COMMISSION OF THE EUROPEAN COMMUNITIES

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

COMMISSION STAFF WORKING DOCUMENT

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

Annex 2, part 2

{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

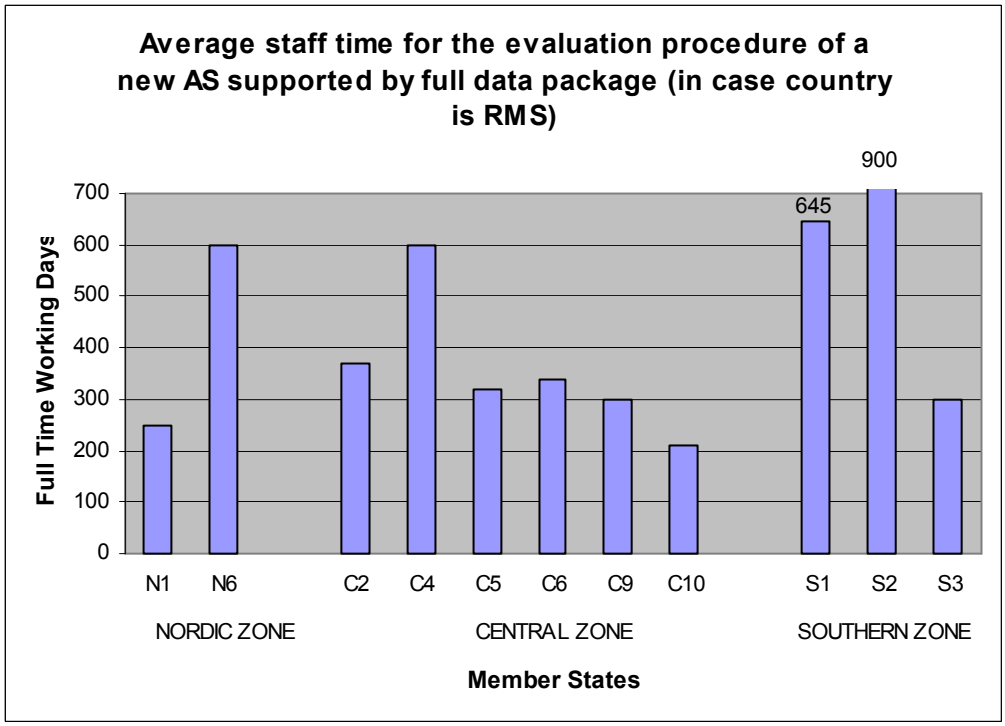
1. IMPACT ASSESSMENT OF POLICY OPTIONS

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

1.1.1. Economic impacts

1.1.1.1. Impacts on administrative burden

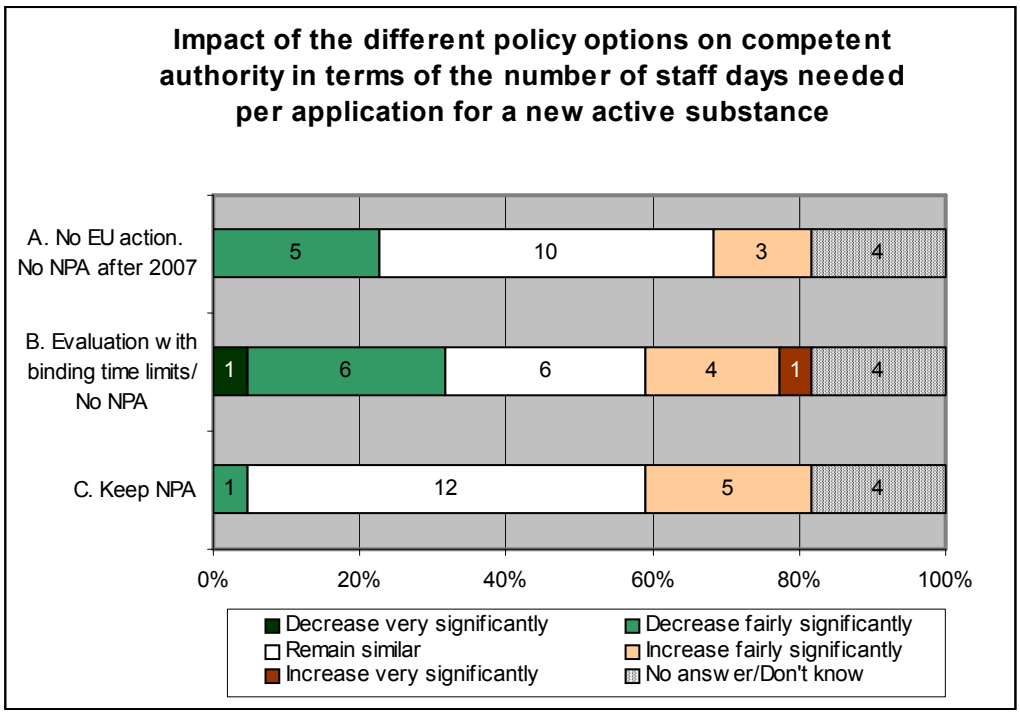
The administrative burden related to the options described in section 5.1 mainly results from the number of authorisation procedures performed for launching a PPP with a new active substance in different Member States and the size and degree of similarity of the dossiers to be delivered by the applicant 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.[1] An overview is given in the graph below:



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

[1] 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.

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:



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.

1.1.1.2. 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.

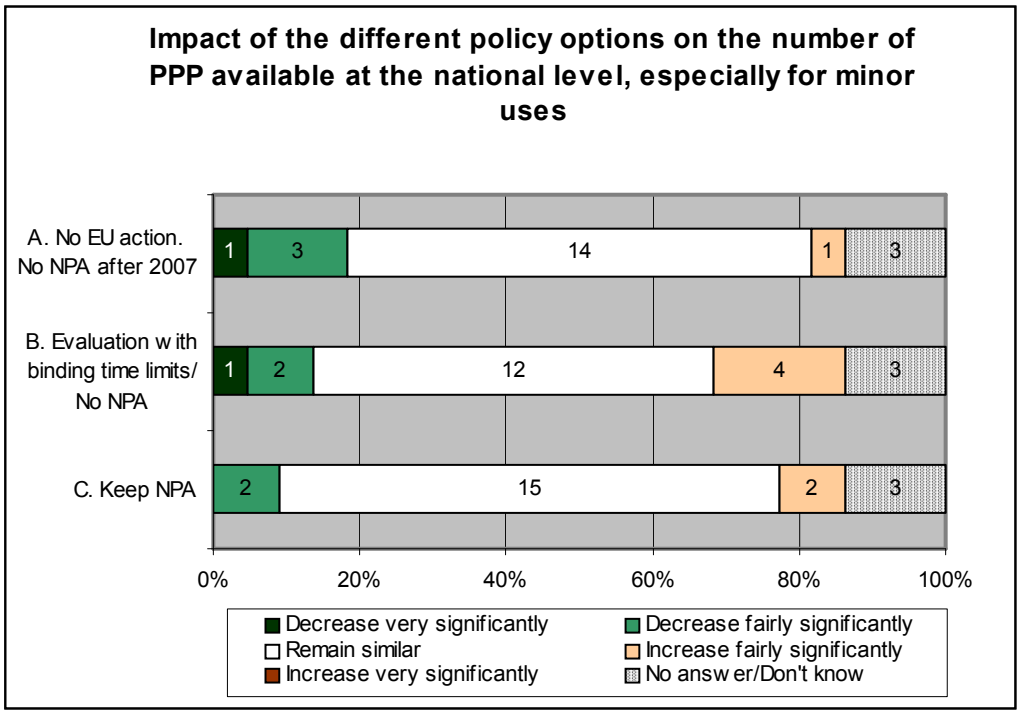
Several stakeholders argued that one or more of these factors would affect farmers. For example, COCERAL stated that "most of the traders support option B as it would increase the number of PPPs available". The Central Union of Agricultural Producers and Forest Owners, Finland expressed a similar position: "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 PPP's 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 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:



Source: Survey of competent authorities

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.

