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ANNEX 2 PART 3

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

Annex 2, part 3

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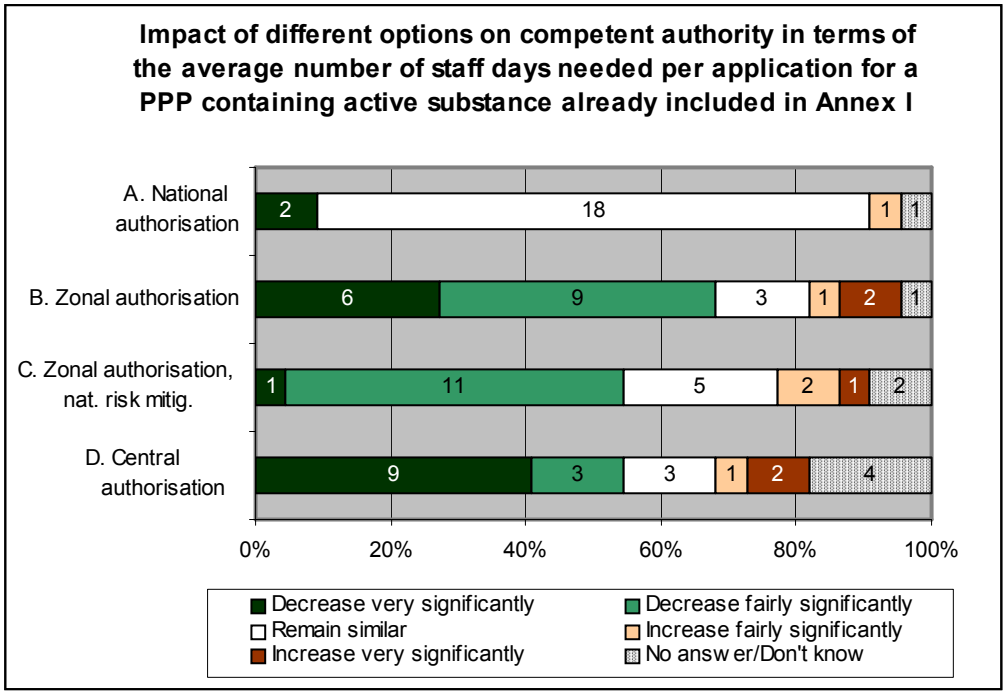
1.1. Assessment of policy action 2: Mutual recognition of PPP containing an active substance already included in Annex I

1.1.1. Economic impacts

1.1.1.1. Impacts on administrative burden

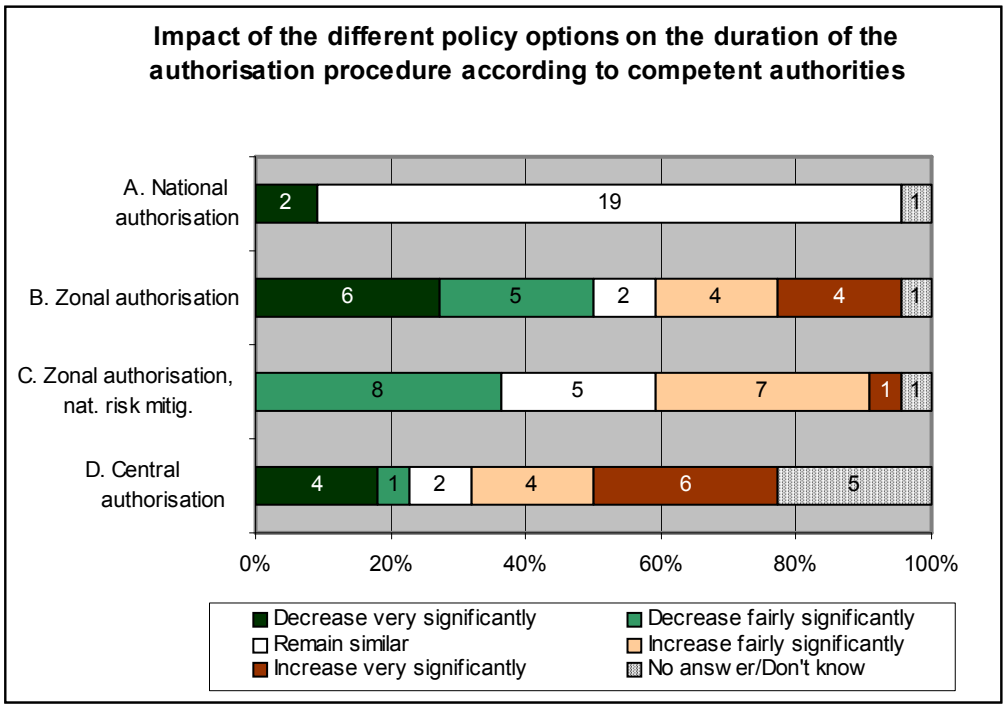
The options described in section 5.2 are aimed at reducing the duplication of efforts for authorising similar PPP in different Member States. According to a large majority of competent authorities all options other than the Status Quo would imply a reduction of at least 10% to 25% in terms of the *average*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



