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

Annex 2, part 4

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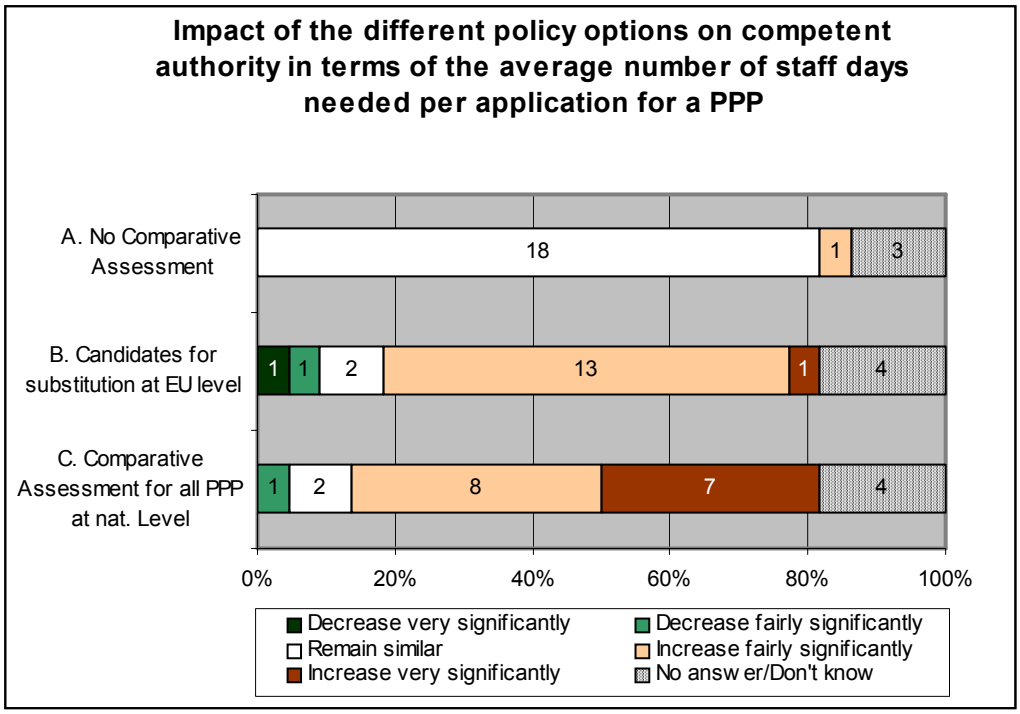
1.1. Assessment of policy action 3: Comparative assessment of PPP

1.1.1. Economic impacts

1.1.1.1. 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 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.

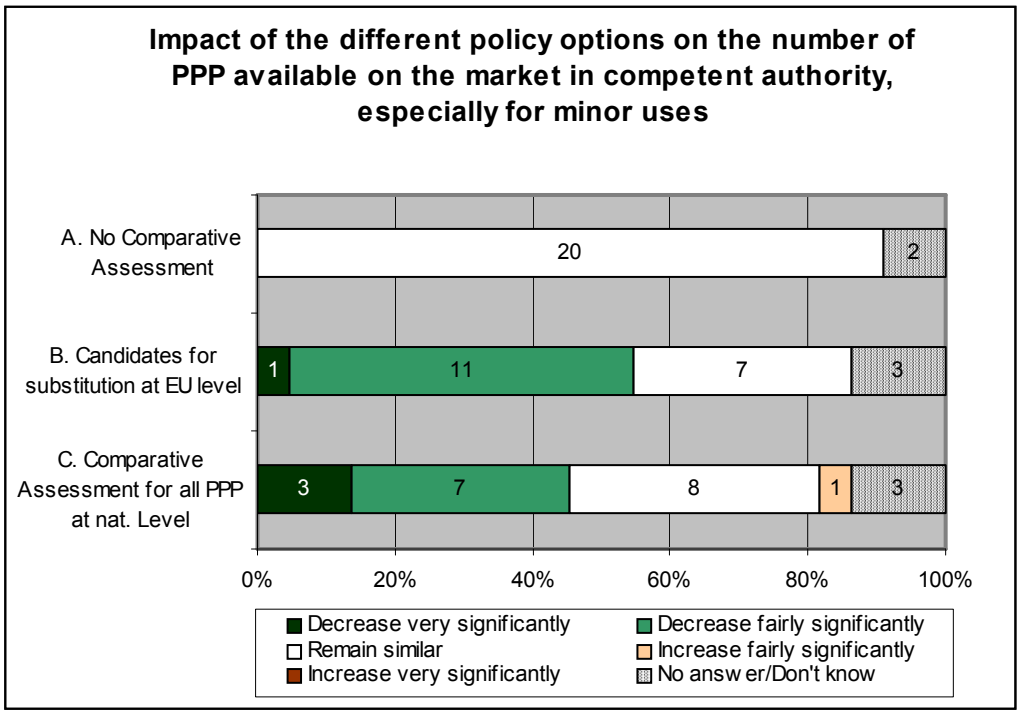
It is not expected that any of the options increases the costs of dossier submission for industry, if absolute and predictable criteria would be used for comparative assessment (see below in section *potential for optimisation*). No increase of administrative burden is also expected for PPP users.