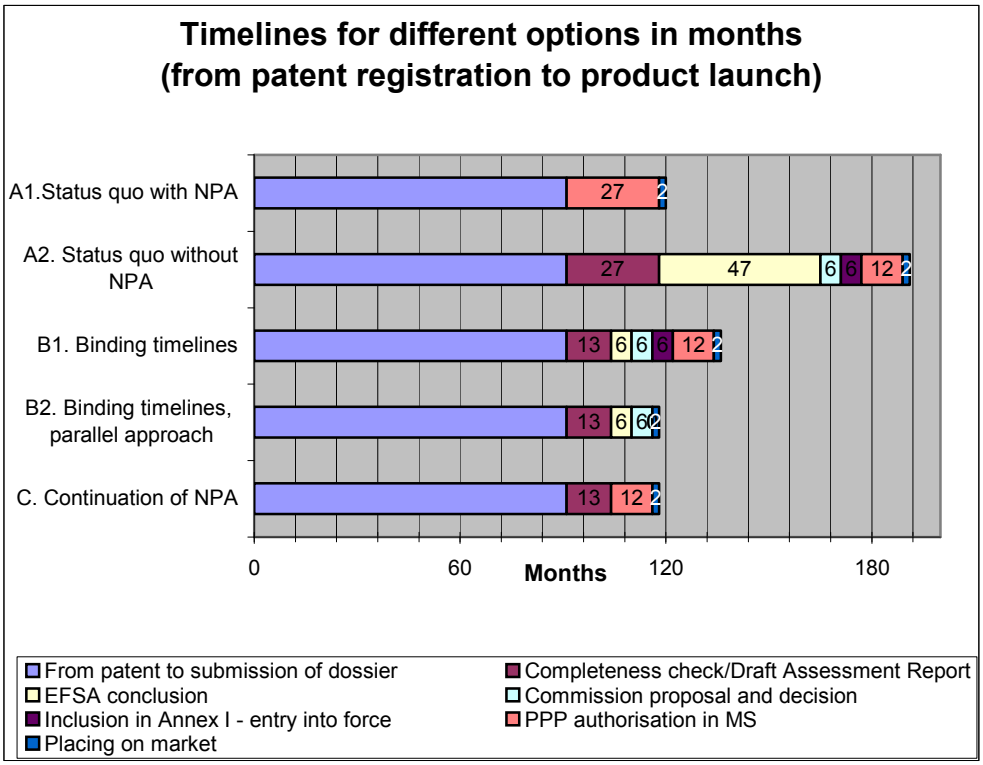
Based on this analysis several conclusions can be drawn:

- Option A1 (the current situation, reference scenario) is not expected to lead to any negative or positive impact;[2]
- 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.

1.1.1.3. 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:

[2] 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)