Source: Survey of competent authorities

The largest number of competent authorities expecting a reduction of administrative effort was registered with option B, where 15 authorities expected a reduction of at least 10-25% of staff input. This figure was slightly lower with option C. This option means a higher workload for national authorities than option B because of national risk mitigation measures. During the interviews with the authorities, however, it was confirmed that even a mutual recognition of a PPP with national risk mitigation measures would imply a significant reduction of administrative effort compared to evaluating a full dossier for a PPP. With option D, the central authorisation of PPP through a central agency for evaluation and authorisation of PPP with use of MS resources, 9 competent authorities would expect a reduction of staff input of more than 25%, a very significant decrease.

No consensus was found among competent authorities, however, whether or not the options would lead to a significant reduction in the duration of the authorisation procedure compared to the status quo. Eleven of the competent authorities expect a reduction of the duration with option B, whereas 8 expect an increase. With option C opinion is nearly evenly split, and with option D (central authorisation) most but not all authorities expect a longer duration of the PPP authorisation procedure. This is illustrated in the graph below:



Source: Survey of competent authorities

The diverging views of authorities on the impact of the options on the duration of PPP authorisation procedures could be interpreted that making a well founded prognosis is difficult and a system of zonal authorisation with compulsory mutual recognition is perceived as carrying a risk of delays, and even more so with central authorisation.

ECPA voiced strong concerns in this respect, bringing forward the following view: "Compulsory mutual recognition is a recipe for failure and will lead to blockage within zones. (...) Option A will likely be the fastest. Options B, C and D will likely result in blocking authorizations in other MS than [the designated Member State] because they are based on compulsory mutual recognition (B and C) or a likely poorly resourced central system (D)"[1]. Does this argument hold? Currently three Member States apply mutual recognition to a significant extent, one country even to hundred percent. An interview with one of these states did not indicate any significant problems with respect to the duration of the mutual recognition procedure. Also, all three Member States having this experience did not expect a longer duration of the authorisation with options B and C. Rather, they expected these options to lead to a similar duration or even a reduction of the duration of the authorisation procedure compared to the current situation. It may also be noted that the assessment of industry associations other than ECPA differed significantly, with ECCA expecting lower costs under

[1] ECPA questionnaire.

option D, and the Coalition of smaller research-based PPP companies[2] assessing options C or D as the "quickest option".

This leads to the following conclusions:

- Option A, the continuation of the status quo would mean the continuation of the current duplication of administrative efforts for competent authorities and industry (dossier has to be translated, re-formatted and partly extended), if the low rate of mutual recognition continues. However, there seems to be a (limited) trend towards more application of mutual recognition;
- Option B, the zonal authorisation of PPP without national risk mitigation measures can be expected to lead to a significant reduction of administrative burden for national authorities. Also, some dossier costs for industry could be reduced compared to the status quo;
- Option C, the zonal authorisation of PPP with national risk mitigation measures, could still be expected to lead to a significant reduction of administrative burden for national authorities, however less than in options B and D. Also a reduction of dossier costs expected for industry is likely compared to status quo (however less than in options B and D, as additional national requirements may have to be addressed);
- Option D, a central agency for evaluation and authorisation would most likely lead to a significant reduction of administrative burden for national authorities and a significant reduction of dossier costs for industry, as only one dossier for authorisation would have to be provided and a separate mutual recognition procedure would not be required.