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 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.

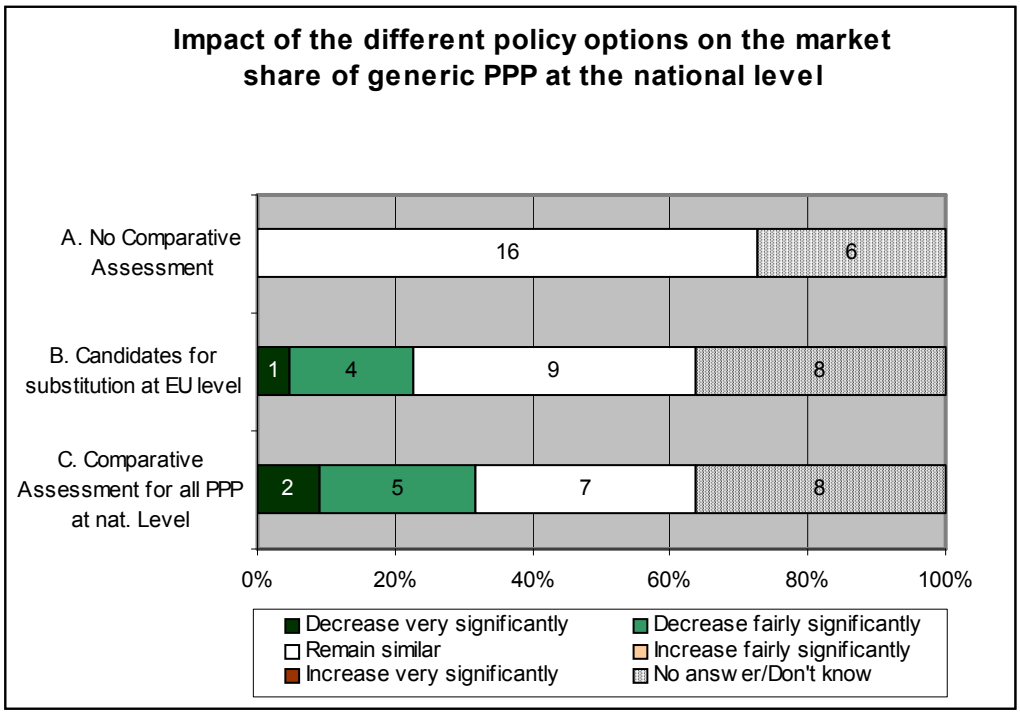
Comparative assessment (both options B and C) is expected to lead to a reduction of availability of PPP by a majority of competent authorities (see following graph):



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.



