COMMISSION OF THE EUROPEAN COMMUNITIES

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ANNEX 1

COMMISSION STAFF WORKING DOCUMENT

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

Annex 1

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Lead DG: SANCO

Other involved services (Members of the Inter-Services Steering Group): SG, SJ, ECFIN, ENTR, COMP, AGRI, MARKT, EMPL, ENV, TRADE, and BUDG

Agenda planning or WP reference: 2003/SANCO/61

Annex 1

Refined Assessment on Administrative burden

A) Questionnaire

IMPACT ASSESSMENT

REVISION OF DIRECTIVE 91/414/EEC

ASSESSMENT OF POTENTIAL ADMINISTRATIVE BURDEN

*****

DG HEALTH AND CONSUMER PROTECTION

EUROPEAN COMMISSION

BRUSSELS

Please return questionnaire by email to SANCO-QUESTIONNAIRE-02@cec.eu.int or by fax to +32-2-296 48 75 before 10.02.2006

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:

specify

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

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. Impact Assessment of the new Regulation replacing Directive 91/414/EEC on plant protection products is being developed simultaneously. The impact assessment team considers the experience and perspective of Member State authorities as crucial inputs into the impact assessment process.

There has been already one detailed questionnaire addressed to Member States and prepared by external consultants (Food Chain Evaluation Consortium), which supports the European Commission in drafting of the Impact Assessment. However, this survey only briefly touched upon the impact of the new Regulation on so-called Administrative Burden that is all costs incurred by enterprises, the voluntary sector, public authorities and citizens in meeting legal obligations to provide information on their action or production, either to public authorities or to private parties.

The recent conclusions of the European Council that took place in Brussels, 15-16 of December, stressed the importance "…of reducing unnecessary burdens for business and citizens", as well as it invited "…the Commission to start measuring administrative burdens, on a consistent basis and in line with transparent criteria, as part of integrated impact assessments launched as of January 2006.".

Having in mind this clear message from the European highest authority, DG Health and Consumer Protection has decided to prepare more detailed analysis of Administrative Costs of new legislation of plant protection products. This survey goes beyond the analysis that will be carried out by Food Chain Evaluation Consortium, therefore we would like endorse for your consideration this additional questionnaire.

Questions in the following sections relate to the current application of Directive 91/414/EEC and alternative policy actions for the future. The detailedness of the questionnaire is driven by underlying effort to quantify the potential costs / benefits with the best possible accuracy.

We would like to apologize for submitting the questionnaire only in English, as due to time constraints we have decided to proceed only with one language version. Thank you for your comprehension.

Similarly as in previous questionnaire, **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.

We would like to thank you in advance for your contribution, as it is highly valuable to us and is crucial in process of assessment of the feasibility of different options.

In case you have any further questions, do not hesitate to contact us:

- On questionnaire related matters:

  Mr. Wojciech Dziworski (Policy Officer, DG Health and Consumer Protection)

  E-mail: wojciech.dziworski@cec.eu.int Phone: +32-2-298 48 08 Fax: +32-2-296 48 75

- On new regulation related matters:

  Mr. Wolfgang Reinert (Legislative Officer, DG Health and Consumer Protection)

  E-mail: wolfgang.reinert@cec.eu.int Phone: +32-2-299 85 86 Fax: +32-2-299 85 66

I. CURRENT APPLICATION OF DIRECTIVE 91/414/EEC

DURATION AND COSTS OF AUTHORISATION/EVALUATION PROCEDURE

1. Please estimate the annual average number of submitted applications for the authorisation/evaluation …

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

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?

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?

specify

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

! Question asked in previous questionnaire – no answer is needed !

3. If possible, please give an estimate of the average cost* (in EUR) of the authorisation / evaluation procedure

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

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?

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?

specify

* Cost – the figure should include all variable costs related to authorisation / evaluation procedure as well as proportion of related fixed costs (i.e. overheads, salaries)

4. **Please give an estimate in % how much of the total cost of the authorisation / evaluation procedure is generated internally, by external bodies (done by other public authorities or public institutes / institutions) or by outsourcing companies (to private institutes or companies).**

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

Appendix 1: ***Internal***	**Appendix 2:** ***External***	**Appendix 3:** ***Internal***
%	%	%

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?

Appendix 4: ***Internal***	**Appendix 5:** ***External***	**Appendix 6:** ***Internal***
%	%	%

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?

Appendix 7: ***Internal***	**Appendix 8:** ***External***	**Appendix 9:** ***Internal***
%	%	%

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

! Question asked in previous questionnaire – no answer is needed !

* 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.

