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

Annex 2, part 6

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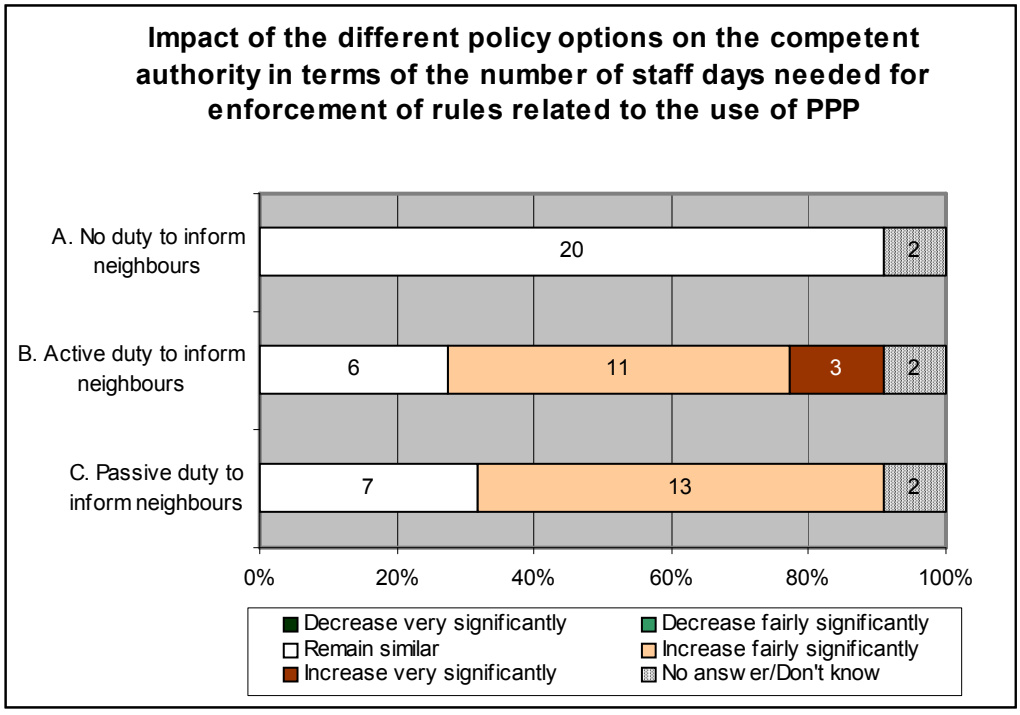
1.1. Assessment of Policy Action 5: Informing neighbours on PPP use

1.1.1. Economic impacts

1.1.1.1. Impacts on administrative burden

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

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



Source: Survey of competent authorities

It is obvious that this would depend on the extent to which the optional requirement would in fact be introduced during the authorisation process. In the interviews with competent authorities, the number of authorities supporting the measure was rather low and those who supported it mainly referred to the need to protect bee keepers from consequences of PPP use. One Member State, in which a provision similar to option B already exists supported the measure, also agreed that enforcing the rules involved some problems for the responsible authorities.

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

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

This leads to the following assessment:

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

1.1.1.2. Impact on indirect costs for PPP users

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

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

No impacts expected.

1.1.1.4. Impact on EU PPP industry competitiveness

No impacts expected.

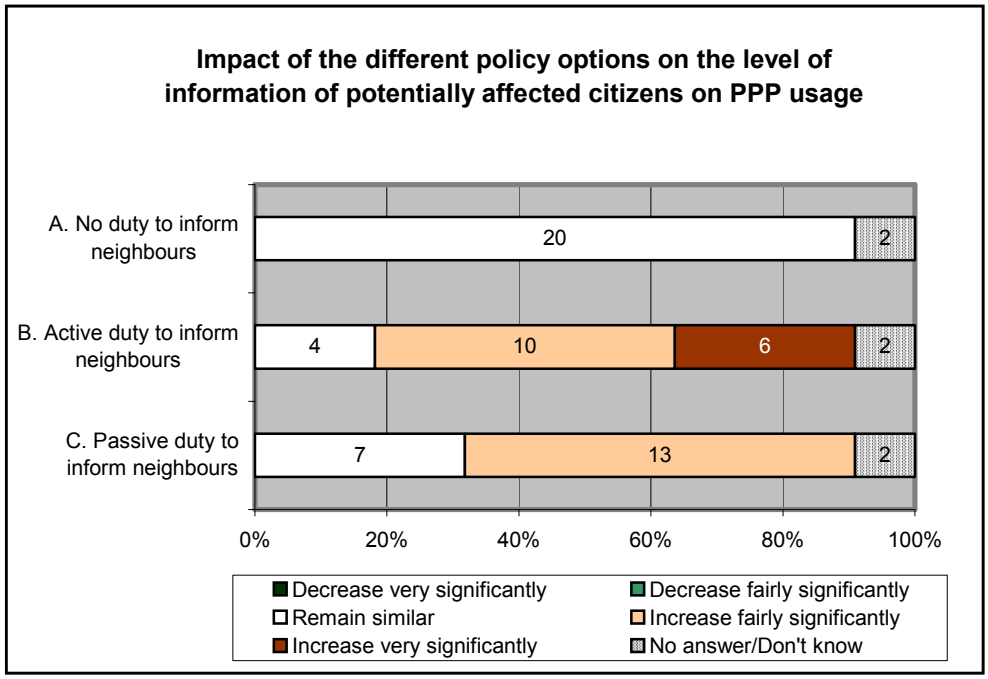
1.1.2. Social impacts

1.1.2.1. Impact on employment

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

1.1.2.2. Impact on information opportunities of citizens

By definition both options B and C will improve information opportunities of citizens. This is reflected in the assessment of most competent authorities. Option B was seen as being significantly more effective as option C by 6 competent authorities:



