

**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

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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 stakeholders 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.**

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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I. PLANT PROTECTION PRODUCTS – MARKET AND AUTHORISATION

AVAILABILITY OF PLANT PROTECTION PRODUCTS (PPP)

1. 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 EU 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%) |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

ESA expects the overall number of (re-)registered product formulations to decrease very significantly. Crop protection companies concentrate on less formulations, a policy which very likely will already become effective at the point of (re-)registration.

With that, ESA also considers the decrease to be at least as significant for minor uses.

For seed treatments, we expect the effect to be fairly significant (decrease between 10% to 25%).

N.B.: the full effects of Annex I inclusion still remain to be seen and properly assessed; these effects could potentially be even bigger than considered likely today.

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

- a) ... the average price of PPP?

ESA does not see a significant impact here. Price changes of PPPs vary greatly over the full range of products and may be due to a large number of factors.

- b) ... the availability of PPP for minor uses?

ESA is of the opinion that crop protection companies will likely concentrate their efforts on an ever smaller number of products and uses. This leads up to a potentially very damaging loss of crop-pest options, in particular as regards minor crops as well as minor uses and Seed Treatments.

Already today, the work of the Minor Use Working Group(s) and the multitude of examples and crops involved clearly show this tendency.

It is therefore safe to predict that the overall number of PPPs for minor uses will drastically decrease with the known negative effects on the seed industry as well as on farmers.

- c) ... the availability of PPP for resistance management?

v. above. Where less products for minor uses and minor crops and specific very small markets are being maintained, this obviously will have a negative impact on resistance management. Not least, this affects also seed companies efforts in resistance breeding with its very long plant breeding and variety development cycles.

GENERIC PRODUCTS

3. 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%) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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

outside the interest of ESA

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

- a) ... the average price of PPP?

outside the interest of ESA

- b) ... the availability of PPP for minor uses?

see answer to 2 b.

PRICE DIFFERENTIALS, UNAUTHORISED IMPORT AND USE

5. Are there significant price differences of PPP in different EU countries (for PPP having identical active substances)?

If your answer is yes:

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

not in the competence of ESA

- 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?

Price differences of PPPs in different MS will result from a multitude of factors with taxes and distribution structures being only two of them.

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

ESA has provided the European Commission as well as Member States representatives with an overview on the existing differences in authorisations for Seed Treatment in the different MS of the EU.

This overview was slightly amended following remarks and input from some MS; still, the general findings of ESA were not challenged.

The overview (v. ESA_05.0355.2 as attached for information) clearly shows the enormous differences between MS as regards their authorisations for Seed Treatments and their use on their respective territory but also regarding imports and exports and the treatment process itself.

Obviously, this scale of differences in association with a sometimes quite incoherent implementation even within one MS cause severe problems including unauthorised imports and use.

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

not in the competence of ESA

AUTHORISATION PROCESS

8. Are there any problems currently experienced related to the authorisation process for PPP?

Despite all efforts undertaken in the implementation of Directive 91/414/EC, ESA sees an increasing DISHARMONISATION and increasing obstacles to a true INTERNAL MARKET for Seed Treatments and treated seed.

The current situation leads ESA to the following general assessment:

- the Directive does not encourage investment in authorisations for minor uses / Seed Treatment.*
- the uncertainties regarding timetable and outcome of decision making particularly disfavour small scale applications.*
- the divergence of national authorisations (v. again overview ESA_05.0355.2) factually requires companies to provide for an unnecessarily vast network of seed treatment locations and to unnecessarily move seeds for treatment (export, re-import, packaging, export) with associated costs.*
- some MS demand very specific additional data for risk assessment. This again increases costs as well as the uncertainty of the outcome of the authorisation process.*
- companies are either favoured or disfavoured by their location in a specific MS depending on whether seed production and seed market are located within the same area or not.*
- potential environmental as well as economic benefits resulting from the application of Seed Treatments are not realised. This leads to unnecessarily high costs, loss of crop value and damages the competitive position of European farmers and growers.*
- farmers and growers in some MS suffer from a competitive disadvantage in comparison to their colleagues if they are not allowed to use products properly authorised in other Member States but not (yet) authorised in their own (e.g. because the market is considered to be too small to recover the authorisation costs).*
- the seed industry is a highly internationalised business. Seed production, processing, packaging and marketing do very often take place in different locations throughout the EU (in fact throughout the world). Any legislation that hinders the free movement of seed leads to an increase of cost and an inefficiency of production processes.*

II. 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.

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

It is in ESA's interest that the autorisation procedure is streamlined and sped up in order to bring more (not less!) attractive and efficient products for all practical problems (i.e. crop-pest combinations) to the market. This is in particular true for Seed Treatments, minor crops and minor uses.