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

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

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

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

However, according to the second argument precisely the opposite would be the case, with optional mutual recognition (options B and C) leading to an increased availability of PPP,

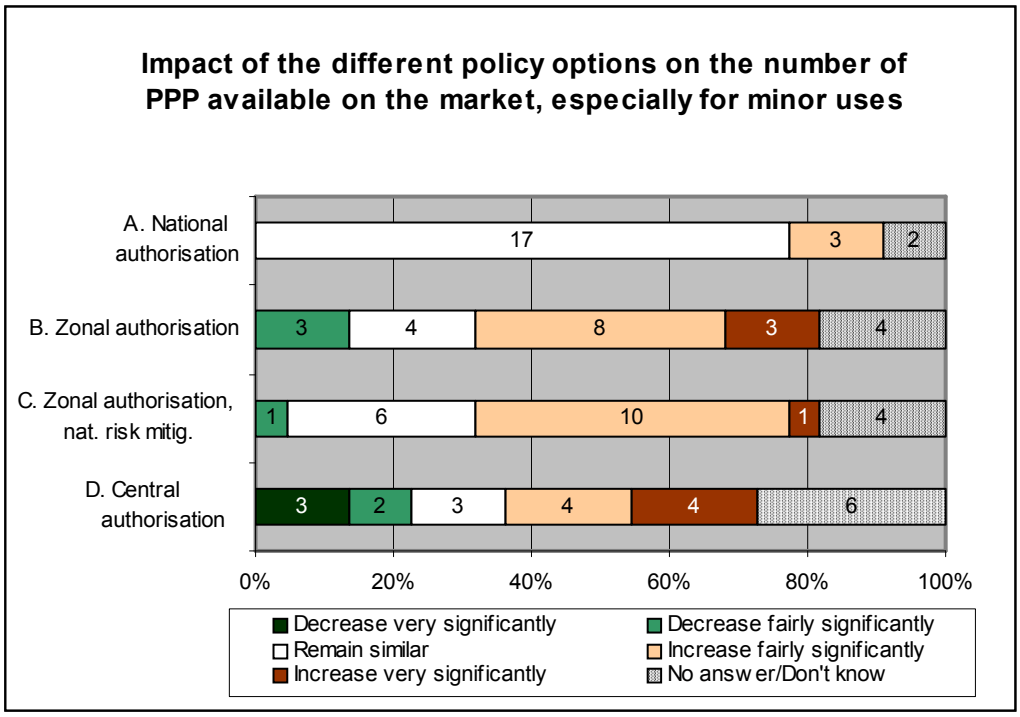
[2] Consisting of Chemtura , Gowan, ISK, Japan Agro Services, Stahler, Taminco, Isagro.

especially for minor uses. This view was shared, for example, by the Central Union of Agricultural Producers and Forest Owners (Finland), the Agricultural Industries Confederation (UK), APCA and FNSEA (France), and Coordinadora de Organizaciones de Agricultores y Ganaderos – Iniciativa Rural (Spain). The Coalition of smaller research-based PPP companies also argued: "A rationalised system with mutual recognition and adapted fees for national registration would be beneficial for minor uses in general. However it should also be taken into account that some minor uses are country specific and in that case there would be no difference. If only relevant for one country, the investment could be too big, unless facilities would be granted like a reduced number of efficacy and residue trials (minor crops already have a lower number of residue trials than major crops, but more extrapolation possibilities etc.). It seems more difficult for a centralised system to recognise (local) minor uses."

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

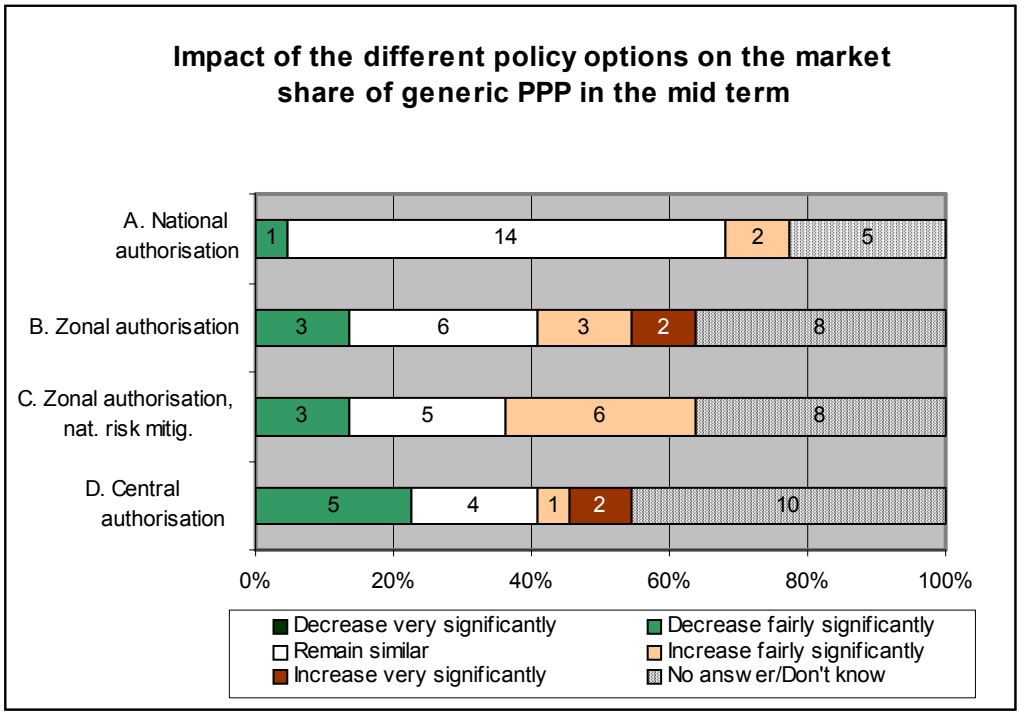
From an analytical point of view it can be expected that compulsory mutual recognition as foreseen in options B and C will increase the number of PPP on the market compared to the current situation, *at least in the smaller markets*. Presently the markets in a zone are not homogenous and larger markets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