Source: Survey of competent authorities

It has to be pointed out that this assessment refers to the impact on information opportunities. It cannot be assessed at this stage how the information provided would affect the awareness of neighbours on PPP use. Several stakeholders were sceptical; the Coalition of smaller research-based PPP companies assumed the impact of this

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

1.1.2.3. Impact on animal welfare

No impacts expected

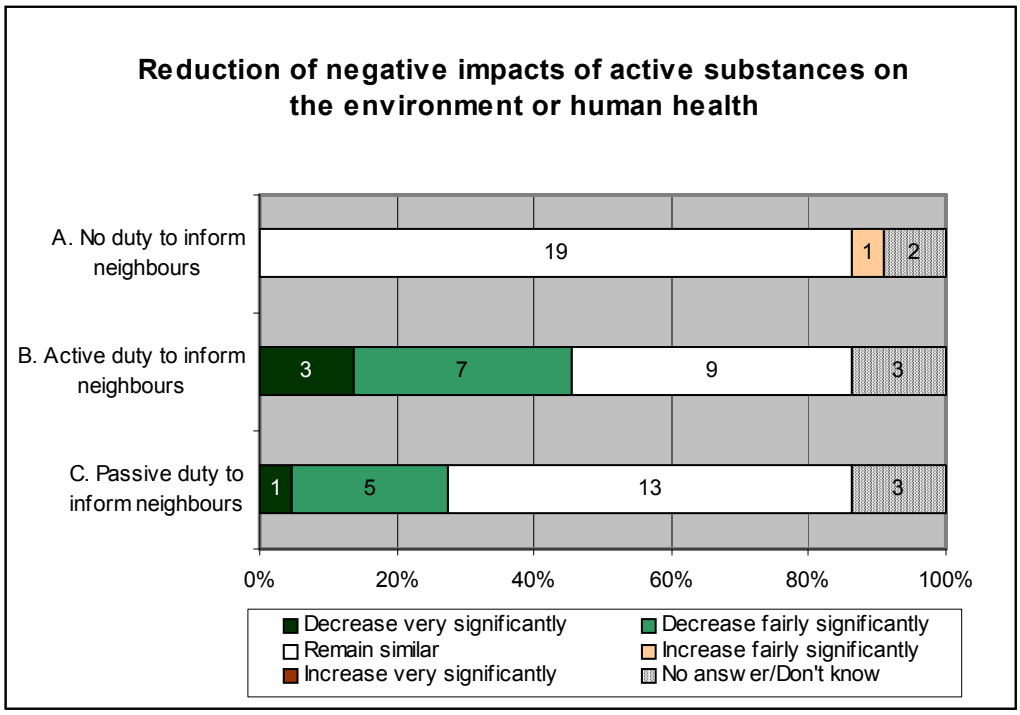
1.1.3. Environmental impacts

1.1.3.1. Impact on unauthorised cross-border sourcing of PPP

No impacts expected

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

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



Source: Survey of competent authorities

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

- Option A (Status quo – No duty to inform neighbours) does not lead to a reduction of impacts on the environment or human health;
- With option B (Active duty to inform neighbours) a reduction of negative impacts of active substances on environment or health is possible under two main scenarios:

  a) Preference of farmers for less toxic products, depending on 4 conditions; 1) application of this provision at national level during authorisation; 2) enforcement; 3) preference of farmers for "easier", less toxic products, where they do not have to inform neighbours, and 4) the environmental impacts of alternative products used;

  b) Activities of bystanders to avoid exposure to spray drift after prior notification.

  The extent to which this actually would happen cannot be assessed at this stage.
- Option C (Passive duty to inform neighbours) could lead to a reduction of negative impacts of active substances on environment or human health, depending on whether farmers would change type and application of PPP and adhere (more) to good agricultural practices because of increased accountability (mainly because of record keeping duty and transparency towards neighbours and authorities) and enforcement. The extent to which this actually would happen cannot be assessed at this stage.

1.1.4. Summary

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

Table 28: Summary of impacts of alternative options for informing neighbours on PPP use

Type of impacts	**Option A**	**Option B**	**Option C**
Description of option	Status quo – No duty to inform neighbours	Active duty to inform neighbours	Passive duty to inform neighbours
Economic impacts			
Impact on administrative burden	o	– (depending on implementation)	o (minor negative impacts possible)
Impact on indirect costs for PPP users	o	o	o
Impact on investment of PPP producers in R&D	o	o	o
Impact on PPP industry competitiveness	o	o	o
Social impacts			
Impact on employment	o	o	o
Impact on information opportunities	o	+	+
Impact on animal welfare	o	o	o
Environmental impacts			
Impact on unauthorised cross-border sourcing of PPP	o	o	o
Impact of AS on environment or human health	o	(+) (positive impacts possible, extent not possible to assess at this stage)	(+) (positive impacts possible, extent not possible to assess at this stage)

