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REPORT

on the Commission report entitled: 'Evaluation of the active substances of plant protection products (submitted in accordance with Article 8(2) of Council Directive 91/414/EEC on the placing of plant protection products on the market)' (COM(2001) 444 – C5-0011/2002 – 2002/2015(COS))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Paul A.A.J.G. Lannoye

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PROCEDURAL PAGE

By letter of 25 July 2001 the Commission forwarded to Parliament its report entitled: 'Evaluation of the active substances of plant protection products (submitted in accordance with Article 8(2) of Council Directive 91/414/EEC on the placing of plant protection products on the market)' (COM(2001) 444 – 2002/2015(COS)).

At the sitting of 16 January 2002 the President of Parliament announced that he had referred the report to the Committee on the Environment, Public Health and Consumer Policy as the committee responsible and to the Committee on Legal Affairs and the Internal Market and the Committee on Agriculture and Rural Development for their opinions (C5-0011/2002).

The Committee on the Environment, Public Health and Consumer Policy had appointed Paul A.A.J.G. Lannoye rapporteur at its meeting of 4 December 2001.

The committee considered the Commission report and the draft report at its meetings of 19 February 2002, 26 March 2002 and 23 April 2002.

At the last meeting it adopted the motion for a resolution by 28 votes to 19, with 4 abstentions.

The following were present for the vote: Caroline F. Jackson (chairman); Mauro Nobilia, Alexander de Roo and Anneli Hulthén (vice-chairmen); Paul A.A.J.G. Lannoye (rapporteur); Jean-Louis Bernié, Hans Blokland, David Robert Bowe, John Bowis, Martin Callanan, Dorette Corbey, Chris Davies, Jillian Evans (for Hiltrud Breyer), Marialiese Flemming, Karl-Heinz Florenz, Cristina García-Orcoyen Tormo, Robert Goodwill, Françoise Grossetête, Cristina Gutiérrez Cortines, Jutta D. Haug (for Anne Ferreira), Heidi Anneli Hautala (for Marie Anne Isler Béguin), Christa Klaß, Eija-Riitta Anneli Korhola, Bernd Lange, Peter Liese, Rolf Linkohr (for María Sornosa Martínez), Giorgio Lisi (for Raffaele Costa), Torben Lund, Jules Maaten, Minerva Melpomeni Malliori, Miguel Angel Martínez Martínez (for Phillip Whitehead, pursuant to Rule 153(2)), Erik Meijer (for Pernille Frahm), Jorge Moreira da Silva, Riitta Myller, Ria G.H.C. Oomen-Ruijten, Neil Parish (for Avril Doyle), Béatrice Patrie, Encarnación Redondo Jiménez (for Emilia Franziska Müller), Frédérique Ries, Dagmar Roth-Behrendt, Guido Sacconi, Giacomo Santini (for Giuseppe Nisticò), Karin Scheele, Ursula Schleicher (for Per-Arne Arvidsson) , Inger Schörling, Renate Sommer (for María del Pilar Ayuso González), Catherine Stihler, Nicole Thomas-Mauro, Astrid Thors, Antonios Trakatellis, Kathleen Van Brempt and Rainer Wieland (for Horst Schnellhardt).

The opinion of the Committee on Agriculture and Rural Development is attached; the Committee on Legal Affairs and the Internal Market decided on 6 November 2001 not to deliver an opinion.

The report was tabled on 25 April 2002.

The deadline for tabling amendments will be indicated in the draft agenda for the relevant part-session.

MOTION FOR A RESOLUTION

European Parliament resolution on the Commission report entitled: 'Evaluation of the active substances of plant protection products (submitted in accordance with Article 8(2) of Council Directive 91/414/EEC on the placing of plant protection products on the market)' (COM(2001) 444 – C5-0011/2002 – 2002/2015(COS))

The European Parliament,

– having regard to the Commission report (COM(2001) 444 – C5-0011/2002)[1],

– having regard to Council Directive 91/414/EEC concerning the placing of plant protection products on the market[2], and having regard to Council Directives 76/895/EC[3], 86/362/EEC[4], 86/363/EEC[5] and 90/642/EEC[6] on the fixing of maximum levels for pesticide residues in and on fruit and vegetables, cereals, and foodstuffs of animal origin,

– having regard to Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy[7],

– having regard to Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption[8],

– having regard to the Commission's White Paper entitled: 'Strategy for a future Chemicals Policy'[9],