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



Source: Survey of competent authorities

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



Source: Survey of competent authorities

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

Several conclusions can be drawn:

- Option A (the current situation, national authorisation) is not expected to lead to any negative or positive impact on availability of PPP, especially for minor uses, and consequently on indirect costs to farmers[3];
- Option B and C can be expected to increase availability of PPP for minor uses especially in smaller markets, depending on the willingness of the PPP industry to apply for mutual recognition. Farmers see an increased availability of PPP for minor uses as beneficial, e.g. in terms of being able to cultivate minor crops or even starting the cultivation of these crops. A larger availability of PPP could in some areas also lead to increased competition, implying a reduction of product prices;
- Option D can also be expected to increase availability of PPP for minor uses especially in smaller markets, without the need that PPP industry applies for mutual

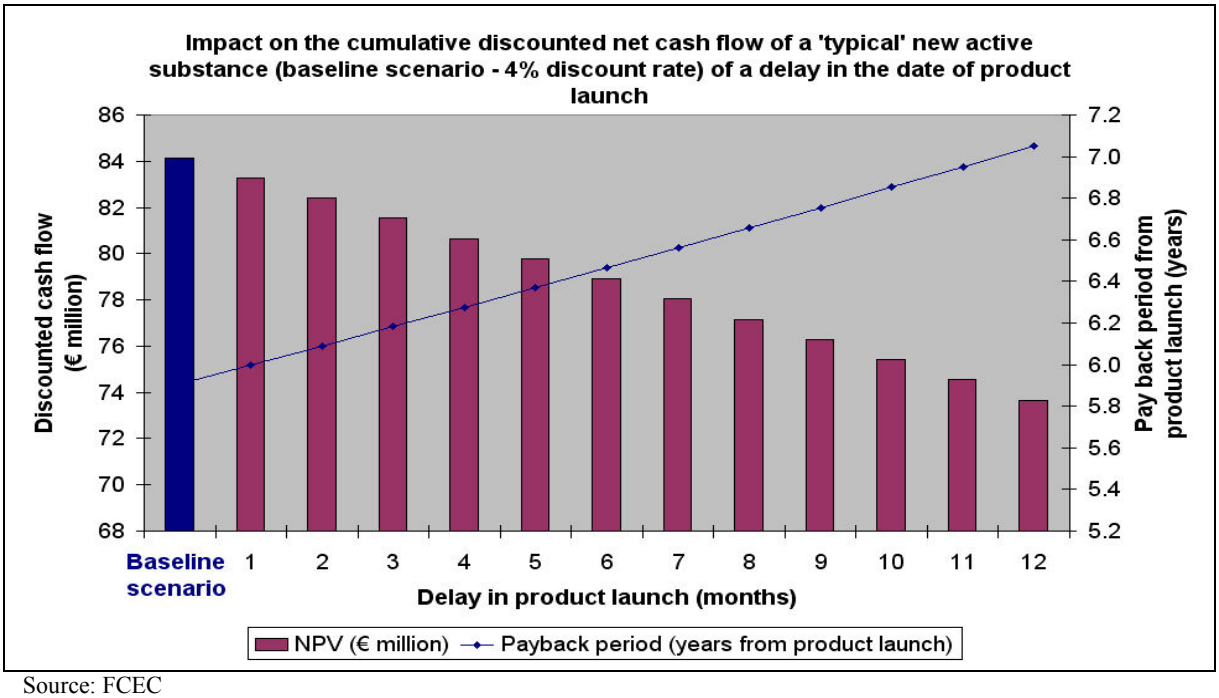
[3] Possible price effects caused by the reduction of the market share of generic PPP after Annex I inclusion of the active substance are discussed in the context of policy action 4 (data protection).

