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WORKING DOCUMENT OF THE COMMISSION SERVICES
TECHNICAL ANNEX TO REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL ON THE EVALUATION OF THE ACTIVE SUBSTANCES OF PLANT PROTECTION PRODUCTS

The function of this document is not only to detail the issues discussed in the above-mentioned report[1] but to go beyond it by giving a broad overview of the implementation of the Directive as a whole, the organisation of work among the players and the approaches used in evaluating active substances at national and Community level. It also describes the progress made in related areas during this time against a changing social, scientific, economic, political and legal backdrop. For the sake of completeness, it gives a perspective on the *new active substances* - 84 substances for which requests to introduce them onto the market have been received since 1993. Finally, it outlines current and future developments in this area in the context of a changing Europe e.g. enlargement, the proposed European Food Authority. It was elaborated by the Services of the Commission following several discussions with the Member States in the Legislation working group of the Standing Committee on Plant Health, with the Members of the Standing advisory group on plant health, and with other stakeholders. Its content also reflects comments received following a written solicitation of views from Community trading partners in the OECD and Codex alimentarius as well as non-governmental organisations.

TABLE OF CONTENTS

[1] Report from the Commission to the European Parliament and the Council on progress in the evaluation of existing active substances under Directive 91/414/EEC on the placing of plant protection products on the market. Document COM(2001)444 of 25 July 2001.

1. THE CONTEXT OF THE DIRECTIVE

Already in 1976, as the Single Market was being developed, it was recognised that Community harmonisation in the area of plant protection products was both desirable and necessary. This was primarily for two reasons. First, the area is complex to regulate and hence could lend itself to a shared approach. Second, it has ramifications touching upon many vital national and international interests including health, worker safety, environment, agriculture and trade.

Other than the Council of Ministers, there was at that time no international forum for Member States to discuss pesticides-related issues. The OECD Pesticides Forum was not established until 1992. After decades of purely national approaches and measures, there was great disparity among the administrations, procedures, requirements and standards prevalent in the Community. Community legislation on pesticides at that time was restricted to four Council directives on maximum levels of residues in agricultural produce and food[2,3,4,5] as well as a Council Directive[6] setting up a list of banned substances.

The enormous difficulties encountered during harmonisation can be gauged from the time it took to agree on a final text for the Directive. The first proposal from the Commission was transmitted to the Council and the Parliament as early as August 1976[7] and the Council did not finally adopt the Directive until July 1991 - 15 years later! The Member States even then tarried still further with its implementation. Transposition into national legislation was not complete until 1997.

Initially, there was no clear idea of the number of active substances on the market in the Community and estimates ranged from 6-900. There was also no clear appreciation of the work that would be involved in reaching harmonised assessments and evaluations of them. The Member States and the Commission, in a declaration made during the adoption in 1991, estimated that two years would be needed to set the rules for evaluations and that about 90 substances could be evaluated per year thereafter during a 10-year period.

This estimate was made without the benefit of hindsight. As will be recorded below, the difficulties that arose in agreeing on harmonised data requirements and testing protocols, on risk assessment methodologies and guidance documents, in developing the new sciences needed, in adapting national administrations and procedures, as well as in training the personnel required to make the assessments, were not factored into the equation. While many of these issues have gradually been resolved and a long learning curve climbed, it is also evident that the programme of evaluation will not be complete by July 2003 and that additional transitional measures will need to

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2 Council Directive 76/895/EEC of 23.11.1976 relating to the fixing of maximum levels of pesticide residues in and on fruit and vegetables, OJ N° L 340, 9.12.1976, p. 26

3 Council Directive 86/362/EEC of 24.07.1986 on the fixing of maximum levels for pesticide residues in and on cereals,, OJ N° L 221, 7.8.1986, p. 37

4 Council Directive 86/363/EEC of 24.07.1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin,, OJ N° L 221, 7.8.1986, p. 43

5 Council Directive 90/642/EEC of 27.11.1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables, OJ N° L 350, 14.12.1990, p. 71

6 Council Directive 79/117/EEC of 21.12.1978 prohibiting the placing on the market and use of plant protection products containing certain active substances, OJ N° L 33, 8.2.1979, p. 36

7 COM (1976) 427 final, OJ N° C 212, 9.9.1976 p. 3

be taken. It can almost be said that, in 2001, we can now appreciate the scale of effort – and final objective – implied in the decision taken so many years earlier.

The process of implementation has not taken place in a static environment. Since 1991 there have been major political and societal changes as well as significant restructuring in the relevant agro-industrial sectors.

First, the adoption of the Directive coincided with discussions in Rio and worldwide recognition that co-ordinated international action was required to combat environmental degradation. There was a sea change in regulatory approaches to authorising pesticide uses and, with the U.S. also embarking on a major re-evaluation programme, a need for a worldwide forum for discussions on approaches and possible co-operation in the assessment of pesticides. This led to the creation of the Pesticide Forum within OECD (see Section 4.5.1) and later, looking at the broader chemicals landscape, to the creation of the Intergovernmental Forum on Chemical Safety.

Second, 1995 saw expansion of the Community to include Austria, Finland and Sweden. This not only required redistribution of the evaluation tasks among the Member States; it also brought new perspectives, new priorities and different expertise to the table. Future enlargement bringing in new Accession countries is also destined to have a major impact on the programme and on decision-making.

Third, although public attitudes to pesticides residues in food had always been negative, a more pervasive shift in perception has occurred, with rising concern about environmental and food safety. New scientific issues e.g. endocrine disruption, a series of food safety scares (e.g. BSE and *Listeria*), the perception that food production and distribution was becoming too industrial and food chains too long and unmanageable, has led at Community level towards a recognition that a European Food Authority was desirable and, more generally, to a discernible trend in consumer spending back towards 'quality' products like traditionally produced and organic food and fresh produce.

These trends were consolidated by the heightening of attention to consumer protection at Community level in the Amsterdam Treaty, by ratification of a new international agreement creating the World Trade Organisation and subsidiary SPS and TBT procedures, and by the greater role given to independent scientific committees to provide opinions to the Commission in the area of food safety. The long-term evaluation programme for existing active substances established by the Commission with the Member States thus had to gather pace, evolve and expand against this backdrop.

2. STRUCTURES ESTABLISHED BY THE COMMISSION

2.1. Interservice Group on Pesticides

Within the Commission, DG Health and Consumer Protection and DG Environment are co-responsible for managing Directive 91/414/EEC. Formerly, and until the re-organisation of the Commission Services in September 1999, co-responsibility rested with DG VI and DG XI. An Interservice Group on Pesticides was established, also involving these and other Directorates-General, to help solve problems of a wider nature in practical implementation. Membership now comprises DGs Health and

Consumer Protection, Environment, Agriculture, Industry, Trade, Development, Research & Development. In addition, the Commission has two Internet sites dedicated to pesticides evaluation under the Directive. The first is a restricted access site used to exchange confidential information among the Commission and the Member States and relates to the preparatory evaluation and legislative work of the SCPH. The second site, publicly accessible on the EUROPA server of the Commission contains a vast array of information in this area as well as links to similar sites in the Member States[8] and elsewhere.

2.2. Standing Committee on Plant Health (SCPH)

The Standing Committee on Plant Health (SCPH) is the Regulatory Committee whose opinion is required under Article 19 of the Directive before Commission Decisions, Directives or Regulations are adopted. It was set up by Council Decision 76/894/EEC.

2.3. Scientific Committee on Plants (SCP)

The Scientific Committee on Plants (SCP) was established by a decision of the Commission in July 1997[9] in the context of a general reform of the system of scientific advice which involved the creation of a Scientific Steering Committee and eight new Scientific Committees, one of which being the SCP. The SCP replaced the Scientific Committee on Pesticides which had existed since 1978[10] and which had provided advice on pesticides and their residues in food[11]. The mandate of the SCP was enlarged, compared to that of its predecessor, to cover scientific and technical matters relating to plants intended for human or animal consumption as well as the production of non-food products with respect to characteristics liable to affect human health or the environment, including the use of pesticides. The 19 members of the SCP are appointed by the Commission on a three-year mandate, following publication in the Official Journal of a call for expressions of interest via a fully transparent selection procedure.

The SCP has to date issued in excess of 100 opinions on general and specific issues relating to plant protection products and to genetically modified organisms (GMOs). These are published on the Internet on the EUROPA Server[12]. In the case of plant protection products the Committee is consulted at the end of a process involving detailed examination of the dossier by a Rapporteur Member State, peer review in ECCO and examination in the Evaluation working group of the SCPH. Two approaches are used when consulting the Committee and these are applied on a case-by-case basis depending on the issues relating to the particular substance. The majority of cases referred to the SCP to date have involved specific questions on unresolved issues. There are also cases in which further reassurance is considered necessary. In the letter, representing a minority of cases, dossiers are referred as they stand to the Committee when no areas of concern have been identified in the evaluation process. In both approaches the SCP can and does draw the Commission's attention to other matters of concern on which it had not been

8 http://europa.eu.int/comm/food/fs/ph_ps/index_en.htm

9 Commission Decision 97/579/EC of 23.7.1997, OJ N° 237 of 28.08.1997, p. 18.

10 Commission Decision 78/436/EEC of 21.4.1978, OJ N° L 124 of 12.05.78, p. 16.

11 Reports of the Scientific Committee for Pesticides Series 1 to 4, Office for Official Publications of the European Communities, 1981, 1985, 1990 and 1999.

12 http://europa.eu.int/comm/food/fs/sc/index_en.html

explicitly consulted. The SCP has also been consulted on a number of generic issues involving draft guidance documents. In all cases, the Commission takes the Committee's advice into account when finalising the documents.

2.4. Standing advisory group on plant health

Of the advisory committees in the field of agriculture[13] set up in 1998, one, on agricultural product health and safety, has a standing group dedicated to plant health. An elected member chairs the group. Being a relatively recent innovation, the Committee has not yet played a real role - neither in the decision-making process for individual active substances, nor in the evolution of the system itself. The Commission services are currently examining the role of the advisory group and how it could better contribute to the process in the future.

2.5. ECCO (European Commission Co-ordination)

It became clear at an early stage in the programme that trust and co-operation between Member States and Commission had to be developed and that a peer-review process needed to be established to improve the quality and consistency of the initial assessments prepared by the Member States. At that time, there was little experience and guidance available and the quality and content of the original dossiers upon which the assessments had to be based also varied - as indeed did both the amount and quality of resources that Member States could dedicate to these tasks. It became clear that better assessments prepared by the Member States would facilitate the decision making by all 15 Member States at the end of the process.

In 1996, the Commission set up ECCO[14] (European Commission Co-ordination), to perform this task. In practice, the ECCO Secretariat is based in the Biologische Bundesanstalt für Land- und Forstwirtschaft (BBA) in Braunschweig and in the Pesticides Safety Directorate (PSD) in York. Its work covers both existing and new active substances. The current ECCO contract was signed late in 2000 and will expire at the end of 2003. The initial tasks of ECCO were to organise a series of small meetings of experts from up to seven Member States to peer-review the initial assessments for up to 10 substances at a time in the areas of (i) physicochemical properties, (ii) mammalian toxicology, (iii) fate and behaviour, (iv) residues, (v) ecotoxicology, and (vi) overview. To date, about 120 such meetings have been organised. In addition, to the above tasks ECCO now also assists the Commission in the development of guidance documents and in managing the extensive documentation associated with the evaluation of substances.

