



COMMISSION OF THE EUROPEAN COMMUNITIES

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ANNEX 4

COMMISSION STAFF WORKING DOCUMENT

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

Annex 4

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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 4

Interactive Policy Making (IPM) online consultation, 10 March – 10 May 2005

A) Questionnaire

The Future of Pesticides in Europe

Interactive Policy Making (IPM) online consultation on the Proposal concerning Amendments made to the Council Directive 91/414/EEC of 15 July 1991 concerning the Placing of Plant Protection Products on the Market.

Confidentiality

Any information collected in this questionnaire that could enable recognition of an individual contributor falls under Regulation (EC) No 45/2001.

Background

Directive 91/414/EEC provides for the establishment of a positive list of active substances for the use in plant protection products, which have been evaluated to be safe for humans and which do not present an unacceptable risk to the environment. Member States are only permitted to authorise the placing on the market and the use of plant protection products if the active substance is on the positive list, except where transitional arrangements apply. The Directive also makes provision for a system, based on mutual recognition of the Member States' authorisations, provided that the agricultural, plant health and environmental conditions in the Member States concerned are comparable.

Ten years after its adoption, the Commission presented an extensive report on the functioning of the above Directive to the Council and the European Parliament (doc. COM (2001)444). The Council and the Parliament called on the Commission to present a proposal to amend the Directive.

This inquiry should be considered as a fine tuning of the consultation process. The objective of this exercise is not to address health and environmental issues, since they have been addressed previously. It is open to all stakeholders both within the EU and outside.

Identification of the main issues:

- Mutual recognition does not function well and national authorisations of products leads to duplication of work in the Member States and to differences in the availability of plant protection products across the European Union. The proposal would set up a more harmonised approach.
- Sharing of data, developed by the companies to support the safety evaluation of pesticides, needs to be further clarified.
- Consumer, operator and environmental protection are key elements in the Directive. Criteria for acceptance of pesticides and the principle of comparative assessment will be considered.
- More than half of all existing active substances were withdrawn from the market in 2003. There is a strong possibility that, in addition, niche substances will also disappear in the years to come,

unless special provisions are made to keep this market attractive to industry.

Background documents

Council Directive 91/414/EEC

Report from the Commission to the European Parliament and the Council : Evaluation of the active substances of plant protection products (Doc. COM (2001) 444)

Technical Annex

Privacy Statement

Profile-related questions

Do you represent(Compulsory)

- a manufacturer
 - a user
 - an individual person
 - an importer
 - a public authority
 - a NGO
 - other, please specify
-

Role in organisation(Compulsory)

- none – answering as an individual management
- researcher
- senior
- management
- strategy/policy function
- specialist/expert
- not applicable

Name of Contact Person

Name of your organisation (write "none" if you reply as an individual)(Compulsory)

Your organisation's country of establishment (indicate your country of residence if answering as an

individual person) (Compulsory)

- | | | |
|--|--|---|
| <input type="checkbox"/> AT - Austria | <input type="checkbox"/> BE - Belgium | <input type="checkbox"/> CY - Cyprus |
| <input type="checkbox"/> CZ - Czech Republic | <input type="checkbox"/> DE - Germany | <input type="checkbox"/> DK - Denmark |
| <input type="checkbox"/> EE - Estonia | <input type="checkbox"/> EL - Greece | <input type="checkbox"/> ES - Spain |
| <input type="checkbox"/> FI - Finland | <input type="checkbox"/> FR - France | <input type="checkbox"/> HU - Hungary |
| <input type="checkbox"/> IE - Ireland | <input type="checkbox"/> IT - Italy | <input type="checkbox"/> LT - Lithuania |
| <input type="checkbox"/> LU - Luxembourg | <input type="checkbox"/> LV - Latvia | <input type="checkbox"/> MT - Malta |
| <input type="checkbox"/> NL - Netherlands | <input type="checkbox"/> PL - Poland | <input type="checkbox"/> PT - Portugal |
| <input type="checkbox"/> SE - Sweden | <input type="checkbox"/> SI - Slovenia | <input type="checkbox"/> SK - Slovak Republic |
| <input type="checkbox"/> UK - United Kingdom | <input type="checkbox"/> Other, | please specify |

Size of your organisation (not applicable for public authorities)

Your organisation's geographical area of activities (Compulsory)

- | | | |
|-----------------------------------|--|---|
| <input type="checkbox"/> local | <input type="checkbox"/> regional | <input type="checkbox"/> national |
| <input type="checkbox"/> European | <input type="checkbox"/> international | <input type="checkbox"/> not applicable |

The Market

Plant Protection Products (PPPs) are active substances or preparations (containing one or more active substances) intended to protect plants or plant products against harmful organisms or to prevent the action of such organisms. Data protection ensures that data generated by a company can not be used by another company, unless specific agreement is given.

