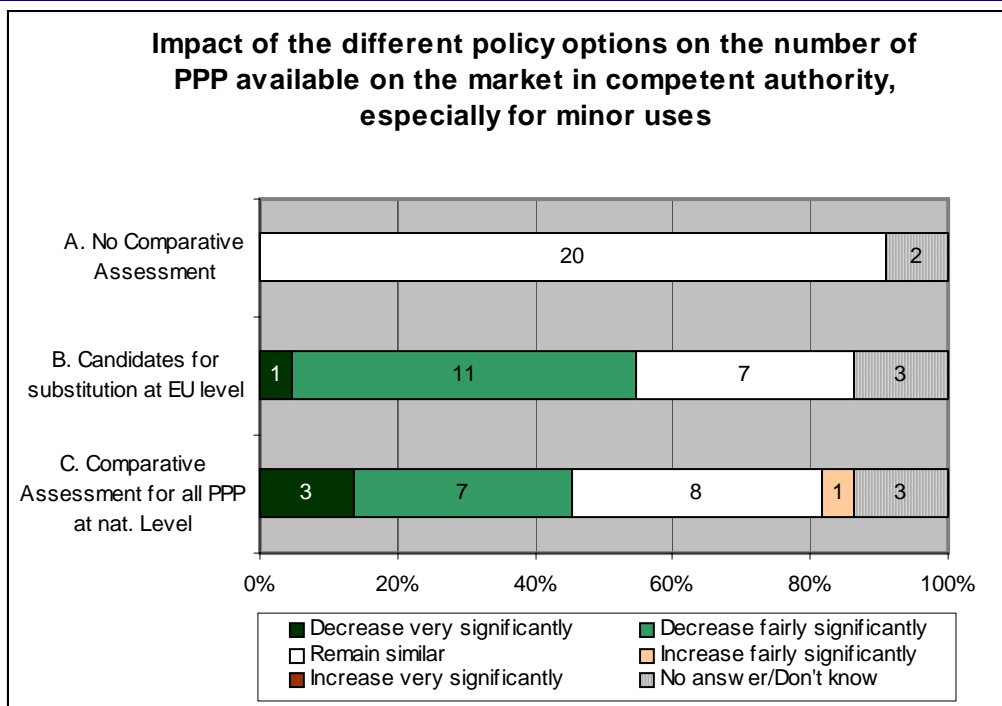
It is not expected that any of the options increases the costs of dossier submission for industry, if absolute and predictable criteria would be used for comparative assessment (see below in section *potential for optimisation*). No increase of administrative burden is also expected for PPP users.

Impact on indirect costs for PPP users

An impact of the options on indirect costs for PPP users could result from a number of factors:

- a. Reduction of the number of PPP available, especially for minor uses, which could also lead to a reduction of competition and related increase of prices;
- b. Increased use of PPP with newer active substances that are higher priced;
- c. Number of generic products on the market that tend to affect price levels of PPP.

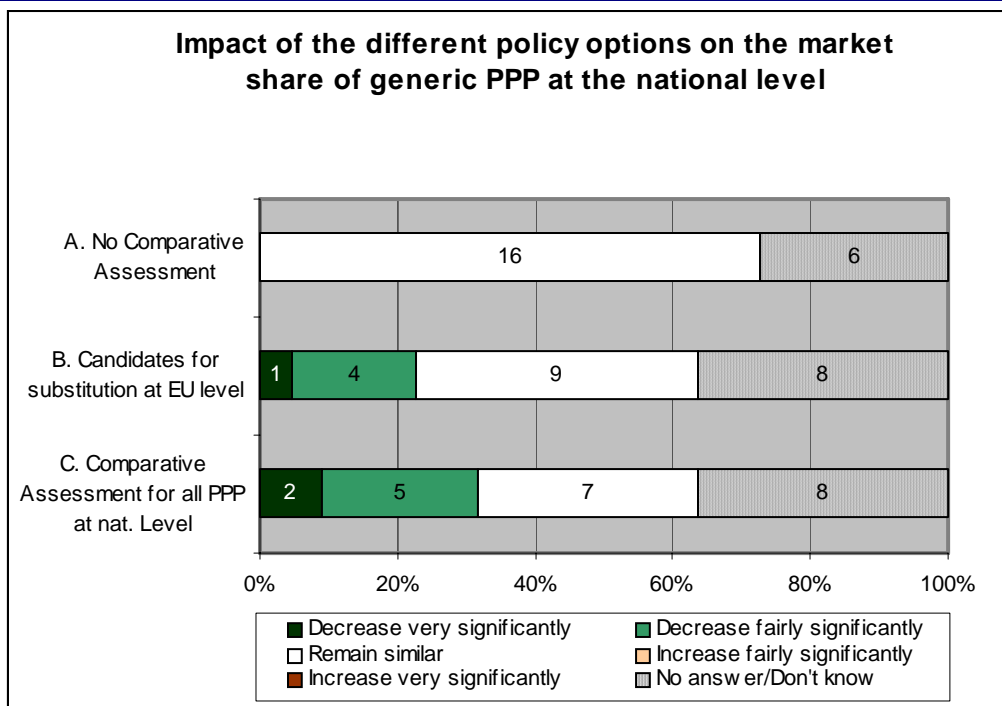
Comparative assessment (both options B and C) is expected to lead to a reduction of availability of PPP by a majority of competent authorities (see following graph):



Source: Survey of competent authorities

The majority of other stakeholders shares the view that comparative assessment will lead to a reduction of PPP available. It has to be noted that 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). However, the present number of authorised PPP in Sweden is still at the lower end of the numbers authorised in other Member States (320 compared to a median of 682 for all 22 Member States replying to the survey), which may partly also be related to the market size.

Comparative assessment may imply a shift from older, off-patent active substances to newer, patented active substances. Five to 7 competent authorities expect a reduction of market share of generic PPP with comparative assessment, none expect this to increase.



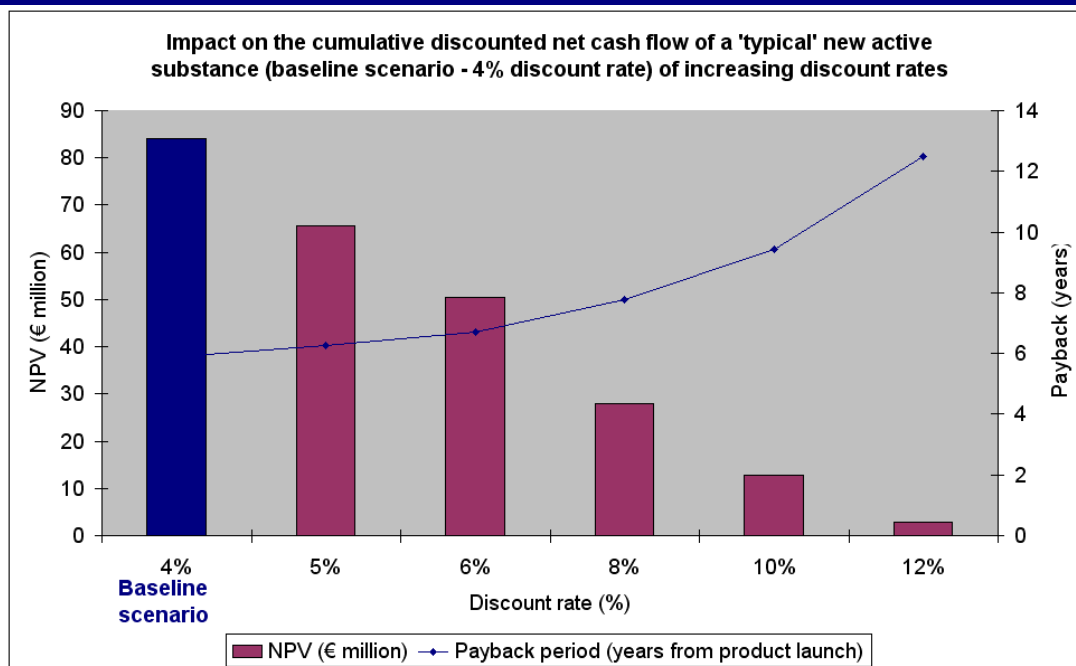
Source: Survey of competent authorities

In Sweden, comparative assessment and substitution has been used as a reason not to approve ca. 20% of the old products, according to data from the Swedish Chemicals Inspectorate (KEMI). The inspectorate also estimates that less than 10% of the decisions on applications for authorisation of PPP are based on comparative assessments. According to KEMI's experience, comparative assessment is less relevant for new active substances. This could increase the average price of PPP, as usually patented products are more expensive due to the lack of generic competition. There is no comprehensive price data available from Sweden. However, no major price increases are reported from Swedish stakeholders (see Annex B of this report).

In conclusion it can be said that comparative assessment (both options B and C) may reduce the market share of generic products and "older" products leading possibly to a price increase of PPP. However, the extent to which this takes place in practice depends on the way comparative assessment is applied at the national level.

Impact on investment of PPP producers in R&D

With comparative assessment, the most significant factor affecting the economics of new product (meaning here: active substance) development would likely be attitude to risk. Any increase in the perceived risk of new product development will likely be reflected in the use of higher discount rates when appraising potential investment in research and development. As shown in the graph below, the use of higher discount rates significantly reduces the NPV of an investment and thus increases the payback period.

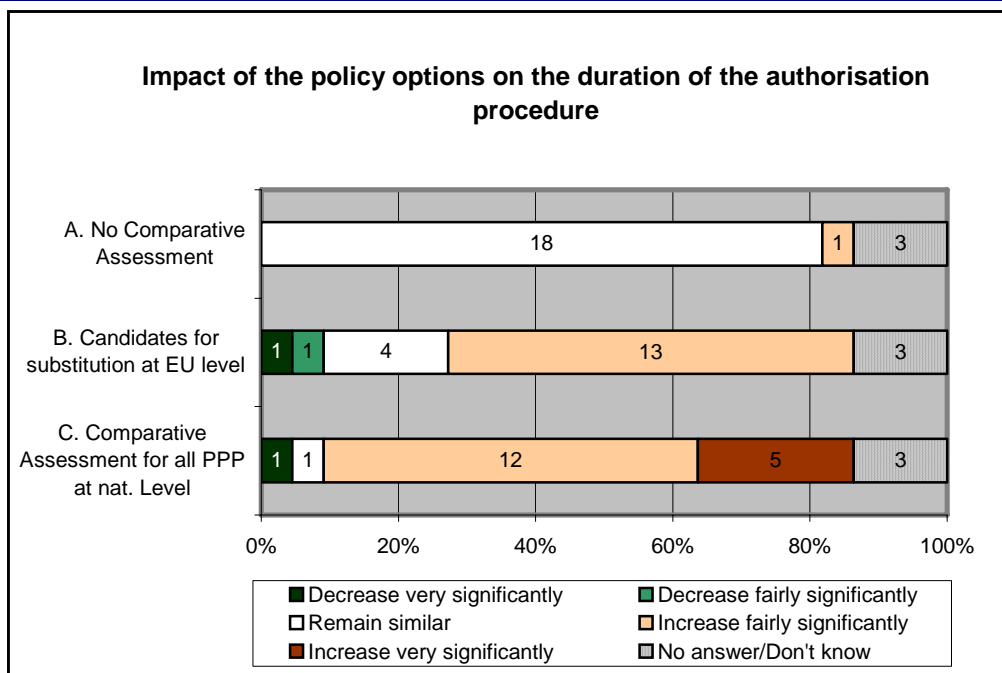


Source: FCEC

The extent to which comparative assessment affects a company's attitude to risk is likely to vary considerably between companies and even within companies. As this attitude to risk is likely to be relatively subjective, it is 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 (No comparative assessment) would not affect any active substance. Comparative assessment at the national level independent from the hazard of the active substances (option C) on the other hand could potentially have impact on all active substances. Option B (Identification of candidates for substitution at the EU level based on hazard criteria) would be somewhere in between. A competent authority provided for this impact assessment an estimate of the number of active substances currently included in Annex I that fulfil the criteria for inclusion in Annex ID (criteria under discussion, see section 5.3). The authority would expect that between 15% - 40% of active substances would have to be included in Annex ID, depending on the interpretation of the criteria. According to ECPA, however, more than 80% of active substances included in Annex I could be affected. This estimate would be reduced to 30% - 35% with limited changes to the criteria such as dropping the sensitisation criteria, which alone could affect up to half of active substances, according to ECPA.

Another factor that may affect company decisions is the average duration of the authorisation procedure. This is expected to increase with comparative assessment, according to competent authorities:



Source: Survey of competent authorities

Both factors therefore make option C the least favourable for industry. It is likely that option C will be perceived by industry as being more risky than option B, which is likely to be perceived as being more risky than option A (Status Quo). Therefore, option C is likely to result in the use of higher discount rates than option B, and in turn option A, when appraising the potential investment in research and development. This would likely have a negative impact on NPV, pay back period and IRR, thereby adversely affecting the economics and attractiveness of new product development. The results of a sensitivity analysis using different discount rates is presented in Table 21:

Table 21: Policy action 3 – sensitivity analysis using different discount rates

	Impact of changes in discount rate					
	4%	5%	6%	8%	10%	12%
NPV (€million)	84.15	65.59	50.44	27.95	12.88	2.80
IRR (%)	12.7	12.7	12.7	12.7	12.7	12.7
Payback period (years from product discovery)	15.91	16.28	16.71	17.79	19.43	22.48
Payback period (years from product launch under status quo)	5.91	6.28	6.71	7.79	9.43	12.48

Impact on EU PPP industry competitiveness

Comparative assessment as part of the authorisation process for PPP is a way of internalising part of the external effects of pesticides on the environment. From a competitiveness and competition perspective, it amounts to regulating the market by a non-price and non-commercial principle. Indeed, the implication of comparative assessment is that, for any crop protection functionality, substances having comparative environmental or toxicological advantages could preferably be marketed. This could have the following effects:

- It could reduce the number of active ingredients for sale. Indeed, if authorisation for environmentally or toxicologically inferior substances is rejected, this will still limit the number of new active substances entering on the market. This will not necessarily reduce the market size, since existing substances will keep being used;
- It could stimulate innovation towards substances offering better hazard reduction. If favourable comparison with existing products on environmental and toxicological grounds is seen as an entry criteria to comply with, this will stimulate research and development towards developing safer and more environmentally friendly substances, such as low rate of use components. Depending on how comparison will be interpreted by authorities, this may however orient R&D towards ecological and toxicological performance at the expense of functional effectiveness;
- It may increase the cost and the complexity in evaluation cost, since comparative assessment work will have to be conducted by the authorisation agencies and financed through fees by the companies registering products;
- It also could influence the relative market shares of selected active substances, since some active substances will be preferred over others for non-functional and non-commercial reasons. This, however, can only be evaluated on a case-by-case basis. A priori, there is no reason why this should favour patent or non-patent covered products, although the Swedish experience shows that existing active substances may be more affected than new active substances.

This leads to the following conclusion:

- Option A (Status Quo - No provision for comparative assessment) is the most competitiveness friendly option;
- Option B (Identification of candidates for substitution at the EU level based on hazard criteria) 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 (Comparative assessment at the national level independent from the hazard of the active substances) can be expected to have the same effects as in Option B, but with a larger span of uncertainty for the industry.

6.3.2. Social impacts

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. Any increase in perceived risk would be reflected in the use of higher discount rates to appraise potential investment in research and development. The results of the discounted cash flow model (impact on investment of PPP producers in R&D) found that the use of higher discount rates significantly reduces the NPV of an investment, thereby increasing the payback period for it to break-even. This in turn may reduce the attractiveness of new product development. Therefore, employment in R&D may be adversely affected if companies perceive that there is increased risk associated with developing new active substances; R&D based companies may become slightly more selective when deciding which active substances they should develop in a riskier environment.

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

Impact on information opportunities of citizens

No impacts expected.

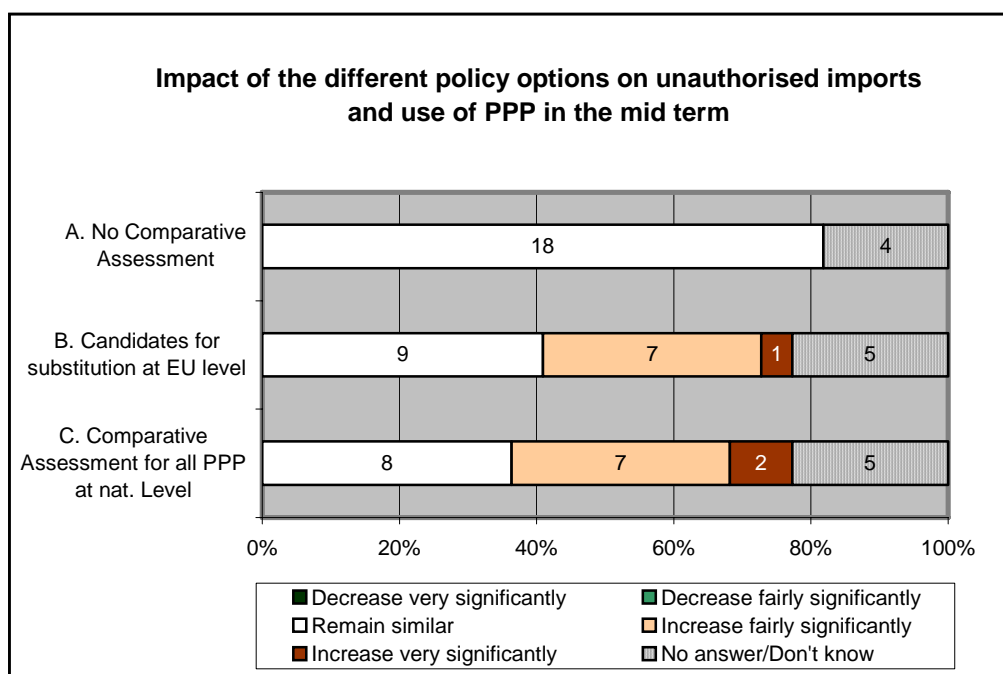
Impact on the duplication of studies on vertebrate animals

No impacts expected.