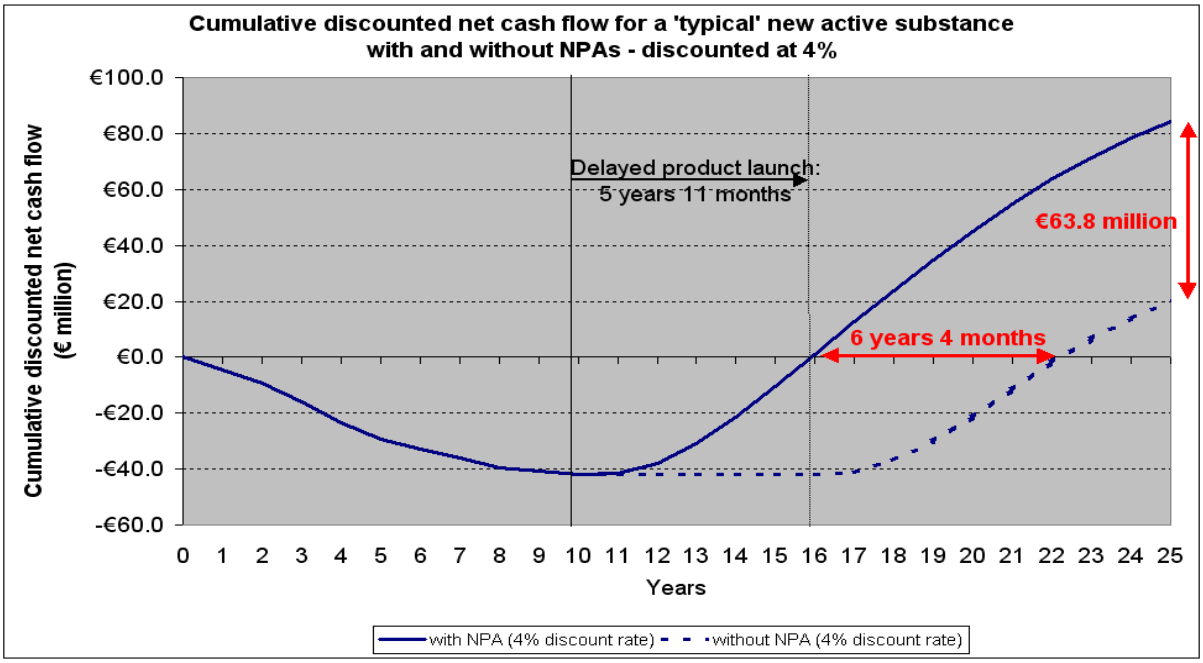


Source: FCEC

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 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.[3]

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

[3] 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.



Source: FCEC

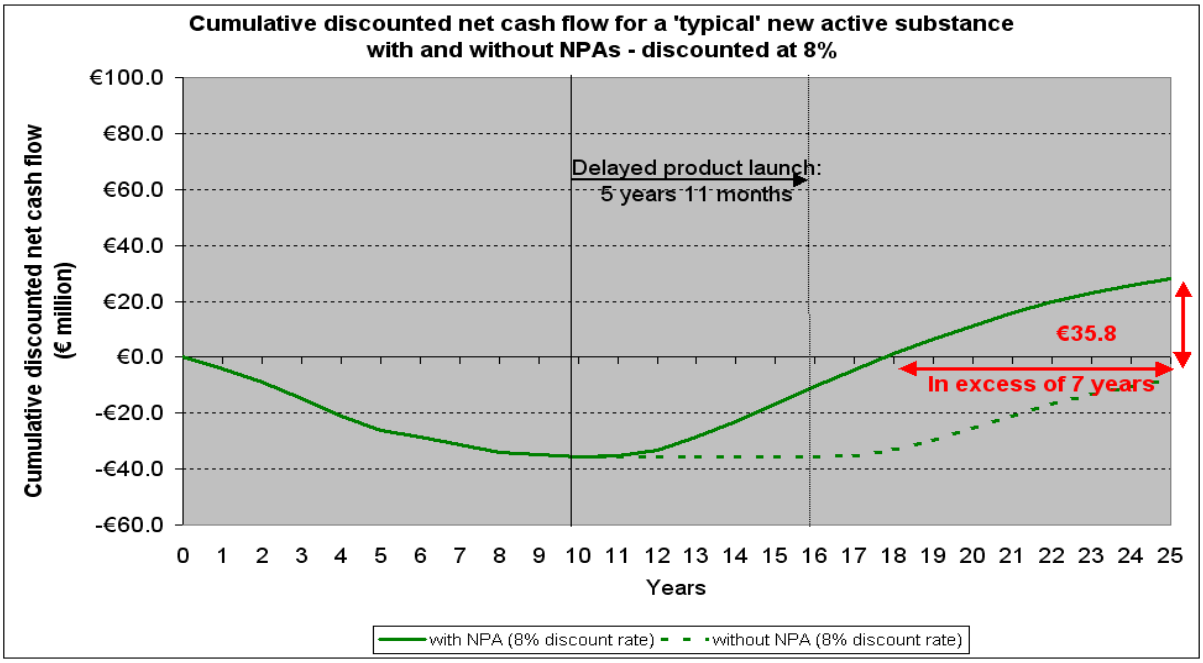
Table 13: Model results: Policy action 1, option A - status quo compared to a system without binding time limits and no NPA after 2007 – discounted at 4%

	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 12.7 years;
- IRR falls by a half from 12.7% to 6.4%.