In your view, what is the importance of different competitive tools listed below on the market for Plant Protection Products (PPP)?

Data Protection(Compulsory)

- Very Important
- Important
- Not Important

- Insignificant
- Do not know

Data Sharing(Compulsory)

- Very Important
- Important
- Not Important
- Insignificant
- Do not know

Centralised Production(Compulsory)

- Very Important
- Important
- Not Important
- Insignificant
- Do not know

Decentralised Production(Compulsory)

- Very Important
- Important
- Not Important
- Insignificant
- Do not know

Distribution Channels(Compulsory)

- Very Important
- Important
- Not Important
- Insignificant
- Do not know

Commercial Name of the Product(Compulsory)

- Very Important
- Important
- Not Important
- Insignificant
- Do not know

Patents(Compulsory)

- Very Important
- Important
- Not Important
- Insignificant
- Do not know

Location of Storage(Compulsory)

- Very Important
- Important
- Not Important
- Insignificant
- Do not know

The Zones

In order to increase the efficiency and the transparency of authorisation, it is proposed that the EU be divided into three separate zones based on geographical, biological and climatological criteria.

- The Nordic Zone includes: Denmark, Estonia, Finland, Latvia, Lithuania and Sweden,
- The Central Zone includes: Austria, Belgium, Czech Republic, Germany, Hungary, Ireland, Luxembourg, the Netherlands, Poland, Slovak Republic, Slovenia and the United Kingdom.
- The Southern Zone includes: Cyprus, France, Greece, Italy, Malta, Portugal and Spain.

A zone is a group of Member States for which it is assumed that the agricultural, plant health and

environmental conditions are relatively similar.

In order to obtain mutual recognition of the authorisation, issued in one of the Member States, the holder of the authorisation would request recognition of this authorisation to the competent authorities of the Member States within the same zone.

The new proposed zoning structure, consisting of three zones or markets (Nordic Zone, Central Zone and Southern Zone), instead of 25 national markets consisting of 25 Member States, may lead to changes for the PPP users.

In your opinion, how important will these changes be on the items listed below?

Price(Compulsory)

- Very Important
- Important
- Not Important
- Insignificant
- Do not know

Administrative burden or complexity(Compulsory)

- Very Important
- Important
- Not Important
- Insignificant
- Do not know

Number of Available Products(Compulsory)

- Very Important
- Important
- Not Important
- Insignificant
- Do not know

Choice of Products(Compulsory)

- Very Important

- Important
- Not Important
- Insignificant
- Do not know

Market Structure(Compulsory)

- Very Important
- Important
- Not Important
- Insignificant
- Do not know

Plant Protection Products Related Questions

In your opinion, should zoning structure lead to a single compulsory risk evaluation and authorisation within each Zone?(Compulsory)

- yes no

In your opinion, should zoning structure lead to a single risk evaluation within each Zone followed by individual national authorisations?(Compulsory)

- yes no

Duration of the authorisation

In your opinion, should the duration of the authorisation be for(Compulsory)

- A fixed period of time

- A fixed period of time expanded tacitly if no unfavourable information has been received
- Only reassessed if unfavourable information is available

The Questionnaire

How did you perceive this questionnaire?(Compulsory)

- Expectations met
- Expectations not met

Why?(Compulsory)

- Too general
- Irrelevant in content
- Too difficult to understand
- Too short
- Too technical
- Too long

B) Report

There were 194 responses to the questionnaire. The majority or 55 % of the responses came from four Member States, France, Belgium, Italy and the Netherlands. No or less than five responses were received from most or 18 Member States. Nobody outside the EU answered to the questionnaire. Most responses were received from individuals (some 40%), 25 responses from NGOs, 20 from manufacturers and 15 from public authorities. Only 4 importers of pesticides responded to the questionnaire. The majority or 70 % of the organisations were small or medium sized and mainly active on the regional or national market (69 %). Only 18 or 9 % operated at a European level.

The Market

Seven questions were asked about the market: data protection, data sharing, decentralisation, distribution, commercial name of the product, patents and location of storage. The most important identified critical market success factors were data sharing, distribution, location and patents.

Data protection was considered to be “important” or “very important” by 64 % of the respondents primarily located in Belgium, Spain and in France. Data sharing received very high support by the respondents (88 %). Strong support was noted in France, Belgium, Spain and Italy. Decentralised production was considered not to be important by the majority of respondents (61 %). There were no clear preferences for decentralised or centralised production of pesticides.