6.3.3. Environmental impacts

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 result in incentives for the unauthorised cross-border sourcing of PPP. Approximately half of the competent authorities having an opinion on this issue assessed that comparative assessment would lead to an increase on unauthorised cross-border sourcing of PPP (see graph):



Source: Survey of competent authorities

A similar view is shared by a significant number of stakeholders. 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, next to marketing policy of companies, market size, differences in VAT and enforcement activities of authorities to prevent unauthorised cross-border sourcing. The impact of option B and C on unauthorised cross-border

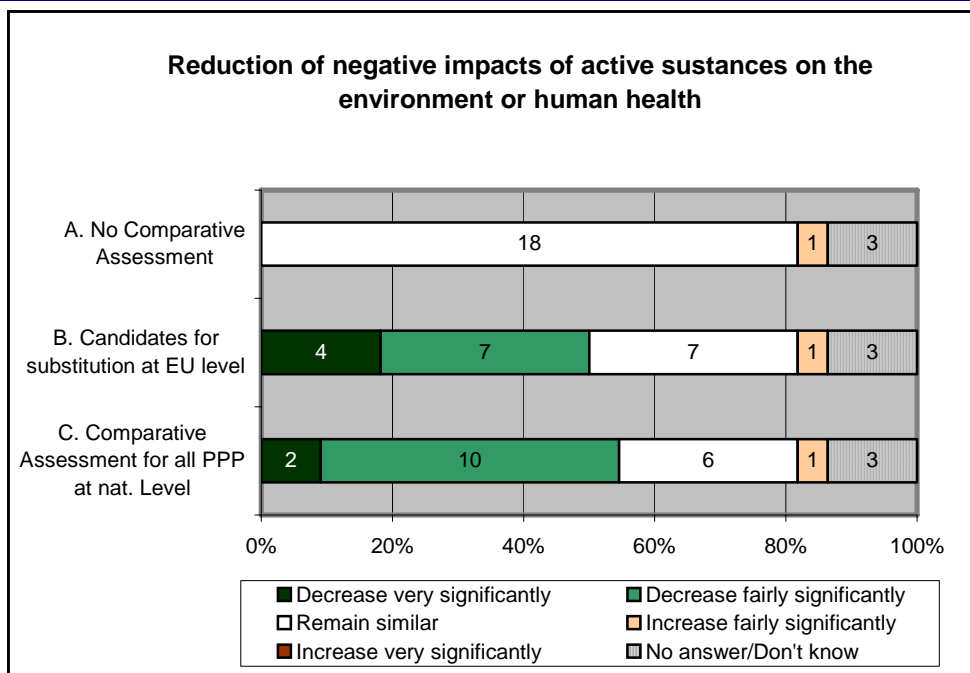
sourcing can therefore be expected to be rather limited in nature compared to the other factors involved.

Impact of active substances on the environment or human health

Two factors relate to the impact of the options on the environment or human health:

- a. The impact the options have on unauthorised cross-border sourcing of PPP, which is a potential risk to the environment or human health;
- b. The impact the options have on reducing the use of active substances that are significantly less safe for human or animal health or the environment than available alternatives.

The first factor has been discussed in the previous section. The second factor is the rationale for comparative assessment, and a positive impact on environment and health with the application of the principle is very likely. For example, some competent authorities provided the percentage of PPP classified under Directive 1999/45/EC as very toxic or toxic. Whereas in a southern Member State this percentage was estimated at 10% of all authorised PPP, in a Nordic country this percentage was estimated to be close to zero. The competent authority in the Nordic country pointed out that before the restrictive pesticide policy was started, a significant number of highly toxic products was on the market in this country, too. Of course, the acute toxicity is only one factor, which is relevant for the safety margin during storage and application of the PPP. Less toxic products may clearly reduce pesticide accidents. However, less toxic products may also have problematic impacts, e.g. when used more often or in higher quantities than the toxic product they replace, or when they have adverse long-term environmental impacts. It is the challenge of comparative assessment to take these aspects into account and provide a comprehensive assessment of the reduction of risk for a PPP to be substituted and a possible increase of risk with alternative products likely to be used. A large majority of 11 to 12 competent authorities is convinced that this challenge can be managed and comparative assessment will indeed provide benefits for the environment or human health under both option B and option C (see following graph).



Source: Survey of competent authorities

Not surprisingly, this view is challenged by industry and also some other stakeholders such as the European Seed Association. “An important factor to take into account is the building up of resistances!,” ESA stated. “To either avoid this building up of resistances or to at least be able to react quickly to it, it is absolutely crucial to have a sufficient range of products available. Where this range of products does not exist, farmers / growers may be forced to use ever higher dosages of a given PPP in order to protect their crop (...) Substitution could lead to exactly the opposite of the desired effect.” Although this could theoretically happen, the described impact does not seem likely, as one of the criteria for comparative assessment is precisely that the “chemical diversity of the active substances should be adequate to minimise occurrence of resistance in the target organism” – this concern therefore refers either to an incorrect application of comparative assessment or to the possibility that interpretations of the needed “chemical diversity” may differ between authorities and industry/users. Comparative assessment is a regulatory intervention, and as any regulatory intervention a certain risk cannot be denied that this intervention may not reach the intended aim. This points to the need for clear guidelines for comparative assessment and thorough monitoring of impacts. The controversy regarding comparative assessment also relates to the general discussion on whether and how priorities should be set to reach a more sustainable agriculture and what costs are acceptable to reach this aim. As a representative of Swedish farmers put it: “We still find pesticides in places where we don’t want to find them. If we want to shift in focus to alternative methods of pest control we should develop the legal framework accordingly.”⁹⁵

In conclusion, the following assessment of the options can be given:

- Option A (Status Quo - No provision for comparative assessment) 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. With inclusion of more active substances in Annex I, the flexibility for national minimisation programmes will be further reduced, leading to possible negative impacts compared to the current situation in Members States which already apply

⁹⁵ Interview Sandrup, Alarik, Lantbrukarnas Riksförbund (Federation of Swedish Farmers), January 2006

such a strategy. In the long term under this option less environmental impacts are possible, depending on the application of the evaluation criteria for the re-inclusion process and development of more targeted active substances;

- Option B (Identification of candidates for substitution at the EU level based on hazard criteria) 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 (Comparative assessment at the national level independent from the hazard of the active substances) can be expected to have similar impacts as option B, with an increased flexibility of Member States.

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6.3.4. Summary

The following table summarises the results of the impact assessment of policy action 3.

Table 22: 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	0	– (depending on implementation)	–/–– (depending on implementation)
Impact on indirect costs for PPP users	0	0 / – (depending on implementation)	0 / – (depending on implementation)
Impact on investment of PPP producers in R&D	0	(0 / –)* (depending on implementation)	(0 / –)* (depending on implementation)
Impact on PPP industry competitiveness	0	+ / – (depending on implementation, positive impacts on innovation possible)	0 / – (depending on implementation, positive impacts on innovation possible)
Social impacts			
Impact on employment	0	(0 / –)* (depending on implementation)	(0 / –)* (depending on implementation)
Impact on information opportunities	0	0	0
Impact on animal welfare	0	0	0
Environmental impacts			
Impact on unauthorised cross-border sourcing of PPP	0	0 (minor negative impacts possible)	0 (minor negative impacts possible)
Impact of AS on environment or human health	0/– (In some MS negative impacts possible compared to current situation)	+/+++ (depending on implementation)	+/+++ (depending on implementation)

++ = Very significant positive impacts
 -- = Very significant negative impacts
 + = Significant positive impacts
 – = Significant negative impacts
 0 = 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.

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6.3.5. Proportionality and added value of EU action

Table 23: Proportionality and added value of alternative options for comparative assessment of PPP

	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 the national level independent from the hazard of the active substances
Proportionality	<ul style="list-style-type: none"> The continuation of the current situation will lead to important restrictions for MS once all AS are included in Annex I. National minimisation strategies will then become difficult to implement Preventing MS from implementing a national minimisations strategy would possibly contradict EU objectives regarding minimisation of PPP impacts and would not lead to a minimisation of related external environmental costs 	<ul style="list-style-type: none"> Introducing comparative assessment would allow MS to continue national strategies to minimise external environmental costs of PPP use and to increase safety margins for human health Limiting comparative assessment to a defined list of AS (Annex ID) would likely reduce perceived risk for industry compared to option C Comparative assessment comes likely at a cost to administrations, industry and PPP users, which has to be balanced with the possible gains for society as a whole 	<ul style="list-style-type: none"> Introducing comparative assessment would allow MS to continue national strategies to minimise external environmental costs of PPP use and to increase safety margins for human health Including all active substances in the comparative assessment process would likely increase administrative burden and increase perceived risk for industry compared to option B Comparative assessment comes likely at a cost to administrations, industry and PPP users, which has to be balanced with the possible gains for society as a whole
Added value of EU action	<ul style="list-style-type: none"> None 	<ul style="list-style-type: none"> Provides tool for MS to implement minimisation objectives Provides tool to reach more sustainable agriculture, if implemented accordingly Increases acceptance of compulsory mutual recognition (if this principle was to be implemented) by limiting it through the possibility of comparative assessment 	<ul style="list-style-type: none"> Provides tool for MS to implement minimisation objectives Provides tool to reach more sustainable agriculture, if implemented accordingly Increases acceptance of compulsory mutual recognition (if this principle was to be implemented) by limiting it through the possibility of comparative assessment

6.3.6. Potential for optimisation of options

Comparative assessment can be implemented in various ways, which gives rise to concerns. As has been detailed above, the main factor affecting investment in R&D of the PPP industry is the *perceived* risk associated with an acceptable return on investment. Comparative assessment is one of several factors that could increase this risk, especially if comparative assessment would not be based on predictable criteria. 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 they can be assessed during the R&D phase;
- Early identifiable – the earlier in the R&D phase that criteria can be assessed the better;
- Absolute – criteria should not refer to relative disadvantages of other (individual) active substances, but rather to fixed threshold values or average values of all active substances included in Annex I that can be easily calculated and are not subject to short or medium term change (< 5-10 years).

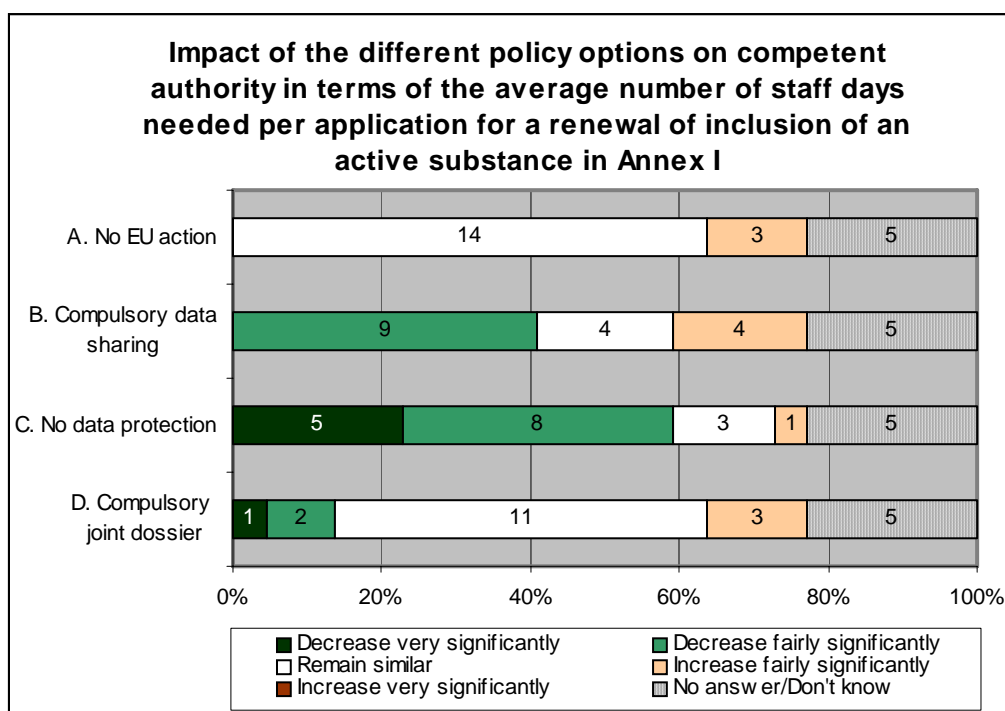
Additionally, predictability could be increased by providing detailed guidance for Member States how to implement comparative assessment, which would also minimise the risk of unintended incentives for unauthorised cross-border sourcing of PPP. Finally, as comparative assessment and national minimisation 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 (see also section 7 on monitoring and evaluation).

6.4. Assessment of Policy Action 4: Data sharing for the renewal of Annex I inclusion of an active substance

6.4.1. Economic impacts

Impacts on administrative burden

In the problem analysis (section 3.4) it has been pointed out that the current data protection rules cause a very significant administrative burden for authorities. More than half of the competent authorities that have an opinion therefore expect a reduction of the average number of staff days needed per application by 10% to 25% with option B (compulsory data sharing), and even more significantly with option C (no data protection), where 5 authorities even expect a reduction of the administrative burden by more than 25%. Although the questionnaire focussed on the issue of data protection/sharing for the renewal of inclusion of an active substance in Annex I, it is clear from the interviews with competent authorities and other stakeholders that data protection for the re-registration of plant production products is causing similar problems and administrative burdens. The situation is different for new active substances and PPP, as in these cases the active substance is usually protected by patents and data protection rules are only of major relevance if patent protection expires before the re-inclusion process.



Source: Survey of competent authorities

Surprisingly, option D, the provision of a compulsory joint dossier by applicants was not seen by competent authorities as a possibility to reduce the workload. This could be caused by two reasons:

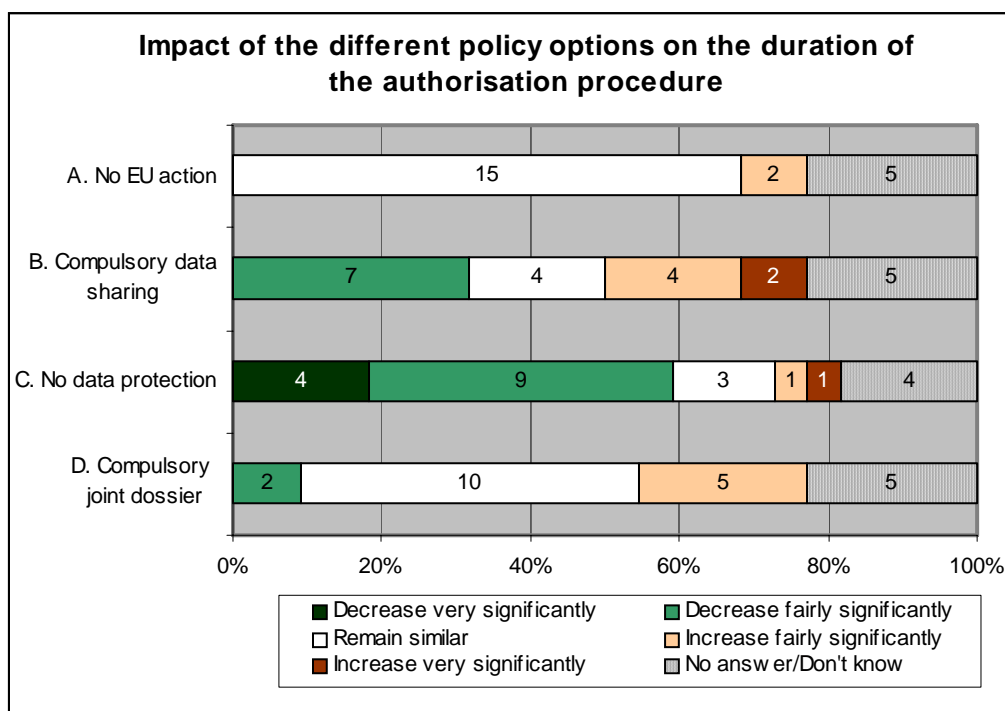
- A lack of experience with a compulsory task force of companies;
- The fear that companies not forming part of the compulsory task force may at a later stage cause similar problems as experienced currently.

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Administrative burden for PPP industry can be expected to be lowest with option C (no data protection) and with option D, as the formation of a compulsory task-force is not unlike forming a joint venture for a specific project, a usual element of doing business. Option C (no data protection) is, however, not preferred by most business organisations. It would provide free-riders easy entry to the market without forcing them to share a part of the regulatory burden. Option A (the status quo) would continue the current situation, leading to legal uncertainty and disputes. Finally, option B (compulsory data sharing) is seen as a risk for the main applicant. The details of a possible arbitration procedure are not yet known, no experience with this type of arbitration procedures exists currently in the EU. Companies intending to defend active substances in the re-inclusion process fear that the procedure will leave them disadvantaged, fair sharing of costs being more difficult to reach years after they invested in producing new data required for the re-inclusion process.

On the other hand, the duration of the re-inclusion procedure can be expected to be reduced by both options B and C, according to the expectations of competent authorities.



Source: Survey of competent authorities

The analysis leads to the following conclusions:

- Option A (Status quo - Data protection, no compulsory data sharing) 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;
- Option B (Data protection, with compulsory data sharing) 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;
- Option C (No data protection) 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;

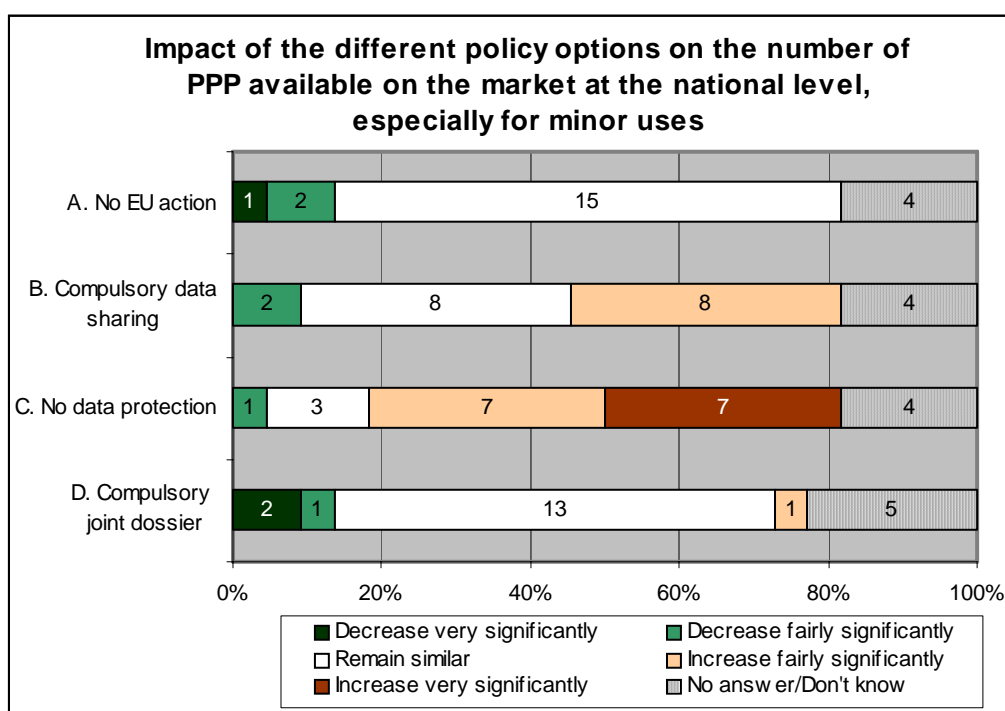
- Option D (Data protection, with compulsory joint dossier of interested companies) would lead to a reduction of the administrative burden for authorities, if authorities are not significantly involved in the mechanism for setting up the joint task force of companies.