recognition. However, the actual number of authorisations would depend on the financial and staff resources provided to a central agency for PPP authorisation as well as the approach taken for authorisation.

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

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

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



Source: FCEC

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

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

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

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

Given the uncertainty surrounding the impact that mutual recognition would have on the duration of authorisation, conclusive statements concerning the impact of each option on the economics and attractiveness of new product (active substance) development cannot be made. Any delay would adversely affect the economics and attractiveness of new product development, although shorter delays would minimise the likely impact on NPV, pay back period and IRR. That said, if mutual recognition results in decreasing the duration of authorisation and products can be marketed earlier, then the likely impact on NPV, pay back period and IRR would be positive.

1.1.1.4. Impact on EU PPP industry competitiveness

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

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

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

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

- A concern rather specific to generics manufacturers is that zone wide authorisations and mutual recognition are not sufficient conditions to open the PPP market, as the administrative burden will still be much higher than with a central authorisation.

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

This leads to the following conclusions:

- Option A (National evaluation and authorisation) is costly and complex, but flexible. It minimises risks for market size reduction through uniform application rates;

- Option B (Zonal authorisation – no national risk mitigation measures) is a rather simple approach (no additional infrastructure necessary) and lowers barriers to entry, as administrative efforts are reduced for applicants that want to reach an authorisation in several Member States (depending on the practical implementation). A market size reduction is likely if lower application rate (according to most vulnerable environment) is applied throughout entire zone;

- Option C (Zonal authorisation – with national risk mitigation measures) may also lead to a market size reduction, but less so than under option B (at a cost of added complexity);

- Option D (Central agency for evaluation and authorisation) requires significant resources at EU level. It can be expected to have the same impacts as option B, but on a larger scale.

1.1.2. Social impacts

1.1.2.1. Impact on employment

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

1.1.2.2. Impact on information opportunities of citizens

No impact is expected under the different options.

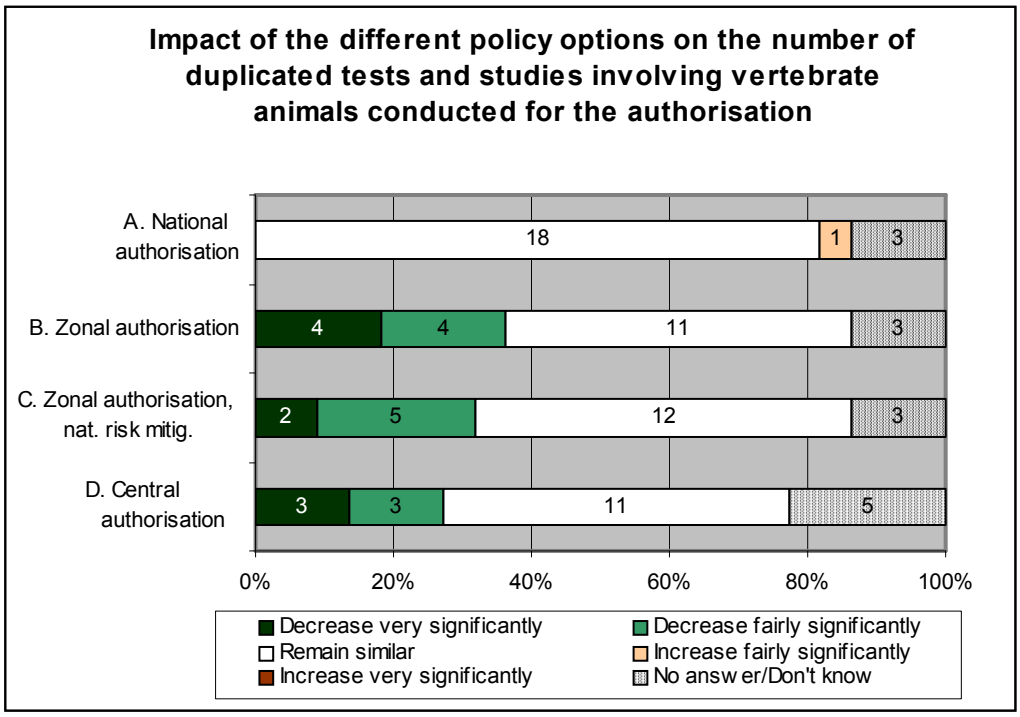
1.1.2.3. Impact on the duplication of studies on vertebrate animals