6. **Please estimate what % of average total staff time (referred to in point 5 or in point 11 of previous questionnaire) for the authorisation/evaluation procedure is dedicated by yourself as competent authority to each of the actions listed below:**

Appendix 10:	**Appendix 11:** Type of action	**Appendix 12:** New active substance	**Appendix 13:** New PPP containing Annex I active substance but	**Appendix 14:** New PPP containing Annex I active substance but
Appendix 15: 1	**Appendix 16:** Familiarising	**Appendix 17:**	**Appendix 18:**	**Appendix 19:**
Appendix 20: 2	**Appendix 21:** Check of	**Appendix 22:**	**Appendix 23:**	**Appendix 24:**
Appendix 25: 3	**Appendix 26:** Analysis of	**Appendix 27:**	**Appendix 28:**	**Appendix 29:**
Appendix 30: 4	**Appendix 31:** Consultation	**Appendix 32:**	**Appendix 33:**	**Appendix 34:**
Appendix 35: 5	**Appendix 36:** Holding	**Appendix 37:**	**Appendix 38:**	**Appendix 39:**
Appendix 40: 6	**Appendix 41:** Co-	**Appendix 42:**	**Appendix 43:**	**Appendix 44:**
Appendix 45: 7	**Appendix 46:** Preparation	**Appendix 47:**	**Appendix 48:**	**Appendix 49:**
Appendix 50: 8	**Appendix 51:** Sending of	**Appendix 52:**	**Appendix 53:**	**Appendix 54:**
Appendix 55: 9	**Appendix 56:** Follow – up	**Appendix 57:**	**Appendix 58:**	**Appendix 59:**
Appendix 60: 10	**Appendix 61:** Other	**Appendix 62:**	**Appendix 63:**	**Appendix 64:**
Appendix 65:	ix 66:	**Appendix 67:**	**Appendix 68:**	**Appendix 69:**
Appendix 70:	ix 71:	**Appendix 72:**	**Appendix 73:**	**Appendix 74:**
Appendix 75:	ix 76:	**Appendix 77:**	**Appendix 78:**	**Appendix 79:**
Appendix 80:	**Appendix 81:**	**Appendix 82:** 100%	**Appendix 83:** 100%	**Appendix 84:** 100%

7. Please estimate for each of actions listed below (similarly as in question 6) what % of working hours is done outside the competent authority, that is externalized (done by other public authorites or public institutes / institutions) and outsourced (to private institutes or companies):

Appendix 85:	Appendix 86: Type of action	Appendix 87: New active substance	Appendix 88: New PPP containing Annex I active substance but	Appendix 89: New PPP containing Annex I active substance but
Appendix 90: 1	Appendix 91: Familiarising	Appendix 92:	Appendix 93:	Appendix 94:
Appendix 95: 2	Appendix 96: Check of	Appendix 97:	Appendix 98:	Appendix 99:
Appendix 100: 3	Appendix 101: Analysis of	Appendix 102:	Appendix 103:	Appendix 104:
Appendix 105: 4	Appendix 106: Consultation	Appendix 107:	Appendix 108:	Appendix 109:
Appendix 110: 5	Appendix 111: Holding	Appendix 112:	Appendix 113:	Appendix 114:
Appendix 115: 6	Appendix 116: Co-	Appendix 117:	Appendix 118:	Appendix 119:
Appendix 120: 7	Appendix 121: Preparation	Appendix 122:	Appendix 123:	Appendix 124:
Appendix 125: 8	Appendix 126: Sending of	Appendix 127:	Appendix 128:	Appendix 129:
Appendix 130: 9	Appendix 131: Follow – up	Appendix 132:	Appendix 133:	Appendix 134:
Appendix 135: 10	Appendix 136: Other	Appendix 137:	Appendix 138:	Appendix 139:
Appendix 140:	ix 141:	Appendix 142:	Appendix 143:	Appendix 144:
Appendix 145:	ix 146:	Appendix 147:	Appendix 148:	Appendix 149:
Appendix 150:	ix 151:	Appendix 152:	Appendix 153:	Appendix 154:

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 <u>without</u> 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 <u>with</u> 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.

8. **How do you assess the impact of the different policy options on yourself as competent authority in terms of <u>the annual average number of applications for the authorisation / evaluation</u> of a new active substance (supported by full data package, in case your country is RMS)?**

! If possible please give an estimate of increase/decrease in number of applications (column 1) !

	1	2	3	4	5	6
Number of applications for the authorisation / evaluation would…	Increase (+) / decrease (-) by number of applications	as % change compared to current situation (**only if column 1 not filled in**)				
		decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	increase very significantly (>25%)
Status quo - without binding t NPA after 2007		☐	☐	☐	☐	☐
With binding time limits. No N		☐	☐	☐	☐	☐
Keep NPA after Draft Assessr		☐	☐	☐	☐	☐

Not marked = Don't know

Comments

9. 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)?