ECCO has contributed much to the achievements of the current programme. Of the draft assessment reports submitted by Rapporteur Member States, most have already been peer-reviewed. ECCO's involvement in development of guidance documents and the improvement of procedures has been very positive. Even more importantly, ECCO has brought together, in open discussions in a spirit of collaboration, about 200 experts from all Member States and a real community of expertise has been created. This has encouraged an increased harmonisation in assessments performed by individual Member States and increased the acceptance by the other Member

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13 Commission Decision of 11 March 1998 on the advisory committees dealing with matters covered by the common agricultural policy, OJ N° L 88 of 24.3.1998, p. 59

14 http://www.bba.de/english/ap/ecco/ecco_en.htm

States of such assessments. It is foreseen that the proposed European Food Authority will gradually take over the work of ECCO and of the scientific committees.

3. DESCRIPTION OF THE PROCESS

3.1. Existing active substances

3.1.1. First priority list

A necessarily complicated flowchart describing the evaluation and legislative processes required to reach decisions on these substances is given in Figure 1. The process flows from Commission Regulation N° 3600/92, as amended over the years and contains many steps, reflecting not only the depth of the evaluation but also the breadth of the consultative process and the feedback procedures involved.

Commission Regulation N° 933/94[15] allocated the substances among the Member States with each acting as the Rapporteur for individual substances. Allocation was according to size, without regard to the then capacity of Member States to undertake the evaluations, adding another source of delay. The Regulation set deadlines for notifiers to submit complete dossiers in advance of agreement on what actually constituted one, which only came in 1996[16]. For this reason a great deal of flexibility had to be built into the procedure. This excess of flexibility contributed more than anything else to the delays encountered and it has subsequently been reduced.

Upon receipt of the dossiers, the Rapporteur Member States had to verify that all data were included and that either timelines were given for the provision of missing data or that justifications were given as to why certain data were not provided. They then had 12 months to complete their assessments of the dossiers and to send them to the Commission carrying one of four possible recommendations: (i) include the substance in Annex I, (ii) not include the substance in Annex I, (iii) suspend the substance from the market pending the provision of further data or (iv) postpone taking a decision on the substance pending the provision of further data. In the event, most of these reports were provided to the Commission well after the deadlines stipulated in the Regulation. Three have still not been provided.

The next step is the peer-review of the draft assessment report. Here, the dossier and the draft assessment are examined in a series of technical meetings by experts from several Member States, with the objective of confirming the assessments and the data gaps identified by the Rapporteur Member State. This process is managed by ECCO and can last from six to nine months. It leads to the identification of data gaps and acts as quality assurance on both the dossier and on the initial assessment. In the early years, it was particularly important as gaps were numerous and the quality and content of the initial assessments varied considerably.

After peer-review and filling of data gaps, the package is examined by the Evaluation working group of the SCPH. This is the first technical discussion in which all Member States participate. It often throws up new issues requiring additional studies,

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15 Commission Regulation (EC) N° 933/94 of 27.4.1994, laying down the active substances of plant protection products and designating the Rapporteur Member State for the implementation of Commission Regulation (EEC) N° 3600/92, OJ N° L 107 of 28.4.1994, p. 8

16 Commission Directive 96/68/EC of 21.10.1996 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market, OJ N° L 277 of 30.10.1996, p. 25

data or clarifications. Depending on the issues and the new data requested, it can take one or two years to complete. A substance will normally leave the evaluation group only when *either* all issues have been addressed and the orientation for a legislative decision is clear *or* when policy issues arise that cannot be solved at the technical level. Sometimes, however, new scientific issues arise at this stage for which an independent scientific view is required.

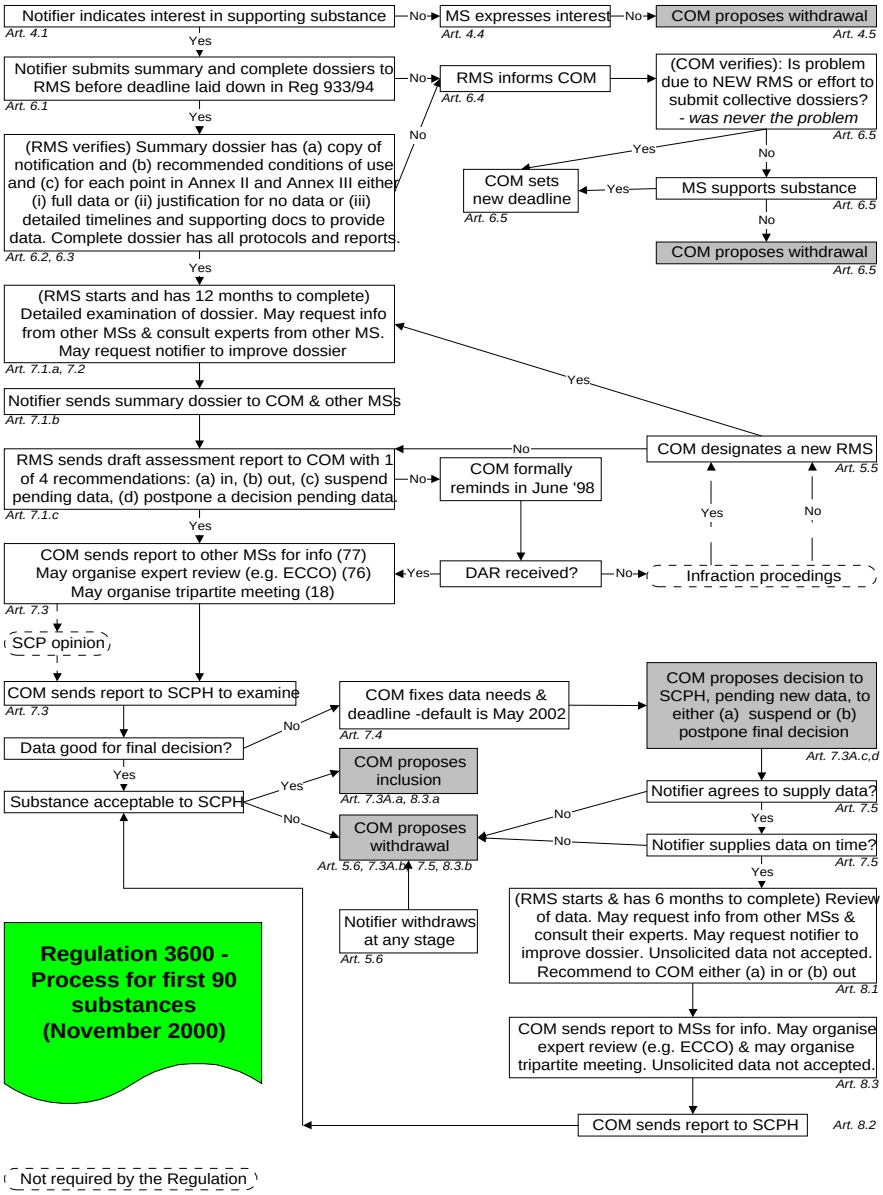

Figure 1: Process to reach decisions on first list of 90 priority substances.

At this point, a substance would normally be forwarded either to the Legislation working group of the SCPH (if a clear negative decision is foreseen), or to the SCP for a scientific opinion (in cases in which an inclusion decision might be foreseen or a scientific issue needs to be resolved). Once an opinion is received from the SCP, the substance proceeds to the SCPH (but could, if necessary, go back to the evaluation group). The Legislation working group of the SCPH takes a final orientation on a substance and the Commission would then draft a proposal for a decision to be submitted to the SCPH for its opinion, as provided for in Article 19 of the Directive.

As noted, the data call in and the review programme under Regulation 3600/92 were undertaken before Member States had reached final consensus in 1996 on the data requirements for the evaluation programme. Because of this "moving target", it was necessary to allow opportunities for notifiers to submit additional information after the original dossier was delivered, and even after the draft assessment report of the Rapporteur Member State was submitted and peer reviewed in ECCO. This provision made it difficult to finalise the reviews for the first list of substances. Additional information could be submitted at any time and this then had to undergo review by the Rapporteur and by all Member States in the Working groups of the SCPH. 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. Superseded by subsequent clarifications, provision for easy submission of additional data has been withdrawn by Regulation 2266/2000. It is no longer foreseen for the second, third and fourth stages of the review programme

The process was all the more time consuming because, even after final consensus on data requirements had been reached for the conventional chemical substances, criteria for the evaluation of the data (in particular technical questions on risk assessment and related triggers for higher-tier studies) were still not completely agreed among the actors involved.

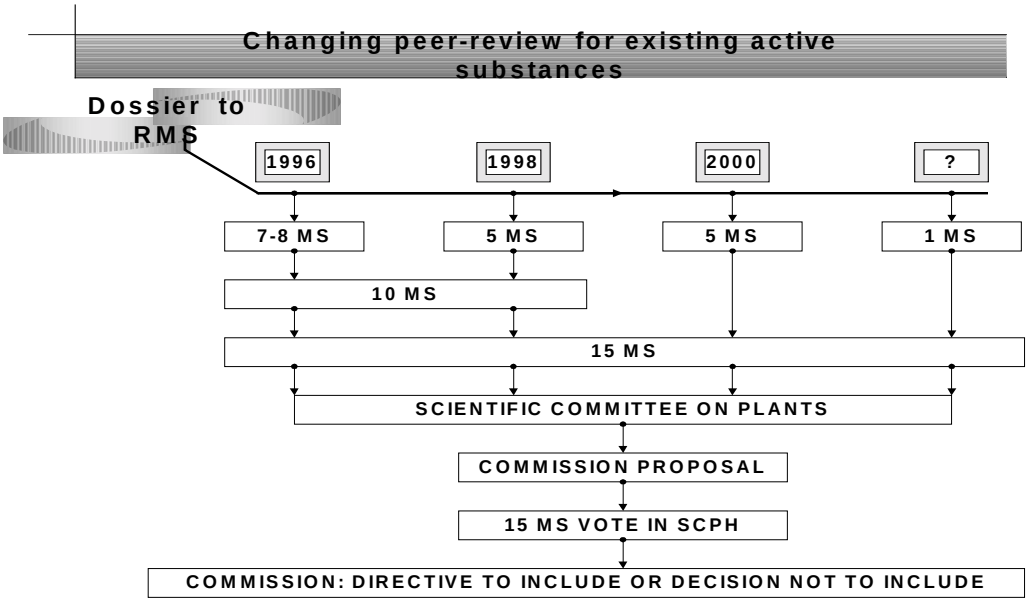

Figure 2: The changing procedure for reaching decisions on existing substances. Following the receipt of the draft assessment report from the Rapporteur Member State, an ECCO peer-review is organised. The early ECCO reviews involved 7-8 Member States and these were followed by a second review by 10 Member States. As experience is gained and dossiers and reports improved, the system moved to a 5 Member State review before going directly to the 15 Member States. The ultimate goal is to have a single Member State review going directly to all Member States.

The procedure and process is being improved for the second, third and fourth lists.

3.1.2. Second priority list

In April 2001, the Commission designated the Rapporteur Member States for each of

the second-list substances notified[17]. Industry is obliged to submit a complete dossier for each substance by April 2002. After the formal completeness checks of the dossiers received, Rapporteur Member States will have 12 months in which to submit their draft assessment reports and their recommendations on each substance. Building on agreements and guidance developed during the first phase, the Regulation contains several provisions that will help speed up decision-making:

(i) completeness check of the dossiers. An incomplete dossier will not be evaluated. The Regulation also provides that the evaluation will be done on the dossier as submitted; further studies will be accepted only in exceptional cases;
(ii) number of uses to be evaluated: industry has to submit a dossier for an active substance along with sufficient data to demonstrate for a limited range of representative uses that they are acceptable. Further uses are to be examined at Member State level after an eventual inclusion of the active substance in Annex I, applying the Uniform Principles;
(iii) submission of further information will only be accepted if requested by the Rapporteur Member State or by the Commission;
(iv) only two types of decisions are foreseen: inclusion or non-inclusion;
(v) criteria for inclusion in Annex I: clear guidance on criteria for the inclusion of active substances in Annex I is being developed. This should reduce the need for discussion in the working groups of the SCPH;
(vi) fees: Member States will request a fee from the notifiers covering their work as Rapporteur and improving the resources available to do the work.