++ = Very significant positive impacts
+ = Significant positive impacts

o = No change from the present situation

1.1.5. Proportionality and added value of EU action

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

	Option A	Option B	Option C
Description of option	Status quo – No duty to inform neighbours	Active duty to inform neighbours	Passive duty to inform neighbours
Proportio-nality	• No EU intervention and no additional administrative burden • Only information on PPP use provided voluntarily by farmers available to neighbours, water industry, scientists, etc.	• Increased information opportunities for neighbours, water industry, scientists, etc. • However, this is likely to cause significant additional administrative burden for farmers and authorities (enforcement)	• Increased information opportunities for neighbours, water industry, scientists, etc. • Only limited additional administrative burden for farmers and authorities, as record keeping is already required by other provisions
Added value of EU action	• None	• Increased information opportunities	• Increased information opportunities

1.1.6. Potential for optimisation of options

Policy action 5 regarding alternative options for informing neighbours on PPP use raises concerns with respect to the objectives of the intervention:

- If the aim is to raise public awareness for use of toxic PPP, then option B might be the most effective. However, questions have been raised as to what the public will do with this information, what mechanisms for action are possible, and if it is possible to request of farmers a delay of spraying and use of alternative PPP;
- If the aim is to reduce the use of toxic PPP, comparative assessment and substitution performed during the authorisation process (policy action 3) may be a better tool;
- If the aim is to increase the transparency of PPP use and accountability of farmers in general, option C seems to be adequate. Implementation details will need to be determined as to who should have access to farmers' records.

To optimise the options it is recommended to clarify the objectives and the related concerns raised above. This discussion could take place in a general discussion on the transparency of PPP authorisation and use. According to several stakeholders, there is a need for a general approach on transparency in PPP authorisation and use:

- *Authorisation:* One competent authority that was reportedly already implementing this approach proposed "no authorisation without motivation", in other words no authorisation decisions without a detailed report published on the website of the authority on the basis for the decision. Other elements of a general approach on transparency could include a more transparent evaluation process, a structured inclusion of stakeholder comments in the process, etc.;
- *Use:* This could include record keeping for all PPP used and possibly a duty to inform neighbours and relevant third parties, e.g. drinking water suppliers,

researchers (options B or C discussed above) and/or other measures to enhance transparency in PPP use, depending on the objectives of the intervention.

2. MONITORING AND EVALUATION

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

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

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

The indicators to be selected for the monitoring of the new legislation should provide a clear analytical tool to assess to what extent a policy action is properly implemented and whether policy objectives (detailed in section 4 of this report) are being achieved[1]. To reach this aim, indicators have to be:

- Relevant, i.e. closely linked to the problem identified / the objectives to be reached;
- Accepted (e.g. by stakeholders);
- Credible for non experts, unambiguous and easy to interpret;
- Easy to monitor (e.g. data collection should be possible at low cost);
- Robust against manipulation[2].

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

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

The table on the following page presents possible indicators to be considered to monitor a new Regulation on PPP authorisation. Please note that a regular evaluation will need the collection of baseline data that is not available at present, as well as the development of adequate methodological tools.

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

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

	Number of full time equivalent staff days used in MS per PPP authorisation for comparative assessment (only relevant if comp. assessment is applied)	Member States	Aim is to reach an efficient comparative assessment procedure. A high number of staff days used for comparative assessment would indicate that more guidance is needed or criteria / procedure could be changed.
Reduction of health risks	Statistics on number and severity of operators accidents	Member States	Aim is to reduce negative impact of PPP on health
	Incidence of unauthorised cross-border sourcing	Member States	Aim is to reduce incidence of unauthorised cross-border sourcing. Indicator requires enforcement efforts targeted at unauthorised sourcing of PPP
Lack of legal clarity concerning data protection	Number of full time equivalent staff days used in Member States for data protection issues	Member States	Aim is to reduce administrative burden of data protection
	Introduction of a central database for protected studies, including the provision of a identification code for protected studies	EC/ Industry	Aim is to reduce administrative burden of data protection through registering centrally the date of first authorisation of a PPP using a specific study, which determines the duration of the data protection period for this study
Possible duplication of vertebrate studies	Introduction of a central database for protected studies, including a register of vertebrate tests conducted	EC/Industry	Aim is to halt the possible duplication of vertebrate testing
Lack of competition in specific product segments	Number of substitute products available for similar crops/uses, including generic PPP	Member States	Aim is to safeguard sufficient level of competition as a requirement for a competitive industry and low prices for PPP users
	Price differences of PPP between Member States	Member States/ EC	Reduction diminishes incentives for unauthorised cross-border sourcing of PPP
	Price differences of selected PPP between EU and third countries	Member States/ EC	Reduction diminishes incentives for unauthorised cross-border sourcing of PPP, very significant price differences may indicate lack of competition in specific product segments
	Differences in VAT for PPP	Member States/ EC	Reduction diminishes incentives for unauthorised cross-border sourcing of PPP
Lack of information / transparency	Number of authorisation and evaluation procedures conducted with participation of NGOs and other stakeholders; number of published reports by competent authorities providing a detailed	Member States/ EC	Aim is to increase transparency of authorisation process

	motivation of the authorisation decision		

ANNEX A: METHODOLOGICAL APPROACH FOR COST QUANTIFICATION MODEL

Theoretical background

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

Developing new active substances requires large initial investments, is long-term and is generally perceived as being a high-risk activity. The expected monopoly profits from agrochemical sales under patent seeks to compensate the innovating companies for its risky investment. In contrast, the onset of competition after patent expiry limits the potential deadweight losses to society that arises from monopoly pricing under the patent.