Impact on indirect costs for PPP users

An impact of the options on indirect costs for PPP users could result from factors such as:

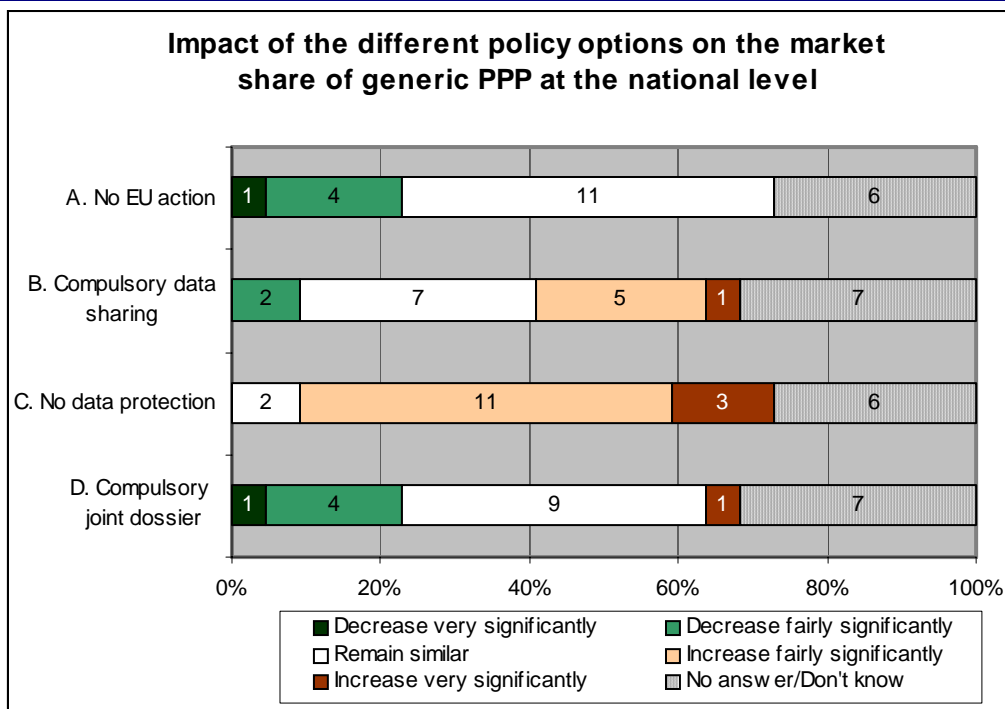
- Reduction of the number of PPP available, especially for minor uses;
- Number of generic products on the market that tend to affect price levels of PPP.

There is a large consensus among competent authorities that both factors would be most positively affected by option C (no data protection), leading to a higher number of products on the market, especially for minor uses, and an increased market share of generic products. If this assessment was correct, the overall impact for farmers would likely to be positive, as an increased market share of generic companies would lead likely to lower PPP prices. The assessment of competent authorities is illustrated in the graphs below:



Source: Survey of competent authorities

Also with option B several authorities expected the number of PPP and the market share of generic companies to increase. According to a majority of competent authorities both option A and option D would not change the current situation, with five authorities even expecting a decrease of the market share of generic products.



Source: Survey of competent authorities

This clear picture is not reflected in the view of other stakeholders, at least with respect to the number of PPP available. Several stakeholders expressed an expectation that option C (no data protection) and also option B would lead to a loss of active substances. ECPA, for example, stated that “Option B ... would result in the loss of many active substances as companies decide that their defence would become unviable. Comparing option B with option A, it is likely that an additional 40-50 substances will be lost from the market. With no data protection at all, the number of substances lost will be even greater. Option D would ensure the defence of the widest number of active substances. It is difficult to evaluate the impact on number of products but with fewer active substances, the impact would be greatest on more minor crops and uses.” Also, in a rare agreement between ECPA and ECCA, the latter declared that “In case of option D, costs are lower, ... the number of PPP for minor uses will increase”. On the other hand, regarding the impact on the market share of generics also ECPA agreed that with option C the highest increase could be expected, and also some increase with option B – for the active substances that are being defended.

At this stage, the following conclusions can be drawn:

- Option A (Status quo - Data protection, no compulsory data sharing) 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;
- Option B (Data protection, with compulsory data sharing) would lead to an increase in the market share of generic products and resulting lower prices for users, but could also imply a lower number of active substances on the market (see also following section) and possible resulting costs for users (e.g. shift to higher priced, patented active substances). It is not possible to assess the net effect of these two potentially contradictory trends at this stage;
- Option C (No data protection) can be expected to lead to a significant increase in the market share of generic products and resulting lower prices for users, but could also imply a significantly lower number of active substances on the market (see

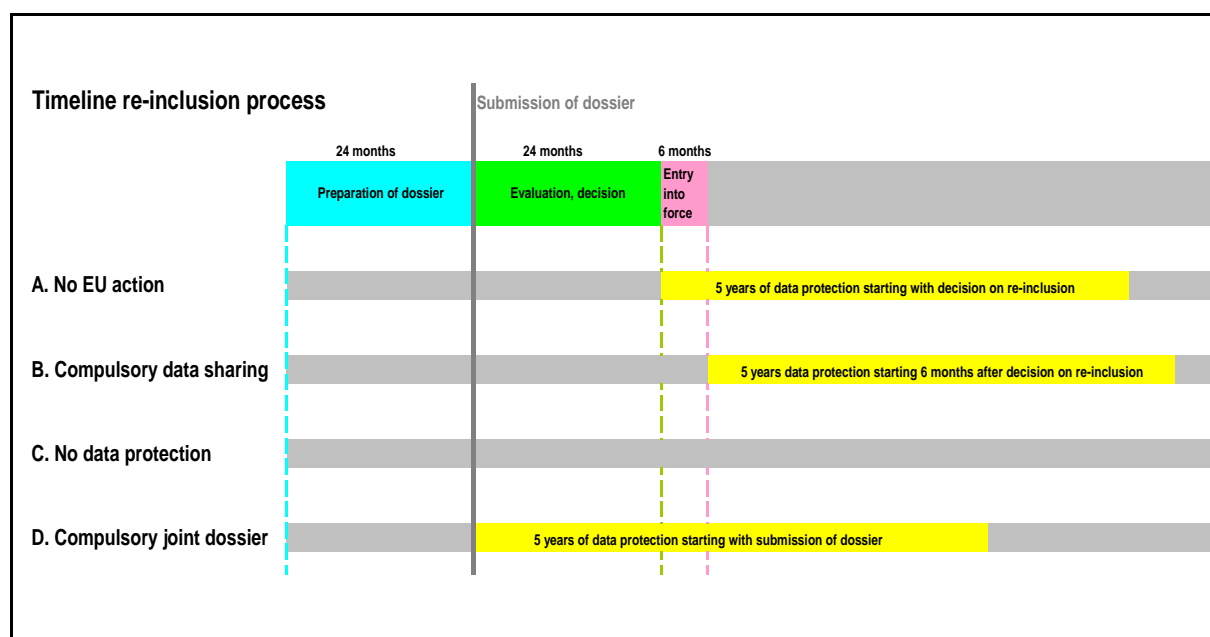
also following section) and possible resulting costs for users (e.g. shift to higher priced, patented active substances). It is not possible to assess the net effect of these two potentially contradictory trends at this stage;

- Option D (Data protection, with compulsory joint dossier of interested companies) 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 (see also following section). This makes increased costs for users unlikely.

Impact on investment of PPP producers in studies for re-registration of an active substance

To assess the impact on investment of PPP producers in studies for re-registration of an active substance, the model was run to analyse the impact of the different policy options on the *NPV* of the cumulative net cash flow over a 15 year period, starting at the point of dossier preparation. Based on the output of the status quo (baseline) scenario, it is assumed that the initial investment has already broken even.

For each policy option, the model assumes those timelines for re-inclusion set out in the graph below:



Source: FCEC

At the point of re-inclusion, annual sales revenue is in decline and assumed to be €15 million for the main notifier (total market value is assumed to be €20 million). Average gross margin is assumed to have fallen slightly to 40% and in line with industry sources, study costs are assumed to total €7 million⁹⁶. 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 and annual sales revenue during periods where there is no data protection.

Under all options, we have assumed that the main notifier would maintain a 75% market share during periods of no data protection and the total value of the market for the active

⁹⁶ See for example the ECPA paper on 'Value of data protection for the crop protection industry', June 2004, page 3.

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substance would decline annually by 1.5% during periods of no data protection. Total value of the market was assumed to remain stable during the period of market exclusivity provided by data protection (depending on the possibility of market entry for competitors). During periods of data protection (based on the timelines for re-inclusion set out in the graph above) we have also assumed that market share would:

- Option A (No EU action – the ‘status quo’): increase to a maximum of 87.5% during the data protection period as market exclusivity would be maintained during this period;
- Option B (Data protection, with compulsory data sharing): increase to 81.25% for the initial two year period of data protection, and thereafter falling back to 75% as compulsory data sharing severely reduces market exclusivity for the main notifier;
- Option C (No data protection period for renewal of inclusion in Annex I): remain at 75% during the five year data protection period as there is no market exclusivity for the main notifier; and,
- Option D (Compulsory joint dossier): remain at 75% during the five year data protection period as this option reduces market exclusivity for the main notifier over the whole five year period (i.e. maintains market exclusivity for a group of notifiers).

Under the assumptions of the model, the impact of the potential loss of market share, and the decline in the total market value of the AS (during periods where there is no data protection) on the NPV of the cumulative net cash flow (over a 15 year period, starting at the point of dossier preparation), for each of the policy options, is summarised in the table below.

Table 24: Policy action 4 – NPV of cumulative discounted net cash flow for the re-registration of a ‘typical’ new active substance (over a 15 year period, starting at the point of dossier preparation) – discounted at 4%

	Option A	Option B	Option C	Option D
Description of option	Status quo - Data protection, no compulsory data sharing	Data protection, with compulsory data sharing	No data protection	Compulsory joint dossier
NPV (€million)	62.86	55.05	54.20	61.41
NPV (€million) – difference from ‘status quo’	-	7.81	8.66	1.45

Under the assumptions of the model, option A - Status quo (baseline) with data protection and no compulsory data sharing – produces a NPV of €62.86 million over the 15 year period, starting at the point of dossier preparation. Compared to the other options, the results suggest that option A would have the highest NPV as market exclusivity would be maintained for a number of years.

In contrast, option B - Data protection, with compulsory data sharing – produces a NPV of €55.05 million over the 15 year period, starting at the point of dossier preparation. Compared to the status quo (option A), the results suggest that option B would have a relatively large impact on NPV, falling by €7.81 million over the period. This is because compulsory data sharing severely reduces market exclusivity for the main notifier.

Option C - No data protection period for renewal of inclusion in Annex I – produces the lowest NPV of all the options, totalling €54.20 million over the 15 year period, starting at the point of dossier preparation. This represents a fall of €8.66 million over the period,

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compared to the status quo (option A). This is because there is no market exclusivity for the main notifier.

Option D - Data protection, with compulsory joint dossier of interested companies - produces a NPV of €1.41 million over the 15 year period, starting at the point of dossier preparation. Compared to the status quo (option A), the results suggest that option D would have a relatively small impact on NPV compared to options B and C, falling by €1.45 million over the period. This is because this option maintains market exclusivity for a number of years for a group of notifiers.

A number of conclusions can be made:

- Under all policy options, it remains profitable for a PPP producer to invest in studies for re-inclusion of an active substance. However, the results are highly sensitive to the assumptions of the model and in particular the value of sales at the point of re-inclusion as well as the intensity of competition (i.e. loss of market share) during periods when market exclusivity is lost. This would particularly be a problem for those active substances that have a lower sales value at the point of re-inclusion such as those active substances that are specifically targeted at niche markets (e.g. biologicals or active substances used on a smaller scale for specific crops (e.g. fruit and vegetables));
- Under the assumptions of the model, the impact of policy option B (data protection, with compulsory data sharing) and policy option C (no data protection period for renewal of inclusion in Annex I) on the economics and attractiveness of defending an active substance during re-inclusion are similar in terms of their affect on NPV, pay back period and IRR;
- The impact of policy option D (compulsory joint dossier) was found to be most like the status quo option A (no EU action), based on the assumptions used in the model.

However, it should be noted that modelling this policy action and its four options is highly dependent on the assumptions of the model. This is because of the unpredictable nature of the marketing environment during the periods where there is no market exclusivity (i.e. level of competition), compared to policy actions 1, 2 and 3 where the active substance is assumed to be protected by patent.

To gain a deeper understanding of the impact of the assumptions, the following table provides a sensitivity analysis of the impact of differing levels of market share on the NPV of the 15 year cumulative net cash flow for option B (data protection, with compulsory data sharing). With an 1% increase in the assumed market share during the data protection period and during the non-data protection period thereafter, the NPV of option B would increase by €0.83 million. Thus, if the assumed market share of the main notifier would increase by 9% with the beginning of the data protection period compared to the initial assumptions (i.e. to 90.25% of the total market instead of 81.25%) and this 9% gain in market share would be maintained after the entry of competitors (i.e. the market share would go down to 84% instead of 75%), then the NPV of option B would be roughly similar to that of option A and D. This highlights the sensitivity of the results on the market share assumptions.

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Table 25: Policy action 4B – Sensitivity analysis: impact of changes in market share of the proprietary company on the NPV of cumulative net cash flow for the re-registration of an active substance (over a 15 year period, starting at the point of dossier preparation) – discounted at 4%

	Option B
Description of option	Status quo - Data protection, no compulsory data sharing
NPV (€million) – as per initial assumptions	55.05
NPV (€million) – increase in market share for the main notifier:	
1%	55.88
2%	56.71
3%	57.56
4%	58.41
5%	59.28
6%	60.15
7%	61.03
8%	61.92
9%	62.82

Impact on EU PPP industry competitiveness

For companies, which have invested in studies for re-inclusion of an active substance in Annex I, sharing re-inclusion data without adequate compensation would amount to lower entry barriers for generic competitors manufacturing at their expense, having to support registration expenses that would benefit to late entrants and competitors. For such companies, reducing the period of data protection would amount to shortening the time over which off-patent products would still be, to some extent, protected by the cost of re-registration. These companies claim that, when the cost of re-inclusion is not compensated by a certain degree of market protection, then maintaining some products through re-registration is not an attractive option any more and re-registration would not be sought. This applies particularly to niche products and minor crops applications. Then, because it is assumed that most generics manufacturers would not undertake re-registration without some access to data, these active ingredients would disappear from the market. The concerned companies endeavoured to quantify this effect by estimating the likely impact of reduced data protection period on product profitability, and on withdrawing products whose NPV would not break even anymore. According to ECPA estimates⁹⁷:

- Out of some currently existing 250 active substances⁹⁸ pending for re-registration in the EU, 152 enjoy annual sales less of than 20 million €

⁹⁷ Source: ECPA, The importance of EU data protection for plant protection products, April 2004; Possible impact of different data protection systems on the support of existing active substances, ECPA, December 2005

⁹⁸ Out of 476 active ingredients of commercial significance, 253 are admissible to re-registration or are under a pending decision. Phillips Mc Dougall, Keeping Europe Attractive for Sustained Business Development, Nov. 2005

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- Out of those 152 active substances, between 16 and 80 would probably, according to ECPA, be withdrawn under a compulsory data sharing scheme, depending on the remaining data protection period and the compensation scheme.

Withdrawing small sales products, which would not necessarily be replaced by larger selling products because many are specialities for minority crops, would reduce overall sales and reduce the range of products made available to users. This would not necessarily affect the profitability of the major companies in the agro-chemicals sector, since they have been striving to reduce their portfolios and to concentrate on large selling products and blockbusters. This would depend on whether: 1) sales from products dropped from a company portfolio bring a significant contribution to fixed costs coverage; and 2) a potential for reducing fixed costs results from managing a reduced portfolio. This can only be assessed on a case by case basis and from individual company accounting data. On the other hand, the perspective is totally different for companies that are seeking to enter the market for off-patent products and need to complete the re-inclusion procedure. For them:

- Data sharing schemes is a way to enable generics manufacturers to benefit of the “out of patent” situation at reasonable conditions. The full cost of re-inclusion is difficult to afford for many of these companies, especially for active substances with low potential sales. Not being able to rely on existing studies and data would oblige them to fully undertake them again at their full expenses. This would only serve to duplicate the cost of producing data that are not company, market or strategy specific. Data sharing creates a level playing field where generics manufacturers companies can enter the market without having to make an investment in data that: 1) are existing; 2) might require vertebrate testing; and 3) concern not market or production sensitive aspects;
- These companies generally agree, nonetheless, that data which has been funded by re-inclusion seeking companies do not have only strategic value but are also a financial investment, which they are prepared to compensate, provided this compensation is “reasonable”.

The following conclusions can be drawn:

- Option A (Status quo - Data protection, no compulsory data sharing) 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 (Data protection, with compulsory data sharing) 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 (No data protection period for renewal of inclusion in Annex I) 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 (Data protection, with compulsory joint dossier of interested companies) 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, a higher number of active substances would be defended compared to options B and C.