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

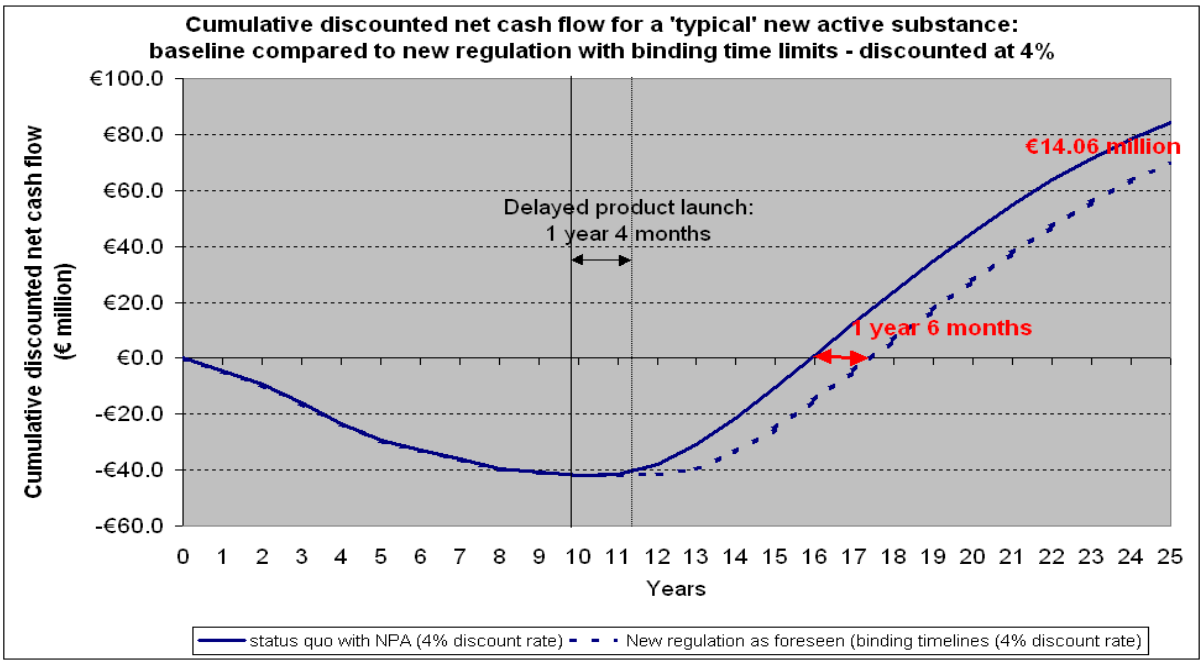
Table 14: Model results: Policy action 1, option A - status quo compared to a system without binding time limits and no NPA after 2007 – discounted at 8%

	Status quo With NPA	**Status quo Without NPA**
NPV (€ million)	€27.9	-€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:



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%

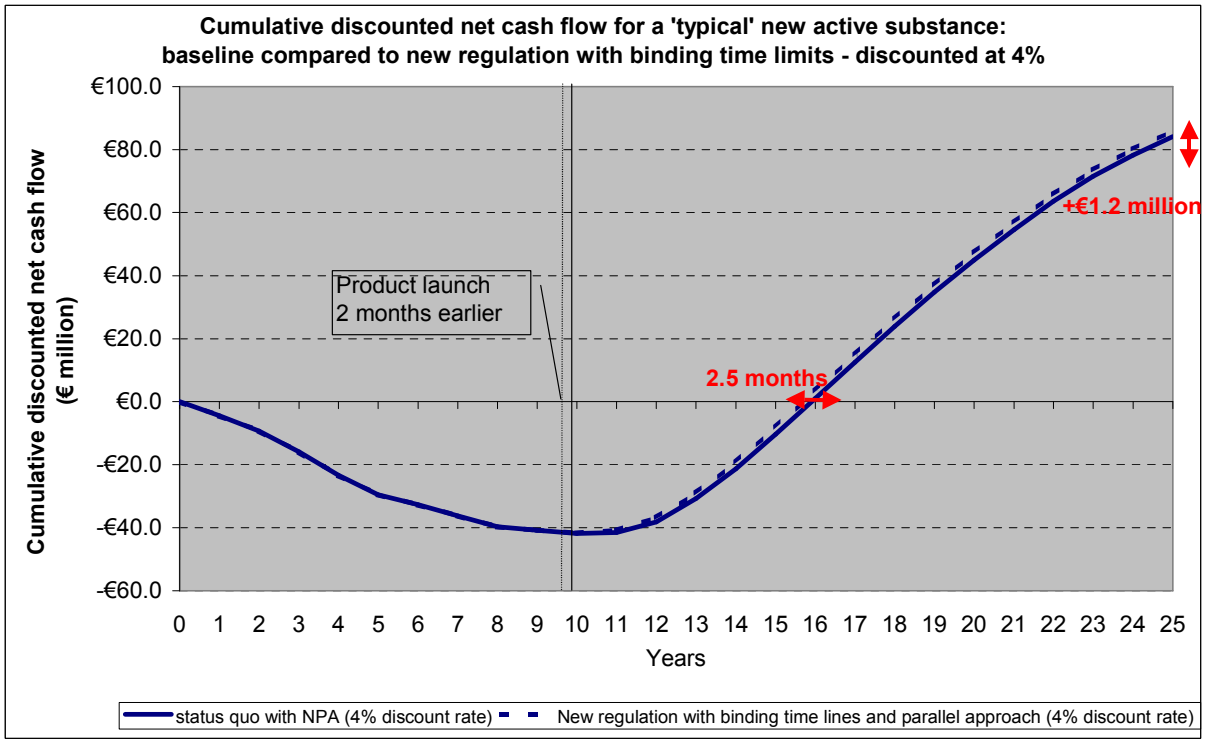
In essence, for a 'typical' active substance over a 25 year investment period, if there was no NPA after 2007 but *with* binding time limits, then under the assumptions of the model:

- 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 months[4] compared to the status quo (baseline scenario).

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 €84.2 million to €86.1 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

[4] Time limits as foreseen, product launch after Annex I inclusion.

attractiveness of new product (active substance) development is not adversely affected (even when using higher discount rates).

1.1.1.4. 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.

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 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.

1.1.2.2. Impact on information opportunities of citizens

No impact is expected under the different options.

1.1.2.3. Impact on the duplication of studies on vertebrate animals

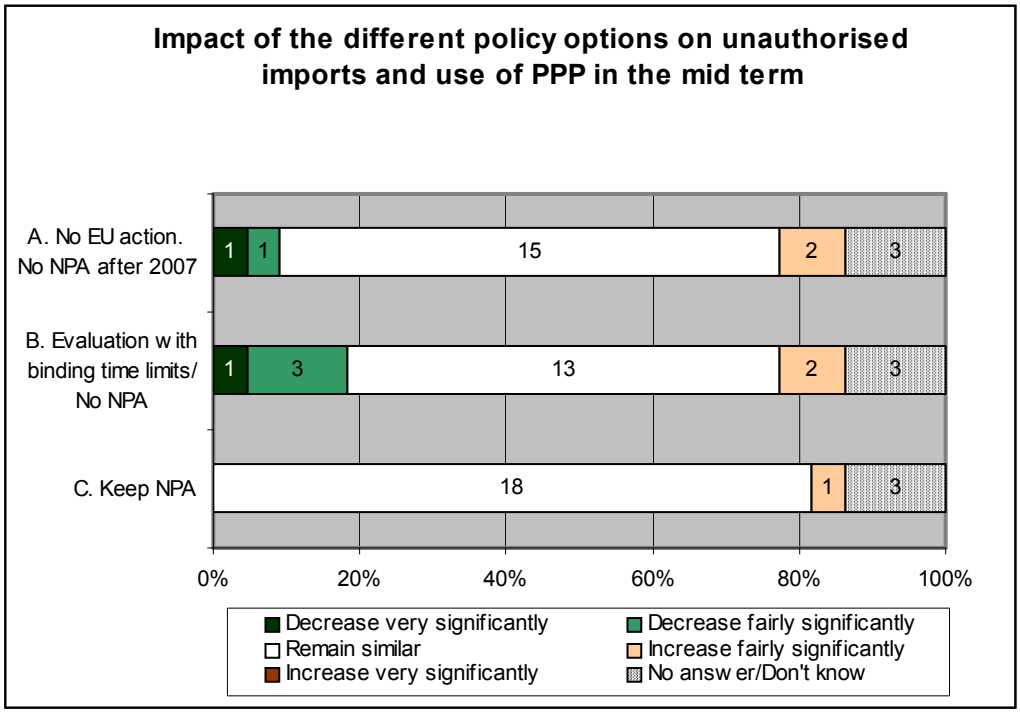
No impact is expected under the options compared to the status quo. All options refer to PPP containing new active substances, for which usually only one applicant submits dossiers, so that a duplication of vertebrate testing is not expected. The extent of vertebrate testing for the production of the 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."