The research orientated nature of proprietary agrochemical companies therefore relies heavily on the protection offered by the regulatory environment (e.g. patents) whereas those agrochemical companies producing generic products rely heavily on the market opportunities after patent expiry. Thus, any change in the regulatory framework on the placing of active substances on the market is likely to have a significant impact on the economics of new product development and hence the level of future investment.

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

2.1.1.1. Modelling the status-quo (baseline)

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

2.1.1.2. Assumptions of the model (baseline)

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

- Length of the research and development phase (i.e. time from discovery to market launch). Based on discussions held with the leading agrochemical companies, the average length of the research and development phase was found to vary

significantly between active substances. However, there was general agreement that the average length of the research and development phase for a typical active substance in recent years has been approximately 9-10 years. A review of published data sources confirmed this range with average lengths of 9.1[3] and 10[4] years reported.

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

- Research and development costs. According to Phillips McDougall[5], the average cost of the research and development phase (i.e. from discovery to launch) for a typical new global active substance was €200 million in 2000. Although the cost of research and development has increased considerably over time[6], the industry[7] still cites the 2000 cost as being representative of the current cost for research and development for a typical new global active substance.

  According to latest ECPA figures, the value of global sales of agrochemicals in 2004 was €24,734 million[8]. Of this, the value of the European (EU-25 and EFTA nations) agrochemical market was €6,769 million[9] in 2004. Accordingly, the European market (i.e. including EFTA nations) accounts for 27.4% of global agrochemical sales.

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

  According to Phillips McDougall[10], of the €200 million research and development cost in 2000, 51.1% was for research (22.3% for chemistry, 23.9% for biology and 4.9% for toxicology and environmental chemistry), 42.9% was for development (8.7% for environmental chemistry, 9.8% for toxicology, 13.6% for field trials and 10.8% for development chemistry) and 6.0% was for registration.

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

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

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

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

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

8 '*ECPA Review 2004/2005'* p. 10.

9 '*ECPA Review 2004/2005'* p. 8.

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

⇒ *Based on this cost allocation, the cost of research and development in the model has therefore been spread over the 10 year research and development phase according to the year when these costs are incurred*[11] *during the research and development phase.*

- Average time from product launch to peak sales. Based on discussions held with the leading agrochemical companies, the average length of the time from launch to peak sales was found to vary significantly between active substances, but typically ranged from 7 to 9 years.

⇒ *We have assumed in our model that the average time from product launch to peak sales is 8 years.*

- Average value of peak sales. Discussions with leading agrochemical companies and a review of industry statistics revealed that there is significant variation in the average value of peak sales between different active substances. Over time variations were reported to be enormous, ranging from less than €5 million (particularly for those active substances that are specifically targeted at niche markets (e.g. biologicals[12] (i.e. natural extracts, insect pheromones and beneficial micro-organisms) and some active substances for use on specific crops (e.g. fruit and vegetables) or because of unsuccessful product launches) to over €150 million (for 'blockbuster' active substances). However, despite this enormous range in average peak sales value, discussions with leading agrochemical companies and a review of industry statistics found that its distribution tends to be '*positively skewed'*[13]. In other words, average peak sales values are typically at the lower end of this range rather than at the higher end. Furthermore, analysis of company sales data[14] over time revealed that since the 1970s, the average value of peak sales has declined by around two-thirds as the number of new active substances has increased.

⇒ *Based on discussions with leading agrochemical companies and a review of industry statistics, we have assumed in our model that peak sales in real terms average €46 million.*

- Average production costs associated with the market exploitation phase of a new active substance. Based on discussions with the leading agrochemical companies and a review of literature, the average gross margin (i.e. the difference between sales revenue and variable (production) costs) for new active substances during the market exploitation phase is approximately 50%[15].

⇒ *We have assumed that production costs are 50% of the sales revenue.*

- Profile of the sales curve. Although the average peak sales value was found to differ significantly between active substances, discussion with leading agrochemical companies suggested that the variation in the profile of the sales curve (i.e. the rate of incline in sales value from product launch to peak sales and the rate of decline following peak sales) between active substances was not as significant (at least during the patent protection period).

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

12 Which provide an alternative to conventional chemical pesticides.

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

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

15 As reported in the ECPA evaluation on '*Data on the value of National Provisional Authorisation'*, November 2005, page 8.

⇒ *The sales profile used in our model was based on that average sales profile of 13 active substances (10 of which have recently been included in Annex 1 and three of which pending Annex I inclusion) from four leading agrochemical companies*[16].

- Average length of patent protection. Patent protection for an active substance is 20 years with a possibility to apply for a further 5 year period of protection.

⇒ *We have assumed an average patent protection period of 22.5 years.*

- Discount rate used. Discounted cash flow analysis, and the calculation of the net present value (NPVs) of future cash flows and the pay back period, is widely used to inform investors on the attractiveness of capital investments However, the calculation of NPV and pay back period is among other things, influenced by the discount rate used; the use of higher discount rates reduce the expected NPV of an investment and increase the pay back period. It is a generally accepted basic principle that the discount rate for a more risky project and for more long-term investments should be higher than that for a more certain project and for more short-term investments. This is because the choice of discount rates should reflect the estimated cost of capital associated with investing in developing new active substances as well as a provision for risk.