All (100 %) manufacturers and public authorities as well as the majority of importers (75 %) considered data protection “important” or “very important”. Data sharing was considered “important” or “very important” by all manufactures (100 %) and the overwhelming majority of NGO’s (88 %), public authorities (93 %) and users (92 %).

Distribution was considered to be “important” or “very important” by 82 % of the respondents. This was especially the case for France, Italy, Belgium, Spain and the Netherlands. Distribution was considered paramount for importers (100 %), manufactures (95 %), but also for NGOs, public authorities and the user. All considered distribution to be a critical success factor (75 – 95 %).

The name of the product or branding was not considered to be “very important”. Most or 64% of the respondents were of this opinion. Meanwhile, the name or brand of the product was considered to be “very important” or “important” for the importer (75 %) and the user (63 %), but also for the manufacturer (60 %) and the NGO (56 %).

Patents were considered to be “important” or “very important” by 74 % of the respondents. This was especially the case for France, Germany and Spain. Patents were considered critical for the manufacturer and the importer (100 %) and significant for the NGOs (68 %), the public authority (80 %) and the user (79 %).

Location was considered to be significant for 75 % of the respondents. This variable was considered “important” or “very important” by all respondents, especially by those from France. This was the critical factor for French respondents which represented nearly half of all those indicating this factor as “very important”. Location of storage was “important” or “very important” for the public authority (80 %), and for the user (79 %) as well as for the importer, but to a lesser extent for the manufacturer (60 %).

The Zones

Five questions were asked on the zones: price, administrative burden or complexity, number of available products, choice of products and market structure. All these factors were considered to be “important” or “very important” by the great majority of respondents.

The price of the pesticides was considered to be “important” or “very important” by the majority of respondents (67 %), but nearly a quarter (24 %) considered it to be either “insignificant” or “not important”. Price was considered “important” or “very important” by the manufacturer (90 %) and by the user (75 %).

Over 70 % of the respondents considered the administrative burden to be too high (important/very important). This was especially the case in France, Belgium and Italy and to a lesser extent in Germany and the Netherlands. Administrative burden was considered to be an “important” or “very important” issue for the manufacturer (85 %), the importer and the user (84 %), but to a lesser extent for the public authority where only 27 % considered it to be “very important” and 40 % “important”. A third of the respondents representing public authorities considered the burden “insignificant” or simply did not know the administrative burden level.

Some 73 % of the respondents considered availability of products to be either “important” or “very important”. But a quarter considered product availability to be either “not important” or “insignificant”. Product availability is critical for the importer and the manufacturer.

Nearly two thirds or 76 % of the respondents considered the choice of products to be “important” or “very important”. The market structure was considered to be “important” or “very important” by the majority of respondents (75 %). The highest supporting figures were received from the importer (100 %) and the manufacturer (95 %). Surprisingly, a fifth of the users considered product choice as “not important” or “insignificant”.

Plant Protection Products Related Questions

Two questions were asked on this subject.

- In your opinion, should zoning structure lead to a single compulsory risk evaluation and authorisation within each zone?
- In your opinion, should zoning structure lead to a single risk evaluation for each zone followed by individual national authorisation?

70 % responded YES to the first question. The only anomaly was Spain where support for a single compulsory risk evaluation and authorisation within each zone was only supported by a minority or 40 % of the respondents.

The responses to the second question were even (52%/47 %). The anomaly was Spain, where 80 % of the respondents were of the opinion that the zoning structure should lead to a single risk evaluation for each zone followed by an individual national authorisation.

Among the responding groups there was overwhelming general support (70 %) for a single compulsory risk evaluation and authorisation within each zone, but support between different respondents varied. Only 60 % of the manufactures and 40 % of the public authorities supported this alternative. Strong support was shown by importers (100 %) and by NGOs (84 %). The YES and NO responses to the second questions were more even 52/48 %. The user e.g. the farmer was strongly against this alternative. Almost two thirds of the farmers voted against.

Duration of the Authorisation

Here the responses were even. 43 % of the respondents supported the statement that a fixed period of time expanded tacitly if no unfavourable information is received. 37 % were for a straight forward fixed time period and 19 % considered that the time period for authorisation should be reassessed only if unfavourable information is available. A simple fixed time period was supported strongly by the Netherlands, Austria and France. The Spanish respondents supported a fixed time period expanded tacitly if no unfavourable information is received and the United Kingdom a reassessment of the authorisation if unfavourable information is available.

37 % of the different respondent groups were for a fixed time period, which was supported by the public authorities (69 %). Some 44 % of the respondents were for a fixed time period if no unfavourable information has been received. This alternative was strongly supported by the

importer (75 %) and the manufacturer (75 %). The third alternative, “reassessed if unfavourable information is available”, was mainly supported by NGOs (44 %).