ESA interprets the term "centralised procedure" to stand for uniform procedures, protocols and guidelines to be applied throughout the whole EU. Having experience with such an approach in the seed marketing and variety protection area, ESA would welcome such centralisation as we expect it to lead to a more reliable and predictable procedure. We would also welcome ambitious timetables as part of this procedure. Still, as a safeguard, ESA would prefer as an additional option a centralised authorisation within a time limit including the option of a provisional national authorisation when either the timetable is not met or where differencing positions prevent the decision making process to work as envisaged.

Once again, ESA would like to point out that for the SEED industry it is important to be able to work with a variety of suitable products in order to provide adequate crop-pest solutions to farmers and growers. To achieve this goal, ESA is convinced that evaluation and authorisation of PPPs for Seed Treatment and minor uses/minor crops must be encouraged by any new regulatory approach. Whether this can be achieved best through harmonised national or a more centralised EU-uniform procedure depends on the details of the future legislation. In any case, the experience with the existing Directive 91/414/EC suggests that Option A is the worst case scenario.

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

Depending on the practical improvement of the current system. Any system that will bring more products and appropriate solutions to the market and final user will automatically at the same time decrease the risk of unauthorised imports and uses.

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

ESA is convinced that any regulatory system that encourages research, authorisation and use of PPPs as Seed Treatments per se also benefits the environment and public health as considerably lower amounts of PPPs are being used. At the same time, the specific technical application of PPPs as Seed Treatments is particularly safe to farmers (no direct exposure to the PPP etc.), is less dependent on and less affects the surrounding environment than classical spraying applications etc..

ESA therefore estimates the overall impact to be positive if the current system (Option A) is changed and improved.

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 (EMA), that consists of a single application which, when approved, grants authorisation for all markets within the European Union.

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

We refer back to our earlier answers. From the point of the seed industry, the current system (Option A) clearly needs to be improved significantly as it has led to the situation we describe in our overview on the differences between MS when it comes to their authorisations for PPPs as seed treatments (import, export, processing and use). From our point of view, a streamlined central authorisation system following the approach of the EMA (and the seed industry has experience with similar systems in seed marketing and plant variety protection legislation) could lead to a considerable improvement as regards authorisations for Seed Treatment and minor uses.

However, this would largely depend on a well defined, reliable and not overly costly or lengthy evaluation and authorisation procedure that includes safeguards against decision making deadlocks.

Any zonal approaches as presented here as Options B and C e.g. must not add an additional third layer with respective administrative burden and associated costs nor must it further delay decision making; it should on the contrary lead to a speeding up of the current system and should limit the expenditure of applicants.

It is under these conditions that ESA considers Option D better than Option B, Option B better than Option C and all Options (B, C and D) better than the status quo (Option A). A well working compulsory mutual recognition system for Seed Treatments and minor uses would in any case greatly improve the current situation of the seed treatment and plant breeding industry and would limit the competitive advantage for those companies that benefit from the fact that seed production and seed market are actually located in the same country.

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

not in the interest of ESA

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

Under the conditions set out above, ESA would expect Options B, C and D to all potentially bring more products to the market, either for the whole of the EU or at least within a zone. As explained before, this would automatically decrease unauthorised imports and uses. The same would be true for a working compulsory mutual recognition procedure for Seed Treatments and minor uses.

15. 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?

not in the competence of ESA

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

See answer 11.

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).**

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

For ESA, it is important that any assessment includes also the effect on seed treatment solutions. With the risk of resistances being build up over time, it is important for the industry to have a sufficient range of products available.