– having regard to its resolution of 15 November 2001 on the Commission's White Paper entitled: 'Strategy for a future Chemicals Policy'[10],

– having regard to Directive 96/56/EC of the European Parliament and of the Council of 3 September 1996 amending Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances[11],

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[1] OJ C not yet published.
[2] OJ L 230, 19.8.1991.
[3] OJ L 340, 9.12.1976.
[4] OJ L 221, 7.8.1986.
[5] OJ L 221, 7.8.1986.
[6] OJ L 350, 14.12.1990.
[7] OJ L 327, 22.12.2000.
[8] OJ L 330, 5.12.1998.
[9] OJ C 258, 27.2.2001.
[10] See adopted texts, Item 9.
[11] OJ L 236, 18.9.1996.

– having regard to Directive 1999/43/EC of the European Parliament and of the Council of 25 May 1999 amending for the 17th time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations[1] ,

– having regard to its resolution of 17 January 2002 on the recommendation for second reading of the European Parliament relating to the European Parliament and Council Decision laying down the Sixth Community Environment Action Programme[2] ,

– having regard to the international treaties signed by the European Union (OSPAR, etc.),

– having regard to the 'Draft Guidance document on relevant metabolites'[3] ,

– having regard to the opinions delivered by the Scientific Committee on Plants in the course of the evaluation of active substances,

– having regard to Rule 47(1) of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Consumer Policy and the opinion of the Committee on Agriculture and Rural Development (A5-0155/2002),

A. whereas, 10 years after the adoption of Directive 91/414/EEC, no more than 31 of the 834 existing active substances to be evaluated have completed the full procedure, whereas it will not be possible to evaluate the remaining substances by July 2003, and whereas, unless there is a change in policy, there can be no guarantee of compliance with the new timetable proposed by the Commission,

B. whereas the application to new and existing substances of totally similar procedures, evaluation standards and decision-making criteria has led to 'pointless' evaluations of existing active substances, given that, with regard to some of them, the extensive scientific literature already available would have led to the conclusion, long before any evaluation had been carried out, that they would not satisfy the requirements of Directive 91/414/EEC, and whereas the existence of unfavourable scientific information should be sufficient grounds for not including an active substance without carrying out an evaluation process, unless the notifier has submitted research which adequately rebuts that information,

C. having regard to the late publication of the various implementing regulations connected with Directive 91/414/EEC and to the excessive flexibility introduced into the procedure for the evaluation of active substances on the first list,

D. whereas certain important events involving the problems caused by pesticides should have prompted a change in priorities as regards evaluation and/or an acceleration of that procedure,

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[1] OJ L 166, 1.7.1999.
[2] See adopted texts, Part I, Item 2.
[3] Doc. Sanco/221/2000 rev. 2.

E. whereas the pesticides listed in Annex I may not be genuinely regarded as 'safe', because of
- the restrictions accompanying the inclusion of an active substance in Annex I,
- the absence of any clear criteria for the inclusion of an active substance in Annex I and of any data relating to the actual usage of existing active substances,
- the definition given to the concept of 'relevant metabolite',
- the absence of any evaluation based on the criterion of 'drinking water produced from surface water',
- the important aspects not covered by evaluation (endocrine disrupters, synergistic additives, the additive and synergistic effects of several pesticides, etc.),
- the absence of any decision not to include a pesticide on the list on grounds connected with human health,

F. whereas the procedure for the application of the Directive is highly complex and requires the involvement of scientists and specialists with a thorough knowledge of the various substances under evaluation, but whereas the right of consumers and interested parties to information must be upheld,

G. whereas the cost involved in the evaluation procedure is such that some lox-toxicity active substances which account for no more than a small percentage of the market will not be defended by the manufacturers and may well, therefore, not be listed in Annex I to the Directive,

H. whereas active substances are in general being withdrawn from the market not because of their intrinsic properties but because of low profitability and/or according to the ability of producers to meet the costs of evaluation,

I. whereas, with regard to 'essential uses', Article 15 of Commission Regulation (EC) No 451/2000 has prompted the submission of a large number of applications for derogations,

J. whereas, in July 2003, more than 300 active substances will be withdrawn from the EU market, and whereas the short-term result of the withdrawal of so many active substances should be investigated and measures taken with regard to certain substances which have been shown to be indispensable,

