COMMISSION OF THE EUROPEAN COMMUNITIES

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**COMMISSION STAFF WORKING DOCUMENT**

**Summary Report on**

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

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## 1. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

The main stakeholders concerned with the amending Directive 91/414/EEC were consulted and participated in meetings in 2002, 2004 and 2006 and in a written consultation in 2005.

In 2005, the Commission carried out an Interactive Policy Making (IPM) online consultation with the general public.

A Commission Inter-Services Steering Group has been established 2005/2006.

An additional in-depth analysis has been carried out on the impact of the proposal on Administrative Burden on Member States' authorities as well as business operators.

## 2. PROBLEM DEFINITION

The use of plant protection products (PPP) may involve risks and hazards for humans, animals and the environment, especially if placed on the market without having been officially tested and authorized and if incorrectly used. Therefore harmonized rules should be adopted on the placing on the market of PPP.

Council Directive 91/414/EEC ("the Directive") concerning the placing of plant protection products on the market entered into force on 25 July 1993 and provides for harmonised rules governing PPP and the active substances contained in those products.

After 13 years of experience gained from the application of the Directive and recent scientific and technical developments, it appears that the basic approach of the Directive is still acceptable but the system is overloaded and efficiency is not satisfactory. Therefore, it is deemed necessary to put in place some corrective measures made to adjust the policy on PPP to existing EU policies in the area, to improve the efficiency or/and to introduce some new policy actions while maintaining the basic principle which is the high level of protection of human and animal health and of the environment.

A number of stakeholders e.g. farmers and users of plant protection products, the pesticide industry, consumers, Member States or the general public, may be affected in considerably different ways. The Impact Assessment contains a detailed analysis of the current situation and the problems arising for the different stakeholders.

## 3. OBJECTIVES

In view of the problems outlined above, the main objectives are the following:

- extend and deepen the single market, to ensure open and competitive markets inside and outside Europe, in conformity to the Lisbon Strategy;
- increase the efficiency of the system through simplification, better definition and streamlining of the procedures;

- increase the level of harmonisation throughout the EU;

- present a text reflecting existing EU policy in the same subject area developed since the entry into force of Directive 91/414/EEC, and also taking into account the ongoing consultation process on a Thematic Strategy on the sustainable use of pesticides.

To achieve the main objectives several policy options have been identified. The in-depth assessment has been focused on a set of five major policy actions.

## 4. POLICY OPTIONS

**Policy Action 1: Authorisation of PPP containing a new active substance/ national provisional authorisation**

**Current problems:**

In order to avoid delays in the introduction of PPP containing new active substances (AS) to the market, Member States can grant national provisional authorisations after a complete dossier has been submitted.

The system has, however, led to a duplication of administrative efforts of competent authorities and applicants and to differences in availability of PPP between Member States markets.

**Policy options:**

- *Option A:* No EU action (Status Quo): Centralised procedure for evaluation of new AS without binding time limits (*option A1*). No national provisional authorisation (NPA) after 2007 (*option A2*).

- *Option B:* Centralised procedure for evaluation of new AS with binding time limits. No national provisional authorisation. Two alternative approaches: a sequential authorisation, where PPP authorisation follows only after the decision on approval of an AS (*option B1*); or a parallel authorisation, here PPP authorisation is prepared during the evaluation of an AS and comes into force immediately after the approval (*option B2*).

- *Option C:* Keep national provisional authorisation after Draft Assessment Report.

**Analysis of impacts:**

*Administrative burden*

Options A, B1 or B2 would reduce the current duplication of administrative efforts for both industry and competent authorities, whereas option C would continue it. This could also lead to a continued lack of incentive for the applicant to finalise the approval procedure after national provisional authorisation is granted.

*Indirect costs for PPP users*

Option A and C are not expected to lead to any additional negative or positive impact, while option B1 or B2 could have a negative impact on indirect costs for PPP users. Option B2 does not affect the timeline of authorisation and is not expected to have any impact.

*Investment of PPP producers in R&D*

The impacts on investment of PPP producers in R&D have been calculated with the help of a (discounted) cash flow model. With option options B2 or C product launch would not change considerably, under options A2 or B1 it could be delayed, compared to the status quo, respectively. A delay in product launch could affect new product development.