3.1.3. Third priority list

For the third list, the 167 detailed notifications needed to include the following information:

(i) identification data on the active substance and the notifier,
(ii) commitment to present a full dossier,
(iii) completeness-check performed by the notifier,
(iv) list of available studies including:
  (a) studies available and further planning to complete the dossier,
  (b) studies performed since August 1994,
  (c) list of authorised crops/uses,
  (d) most recent review,
(v) list of endpoints: this will provide detailed information on the properties of the active substance and might be used to further prioritise their review.

These notifications are currently being examined by the Commission to weed out frivolous or incomplete notifications. The Commission will adopt a Regulation in the second half of 2001 designating the Rapporteur Member States for each substance and laying out the detailed rules for their evaluations. Notifiers will be obliged to submit a complete data package for each substance by May 2003. As with the second list, a completeness check and fee charging will be provided for. Any substance for which a complete data package is not received by May 2003 should be subject to a Commission Decision not to include it in Annex I thus withdrawing all uses from the market. For all the others, after the decisions on completeness and subsequent receipt

[17] Commission Regulation (EC) N° 703/2001 of 6.4.2001 laying down the active substances of plant protection products to be assessed in the second stage of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC and revising the list of Member States designated as rapporteurs for those substances, OJ N° L 98 of 7.4.2000, p. 6

of the dossiers, Rapporteur Member States will again have 12 months in which to submit their draft assessment reports.

3.1.4. Fourth and final list of existing substances

The procedures for the fourth list are still under discussion. It is likely that a notification procedure in late 2001 or early 2002 and a call for submission of data would substantially reduce the number of substances to be evaluated. Most are authorised in small niche markets, though some do have wide use. As a mere matter of economics, a data call along the lines of that for the first three lists would find many producers unable to afford to provide complete dossiers. Other interested parties might therefore decide to be involved in notification, e.g. grower groups. Although the Directive provides that data requirements can be waived if scientifically justified, it does not allow for waivers to be granted for economic reasons. Moreover, given the extent of use, to the Commission the provision of data seems advisable.

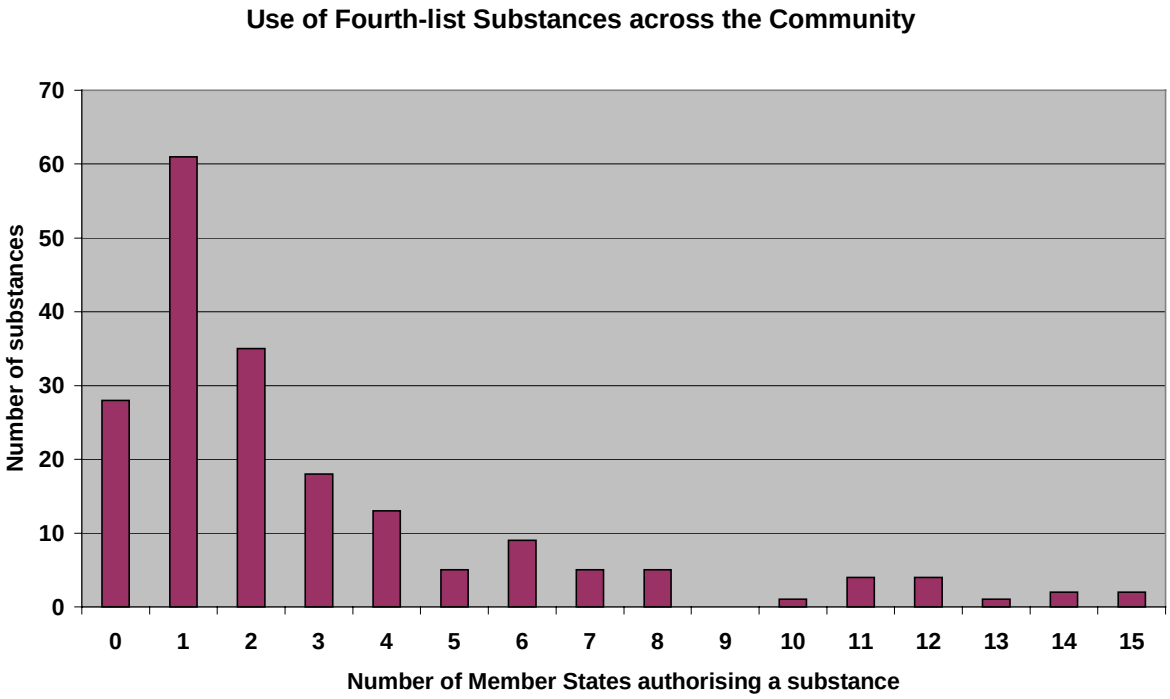

Figure 3: The extent to which individual existing active substances on the fourth list are currently authorised in Member States.

For certain categories of these active substances, further harmonisation is still needed with regard to the content of the dossier and the criteria for evaluation. Launch of a notification procedure is foreseen in late-2001 and it can be expected that as many as 90 fourth list substances will not be notified. A sufficiently detailed notification procedure will be designed to allow an initial classification as high-risk or low-risk. The precise details and timetable for the review of these categories of substances will be established later. No derogations will be made for high-risk substances unless convincing evidence can be supplied showing that any such risks can be effectively managed. In all cases for the fourth list, as a minimum for granting any derogations beyond 2003, data will need to be provided beforehand showing that no particular problems or concerns can be expected from their use. To supplement available information, where appropriate, and in cases where some data may be missing,

evaluations made in other fora and under other legislation may be used. In any event, restrictions on use may be necessary. The categories of substances on the fourth list are listed below, as are the approaches envisaged for dealing with them. Many substances fit into more than one category.

3.1.4.1. Micro-organisms including viruses

There are 17 species used as active substances, four of which are no longer authorised in any Member State. Data requirements were recently been fixed for these substances and uniform principles for their risk assessment are now being prepared. It is agreed however that dossiers and evaluations will have to be done at the level of individual strains rather than at the species level. A notification procedure can be issued at any time. Given recently acquired experience in evaluating new active microbials, this should be a *relatively* straightforward exercise.

3.1.4.2. Substances whose use is authorised in foodstuffs or animal feeding stuffs

There are 26 such substances, five of which are no longer authorised in any Member State. The data justifying such authorisations will need to be examined case-by-case. Environmental data should also be provided. Where exemptions from existing requirements are to be made, these should be justified.

3.1.4.3. Plant extracts

There are 35 such substances, five of which are no longer authorised in any Member State. Full data packages will normally need to be provided although, depending on uses e.g. plant strengtheners, reduced data requirements might apply (see also Section 3.6.3).

3.1.4.4. Animal products or substances derived thereof by simple processing

There are seven such substances i.e. gelatine, bone oil and hydrolysed proteins. As a first step, the continued use of these substances has to be verified and a decision made as to whether they need to be evaluated under the Directive. If so, as a minimum, toxicological and environmental data will need to be provided.

3.1.4.5. Substances used as attractants or repellents

An estimated 30 pheromones and possibly a similar number of other substances falling in this category are on the European market today, and about 30 more are in use world-wide. The exact number of substances in this category cannot be determined at present because not all of them fall under the Directive if today's definitions of Article 2 are applied. To bring assessment of all substances in this category under the Directive will require an amendment of Article 2, something that is in any case desirable to clarify borderlines with the Biocides Directive 98/8/EC[18]. This field must be regulated with caution so as not to discourage the marketing and use of these - in most cases - environmentally friendly solutions. As a first step, data requirements for pheromones and semiochemicals are currently being developed in collaboration with other countries in the OECD. A reduced set of requirements will be proposed, part of which can be covered by weight of evidence assessments to

[18] Council Directive 98/8/EC on the placing of biocidal products on the market. OJ N° L 123 of 24.4.1998, p. 1

further reduce the need for costly experimental studies wherever possible, without compromising operator, consumer or environmental safety. The approach outlined for pheromones will serve as an example for other attractants/repellents.

3.1.4.6. Substances used in traps/dispensers (Regulation 2092/9119 - organic farming)

There are 55 such substances, nine of which are no longer authorised in any Member State. A full toxicological and environmental data will need to be provided. A restriction on uses to traps or dispensers may be made as a condition permitting the waiving of certain data requirements once exposure of operators, consumers and certain environmental compartments can be excluded. Such an approach would safeguard high safety standards, while at the same time limiting burdens on notifiers to the necessary minimum, thus encouraging the further uptake of environmentally friendly practices. Although there is some overlap with pheromones here, there is a difference for attractants/repellents.

3.1.4.7. Substances that are or will be exclusively used as rodenticides

There are 30 such substances, five of which are no longer authorised in any Member State. It needs to be verified which of these substances should fall within the scope of the Directive or whether they would be better treated under the Biocides Directive. Agreement has almost been established whereby rodenticides used *exclusively* in the field to protect crops would fall under the Directive. A full data package will need to be provided for uses that remain under 91/414/EEC and appropriate restrictions would be applied. A full data package would also be required under the Biocides directive and co-ordinated reviews under both directives would be desirable.

3.1.4.8. Substances used exclusively on stored plants or plant products

There are three such substances. If it were demonstrated that no residues would be present in the marketed commodities, then it is possible that they would not require full toxicological or environmental data packages. Otherwise, as with other substances, the full data would have to be provided. A restriction on uses can be made as a condition for any derogation.

3.1.4.9. Commodity substances

Of the 31 such substances e.g. carbon dioxide, table salt, lime, and wax, five are no longer authorised in any Member State. Toxicological and environmental data will need to be provided and use could possibly be made of evaluations performed under other legislation e.g. Regulation 793/93/EC[20]. In any case, the IUCLID database would be used wherever it would be useful. A restriction on uses can be made as a condition for any derogation.

3.2. New active substances

Unlike the priority-list approach for existing active substances, the evaluation of a new active substance can be triggered at any time by an application from industry to a Rapporteur Member State *of its choice*. Another major difference is the provision

[19] Council Regulation (EEC) N° 2092/91 of 24.6.1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs, OJ N° L 198 of 22.7.1991, p. 1

[20] Council Regulation (EEC) N° 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances, OJ N° L 84 of 5.4.1993, p. 1

in the procedure for a completeness check. There are additional minor differences in evaluation procedures between the two categories - some due to legislation, some for practical reasons. The diagram below outlines procedures for new active substances.

Since 1993, applicants have concentrated on a limited number of Member States with over half of all applications being submitted to France and Germany - Member States that present a large potential market for industry's products. Although there was a peak of 16 applications during 1997, currently about eight new applications are received annually. In total the Community has 84 new active substances at various stages of examination with decisions having been taken on 15 (14 of which were for Annex I listing). Unlike existing active substances the number of applications submitted is in the hands of the applicants and this has made the planning of the work and resource allocation difficult because of peaks and troughs in the workload. The majority of new active substances have been herbicides, followed by fungicides and then insecticides.

As mentioned above, the Directive sets out special provisions to be followed for the evaluation of new active substances - the most important being the administrative check for completeness of a dossier. Once an applicant submits a dossier to the Rapporteur Member State, the Rapporteur carries out a "completeness check" to ensure that all the studies that are necessary for the evaluation are present. Without a Commission Decision on completeness, detailed evaluation of the dossier does not begin. The intention is to avoid delays in evaluation caused by lack of key studies hampering full assessment of the safety of the active substance. The completeness check has been a useful innovation that has assured a uniform high standard for the dossier. A similar check has subsequently been introduced in the procedure for existing substances.