K. whereas Commission reports on the evaluation of the control systems relating to the placing on the market and use of plant protection products and to residues in foodstuffs of plant origin have revealed severe shortcomings in the control systems of the Member States,

L. whereas the WTO rules currently in force (for example, the Codex alimentarius) may well totally nullify the efforts being made under European legislation with a view to securing a high level of protection of human health and of the environment,

M. whereas a study by the European Environment Agency in 1995 showed that concentrations of pesticides in groundwater exceeded the limit of 0.5 µg/l in 75% of agricultural areas, and whereas the Commission recognises that the problem of the pollution of groundwater by pesticides is still increasing,

N. whereas, with regard to plant protection products, it will not be possible to attain a high level of protection of human and animal health and of the environment simply by the application of Directive 91/414/EEC, particularly as that Directive is not capable of curbing the constant rise in the use of and dependence on pesticides, and whereas, since 1996, there has been a general increase in pesticide use in most of the Member States,

O. whereas the implementation of the fifth Environmental Action Programme was a complete failure as regards the aim of significantly reducing the use of pesticides, and whereas publication of the Commission communication on sustainable pesticide use has constantly been postponed, despite the fact that, after a very extensive study in 1998, the Commission reached the general consensus that there was a need for additional European risk-reduction measures,

P. whereas Parliament has not been duly informed of cases where industry has failed to meet deadlines or where the information provided by industry has been inadequate,

1. Agrees to an extension of the evaluation deadlines, subject to the following conditions:

   i. no extension is to be granted in respect of the evaluation of the active substances set out in List 1,
   ii. the active substances set out in List 2 are to be evaluated no later than July 2005, those set out in Lists 3 and 4 no later than July 2008,
   iii. extensions of authorisations beyond 2003 with regard to the active substances set out in Lists 2 to 4 will be granted solely for substances in respect of which complete dossiers have been submitted by the prescribed date and of which a preliminary evaluation, carried out by industry, has shown that the requirements of the Directive may be satisfied, unless they are covered by the procedure under Article 15 of Regulation (EC) No 451/2000 and subject to at least the strict criteria laid down in the technical annex to the Commission report COM(2001) 444 or by the proposals put forward by the Commission pursuant to this resolution on active substances with low toxicity levels on priority Lists 3 and 4,
   iv. substances deemed to cause problems for health, the environment and drinking water sources are to be evaluated as a matter of priority,
   v. the Commission is to submit every year to the European Parliament a detailed report, i.e. on a substance-by-substance basis, on the progress made with the evaluation programme,
   vi. the Commission is to report, before the end of December 2003, on the stage reached in the implementation of the review programme and the probable impact thereof and to include a list of fruit and vegetable crops, specifying for each one the pests and the diseases which affect it and the number of maximum Community residue limits established in respect of the use of plant protection products,
   vii. the Commission is to submit, before the end of June 2006, an update of the above report and an estimate of the number of substances included in Annex I to the Directive at the end of the programme, specifying how each one is used and whether its use is new or revised,
   viii. the Commission is to submit a proposal for the revision of the Directive before the end of 2002;

2. Notes that the technical annex to the Commission report clearly indicates a number of shortcomings in the current measures to implement Directive 91/414/EEC, including:
   - a lack of monitoring and inspection measures to check that the Directive is being applied correctly: checks on the further use of banned substances and checks on the implementation of the required risk-reduction measures on which inclusion in Annex 1 was conditional,
   - limitation of the evaluation to active substances, and no systematic evaluation of the other, inert substances contained in product formulae,
     and calls for these aspects to be tackled when the Directive is revised;

3. Agrees with the proposals for the amendment of Directive 91/414/EEC submitted by the Commission in the technical annex which accompanies its report and supports in particular the introduction of comparative assessments and of the substitution principle; believes that
   - these two elements should be fully implemented in a structured way in the future authorisation system, so that active substances that represent the lowest toxicity are chosen and no authorisation is given in respect of an active substance when other less harmful agricultural techniques, methods and practices are available,
   - serious consideration must be given to issues such as resistance to plant protection products, integrated pest management and good agricultural practice;