6.4.2. Social impacts

Impact on employment

Based on the results of the discounted cash flow model (impact on investment of PPP producers in R&D), the following conclusions can be made:

- Under all policy options, the 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 (or having a large proportion of their product portfolio) in active substances for niche markets, then option B (data protection, with compulsory data sharing) and option C (no data protection period for renewal of inclusion in Annex I) are more likely to adversely affect employment levels in R&D based companies. In contrast, it is likely that employment would remain relatively unaffected with option D (compulsory joint dossier) 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) in terms of NPV, payback period and IRR;
- 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 (data protection, with compulsory data sharing) and policy option C (no data protection period for renewal of inclusion in Annex I) offer the greatest potential.

Impact on information opportunities of citizens

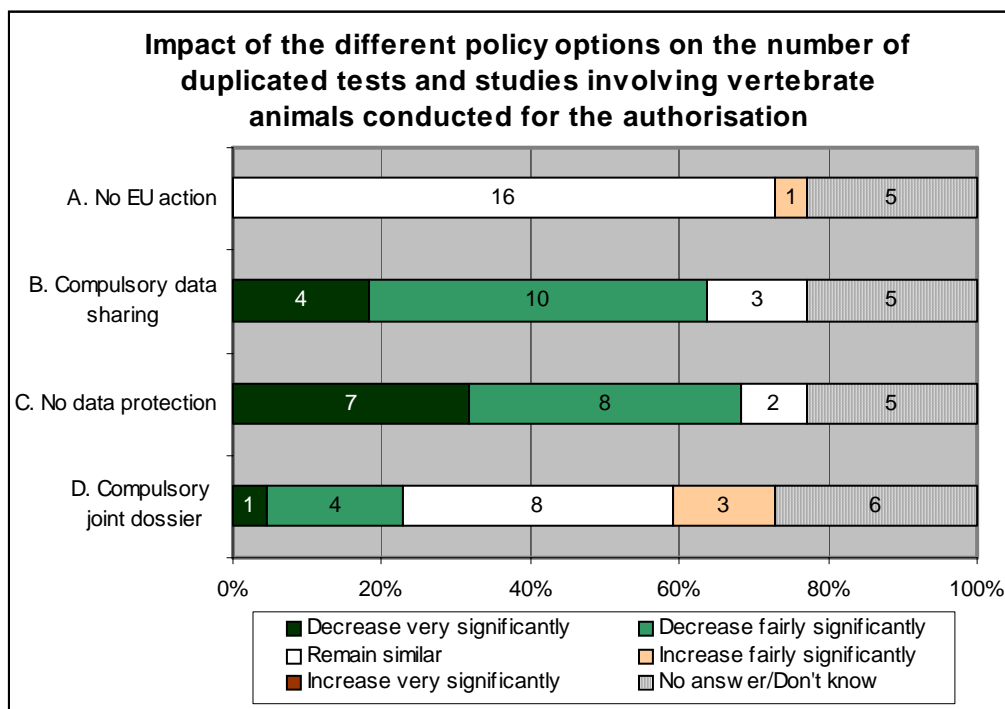
It is not expected that this policy action has significant impact on the information opportunities of citizens, as data protection concerns the commercial access of competitors to protected data and the right to refer to these studies and is not related to the opportunity for the public to get access to the content of studies.

Impact on animal welfare

As already has been pointed out in section 6.2.2, under Directive 91/414/EEC data sharing of studies involving vertebrate animals may be required by the Member States (Art. 13). Several Member States have introduced legislation in this effect, others have not. 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 Coalition of smaller research-based PPP companies does not expect a very significant impact and argues as follows: “In the case of option B and D, the number [of duplicated vertebrate tests] would be lower, also probably where there is no data protection, since generics would not have to repeat anything, vertebrate data or other. However, the total difference would not be very big. The majority of vertebrate data are in the toxicological data package, which is mostly older for existing products and does therefore not benefit from data protection. The vertebrate data under data protection are mostly one or two ecotox studies.”

The major data source with respect to a duplication of vertebrate studies and a possible reduction are competent authorities. An overwhelming majority expects a significant reduction of the number of duplicated tests involving vertebrate animals with option B

and C. This was only true for a minority of five authorities with respect to option D (see following graph):



Source: Survey of competent authorities

This leads to the following conclusion: 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.

6.4.3. Environmental impacts

Impact on unauthorised cross-border sourcing of PPP

No impact expected.

Impact of active substances on the environment or human health

No impact expected.

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6.4.4. Summary

A summary of impacts expected with policy action 4 is presented in the following table.

Table 26: Summary of impacts of alternative options for data sharing for the renewal of Annex I inclusion of an active substance

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	–	+ / 0 (lower prices but may also lead to lower number of AS)	+ / – (lower prices but may also lead to significantly lower number of AS)	0
Impact on investment in studies for re-registration of an AS	0	(–)* (however: remains profitable to invest)	(–)* (however: remains profitable to invest)	(0)*
Impact on PPP industry competitiveness	– (high entry barriers)	+ / – (lower entry barriers, less profitability)	+ / – (lower entry barriers, less profitability)	+ / 0 (lower entry barriers, depending on implementation)
Social impacts				
Impact on employment (R&D based companies)	0	0 /– (depending on reduction in profitability)	0 /– (depending on reduction in profitability)	0
Impact on employment (generics)	–	+	+	0
Impact on inform. opportunities	0	0	0	0
Impact on animal welfare	0	(++)**	(++)**	(+)**
Environmental impacts				
Impact on unauthor. cross-border sourcing of PPP	0	0	0	0
Impact of AS on environment / health	0	0	0	0

++ = Very significant positive impacts
 -- = Very significant negative impacts
 + = Significant positive impacts
 – = Significant negative impacts
 0 = No change from the present situation

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Note: * Results are highly sensitive to model assumptions. This is particularly a problem for those active substances that have a lower sales value at the point of re-inclusion. ** Assessment only provisional, as no reliable data exists on the extent to which vertebrate studies are duplicated at present.

6.4.5. Proportionality and added value of EU action

Table 27: Proportionality and added value of alternative options for data sharing for the renewal of Annex I inclusion of an active substance

	Option A	Option B	Option C	Option D
Description of option	Status quo - Data protection, no compulsory data sharing	Data protection, with compulsory data sharing	No data protection	Compulsory joint dossier
Proportionality	<ul style="list-style-type: none"> Complex legal situation leads to significant administrative burden Entry barriers for generic companies and new entrants 	<ul style="list-style-type: none"> Would reduce administrative burden for authorities Lowers entry barriers for generic companies and new entrants 	<ul style="list-style-type: none"> Would reduce administrative burden for authorities and industry significantly Lowers entry barriers for generic companies and new entrants May endanger the willingness to defend AS to a significant degree 	<ul style="list-style-type: none"> Would reduce administrative burden for authorities Lowers entry barriers for generic companies and new entrants
Added value of EU action	<ul style="list-style-type: none"> None 	<ul style="list-style-type: none"> Creates conditions for a more competitive market for PPP 	<ul style="list-style-type: none"> Creates conditions for a more competitive market for PPP, but reduces incentives for defending AS through re-inclusion process 	<ul style="list-style-type: none"> Creates conditions for a more competitive market for PPP, if adequate procedures guarantee participation of all interested companies into joint task forces, including smaller companies/new entrants, and fair sharing of costs is reached

6.4.6. 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.

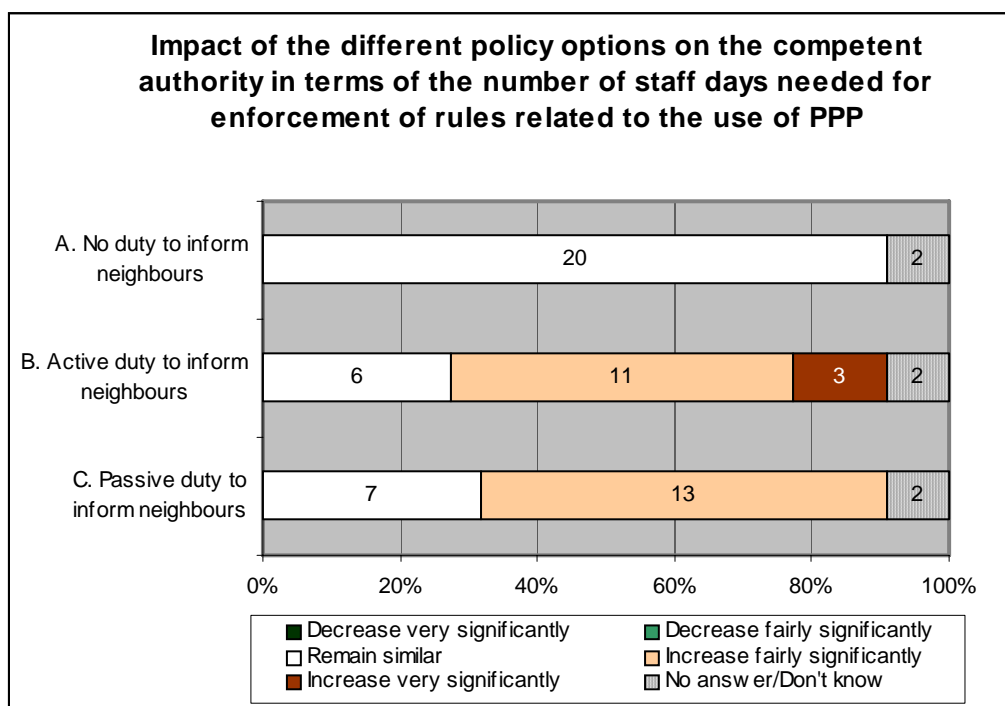
6.5. Assessment of Policy Action 5: Informing neighbours on PPP use

6.5.1. Economic impacts

Impacts on administrative burden

Measures under policy action 5 could result in an administrative burden for PPP users and authorities. An increase of the administrative burden of PPP industry is not expected. The increase in administrative burden for PPP users and authorities directly depends on the number of PPP affected by the options. Under option A (Status quo) a duty to inform neighbours prior to spraying of PPP does not exist, therefore no product would be affected. With option B competent authorities could stipulate a requirement to inform neighbours who could be exposed to the spray drift before the product is used. This is optional and could only be introduced for plant protection products applied by spraying classified under Directive 1999/45/EC as very toxic or toxic. According to ECPA, this provision could affect 10%-20% of existing PPP. Estimates of several competent authorities regarding PPP that are classified under Directive 1999/45/EC as very toxic or toxic as percentage of all PPP authorised are lower, reaching from <1% to 10%, depending on the country (data was not available from all countries). Option C, a passive duty to inform neighbours on demand could affect significantly more products, depending on the precise definition of such a duty. At least the same number of PPP would be affected as with option B, probably reaching up to 100% of PPP, as a passive duty to inform neighbours on demand could be valid for all farmers using PPP (independent from toxicity of the PPP).

Two thirds of competent authorities expect increase of administrative burden for enforcement with options B and C:



Source: Survey of competent authorities

It is obvious that this would depend on the extent to which the optional requirement would in fact be introduced during the authorisation process. In the interviews with

competent authorities, the number of authorities supporting the measure was rather low and those who supported it mainly referred to the need to protect bee keepers from consequences of PPP use. One Member State, in which a provision similar to option B already exists supported the measure, also agreed that enforcing the rules involved some problems for the responsible authorities.

The main administrative burden of the measures under options B and C would result for farmers that would have to apply the rules. Farmers' organisations were therefore generally opposed to the measure: for example, the Agricultural Industries Confederation (UK) stated: "Option B would place a high administrative burden on farmers if they were obliged to inform neighbours before toxic PPP's are applied. Changes in weather could mean that neighbours would have to be informed on numerous occasions before the application takes place. Some neighbours may not want to be informed of the applications, whilst others could be unduly alarmed by the information supplied. Option C - providing information to neighbours on demand whilst reducing the administrative burden, still presents problems. The information provided may be commercially sensitive. Also a lay-person may demand additional information over and above the fact that a toxic PPP is being used e.g. Safety Data sheets etc which could require an intermediary to interpret this information." The Federation of Swedish Farmers had a different view with respect to option C: "We believe that option C is the natural option. It would be considered as very strange if neighbours could not find out what kind of PPP that has been used and perhaps has drifted into their fields or gardens. On the other hand a duty to inform would create an impossible bureaucracy."

For assessing option C it has to be noted that this option would be based on record keeping requirements that, at least for food and feed producing farmers, are already in place. The Food Hygiene Regulation (Regulation 852/2004) requires in Annex I: "Food business operators producing or harvesting plant products are, in particular, to keep records on ... any use of plant protection products and biocides". Also, a planned regulation on pesticide statistics will require record keeping to some extent. The additional administrative burden for farmers would therefore not be related to record keeping as such, but rather to the actual provision of information on demand.

This leads to the following assessment:

- Option A (Status quo – No duty to inform neighbours) would not imply an increase of the administrative burden of authorities and PPP users;
- Option B (Active duty to inform neighbours) 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. The practicality of the measure is questioned by farmers, e.g. with respect to early morning spraying and changes in weather conditions;
- Option C (Passive duty to inform neighbours) would lead to an increased administrative burden for authorities and farmers, but significantly less than in option B. The most time-consuming requirement (record keeping of PPP use) is also required under other measures.

Impact on indirect costs for PPP users

No impacts expected, as neither the availability of PPP nor the market share of generic products is expected to be affected. Direct costs have been discussed in the previous section.

Impact on investment of PPP producers in R&D

No impacts expected.

Impact on EU PPP industry competitiveness

No impacts expected.

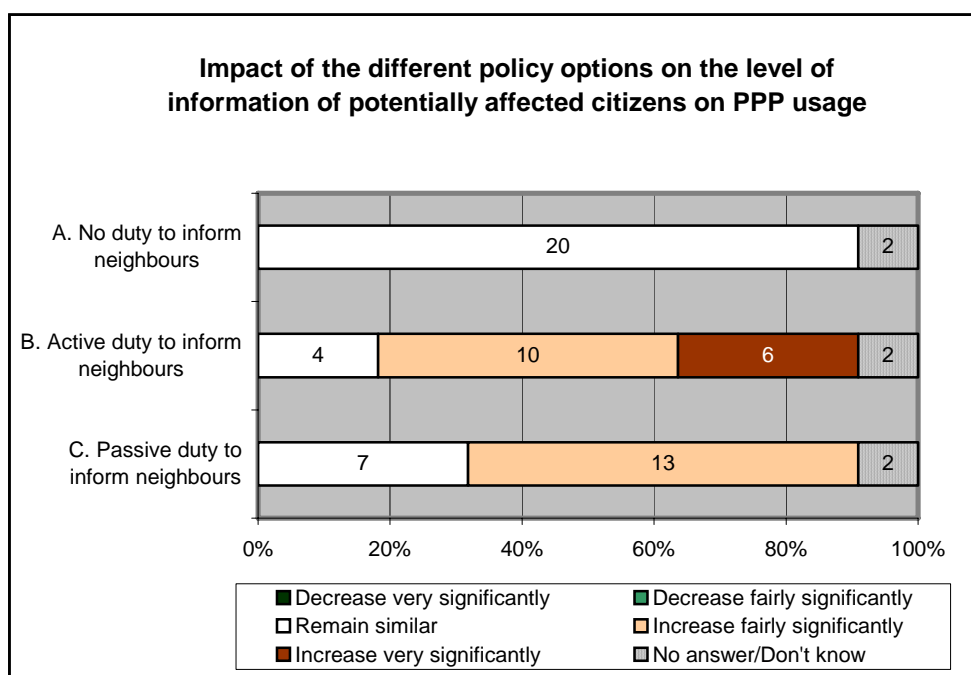
6.5.2. Social impacts

Impact on employment

No impacts on the employment in the PPP industry are expected.

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 by 6 competent authorities:



Source: Survey of competent authorities

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. Several stakeholders were sceptical; the Coalition of smaller research-based PPP companies assumed the impact of this information as “initially negative” and stated; “if people are informed that a toxic pesticide is sprayed under their window and they get a headache they will attribute it to the pesticide, with all the ensuing administrative and medical activities. Long term, when people get used to it, the impact would probably level out.” The Central Union of Agricultural Producers and Forest Owners (Finland) expected serious impacts: “If the options B or C comes true, farmers [would] not want to sell the land to anybody to build houses near the fields. [There are] always neighbours who are complaining [about] everything and this kind of system would cause only problems for farmers without any real reason.”

Impact on animal welfare

No impacts expected

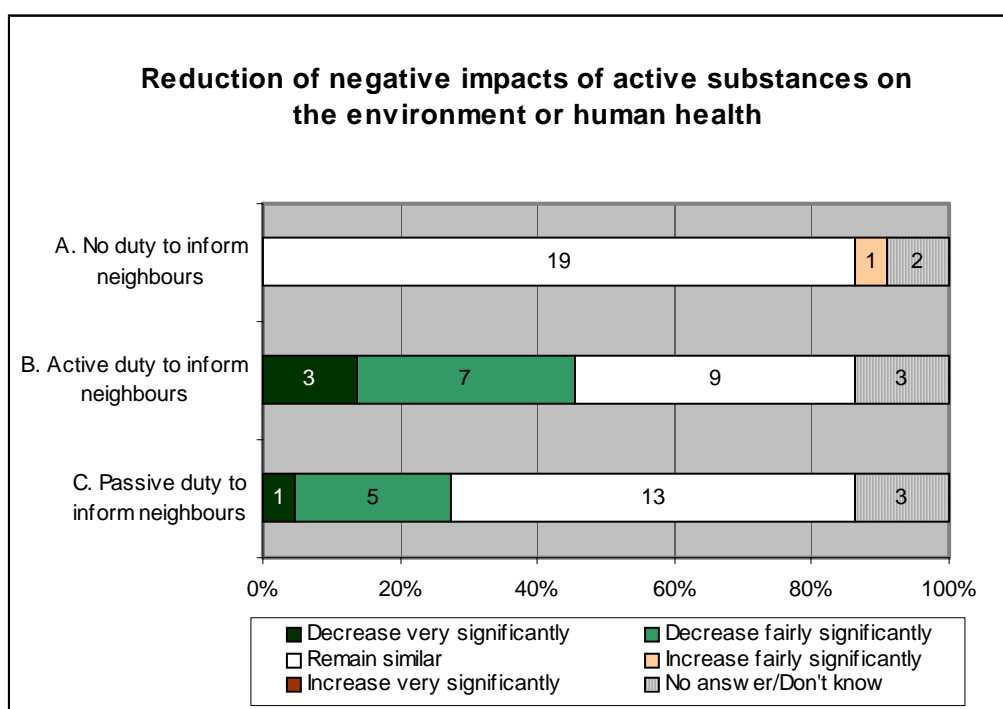
6.5.3. Environmental impacts

Impact on unauthorised cross-border sourcing of PPP

No impacts expected

Impact of active substances on the environment or human health

Questions are raised as whether information provided to neighbours can have an impact on the environment or human health. Stakeholders such as PAN-Europe are of this opinion and stated: "... a combination of option B and option C would produce the best effects. Through option B, individuals with particular sensitivity (pregnant women, children or the elder) might avoid exposure to pesticides. Through option C, residents and bystanders, and the scientific community might access information about specific substances and impacts on health." Eureau, representing the interest of the European water industry, also expected positive impacts: "... we do seek for an obligation to inform water companies on which substances, in which amounts and when are sprayed in a particular river basin or groundwater body. This would be very helpful in preventing problems with PPP's in drinking water resources. At the moment drinking water companies too often have to look for 'a needle in a haystack'". On the other hand, industry and farmer organisation mainly did not see a positive impact on the environment or human health, as with correct application there would be no relevant risk expected. Several competent authorities shared this view. However, there was a slight majority of authorities having an opinion on the issue that option B (active duty to inform neighbours) would indeed have a positive impact on the environment. With option C (passive duty to inform on demand) only a minority of authorities expected this to be the case.