⇒ *In line with the European Commission's Impact Assessment guidelines, we have used a discount rate of 4%. (Based on discussions with the leading agrochemical companies, this is far lower than that used by the industry to appraise capital projects such as investment in new active substances).*

2.1.1.3. Model results for the status-quo (baseline)

Having established the assumptions for the model, we then used discounted cash flow analysis[17], using a discount rate[18] (in line with the European Commission's Impact Assessment guidelines), to determine the annual present value[19] of the expected cash flows. (Discounted cash flow analysis takes account of the time value of money and the risk-adjusted opportunity cost of investing in the development of AS) Annual present values were then added together to identify the following indicators:

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

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16 As reported in the ECPA evaluation on '*Data on the value of National Provisional Authorisation'*, November 2005, page 5.

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

18 The interest rate used in discounting future cash flows.

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

The results of the model and the aforementioned three indicators (NPV, pay back and IRR) are presented in the graph below. Under the status quo (baseline), an investment in a 'typical' new active substance breaks-even after 15.9 years from product discovery (5.9 years from product launch) and produces a net cash flow of €84.2 million over a 25 year period (i.e. the period under which the active substance can be protected by its patent).

Although this is based on the use of a 4% discount rate, the IRR calculation shows that the investment would still break-even over the 25 year period when using discount rates of up to 12.7%.

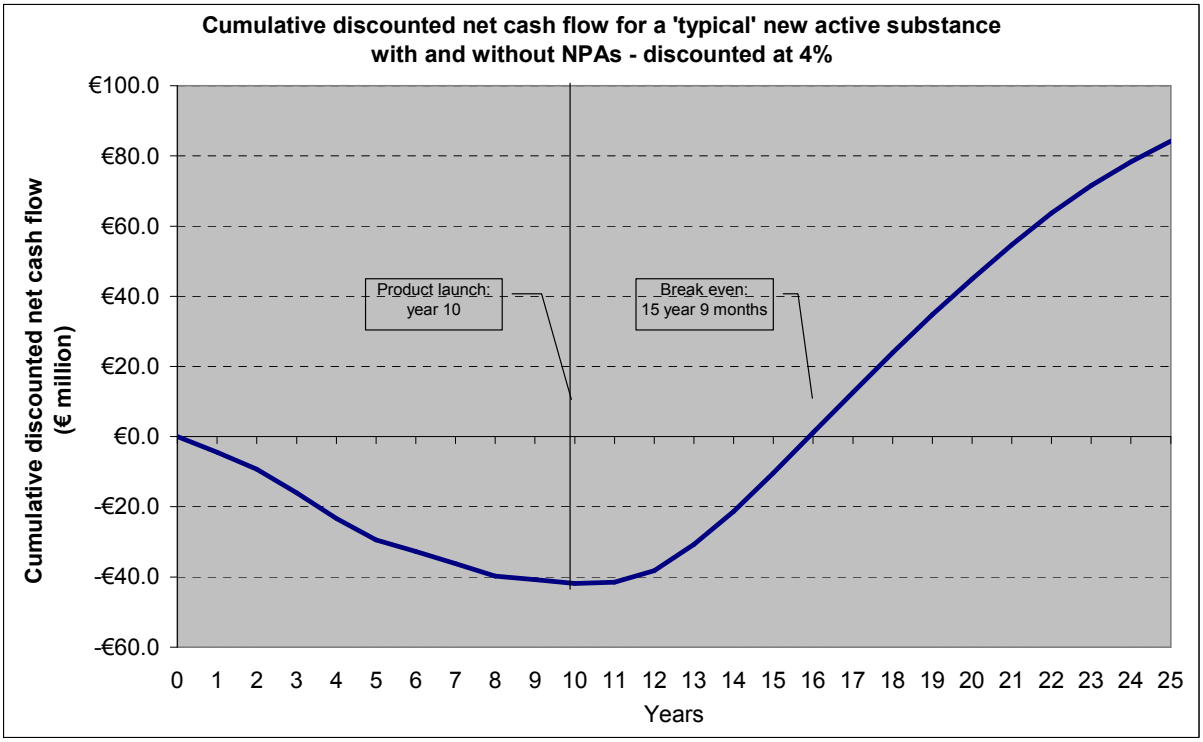

Table 31: Model results: status quo (baseline) scenario

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

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

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

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

ANNEX B: COMPARATIVE ASSESSMENT - THE SWEDISH EXPERIENCE

One of the policy actions under consideration in this impact assessment is comparative assessment combined with the substitution principle (policy action 3). Within the EU25, Sweden has been applying these mechanisms on national level since more than a decade. The substitution principle was first introduced in Sweden in 1990, in a general provision as a part of the Chemicals Control Act. It was then supported with additional provisions that add a theoretical possibility for sanctions in case the operator would not apply substitution. From 1999 onwards the substitution principle has been in line with the broader Environment Code, which has replaced a number of acts[20].

Background

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

- Presents significantly less risk to human and animal health or the environment;
- Is sufficiently effective, also taking into account risk for development of resistance;
- Can be used without unreasonable economic or practical disadvantages for the user"[21].