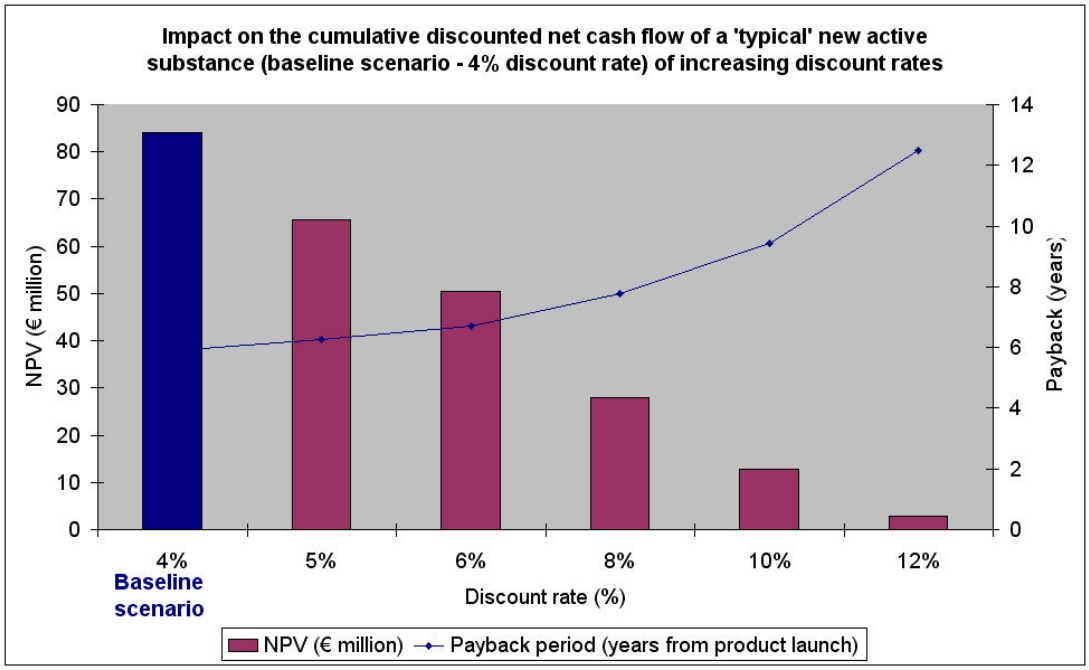
Source: Survey of competent authorities

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.

1.1.1.3. 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.

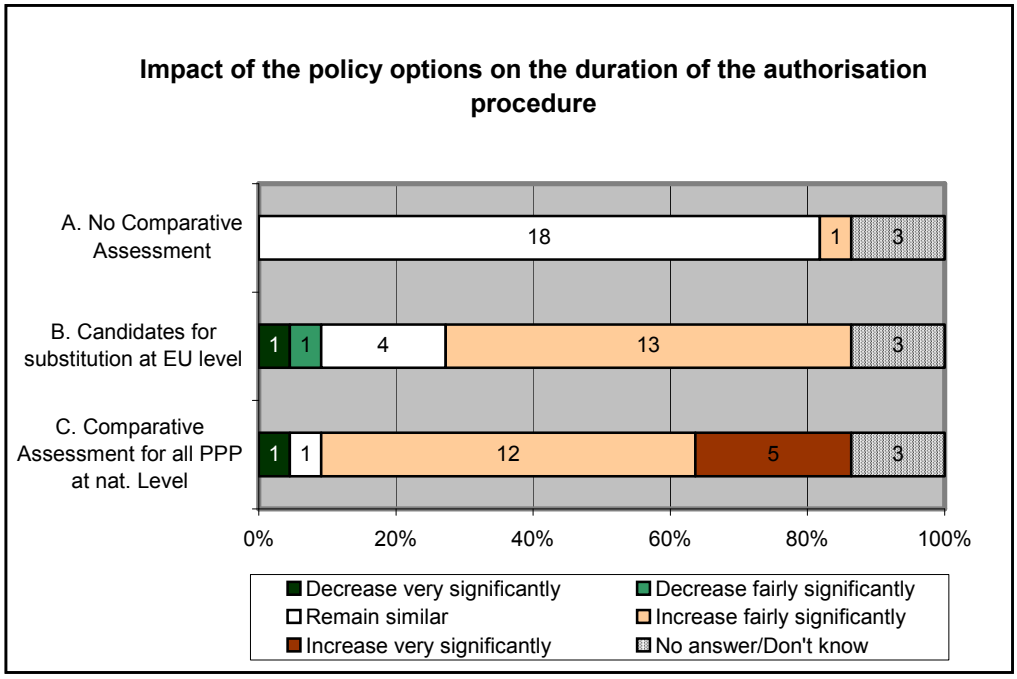


Source: FCEC

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 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

1.1.1.4. 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.

1.1.2. Social impacts

1.1.2.1. 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.

1.1.2.2. Impact on information opportunities of citizens

No impacts expected.