ESA fears that comparative assessments may lead to areas where a Seed Treatment product may be lost because the comparative assessment is just done on the basis of regular applications.

It is also obvious that compulsory substitution will significantly increase the financial risk of investment, in particular as regards small scale applications (Seed Treatments, minor uses).

Finally, it should not be underestimated that any compulsory substitution will lead to less competition (or even to monopoly situations) which may have a considerable effect on prices to the seed industry and farmers / growers. ESA therefore is of the opinion that all products assessed as safe to use should be allowed to remain on the market.

18. How do you assess the impact of the different policy options on the market share of generic PPP?

not in the interest of ESA.

We however estimate that depending on whether a compulsory assessment leads to an automatic substitution, this will either benefit or disfavour producers of generics.

ESA's interest lies in a sufficient choice of products being available for all current and potential crop-pest problems in order to avoid or being able to deal with any resistances being build up.

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

As pointed out in the different answers above, any increase of available products (generally and specifically for Seed Treatments / minor uses) for farmers and growers will decrease unauthorised imports and uses. If investment in new products is discouraged by lengthy and unreliable authorisation and decision making procedures and if the current differences in implementation and interpretation of the legislation persist and continue to lead to differences in available products, i.e. solutions for concrete crop-pest problems, this will very likely lead to an increase of unauthorised imports and use of PPPs.

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

An important factor to take into account is the building up of resistances! To either avoid this building up of resistances or to at least be able to react quickly to it, it is absolutely crucial to have a sufficient range of products available.

Where this range of products does not exist, farmers / growers may be forced to use ever higher dosages of a given PPP in order to protect their crop. This would be detrimental to the possibilities of limiting dosages and overall use of active ingredient per ha offered by a sufficient choice of products useable as Seed Treatments. With this, the substitution could lead to exactly the opposite of the desired effect.

Any mix of the policy options set out in this questionnaire that would lead to a significant decrease of products (e.g. by introducing an obligatory substitution principle) therefore increases the risk that new resistance problems may not be addressed appropriately.

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 authorisation* 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.

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

not in the competence of ESA

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

not in the competence of ESA

23. 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?

not in the competence of ESA

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).

24. How do you assess the impact of the different policy options on the administrative costs for PPP users (i.e. costs related to inform neighbours)?

Due to the technical specificities of PPPs when being used as Seed Treatments, ESA does not consider an information of neighbours to be necessary.

25. How do you assess the impact of the different policy options on the level of information of potentially affected citizens on PPP usage?

see above. When PPPs are being properly used as Seed Treatments, it is difficult to imagine any potential negative effect on neighbouring citizens.

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

For PPPs used as Seed Treatments, ESA does not consider any of the three options to be relevant.

III. OTHER ISSUES

27. Are there any **other significant impacts** that you would expect from one of the five policy actions listed in the previous section?

Any revision of Directive 91/414/EC should focus on those policy options that help to streamline, speed-up and harmonise and/or centralise the evaluation and authorisation of PPPs including their use as Seed Treatments and for minor uses.

In addition, a revision should not increase but rather decrease the crop protection industry's costs and lead to reliable and predictable decision making which in turn will help to support investment in research and innovation.

Under such conditions, ESA sees positive impacts on the future availability of PPPs as Seed Treatments and for minor uses, for the free movement of treated seed throughout the Internal Market and the associated benefits to the environment and public health due to the resulting limitation of the amounts of active substance(s) being used on the field.

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

Yes No Don't know

In principle, ESA has no clear preference whether the future legislation on PPPs should be a Directive or rather a Regulation as long as the policy goals set out above are being achieved.

Looking at the implementation of the current Directive 91/414/EC and in particular at the practice of the implementation of the provisions on mutual recognition for minor uses and on the effect on PPPs authorised as Seed Treatments, we would however prefer a more coherent approach which might be helped by using a Regulation as legal base.

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

Yes No Don't know

ESA shares the EU's general policy to support self regulation where possible and appropriate.

We consider it possible to define areas currently under the scope of Directive 91/414/EC and its various implementing measures which could be left to industry self regulation (product stewardship).

As this question concerns foremost the crop protection industry itself, ESA does not comment in detail on this point.

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.