COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 12.7.2006
SEC(2006) 931
ANNEX 2 PART 5

COMMISSION STAFF WORKING DOCUMENT

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

Annex 2, part 5

{COM(2006) 388 final}
{SEC(2006) 930}

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

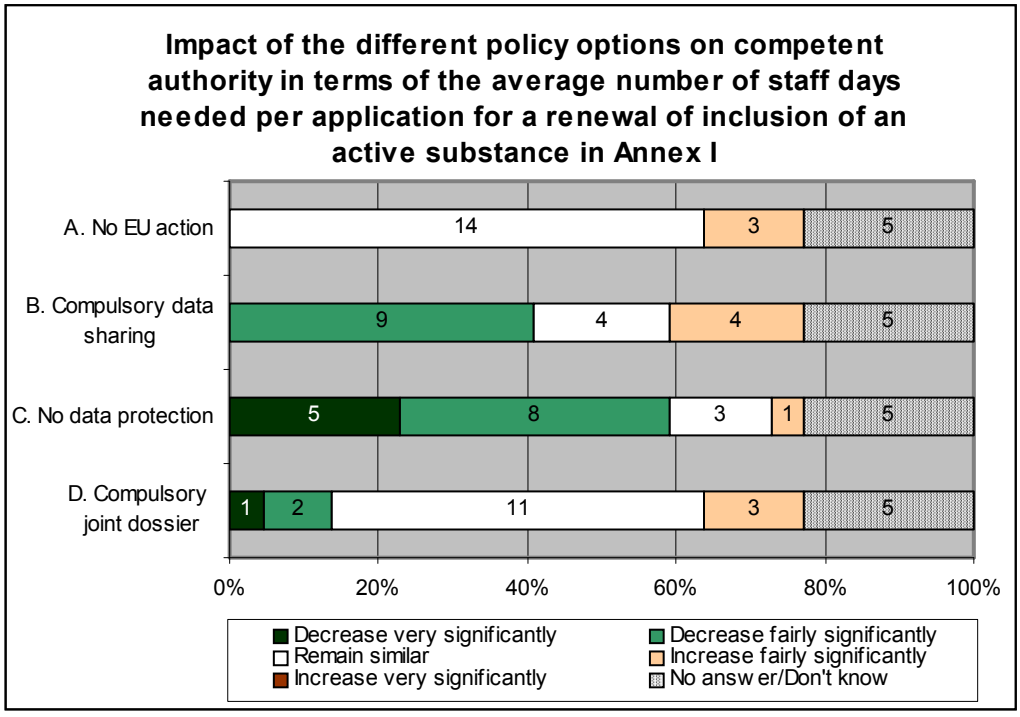
Agenda planning or WP reference: 2003/SANCO/61

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

1.1.1. Economic impacts

1.1.1.1. 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

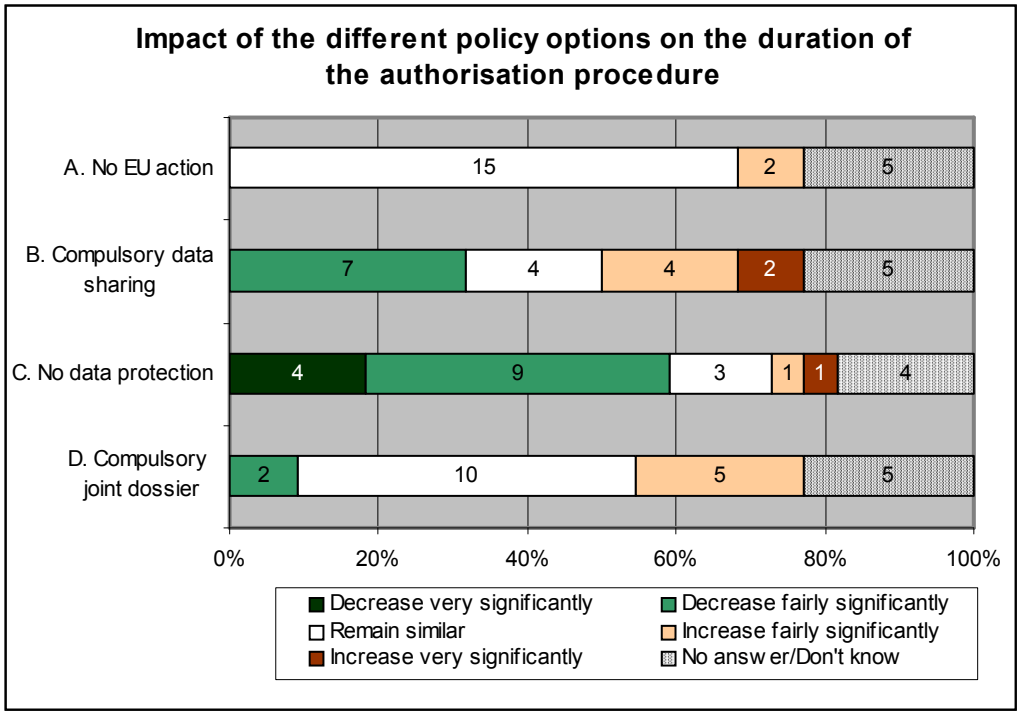
Surprisingly, option D, the provision of a compulsory joint dossier by applicants was not seen by competent authorities as a possibility to reduce the workload. This could be caused by two reasons:

- 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.

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.

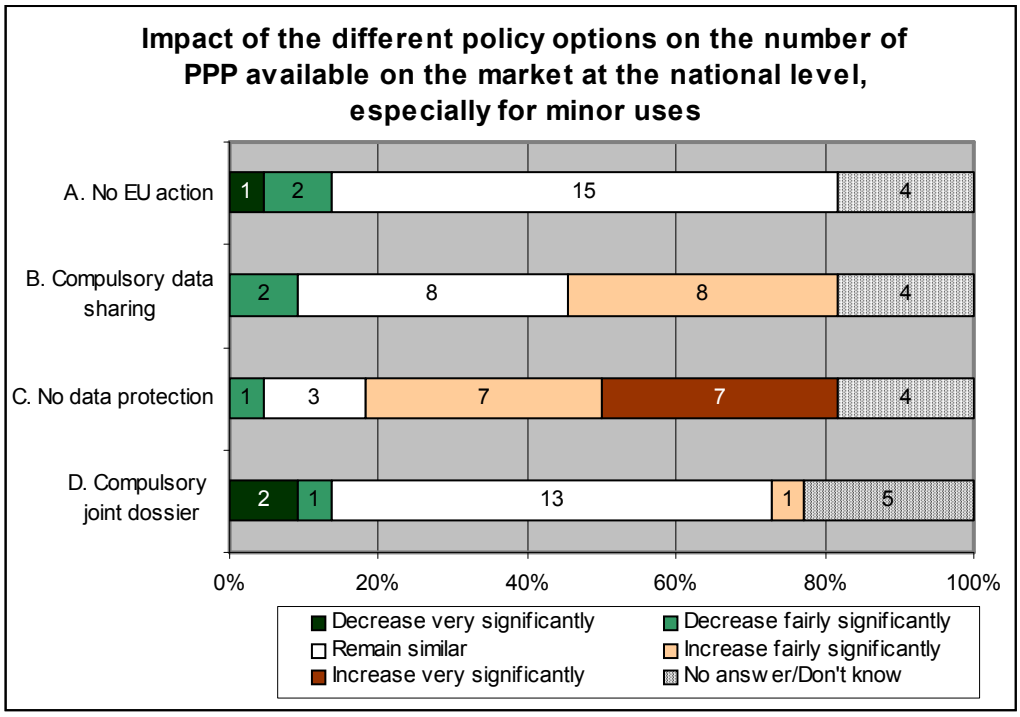
1.1.1.2. Impact on indirect costs for PPP users

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

a. Reduction of the number of PPP available, especially for minor uses;

b. Number of generic products on the market that tend to affect price levels of PPP.