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

Application of the substitution principle

2.1.1.5. Synchronizing national system

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

2.1.1.6. Availability

A concern of applying substitution is that after application only few PPP would be available at the market. This lack of availability could distort competition and raise prices

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[20] Swedish Chemicals Inspectorate, 2004, p. 1.

[21] Swedish Chemicals Inspectorate, 2004, p. 8.

of PPP. In the Swedish experience the number of authorized PPP dropped significantly after implementation of the substitution program. However, their experience is that the drop is very temporary. Within a few years the number of authorized products returned to the previous level. The major impact of the substitution program in respect to availability of PPP was felt during the early nineties. Due to the national re-registration program many PPP were taken off the market. The year before 1990, 618 pesticide products were on the Swedish market. The amount of authorised pesticide products decreased until 343 in the middle of the program, which took five years in total. However, already in 1996 there were 521 pesticide products authorised, increasing to over 700 in 2004. The number of PPP is lower than the number of pesticide products, which also includes biocides. Currently there are 320 authorised PPP on the market[22].

Comparative assessment affected existing active substances. "Substitution has been used as a reason not to approve ca 20% of the old products"[23]. According to the experience of KEMI, comparative assessment is less relevant for new active substances. The Swedish Crop Protection Association did not contest this view[24]. KEMI also stressed that most of the substitution cases in Sweden have been related to the formulation type, such as substitution between products with the same active substance but based on different solvents or substitution of powder with granule formulations to reduce exposure by dusting. "These types of substitution cases have also been considered to be the easy ones", stated KEMI[25].

Prices of PPP

No studies on the price effects of the PPP substitution policy in Sweden. According to the Federation of Swedish Farmers after the implementation of the policy, however, there was no public debate on mounting prices. This was interpreted as indicating that there have been no major increases in prices caused by comparative assessment and substitution[26].

However, ECPA estimates that costs for Swedish farmers have risen through the market disappearance of relatively cheaper herbicides in the so-called 'fops' group (e.g. quizalofop). Swedish farmers thus have to use products from the more expensive so-called 'dim' group (e.g. sethoxydim, clethodim). For pesticide treatment of oilseed rape, this has added an extra cost of about €5/hectare[27]. According to the Swedish Competent Authority these are only short-term costs. In the long run substitution has not led to higher user costs[28].

Unknown effects of new PPP

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22 Questionnaire Sweden, question 1.

23 Swedish Chemicals Inspectorate, 2004, p. 11.

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

25 Email Swedish Chemicals Inspectorate, 23 February 2006.

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

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

28 Swedish Chemicals Inspectorate, 2004, p. 9.

It might occur that when a product is substituted by a newer, less-hazardous product, the new product shows significant negative side effects after some time of usage. In order to prevent this from happening, products are not immediately replaced after the new alternative product is brought on the market. Normally the existing product will be reviewed, usually in five years time, during which the new product is on the market. During this time data is obtained on how the new product performs in practice. This information will then be taken into consideration for the comparative assessment[29].

Net administrative costs

According to the Swedish competent authority, it is easier to apply comparative assessment and compare products than to conduct full-scale risk analysis. Consequently, after applying 15 years of substitution, KEMI assessed that the administrative effort would significantly rise if substitution would be abolished[30].

Impact on R&D

According to Swedish competent authorities, comparative assessment with substitution provides an incentive for the development of new, less hazardous alternative products. As described above, the number of authorised PPP initially dropped significantly. Within a few years the number of authorised products was back at its previous level. However, these products were improved from a health or environmental point of view. "There are many examples in practise on how manufacturers/applicants with more favourable alternatives from a risk perspective have been encouraged to establish themselves on the market or increase their market shares as a result of regulatory action based on comparative assessments"[31].

29 Swedish Chemicals Inspectorate, 2004, p. 11. This number includes PPP and biocides.
30 Questionnaire Sweden, question 33d.
31 Swedish Chemicals Inspectorate, 2004, p. 10.

ANNEX C: STAKEHOLDER ORGANISATIONS RETURNING CONSULTATION QUESTIONNAIRE

Competent Authorities

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

Plant Protection Industry

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

Farmer Organisations and other stakeholders

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

ANNEX D: CONSULTATION QUESTIONNAIRE

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

fcec

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

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

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

IDENTIFICATION DATA

Name and country of organisation:

Please specify

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

Please specify

INTRODUCTION

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

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

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

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(Managing Director Civic Consulting)
Merle Achten (office@civic-consulting.de) Phone: +49-30-2196 2295 Fax: +49-30-21962298
(contact point for setting up appointments for interviews)

I. MARKET FOR PLANT PROTECTION PRODUCTS IN YOUR COUNTRY

AVAILABILITY OF PLANT PROTECTION PRODUCTS (PPP)

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

Please specify

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

1	2	3	4	5
decreased very significantly (>25%)	decreased fairly significantly (10-25%)	remained similar (<10%)	increased fairly significantly (10-25%)	increased very significantly (>25%)
☐	☐	☐	☐	☐

Comments

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

a) … the average price of PPP?

Please specify

b) … the availability of PPP for minor uses?

Please give examples and specify the relevant crops

c) … the availability of PPP for resistance management?

Please give examples and specify the relevant crops

GENERIC PRODUCTS

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

1	2	3	4	5
decreased very significantly (>25%)	decreased fairly significantly (10-25%)	remained similar (<10%)	increased fairly significantly (10-25%)	increased very significantly (>25%)
☐	☐	☐	☐	☐

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

Comments

2

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

Please specify

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

   a) … the average price of PPP?

