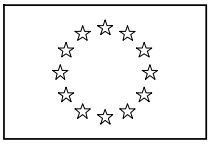

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 25.07.2001
COM(2001) 444 final

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

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)

1 INTRODUCTION

1. Council Directive 91/414/EEC[1] of 15 July 1991 concerning the placing of plant protection products on the market sets out a Community harmonised framework for authorisation, use and control of plant protection products. It is a dual-system where the Community evaluates active substances and Member States evaluate and authorise products containing them. A basic principle of the Directive is the development of a positive list (Annex I) of active substances that are acceptable for the environment, human and animal health. Substances listed in Annex I are eligible for inclusion in plant protection products that Member States may authorise to be placed on the market at national level.

2. The Directive provided for a 12-year programme of evaluation of the 834 active substances already on the market at the time of its entry into force in July 1993 (the "existing" active substances) and, pending Commission Decisions on their inclusion in Annex I, permitted their remaining on the market until July 2003 under certain conditions. The Commission split the review programme for these substances into four phases. All other substances presented since July 1993 are considered as "new" substances. Both new and existing substances are evaluated in parallel.

3. Article 8(2) of the Directive stipulated that in July 2001 the Commission should present to the European Parliament and to the Council a Progress Report on the evaluation programme for existing substances. In the same article, it was provided that, depending on the conclusions of this report, the Commission might decide whether, for certain substances, the deadline of 12 years should be extended. Experience shows that it will not be possible to evaluate all 834 existing substances before 2003, 10 years after the entry into force of the Directive. Progress at the initial pace of the first phase would have meant finishing the review around 2015. With new measures and resources, some of which are already in place for the first and following phases, 2008 is a more appropriate end-date. Meeting this challenging deadline will be contingent on these new resources and procedures being put in place and on deadlines being respected by all stakeholders.

4. The goal of this report is to meet the obligation of the Commission to submit a progress report on the evaluation of existing active substances. In addition, it draws attention to the need to extend the 12-year programme of evaluation for certain substances. In so doing, the goal is to obtain clear confirmation from the European Parliament and the Council that the approaches to be taken by the Commission in deciding on such extensions are sound. The report also highlights problematic areas where the functioning of the Directive could and should be improved, and to identify issues to be addressed in any future amendment. In this respect, it serves as a basis to inform the European Parliament and the Council of the current perspective of the Commission in this area and to solicit their views on how the Commission may proceed in the future.

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[1] OJ L 230, 19.8.1991, p. 1.

5. The Commission emphasises that, for the sake of concision and clarity, the content of this report is restricted to progress in the evaluation of existing active substances and that a limited amount of information can be communicated in such a document. Complementing this report is a technical annex[2] which gives full details of the process, procedures, measures taken, impacts, problems and possible solutions. It also includes details of the situation for new active substances

2 THE ESTABLISHMENT AND ORGANISATION OF THE PROGRAMME

6. Directive 91/414/EEC was a new departure for the Community in several respects. It was one of the first major items of legislation to anticipate not only the principle of subsidiarity, but also the precautionary principle. From the outset, it explicitly placed protection of human health and of the environment above the needs of agricultural production. The outlines of the legislation are relatively straightforward.

7. First, it provided for a positive list of acceptable substances that Member States could authorise as plant protection products. If a substance was not on the list then it could not be used in the Community as part of a plant protection product.

8. Second, it established a dual assessment system. Active substances are evaluated at Community level but the Member States evaluate and authorise products containing those substances. The Directive provides a uniform set of risk assessment principles and decision-making criteria that Member States must use when evaluating products.

9. Third, it set a new, demanding standard for safety assessments. The Commission and the Member States agreed that if the basic principles of the Directive were to be attained, Community evaluations would need to be comprehensive and detailed. As a result, the data requirements that were fixed for pesticides greatly exceed 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.

10. Fourth, although the condition for inclusion of an active substance in Annex I to the Directive is the expectation that "a safe use may be demonstrated", it was decided that all uses of all existing substances would be assessed. While this was seen as useful to the Member States in their downstream authorisations of products, it proved a significant drain on resources and an important source of delay.

11. Given the resources required, it was agreed that a system to share the work between the Commission and Member States was required and that policy development, decision-making and other progress should be by consensus. This has since been recognised as a contributory factor to the delays encountered. Now, while consensus in decision-making is always sought, it is accepted that it cannot always be achieved.

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[2] http://europa.eu.int/comm/food/fs/ph_ps/index.htlm.