! In addition to previous questionnaire, if possible, please give an estimate of increase/decrease in number of days !

Number of staff days per application would …	Increase (+) / decrease (-) by number of days
Status quo - without binding time limits. No NPA after 20	
With binding time limits. No NPA	
Keep NPA after Draft Assessment Report	

Not marked = Don't know

Comments

10. How do you assess the impact of the different policy options <u>on the duration (in days) of the evaluation procedure</u>?

<u>! In addition to previous questionnaire, if possible, please give an estimate of increase/decrease in number of days !</u>

Duration of the evaluation procedure would …	Increase (+) / decrease (-) by number of days
Status quo - <u>without</u> binding time limits. No NPA after 20	
<u>With</u> binding time limits. No NPA	
Keep NPA after Draft Assessment Report	

Not marked = Don't know

Comments

11. How do you assess the impact of the different policy options in terms of increase or decrease (in %) of cost of work done internally (competent authority), by external bodies (other public authorities or public institutes / institutions) or by outsourcing companies (private companies)?

		1	2	3	4	5
Cost of work done internally, externally or outsourced 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%)
Status quo - <u>without</u> binding t NPA after 2007	Internal	☐	☐	☐	☐	☐
	External	☐	☐	☐	☐	☐
	Outsourced	☐	☐	☐	☐	☐
<u>With</u> binding time limits. No N	Internal	☐	☐	☐	☐	☐
	External	☐	☐	☐	☐	☐
	Outsourced	☐	☐	☐	☐	☐
Keep NPA after Draft Assessr	Internal	☐	☐	☐	☐	☐
	External	☐	☐	☐	☐	☐
	Outsourced	☐	☐	☐	☐	☐

Not marked = Don't know

Comments

12. How do you assess the impact of the different policy options in terms of relative increase or decrease (in %) of average staff time (meant as in question 5 & 6) for the authorisation/evaluation procedure dedicated to each of the actions listed below:

Appendix 155:	Appendix 156: Type of action	Appendix 157: *Option A: Status quo - without binding time limits. No*	Appendix 158: *Option B: With binding time limits. No NPA*	Appendix 159: *Option C: Keep NPA after Draft Assessment Report*
Appendix 160: 1	Appendix 161: Familiarising	Appendix 162:	Appendix 163:	Appendix 164:
Appendix 165: 2	Appendix 166: Check of	Appendix 167:	Appendix 168:	Appendix 169:
Appendix 170: 3	Appendix 171: Analysis of	Appendix 172:	Appendix 173:	Appendix 174:
Appendix 175: 4	Appendix 176: Consultation	Appendix 177:	Appendix 178:	Appendix 179:
Appendix 180: 5	Appendix 181: Holding	Appendix 182:	Appendix 183:	Appendix 184:
Appendix 185: 6	Appendix 186: Co-	Appendix 187:	Appendix 188:	Appendix 189:
Appendix 190: 7	Appendix 191: Preparation	Appendix 192:	Appendix 193:	Appendix 194:
Appendix 195: 8	Appendix 196: Sending of	Appendix 197:	Appendix 198:	Appendix 199:
Appendix 200: 9	Appendix 201: Follow – up	Appendix 202:	Appendix 203:	Appendix 204:
Appendix 205: 10	Appendix 206: Other	Appendix 207:	Appendix 208:	Appendix 209:
Appendix 210:	ix 211:	Appendix 212:	Appendix 213:	Appendix 214:
Appendix 215:	ix 216:	Appendix 217:	Appendix 218:	Appendix 219:
Appendix 220:	ix 221:	Appendix 222:	Appendix 223:	Appendix 224:

Not marked = Don't know

Comments

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.

13. How do you assess the impact of the different policy options on yourself as competent authority in terms of <u>the annual average number of applications</u> for a PPP containing an active substance already included in Annex I?

! If possible please give an estimate of increase/decrease in number of applications (column 1) !

	1	2	3	4	5	6
Number of applications for a PPP would…	Increase (+) / decrease (-) by number of applications	as % change compared to current situation (**only if column 1 not filled in**)				
		decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	increase very significantly (>25%)
Status quo - National evaluation		☐	☐	☐	☐	☐
Zonal evaluation and national evaluation – no national risk mitigation		☐	☐	☐	☐	☐
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

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

<u>! In addition to previous questionnaire, if possible, please give an estimate of increase/decrease in number of days !</u>

Number of staff days per application for a PPP would …	Increase (+) / decrease (-) by number of days
Status quo - National evaluation and authorisation	
Zonal evaluation and national authorisation – <u>no</u> nationa 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

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

<u>! In addition to previous questionnaire, if possible, please give an estimate of increase/decrease in number of days !</u>

Duration of the authorisation procedure would …	Increase (+) / decrease (-) by number of days
Status quo - National evaluation and authorisation	
Zonal evaluation and national authorisation – <u>no</u> national 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

16. How do you assess the impact of the different policy options in terms of increase or decrease (in %) of cost of work done internally (competent authority), by external bodies (other public authorities or public institutes / institutions) or by outsourcing companies (private companies)?