Under Directive 91/414 data sharing of vertebrate studies may be required by the Member States (Art. 13). Several Member States have introduced legislation in this effect, other Member States have not. This provision has led to different rules in Member States, which makes it difficult to assess the extent to which a duplication of vertebrate studies is actually taking place at present. Two cases have to be differentiated: a) The same company registers a similar product in different Member States. Then the company normally would use the same studies for all national dossiers, except in cases where differences in the national authorisation requirements would lead to the need to produce additional studies involving vertebrate animals; b) A generic company registers a product that has already been registered by another company. In this case the application of the national data protection/sharing rules would decide whether or not a duplication of a study involving vertebrate animals might occur.

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

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

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



Source: Survey of competent authorities

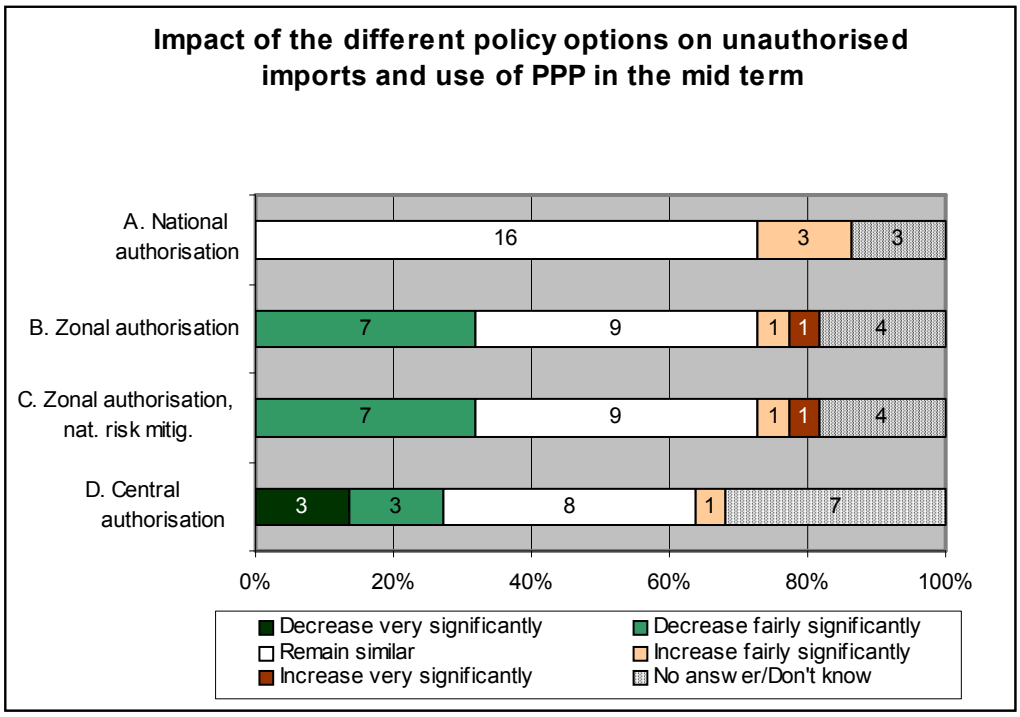
This leads to the following conclusion: Options B, C, D have the potential to reduce the number of duplicated studies involving testing on vertebrate animals depending on the degree to which national legislation does not prevent this to happen currently and industry actually duplicates such tests – an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

1.1.3. Environmental impacts

1.1.3.1. Impact on unauthorised cross-border sourcing of PPP

Both zonal authorisation with compulsory mutual recognition (options B and C) and central authorisation (option D) will by definition lead the more homogenous national markets. This is valid for the respective zones to the degree that industry uses this possibility and applies for mutual recognition in all member states of a zone. A centralised system will clearly lead to more homogenous national markets (see also discussion in section *Impact on indirect costs for PPP users,* above).