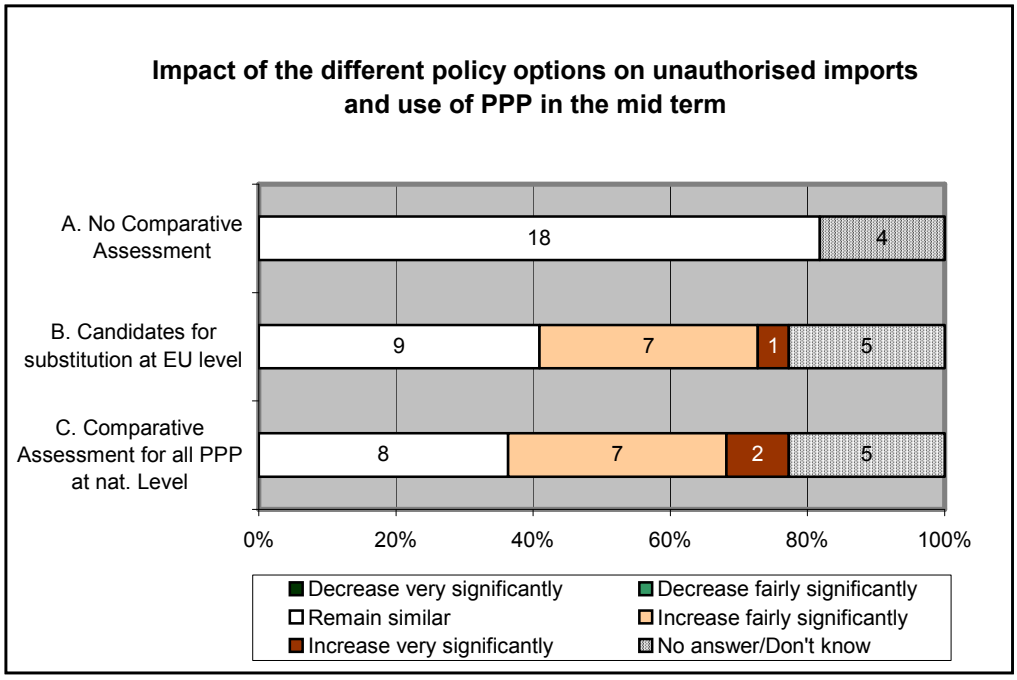
1.1.2.3. Impact on the duplication of studies on vertebrate animals

No impacts expected.

1.1.3. Environmental impacts

1.1.3.1. 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.

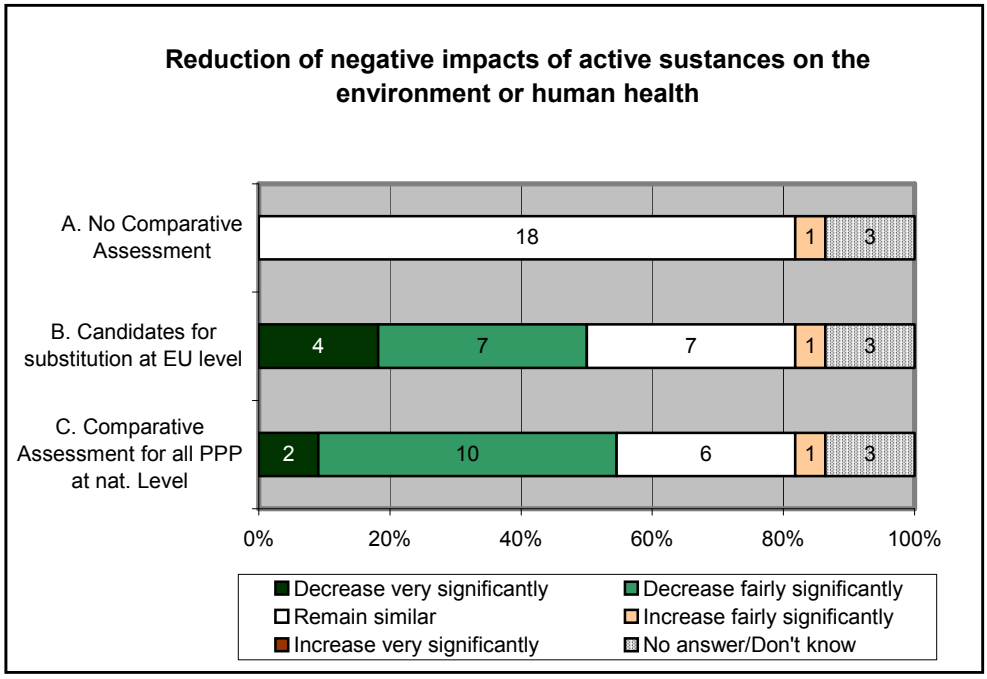
1.1.3.2. Impact of active substances on the environment or human health

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"[1].

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

[1] Interview Sandrup, Alarik, Lantbrukarnas Riksförbund (Federation of Swedish Farmers), January 2006 .

- 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 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.

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

++ = Very significant positive impacts

– – = Very significant negative impacts

+ = Significant positive impacts

– = Significant negative impacts

o = No change from the present situation

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

1.1.5. 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
Proportio-nality	• 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	• 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	• 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	• 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	• 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

1.1.6. 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).