Please give examples and specify the price differences

   b) … the availability of PPP for minor uses?

Please give examples and specify the relevant crops

PRICE DIFFERENTIALS, UNAUTHORISED IMPORT AND USE

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

   If your answer is yes:

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

Please specify

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

Please specify

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

Please specify

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

Please specify

II. CURRENT APPLICATION OF DIRECTIVE 91/414/EEC

DURATION AND COSTS OF AUTHORISATION/EVALUATION PROCEDURE

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

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

Please specify

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

Please specify

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

Please specify

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

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

Please specify

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

Please specify

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

Please specify

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

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

Please specify

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

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

Please specify

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

Please specify

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

Please specify

OTHER ASPECTS RELATED TO THE AUTHORISATION PROCEDURE

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

Please specify

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

Please specify

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

Please specify

5

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

If your answer is yes:

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

Please specify

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

Please specify

CURRENT PROBLEMS

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

Please specify

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

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

Please compare the following options:

- **Option A - No EU action (Status Quo): Centralised procedure for evaluation of new AS without binding time limits. No national provisional authorisation (NPA) after 2007.** Due to a change to Directive 91/414/EEC introduced by new MRL regulation (which will be applicable +/- 2007) provisional national MRL can no longer be set by Member States (Art. 4.1. f of Directive 91/414/EEC as modified by Art. 48 of Regulation 396/2005).

- **Option B: Centralised procedure for evaluation of new AS with binding time limits. No national provisional authorisation**. The authorisation procedure for AS is subjected to time limits for each steps, leading to a foreseen maximum duration of 25 months.

- **Option C: Keep national provisional authorisation after Draft Assessment Report and continue to foresee provisional national MRLs after 2007.** This would require a change in the new MRL regulation.

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

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

Not marked = Don't know

Comments

7

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

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

Not marked = Don't know

Comments

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

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

Not marked = Don't know

Comments

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

	1	2	3	4	5
Unauthorised imports and use of PPP would …	decrease very significantly	decrease fairly significantly	remain similar	increase fairly significantly	increase very significantly
Option A: Status quo - without binding time limits. No NPA after 2007	☐	☐	☐	☐	☐
Option B: With binding time limits. No NPA	☐	☐	☐	☐	☐
Option C: Keep NPA after Draft Assessment Report	☐	☐	☐	☐	☐

Not marked = Don't know

Comments

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

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

Not marked = Don't know

Comments

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

Please specify

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

Please specify

9

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

Please compare the following options:

- **Option A - No EU action (Status Quo): National evaluation and authorisation of PPP with optional mutual recognition.**
- **Option B: Zonal evaluation and national authorisation of PPP with compulsory mutual recognition. No national risk mitigation measures.** The application shall be examined in each of the three zones by one Member State proposed by the applicant, unless another Member State in the same zone agrees to examine the application. When this MS authorises, all other MSs in the same zone must authorise the PPP too, if an application is made. Conciliation procedure in case of disagreement between MS.
- **Option C: Zonal evaluation and national authorisation of PPP with compulsory mutual recognition. However, national risk mitigation measures.** As Option B, however with the possibility to require national risk mitigation measures during the authorisation process.
- **Option D: Central agency for evaluation and authorisation of PPP with use of MS resources.** Such a system would have some similarities to the centralised procedure of the European Medicines Agency (EMEA), that consists of a single application which, when approved, grants authorisation for all markets within the European Union.

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

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

Not marked = Don't know

Comments

10

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

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

Not marked = Don't know

Comments

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

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

Not marked = Don't know

Comments

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

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

Not marked = Don't know

Comments

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

	1	2	3	4	5
Unauthorised imports and use of PPP would …	decrease very significantly	decrease fairly significantly	remain similar	increase fairly significantly	increase very significantly
Option A: Status quo - National evaluation and authorisation	☐	☐	☐	☐	☐
Option B: Zonal evaluation and national authorisation – no national risk mitigation measures	☐	☐	☐	☐	☐
Option C: Zonal evaluation and national authorisation – with national risk mitigation measures	☐	☐	☐	☐	☐
Option D: Central agency for evaluation and authorisation	☐	☐	☐	☐	☐

Not marked = Don't know

Comments

12

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

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

Not marked = Don't know

Comments

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

	1	2	3	4	5
Negative impacts of active substances on the environment or human health would…	decrease very significantly	decrease fairly significantly	remain similar	increase fairly significantly	increase very significantly
Option A: Status quo - National evaluation and authorisation	☐	☐	☐	☐	☐
Option B: Zonal evaluation and national authorisation – no national risk mitigation measures	☐	☐	☐	☐	☐
Option C: Zonal evaluation and national authorisation – with national risk mitigation measures	☐	☐	☐	☐	☐
Option D: Central agency for evaluation and authorisation	☐	☐	☐	☐	☐

Not marked = Don't know

Comments

13

POLICY ACTION 3: COMPARATIVE ASSESSMENT OF PPP

Please compare the following options:

- **Option A - No EU action (Status Quo): No provision for comparative assessment.**
- **Option B: Identification of candidates for substitution at the EU level based on hazard criteria (Annex ID). Comparative assessment of PPP at the national level**. The assessment has to be done when an application for authorization of a plant protection product containing an active substance included in Annex ID is made. *A draft of possible criteria for comparative assessment is given in the Annex of this questionnaire.*
- **Option C: Comparative assessment for all PPP at national level when an application for the authorisation is made, independent from the hazard of the active substances (i.e. for all active substances).**