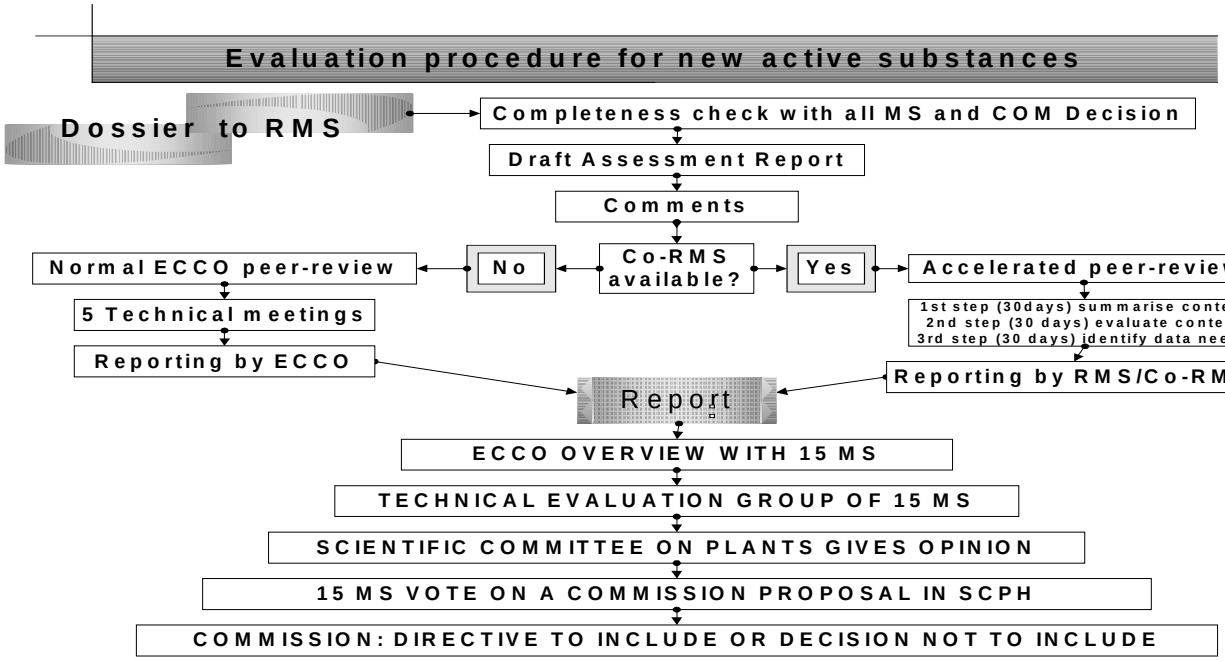

Figure 4: The evaluation procedure for new active substances is gradually moving from the "normal ECCO" scheme on the left of the figure to the "accelerated peer-review scheme on the right.

In theory, new dossiers prepared to modern data standards should be more complete than those for existing active substances. In practice, many problems arose in early years as Member States and the Commission faced difficulties in defining exactly what was meant by 'completeness'. Some Member States were of the opinion that the check was purely administrative; others maintained that a pre-evaluation of the studies in the dossier should be carried out to ensure that they could be used. These early problems with the completeness check were compounded by the fact that all Member States and the Commission have to be involved in the check and in confirming the findings of the Rapporteur Member State. This led to difficulties and delays in the process. These delays also had an impact on applicants. Without a Commission decision recognising in principle the completeness of a dossier, the applicants cannot gain provisional authorisations for uses of the substance in the Member States.

Provisional authorisation was another innovation of the Directive that only applies to new active substances. It was recognised at the time of adoption of the Directive that the process of evaluating active substances was lengthy and complex. To avoid delaying the introduction of new active substances onto the market, it was decided to allow the Member States to have the possibility to 'provisionally authorise' them in advance of a decision on Annex I inclusion. An important condition for the granting of such provisional authorisations is that Member States have to establish that the active substance can satisfy the requirements of Articles 5(1) and may be expected to meet the requirements of Articles 4(1)(b) to (f) of the Directive before they are granted. It was generally expected that new active substances would be more targeted in their mode of action and would *generally* be of less concern than existing substances. The Commission has to date taken 79 positive decisions concerning completeness of dossiers and all Member States have used the possibility of granting provisional authorisations.

Over the last five years there has been a trend for the Member States to wait until the Rapporteur Member State has completed the draft assessment report before granting provisional authorisations.

Once a positive Decision on completeness has been taken, the detailed evaluation of the dossier begins in the Rapporteur Member State which then has 12 months to complete its work and to submit the draft assessment report to the Commission. In 70% of cases, this target has been met. For new active substances the number of uses applied for are far fewer than for existing active substances and this greatly simplifies evaluation.

Generally as experience in the Member States and among applicants has increased, delays in the submission of the assessment reports are becoming less frequent. Member States have completed some 55 draft assessment reports to date. This constitutes a major achievement in terms of the pooled evaluation capacity represented by the Community. Currently, the peak of applications for new active substances received in 1997 has now worked its way through the evaluation system and is at the final stage of evaluation.

In general, and for the reasons outlined above, discussions on new active substances have been less difficult and less time consuming than for existing substances. Some new active substances have however presented the Commission and the Member States with regulatory and scientific challenges - often because the substances use

new chemistry to achieve their modes of action. Other issues such as leaching of metabolites into groundwater have also generated detailed discussions.

In 1998, following a detailed analysis of the delays encountered at each stage of the evaluation procedure, measures were introduced to speed up the process. Many of these solutions have since been applied also for existing active substances. The changes and their impacts are outlined below.

In 1994, information exchange was slow for the initial step in which the Rapporteur Member State informs the Commission and the other Member States of an application from a notifier. This has increased considerably with the use of e-mail. Rapid information exchange discourages applicants from making multiple applications to several Member States - a practice that can use up limited resources. A very recent trend is for applicants to alert Member States and Commission of a forthcoming application. This has the advantage of allowing better planning and allocation of resources.

The subsequent completeness check was taking more than a year to complete in 1994 because at that time, rather than doing a simple administrative check, Rapporteurs were checking the studies in the dossier in detail. By 1995-7 the trend was towards a quicker check although some notable exceptions occurred where applicants were requested to generate new data. In 1998, one Member State introduced a 'turbo check' (a 3-day intensive administrative check of the dossier). With all factors optimised, a check, from original application through to publication of the decision, can take as little as 90 days. Most Member States agree that only a more detailed examination of the dossier by the Rapporteur will determine whether data is missing. A lengthy check has often been followed by long detailed examinations and technical discussions in the various working groups - its value is thus questionable.

After publication of the Commission Decision on completeness, the Rapporteur Member State begins the detailed scientific and technical evaluation culminating in the draft assessment report. In 1996, the average time needed to prepare a report was 328 days. This was unchanged until 1999. In 70% of cases the target of one year was met. For the remaining 30% of cases, the delays are not linked to any one Member State - all have had difficulties at times. Reasons include:

- problems with the dossier,
- difficult issues e.g. relevance of metabolites, new modes of action,
- new data requested from the applicant to address data gaps,
- heavy national work pressures,
- data requirements not fully defined e.g. microbial pesticides.

The next step is the ECCO peer review. To make the peer review process as efficient as possible, the duration of each round of meetings has been extended to allow for as fuller consultation between Rapporteurs and notifiers so as to ensure that as many data requirements are fulfilled as possible prior to consideration of the review in the technical working group. From 1996 to 2000, peer review was extended from the original four to about nine months, allowing applicants and Rapporteurs to resolve issues before the closing overview meeting. This led to more conclusive overview meetings and in consequence, shorter discussions later in the technical working groups of the SCPH. At the same time, the number of active substances dealt with at each meeting increased from four to nine.

Referral to the SCPH evaluation working group after ECCO can be lengthy due to:

- work load of the technical working group,
- lack of human resources to organise the meetings,
- limited availability of meeting rooms,
- budgetary restrictions and freezing of budgets,

However, any delays between the peer review and discussion in the working group are used by the Rapporteur and applicant to resolve outstanding issues, expediting the final decision relating to Annex I inclusion.

Since 1997, the evaluation working group of the SCPH has discussed key issues of concern identified in the ECCO peer review. Because discussions on new active substances referred to the group in 1997 were taking a long time to conclude, in 1999, in a new approach, it was decided that the evaluation for new active substances should concentrate on deciding if there was a single safe use. This is in line with the Directive. Additionally, a limit of 2 discussions was introduced. Streamlining has had a big impact on the length of discussions and, at the same time, the benefits of an extended peer review were also beginning to emerge. In fact, since 1999, discussions have been more incisive and taken much less time.

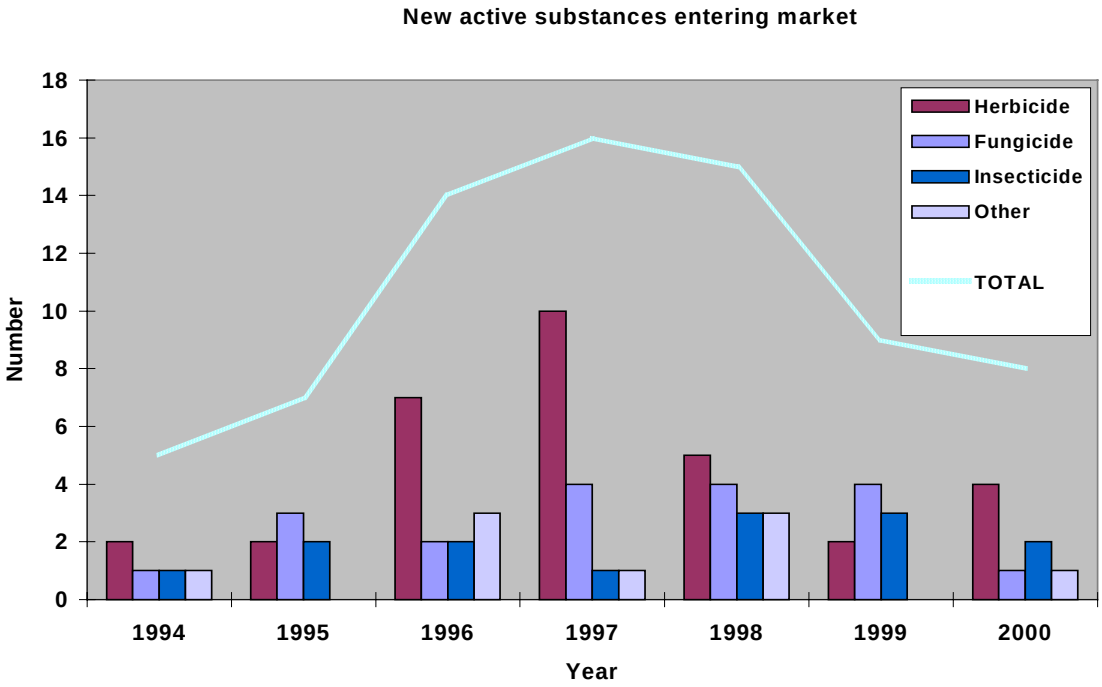

Figure 5: The numbers and types of new active substances for which applications for inclusion in Annex I were received during 1994-2000.