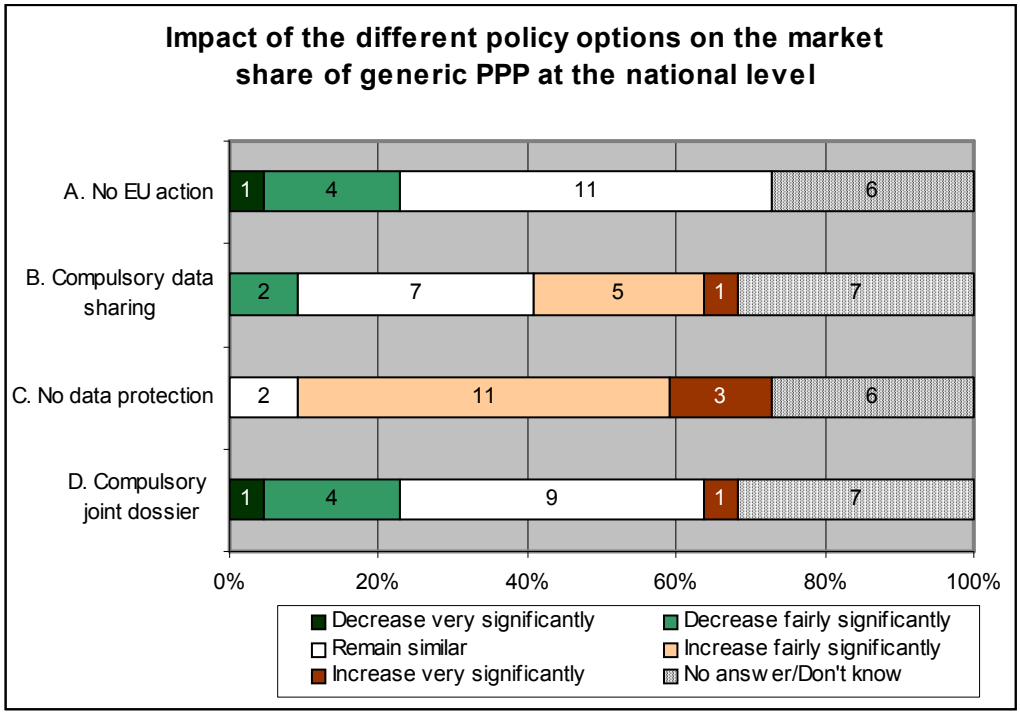
There is a large consensus among competent authorities that both factors would be most positively affected by option C (no data protection), leading to a higher number of products on the market, especially for minor uses, and an increased market share of generic products. If this assessment was correct, 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

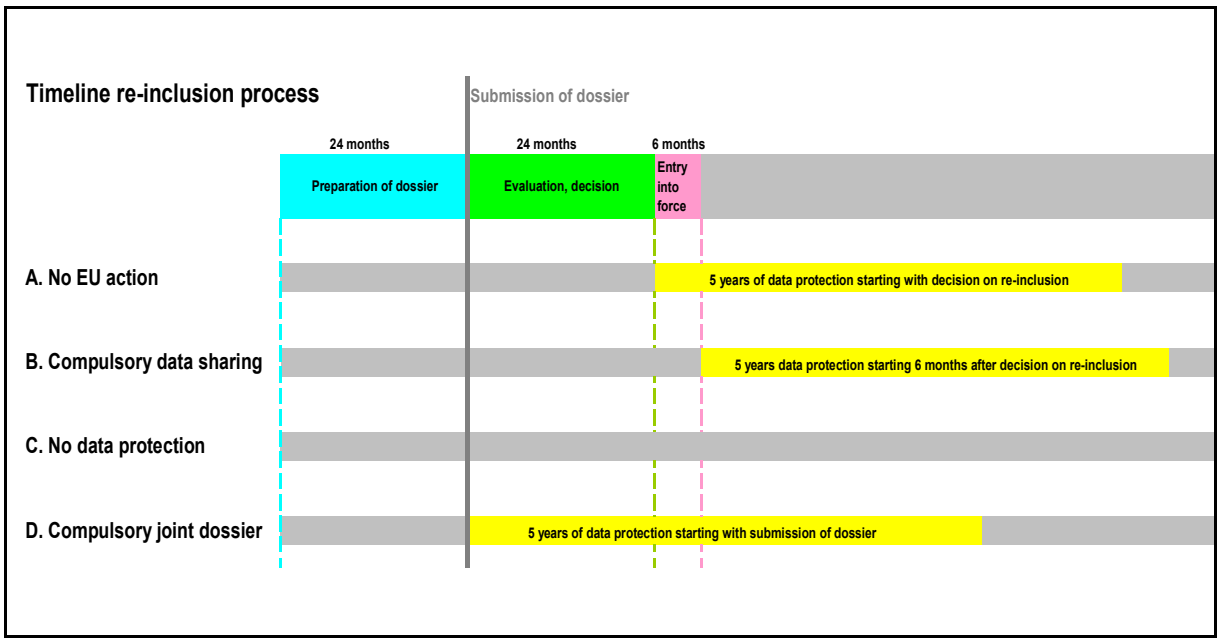
priced, patented active substances). It is not possible to assess the net effect of these two potentially contradictory trends at this stage;

- 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.