12. It was recognised that, whenever possible, the procedures for existing and new substances as well as the standards for assessments and the decision-making criteria should be the same. In a parallel approach, extensive data requirements for dossiers were also drawn up and agreed for the major classes of substances. For minor categories, this work continues even today. Similarly, in many instances, the risk assessment methodologies required for the evaluations did not exist and had to be developed. It was necessary to develop new science, and then to ensure agreement on its application. The numerous measures that had to be introduced are listed in the annex.

13. The main sectors and interests involved as well as their roles and the impacts of the programme on them are described in the annex.

14. The Commission has acted in several roles: as a co-ordinating Secretariat, as chair of the Standing Committee on Plant Health[3], as developer of new science, as secretariat of the scientific committee on plants and as final decision-maker. Within the Commission, DG Health and Consumer Protection and DG Environment are co-responsible for managing Directive 91/414/EEC. Details of the coordination and consultation mechanisms used are given in the annex.

15. The Member States have acted in four roles. First, each took the lead both in preparing the draft assessment reports on the one or more active substances assigned to them by the Commission and in acting as interlocutors with the notifiers of those active substances during the process. Second, all acted as peer-reviewers of the draft reports of the other Member States, identifying additional data needs and furnishing critiques etc. as appropriate. Third, as members of the Standing Committee on Plant Health, all participated in the decision-making on active substances. Fourth, they also provided expertise and resources to develop the new scientific methodologies needed to complete the assessments. A major contribution of the Member States in this area was in agreeing to conduct the work relating to Community technical assessments in one language. This imposed considerable difficulty at national level in the interest of improving the Community procedure and the measure deserves recognition.

16. Notifiers are entities established in the Community that support the evaluation of active substances by providing dossiers with the required data. Most are the producers of active substances, acting as individual companies or collectively.

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[3] OJ L 340 of 9.12.1976, p. 25.

17. A list of all legal acts taken under 91/414/EEC for existing active substances is given in the annex to this report. The general legal acts are threefold in nature. First, a group of measures sets out data requirements and assessment and decision-making criteria. When the Council adopted Directive 91/414/EEC, it included no detailed provisions concerning the data requirements and criteria to be used by Member States (Uniform Principles). The Commission defined these during 1993-1996. Second, the practical details of the first phase of the review programme needed to be elaborated. Commission Regulation (EC) No 3600/92[4] had to be amended to involve Austria, Finland and Sweden upon their accession and to take further experience acquired during the evaluation process into account. Third, the later phases of the programme were established by Commission Regulation (EC) No 451/2000[5].

18. Data requirements for the conventional chemical pesticides used as active substances in plant protection products were adopted in 1994-1996 and this work is still ongoing for several other specific categories of active substances. Full details are given in the annex. Due to the initial lack of consensus on criteria to assess the conventional substances, even after harmonised data requirements had been agreed, a significant degree of variation became apparent between review practices among individual Rapporteur Member States. This problem had to be corrected by the development and adoption of a series of guidance documents. Some of these required in-depth research efforts that are still not complete. Details of guidance documents developed or being developed are given in the annex. There were several specific problems that arose with the first 90 substances for which individual solutions were found. In addition, many of the lessons learned with new active substances were also applied to existing substances. Details of these and other measures taken are given in the annex.

3 DESCRIPTION OF THE PROGRESS MADE IN 10 YEARS

3.1 Annex I of the Directive

19. The 834 substances on the market were divided into four lists. Details of the 834 substances, as well as their current status and authorisations in the Member States are available on the Internet[6]. As reported in the Table below, it is already clear that in July 2003 decisions will have been taken on at least 380 of the 834 substances, mainly decisions withdrawing substances from the market.

20. The first priority list of 90 substances, established in 1992, comprised those substances considered at that time to be the most widely used on the market as well as those of clear concern. Details of the decision-making process flowing from Commission Regulation No 3600/92, as amended over the years are described in the annex. Almost all dossiers were deficient in one respect or another and, to date, there has not been one substance that did not cause problems at some stage of the process. This phase is not yet complete. Final decisions on all active substances on this list are expected to have been taken by July 2003.

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4 OJ L 366 of 15.12.1992, p. 10.
5 OJ L 55 of 29.2.2000, p. 25.
6 http://europa.eu.int/comm/food/fs/ph_ps/index.htlm.

21. The current situation is that (a) Commission Directives have been or are about to be adopted including 13 existing substances in Annex I of the Directive, (b) Commission Decisions have been taken not to include 16 substances in Annex I and withdrawing them from the market, (c) 39 substances have been peer-reviewed, and final discussions are ongoing, (d) 21 substances are undergoing or are scheduled for peer review, and (e) one assessment report still has to be submitted to the Commission.