Over the last few years much experience has been gained in the evaluation of new active substances. Many generic issues, faced for the first time in 1997, have been resolved in particular following detailed discussion of problems and development of specific guidance documents in the ECCO peer review process. Although still providing a valuable service for the more complex reviews of existing active substances, ECCO peer review has been of more limited value with respect to new active substances. Improvement in the quality of the newer dossiers submitted for new active substances, together with the higher quality assessment reports that are

generally prepared for new active substances, has resulted in fewer issues requiring consideration in the full peer review programme. A more flexible and rapid procedure was thus required for handling the specific issues arising from these evaluations and the co-rapporteur system was stepwise introduced in 2000. The project used a second Member State acting as a co-Rapporteur in examination of the dossier. The results of this project proved positive and the Commission and Member States extended it to become the default procedure for evaluating new active substances. The new procedure is now known as 'accelerated peer-review'.

One temporary problem is that a batch of 45 applications for these substances received in 1996-1998 temporarily overloads resources in the Commission and the Member States at each step of the evaluation process as their assessments progress towards completion. Of the applications received during this period, 32 were for herbicides, 19 for fungicides, 14 for insecticides and 9 were for other types of use e.g. growth regulation.

At the time of writing, decisions have been taken for 15 (14 inclusions and one exclusion) and the remainder at at various stages of the evaluation process.

4. THE MEASURES TAKEN

4.1. General

This section describes measures, data requirements, guidance documents, uniform principles, international workshops in related areas, linkages to other legislation, international fora, R&D, etc. While an effort has been made to keep the following text as simple as possible, it is of necessity complex and detailed - reflecting the degree of commitment of the various actors in the process over the years.

The first measure after adoption of the Directive and before it entered into force was the inventory of existing active substances[21]. Based on this inventory, the first priority list was selected for review under Regulation 3600/92. The selection of the 90 substances was made following broad consultations with Member States and other stakeholders. Many of the measures taken since that time have been in response to difficulties or concerns encountered during their subsequent evaluation.

Although detailed guidance had still to be developed, a pilot project was started in 1992 on three active substances. At its conclusion in 1994, a meeting was organised with all Member States. This formed the basis to develop further the evaluation procedures for both new and existing active substances and co-ordination of the evaluations carried out by the Rapporteur Member States. BBA and PSD, together with the Commission, held the first ECCO meetings in 1996. ECCO started with three rounds of peer review per year, dealing with six to eight active substances each time. The process has been improved to the extent that ECCO now covers up to 17 active substances in one round of meetings. Clearer conclusions are resulting from these meetings and more usable recommendations are being proposed to the Commission. However the process of follow-up discussions with all Member States in the evaluation group meetings and decision-making by the SCPH and the Commission can be bettered.

[21] Document 3010/VI/92, revision 18 of which is attached as Section 13 of this report.

4.2. Legislative measures taken

A list of all legal acts taken under 91/414/EC for existing active substances is given in Annex I of this report. The general legal acts are threefold in nature:

First, a group of measures setting 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 1993-6.

Second, the practical details of the first phase of the review programme needed to be elaborated. The original Commission Regulation (EC) N° 3600/92 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 review programme were established by Commission Regulation (EC) N° 451/2000.

4.3. Data requirements

Data requirements for the conventional chemical pesticides used as active substances in plant protection products were adopted in 1996 and work on data requirements is still ongoing for several other specific categories of active substances. For pheromones and semiochemicals agreements have been reached at OECD level and are now pending final approval and endorsement in the Community. Final adoption can be expected by summer 2002. These requirements will serve as a model for other categories on the fourth list. For active substances, which are microorganisms and for plant protection products containing such active substances, data requirements were laid down in Annexes IIB and IIIB of the Directive earlier this year. A project to consolidate the Uniform Principles for decision-making on authorisations of such products in Member States is ongoing with a view to finalisation late in 2001. A project to define data requirements for substances that are known to be of low-risk (such as diatomaceous earth, silicates etc.) is underway in the workgroups of the SCPH and, finally, a similar project for "plant tonics" or "plant strengtheners" has been initiated. Certain plant strengtheners have no direct impact on pests but are claimed to enhance the natural resistance and vigour of the cultivated plant. Substances in this group include, for example, several mixtures of minerals and extracts from plants or algae. An amendment of Article 2 is necessary to draw precise boundaries to the scope of the Directive and its borderlines with other areas including the field of plant nutrition. Until a harmonised Community approach can be agreed, regulatory approaches and data requirements will differ among Member States for some of the above categories.

4.4. Guidance Documents

Due to the initial lack of consensus on criteria to assess the information on 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 further contributed to the "moving target" image of Regulation 3600/92, which 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. A lack of guidance documents does not imply that dossiers or previous assessments are somehow flawed. Rather,

the main function of guidance documents is to accelerate and harmonise the review and interpretation of the data - without changing the quality of that data itself or of decisions stemming from it.

To avoid market distortion between Member States, a guidance document to help interpretation of the provisions on data protection is under discussion. Progress has been slow due to a lack of resources and to major problems of interpretation between Member States and the two main industry groupings in this sector (ECPA representing the major producers and ECCA, representing minor producers). A guidance document on parallel import was finalised in April 2001.

As the review of the first list progresses and experience is gained, the emphasis of guidance development has shifted towards issues that arise later in the application of the Directive, implications for the Single Market are being felt after Annex I inclusions. Current new projects concern for instance criteria to allow parallel imports of products registered in the importing country and guidance for dossiers submitted at Member State level for products containing active substances already included in Annex I. Some niche problems are also now being tackled e.g. data requirements for pheromones or plant strengtheners, products used in rice fields etc.

Four examples, out of the 25 guidance documents developed to date, highlight these activities and the hurdles that have to be overcome. A full overview of adopted and ongoing guidance document development projects is provided in Section 12.

4.4.1. FOCUS

The FOCUS (acronym for FOrum for the Co-ordination of pesticide fate models and their USe) groundwater project developed an EU-wide representative and scientifically valid scheme for the assessment and quantification of potential groundwater contamination. It started in 1995 and was finally adopted in December 2000. The Member States mainly funded the cost of about 1.5 Mio Euro. The (unanimous) adoption of the 10 FOCUS scenarios is a big step towards harmonised risk assessment in the EU. It will lead to significant gains in time and effort in the review process and provide – finally – the necessary orientation for notifiers to submit uniformly formatted groundwater sections in their dossiers. This work is now being extended and built upon in a research project funded by the Commission under the Framework Programme[22]. The full benefit of this achievement will only be felt in future reviews in coming phases of the evaluation programme.

4.4.2. Ecotoxicology

After 4-5 years of study and development, agreed guidance was finally adopted in September 2000 on triggers for higher-tier studies and on decision-making in the fields of terrestrial and aquatic ecotoxicology and of persistent active substances. Here also, Member States contributed the main financial resources and manpower. The full benefit of these projects will again be felt in the next phases of the programme. Clear guidance is now provided upstream to notifiers on what is expected of them and clear criteria have been defined for Rapporteur Member States to assist their assessments - both will greatly facilitate the review of submitted data.

[22] QLK4-2000-1238

4.4.3. Assessment of Operator Exposure

In 1991, approaches to model the exposure of operators differed widely between Member States. Although all models in use were based on empirical data, predicted operator exposure for identical uses could easily vary by a factor of five or more depending on the model used. Such discrepancies arose in particular when uses were assessed for which the available date was limited or of variable quality. This led to inconsistent risk assessments in Member States, resulting in their identifying certain uses as "safe" which appeared unsafe to others. Divergent views in this very important area have contributed to slow decision-making for substances. The lack of consensus made it necessary to consult the SCP frequently.

In 1993, a project[23] was initiated to develop (i) a harmonised protocol for field monitoring studies and (ii) a European consensus model to predict operator exposure (EURO-POEM: **p**redictive **o**perator **e**xposure **m**odel) and also to define a tiered approach in the exposure and risk assessment. This resulted in the EURO-POEM I model which was, however, unacceptable to most Member States. One shortcoming was the limited database that could be included in it. Therefore, in 1997 a second project (EURO-POEM II) was sponsored under the 3rd Framework Programme[24] to tackle the shortcomings identified and to refine it based on additional data becoming available. This was complemented by another project on the assessment of exposure to pesticides under the 4th Framework Programme[25]. It further refined it by specifically contributing data for operator, bystander and environmental exposure in Mediterranean and Nordic areas. Industry also expanded the available database by conducting new monitoring studies and reconsidering its previous position concerning ownership and confidentiality of the data. The database will be expanded when a new co-ordinated industry research project which undertakes to fill critical data gaps identified for specific use scenarios is completed.

Final reports should be available by end 2001. A user-friendly computer shell is currently under development to allow a convenient application of the model. As all individual data meeting acceptability criteria are fully accessible within the model files, probabilistic methods of assessment may also become easily applicable in the future. It is hoped that EURO-POEM II will find agreement and be adopted in early 2002 as the standard approach for the review of uses under the Directive - important to streamline and speed up the review of substances in the next phases.

The Commission accepts that Member States are still free to use their own assessment tools when they execute their national reviews for authorisation of products containing substances in Annex I - as long as these tools are at least as strict as the model utilised for Annex I inclusion. Policies in Member States are still too divergent to achieve full harmonisation of the national approaches.

4.4.4. Consumer exposure models

Classically, exposure of consumers to pesticides residues has focused on the concept of acceptable daily intake (ADI). This is the maximum amount of residue that a 60-kg adult could ingest per day every day over a lifetime without experiencing any adverse effects. This is usually derived from the highest no-observed-adverse-effects

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23 AIR3-CT-93-1370

24 FAIR3-CT96-1406

25 SMT4-CT96-2048

level (NOAEL; this is a lower dose than the lowest dose causing an effect) in the most sensitive animal model and then applying an additional safety factor of 100. The concept includes acceptance that the ADI can be exceeded for short periods without detriment. In recent years this practice has been extended to include exposure assessments of children and infants.

Recently, a new concept in regulatory toxicology has evolved - the Acute Reference Dose (ARfD). This is the maximum amount of residue one could ingest at one sitting without experiencing an adverse effect. Globally, scientists and regulators are still trying to reach a consensus on how to apply the concept in practice. In the Community, both the ADI and the ARfD are systematically used in exposure assessments for adults, children and infants.

In recent years, the applicability of the ADI concept to babies of less than 12 weeks old has been queried[26] and this in turn has brought the assessment process itself into question for decisions having an impact on this age-group. After having examined the question, the 32nd meeting of the Codex Committee on pesticides residues reaffirmed in April 2001 that the ADI applies to all segments of the population. It asked the WHO-FAO Joint Meeting on pesticides residues to consider the adequacy of databases underpinning the fixing of ADIs. In the Community, this aspect is looked at closely in all evaluations and the Community supports the development of appropriate testing methods. As a precautionary measure, the Commission fixed a temporary MRL of 0.01 mg/kg for residues in foods intended for consumption by babies and young children[27,28]. It is now considering a ban on the use of particularly toxic substances in the production of such foods.

One problem at Community level is that there is no Community diet that can be used to assess exposures of sub-groups. The current practice is to use a tiered approach. First, the WHO European diet is used in calculation. This is a worst-case diet for all of the WHO European Region. If no problems are identified then it can be assumed with some confidence that there will be no national dietary problems. If the WHO diet shows areas of concern, then more detailed estimates are necessary. National diets are used and any problems arising are signalled during ECCO or evaluation working group meetings. These are addressed in the residues legislation when MRLs are set. However, not all Member States have data for all population subgroups. In addition the dietary information for acute intake (e.g. large portion sizes) is lacking in most of them. There is an ongoing effort to collect data to fill these lacunae.

The approach currently used is deterministic - it uses fixed worst-case estimates for the calculations. There is a trend as more data becomes available to move towards probabilistic modelling but, in the absence of agreed guidelines and data, this approach is neither widely accepted nor used. Two projects funded by DG Research under the Fifth Framework Programme[29,30] develop new approaches for consumer dietary exposure modelling. The current approach also looks at intake of a specific residue from all dietary sources (methodology to include residential exposures in the

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26 Opinions given by the Scientific Committee on Food on 19.9.1997 and 4.6.1998 on the ADI applicability to infants and young children.