1.1.3. Environmental impacts

1.1.3.1. 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:



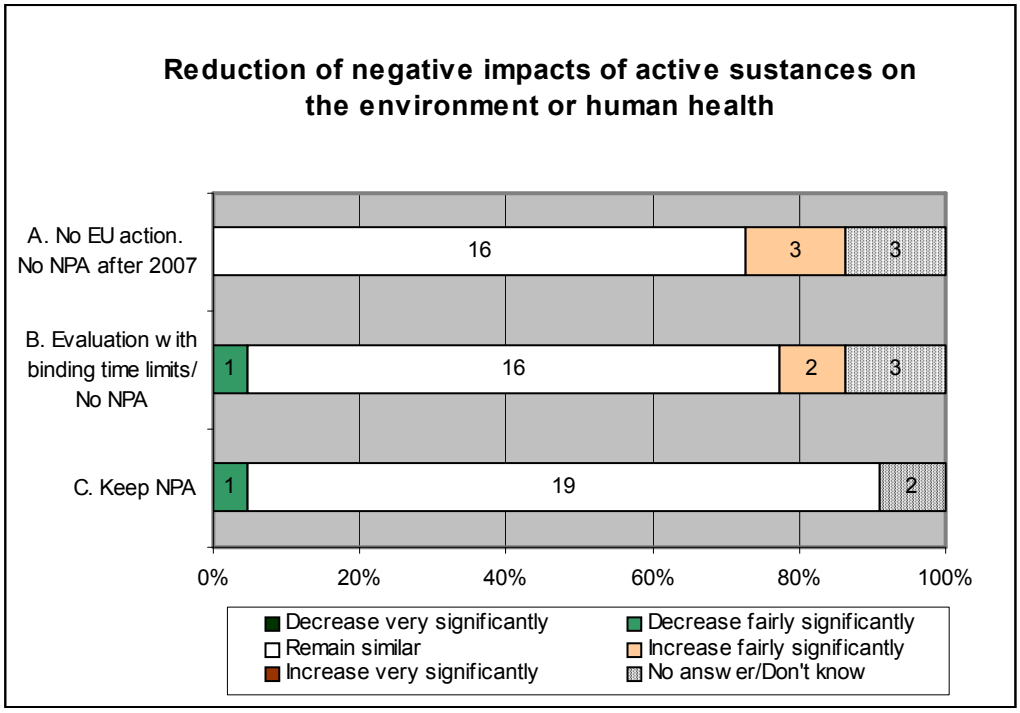
Source: Survey of competent authorities

1.1.3.2. 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.[5]

[5] 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

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:



Source: Survey of competent authorities

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

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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.

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.

1.1.4. 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:

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**
Description of option	Status quo - without binding time limits. No NPA after 2007		With binding time limits. ** No NPA		Keep NPA after DAR
	A1 current	**A2** after 2007	**B1** sequential	**B2** parallel	

Economic impacts					
Impact on administrative burden	o	+ (may increase coordination efforts)	++	++	o
Impact on indirect costs for PPP users	o	(–)*	(o)* (minor negative impacts possible)	o	o (may contribute to fragmented market)
Impact on investment of 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 (slight reduction possible)	o (slight reduction possible)	o
Impact of AS on environment or human health	o	o (minor impacts possible)	o (minor impacts possible)	o (minor impacts possible)	o (minor impacts possible)

++ = Very significant positive impacts

–– = Very significant negative impacts

+ = Significant positive impacts

– = Significant negative impacts

o = No change from the present situation

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

1.1.5. 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 - without binding time limits. No NPA after 2007	With binding time limits. No NPA	Keep NPA after Draft Assessment Report
Proportio-nality	• 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	• 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	• 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	• 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	• 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	• Limited added value of EU action, as current duplication of administrative efforts continues

1.1.6. 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.";

- 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.