1.1.1.3. 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 million[1]. 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 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	-	7.81	8.66	1.45

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

'status quo'				

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, 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 €61.41 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.

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

1.1.1.4. 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 estimates[2]:

- Out of some currently existing 250 active substances[3] pending for re-registration in the EU, 152 enjoy annual sales less of than 20 million €;
- 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".

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2 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.

3 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, November 2005.

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.

1.1.2. Social impacts

1.1.2.1. 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.

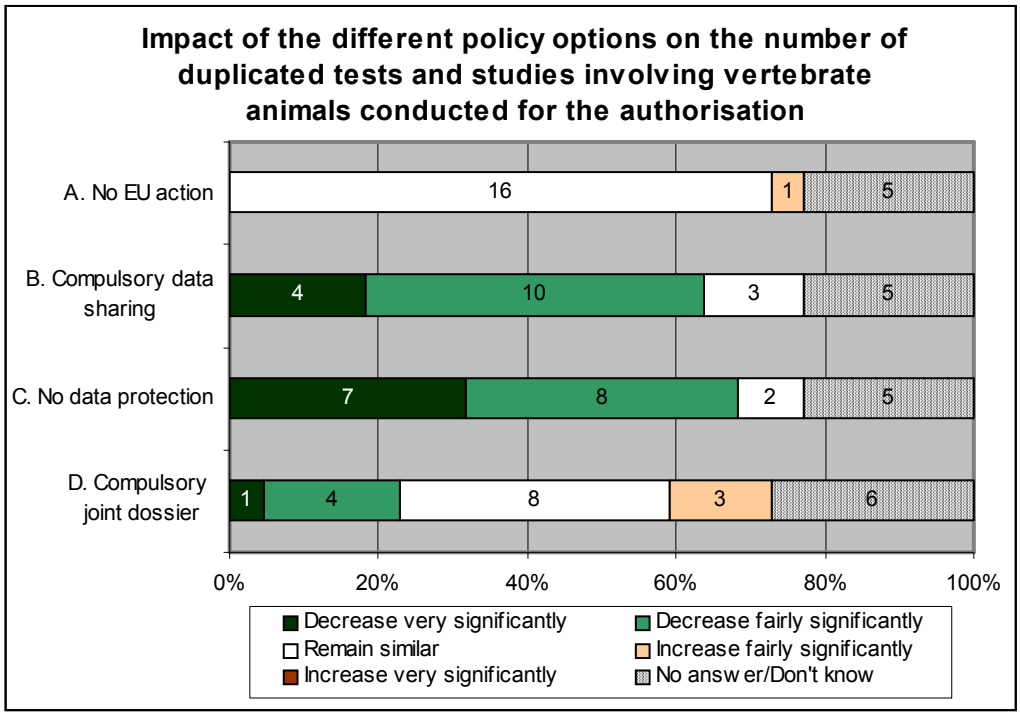
1.1.2.2. Impact on information opportunities of citizens

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.

1.1.2.3. Impact on animal welfare

As already has been pointed out in section **Error! Reference source not found.**, 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 eco-tox 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.

1.1.3. Environmental impacts

1.1.3.1. Impact on unauthorised cross-border sourcing of PPP

No impact expected.

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

No impact expected.

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

++ = Very significant positive impacts

+ = Significant positive impacts

o = No change from the present situation

Note: * Results are highly sensitive to model assumptions. 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.

1.1.5. 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	• Complex legal situation leads to significant administrative burden • Entry barriers for generic companies and new entrants	• Would reduce administrative burden for authorities • Lowers entry barriers for generic companies and new entrants	• 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	• Would reduce administrative burden for authorities • Lowers entry barriers for generic companies and new entrants
Added value of EU action	• None	• Creates conditions for a more competitive market for PPP	• Creates conditions for a more competitive market for PPP, but reduces incentives for defending AS through re-inclusion process	• 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

1.1.6. 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.