27 Commission Directive 1999/39/EC of 6.5.1999 amending Directive 96/5/EC on processed cereal-based foods and baby foods for infants and young children, OJ N° L 124 of 18.5.1999, p. 8.

28 Commission Directive 1999/50/EC of 25.5.1999 amending Directive 91/321/EEC on infant formulae and follow-on formulae OJ N° L 139 of 2.6.1999, p. 29.

29 QLK1 1999 00155

30 QLK1 1999 00156

dietary assessment is not yet developed). However, the criterion for Annex I inclusion is that 'a safe use may be demonstrated'. Thus the assessment leading to an inclusion decision should not reject a substance on the grounds that it has, say, a hundred uses which, when considered together, might give rise to excedence of the ADI. This issue is more appropriately addressed in the residues legislation.

In addition, assessment of cumulative exposure is now gaining ground. This applies to similar substances with similar modes of action. Although methodology in this area is lacking worldwide, there is already a limited application of the concept in the residues legislation, e.g. for dithiocarbamates. Methodologies to routinely apply it are being developed in some Member States and in the U.S.A. Applicability will be tested in the U.S.A. soon for the cases of exposure to organophosphates and to carbamates. Based on the outcome and conclusions of that assessment, cumulative assessment will be more fully considered within the Community. The benefits of these efforts will be felt mainly in the next stages of the review programme. They will also facilitate decision-making under the residue directives.

4.5. Electronic databases, archiving and communication

4.5.1. CIRCA

The Community evaluation process is highly complex and there is a constant everyday need to consult many partners both in the Commission Services and in the Member States. Large numbers of voluminous documents have to be physically copied and moved around. Up until 1998 this was done using paper copies and fax or postal services. In 1998, the decision was taken to begin efforts to move away from a paper-based system to an electronic one. The vehicle chosen to do this was CIRCA (**C**ommunication and adm**I**nistration **R**esource **C**entre **A**dministrator), an Internet tool developed under the Commission's IDA programme. An interest group 'Plant Protection Products' was set up to link the competent authorities in the Member States and the Commission. To date the group has 300 authorised Members and all documents are now distributed in electronic format - saving significant amounts of paper, time and energy.

4.5.2. Pesticide database

Developed under IDA, the Commission established a database to track and record data on the EU evaluation programmes. The database also stores details of the approximately 20,000 harmonised EU MRLs. It also helps the Commission to draw up its annual co-ordinated pesticide residue-monitoring programme. Its design, utility and connectivity with databases in the Member States are still being improved. To date, few Member States have developed a national interface to the database and all Member States still use paper to comply with their reporting requirements under Articles 8 and 12 of the Directive.

4.5.3. CADDY

The average dossier submitted for review in the EU is about 50,000 pages long. This bulk, multiplied by the number of different dossiers received for an individual substance, and multiplied again by the number of copies required for a Community evaluation, represents an enormous logistical problem of storage, archivation, data security and distribution - before the evaluation even starts - not only for the Commission Services but also for competent authorities in the Member States. In

1996, in co-operation with industry, the Commission and the Member States began work on developing an electronic archival version of dossiers. The result was CADDY (**C**omputer **A**ided **D**ossier and **D**ata Suppl**Y**). CADDY can provide, on 3 CD-ROMS, the same dossier of 50,000 pages.

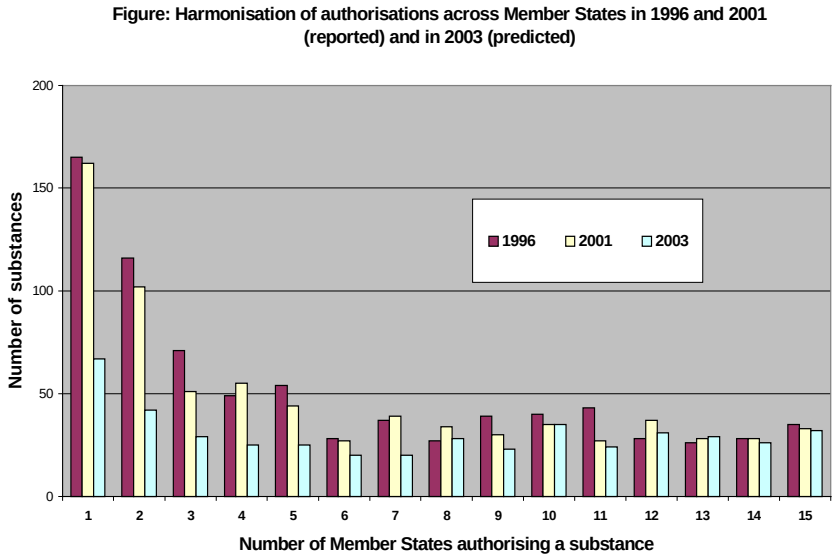

Figure 6: Trend in the evolution of dossiers during last three decades.

Dossiers for new active substances are routinely submitted using the CADDY format. Dossiers for substances on the second, third and fourth lists will also be submitted on CD-ROM. Circulation of documents among all participants in the evaluation process is now predominantly by e-mail and final reports are posted on the EUROPA Internet site. Background documents are now archived on CD-ROM.

Figure 7: Dossier for a new active substance - now available on 3 CD-ROMs (photo courtesy Syngenta).

Care has been taken to ensure that the format used in CADDY is future-proof. CADDY has also provided spin-off benefits for evaluators who can now easily access the information via a central server system in the authorities of the Member States. The contribution to transparency is evident.

4.6. Other measures

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. There are three particular problems not discussed elsewhere in this report that merit special mention.

First: the problem of evaluating 'all' rather than just 'representative' uses. For the first 90 active substances, notifiers were expected to provide information on every possible use. Evaluation of everything proved extremely labour-intensive and time-consuming. Now, as for new active substances, notifiers will have to submit a dossier for an active substance with sufficient data to demonstrate for a limited range of representative uses that they are acceptable. The further uses are then examined at Member State level, after inclusion of the active substance in Annex I, applying the Uniform Principles.

Second: unclear inclusion criteria. No clear criteria were established in the Directive for inclusion of an active substance into Annex I. and evaluations done by Member States were therefore not fully harmonised. To resolve this, a guidance document with criteria for the inclusion of active substances in Annex I has been developed and is almost finalised. This should reduce the need for extended discussions in the working groups of the SCPH.

Third: multiple dossiers. Many different dossiers were submitted for the same substances, unnecessarily multiplying the number of evaluations required. While every effort was made to encourage notifiers to create taskforces and to submit a single dossier per substance, it was not always possible to achieve this. For example, there were 35 notifiers for the active substance glyphosate and 11 dossiers were submitted. This proved wasteful of resources, as the Rapporteur Member State (Germany) had to examine each one. In the event, only four dossiers were considered complete and could be assessed in detail. Ideally, there would have been a single dossier. This would have saved resources both for the various notifiers and for the Rapporteur Member State. It would also have resulted in fewer laboratory animals being sacrificed in duplicated testing. While every effort is still being made to encourage notifiers to create taskforces and to submit a single dossier per substance, it is still not always possible to achieve this. A solution could be to introduce provisions in the legislation to avoid duplicate testing e.g. action point 5F in the White Paper on a Chemicals Strategy[31] proposes that any duplicate testing on vertebrate animals will not result in an exemption from the duty to reimburse the party that owns the property rights to the first test.

Animal testing concerns are just one - important - aspect of the ongoing R&D effort involved in pesticide registration. In fact, the first phase of the review initiated enormous research and development efforts in many fields. These ultimately served to provide a better understanding of hazard and exposure and of their modelling. This in turn is leading to greatly improved overall quality of risk assessment with regard to chemical plant protection. Development of guidance came via a series of workshops and expert meetings - some sponsored by Commission services, some by Member States, some by associations such as SETAC and EPPO - which have not only served as a forum for new science, but have built a community of Member States experts, the necessary basis for any successful pan-European project.

[31] White Paper: Strategy for a future chemicals policy. COM (2001)88 final of 27.2.2001

Thus 10 years of continuous effort has built networks of communication, personal acquaintance and trust. Europe has grown together in a very technical field – that of risk assessment - which remains close to the heart of national regulation and responsibility. It is crucial that a foundation of competence, trust and understanding links the Member States in an area so prone to controversy such as this. The best testimony to the progress made in 10 years is one Member State delegation noting at a recent meeting of the Working Group Evaluation: "We had no time to look at the data in detail but if XXX is acting as a Rapporteur, we know that the evaluation was done correctly. We therefore have no objections to the proposed decision" - a remark unthinkable even two years ago.

Measures will need to be considered regarding mutual recognition which go beyond provisions for minor uses and a guidance document. After a substance is included in Annex I, Member States mutually recognise authorisations of products issued in other Member States. Some Member States view this aspect with concern – and this even if they are permitted to refuse mutual recognition on the basis of their own national assessment using the Uniform Principles.

Experience gained during the reviews so far, the inventory of available opinions from the SCP and precedents from decisions already taken provide the basis on which consensus in these very controversial fields can now finally be built. It took many years to get to this stage; these years have not been wasted. Many hurdles have been overcome, some hidden deep in technical detail, some highly political. Benchmarking with other work sharing and harmonisation projects shows that the progress made is well within the range that can realistically be expected.

5. RELATION TO AND LINKAGES WITH OTHER LEGISLATION AND SECTORS

5.1. The Directives on Maximum Levels of Pesticides Residues (MRLs)

There are four Council Directives under which maximum levels for residues (MRLs) of pesticides in food and agricultural commodities may be set. These are Council Directive 76/895/EEC for some fruit and vegetables, 86/362/EEC for products of animal origin, 86/363/EEC for cereals, and 90/642/EEC for products of plant origin. These directives are independent of Directive 91/414/EEC but are managed by the same Service within the Commission. The Commission has undertaken, in its programme of work for 2001, to bring forward a proposal to consolidate and amend the four directives.

With about 900 new and existing active substances on the market and about 150 food and agricultural commodities, there are theoretically about 135,000 MRLs that need to be set by the Community. The standards for data and decisions are no less rigorous for these than they are for the evaluations of the substances themselves. Wherever possible, the same Rapporteur Member State is nominated under both sets of directives and the 91/414/EEC evaluations are used in the preparation of MRL proposals. In addition, wherever possible, decisions are co-ordinated with a residues MRL proposal following a 91/414/EEC decision. This is not always possible however because requests for changes in MRLs (e.g. new uses of a substances, new concerns etc) arrive continuously and because consumer safety and trade aspects need to be addressed without undue delay.

Full information on residues legislation, the MRLs in force and on the programme of

work on pesticides residues is available on the EUROPA server of the Commission[32]. In addition, annual reports of the Co-ordinated Community monitoring Programmes for pesticides residues in food are produced by the Commission and also posted on the EUROPA server[33]. A report on the operation of the articles in the residues directives that deal with monitoring was submitted by the Commission to the Council and copied to the Parliament in January 2000[34]. Directive 91/414/EC throws up problems in four areas related to the setting of MRLs.

First, it sometimes happens during an evaluation that new toxicological data becomes available showing that the margin of safety in existing MRLs *may* not be as large as would be desired. There then follows a lengthy period during which the data needs to be evaluated and a conclusion drawn at Community level on the validity and implication of the data for the MRLs. During this period there can be uncertainty and unease among regulators about what to do with the existing uses of the substance in question and the MRLs. In all cases to date where this has arisen, there has been no problem for the consumer although the safety margins in the MRLs may have been eroded. The agreed policy is that when problems to the consumer are clear, proportionate but appropriate action is taken in the residues legislation without delay.