Source: Survey of competent authorities

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The impact on the environment or human health can therefore be assessed as follows:

- Option A (Status quo – No duty to inform neighbours) does not lead to a reduction of impacts on the environment or human health;
- With option B (Active duty to inform neighbours) a reduction of negative impacts of active substances on environment or health is possible under two main scenarios:
 - a) Preference of farmers for less toxic products, depending on 4 conditions; 1) application of this provision at national level during authorisation; 2) enforcement; 3) preference of farmers for “easier”, less toxic products, where they do not have to inform neighbours, and 4) the environmental impacts of alternative products used;
 - b) 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.
- Option C (Passive duty to inform neighbours) 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 (mainly because of record keeping duty and transparency towards neighbours and authorities) and enforcement. The extent to which this actually would happen cannot be assessed at this stage.

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6.5.4. Summary

The results of the impact assessment of *policy action 5: informing neighbours on PPP use* are presented in the table below:

Table 28: 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
<i>Economic impacts</i>			
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
<i>Social impacts</i>			
Impact on employment	o	o	o
Impact on information opportunities	o	+	+
Impact on animal welfare	o	o	o
<i>Environmental impacts</i>			
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 at this stage)	(+) (positive impacts possible, extent not possible to assess at this stage)

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

6.5.5. Proportionality and added value of EU action

Table 29: Proportionality and added value of alternative options for informing neighbours on PPP use

	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
Proportionality	<ul style="list-style-type: none"> • No EU intervention and no additional administrative burden • Only information on PPP use provided voluntarily by farmers available to neighbours, water industry, scientists, etc. 	<ul style="list-style-type: none"> • Increased information opportunities for neighbours, water industry, scientists, etc. • However, this is likely to cause significant additional administrative burden for farmers and authorities (enforcement) 	<ul style="list-style-type: none"> • Increased information opportunities for neighbours, water industry, scientists, etc. • Only limited additional administrative burden for farmers and authorities, as record keeping is already required by other provisions
Added value of EU action	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Increased information opportunities 	<ul style="list-style-type: none"> • Increased information opportunities

6.5.6. Potential for optimisation of options

Policy action 5 regarding alternative options for informing neighbours on PPP use 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. According to several stakeholders, there is a need for a general approach on transparency in PPP authorisation and use:

- *Authorisation:* One competent authority that was reportedly already implementing this approach proposed “no authorisation without motivation”, in other words no authorisation decisions without a detailed report published on the website of the authority on the basis for the decision. Other elements of a general approach on transparency could include a more transparent evaluation process, a structured inclusion of stakeholder comments in the process, etc.;
- *Use:* This could include record keeping for all PPP used and possibly a duty to inform neighbours and relevant third parties, e.g. drinking water suppliers, researchers (options B or C discussed above) and/or other measures to enhance transparency in PPP use, depending on the objectives of the intervention.

7. Monitoring and evaluation

The effective monitoring of new legislation on PPP authorisation requires evaluation at regular intervals. For this purpose, it is necessary to put a system in place to carry out regulatory monitoring. This is especially relevant as the present system of evaluation and authorisation is in a state of transition. A significant number of existing active substances will have to be included in Annex I in 2006 and 2007 before the new legislation comes into force, which is expected for 2008. This leads to the current, exceptionally high workload for all parties involved, which gives little indication on the situation after the implementation of the new system. After 2008 a reduced workload is to be expected, because the system will then focus mainly on (a rather limited number of) new active substances and the regular re-inclusion process, which is not to be expected to require the evaluation of a full dossier. Parameters such as the duration of the evaluation procedure could therefore be expected to be reduced in the future, but this requires monitoring, especially if a system of binding time limits were to be implemented. The results of the evaluation should be at least communicated to the responsible Commission services, the European Parliament and the relevant stakeholders.

Problems related to the implementation of Directive 91/414/EEC are discussed in detail in section 3 of this report. The main problems to be addressed by new legislation are:

- Duplication of administrative efforts
- Duration of the evaluation process
- Availability of PPP / Fragmented PPP market
- Illegal cross-border sourcing of PPP
- Lack of possibility for minimisation of environmental externalities after Annex I inclusion
- Lack of legal clarity in the area of data protection
- Possible duplication of vertebrate testing
- Limited competition in specific PPP market segments
- Transparency of the evaluation procedure
- Information availability for neighbours and third parties

The indicators to be selected for the monitoring of the new legislation should provide a clear analytical tool to assess to what extent a policy action is properly implemented and whether policy objectives (detailed in section 4 of this report) are being achieved.⁹⁹ To reach this aim, indicators have to be:

- Relevant, i.e. closely linked to the problem identified / the objectives to be reached;
- Accepted (e.g. by stakeholders);
- Credible for non experts, unambiguous and easy to interpret;
- Easy to monitor (e.g. data collection should be possible at low cost);
- Robust against manipulation.¹⁰⁰

The table on the following page presents possible indicators to be considered to monitor a new Regulation on PPP authorisation. Please note that a regular evaluation will need the

⁹⁹ EC, Impact Assessment Guidelines with Annexes, 2005, p.45

¹⁰⁰ EC, Annexes of Impact Assessment Guidelines, 2005, p.45

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collection of baseline data that is not available at present, as well as the development of adequate methodological tools.

Table 30: Potential indicators to monitor the implementation of a new Regulation on placing PPP on the market

Problem	Potential Indicator	Data Source	Rationale
Duration of evaluation procedure	Average time for evaluation of new active substance / re-inclusion of active substance	EC	Annex I evaluation process should speed up with the new legislation / Binding timelines need to be monitored, if introduced
Duration of mutual recognition procedure	Average time for compulsory mutual recognition procedure	Member States	Aim is to reach a smooth mutual recognition procedure. A long duration of the mutual recognition procedure would indicate that process is not as smooth as expected.
Duplication of administrative efforts for PPP authorisation	Average number of full time equivalent staff days used in Member States per PPP authorisation (incl. through mutual recognition and when MS is designated MS)	Member States	Aim is to reduce overall administrative burden. Total number of staff days should be reduced, e.g. when a zonal or central authorisation system is introduced.
	Number of full time equivalent staff days used in Member States per PPP authorisation, if compulsory mutual recognition is applied (relevant for zonal system)	Member States	Aim is to reach a smooth mutual recognition procedure. A high number of staff days used for the mutual recognition procedure would indicate that administrative burden is not reduced as expected.
	Number of PPP of similar composition authorised in several MS without application of mutual recognition (only relevant for zonal system)	Member States/EC (requires uniform database of authorised PPP)	A significant number of PPP of similar composition authorised in several MS of one zone would indicate that compulsory mutual recognition is not applied as intended. A significant number of PPP of similar composition authorised in several MS of different zones would indicate that the authorisation system could be more centralised.
Availability of PPP and alternative methods of pest control	Perceived availability of PPP and alternative methods of pest control for minor uses and resistance management in Member States	Member States/ Farmers' organisations	Aim is to provide a sufficient number of PPP and alternative methods of pest control for minor uses and resistance management in Member States
Environmental externalities of PPP use	Cost of removal of PPP from drinking water sources for water industry	Member States/ Water industry	Aim is to reduce negative impact of PPP on the environment. Water purification costs are a significant externality that is measurable to a certain extent.
	Number of full time equivalent staff days used in MS per PPP authorisation for comparative assessment (only relevant if comp. assessment is applied)	Member States	Aim is to reach an efficient comparative assessment procedure. A high number of staff days used for comparative assessment would indicate that more guidance is needed or criteria / procedure could be changed.
Reduction of health risks	Statistics on number and severity of operators	Member States	Aim is to reduce negative impact of PPP on health

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	accidents		
	Incidence of unauthorised cross-border sourcing	Member States	Aim is to reduce incidence of unauthorised cross-border sourcing. Indicator requires enforcement efforts targeted at unauthorised sourcing of PPP
Lack of legal clarity concerning data protection	Number of full time equivalent staff days used in Member States for data protection issues	Member States	Aim is to reduce administrative burden of data protection
	Introduction of a central database for protected studies, including the provision of a identification code for protected studies	EC/ Industry	Aim is to reduce administrative burden of data protection through registering centrally the date of first authorisation of a PPP using a specific study, which determines the duration of the data protection period for this study
Possible duplication of vertebrate studies	Introduction of a central database for protected studies, including a register of vertebrate tests conducted	EC/Industry	Aim is to halt the possible duplication of vertebrate testing
Lack of competition in specific product segments	Number of substitute products available for similar crops/uses, including generic PPP	Member States	Aim is to safeguard sufficient level of competition as a requirement for a competitive industry and low prices for PPP users
	Price differences of PPP between Member States	Member States/ EC	Reduction diminishes incentives for unauthorised cross-border sourcing of PPP
	Price differences of selected PPP between EU and third countries	Member States/ EC	Reduction diminishes incentives for unauthorised cross-border sourcing of PPP, very significant price differences may indicate lack of competition in specific product segments
	Differences in VAT for PPP	Member States/ EC	Reduction diminishes incentives for unauthorised cross-border sourcing of PPP
Lack of information / transparency	Number of authorisation and evaluation procedures conducted with participation of NGOs and other stakeholders; number of published reports by competent authorities providing a detailed motivation of the authorisation decision	Member States/ EC	Aim is to increase transparency of authorisation process

Annex A: Methodological approach for cost quantification model

Theoretical background

The central tenet of this analysis is that innovation (i.e. the ability to develop new products to meet customer needs) is the most important source for long-term competitive success for an individual company (although in the short-term competitive success is more commonly achieved from the ability to exploit existing products profitability). However, in a regulated environment there is a trade-off between promoting innovation for individual companies and securing competitive market outcomes for the sector and users at large.

Developing new active substances requires large initial investments, is long-term and is generally perceived as being a high-risk activity. The expected monopoly profits from agrochemical sales under patent seeks to compensate the innovating companies for its risky investment. In contrast, the onset of competition after patent expiry limits the potential deadweight losses to society that arises from monopoly pricing under the patent. The research orientated nature of proprietary agrochemical companies therefore relies heavily on the protection offered by the regulatory environment (e.g. patents) whereas those agrochemical companies producing generic products rely heavily on the market opportunities after patent expiry. Thus, any change in the regulatory framework on the placing of active substances on the market is likely to have a significant impact on the economics of new product development and hence the level of future investment.

Measuring the potential impact on investment of PPP producers in R&D – the theoretical model

Modelling the status-quo (baseline)

To understand the likely impact of amending the regulatory framework (i.e. policy actions 1, 2, 3 and 4) on the economics of new product development (including re-inclusion), we developed a (discounted) cash flow model. Discounted cash flow analysis is a method of evaluating an investment opportunity by estimating future net cash flows (i.e. expected revenues and costs) of a typical new product development for its complete life cycle, taking into consideration the time value of money.

Assumptions of the model (baseline)

First, we established the economics of new product development under the status quo (i.e. our baseline scenario). With the assistance of economic and regulatory experts from leading agrochemical companies and their professional organisations, we identified the principal assumptions and expected costs and revenues for a typical new product development for its complete life cycle (including both the R&D and market exploitation phases). The main assumptions used in the model are:

- Length of the research and development phase (i.e. time from discovery to market launch). Based on discussions held with the leading agrochemical companies, the average length of the research and development phase was found to vary significantly between active substances. However, there was general agreement that the average length of the research and development phase for a typical active substance in recent years has been approximately 9-10 years. A review of

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published data sources confirmed this range with average lengths of 9.1¹⁰¹ and 10¹⁰² years reported.

⇒ *We have assumed in our model that the average length of the research and development phase (i.e. time from discovery to market launch) is 10 years.*

- **Research and development costs.** According to Phillips McDougall¹⁰³, the average cost of the research and development phase (i.e. from discovery to launch) for a typical new global active substance was €200 million in 2000. Although the cost of research and development has increased considerably over time¹⁰⁴, the industry¹⁰⁵ still cites the 2000 cost as being representative of the current cost for research and development for a typical new global active substance.

According to latest ECPA figures, the value of global sales of agrochemicals in 2004 was €24,734 million¹⁰⁶. Of this, the value of the European (EU-25 and EFTA nations) agrochemical market was €6,769 million¹⁰⁷ in 2004. Accordingly, the European market (i.e. including EFTA nations) accounts for 27.4% of global agrochemical sales.

⇒ *On the basis that the EU market (i.e. excluding EFTA nations) accounts for approximately a quarter of global sales, our model therefore assumes that the allocation of research and development costs for a typical new product in the EU market would be around €50 million.*

According to Phillips McDougall¹⁰⁸, of the €200 million research and development cost in 2000, 51.1% was for research (22.3% for chemistry, 23.9% for biology and 4.9% for toxicology and environmental chemistry), 42.9% was for development (8.7% for environmental chemistry, 9.8% for toxicology, 13.6% for field trials and 10.8% for development chemistry) and 6.0% was for registration.

⇒ *Based on this cost allocation, the cost of research and development in the model has therefore been spread over the 10 year research and development phase according to the year when these costs are incurred¹⁰⁹ during the research and development phase.*

¹⁰¹ See for example: Phillips McDougall study on 'The cost of new agrochemical product discovery, development and registration in 1995 and 2000' for the European Crop Protection Association and CropLife America, May 2003, pages 13; where it is reported that in 2000 the average length of the research and development phase was 9.1 years.

¹⁰² See for example: Enigma Marketing Research paper presented by Dr Nigel Uttley on the 'Development of a generic product', at Registration of Agrochemicals in an Enlarged Europe, 22 September 2003, Brussels, page 5.

¹⁰³ Phillips McDougall study on 'The cost of new agrochemical product discovery, development and registration in 1995 and 2000' for the European Crop Protection Association and CropLife America, May 2003, pages 7-8.

¹⁰⁴ DM 50 million in 1975-80, DM 80 million in 1980-85, DM 120 million in 1985-90 and DM 250 million (€200 million) in 1990-95 (see Phillips McDougall study on 'The cost of new agrochemical product discovery, development and registration in 1995 and 2000' for the European Crop Protection Association and CropLife America, May 2003, page 18).

¹⁰⁵ Based on discussions with a sample of leading agrochemical companies as well as published industry sources (see for example: ECPA evaluation on 'Data on the value of National Provisional Authorisations', 9 November 2005, page 8 and ECPA presentation on 'the importance of EU data protection for plant protection products', April 2004).

¹⁰⁶ 'ECPA Review 2004/2005' p10

¹⁰⁷ 'ECPA Review 2004/2005' p8

¹⁰⁸ Phillips McDougall study on 'The cost of new agrochemical product discovery, development and registration in 1995 and 2000' for the European Crop Protection Association and CropLife America, May 2003, page 11.

¹⁰⁹ Based on discussions with a sample of leading agrochemical companies.

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- Average time from product launch to peak sales. Based on discussions held with the leading agrochemical companies, the average length of the time from launch to peak sales was found to vary significantly between active substances, but typically ranged from 7 to 9 years.
⇒ *We have assumed in our model that the average time from product launch to peak sales is 8 years.*
- Average value of peak sales. Discussions with leading agrochemical companies and a review of industry statistics revealed that there is significant variation in the average value of peak sales between different active substances. Over time variations were reported to be enormous, ranging from less than €5 million (particularly for those active substances that are specifically targeted at niche markets (e.g. biologicals¹¹⁰ (i.e. natural extracts, insect pheromones and beneficial micro-organisms) and some active substances for use on specific crops (e.g. fruit and vegetables) or because of unsuccessful product launches) to over €150 million (for ‘blockbuster’ active substances). However, despite this enormous range in average peak sales value, discussions with leading agrochemical companies and a review of industry statistics found that its distribution tends to be ‘positively skewed’¹¹¹. In other words, average peak sales values are typically at the lower end of this range rather than at the higher end. Furthermore, analysis of company sales data¹¹² over time revealed that since the 1970s, the average value of peak sales has declined by around two-thirds as the number of new active substances has increased.
⇒ *Based on discussions with leading agrochemical companies and a review of industry statistics, we have assumed in our model that peak sales in real terms average €46 million.*
- Average production costs associated with the market exploitation phase of a new active substance. Based on discussions with the leading agrochemical companies and a review of literature, the average gross margin (i.e. the difference between sales revenue and variable (production) costs) for new active substances during the market exploitation phase is approximately 50%¹¹³.
⇒ *We have assumed that production costs are 50% of the sales revenue.*
- Profile of the sales curve. Although the average peak sales value was found to differ significantly between active substances, discussion with leading agrochemical companies suggested that the variation in the profile of the sales curve (i.e. the rate of incline in sales value from product launch to peak sales and the rate of decline following peak sales) between active substances was not as significant (at least during the patent protection period).
⇒ *The sales profile used in our model was based on that average sales profile of 13 active substances (10 of which have recently been included in Annex 1 and three of which pending Annex 1 inclusion) from four leading agrochemical companies¹¹⁴.*

¹¹⁰ Which provide an alternative to conventional chemical pesticides.