4. Calls, before an active substance is included in Annex I, for

   i. the criteria for inclusion to be clarified and for them to constitute an integral part of the Directive and to be established in conformity with Community legislation, in particular the Water Framework Directive, and international treaties,
   ii. the evaluation and authorisation procedure to consist of two stages:
      - exclusion of any active substance which presents - or of which the metabolites present - one of the following characteristics:
        - classified as carcinogenic
        - classified as toxic for reproduction
        - classified as mutagenic
        - endocrine disrupter
        - persistent
        - bioaccumulable
        - inclusion on a priority list established under other European legislation or international treaties ratified by the European Union, such as the list of priority substances for water policy annexed to Directive 2000/60/EC,

      - in the case of active substances not excluded, evaluation must take account of their incidence on the health of children and foetuses as well as any possible additive and synergetic effects linked to total exposure to certain pesticide products;

5. Calls on the Commission not to authorise any active substances in connection with which strict but unenforceable conditions for use (risk-reduction measures) are required in order to comply with the uniform principles;

6. Calls for the granting of authorisation to be conditional upon the producer providing information on the appropriate method of detecting the substance in respect of which authorisation is requested;

7. Calls for the redefinition of the concept of 'relevant metabolites' and for the revision of the corresponding 'Guidance document', with a view to ensuring a complete toxicological evaluation of metabolites of active substances equivalent to the toxicological evaluation of the primary substances, as well as for the publication, at the earliest possible opportunity, of the Guidance document entitled 'Drinking Water produced from surface water';

8. Calls for the rapid creation, at European Union level, of a publicly accessible database relating to the quantities of all pesticides produced and sold, the volumes used and the way in which they are used (including a breakdown by type of crop and class of product), the toxicological (including ecotoxicological) characteristics of pesticides and non-chemical alternatives to pesticides;

9. Calls for the evaluation and decision-making procedure under Directive 91/414/EEC to be made more transparent and more democratic, in particular by allowing representatives of interest groups (e.g. consumers, NGOs and water producers) to participate therein and by ensuring that they have access to information, in particular to evaluation documents relating to the active substances produced by the Member States;

10. Calls on the Commission , before the end of 2002, to propose a clear procedure for the essential use of certain active substances pursuant to Article 15 of Regulation (EC) No 451/2000, which should ensure that this article is used as sparingly as possible and only
    - temporarily,
    - when the business in question is fully certified for integrated crop management,
    - in cases which satisfy the restrictions laid down in the technical annex to the Commission proposal (COM(2001) 444),
    - in cases which do not involve substances known to be of concern and/or a clear priority in regard to international obligations or environmental programmes;

    requires the new procedure to be fully consistent with the principles laid down in the Directive and the protection of human health and the environment to take precedence over the requirements of agricultural production;

11. Calls for an end to the insecurity created by the differences which exist between the laws of the individual Member States relating to the maximum permitted pesticide residue limits and on the Commission to give priority to the harmonisation thereof in respect of all active substances which will continue to be placed on the market after 2003;

12. Calls on the Commission to devote special attention to the financing of research into alternative products;

13. Calls on the Commission to notify Parliament, before the end of the year, of the measures which it intends to take to ensure that useful substances which have low toxicity levels and appear on priority Lists 3 and 4, but which have not been notified because of a limited commercial interest or of high evaluation costs, may be evaluated with the help of an

appropriate restricted data package that does not compromise their safety, so that they may continue to be marketed;

14. Calls for the publication, before July 2003, of a new proposal for a directive establishing a programme for a reduction in the use of pesticides, similar to the one introduced in some Member States, which lays down quantitative reduction targets, a time schedule and measures and means to achieve these targets; that directive should devote special attention to

    - compulsory training in integrated crop management methods and certification of farmers and professional users of pesticides,
    - national action plans for reducing the use of and dependence on pesticides, with specific objectives and target dates,
    - extra financial assistance for research into and application of non-chemical pest-control methods, integrated crop management and organic farming,
    - coordinated monitoring of and gathering of data concerning the impact of pesticide use on the environment and health,
    - the creation of a link to agricultural environmental programmes (both existing and new), so that the payment of subsidies is made conditional on the implementation of environmental measures;

15. Calls for the drawing up of a 'Code of Best Practice' for each crop with regard to the use of authorised pesticides, as is already customary in some Member States, to be based on integrated crop management methods, with priority assigned to non-chemical agricultural methods; this Code should also establish:

    - a system of spraying licences,
    - a system for the recording of the products used and their quantities,
    - a system of cultivation-free zones along watersides,
    - a system of application of the best available techniques;