		1	2	3	4	5
Cost of work done internally, externally or outsourced 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%)
Status quo - National evaluation	Internal	☐	☐	☐	☐	☐
	External	☐	☐	☐	☐	☐
	Outsourced	☐	☐	☐	☐	☐
Option B: Zonal evaluation and national authorisation – no national risk mitigation measure	Internal	☐	☐	☐	☐	☐
	External	☐	☐	☐	☐	☐
	Outsourced	☐	☐	☐	☐	☐
Zonal evaluation and national evaluation – with national risk mitiga	Internal	☐	☐	☐	☐	☐
	External	☐	☐	☐	☐	☐
	Outsourced	☐	☐	☐	☐	☐
Central agency for evaluation	Internal	☐	☐	☐	☐	☐
	External	☐	☐	☐	☐	☐
	Outsourced	☐	☐	☐	☐	☐

Not marked = Don't know

Comments

17. How do you assess the impact of the different policy options in terms of relative increase or decrease (in %) of average staff time (meant as in question 5 & 6) needed per application for a PPP containing an active substance already included in Annex I, dedicated to each of the actions listed below:

Appendix 226: Type of action	**Appendix 227:** *Option A: Status quo - National evaluation and authorisation*	**Appendix 228:** *Option B: Zonal evaluation and national authorisation – no national risk mitigation measures*	**Appendix 229:** *Option C: Zonal evaluation and national authorisation – with national risk mitigation measures*	A
Appendix 232: Familiarising	**Appendix 233:**	**Appendix 234:**	**Appendix 235:**	
Appendix 238: Check of	**Appendix 239:**	**Appendix 240:**	**Appendix 241:**	
Appendix 244: Analysis of	**Appendix 245:**	**Appendix 246:**	**Appendix 247:**	
Appendix 250: Consultation	**Appendix 251:**	**Appendix 252:**	**Appendix 253:**	
Appendix 256: Holding	**Appendix 257:**	**Appendix 258:**	**Appendix 259:**	
Appendix 262: Co-	**Appendix 263:**	**Appendix 264:**	**Appendix 265:**	
Appendix 268: Preparation	**Appendix 269:**	**Appendix 270:**	**Appendix 271:**	
Appendix 274: Sending of	**Appendix 275:**	**Appendix 276:**	**Appendix 277:**	
Appendix 280: Follow – up	**Appendix 281:**	**Appendix 282:**	**Appendix 283:**	
Appendix 286: Other	**Appendix 287:**	**Appendix 288:**	**Appendix 289:**	
x 292:	**Appendix 293:**	**Appendix 294:**	**Appendix 295:**	
x 298:	**Appendix 299:**	**Appendix 300:**	**Appendix 301:**	
x 304:	**Appendix 305:**	**Appendix 306:**	**Appendix 307:**	

Not marked = Don't know

nts

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 <u>hazard criteria</u> (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, <u>independent from the hazard</u> of the active substances (i.e. for all active substances).**

18. How do you assess the impact of the different policy options on yourself as competent authority in terms of the annual average <u>number of applications for a PPP</u>?

! If possible please give an estimate of increase/decrease in number of applications (column 1) !

	1	2	3	4	5	6
Number of applications for a PPP would…	Increase (+) / decrease (-) by number of applications	as % change compared to current situation (**only if column 1 not filled in**)				
		decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	increase very significantly (>25%)
Status Quo - No provision fo ve 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

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

<u>! In addition to previous questionnaire, if possible, please give an estimate of increase/decrease in number of days !</u>

Number of staff days per application for a PPP would …	Increase (+) / decrease (-) by number of days
Status Quo - No provision for comparative assessment	
Identification of candidates for substitution at the EU lev criteria	
Option C: Comparative assessment at the national level independent from the hazard of the active substances	

Not marked = Don't know

Comments

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

<u>! In addition to previous questionnaire, if possible, please give an estimate of increase/decrease in number of days !</u>

Duration of the authorisation procedure would …	Increase (+) / decrease (-) by number of days
Status Quo - No provision for comparative assessment	
Identification of candidates for substitution at the EU lev criteria	
Option C: Comparative assessment at the national level independent from the hazard of the active substances	

Not marked = Don't know

Comments

21. How do you assess the impact of the different policy options in terms of increase or decrease (in %) of cost of work done internally (competent authority), by external bodies (other public authorities or public institutes / institutions) or by outsourcing companies (private companies)?