¹¹¹ When a distribution is positively skewed, the mean is greater than the median.

¹¹² Based on confidential information provided by a leading agrochemical company.

¹¹³ As reported in the ECPA evaluation on ‘Data on the value of National Provisional Authorisation’, November 2005, page 8.

¹¹⁴ As reported in the ECPA evaluation on ‘Data on the value of National Provisional Authorisation’, November 2005, page 5.

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- Average length of patent protection. Patent protection for an active substance is 20 years with a possibility to apply for a further 5 year period of protection.
⇒ *We have assumed an average patent protection period of 22.5 years.*
- Discount rate used. Discounted cash flow analysis, and the calculation of the net present value (NPVs) of future cash flows and the pay back period, is widely used to inform investors on the attractiveness of capital investments. However, the calculation of NPV and pay back period is among other things, influenced by the discount rate used; the use of higher discount rates reduce the expected NPV of an investment and increase the pay back period. It is a generally accepted basic principle that the discount rate for a more risky project and for more long-term investments should be higher than that for a more certain project and for more short-term investments. This is because the choice of discount rates should reflect the estimated cost of capital associated with investing in developing new active substances as well as a provision for risk.
⇒ *In line with the European Commission's Impact Assessment guidelines, we have used a discount rate of 4%. (Based on discussions with the leading agrochemical companies, this is far lower than that used by the industry to appraise capital projects such as investment in new active substances).*

Model results for the status-quo (baseline)

Having established the assumptions for the model, we then used discounted cash flow analysis¹¹⁵, using a discount rate¹¹⁶ (in line with the European Commission's Impact Assessment guidelines), to determine the annual present value¹¹⁷ of the expected cash flows. (Discounted cash flow analysis takes account of the time value of money and the risk-adjusted opportunity cost of investing in the development of AS) Annual present values were then added together to identify the following indicators:

- Net present value (NPV). The NPV is the arithmetic sum of discounted future expected cash-flow.
- Payback period. The time needed for the new active substance to achieve a NPV of zero (i.e. the date of the discounted break-even period of the new active substance). (At this point, the net returns from the new product development would be considered to be equal to the opportunity cost of capital.)
- Internal rate of return (IRR). The IRR for an investment is the discount rate for which the total present value of future cash flows equals the cost of the investment. It is the interest rate that produces a NPV of zero.

The results of the model and the aforementioned three indicators (NPV, pay back and IRR) are presented in the graph below. Under the status quo (baseline), an investment in a 'typical' new active substance breaks-even after 15.9 years from product discovery (5.9 years from product launch) and produces a net cash flow of €84.2 million over a 25 year period (i.e. the period under which the active substance can be protected by its patent). Although this is based on the use of a 4% discount rate, the IRR calculation shows that the investment would still break-even over the 25 year period when using discount rates of up to 12.7%.

¹¹⁵ A method of evaluating an investment by estimating future cash flows and taking into consideration the time value of money.

¹¹⁶ The interest rate used in discounting future cash flows.

¹¹⁷ The current value of one or more future cash payments, discounted at some appropriate interest rate.

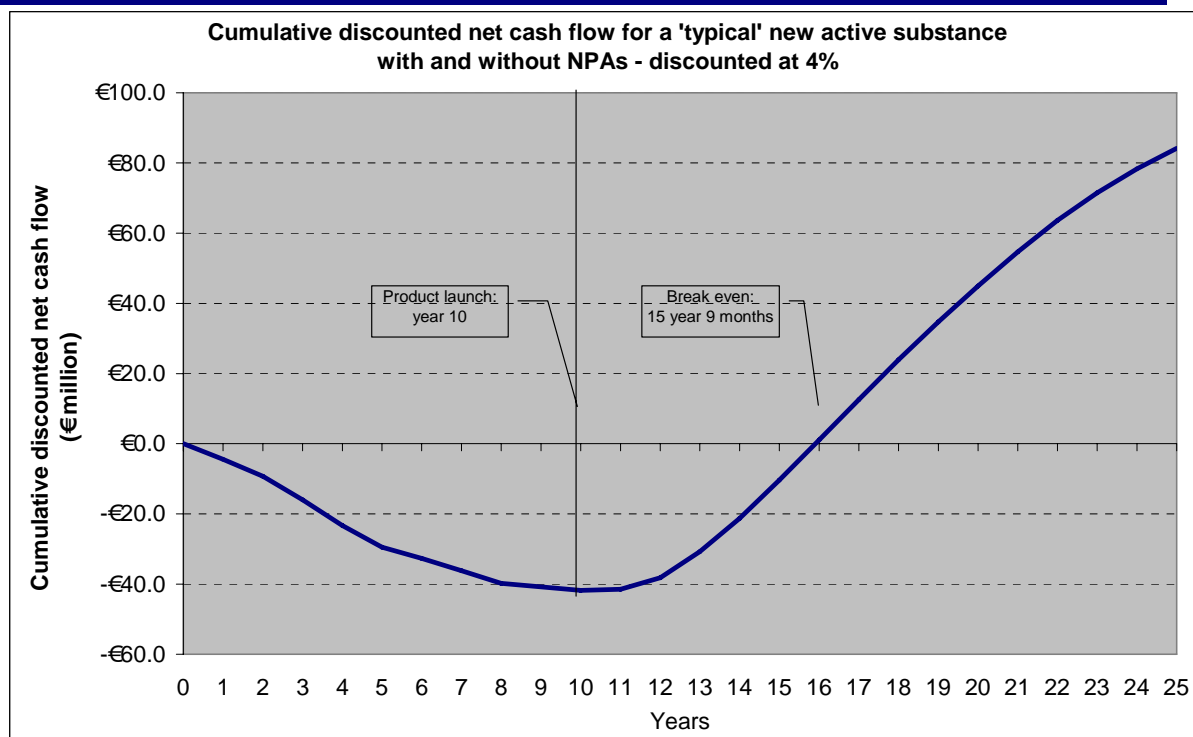


Table 31: Model results: status quo (baseline) scenario

	Status Quo (Baseline)
NPV (€million)	€84.2
IRR (%)	12.7
Payback period (years from product discovery)	15.9
Payback period (years from product launch)	5.9
Discount rate	4%

Modelling the impact of policy actions 1, 2, 3 and 4

The model was then used to assess the potential impact of amending the regulatory framework of each of the previously developed policy actions 1, 2, 3 and 4, on the expected cash flows of the typical new active substance. Similarly, these expected cash flows were converted into present values using the same cost of capital estimates and standard discounted cash flow techniques as in the baseline scenario.

NPVs, payback periods and IRRs were then calculated for each of the policy actions and compared with those of the status quo (baseline) to assess the potential impact on investment in new active substances.

Annex B: Comparative Assessment - the Swedish Experience

One of the policy actions under consideration in this impact assessment is comparative assessment combined with the substitution principle (policy action 3). Within the EU25, Sweden has been applying these mechanisms on national level since more than a decade. The substitution principle was first introduced in Sweden in 1990, in a general provision as a part of the Chemicals Control Act. It was then supported with additional provisions that add a theoretical possibility for sanctions in case the operator would not apply substitution. From 1999 onwards the substitution principle has been in line with the broader Environment Code, which has replaced a number of acts.¹¹⁸

Background

Comparative assessment and substitution are risk reduction measures regarding risks for human health and environment. Substitution is based on three principles, namely that “another active substance, product or method [is] available for the same use area which:

- Presents significantly less risk to human and animal health or the environment;
- Is sufficiently effective, also taking into account risk for development of resistance;
- Can be used without unreasonable economic or practical disadvantages for the user”¹¹⁹

To measure whether or not alternative active substances, PPP or methods pose a significantly lower threat to human and animal health and the environment, a comparative assessment is performed.

Application of the substitution principle

Synchronizing national system

Sweden implemented its policy on comparative assessment and substitution in 1990, whereas it entered the EU in 1995. As in other Member States, currently there are two regulatory systems in operation for PPP. On the one hand there is the national authorization procedure, including comparative assessment for active substances not included in Annex I of Directive 91/414/EEC. On the other hand there is the EU wide evaluation program for active substances leading to Annex I inclusion. As soon as an active substance has been included in Annex I, Sweden cannot subject it anymore to substitution.

Availability

A concern of applying substitution is that after application only few PPP would be available at the market. This lack of availability could distort competition and raise prices of PPP. In the Swedish experience the number of authorized PPP dropped significantly after implementation of the substitution program. However, their experience is that the drop is very temporary. Within a few years the number of authorized products returned to the previous level. The major impact of the substitution program in respect to availability of PPP was felt during the early nineties. Due to the national re-registration program many PPP were taken off the market. The year before 1990, 618 pesticide products were on the Swedish market. The amount of authorised pesticide products decreased until 343 in the middle of the program, which took five years in total. However, already in 1996

¹¹⁸ Swedish Chemicals Inspectorate, 2004, p.1

¹¹⁹ Swedish Chemicals Inspectorate, 2004, p.8

there were 521 pesticide products authorised, increasing to over 700 in 2004. The number of PPP is lower than the number of pesticide products, which also includes biocides. Currently there are 320 authorised PPP on the market.¹²⁰

Comparative assessment affected existing active substances. “Substitution has been used as a reason not to approve ca 20% of the old products.”¹²¹ According to the experience of KEMI, comparative assessment is less relevant for new active substances. The Swedish Crop Protection Association did not contest this view.¹²² KEMI also stressed that most of the substitution cases in Sweden have been related to the formulation type, such as substitution between products with the same active substance but based on different solvents or substitution of powder with granule formulations to reduce exposure by dusting. “These types of substitution cases have also been considered to be the easy ones”, stated KEMI.¹²³

Prices of PPP

No studies on the price effects of the PPP substitution policy in Sweden. According to the Federation of Swedish Farmers after the implementation of the policy, however, there was no public debate on mounting prices. This was interpreted as indicating that there have been no major increases in prices caused by comparative assessment and substitution.¹²⁴ However, ECPA estimates that costs for Swedish farmers have risen through the market disappearance of relatively cheaper herbicides in the so-called ‘fops’ group (e.g. quizalofop). Swedish farmers thus have to use products from the more expensive so-called ‘dim’ group (e.g. sethoxydim, clethodim). For pesticide treatment of oilseed rape, this has added an extra cost of about €5/hectare.¹²⁵ According to the Swedish Competent Authority these are only short-term costs. In the long run substitution has not led to higher user costs.¹²⁶

Unknown effects of new PPP

It might occur that when a product is substituted by a newer, less-hazardous product, the new product shows significant negative side effects after some time of usage. In order to prevent this from happening, products are not immediately replaced after the new alternative product is brought on the market. Normally the existing product will be reviewed, usually in five years time, during which the new product is on the market. During this time data is obtained on how the new product performs in practice. This information will then be taken into consideration for the comparative assessment.¹²⁷

Net administrative costs

According to the Swedish competent authority, it is easier to apply comparative assessment and compare products than to conduct full-scale risk analysis. Consequently, after applying 15 years of substitution, KEMI assessed that the administrative effort would significantly rise if substitution would be abolished.¹²⁸

¹²⁰ Questionnaire Sweden, question 1

¹²¹ Swedish Chemicals Inspectorate, 2004, p.11

¹²² Interview Ljunggren, Cecilia, Svenskt Växtskydd (Swedish Crop Protection Association), January 2006

¹²³ Email Swedish Chemicals Inspectorate, 23 February 2006

¹²⁴ Interview Sandrup, Alarik, Lantbrukarnas Riksförbund (Federation of Swedish Farmers), January 2006

¹²⁵ Graham Brookes for ECPA (2006). Briefing paper Impact Assessment of the EU Commission’s proposal to change the way in which plant protection products are authorised in the EU

¹²⁶ Swedish Chemicals Inspectorate, 2004, p.9

¹²⁷ Swedish Chemicals Inspectorate, 2004, p.11. This number includes PPP and biocides.

¹²⁸ Questionnaire Sweden, question 33d

Impact on R&D

According to Swedish competent authorities, comparative assessment with substitution provides an incentive for the development of new, less hazardous alternative products. As described above, the number of authorised PPP initially dropped significantly. Within a few years the number of authorised products was back at its previous level. However, these products were improved from a health or environmental point of view. “There are many examples in practise on how manufacturers/applicants with more favourable alternatives from a risk perspective have been encouraged to establish themselves on the market or increase their market shares as a result of regulatory action based on comparative assessments.”¹²⁹

¹²⁹ Swedish Chemicals Inspectorate, 2004, p.10

Annex C: Stakeholder organisations returning consultation questionnaire

Competent Authorities

- Austria
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Latvia
- Lithuania
- Luxembourg
- Poland
- Portugal
- Slovakia
- Slovenia
- Spain
- Sweden
- The Netherlands
- UK

Plant Protection Industry

- AEFISA (*Asociación Española de Fitosanitarios y Sanidad Ambiental*)
- Coalition of smaller research-based PPP companies (Chemtura, Gowan, ISK, Japan Agro Services, Stahler, Taminco, Isagro)
- ECCA
- ECPA
- International Plant Protection Association (IPPA)
- Japan Agro Services (also included in Coalition of smaller research based PPP companies)

Farmer Organisations and other stakeholders

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- Agricultural Industries Confederation (AIC)
- APCA and FNSEA, France
- Central Union of Agricultural Producers and Forest Owners, Finland
- COCERAL, European federation of agrosupply traders
- Confederación de Cooperativas Agrarias de España (CCAЕ)
- Coordinadora de Organizaciones de Agricultores y Ganaderos-Iniciativa Rural (COAG-IR)
- Dutch Organisation for Agriculture and Horticulture (Land- en Tuinbouw Organisatie Nederland, LTO)
- EUREAU
- European Coalition to End Animal Experiments (ECEAE) and Eurogroup for Animal Welfare
- European Seed Association (ESA)
- Federation of Swedish Farmers (Lantbrukarnas Riksförbund)
- Freshfel Europe- The European Fresh Produce Association
- International Biocontrol Manufacturers Association (IBMA)
- Pesticide Action Network Europe (PAN Europe)

Annex D: Consultation questionnaire

Following is the consultation questionnaire for competent authorities as example. The questionnaire for industry and other stakeholders was similarly structured, although different in some details.

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IMPACT ASSESSMENT
REVISION OF DIRECTIVE 91/414/EEC
*
FOOD CHAIN EVALUATION CONSORTIUM SURVEY

Please return questionnaire by email to office@civic-consulting.de or by fax to +49-30-2196-2298 before
17.1.2006

We also offer to jointly fill in the questionnaire and discuss your comments during a phone interview,
should you prefer this (see contact details below).

IDENTIFICATION DATA

Name and country of organisation:

Please specify

Questionnaire completed by (Name of person, position, contact details):

Please specify

INTRODUCTION

The European Commission intends to revise Directive 91/414/EEC on the placing of Plant Protection Products (PPP) on the market. 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 already been drafted. Due to the importance of the new regulation DG SANCO has decided to commission Civic Consulting, Agra CEAS and Arcadia International of the Food Chain Evaluation Consortium (FCEC) to finalize the impact assessment for the proposal for a Regulation replacing Directive 91/414/EEC on plant protection products.

The impact assessment team considers the experience and perspective of Member State authorities as crucial inputs into the impact assessment process. Questions in the following sections are related to the market situation of PPP, the current application of Directive 91/414/EEC and alternative policy actions for the future. For this last section we would like to ask you to give an estimate of the possible impacts in the mid-term (e.g. five years after implementation) if a specific option were to be included in a new Regulation. The new Regulation is expected to come into force not before 2008. **Please note that the point of reference for all questions related to your assessment of impacts is the current situation in your country.** The answers you will give are assumed to reflect your expertise in authorisation of PPP and are not considered to be the official position of your country. Results will be presented in aggregated form only.

The information you will provide through this questionnaire of FCEC will be crucial to assess the feasibility of different options. We therefore greatly appreciate your contribution. In case you have any further questions, do not hesitate to contact us:

Dr. F. Alleweldt (alleweldt@civic-consulting.de)
(Managing Director Civic Consulting)

Phone: +49-30-2196 2297 Fax: +49-30-21962298

Merle Achten (office@civic-consulting.de)

Phone: +49-30-2196 2295 Fax: +49-30-21962298

(contact point for setting up appointments for interviews)

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I. MARKET FOR PLANT PROTECTION PRODUCTS IN YOUR COUNTRY

AVAILABILITY OF PLANT PROTECTION PRODUCTS (PPP)

1. How many authorised plant protection products are currently available on your national market? (rounded number are sufficient, e.g. "approx. 350")

Please specify

2. Please complete the following statement relating to PPP containing active substances already included in Annex I of Directive 91/414/EEC: After the inclusion in Annex I the number of authorised PPP on the national market containing this active substances has ...

1	2	3	4	5
decreased very significantly (>25%)	decreased fairly significantly (10-25%)	remained similar (<10%)	increased fairly significantly (10-25%)	increased very significantly (>25%)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments

3. If there has been a significant change in the number of PPP on the national market after Annex I inclusion of their active substance, what impact did that have on ...

- a) ... the average price of PPP?

Please specify

- b) ... the availability of PPP for minor uses?

Please give examples and specify the relevant crops

- c) ... the availability of PPP for resistance management?

Please give examples and specify the relevant crops

GENERIC PRODUCTS

4. Please complete the following statement relating to PPP containing active substances already included in Annex I of Directive 91/414/EEC: After the inclusion in Annex I the market share of generic PPP containing this active substances has ...

1	2	3	4	5
decreased very significantly (>25%)	decreased fairly significantly (10-25%)	remained similar (<10%)	increased fairly significantly (10-25%)	increased very significantly (>25%)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Definition of generic PPP used in this survey: Off-patent product not produced by the former patent holder.

Comments

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5. Please estimate as accurately as possible the current market share of generic products, i.e. of off-patent products not produced by the former patent holder.

Please specify

6. If there has been a significant change in the number of generic PPP on the national market after Annex I inclusion of their active substance, what impact did that have on ...

- a) ... the average price of PPP?

Please give examples and specify the price differences

- b) ... the availability of PPP for minor uses?

Please give examples and specify the relevant crops

PRICE DIFFERENTIALS, UNAUTHORISED IMPORT AND USE

7. Are there significant price differences of PPP in comparison with neighbouring countries (for PPP having identical active substances)?