Second, evaluations often result in use patterns of substances being changed so that the existing MRLs become inappropriate for the new uses. The fact that there are Community MRLs in force however, prevents Member States from issuing new authorisations for the new uses. The problem was partly foreseen in Article 4(1)f of the Directive and while it works reasonably well to new active substances, there have been problems in applying it for existing active substances. Although the problems with existing active substances have now also largely been resolved, any remaining problems will be also addressed in the forthcoming Commission proposal to consolidate the residues legislation.

Third, scheduling of the programme of work on MRLs is not perfectly co-ordinated with that under the Directive. This is because (i) the residues legislation preceded the Directive and had a separate programme of work, (ii) the long lead time and evaluation time needed for the 90 substances being evaluated under the Directive is incompatible with the need to act quickly to protect consumer safety for all 834 substances on the market, (iii) MRLs need to be changed continually to address cases of concern or new uses of substances. Retaining the management of both sets of legislation within the same service ensures as coherent a co-ordination as is possible.

Fourth, for substances where decisions have been taken not to include them in Annex I, MRLs for their residues in commodities are normally set at the limit of determination in the residues legislation. Conflicts may arise when the substances are still used outside the Community but where the data is lacking to set non-zero MRLs to facilitate imports.

5.2. The Biocidal Products Directive 98/8/EC

Many active substances contained in plant protection products are also used in

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32 http://europa.eu.int/comm/food/fs/ph_ps/pest/index_en.htm

33 http://europa.eu.int/comm/food/fs/inspections/fnaoi/reports/pesticides/mon_rep/index_en.html

34 Report from the Commission to the Council on the application of Article 7 of Council Directive 86/362/EEC and Article 4 of Council Directive 90/642/EEC, concerning the monitoring of pesticide residues. COM (2000) 98 final

biocidal products, e.g. against household pests, in wood conservation, in hygiene products, in paints or as anti-fouling agents on ships. The borderlines between both directives are continually being defined and further clarified in amendments and guidance documents. It is estimated that around 100 active substances will need to be assessed under both directives.

It will be essential to do the review under both directives in a co-ordinated way to (i) make the best uses of available resources and avoid duplication of work wherever possible, (ii) minimise the unnecessary use of animals in testing and (iii) avoid inconsistencies in the result of the review, particularly in the hazard assessment of the active substances.

Whilst it is evident that uses of a substance as a biocide, for example in a home or in empty storage structures, would present a very different risk profile than were it to be used in a plant protection product (for operators, consumers and the environment), the conclusion of the hazard assessment for the same substance under each legislation must be the same.

To avoid such inconsistencies, assessment reports for plant protection products are made available at early stage and the Commission services collaborate closely at the working level. It was further agreed that a dossier for a certain active substance could be used under both directives even though the formatting guidelines are different in principle. It remains to be seen, whether these measures will suffice in practice. A dossier submitted under Directive 91/414/EEC might not be available to a notifier intending to commercialise the same substance as a biocide and the Commission encourages notifiers under both directives to share data wherever possible - minimising duplication and unnecessary use of laboratory animals in testing. Overall workload may lead to difficulty in following up closely enough on ongoing reviews so that minor discrepancies may become apparent only late in the process. Although this potential source of inconsistency will be managed carefully, only practical experience will allow the identification of the need for additional measures.

5.3. Water Legislation

The Water Framework Directive[35] is the central piece of Community legislation for the integrated management of groundwater, surface, transitional and coastal water quality, *inter alia* including provisions for control of pollution by plant protection products. The directive repeals, after certain transitional periods, several existing directives including the Groundwater Directive[36] and the Directive on Discharges of Dangerous Substances[37]. The key provisions with relation to Directive 91/414/EEC are set out in Article 16 for surface and coastal waters and in Article 17 for groundwater. Both articles require the Commission to prepare specific measures against pollution in coming years. Examination of the interactions with Directive 91/414/EEC is based on existing legislation as well as the anticipated specific measures under preparation.

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35 Directive 2000/60/EC of the European Parliament and of the Council of 23.10.2000 establishing a framework for Community action in the field of water policy, OJ N° L 327, 22.12.2000 p. 1

36 Council Directive 80/68/EEC of 17.12.1979 on the protection of groundwater against pollution caused by certain dangerous substances, OJ N° L 20, 26.1.1980 p. 43

37 Council Directive 76/464/EEC of 4.5.1976 on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community, OJ N° L 129, 18.5.1976 p. 23

5.3.1. Groundwater

The safety of plant protection products for groundwater is evaluated to the higher drinking-water standards rather than, as might be expected, according to Council Directive 80/68/EEC on the protection of groundwater. The Uniform Principles (Annex VI) of Directive 91/414/EEC provide that groundwater contamination related to the use of plant protection products must not exceed the standards set on the quality of water intended for human consumption[38]. This standard is currently 0.1 microgram per litre and is used moreover with a model groundwater horizon of only 1 m depth. If consumer protection eventually demands an even stricter limit value, the stricter level would be applied.

Experience shows that abiding by these provisions is quite challenging and has a significant impact on use patterns that may be authorised after Annex I inclusion. Application rates, the range of crops treated and the timing of applications have been modified in many cases to meet these standards. In this respect, groundwater protection is a major determinant not only of the number of substances available but also of the range of uses of individual substances and products which can be authorised.

To check whether an active substance can be used safely, the assessment under the Directive evaluates the 10 standard FOCUS scenarios of soil and climatic conditions, representative for European agriculture. It still remains the responsibility of the Member States to confirm in national authorisations whether this assessment is valid under their respective regional conditions, because the risk to groundwater can vary strongly and it is conceivable that a substance that might pose a risk to groundwater in The Netherlands or Finland may be used safely under soil or climate conditions relevant, say, for Spain or Italy. This may pose a problem for surveillance and enforcement in Member States and it might be suggested that the Community should have similar means to check national enforcement systems as it has in the Food and Veterinary Office (see Section 6.2.10).

Complementary measures for the prevention and control of groundwater pollution will be prepared by the Commission under the Water Framework Directive. The aim of these measures is to achieve the objective of "good groundwater status" and to reverse any sustained upward trend in the concentration of any pollutant - including plant protection products - in order progressively to reduce pollution of groundwater.

5.3.2. Surface, transitional and coastal waters

With regard to surface water, assessment under Directive 91/414/EEC focuses on water bodies found immediately adjacent to treated areas. Contamination of such water bodies due to spray drift, run-off or drainage must not exceed "no effect" concentrations for different trophic levels of aquatic organisms (algae, invertebrates and fish) including certain safety factors; otherwise, authorisations must not be granted.

Risk assessment for the aquatic environment under Directive 91/414/EEC is fairly robust and reliable, though refinements are continuing also in this area, for example

[38] Council Directive 80/778/EEC of 15.7.1980 relating to the quality of water intended for human consumption, OJ N° L 229, 30.8.1980 p. 11 as amended by Council Directive 98/83/EC of 3.11.1998 on the quality of water intended for human consumption, OJ N° L 330, 5.12.1998 p. 32

better to understand potential endocrine effects. Further developments may be necessary to increase the use of monitoring data of waters and to systematically include aspects of risk evaluation for the marine environment.

While the scenario of an adjacent water body represents a worst case, it cannot be excluded that heavy use in a specific region or river basin catchment area might lead to an accumulation of contamination from various sources, which cumulatively may reach unacceptable levels. This may be the case in particular for substances that degrade slowly or for products used several times during one growing season. Furthermore, monitoring data in surface waters suggest that there are other significant sources of plant protection products that cannot be predicted through the above-mentioned models (e.g. non-intentional use, farmyard run-off, rinsing of equipment, disposal of containers and packaging, discharges at production and manufacturing sites).

The Water Framework Directive therefore provides valuable, supplementary tools to address the wider, regional context of the use of plant protection products in areas such as the setting of quality standards for surface, transitional and coastal waters. In particular, integrated and comprehensive monitoring, assessment and management on a river basin level will provide an overview on pressures and impacts on European waters which has not been available until now.

As regards the provisions for specific active substances, Article 16 of the Water Framework Directive requires the establishment of a list of priority substances that are subject to Community measures. The objective of these measures is to aim for a progressive reduction or cessation of all releases of priority substances. Currently, about a third of the 32 priority substances proposed by the Commission[39] are also used as active ingredients in plant protection products. Subject to the adoption of the proposal by the Council and the European Parliament, the Commission will propose specific measures for these priority substances within two years. Furthermore, other pollutants of concern in specific river basins which prevent achieving the objectives of the Directive should be subject to specific measures by Member States based on the "combined approach". The approach integrates measures based on emission control like the application of best available techniques (BAT) and best environmental practice (BEP) with approaches based on environmental quality standards.

For reasons of consistent policy making and communication it is important that both Directives are applied in a co-ordinated way. Therefore water suppliers and river management authorities should be able to feedback their assessment of water quality into the national authorisation process in order to ensure the same level of protection and a consistent application of the measures foreseen under the different directives. To ensure this consistency, the Commission will use the large body of information developed and evaluated under Directive 91/414/EEC for its work on priority and priority hazardous substances under the Water Framework Directive. In addition, the Commission will consider how to use this information for providing guidance for other pollutants (active substances) which in accordance with Article 4, 11 and Annex V of the Water Framework Directive 2000/60/EC are subject to regulation by Member States. The operational aspects of this work are currently being discussed by the services of the Commission.

[39] COM(2000) 47-final of 7.2.2000 as amended by COM(2001)17-final of 16.1.2001

5.4. The Chemicals Directives

Council Directive 67/548/EEC on dangerous substances governs, *inter alia*, the classification and labelling of dangerous "chemical" substances. Its provisions also apply to the active substances of plant protection products. Directive 1999/45/EC on dangerous preparations contains provisions for the classification and labelling of dangerous preparations - including plant protection products. Thus plant protection products are classified and labelled in the same way as any other dangerous preparation. They are a coherent part of the legislative system for the classification and labelling of dangerous substances and preparations.

The objective of classification is to identify the physico-chemical, toxicological and ecotoxicological properties of substances and preparations which may constitute a risk during normal handling and use. It identifies hazardous properties and entails labelling in order to inform and protect the user, the general public and the environment. Directive 91/414/EEC complements the provisions on the classification and labelling of the above-mentioned Directives and considerably improves the protection of users of plant protection products and consumers of plants and plant products. It also contributes to the protection of the environment.

5.5. Endocrine Disruption

In May 2001, the Commission adopted a Communication to Council and Parliament with a Progress Report on the Community Strategy for Endocrine Disrupters [40]. A candidate list of 553 substances was identified for further evaluation of their role in endocrine disruption. To date, evidence of endocrine disruption or potential endocrine disruption has been found for 31 active substances used in plant protection products in the Community. Commission Decisions have already been taken not to include 3 of these (lindane, parathion ethyl and zineb) in Annex I and the remaining 28 are currently under review under the Directive. The Commission and the Member States will take available evidence of endocrine disruption into account during the assessment process and will, where appropriate, request additional data and speed up their assessment under the Directive.

Regulation 451/2000 considerably improved the situation as all substances bound to be withdrawn are identified, notifiers are known for those substances which are intended to remain on the market and, most important in this context, notifiers have expressed their commitment to defend their substances. The Commission is, therefore, now in a position to subject any active substance to a specific data call-in for review of its endocrine potency, should this be necessary.