		1	2	3	4	5
Cost of work done internally, externally or outsourced 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%)
Status Quo - No provision fo *ve assessment*	Internal	☐	☐	☐	☐	☐
	External	☐	☐	☐	☐	☐
	Outsourced	☐	☐	☐	☐	☐
Identification of candidates fo *n at the EU level based on ha*	Internal	☐	☐	☐	☐	☐
	External	☐	☐	☐	☐	☐
	Outsourced	☐	☐	☐	☐	☐
Comparative assessment at th *evel independent from the haza* *stances*	Internal	☐	☐	☐	☐	☐
	External	☐	☐	☐	☐	☐
	Outsourced	☐	☐	☐	☐	☐

Not marked = Don't know

Comments

22. How do you assess the impact of the different policy options in terms of relative increase or decrease (in %) of average staff time (meant as in question 5 & 6) needed per application for a PPP, dedicated to each of the actions listed below:

dix 309:	Appendix 310: Type of action	Appendix 311: *Option A: Status Quo - No provision for comparative assessment*	Appendix 312: *Option B: Identification of candidates for substitution at the EU level based on hazard criteria*	Appendix 3 *C: Comp assessme nationa independe*
dix 314: 1	Appendix 315: Familiarising	Appendix 316:	Appendix 317:	Appendix 3
dix 319: 2	Appendix 320: Check of	Appendix 321:	Appendix 322:	Appendix 3
dix 324: 3	Appendix 325: Analysis of	Appendix 326:	Appendix 327:	Appendix 3
dix 329: 4	Appendix 330: Consultation	Appendix 331:	Appendix 332:	Appendix 3
dix 334: 5	Appendix 335: Holding	Appendix 336:	Appendix 337:	Appendix 3
dix 339: 6	Appendix 340: Co-	Appendix 341:	Appendix 342:	Appendix 3
dix 344: 7	Appendix 345: Preparation	Appendix 346:	Appendix 347:	Appendix 3
dix 349: 8	Appendix 350: Sending of	Appendix 351:	Appendix 352:	Appendix 3
dix 354: 9	Appendix 355: Follow – up	Appendix 356:	Appendix 357:	Appendix 3
ix 359: 10	Appendix 360: Other	Appendix 361:	Appendix 362:	Appendix 3
dix 364:	ix 365:	Appendix 366:	Appendix 367:	Appendix 3
dix 369:	ix 370:	Appendix 371:	Appendix 372:	Appendix 3
dix 374:	ix 375:	Appendix 376:	Appendix 377:	Appendix 3

Not marked = Don't know

Comments

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.

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

! If possible please give an estimate of increase/decrease in number of applications (column 1) !

	1	2	3	4	5	6
Number of applications would…	Increase (+) / decrease (-) by number of applications	as % change compared to current situation (**only if column 1 not filled in**)				
		decrease very significantly (>25%)	decrease fairly significantly (10-25%)	remain similar (<10%)	increase fairly significantly (10-25%)	increase very significantly (>25%)
Status quo - Data protection, no y data sharing		(a) ☐	(b) ☐	(c) ☐	(d) ☐	(e) ☐
Data protection, with compulsor		☐	☐	☐	☐	☐
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

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

<u>! In addition to previous questionnaire, if possible, please give an estimate of increase/decrease in number of days !</u>

Number of staff days per application would …	Increase (+) / decrease (-) by number of days
Status quo - Data protection, no compulsory data sharing	
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

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

<u>! In addition to previous questionnaire, if possible, please give an estimate of increase/decrease in number of days !</u>

Duration of the authorisation procedure would …	Increase (+) / decrease (-) by number of days
Status quo - Data protection, no compulsory data sharing	
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

26. How do you assess the impact of the different policy options in terms of increase or decrease (in %) of cost of work done internally (competent authority), by external bodies (other public authorities or public institutes / institutions) or by outsourcing companies (private companies)?