A more homogenous market will reduce incentives for unauthorised cross-border sourcing of PPP, but only to the extent that price differences are also reduced. As the existing differences in VAT are one of the relevant factors, this is far from being definitive. Also, illegal imports from third countries may still be a problem especially for active substances that are not included in Annex I. This reduces likely possible impacts on unauthorised cross-border sourcing of PPP under options B, C and D. The assessment of the competent authorities is presented in the following graph. A majority of authorities does not expect a change, however a strong minority of 6 to 7 authorities is of the opinion that all "new" options will indeed reduce unauthorised cross-border sourcing of PPP.



Source: Survey of competent authorities

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

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

a. The impact the options have on unauthorised cross-border sourcing of PPP, which is a potential risk to environment and human health;

b. The impact the options have on the time to market for new active substances that may have fewer impacts on the environment;

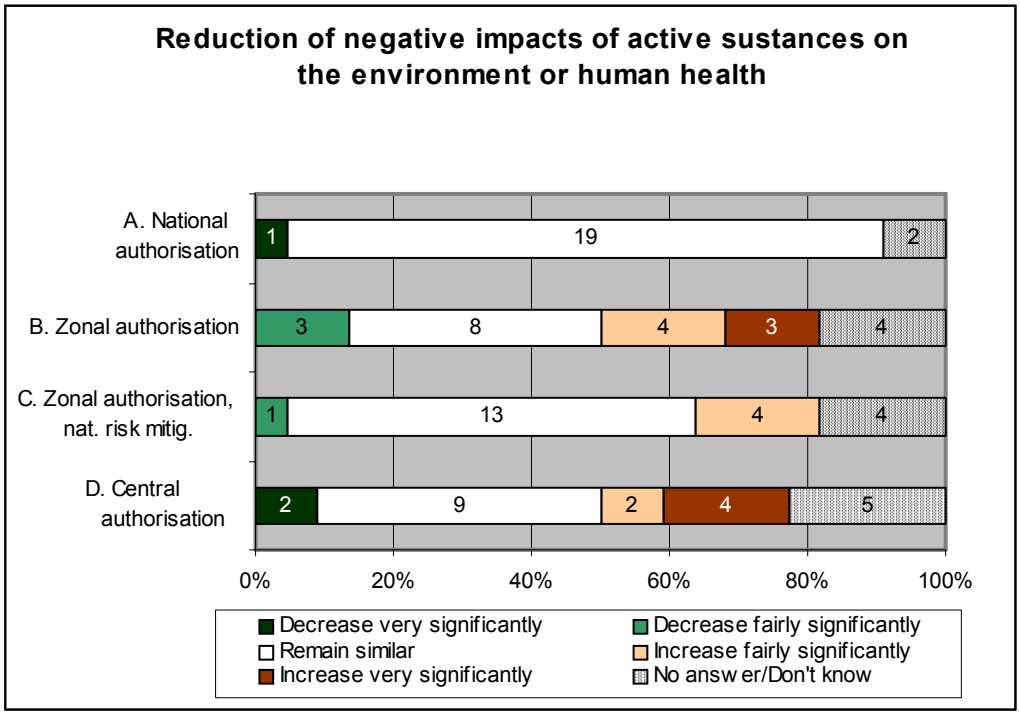
c. The impact the options have on the way national (or regional) environmental conditions are taken into account during the authorisation.

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

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

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

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



Source: Survey of competent authorities

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

- Option A (National evaluation and authorisation) makes it much easier to take into account varying environmental conditions. However, the status quo will contribute to continuing incentives for unauthorised cross-border sourcing of PPP with the related potential risks;
- With option B (the zonal approach without national risk mitigation measures) some negative impacts may be expected because of the difficulty for one authority to take into account all environmental/climatic conditions in a zone. The risk of "zonal averaging" that does not take into account vulnerable hydrological and soil conditions cannot be ruled out. However, more homogenous markets in a zone would lead to fewer incentives for unauthorised cross-border sourcing of PPP with the related potential risks;
- Option C (the zonal approach with national risk mitigation measures) will make it easier to take into account variations in environmental conditions. At the same time, more homogenous markets in a zone would lead to fewer incentives for unauthorised cross-border sourcing of PPP with the related potential risks;
- With option D (the central agency for evaluation and authorisation) some negative impacts may be expected because of the difficulty for the agency to take into account all environmental/climatic conditions in a zone. However, more homogenous markets in a zone would lead to fewer incentives for unauthorised cross-border sourcing of PPP with the related potential risks (even more than in options B and C)[4].