16. Calls, further, on the Commission to give priority to the strict enforcement and monitoring of residue levels in food products. Each year, the food authority should carry out representative checks on all agricultural products produced in the various Member States and on agricultural products from third countries which are sold on the European market. Reports on the checks carried out by the food authority should take the EU rules on food-product residue levels as a benchmark;

17. Calls on the Commission, before the end of 2003, to report on possible ways of promoting mutual recognition of product registration between Member States and introducing product authorisation zones to replace the present need to register a product separately in each Member State, provided that the product:

    - is used only in those Member States with similar types of climate, hydrology and soil,
    - is not used in the case of active substances which are registered in a Member State for essential use, which should remain confined to the Member State concerned;

18. Calls on the European Union to work within the WTO to ensure that WTO rules do not weaken standards at European level in the field of public health and environmental protection;

19. Emphasises that maximum residue levels (MRLs) will in principle be set at an extremely low level (0.01 mg/kg) unless the notifier can prove that even the best available techniques (treatment frequency, dosage, waiting period before harvesting, etc.) cannot prevent a certain residue level;

20. Calls on the Commission to ensure that the plant-protection product evaluation criteria explicitly include assessment of the impact which the active substances have on domestic bee populations and the views of professional beekeepers organisations regarding those substances;

21. Instructs its President to forward this resolution to the Council and to the Commission.

EXPLANATORY STATEMENT

Background

Immediately after the adoption of Directive 91/414/EEC, it became clear that the implementation thereof would constitute a very extensive task. Some delay in the evaluation of the existing active substances was, therefore, to be expected. We note that, after a period of 10 years, no more than 31 of the 834 existing active substances have completed the full procedure.

The explanations put forward by the Commission justify that delay only to some extent. We are obliged to note that the Directive was adopted on a very haphazard basis. The slowness with which the requisite implementing regulations were drawn up confirm this thesis:

- the 'operational' Annexes II and III did not become available until 1996,
- Directive 94/43/EC establishing Annex VI to the Directive (Uniform principles for the evaluation of plant protection products) was annulled by the European Court of Justice on 18 June 1996, and it was not until September 1997 that the new version was adopted. Accordingly, the evaluation procedure could not be implemented until that date,
- Annexes IV (Risk phrases) and V (Safety phrases) are still incomplete.

What is more, with regard to standards for assessment and decision-making criteria, existing active substances and new active substances have been put on an equal footing. That has resulted in pointless evaluations and has exacerbated the delay. For example, in the case of lindane, it was known as early as 1991 from the extensive scientific literature already available that it was one of the substances which would not satisfy the requirements of the Directive. Why, then, was it subjected to the evaluation procedure?

Furthermore, the Commission demonstrated an excessive degree of indulgence when it set May 2002 as the deadline for the compilation of complete dossiers in respect of the substances still outstanding after the first phase of the review programme.

Finally, the timetable proposed by the Commission with a view to the completion of all the evaluations by 2008 relies on the publication in 2001 of 19 decisions relating to substances on the first list. In fact, no more than 9 decisions were actually taken!

Lack of flexibility with regard to priority activities

Some priorities should have been reviewed as work progressed, and the failure to take certain decisions is totally inexcusable:

- the arrival of seeds genetically modified so as to resist herbicides should have entailed the evaluation of the relevant herbicides as a matter of priority. However, glufosinate ammonium, for example, is included in the second list of substances,
- it is suspected that imidacloprid may be dangerous for bees. In France, authorisation of that pesticide has been suspended. The Commission has earmarked it for the third phase of the review programme,

- as long ago as 1992, the Commission possessed information which indicated that atrazine might fulfil the conditions for prohibition laid down in Directive 79/119/EEC. However, to date, no decision has been taken relating to that active

substance which is included in the first list.

Unsatisfactory evaluations

Throughout its report and the so-called 'technical' annex accompanying it, the Commission would have us believe that the active substances listed in Annex I may be deemed to be 'safe'. A simple reading of the opinions of the Scientific Committee on Plants (with regard, for example to esfenvalerate) and of the tight restrictions imposed on some of the active substances listed in Annex I (e.g. amitrol and thiabendazole) is sufficient to show that some active substances which present a serious risk have been authorised.

With regard to pesticides which might cause problems for human health, the Commission refers to legislation relating to maximum residue limits. That means that evaluation is always based on the concept that there is an acceptable minimum. However, with regard to a large number of substances, we now know that that concept has been disproved and that there is no safety threshold.