*EU PPP industry competitiveness*

Any increase in the duration of the authorisation procedure could carry disadvantages for new product (here: AS) development; this would particularly be the case for option A2. In case of simplification of the process (option B), clear timelines are crucial (B2). However, some important factors influencing the duration of the evaluation/authorisation process do not fall under Community competence.

*Employment, Environment or human health*

Only minor impacts seem possible under all options.

*Unauthorised cross-border sourcing of PPP*

The system of NPA is one of the factors contributing to the fragmentation of the EU PPP market, which may lead to unauthorised cross-border sourcing of PPP. Therefore, slightly positive impacts under options B and A2 are possible.

**Policy action 2: Mutual recognition of PPP containing an active substance already approved**

**Current problems:**

Directive 91/414/EEC contains an optional provision for Member States to mutually recognise PPP authorisations, which has only been exceptionally applied in the past, from several reasons. This led to a significant duplication of work and a fragmentation of the market for PPP in Europe.

**Policy options:**

- *Option A:* No EU action (Status Quo): National evaluation and authorisation of PPP with optional mutual recognition.
- *Option B:* Zonal[1] evaluation and national authorisation of PPP with compulsory mutual recognition within the zone. No national risk mitigation measures.
- *Option C:* Zonal evaluation and national authorisation of PPP with compulsory mutual recognition within the zone. However, with national risk mitigation measures.
- *Option D:* Central agency for evaluation and authorisation of PPP with use of MS resources.

**Analysis of impacts:**

*Administrative burden*

For all options, there is a decrease in administrative burden in relation to the degree of centralisation, in particular to the authorities but also for the industry.

*Indirect costs for PPP users*

Increasing the level of centralisation is very likely to increase the availability of PPP. An increased number of PPP might have positive effects on the indirect costs for the user (more niche production, more competition n the PPP market), with a positive effect increasing gradually from option A to D.

*Investment of PPP producers in R&D*

No significant impact can be predicted, on the base of the experience with mutual recognition so far.

[1] Zonal evaluation means, that the Member States with comparable agricultural and climatic conditions are grouped into one "zone", on the basis of expertise in Member States and the Commission.

*EU PPP industry competitiveness*

Zonal authorisation lowers barriers to entry, as administrative efforts are reduced to reach an authorisation in several Member States. A market size reduction could occur if lower application rate would be applied throughout the entire zone (less for option C). A central agency can be expected to have the same impacts, but on a larger scale.

*Employment*

Employment in R&D companies might be affected, if mutual recognition would lead to a delay in authorisation. However, experience in Member States currently applying mutual recognition does not indicate a risk for major delays.

*Duplication of studies on vertebrate animals*

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 at the moment.

*Unauthorised cross-border sourcing of PPP*

Zonal as well as centralised authorisation will by definition lead to more homogenous national markets. A more homogenous market will reduce incentives for unauthorised cross-border sourcing of PPP.

*Environment or human health*

National evaluation and authorisation makes it easier to take into account varying local conditions, but also contribute to continuing incentives for unauthorised cross-border sourcing of PPP with the related potential risks. Options B, C and D can reduce the risks related to that. "Zonal averaging", i.e. not taking into account particularly vulnerable local conditions, might have a negative impact under options B and D.

**Policy action 3: Comparative assessment of PPP**

**Current problems:**

Although there is no harmful effect on human or animal health or any unacceptable influence on the environment identified from authorised uses of approved active substances (AS), an approval of an AS does not mean that it is without any risk.

Comparative assessment can help to further minimise the hazards and risks to health and environment from the use of PPP.

**Policy options:**

The following policy options are included in the Impact Assessment:

- *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. Comparative assessment of PPP at the national level.

- *Option C:* Comparative assessment for all PPP at national level when an application for the authorisation is made, independent from the hazard of the AS.

**Analysis of impacts:**

*Administrative burden*

Comparative assessment will, at least in the short to mid-term, require additional staff input for the authorities. It is not expected that any of the options increase in practice the costs of dossier submission for industry. No increase of administrative burden is also expected for PPP users.

*Indirect costs for PPP users*

Comparative assessment may reduce the market share of generic products and "older" products leading possibly to a price increase of PPP. However, the extent to which this takes place depends on the way comparative assessment is applied in practice.

*Investment of PPP producers in R&D, Employment*

A significant factor affecting the economics of a new AS development is the attitude to risk of a company, which might significantly be influenced by the number of AS potentially affected by a comparative assessment. With option C being likely to be perceived as being more risky than option B, which is likely to be perceived as being more risky than Option A, the greatest potential impact on investment and employment is likely to be associated with option C.