		1	2	3	4	5
Cost of work done internally, externally or outsourced 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%)
Status quo - Data protection, y data sharing	Internal	☐	☐	☐	☐	☐
	External	☐	☐	☐	☐	☐
	Outsourced	☐	☐	☐	☐	☐
Option B: Data protection, with compulsory data sharing	Internal	☐	☐	☐	☐	☐
	External	☐	☐	☐	☐	☐
	Outsourced	☐	☐	☐	☐	☐
Option C: No data protection period for renewal of inclusion in Annex I	Internal	☐	☐	☐	☐	☐
	External	☐	☐	☐	☐	☐
	Outsourced	☐	☐	☐	☐	☐
Two stage data protection sta f dossier submission	Internal	☐	☐	☐	☐	☐
	External	☐	☐	☐	☐	☐
	Outsourced	☐	☐	☐	☐	☐

Not marked = Don't know

Comments

27. How do you assess the impact of the different policy options in terms of relative increase or decrease (in %) of <u>average staff time</u> (meant as in question 5 & 6) <u>needed per application</u> that you would expect for a renewal of inclusion of an active substance in Annex I (please use Option A as reference), dedicated to each of the actions listed below:

Appendix 380: Type of action	**Appendix 381:** *Option A: Status quo - Data protection, no compulsory data sharing*	**Appendix 382:** *Option B: Data protection, with compulsory data sharing*	**Appendix 383:** *Option C: No data protection period for renewal of inclusion in Annex I*	A
Appendix 386: Familiarising	**Appendix 387:**	**Appendix 388:**	**Appendix 389:**	
Appendix 392: Check of	**Appendix 393:**	**Appendix 394:**	**Appendix 395:**	
Appendix 398: Analysis of	**Appendix 399:**	**Appendix 400:**	**Appendix 401:**	
Appendix 404: Consultation	**Appendix 405:**	**Appendix 406:**	**Appendix 407:**	
Appendix 410: Holding	**Appendix 411:**	**Appendix 412:**	**Appendix 413:**	
Appendix 416: Co-	**Appendix 417:**	**Appendix 418:**	**Appendix 419:**	
Appendix 422: Preparation	**Appendix 423:**	**Appendix 424:**	**Appendix 425:**	
Appendix 428: Sending of	**Appendix 429:**	**Appendix 430:**	**Appendix 431:**	
Appendix 434: Follow – up	**Appendix 435:**	**Appendix 436:**	**Appendix 437:**	
Appendix 440: Other	**Appendix 441:**	**Appendix 442:**	**Appendix 443:**	
x 446:	**Appendix 447:**	**Appendix 448:**	**Appendix 449:**	
x 452:	**Appendix 453:**	**Appendix 454:**	**Appendix 455:**	
x 458:	**Appendix 459:**	**Appendix 460:**	**Appendix 461:**	

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 plant protection products 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).

28. 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?

<u>! In addition to previous questionnaire, if possible, please give an estimate of increase/decrease in number of days !</u>

Number of staff days per application would …	Increase (+) / decrease (-) by number of days
Status quo – No duty to inform neighbours	
Active duty to inform neighbours	
Option C: Passive duty to inform neighbours	

Not marked = Don't know

Comments

B) Report on Administrative Burden

Introduction

During the stakeholder consultations in 2004 and 2005, some participants highlighted the importance of assessment of impact of the proposal on so-called Administrative Burden. This term covers all costs incurred by enterprises, the voluntary sector, public authorities and citizens in meeting legal obligations to provide information on their action or production, either to public authorities or to private parties.

The Administrative Burden was already considered and assessed by the European Commission in the early drafts of the Impact Assessment, however assessment remained only qualitative. In a similar manner, the administrative costs resulting from the proposal were also analysed by the consultant (FCEC) in its report (see Annex 2).

However, conclusion of work on the impact assessment came at the time of extensive work within the European Commission on methodologies for assessment and quantification of the Administrative Burden. The European Council which took place in Brussels on 15-16 of December, stressed the importance "…of reducing unnecessary burdens for business and citizens", as well as inviting "…the Commission to start measuring administrative burdens, on a consistent basis and in line with transparent criteria, as part of integrated impact assessments launched as of January 2006.". Having this in mind, The European Commission adopted in October 2005, the Communication[1] on an EU common methodology for assessing administrative costs imposed by legislation along with detailed Staff Working Paper[2] outlining the proposed EU common methodology and presenting Report on the Pilot Phase (April– September 2005) This process eventually concluded with revision of Impact Assessment Guidelines[3] in March 2006 and addition of Annex on Administrative Burden's quantification methodologies.

Even though, accordingly to the Communication, only impact assessments which were started to be drafted in 2006 are subject to the obligation to quantify Administrative Burden in case of assessment of impacts of major proposals, DG Health and Consumer Protection has decided to prepare a more detailed analysis of Administrative Costs of new legislation of plant protection products, attempting to apply the new methodology.

Data limitations

The administrative processes which were to be assessed proved to be very complex, hence any attempt for quantification required estimation of numerous variables. Only few of the variables were available from public sources (i.e. Eurostat), therefore the significant data gaps had to be filled in with help of detailed questionnaires sent in to both Member States and business operators in the market.