What is more, no account is taken during the evaluation procedure of some important aspects such as endocrine disruption and the existence of vulnerable groups (e.g. children and foetuses). In addition, in order to ensure, on the one hand, a high level of protection and, on the other, to accelerate the evaluation procedure, criteria need to be laid down which automatically exclude substances which present specific dangerous characteristics. A programme for the reduction in the use of pesticides should also be introduced very rapidly, together with a Code of Best Practice with regard to the use of authorised pesticides.

Essential uses

With regard to 'essential uses', the Commission has exceeded its powers by adopting Article 15 of Regulation (EC) No 451/2000. The third subparagraph of Article 8(2) of the Directive provides for the possibility of an extension to the derogation period in respect of certain substances after presentation to Parliament and to the Council by the Commission of a progress report on the evaluation programme.

Furthermore, the fact that the measure relating to 'essential uses' was published before the notifiers took a decision on the substances to be defended is likely to increase the number of substances not defended.

Transparency

Parliament no longer has any power of scrutiny over the implementation of the Directive which is manifestly being applied without any transparency whatsoever and in secret, the only interlocutors of the Commission and the Member States being the pesticide manufacturers. This procedure must be made more transparent, and the representatives of interest groups (such as consumers, NGOs concerned and water producers) must be involved.

17 April 2002

OPINION OF THE COMMITTEE ON AGRICULTURE AND RURAL DEVELOPMENT

for the Committee on the Environment, Public Health and Consumer Policy

on the Commission report entitled: 'Evaluation of the active substances of plant protection products (submitted in accordance with Article 8(2) of Council Directive 91/414/EEC on the placing of plant protection products on the market)
(COM(2001) 444 – C5-0011/2002 – 2002/2015 (COS))

Draftsman: Neil Parish

PROCEDURE

The Committee on Agriculture and Rural Development appointed Neil Parish draftsman at its meeting of 19 February 2002.

The committee considered the draft opinion at its meeting of 17 April 2002.

At that meeting it adopted the following conclusions by 32 votes to 4.

The following were present for the vote: Joseph Daul, chairman; Friedrich-Wilhelm Graefe zu Baringdorf, Albert Jan Maat and María Rodríguez Ramos, vice-chairmen; Neil Parish, draftsman; Gordon J. Adam, Danielle Auroi, Alexandros Baltas (for Vincenzo Lavarra), Carlos Bautista Ojeda, Sergio Berlato, Niels Busk, Arlindo Cunha, Michl Ebner, Francesco Fiori, Jean-Claude Fruteau, Georges Garot, Lutz Goepel, Willi Görlach, Liam Hyland, Elisabeth Jeggle, Salvador Jové Peres, Hedwig Keppelhoff-Wiechert, Heinz Kindermann, Astrid Lulling (for Christos Folias), Jean-Claude Martinez, Xaver Mayer, Jan Mulder (for Giovanni Procacci), Karl Erik Olsson, Ioannis Patakis (for Dimitrios Koulourianos), Mikko Pesälä, Christa Prets (for María Izquierdo Rojo), Encarnación Redondo Jiménez, Agnes Schierhuber, Dominique F.C. Souchet, Robert William Sturdy and Eurig Wyn (for Giorgio Celli).

SHORT JUSTIFICATION

The Committee on Agriculture notes that the EU review programme for existing active substances was given the ambitious target of 12 years in which to complete the evaluation of over 800 substances in plant protection products (PPPs). The 12-year period expires in July 2003.

Experience has shown that, because of the sheer complexity of this task, it has been impossible to evaluate all these substances in the given timeframe. To date, the review programme has fully processed some 30 substances, with many more substances on the first list close to a decision, while clear processes and timelines are now in place to complete the programme by the end of 2008. The extension of the evaluation process to 2008 is therefore fully supported.

Given the detailed Community evaluations, data requirements for PPP authorisation have greatly exceeded those required for any other class of substance including pharmaceuticals, food additives and commodity chemicals. A typical dossier contains about 50 000 pages and takes about four and a half years to prepare.

The exhaustive and sophisticated evaluation process in place under Directive 91/414/EEC ensures that active substances included in Annex I to Directive 91/414/EEC are in fact safe for man, animals and the environment when used in accordance with label instructions and with any conditions linked to inclusion in Annex I.