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

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

Not marked = Don't know

Comments

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

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

Not marked = Don't know

Comments

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

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

Not marked = Don't know

Comments

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

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

Not marked = Don't know

Comments

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

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

Not marked = Don't know

Comments

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

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

Not marked = Don't know

Comments

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

Please compare the following options:

- **Option A - No EU action (Status Quo): 5 years of data protection starting with the renewal of Annex I inclusion. No provisions on compulsory data sharing.**

- **Option B: 5 years of data protection starting six month after the renewal of Annex I inclusion. Compulsory data sharing with compensation and an arbitration mechanism.** If the applicant and holders of previous authorizations can not reach an agreement on the sharing of test and study reports, the matter may be submitted for binding arbitration to an arbitration organisation unless the applicant decides to withdraw his application or to generate the data himself. Tests and studies involving vertebrate animals may not be repeated.

- **Option C: No data protection period for renewal of inclusion in Annex I.**

- **Option D: 5 years of data protection starting with the time of dossier submission for the renewal of Annex I inclusion. No provisions on compulsory data sharing.** However, it would be compulsory for interested companies to cooperate to provide a joint dossier containing all additional data required to maintain an authorisation. Non-cooperating companies would only be allowed onto the market if they generate their own data or negotiate access with the cooperating parties.

Note: The duration of data protection for the *first inclusion* of a new active substance and the *first authorisation* of a PPP is not foreseen to change under the draft Regulation and will remain 10 years of exclusivity without compulsory data sharing. However, the principles of data sharing with compensation and an arbitration mechanism also apply for the *renewal of authorization* of a PPP. Tests and studies involving vertebrate animals *may not be repeated* for the purpose of an application for the inclusion or renewal of inclusion of an active substance in Annex I or for the authorization of a PPP.

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

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

Not marked = Don't know

Comments

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

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

Not marked = Don't know

Comments

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

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

Not marked = Don't know

Comments

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

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

Not marked = Don't know

Comments

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

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

Not marked = Don't know

Comments

POLICY ACTION 5: INFORMING NEIGHBOURS ON PPP USE

Please compare the following options:

- **Option A - No EU action (Status Quo): No duty to inform neighbours on use of toxic PPP.**
- **Option B: Active duty to inform neighbours on use of toxic PPP.** For PPP classified under Directive 1999/45/EC as very toxic or toxic applied by spraying, the authorisation can stipulate the obligation to inform neighbours who could be exposed to the spray drift before the product is used.
- **Option C: Passive duty to inform neighbours on use of dangerous PPP (i.e. providing information to neighbours on demand).** Application for similar PPP as under Option B (classified under Directive 1999/45/EC as very toxic or toxic applied by spraying).

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

	1	2	3	4	5
Number of staff days needed for enforcement of rules related to use of PPP would …	decrease very significantly	decrease fairly significantly	remain similar	increase fairly significantly	increase very significantly
Option A: Status quo – No duty to inform neighbours	☐	☐	☐	☐	☐
Option B: Active duty to inform neighbours	☐	☐	☐	☐	☐
Option C: Passive duty to inform neighbours	☐	☐	☐	☐	☐

Not marked = Don't know

Comments

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

	1	2	3	4	5
Level of information of potentially affected citizens on PPP usage would…	decrease very significantly	decrease fairly significantly	remain similar	increase fairly significantly	increase very significantly
Option A: Status quo – No duty to inform neighbours	☐	☐	☐	☐	☐
Option B: Active duty to inform neighbours	☐	☐	☐	☐	☐
Option C: Passive duty to inform neighbours	☐	☐	☐	☐	☐

Not marked = Don't know

Comments

20

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

	1	2	3	4	5
Negative impacts of active substances on the environment or human health would…	decrease very significantly	decrease fairly significantly	remain similar	increase fairly significantly	increase very significantly
Option A: Status quo – No duty to inform neighbours	☐	☐	☐	☐	☐
Option B: Active duty to inform neighbours	☐	☐	☐	☐	☐
Option C: Passive duty to inform neighbours	☐	☐	☐	☐	☐

Not marked = Don't know

Comments

IV. OTHER ISSUES

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

Please specify

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

Yes ☐ No ☐ Don't know ☐

If yes, please justify

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

Yes ☐ No ☐ Don't know ☐

If yes, please justify

ANNEX

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

An active substance will be listed in Annex ID if it meets the criteria for inclusion into Annex IA but where:

- its ADI, ARfD or AOEL are very low compared to the active substances included in Annex IA
- it meets [one] [two] of the criteria to be considered as a PBT substance
- there are reasons for concern linked to the nature of the critical effects (such as sensitisation, corrosivity, neurotoxicity, carcinogenicity, mutagenicity and reproductive toxicity, high toxicity to environmental organisms and bioaccumulation), which, in combination with the use/exposure patterns, imply use situations that could still cause concern. This is the case when its conditions of use are such that only with very restrictive risk management options (such as very extensive personal protective equipment or very large buffer zones) it can be achieved that its use is not harmful for human or animal health or not unacceptable for the environment
- the active substance contains an important proportion of non-active isomers.