If your answer is yes:

- a) Could you please provide examples and estimate price differences in percent?

Please specify

- b) Do you think that these price differences can be explained mainly by differences in taxes and distribution structures for PPP? Are there other significant factors?

Please specify

8. Are there problems with unauthorised imports and use? What are the causes?

Please specify

9. Are there any problems with unauthorised (self-)mixing of PPP?

Please specify

II. CURRENT APPLICATION OF DIRECTIVE 91/414/EEC

DURATION AND COSTS OF AUTHORISATION/EVALUATION PROCEDURE

10. What is the average time (in calendar months) for the authorisation/evaluation procedure (from day of receiving the application) ...

a) ... of a new active substance that supported by a full data package (in case your country is RMS)?

Please specify

b) ... of a new PPP containing an active substance already included in Annex I where the type of use is similar to those previously considered for the active substance?

Please specify

c) ... of a new PPP containing an active substance already included in Annex I where the type of use is very different to those previously considered for the active substance?

Please specify

11. Please estimate the average staff time (in full time equivalent working days*) for the authorisation/evaluation procedure ...

a) ... of a new active substance that supported by a full data package (in case your country is RMS)?

Please specify

b) ... of a new PPP containing an active substance already included in Annex I where the type of use is similar to those previously considered for the active substance?

Please specify

c) ... of a new PPP containing an active substance already included in Annex I where the type of use is very different to those previously considered for the active substance?

Please specify

* Example: If one staff would work full time for 600 working days and a second staff 50% of the time for the same period, this would amount in total to 900 full time equivalent working days.

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12. Please give a rough estimate of the average costs of a working day of the staff involved in the authorisation procedure (across all staff categories involved).

Please specify

13. What is the average fee (in Euro) for the authorisation procedure to be paid by the applicant ...

- a) ... of a new active substance that supported by a full data package (in case your country is RMS)?

Please specify

- b) ... of a new PPP containing an active substance already included in Annex I where the type of use is similar to those previously considered for the active substance?

Please specify

- c) ... of a new PPP containing an active substance already included in Annex I where the type of use is very different to those previously considered for the active substance?

Please specify

OTHER ASPECTS RELATED TO THE AUTHORISATION PROCEDURE

14. Have you ever applied mutual recognition for a PPP authorised in a different Member State? If yes, please estimate the number of PPP authorised on basis of mutual recognition per year (absolute and as percentage of total number authorised).

Please specify

15. Please estimate the number of PPP authorised on basis of National Provisional Authorisation per year (absolute and as percentage of total number authorised).

Please specify

16. At what point during the Annex I evaluation process does your country grant a National Provisional Authorisation?

Please specify

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17. Have you ever granted extensions of the field of application for minor uses according to provisions of Art 9 (1) of Directive 91/414/EEC?

If your answer is yes:

- a) Please estimate the number of PPP for which an extension was granted (approx. absolute figure and percentage of total number of PPP)?

Please specify

- b) Please estimate the number of uses for which an extension was granted (approx. absolute figure and percentage of total number of uses)?

Please specify

CURRENT PROBLEMS

18. Are there any problems currently experienced in your country related to the authorisation process, in particular with regard to data protection and determination of unprotected data?

Please specify

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III. POLICY ACTIONS RELATED TO THE REVISION OF DIRECTIVE 91/414/EEC

POLICY ACTION 1: AUTHORISATION OF PPP CONTAINING A NEW ACTIVE SUBSTANCE / NATIONAL PROVISIONAL AUTHORISATION

Please compare the following options:

- ❑ **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.** Due to a change to Directive 91/414/EEC introduced by new MRL regulation (which will be applicable +/- 2007) provisional national MRL can no longer be set by Member States (Art. 4.1. f of Directive 91/414/EEC as modified by Art. 48 of Regulation 396/2005).
- ❑ **Option B: Centralised procedure for evaluation of new AS with binding time limits. No national provisional authorisation.** The authorisation procedure for AS is subjected to time limits for each steps, leading to a foreseen maximum duration of 25 months.
- ❑ **Option C: Keep national provisional authorisation after Draft Assessment Report and continue to foresee provisional national MRLs after 2007.** This would require a change in the new MRL regulation.

19. How do you assess the impact of the different policy options on yourself as competent authority in terms of the number of staff days needed per application for a new active substance (supported by full data package, in case your country is RMS)?

	1	2	3	4	5
Number of staff days per application would ... % change compared to current situation	decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	increase very significantly (>25%)
<i>Option A: Status quo - without binding time limits. No NPA after 2007</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: With binding time limits. No NPA</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: Keep NPA after Draft Assessment Report</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

Comments

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20. How do you assess the impact of the different policy options on the duration of the evaluation procedure?

	1	2	3	4	5
Duration of the evaluation procedure would ...	decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	increase very significantly (>25%)
<i>% change compared to current situation</i>					
<i>Option A: Status quo - without binding time limits. No NPA after 2007</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: With binding time limits. No NPA</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: Keep NPA after Draft Assessment Report</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

<i>Comments</i>

21. How do you assess the impact of the different policy options on the number of PPP available on the market in your country, especially for minor uses?

	1	2	3	4	5
Number of PPP available would ...	decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	increase very significantly (>25%)
<i>% change compared to current situation</i>					
<i>Option A: Status quo - without binding time limits. No NPA after 2007</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: With binding time limits. No NPA</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: Keep NPA after Draft Assessment Report</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

<i>Comments</i>

22. How do you assess the impact of the different policy options on unauthorised imports and use of PPP in the mid term?

	1	2	3	4	5
Unauthorised imports and use of PPP would ...	decrease very significantly	decrease fairly significantly	remain similar	increase fairly significantly	increase very significantly
<i>Option A: Status quo - without binding time limits. No NPA after 2007</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: With binding time limits. No NPA</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: Keep NPA after Draft Assessment Report</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

<i>Comments</i>

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23. Would the different policy options reduce the negative impacts of active substances on the environment or human health?

	1	2	3	4	5
Negative impacts of active substances on the environment or human health would...	decrease very significantly	decrease fairly significantly	remain similar	increase fairly significantly	increase very significantly
<i>Option A: Status quo - without binding time limits. No NPA after 2007</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: With binding time limits. No NPA</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: Keep NPA after Draft Assessment Report</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

<i>Comments</i>

24. What are in your opinion possible sanctions/mechanisms to safeguard that time limits in the authorisation procedure (Option B) are adhered to?

<i>Please specify</i>

25. Should there be a harmonisation of authorisation fees for PPP in the EU?

<i>Please specify</i>

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POLICY ACTION 2: MUTUAL RECOGNITION OF PLANT PROTECTION PRODUCTS CONTAINING AN ACTIVE SUBSTANCE ALREADY INCLUDED IN ANNEX I

Please compare the following options:

- ❑ **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.** The application shall be examined in each of the three zones by one Member State proposed by the applicant, unless another Member State in the same zone agrees to examine the application. When this MS authorises, all other MSs in the same zone must authorise the PPP too, if an application is made. Conciliation procedure in case of disagreement between MS.
- ❑ **Option C: Zonal evaluation and national authorisation of PPP with compulsory mutual recognition. However, national risk mitigation measures.** As Option B, however with the possibility to require national risk mitigation measures during the authorisation process.
- ❑ **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 (EMA), that consists of a single application which, when approved, grants authorisation for all markets within the European Union.

26. How do you assess the impact of the different policy options on yourself as competent authority in terms of the average number of staff days needed per application for a PPP containing an active substance already included in Annex I?

	1	2	3	4	5
Number of staff days per application for a PPP would ... % change compared to current situation	decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	increase very significantly (>25%)
<i>Option A: Status quo - National evaluation and authorisation</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: Zonal evaluation and national authorisation – <u>no</u> national risk mitigation measures</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: Zonal evaluation and national authorisation – <u>with</u> national risk mitigation measures</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option D: Central agency for evaluation and authorisation</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

Comments

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27. How do you assess the impact of the different policy options on the duration of the authorisation procedure?

	1	2	3	4	5
Duration of the authorisation procedure would ... % change compared to current situation	decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	increase very significantly (>25%)
<i>Option A: Status quo - National evaluation and authorization</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: Zonal evaluation and national authorization – <u>no</u> national risk mitigation measures</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: Zonal evaluation and national authorization – <u>with</u> national risk mitigation measures</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option D: Central agency for evaluation and authorization</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

Comments

28. How do you assess the impact of the different policy options on the number of PPP available on the market in your country, especially for minor uses?

	1	2	3	4	5
Number of PPP available on the market would ... % change compared to current situation	decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	increase very significantly (>25%)
<i>Option A: Status quo - National evaluation and authorization</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: Zonal evaluation and national authorization – <u>no</u> national risk mitigation measures</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: Zonal evaluation and national authorization – <u>with</u> national risk mitigation measures</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option D: Central agency for evaluation and authorization</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

Comments

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29. How do you assess the impact of the different policy options on the market share of generic PPP in your country in the mid term?

	1	2	3	4	5
Market share of generic PPP would... % change compared to current situation	decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	increase very significantly (>25%)
<i>Option A: Status quo - National evaluation and authorisation</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: Zonal evaluation and national authorisation – <u>no</u> national risk mitigation measures</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: Zonal evaluation and national authorisation – <u>with</u> national risk mitigation measures</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option D: Central agency for evaluation and authorisation</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

<i>Comments</i>

30. How do you assess the impact of the different policy options on unauthorised imports and use of PPP in the mid term?

	1	2	3	4	5
Unauthorised imports and use of PPP would ...	decrease very significantly	decrease fairly significantly	remain similar	increase fairly significantly	increase very significantly
<i>Option A: Status quo - National evaluation and authorisation</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: Zonal evaluation and national authorisation – <u>no</u> national risk mitigation measures</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: Zonal evaluation and national authorisation – <u>with</u> national risk mitigation measures</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option D: Central agency for evaluation and authorisation</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

<i>Comments</i>

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31. How do you assess the impact of the different policy options on the number of duplicated tests and studies involving vertebrate animals conducted for the authorisation?

	1	2	3	4	5
Number of duplicated tests involving vertebrate animals would ... % change compared to current situation	decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	increase very significantly (>25%)
<i>Option A: Status quo - National evaluation and authorisation</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: Zonal evaluation and national authorisation – <u>no</u> national risk mitigation measures</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: Zonal evaluation and national authorisation – <u>with</u> national risk mitigation measures</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option D: Central agency for evaluation and authorisation</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

<i>Comments</i>

32. Would the different policy options reduce the negative impacts of active substances on the environment or human health?

	1	2	3	4	5
Negative impacts of active substances on the environment or human health would...	decrease very significantly	decrease fairly significantly	remain similar	increase fairly significantly	increase very significantly
<i>Option A: Status quo - National evaluation and authorisation</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: Zonal evaluation and national authorisation – <u>no</u> national risk mitigation measures</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: Zonal evaluation and national authorisation – <u>with</u> national risk mitigation measures</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option D: Central agency for evaluation and authorisation</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

<i>Comments</i>

POLICY ACTION 3: COMPARATIVE ASSESSMENT OF PPP

Please compare the following options:

- 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.** The assessment has to be done when an application for authorization of a plant protection product containing an active substance included in Annex ID is made. *A draft of possible criteria for comparative assessment is given in the Annex of this questionnaire.*
- 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).**

33. How do you assess the impact of the different policy options on yourself as competent authority in terms of the average number of staff days needed per application for a PPP?

	1	2	3	4	5
Number of staff days per application for a PPP would ... % change compared to current situation	decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	increase very significantly (>25%)
<i>Option A: Status Quo - No provision for comparative assessment</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: Identification of candidates for substitution at the EU level based on hazard criteria</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: Comparative assessment at the national level independent from the hazard of the active substances</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

<i>Comments</i>

34. How do you assess the impact of the policy options on the duration of the authorisation procedure?

	1	2	3	4	5
Duration of the authorisation procedure would ... % change compared to current situation	decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	increase very significantly (>25%)
<i>Option A: Status Quo - No provision for comparative assessment</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: Identification of candidates for substitution at the EU level based on hazard criteria</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: Comparative assessment at the national level independent from the hazard of the active substances</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

<i>Comments</i>

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35. How do you assess the impact of the different policy options on the number of PPP available on the market in your country, especially for minor uses?

	1	2	3	4	5
Number of PPP available would ...	decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	increase very significantly (>25%)
% change compared to current situation					
<i>Option A: Status Quo - No provision for comparative assessment</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: Identification of candidates for substitution at the EU level based on hazard criteria</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: Comparative assessment at the national level independent from the hazard of the active substances</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

Comments

36. How do you assess the impact of the different policy options on the market share of generic PPP in your country?

	1	2	3	4	5
Market share of generic PPP would...	decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	increase very significantly (>25%)
% change compared to current situation					
<i>Option A: Status Quo - No provision for comparative assessment</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: Identification of candidates for substitution at the EU level based on hazard criteria</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: Comparative assessment at the national level independent from the hazard of the active substances</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

Comments

37. How do you assess the impact of the different policy options on unauthorised imports and use of PPP in the mid term?

	1	2	3	4	5
Unauthorised imports and use of PPP would ...	decrease very significantly	decrease fairly significantly	remain similar	increase fairly significantly	increase very significantly
<i>Option A: Status Quo - No provision for comparative assessment</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: Identification of candidates for substitution at the EU level based on hazard criteria</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: Comparative assessment at the national level independent from the hazard of the active substances</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

Comments

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38. Would the different policy options reduce the negative impacts of active substances on the environment or human health?

	1	2	3	4	5
Negative impacts of active substances on the environment or human health would...	decrease very significantly	decrease fairly significantly	remain similar	increase fairly significantly	increase very significantly
<i>Option A: Status Quo - No provision for comparative assessment</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: Identification of candidates for substitution at the EU level based on hazard criteria</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: Comparative assessment at the national level independent from the hazard of the active substances</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

<i>Comments</i>

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POLICY ACTION 4: DATA SHARING FOR THE RENEWAL OF ANNEX I INCLUSION OF AN ACTIVE SUBSTANCE

Please compare the following options:

- ❑ **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. 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. Tests and studies involving vertebrate animals may not be repeated.**
- ❑ **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. Non-cooperating companies would only be allowed onto the market if they generate their own data or negotiate access with the cooperating parties.**

Note: The duration of data protection for the *first inclusion* of a new active substance and the *first authorization* of a PPP is not foreseen to change under the draft Regulation and 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.

39. How do you assess the impact of the different policy options on yourself as competent authority in terms of the average number of staff days needed per application that you would expect for a renewal of inclusion of an active substance in Annex I? Please use Option A as reference.

	1	2	3	4	5
Number of staff days per application would ...	decrease very significantly	decrease fairly significantly	remain similar	increase fairly significantly	increase very significantly
<i>Option A: Status quo - Data protection, no compulsory data sharing</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: Data protection, with compulsory data sharing</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: No data protection period for renewal of inclusion in Annex I</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option D: Two stage data protection starting with the time of dossier submission</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

<i>Comments</i>

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40. How do you assess the impact of the different policy options on the duration of the authorisation procedure?

	1	2	3	4	5
Duration of the authorisation procedure would ...	decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	increase very significantly (>25%)
% change compared to current situation					
<i>Option A: Status quo - Data protection, no compulsory data sharing</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: Data protection, with compulsory data sharing</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: No data protection period for renewal of inclusion in Annex I</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option D: Two stage data protection starting with the time of dossier submission</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

Comments

41. How do you assess the impact of the different policy options on the number of PPP available on the market in your country, especially for minor uses?

	1	2	3	4	5
Number of PPP available would ...	decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	increase very significantly (>25%)
% change compared to current situation					
<i>Option A: Status quo - Data protection, no compulsory data sharing</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: Data protection, with compulsory data sharing</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: No data protection period for renewal of inclusion in Annex I</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option D: Two stage data protection starting with the time of dossier submission</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

Comments

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42. How do you assess the impact of the different policy options on the market share of generic PPP in your country?

	1	2	3	4	5
Market share of a generic PPP would ...	Decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	Increase very significantly (>25%)
% change compared to current situation					
<i>Option A: Status quo - Data protection, no compulsory data sharing</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: Data protection, with compulsory data sharing</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: No data protection period for renewal of inclusion in Annex I</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option D: Two stage data protection starting with the time of dossier submission</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

Comments

43. How do you assess the impact of the different policy options on the number of duplicated tests and studies involving vertebrate animals conducted for the authorisation?

	1	2	3	4	5
Number of duplicated tests involving vertebrate animals would ...	decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	increase very significantly (>25%)
% change compared to current situation					
<i>Option A: Status quo - Data protection, no compulsory data sharing</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: Data protection, with compulsory data sharing</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: No data protection period for renewal of inclusion in Annex I</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option D: Two stage data protection starting with the time of dossier submission</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

Comments

POLICY ACTION 5: INFORMING NEIGHBOURS ON PPP USE

Please compare the following options:

- 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.** For PPP classified under Directive 1999/45/EC as very toxic or toxic applied by spraying, the authorisation can stipulate the obligation to inform neighbours who could be exposed to the spray drift before the product is used.
- Option C: Passive duty to inform neighbours on use of dangerous PPP (i.e. providing information to neighbours on demand).** Application for similar PPP as under Option B (classified under Directive 1999/45/EC as very toxic or toxic applied by spraying).

44. How do you assess the impact of the different policy options on the responsible authority in terms of the number of staff days needed for enforcement of rules related to the use of PPP?

	1	2	3	4	5
Number of staff days needed for enforcement of rules related to use of PPP would ...	decrease very significantly	decrease fairly significantly	remain similar	increase fairly significantly	increase very significantly
<i>Option A: Status quo – No duty to inform neighbours</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: Active duty to inform neighbours</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: Passive duty to inform neighbours</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

<i>Comments</i>

45. How do you assess the impact of the different policy options on the level of information of potentially affected citizens on PPP usage?

	1	2	3	4	5
Level of information of potentially affected citizens on PPP usage would...	decrease very significantly	decrease fairly significantly	remain similar	increase fairly significantly	increase very significantly
<i>Option A: Status quo – No duty to inform neighbours</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: Active duty to inform neighbours</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: Passive duty to inform neighbours</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

<i>Comments</i>

46. Would the different policy options reduce the negative impacts of active substances on the environment or human health?