Directive 91/414/EEC is an important instrument in the common agricultural policy, since an adequate number of active substances is required for agricultural production in order to provide proper protection for plants and plant products in the European Union. However, because of the high cost of drawing up authorisation dossiers in each Member State, the availability of plant protection products for minor uses is limited. The possibility of introducing European authorisation zones for plant protection products should therefore be considered in order to provide further options for controlling pests in these minor crops.

It is noted that some 330 existing active substances are not being defended by industry and that these will be withdrawn from the market in 2003. With such a reduction in the number of active substances, there is concern that farmers will not have all the necessary tools to control pests and diseases. This is likely to reduce the diversity of crops grown within the European Union, and it is essential that niche products have access to essential chemicals. Withdrawal of a pesticide before an alternative can be developed will result in a significant adverse impact on the rural economy and in import substitution into the EU. The Commission should therefore consider allowing the essential uses of certain compounds so as to ensure that European Union farmers may remain competitive. The loss of certain compounds has already led to a situation where no effective pest control options are available for certain crops. An example of this is the loss of fenpropathrin in blackcurrant growing.

The long-term impact of withdrawing such a large number of active substances from the market also needs to be considered, and the Committee on Agriculture believes that a detailed study into the impact of the withdrawal of compounds should be carried out before any additional legislative requirements are put forward for consideration.

CONCLUSIONS

The Committee on Agriculture and Rural Development calls on the Committee on the Environment, Public Health and Consumer Policy, as the committee responsible, to incorporate the following points in its motion for a resolution:

1. Recognises the justified need for an extension of the evaluation deadlines and calls on the Commission to comply with the timetable laid down;

2. Calls on the Commission to consider and incorporate into its proposed amendment of Directive 91/414/EEC the possibility of:
   (a) promoting mutual recognition of product authorisations between Member States, and
   (b) introducing the delineation of areas with common agri-environmental characteristics within which the requirements for the mutual recognition of plant-protection product authorisations are satisfied;

3. Stresses the importance of maintaining adequate crop protection options for all crops in the European Union, welcomes the intent expressed by the Commission in Article 15 of Regulation (EC) No 451/2000 relating to 'essential uses' of specific non-defended active substances and calls on the Commission to draw up a clear procedure for the acceptance of those 'essential uses' of certain active substances. This procedure should ensure full compliance with the principles of the Directive and the inclusion of the restrictions which are needed in order to ensure that the protection of human health and of the environment takes precedence over the needs of agricultural production;

4. Urges the Commission to ensure that at least two effective products remain available for all crops in the European Union so as to ensure both competition and diversity in existing crop protection options and to prevent those crops from developing resistance. Such availability also involves the establishment of Community maximum residue limits which can be applied to the use of those products, where possible by means of data extrapolation;

5. Calls on the Commission to ensure that the plant-protection product evaluation criteria explicitly include assessment of the impact which active substances have on domestic bee populations and the views of professional beekeepers organisations regarding those substances;

6. Calls on the Commission to give urgent, priority consideration to the two active substances of neurotoxic systemic insecticides which are reported as having devastating effects on domestic bee populations, namely imidaclopride and fipronil;

7. Calls on the Commission to report:
   (a) before the end of December 2003 on the stage reached in the implementation of the review programme and on the probable impact thereof and to include a list of fruit and vegetable crops, specifying for each one the pests and the diseases which affect it and the number of Community maximum residue limits established in respect of the use of plant protection products;
   (b) before the end of June 2006 and to include an update of the above report and an estimate of the number of substances included in Annex I to the Directive at the end of the programme, specifying how each one is used and whether it is new or revised;

8. Calls on the Commission to include in its proposal for the revision of the Directive provisions which will enable an adequate response to be made to what is expressed in the preceding paragraphs and ones which, in the light of the results of the Community programme for the review of existing active substances, provide a means of remedying possible unwelcome effects and, at all events, to have them reviewed in the light of the results of the report referred to in paragraph 7(b);

9. Calls, further, on the Commission to give priority to the strict enforcement and monitoring of residue levels in food products. Each year the food authority should carry out representative checks on all agricultural products produced in the various Member States and on agricultural products from third countries which are sold on the European market. Reports on the checks carried out by the food authority should take the EU rules on food-product residue levels as a benchmark;

10. Calls on the Commission to draw up a code of good farming practices relating to the use of plant protection products.