[4] It should be noted that in theory option D could also be combined with national risk mitigation measures, which would lead to a similar assessment as in option C.

1.1.4. Summary

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

Table 19: Summary of impacts of alternative options for mutual recognition of PPP containing an active substance already included in Annex I

Type of impacts	Option A	Option B	Option C	Option D
Description of option	Status quo - National evaluation and authorisation	Zonal authorisation – no national risk mitigation measures	Zonal authorisation – with national risk mitigation measures	Central agency for evaluation and authorisation*
Economic impacts				
Impact on administrative burden	o	++	+	++
Impact on indirect costs for PPP users	o	+ (increased availability of PPP)	+ (increased availability of PPP)	+ (increased availability of PPP, depending on approach of agency)
Impact on investment of PPP producers in R&D	o	o (negative impact, if unclear procedures lead to delays)	o (negative impact, if unclear procedures lead to delays)	o
Impact on PPP industry competitiveness	o	o (minor impacts possible)	o (minor impacts possible)	+ (lower barriers to entry)
Social impacts				
Impact on employment	o	o	o	o
Impact on information opportunities	o	o	o	o
Impact on animal welfare	o	(+)**	(+)**	(+)**
Environmental impacts				
Impact on unauthorised cross-border sourcing of PPP	o	+ (more homogenous markets)	+ (more homogenous markets)	+ (more homogenous markets)
Impact of AS on environment or human health	o	– (difficulty to take into account all environ-mental conditions)	o	– (difficulty to take into account all environ-mental conditions)

++ = Very significant positive impacts

– – = Very significant negative impacts

+ = Significant positive impacts

– = Significant negative impacts

o = No change from the present situation

Notes: * Staff and financial resources provided to a central agency affects the assessment significantly. For this assessment it has been assumed that the agency would have access to adequate financial and staff resources. ** Assessment only provisional, as no reliable data exists on the extent to which vertebrate studies are duplicated at present.

1.1.5. Proportionality and added value of EU action

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

	Option A	**Option B**	**Option C**	**Option D**
Description of option	Status quo - National evaluation and authorisation	Zonal authorisation – no national risk mitigation measures	Zonal authorisation – with national risk mitigation measures	Central agency for evaluation and authorisation*
Proportio-nality	• This approach leaves the most room for national policies on PPP use • However, also implies significant duplication of administrative efforts • Leads also to high entry barriers, especially for small PPP companies	• A zonal approach leaves existing infrastructure in place (national competent authorities remain at the core of the PPP evaluation process) • Reduces administrative burden and entry barriers, depending on implementation • May lead to negative environmental impacts, if "zonal averaging" would result	• A zonal approach leaves existing infrastructure in place (national competent authorities remain at the core of the PPP evaluation process) • Reduces administrative burden and entry barriers, depending on implementation • Prevents risk of "zonal averaging"	• A central agency would require substantial resources and would take over some functions of the existing infrastructure for PPP authorisation, similar to EMEA • Reduces administrative burden and entry barriers significantly • May lead to negative environmental impacts, if "EU averaging" would result
Added value of EU action	• No EU action	• Zonal system is only workable with EU coordination (and intervention, e.g. to reconcile diverging views of MS)	• Zonal system is only workable with EU coordination (and intervention, e.g. to reconcile diverging views of MS)	• In the long run the simplest solution, transparent with lower entry barriers

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

1.1.6. Potential for optimisation of options

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

1. The diverging views on the possible impacts of a zonal approach on the duration of the authorisation indicates the need to clarify procedural details for compulsory mutual recognition and related procedures, including the withdrawal of authorisation (relevant for options B and C);

2. Under options B and C as much parallel authorisation activities as possible could be done to speed up authorisation, similar to the parallel approach discussed in the context of policy action 1. For example, national authorities could already decide on national risk mitigation measures after the designated Member State provides a draft registration report, i.e. before the first authorisation of the product in the designated Member State;
3. One of the factors providing incentives for unauthorised cross-border sourcing of PPP are differences in VAT among Member States, reportedly of up to 17%. This is especially significant, as in some Member States not all farmers are required to apply formal financial bookkeeping but can deduct costs on a fixed rate basis, which means that the difference in taxes is net saving for a farmer involved in unauthorised cross-border sourcing of PPP. It is strongly recommended to harmonise VAT in the area of PPP to reduce incentives, as unauthorised cross-border sourcing of PPP constitutes a potential risk for the environment and human health.