22. The second list of 149 substances, established in Regulation No 451/2000, comprised all those organophosphates and carbamates that were not on the first list as well as other substances of concern and substances for which industry had indicated early availability of dossiers. Commitments to support 60 of these for Annex I inclusion were received in September 2000. Details of this list and of the decision-making procedures foreseen are given in the annex. The outcome of the notification procedure already implies that at least 89 substances should be withdrawn from the market in July 2003. On past experience, it can be expected that the Community evaluations will be ongoing for the substances on this list during 2003-2005, even with the corrective measures provided for in the new regulation to help speed up decision-making. Further Commission Regulations will be adopted in the second half of 2001 containing detailed rules for evaluation of this and the third list of substances. For the up to 60 active substances for which both a complete dossier is available in April 2002 and for which a draft assessment report prepared by the Rapporteur Member State will be available in 2003, a derogation to extend the deadline of July 2003 would be necessary to allow detailed evaluation of the dossiers submitted. About 55 active substances are expected to fall into this category.

23. The third list was also introduced by Regulation No 451/2000. It comprises the 402 remaining chemical substances, also considered 'pesticides' (as the term is commonly understood) but not as widely used as the second list. In a first step, notifications of interest were received in June 2000 for 192 of them. In a second step in November 2000, detailed notifications including lists of studies and endpoints were received for 167 of these. The institution of this list and the outcome of the notification procedure already implies that at least 235 substances should be withdrawn from the market in July 2003. Details of this list and of the decision-making procedures foreseen are given in the annex. Derogations for Member States to continue authorising some of these substances beyond July 2003 will therefore be necessary. It is estimated that such derogations will be required for about 150 notified substances. Derogations will not be given where there are safety problems.

24. The fourth list, established by default, comprises the 193 remaining substances identified as being of lower concern and to which other data requirements than those for lists 1-3 might apply. It includes (a) microbial pesticides, (b) substances already authorised in foodstuffs, (c) plant extracts, (d) animal products, (e) substances used in organic farming, (f) rodenticides, (g) storage products and (h) commodity chemicals. While these are conventionally viewed as being of lower concern, some find wide use in the Community. 27 of these substances are no longer authorised in any Member State. A notification procedure is envisaged in 2002 and about 69 notifications are expected. Thus, at least 124 of the substances on this list may be expected to be withdrawn from the market in 2003 and about 69 (but the number could be as high as 166) substances on the list will thus need to be evaluated in the final phase during 2004-2008. For those active substances for which preliminary

evaluations or acceptable data are available in May 2003, a derogation to extend the deadline of July 2003 will be considered to allow their evaluation. Such derogations will be withdrawn where a complete dossier is not submitted.

Table: The situation in 2001 for the existing active substances to be evaluated in each phase of the review programme (with approximate share of total market in 1993).

Phase	N° substances (& % 1993 market share)	Being examined	To be examined	Already clear that will be withdrawn	In Annex I
First	**90 (30%)**	**61**	**0**	**16**	**13**
Second	**149 (40%)**	**0**	**60**	**89**	**0**
Third	**402 (25%)**	**0**	**167**	**235**	**0**
Fourth	**193 (5%)**	**0**	**166**	**27**	**0**
TOTAL	**834 (100%)**	**61**	**393**	**367**	**13**

3.2 Other Annexes of the Directive

25. Directive 91/414/EEC was adopted with Annexes II and III containing only a skeleton list of headings. Data requirements for chemical active substances (Annex IIA) and for products containing those substances (Annex IIIA) were adopted, for all the headings in the original text of the Annexes to the Directive by Commission Directives during 1994-1996. Data requirements for microbial active substances and for products containing them were adopted by Commission Directive in 2001.

26. Directive 91/414/EEC was adopted with Annexes IV and V empty. Work is currently underway to fill Annex IV (Risk phrases) and V (Safety phrases) to complement those in Council Directives 67/548/EEC[7] (on dangerous substances) and 1999/45/EC[8] (on dangerous preparations). The Commission intends to adopt a Directive early in 2002 filling these annexes.

27. Directive 91/414/EEC was adopted with Annex VI empty. The Uniform Principles for risk assessment were adopted by Council Directive 97/57/EC[9]. The Commission intends to update these for microbial plant protection products early in 2002 and later for other minor categories of plant protection product.

4. CRITIQUE OF THE ORGANISATION AND EFFICIENCY OF THE REVIEW PROCESS

28. In looking at the programme's achievements and the problems encountered, consideration has to be given first and foremost to the time it took to establish the required legislative, administrative, technical and informal structures, and to the arduous scientific and methodological learning curve that had to be climbed.