Due to the relative novelty of this process and unfamiliarity with the concept of Administrative Burden within the European Union, the quality of data collected through

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1 COM(2005) 518.
2 SEC(2005) 1329.
3 SEC(2005) 791.

questionnaires is very poor. Thus the accuracy of the assessment decreased. In addition, detailed verification of all the data collected due to their sheer volume was not feasible, therefore in case of frequent consistencies or remaining gaps, extra assumptions had to be made, diminishing further the exactness of the calculations. Based on aforementioned, even though the results presented below give a good idea of the scale of costs involved, they should be treated with a degree of reservation, as a quantification of Member States' authorities predictions / wishes rather than thorough forecasting.

Methodology

The core equation of the model for assessment of the Administrative Burden agreed by the European Commission is based on the Dutch Standard Cost Model. Administrative costs is assessed on the basis of the average cost of the required action (Price) multiplied by the total number of actions performed per year (Quantity). For the purpose of this exercise (Administrative Burden in public authorities) the equation is the following

Σ Price x Quantity

- Price = Tariff x Time;
  - Tariff = labour cost per day in public administration
  - Time = number of working days needed for evaluation / authorisation
- Quantity = Number of actions x Frequency
  - Number of entities actions = annual number of submitted applications for evaluation / authorisation
  - Frequency = 1 (one-year)

The data were collected through questionnaires and analysis of general statistics. The questionnaires were sent to all 25 Member States and main industry organisation for distribution among their members. There were 15 responses from the Member States authorities and only 8 answers from business operators. The response rate from Member States, even though the quality of the answers varies substantially, is sufficient to perform basic estimation. The results from 15 Member States were then used for extrapolation for EU-25 on the basis GDP at market prices generated by agricultural sector in each of the countries.

As far as analysis of Administrative Burden on business operators is concerned, very low number of received responses makes even indicative estimation too unreliable, therefore quantitative analysis was not be carried out.

The data collected through questionnaires were then combined with publicly available data from Eurostat (i.e. labour costs) for estimation of impact of each policy option in each of the 5 policy actions. Both the data from the questionnaires as well as from Eurostat depict significant differences, or rather gaps, between some Member States i.e. labour costs per hour in public administration in Denmark exceed 31 euros, while in Latvia reach only 3,5 euros.

The assessment methodology proposed by the European Commission however could not be fully applied. Due to poor quality and low volume of data collected, a breakdown into types of obligations linked with Administrative Burden and their further division into specific actions was not possible.

Analysis of the results

The results will be presented below following the division into 5 policy actions.

In one of the questions, the Member States authorities were asked to give an estimate of the cost of the authorisation / evaluation of one dossier. The responses varied significantly:

Appendix 463:

Appendix 464: The average cost (in EUR) of the authorisation / evaluation procedure of 1 dossier

Appendix 465: New active substance that supported by a full data package (in case your country is RMS)

Appendix 466: 50.000 – 360.000, with majority of responses > 100.000

Appendix 467: 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

Appendix 468: 10.000 – 240.000, with majority of responses < 50.000

Appendix 469: 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

Appendix 470: 10.000 – 2400.000, with majority of responses < 50.000

As the analysis below proves that reality is less costly.

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

	Annual Administrative Burden ('000 eur) for EU-25	average % change in number of days needed for revision of a dossier	average % change in number of applications for evaluation / authorisation
2005	22.775,67	-	-
Option A: Status quo - without binding time limits. No NPA after 2007	21.832,68	0,00%	-1,97%
Option B: With binding time limits. No NPA	24.688,78	1,65%	-0,72%
Option C: Keep NPA after Draft Assessment Report	24.220,66	1,65%	0,18%

By abolishing National Provisional Authorisations (options A and B) the number of applications for evaluation / authorisations reduces. However, the Member States authorities suggest that binding limits (option B) can surprisingly result in increase of labour costs as shortened time limits might create a demand for additional staff.

- *Policy action 2: Mutual recognition of PPP containing an active substance already included in Annex I*

	Annual Administrative Burden ('000 eur) for EU-25	average % change in number of days needed for revision of a dossier	average % change in number of applications for evaluation / authorisation
2005	22.775,67	-	-
Option A: Status quo - National evaluation and authorisation	22.775,67	0,00%	0,00%
Option B: Zonal evaluation and national authorisation - no national risk mitigation measures	25.349,77	-3,87%	17,22%
Option C: Zonal evaluation and national authorisation - with national risk mitigation measures	25.221,80	-3,73%	17,24%
Option D: Central agency for evaluation and authorisation	21.200,32	-4,63%	-15,06%

The Member States authorities predict that zonal system with mutual recognition will reduce the number of days needed for revision of a dossier, however at the same time each of them situate itself as the one that will carry the burden of zonal authorisation / evaluations the most (number of applications) i.e. UK. The option D (Central Agency) is certainly the best option from the point of view of Member States' authorities since they do not take into account all the costs linked with establishment of such an agency.