*EU PPP industry competitiveness*

The status quo is the most competitiveness friendly option. Comparative assessment may reduce the number of commercialised AS and could reduce the market size, but also drives innovation efforts towards hazard free substances and may act in favour of some companies at the expense of others, depending of their profile.

*Unauthorised cross-border sourcing of PPP*

Comparative assessment could become a (minor) factor contributing to fragmented markets for PPP in Europe, if it would be implemented very differently between neighbouring Member States.

*Environment or human health*

The status quo means a lack of flexibility to implement PPP minimisation strategies. Option B and C provide this possibility, likely resulting in a reduction of environmental impacts and an increase in safety margins for the protection of human health.

**Policy action 4: Data sharing for the renewal of approval of an active substance**

**Current Problems:**

Directive 91/414/EEC establishes only general rules on the complex problem of data protection and data sharing. This led to interpretation problems of data protection rules and to a high administrative burden for competent authorities.

Problems for companies owning the data on AS are not the same as for the generic industry. Currently the data protection rules are working against generic competition and the market share of generic companies remains low in most EU countries.

**Policy options:**

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

- *Option B:* 5 years of data protection starting six months after the renewal of approval. Compulsory data sharing with compensation and an arbitration mechanism.

- *Option C:* No data protection period for renewal of approval.

- *Option D:* 5 years of data protection starting with the time of dossier submission for the renewal of approval. No provisions on compulsory data sharing. However, it would be compulsory for interested companies to cooperate in order to provide one joint dossier.

**Analysis of impacts:**

*Administrative burden*

The status quo causes a very significant administrative burden for authorities, with an increasing tendency. Option B would increase the administrative burden for the parties involved in the arbitration procedure. Option C would lead to a significant reduction of administrative burden for all parties. Option D would lead to a reduction of the administrative burden for the parties not involved in setting up the joint task force of companies.

*Indirect costs for PPP users*

A reduced market share of generic companies (under option A) could cause higher costs to PPP users. Options B and C could lead to lower prices for users by increasing the market share of generic companies, but could also imply a lower number of AS on the market and possible resulting costs for users. Option D can be expected to have the lowest impact on the status quo.

*Investment of PPP producers in R&D, Employment*

Under all policy options, it remains according to the results of the discounted cash flow model profitable for a PPP producer to invest in studies for re-inclusion of an AS (although the quantitative result is sensitive to the assumptions of the model used). For options B and C positive effects on employment for generic producers may be counterbalanced by negative effects on producers for niche markets.

*EU PPP industry competitiveness*

The status quo gives high protection to the owner of studies and keeps high entry barriers to all other companies. Options B and C reduce the entry barrier and will lead to a more competitive market, but may also reduce the profitability of some AS. For option D comparable effects can be predicted, but since it gives high protection to the owner of the studies, its impact would largely depend on the arrangements for joint task force and cost-sharing.

*Duplication of studies on vertebrate animals*

Options B and C, followed by option D, have the largest potential to reduce the number of duplicated studies involving testing on vertebrate animals.

**Policy Action 5: Informing neighbours on PPP use**

**Current Problems:**

Neighbours and bystanders may perceive the application of PPP as a health risk, as they might come in contact with spray drift. The availability of information on PPP could be optimised.

**Policy options:**

The following policy options are included in the Impact Assessment:

- *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.
- *Option C:* Passive duty to inform neighbours on use of dangerous PPP.

**Analysis of impacts:**

*Administrative burden*

Measures under policy action 5 could result in an administrative burden for PPP users and authorities, but not for PPP industry. The extent of burden is, however, expected to remain insignificant.

*Information opportunities of citizens*

By definition both options B and C will improve information opportunities of citizens. However, it cannot be assessed at this stage how the information provided would affect the awareness of neighbours on PPP use.

*Environment or human health*

Under a duty to inform neighbours a reduction of negative impacts of active substances on environment or health is possible, namely through a preference of farmers for less toxic products and through activities of bystanders to avoid exposure to spray drift.

## 5. MONITORING AND EVALUATION

In order to put a system in place to carry out regulatory monitoring, a list of indicators, comprising

- the average timing for approval and authorisation of active substances and PPP;
- the number of PPP and
- the availability under several regards

is proposed to be used for monitoring and evaluation of the future system.