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7 OJ L 196 of 16.8.1967, p. 1.
8 OJ L 200 of 30.7.1999, p. 1.
9 OJ L 265 of 27.9.1997, p. 87.

29. Decision-making was slow between 1993, when the Directive entered into force, and 1999 for the reasons already noted. An already complex piece of legislation became progressively more complex in application as expectations mounted on all sides, ensuring that standards and criteria were not only maintained at a high level but were effectively raised. One particular problem relates to lack of resources. Others include the procedures foreseen in the legislation, the need to build confidence among Member States, the time needed to agree on data requirements and for industry to generate the data. These problems are now largely solved and the decision-making rate for existing substances has recently improved dramatically, from 2 decisions per year during 1994-1999 to 13 in 2000 and 21 (projected) in 2001. The rate for new active substances is also accelerating at the same rate.

30. The evaluation programme could be complete by end 2008, when the last decision on an existing active substance will be taken. Review at national level of products containing that substance would still continue for an additional two years after the decision. During 1993-2008, there will be progressive reduction in the market availability of substances on each of the priority lists. There will also be a significant cut in July 2003 in the numbers of substances available. The substances in question will be predominantly those that have limited use in agriculture. Offsetting this, there will be a progressive increase in the availability of new active substances.

31. It is clear that the market will experience a sharp change after July 2003 - the watershed - with the loss of up to 500 substances. There will be a smaller number of substances, albeit of demonstrated safety, and these will be more widely used than today. Authorisations of substances in just one or two Member States will be uncommon and this may encourage wider co-operation among Member States for national authorisations. By 2008, about 450 substances should be available on the European market. Examining the numbers of substances used today without consideration of the types of substances available, the conclusion is that this number will be adequate. However, given that many of the existing substances being lost are insecticides, and that insecticides account for only a small proportion of the new actives coming onto the market, there may well be a discordance between what is needed and what will be available. Market forces should eventually correct this situation, but not necessarily in a time frame solving all problems. Related to this loss of substances, there may be repercussions for trade due to subsequent amendments of the pesticides residues legislation. Community trading partners will be informed through WTO procedures and developing countries through the procedures established under the ACP-EC Partnership Agreement signed in Cotonou in June 2000.

5. PLANNING OF THE WORK PROGRAM UP TO AND BEYOND 2003

32. It is proposed to finish the first list by July 2003 with the established system and process. The evaluation of the second list should be complete in 2005 and the third and fourth lists in 2008, by which time re-evaluation of substances already in Annex I will have to start. It is essential to recognise that derogations foreseen until 2008 are contingent on the necessary resources, structures and procedures being available. It also has to be understood that any major new area of concern for which new data requirements might be identified could also delay dossier preparation and evaluation.

33. In spite of the recent major increase in decision-making from 2 to 20 decisions per year, it should be noted that, if the programme is to be concluded by the end of 2008, an average of 50 decisions per year on existing active substances (peaking at 85 in 2007) will need to be attained. This will be brought about by (i) procedural changes for dossier examination and evaluation, (ii) increased resources in the Commission and the European Food Authority, (iii) tighter timelines and (iv) improved dossiers and use of information technologies.

34. The evaluation process is an enormous task that cannot successfully be managed without improving procedures for evaluation and decision-making. The Commission together with the Member States has made a series of improvements in the procedure in the second and later phases of the review. Some of these have also been adopted for the remaining first list substances. For the future development of the process and to bring it closer to the citizen, the Commission is looking at ways to improve the participation of other stakeholders. Future activities aim at the harmonised development of advanced methods of risk assessment allowing better identification of critical areas of concern and a focus on the most effective risk mitigation measures. This next generation of tools will be developed on a global scale with full consultation of partners in the OECD, to make sure that scientifically valid methodology will be defined and accepted worldwide. Sizeable resources and research will be needed to create the necessary data for this next generation of risk assessments.

35. The evaluation of a dossier takes two to three man-years and the Commission, and Member States have limited capacity. Decision making at Community level with 15 Member States is also very demanding of time and resources. To ensure that Member States can carry out the necessary evaluation work, Regulation No 451/2000 provides that Rapporteur Member States request a fee from the notifiers to cover the work they have to do. This and other measures taken recently should permit acceleration to be maintained. One solution to the resource problem, found at the beginning, was to share the work using the Rapporteur Member State system. Other solutions are also being explored. Non-EU countries face the same resource problems and the long-term strategy is to share the work of pesticide evaluation at global level.

36. The increases in resources in the Commission and the Member States, alongside the ascent of the long learning curve, have permitted a dramatic increase in the last year in the rate of decision-making (up from two to about 20 per year) for active substances. To maintain this level will require a major and additional influx of new resources.