- *Policy action 3: Comparative assessment of PPP*

	Annual Administrative Burden ('000 eur) for EU-25	average % change in number of days needed for revision of a dossier	average % change in number of applications for evaluation / authorisation
2005	22.775,67	-	-
Option A: Status Quo - No provision for comparative assessment	22.775,67	0,00%	0,00%
Option B: Identification of candidates for substitution at the EU level based on hazard criteria	22.354,50	2,53%	-12,61%
Option C: Comparative assessment at the national level independent from the hazard of the active substances	23.104,78	6,06%	-12,26%

The Member States' authorities accentuate the risk of increased staff needs resulting from the implementation of the comparative assessment. However, as at the same time, comparative assessment should lead to reduction in the number of active substance / PPPs (number of applications for evaluation / authorisation), the overall costs should decrease in option B and slightly increase as for option C.

- *Policy action 4: Data sharing for the renewal of Annex I inclusion of an active substance*

	Annual Administrative Burden ('000 eur) for EU-25	average % change in number of days needed for revision of a dossier	average % change in number of applications for evaluation / authorisation
2005	22.775,67	-	-
Option A: Status quo - Data protection, no compulsory data sharing	22.775,67	0,00%	0,00%
Option B: Data protection, with compulsory data sharing	26.023,79	-0,40%	11,07%
Option C: No data protection period for renewal of inclusion in Annex I	27.128,28	-0,71%	15,41%
Option D: Two stage data protection starting with the time of dossier submission	23.257,38	-0,16%	0,04%

The Member States' authorities predict that data sharing should directly result in increased number of applications / evaluations thus increasing the Administrative Burden. Rather surprisingly the same authorities see no impact of data sharing on quality of the dossier and subsequently the time required for their revision.

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

	Annual Administrative Burden ('000 eur) for EU-25
Option A: Status quo - No duty to inform neighbours	0,00
Option B: Active duty to inform neighbours	690,90
Option C: Passive duty to inform neighbours	525,88

The Administrative Burden linked with obligation to inform neighbours is rather negligible as this cost annually for EU-25 is not expected to exceed 1 million euro in both active and passive duty approach.

Conclusion

Administrative Burden is only one of the impacts that were evaluated in the course of the impact assessment drafting. The analysis proved that Administrative Burden on Member States' authorities resulting from Plant Protection Products authorisation / evaluation procedures will not change significantly following the proposed revision of the new Regulation replacing the currently functioning Directive. The effect of the provisions depends largely on their implementation. The most of the Member States' authorities still remains unsure about how both mutual recognition and data sharing will work in practice, therefore predict increased numbers of applications for authorisations / evaluation in coming years, thus adversely affecting the calculations.

However, as Report FCEC (Annex 2) presents the large part of the benefits of proposed policy options in terms of Administrative Burden lies with business operators. The two parts should be therefore analysed together, despite the fact that due to low response rate, the impact of the proposal on Administrative Burden on business operators could not be quantified.

List of received answers:

- Member States' authorities:
  1. Austria – Federal Office for Food Safety
  2. Denmark - Environmental Protection Agency
  3. Estonia – Plant Protection Inspectorate
  4. Finland - Plant Production Inspection Centre
  5. Germany - Federal Office of Consumer Protection and Food Safety
  6. Greece - Ministry of Rural Development & Food, Directorate General for Plant Production, Dept. of Pesticides
  7. Ireland - Pesticide Control Service, Department of Agriculture Laboratories
  8. Italy – Ministero della Salute, Dipartimento della Sanita' Pubblica Veterinaria, La Nutrizione e la Sicurezza degli Alimenti
  9. Latvia - State Plant Protection Service
  10. Lithuania – State Plant Protection Service
  11. The Netherlands - Ministry of Agriculture, Nature and Food Quality
  12. Slovak Republic - Ministry of Agriculture
  13. Slovenia - Phytosanitary Administration
  14. Sweden - Swedish Chemicals Inspectorate
  15. United Kingdom - Pesticides Safety Directorate

- Business operators or industry organisations:
  1. AgriChem b.v. – The Netherlands
  2. Bayer CropScience – Germany
  3. Herbex – Portugal
  4. Coalition of smaller research-based PPP companies (Chemtura , Gowan, ISK, Japan Agro Services, Stahler, Taminco, Isagro) – international
  5. Syngenta – Switzerland
  6. Rokita-Agro Spólka Akcyjna – Poland
  7. Asociacón Española de Fitosanitarios y Sanidad Ambiental AEFISA – Spain
  8. European Seed Association – Belgium