	1	2	3	4	5
Negative impacts of active substances on the environment or human health would...	decrease very significantly	decrease fairly significantly	remain similar	increase fairly significantly	increase very significantly
<i>Option A: Status quo – No duty to inform neighbours</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option B: Active duty to inform neighbours</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Option C: Passive duty to inform neighbours</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Not marked = Don't know

<i>Comments</i>

IV. OTHER ISSUES

47. Are there any other significant impacts that you would expect from one of the five policy actions listed in the previous section?

<i>Please specify</i>

48. Would you prefer a Directive instead of a Regulation as legislative approach?

Yes No Don't know

<i>If yes, please justify</i>

49. Would you prefer (additional) non-regulatory measures in the area of authorisation of PPP?

Yes No Don't know

<i>If yes, please justify</i>

ANNEX

Possible criteria for Comparative Assessment (criteria for inclusion in Annex ID)

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.

Annex 3

Exhaustive list of stakeholders that have been invited to participate in at least one of the stakeholders meetings hold in July 2002, January 2003, January 2005 and January 2006.

Representatives of EU Member States

Representatives of EU Acession Countries and Candidate Countries

Representatives of EEA Member Countries

Representatives of the following non-governmental organisations:

AUDACE

BEUC

BUAV/ECEAE

CEFIC

CELCAA

CIAA asbl

COCERAL

COLEACP

COPA/COGECA

Croplife

ECCA

ECPA

EEB

EFSA

EFTA

EPPO

ESA

EUREAU

EUREPGAP

Eurogroup for Animal Welfare

FEFAC asbl

Foodplus

Freshfel

Fyffes

Friends of the Earth

IBMA

IPPA

OECD

PAN

UEAPME

WWF

Annex 4

Interactive Policy Making (IPM) online consultation, 10 March – 10 May 2005

A) Questionnaire

The Future of Pesticides in Europe

Interactive Policy Making (IPM) online consultation on the Proposal concerning Amendments made to the Council Directive 91/414/EEC of 15 July 1991 concerning the Placing of Plant Protection Products on the Market.

Confidentiality

Any information collected in this questionnaire that could enable recognition of an individual contributor falls under Regulation (EC) No 45/2001.

Background

Directive 91/414/EEC provides for the establishment of a positive list of active substances for the use in plant protection products, which have been evaluated to be safe for humans and which do not present an unacceptable risk to the environment. Member States are only permitted to authorise the placing on the market and the use of plant protection products if the active substance is on the positive list, except where transitional arrangements apply. The Directive also makes provision for a system, based on mutual recognition of the Member States' authorisations, provided that the agricultural, plant health and environmental conditions in the Member States concerned are comparable.

Ten years after its adoption, the Commission presented an extensive report on the functioning of the above Directive to the Council and the European Parliament (doc. COM (2001)444). The Council and the Parliament called on the Commission to present a proposal to amend the Directive.

This inquiry should be considered as a fine tuning of the consultation process. The objective of this exercise is not to address health and environmental issues, since they have been addressed previously. It is open to all stakeholders both within the EU and outside.

Identification of the main issues:

- Mutual recognition does not function well and national authorisations of products leads to duplication of work in the Member States and to differences in the availability of plant protection products across the European Union. The proposal would set up a more harmonised approach.
- Sharing of data, developed by the companies to support the safety evaluation of pesticides, needs to be further clarified.
- Consumer, operator and environmental protection are key elements in the Directive. Criteria for acceptance of pesticides and the principle of comparative assessment will be considered.
- More than half of all existing active substances were withdrawn from the market in 2003. There is a strong possibility that, in addition, niche substances will also disappear in the years to come, unless special provisions are made to keep this market attractive to industry.

Background documents

Council Directive 91/414/EEC

Report from the Commission to the European Parliament and the Council : Evaluation of the active substances of plant protection products (Doc. COM (2001) 444)

Technical Annex

Privacy Statement

Profile-related questions

Do you represent (Compulsory)

- | | | |
|--|---|---|
| <input type="checkbox"/> a manufacturer | <input type="checkbox"/> a user | <input type="checkbox"/> an individual person |
| <input type="checkbox"/> an importer | <input type="checkbox"/> a public authority | <input type="checkbox"/> a NGO |
| <input type="checkbox"/> other, please specify | | |

Role in organisation (Compulsory)

- | | | |
|---|---|--|
| <input type="checkbox"/> none – answering as an individual management | <input type="checkbox"/> researcher | <input type="checkbox"/> senior |
| <input type="checkbox"/> management | <input type="checkbox"/> strategy/policy function | <input type="checkbox"/> specialist/expert |
| <input type="checkbox"/> not applicable | | |

Name of Contact Person

Name of your organisation (write "none" if you reply as an individual) (Compulsory)

Your organisation's country of establishment (indicate your country of residence if answering as an individual person) (Compulsory)

- | | | |
|--|---------------------------------------|---|
| <input type="checkbox"/> AT - Austria | <input type="checkbox"/> BE - Belgium | <input type="checkbox"/> CY - Cyprus |
| <input type="checkbox"/> CZ - Czech Republic | <input type="checkbox"/> DE - Germany | <input type="checkbox"/> DK - Denmark |
| <input type="checkbox"/> EE - Estonia | <input type="checkbox"/> EL - Greece | <input type="checkbox"/> ES - Spain |
| <input type="checkbox"/> FI - Finland | <input type="checkbox"/> FR - France | <input type="checkbox"/> HU - Hungary |
| <input type="checkbox"/> IE - Ireland | <input type="checkbox"/> IT - Italy | <input type="checkbox"/> LT - Lithuania |
| <input type="checkbox"/> LU - Luxembourg | <input type="checkbox"/> LV - Latvia | <input type="checkbox"/> MT - Malta |

- | | | |
|--|--|---|
| <input type="checkbox"/> NL - Netherlands | <input type="checkbox"/> PL - Poland | <input type="checkbox"/> PT - Portugal |
| <input type="checkbox"/> SE - Sweden | <input type="checkbox"/> SI - Slovenia | <input type="checkbox"/> SK - Slovak Republic |
| <input type="checkbox"/> UK - United Kingdom | <input type="checkbox"/> Other, please specify | |

Size of your organisation (not applicable for public authorities)

Your organisation's geographical area of activities (Compulsory)

- | | | |
|-----------------------------------|--|---|
| <input type="checkbox"/> local | <input type="checkbox"/> regional | <input type="checkbox"/> national |
| <input type="checkbox"/> European | <input type="checkbox"/> international | <input type="checkbox"/> not applicable |

The Market

Plant Protection Products (PPPs) are active substances or preparations (containing one or more active substances) intended to protect plants or plant products against harmful organisms or to prevent the action of such organisms.

Data protection ensures that data generated by a company can not be used by another company, unless specific agreement is given.

In your view, what is the importance of different competitive tools listed below on the market for Plant Protection Products (PPP)?

Data Protection(Compulsory)

- Very Important
- Important
- Not Important
- Insignificant
- Do not know

Data Sharing(Compulsory)

- Very Important
- Important
- Not Important
- Insignificant
- Do not know

Centralised Production(Compulsory)

- Very Important
- Important
- Not Important
- Insignificant
- Do not know

Decentralised Production(Compulsory)

- Very Important
- Important
- Not Important
- Insignificant
- Do not know

Distribution Channels(Compulsory)

- Very Important
- Important
- Not Important
- Insignificant
- Do not know

Commercial Name of the Product(Compulsory)

- Very Important
- Important
- Not Important
- Insignificant
- Do not know

Patents(Compulsory)

- Very Important
- Important

- Not Important
- Insignificant
- Do not know

Location of Storage(Compulsory)

- Very Important
- Important
- Not Important
- Insignificant
- Do not know

The Zones

In order to increase the efficiency and the transparency of authorisation, it is proposed that the EU be divided into three separate zones based on geographical, biological and climatological criteria.

- The Nordic Zone includes: Denmark, Estonia, Finland, Latvia, Lithuania and Sweden,
- The Central Zone includes: Austria, Belgium, Czech Republic, Germany, Hungary, Ireland, Luxembourg, the Netherlands, Poland, Slovak Republic, Slovenia and the United Kingdom.
- The Southern Zone includes: Cyprus, France, Greece, Italy, Malta, Portugal and Spain.

A zone is a group of Member States for which it is assumed that the agricultural, plant health and environmental conditions are relatively similar.

In order to obtain mutual recognition of the authorisation, issued in one of the Member States, the holder of the authorisation would request recognition of this authorisation to the competent authorities of the Member States within the same zone.

The new proposed zoning structure, consisting of three zones or markets (Nordic Zone, Central Zone and Southern Zone), instead of 25 national markets consisting of 25 Member States, may lead to changes for the PPP users.

In your opinion, how important will these changes be on the items listed below?

Price(Compulsory)

- Very Important
- Important
- Not Important
- Insignificant
- Do not know

Administrative burden or complexity(Compulsory)

- Very Important
- Important
- Not Important
- Insignificant
- Do not know

Number of Available Products(Compulsory)

- Very Important
- Important
- Not Important
- Insignificant
- Do not know

Choice of Products(Compulsory)

- Very Important
- Important
- Not Important
- Insignificant
- Do not know

Market Structure(Compulsory)

- Very Important
- Important
- Not Important
- Insignificant
- Do not know

Plant Protection Products Related Questions

In your opinion, should zoning structure lead to a single compulsory risk evaluation and authorisation within each Zone?(Compulsory)

- yes no

In your opinion, should zoning structure lead to a single risk evaluation within each Zone followed by individual national authorisations?(Compulsory)

- yes no

Duration of the authorisation

In your opinion, should the duration of the authorisation be for(Compulsory)

- A fixed period of time
 A fixed period of time expanded tacitly if no unfavourable information has been received
 Only reassessed if unfavourable information is available

The Questionnaire

How did you perceive this questionnaire?(Compulsory)

- Expectations met Expectations not met

Why?(Compulsory)

- Too general Irrelevant in content Too difficult to understand
 Too short Too technical Too long

B) Report

There were 194 responses to the questionnaire. The majority or 55 % of the responses came from four Member States, France, Belgium, Italy and the Netherlands. No or less than five responses were received from most or 18 Member States. Nobody outside the EU answered to the questionnaire. Most responses were received from individuals (some 40%), 25 responses from NGOs, 20 from manufacturers and 15 from public authorities. Only 4 importers of pesticides responded to the questionnaire. The majority or 70 % of the organisations were small or medium sized and mainly active on the regional or national market (69 %). Only 18 or 9 % operated at a European level.

The Market

Seven questions were asked about the market: data protection, data sharing, decentralisation, distribution, commercial name of the product, patents and location of storage. The most important identified critical market success factors were data sharing, distribution, location and patents.

Data protection was considered to be “important” or “very important” by 64 % of the respondents primarily located in Belgium, Spain and in France. Data sharing received very high support by the respondents (88 %). Strong support was noted in France, Belgium, Spain and Italy. Decentralised production was considered not to be important by the majority of respondents (61 %). There were no clear preferences for decentralised or centralised production of pesticides.

All (100 %) manufacturers and public authorities as well as the majority of importers (75 %) considered data protection “important” or “very important”. Data sharing was considered “important” or “very important” by all manufactures (100 %) and the overwhelming majority of NGO’s (88 %), public authorities (93 %) and users (92 %).

Distribution was considered to be “important” or “very important” by 82 % of the respondents. This was especially the case for France, Italy, Belgium, Spain and the Netherlands. Distribution was considered paramount for importers (100 %), manufactures (95 %), but also for NGOs, public authorities and the user. All considered distribution to be a critical success factor (75 – 95 %).

The name of the product or branding was not considered to be “very important”. Most or 64% of the respondents were of this opinion. Meanwhile, the name or brand of the product was considered to be “very important” or “important” for the importer (75 %) and the user (63 %), but also for the manufacturer (60 %) and the NGO (56 %).

Patents were considered to be “important” or “very important” by 74 % of the respondents. This was especially the case for France, Germany and Spain. Patents were considered critical for the manufacturer and the importer (100 %) and significant for the NGOs (68 %), the public authority (80 %) and the user (79 %).

Location was considered to be significant for 75 % of the respondents. This variable was considered “important” or “very important” by all respondents, especially by those from France. This was the critical factor for French respondents which represented nearly half of all those indicating this factor as “very important”. Location of storage was “important”

or “very important” for the public authority (80 %), and for the user (79 %) as well as for the importer, but to a lesser extent for the manufacturer (60 %).

The Zones

Five questions were asked on the zones: price, administrative burden or complexity, number of available products, choice of products and market structure. All these factors were considered to be “important” or “very important” by the great majority of respondents.

The price of the pesticides was considered to be “important” or “very important” by the majority of respondents (67 %), but nearly a quarter (24 %) considered it to be either “insignificant” or “not important”. Price was considered “important” or “very important” by the manufacturer (90 %) and by the user (75 %).

Over 70 % of the respondents considered the administrative burden to be too high (important/very important). This was especially the case in France, Belgium and Italy and to a lesser extent in Germany and the Netherlands. Administrative burden was considered to be an “important” or “very important” issue for the manufacturer (85 %), the importer and the user (84 %), but to a lesser extent for the public authority where only 27 % considered it to be “very important” and 40 % “important”. A third of the respondents representing public authorities considered the burden “insignificant” or simply did not know the administrative burden level.

Some 73 % of the respondents considered availability of products to be either “important” or “very important”. But a quarter considered product availability to be either “not important” or “insignificant”. Product availability is critical for the importer and the manufacturer.

Nearly two thirds or 76 % of the respondents considered the choice of products to be “important” or “very important”. The market structure was considered to be “important” or “very important” by the majority of respondents (75 %). The highest supporting figures were received from the importer (100 %) and the manufacturer (95 %). Surprisingly, a fifth of the users considered product choice as “not important” or “insignificant”.

Plant Protection Products Related Questions

Two questions were asked on this subject.

- In your opinion, should zoning structure lead to a single compulsory risk evaluation and authorisation within each zone?

- In your opinion, should zoning structure lead to a single risk evaluation for each zone followed by individual national authorisation?

70 % responded YES to the first question. The only anomaly was Spain where support for a single compulsory risk evaluation and authorisation within each zone was only supported by a minority or 40 % of the respondents.

The responses to the second question were even (52%/47 %). The anomaly was Spain, where 80 % of the respondents were of the opinion that the zoning structure should lead to a single risk evaluation for each zone followed by an individual national authorisation.

Among the responding groups there was overwhelming general support (70 %) for a single compulsory risk evaluation and authorisation within each zone, but support between different respondents varied. Only 60 % of the manufactures and 40 % of the public authorities supported this alternative. Strong support was shown by importers (100 %) and by NGOs (84 %). The YES and NO responses to the second questions were more even 52/48 %. The user e.g. the farmer was strongly against this alternative. Almost two thirds of the farmers voted against.

Duration of the Authorisation

Here the responses were even. 43 % of the respondents supported the statement that a fixed period of time expanded tacitly if no unfavourable information is received. 37 % were for a straight forward fixed time period and 19 % considered that the time period for authorisation should be reassessed only if unfavourable information is available. A simple fixed time period was supported strongly by the Netherlands, Austria and France. The Spanish respondents supported a fixed time period expanded tacitly if no unfavourable information is received and the United Kingdom a reassessment of the authorisation if unfavourable information is available.

37 % of the different respondent groups were for a fixed time period, which was supported by the public authorities (69 %). Some 44 % of the respondents were for a fixed time period if no unfavourable information has been received. This alternative was strongly supported by the importer (75 %) and the manufacturer (75 %). The third alternative, “reassessed if unfavourable information is available”, was mainly supported by NGOs (44 %).

Annex 5

Measures assessed earlier in a different context

A couple of measures taken into account in the proposal have not been subject to a new, detailed assessment, because they are either required to bring the text in coherence with other EU policies or because the working experience that has been gained so far showed that some of measures contained in Directive 91/414/EEC were not sufficient to fulfil the objectives defined and therefore, those provisions are adjusted in the current proposal in order to optimise them.

These measures are:

- The legal status of the text will change from a Council Directive to a Regulation of the European Parliament and the Council (harmonised implementation throughout EU)
- Widening the scope of the text to include safeners, synergists and co-formulants: Safeners and synergists contained in plant protection products should be assessed in an approach comparable to that for active substances; harmful co-formulants should not be contained in plant protection products. (harmonised implementation throughout the EU and high level of protection of human and animal health and of the environment)
- Introducing criteria for approval of active substances at EU level (increase the efficiency of the system by streamlining the procedures)
- Setting deadlines for all stakeholders participating in the process for approval of active substances and/or authorisation of plant protection products (the aim is to increase the efficiency of the system – first objective)
- Synchronising timelines for approval of active substances and granting authorisations by Member States (simplify the procedures)
- Setting procedures for “low risk” and “basic” substances and extending the time for approval of “low risk” substances (increase the efficiency of the system)
- Defining the role of European Food Safety Authority (EFSA) (better definition of procedures)
- Avoiding duplication of tests on vertebrate animals (coherence with general EU policy)
- Setting the procedures for authorization of plant protection products containing GMOs (coherence with general EU policy)
- Labelling of plant protection products according to Directive 1999/45 (coherence with general EU policy)
- Obligation for record keeping by farmers as already foreseen for food producing farmers in Regulation (EC) No 882/2004 (coherence with general EU policy)
- Setting rules for the advertisement of plant protection products (coherence with general EU policy)
- Defining roles and competencies of the Commission in inspection and in monitoring inspection programmes that Member States are carrying out (better definition of procedures)
- Possibility for Member States to establish fees and charges (increase the efficiency of the system)
- Procedures for access to information (coherence with general EU policy)

- Linking the authorisation of plant protection products and the MRL setting (streamlining the procedures)
- Clarification of the status of non-approved active substances by repealing Directive 79/117/EEC (simplification of procedures)
- Synchronising the periods of approval of active substances and of authorisation of related plant protection products (streamlining of procedures)
- Speeding up the entry on the market of active substances by establishing a parallel procedure for the evaluation of the requests for approval and authorisation (streamlining of procedure)
- Setting rules for checking the equivalence of technical material (increase the level of harmonisation)
- Setting rules for issuing guidance documents (increase the level of harmonisation)
- Providing the Commission with the possibility for expenditure (increase the level of harmonisation)