37. The Commission proposal for a European Food Authority foresees a significant increase in personnel for the assessment of active substances in the Community but it is necessary in the planning of such increases to take note of the recent opinion of the Scientific Steering Committee, which draws attention to a critical lack of expertise in Europe in the field of regulatory risk assessment[10]. The EFA will provide the foundation upon which to build coming phases of the

[10] Conclusion 19 of the first report on the harmonisation of risk assessment procedures. Part 1: The report of the Scientific Steering Committee's Working Group on Harmonisation of Risk Assessment Procedures in the Scientific Committees advising the European Commission in the area of human and environmental health 26-27.10.2000.

programme. The switch from the current system to a new arrangement that is both sustainable and efficient in the long term can only be achieved via close co-operation with the Member State institutions in this field. Existing procedures in similar fields (medicines, veterinary drugs, food or feed additives) could be used as models. Based on current work procedures, about 25 qualified evaluators are going to be required at the level of the European Food Authority for active substances, complemented by additional staff to fix MRLs for residues in food and agricultural commodities.

38. The potential impact of a significantly reduced number of substances is described in the annex. Regulation No 451/2000 provides for the eventuality that, if necessary, and on a case by case basis, the Commission may take temporary measures for uses for which additional technical evidence has been provided demonstrating (i) no safety concerns, (ii) the essential need for further use of the active substance and (iii) that there is no efficient alternative. The Commission will be sparing in granting such derogations.

39. Article 9 of Directive 91/414/EEC provides that Member States can, at national level, apply a relatively flexible system for extensions of authorisations of plant protection products for minor uses. A guidance document on voluntary mutual recognition of authorisations for minor uses has been developed together with Member States and stakeholders. Member States are invited to define at national level minor uses and minor crops and to apply the system proposed in the guidance document to facilitate authorisations for minor uses.

40. The July 2003 deadline would only be extended for active substances for which sufficient information concerning their impact on health and the environment has been submitted and for which there is a clear commitment by industry to demonstrate that there are acceptable uses in the sense of the Directive. As explained above, the Commission aims to finalise the review programme in 2008 and therefore an extension of the deadline until end of 2008 is proposed. The measure extending the deadline would be adopted in June 2003 and follow the approaches outlined below.

41. First list: For all remaining active substances, a full dossier has to be available in May 2002. In exceptional cases this deadline might be later because the evaluation and the setting of specific additional data requirements for individual substances is not yet finalised. The number of active substances for which no final decision can be made will be very limited and known by early 2003.

42. Second List: The completeness checks will be finalised by end 2002. Decisions on extending the deadline can be taken early in 2003 for those active substances for which there is a complete dossier.

43. Third list: It is expected that a full data package will be submitted by May 2003 for about 150 of the 402 active substances. Since this deadline is very close to the overall deadline of 25 July 2003, it will not be possible to exclude that for some of the active substances a decision on extension will have to be repealed in autumn 2003. The number should be rather limited, since industry has already made its selection of substances for which it still has an interest.

44. Fourth list: Only for those active substances for which an acceptable notification has been received would prolongation of the deadline be proposed.

6. CONCLUSIONS

45. In presenting this progress report, the Commission considers that the requirement to report under Article 8(2) of the Directive is fulfilled.

46. Although progress, in terms of the numbers of evaluations that have been finalised, has not been as good as was originally anticipated, a solid foundation has been laid in legislation, in organisation and collaboration, and in learning from experience and in planning. This has now started to yield dividends. The next few years will see a tremendous change in the marketing and use of plant protection products and the high safety standards set in the Directive will be realised, albeit at a cost.

47. With the new measures provided for in the second and third phases of the programme, combined with the infrastructures and expertise developed in the Member States, and the resources proposed for this area in the European Food Authority, evaluation and decision-making on existing active substances will increase significantly in the future; barring unforeseen surprises the current programme should be complete by end 2008. The Commission notes the need to recognise that the derogations foreseen until 2008 are contingent on the necessary resources, structures and procedures being made available at all levels. It is crucial, however, if the deadlines are to be met that all partners in the process recognise and meet their responsibilities in this regard.

48. The deadline of July 2003 needs to be extended, as provided for by the Directive, for certain specific substances. Specific derogations will only be proposed for substances that meet agreed criteria, and where there is sufficient data and no identified concerns. In addition, derogations will take into account essential uses to be identified as soon as possible to facilitate the planning of appropriate national measures.

49. Finally, although the Commission recognises the need to amend Directive 91/414/EEC, it will await the reactions of Parliament and Council to this report before bringing forward proposals for amendment in 2002.