At OECD, the development of test methods is proceeding. The latest estimates are that agreed test methods for human health will be available in 2002 while tests for environmental effects are expected in the timeframe of 2003-2005. There is unanimous agreement between the Commission and Member States that these revised test guidelines will be applied immediately after their adoption and further studies requested for all substances suspected to be endocrine disrupters. Until this can be done, case-by-case decisions are taken, taking into account the data base available and the degree of concern. The SCP is consulted regularly in such cases. Options available to deal with any remaining uncertainty are a reduced period of

[40] Progress Report to Council on Commission Communication COM (1999) 706: Community strategy for endocrine disrupters.

inclusion in Annex I, enhanced safety factors, further data requirements or the mandatory commitment of the notifier to carry out further tests as soon as agreed guidance becomes available. Discussions are currently ongoing in the Working Group Legislation on whether these options should be laid down and formalised in a strategy paper.

The SCP is consulted regularly in such cases and has, in addition to specific opinions on individual substances, also issued a more general opinion[41] in which it stated that for human concerns (consumer and operator), the database is generally sufficient to detect problems. Of the environment however, the SCP also stated that "although these ecotoxicological tests are the most advanced tests currently available with validated and internationally-harmonised protocols, nevertheless they are not fully satisfactory when endocrine-disrupting chemicals are in question".

5.6. The Rotterdam Convention (PIC)

Voluntary UNEP/FAO arrangements, which are applied on a mandatory basis within the Community under Council Regulation N° 2455/92, provide for an export notification procedure and a prior informed consent (PIC) procedure for exports of dangerous chemicals. These voluntary arrangements have been subsumed into the Rotterdam Convention, the provisions of which are being applied on an interim basis pending entry into force (expected by 2003)[42]. The Commission is expected to put forward legislative proposals later this year enabling the Community to ratify the Convention.

The Convention also provides for an information procedure on chemicals and pesticides that could be used as a complementary early warning for countries exporting commodities to the Community that contain residues of substances where MRLs at the limit of determination are foreseen due to lack of adequate or even absence of data.

In cases where, under Directive 91/414/EEC, negative decisions have been taken on substances based on human or environmental concerns, then such substances become subject to the export notification procedure and are notified to the PIC secretariat for possible inclusion in the PIC procedure. In addition, the review reports for such substances are made available to the PIC secretariat and posted on the EUROPA Internet site of the Commission. Currently 26 pesticides are subject to the international PIC procedure.

Decisions on whether substances withdrawn from the market, either before notification under Regulation 451/2000 or after notification but before an evaluation is complete, should be subject to the above rules and will be made on a case-by-case basis having regard to the underlying reasons for the non-inclusion decision.

5.7. The Stockholm Convention on Persistent Organic Pollutants (POPs)

In the framework of UNEP, negotiations on a global Convention of Persistent Organic Pollutants were successfully completed in December 2000 in Johannesburg. The Convention includes an initial cluster of twelve POPs, including one industrial

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41 Opinion of the SCP on endocrine-disruption relevance in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (opinion expressed on 2.12.1999).

42 http://edexim.ei.jrc.it:8080/

chemical, two by-products (furans and dioxins) and the following pesticides: aldrin, chlordane, DDT, dieldrin, endrin, mirex, heptachlor, toxaphene, and HCB. These POPs are no longer used or produced in the Community. The Convention was formally adopted and signed in May 2001 in Stockholm by the Swedish Presidency and the Commission on behalf of the Community.

The Convention sets out control measures covering the production, import, export, disposal, and use of POPs. In relation to the functioning of Directive 91/414/EEC, it is important to note that each Party that has one or more regulatory and assessments schemes for new pesticides shall take the necessary measures to regulate with the aim of preventing the production and use of new pesticides which exhibit the characteristics of persistent organic pollutants. Furthermore, each Party that has one or more regulatory and assessments schemes for pesticides shall, where appropriate, take into consideration within these schemes the criteria with POPs characteristics of the Convention, when conducting assessments of pesticides currently in use.

The EU clearly qualifies to be obliged to implement these provisions in the framework of the Directive. Therefore, where necessary the Directive will have to be amended in order fully to implement the requirements of the POPs Convention.

6. ACTIVITIES IN INTERNATIONAL FORA

Seven areas are relevant here: the OECD, the World Trade Organisation, the Codex Alimentarius, the ACP-Lomé countries, the Accession countries, EPPO and CIPAC.

6.1. The OECD

The embarking of the Community on a major programme of evaluation at the same time as another in the United States, the other major global player in pesticides evaluation spurred establishment in 1992 of the OECD Pesticides Forum (renamed in 2000 as the Pesticides Working Group) to provide for exchange of views and information.

The situation in the OECD resembles the situation in the Community before adoption of the Directive. The Community has been particularly active, with a long-term objective of achieving better co-ordination at OECD level of evaluation, test protocols and guidelines, better use of new science and common approaches to emerging issues wherever possible, in line with a Community strategy of sharing the work of pesticides evaluation among as wide a range of partners as possible whilst advocating that the same high level of protection be applied in all OECD Member Countries and, ultimately, world-wide.

A major breakthrough in international co-operation was achieved when the Community dossier and data requirements (with minor amendments) were adopted as the agreed OECD dossier in 2000. The approach to develop data requirements further in joint projects within OECD wherever possible has also proven successful and is bearing fruit.

Annexes IIB and IIIB of the Directive, setting data requirements for microorganisms were developed in full collaboration with OECD partners. Also dossier structures and formatting principles of assessment reports from authorities are agreed OECD-wide. A similar approach was taken for pheromones and semiochemicals, i.e. to

define data requirements, dossier structures and principles of assessment in an OECD project. Member States agreed to collaborate under the OECD umbrella and are committed to endorse the result as the Community standard. This project should be concluded in February 2002 and it will be instrumental for several substances currently on the 4th list. These steps will also facilitate worldwide acceptability of dossiers and help to avoid future trade problems.

In addition to these collaborative activities in the development of guidance and data requirements, pilot projects have been started with OECD partners on parallel assessments of active substances. These, and the results of an OECD workshop on worksharing in February 2001 (co-hosted in Brussels by the Commission and the U.S. Environmental Protection Agency), are useful not just in establishing trust and co-operation, but also in highlighting areas where more work need to be done to facilitate, in the longer term, a situation where there would be a single dossier submitted at global level and a single assessment that all interested parties could avail themselves of in decision-making.

At global level, a single dossier system would provide great savings, in terms of animals used in testing and in resources for both regulators and industry. A single evaluation would also improve the global acceptability of regulatory decisions taken and minimise the emergence of trade problems related to plant protection products.

6.2. The World Trade Organisation

The adoption of the Directive preceded the creation of the World Trade Organisation. The subsequent obligation of the Community to notify in advance, all decisions to withdraw substances has added an unforeseen additional delay of up to six months to the decision-making process for individual active substances. As with the OECD, the WTO provides a forum to disseminate EC high levels of protection on a wider scale.

6.3. The Codex Alimentarius Commission

The work of the Codex Alimentarius Commission, and more particularly of the Codex Committee on Pesticide Residues (CCPR) deals with consumer safety. It has an indirect bearing on the evaluation programme - particularly since the WTO recognised that Codex standards shall be the international basis for setting national standards. The Community is not a member of the Codex Alimentarius Commission and this hampers its effectiveness in promoting Community interests therein. The White Paper on Food Safety[43] included - as an action point - a request from the Community for adhesion to the Codex Alimentarius Commission. In April 2001, the Community, in the Codex Committee on General Principles, requested that the Codex procedural manual be amended to facilitate it supplying inputs to the process of decision-making in Codex. The Council is currently discussing whether the Community should apply for Membership. This has a bearing on two levels.

First, the CCPR recognises and uses in its work the toxicological and residue evaluations of the WHO-FAO Joint Meeting on Pesticides Residues (JMPR). The meetings of this group are not open to the Commission and there have been concerns raised not only about the resource-capacity of the JMPR to make evaluations but also the transparency of the process leading to JMPR conclusions. The JMPR sets acceptable daily intakes and fixes acute reference doses for active substances. Due to

[43] White Paper on Food Safety. COM (1999) 719 final of 12.1.2000

differences in the scheduling of evaluations, different methodologies used, and the higher safety standards required by the Community, the JMPR conclusions often differ from those fixed in Community evaluations, where a more up-to-date dossier is used. This has implications for trade.

Second, the Codex does not yet recognise other legitimate factors (such as operator and environmental safety and the efficacy of active substances) when setting its standards. Thus, growers in countries that export their produce to the Community may use pesticides that are banned in the Community. European growers perceive this as placing them at a competitive disadvantage.

These differences may also lead to problems in the setting of MRLs for pesticides residues in food and agricultural commodities at the international level and consequently to trade problems. The Commission is acting to resolve these issues by (i) requesting membership of the Codex Alimentarius Commission, (ii) requesting that WHO-FAO give the Commission access to JMPR meetings, (iii) insisting that higher and more broad-based standards are used at international level, and (iv) requesting that WHO-FAO improve the working procedure of JMPR in particular concerning the selection of experts, the transparency of the process and the acceptance of assessments done on OECD-format dossiers.

6.4. The ACP-EC Partnership Agreement

The ACP-EC Partnership Agreement signed in Cotonou on 23 June 2000, provides that the Community notifies to ACP countries technical measures taken in the area of pesticides when they are likely to affect the interests of one or more ACP States. This is done by the Commission notifying the ACP Secretariat of measures taken. Many of the existing substances being evaluated under the Directive are old, generic and relatively inexpensive and they are often widely used in ACP countries. Negative decisions taken under 91/414/EEC have a potentially significant impact on less-developed countries in that, as a rule, Community MRLs for the pesticides in question would effectively be set at zero (whilst respecting Codex and WTO obligations). This prevents their use on commodities destined for export to the Community. In addition to the impact this would have on these countries, it would also affect consumer choice in the Community by halting the import of a range of tropical fruits and vegetables.

In anticipation of these impacts, the Commission has established two development programmes. The first of these is aimed at promoting Integrated Crop Management in these countries, lessening their dependence on pesticides use and reducing where possible the residue levels found in their commodities. The second, the 'Pesticides Initiative' is aimed at promoting better co-ordination and information gathering in the ACP area with a view to providing, in good time, the data necessary to the Commission to set MRLs for tropical fruit and vegetables. In addition, by putting its completed review reports on the EUROPA server, the Commission provides information to these countries that may be useful to them in their own assessments.

6.5. The Accession countries

In preparation for their eventual accession to the Community, there are intensive contacts between the Commission services and the Accession Countries in this as in all other areas of the *acquis*. In addition, bilateral contacts between these countries

and the Member States were already well established at the opening of the accession negotiations. These contacts had been formed along the traditional historical, cultural or language ties e.g. Greece with Cyprus, Sweden and Finland with the Baltic States. Some of these bilateral ties were formalised in twinning agreements and the specific aims of the twinning were specified e.g. the establishment of residue monitoring laboratories in the Accession Countries. These ties were later exploited by the TAIEX screening programme that the Commission put in place. Currently, contacts between the Accession countries and the Commission Services at the technical level are being intensified and given the highest priority. This is putting the services of the Commission under increasing pressure as other tasks have to be postponed or even cancelled. Analysis of the current situation in these countries and of the plans to put the *acquis* into their national legislation shows that, unlike many other sectors and apart from the general problem of resources, infrastructure and timing, no specific problems related to the plant protection sector exist in this area.

6.6. The European Plant Protection Organisation (EPPO)

EPPO is an intergovernmental regional FAO organisation responsible for international co-operation in plant protection in the European and Mediterranean region. It develops guidelines or protocols in areas such as efficacy evaluation and impact of plant protection products on the environment. The Commission is closely involved in the activities of EPPO and in particular in its Working Party on plant protection products.

In relation to data requirements for registration of plant protection products, EPPO has published over 200 guidelines on efficacy evaluation, which are referred to in Directive 91/414. One of the criteria for authorisation of plant protection products provides that they may not be authorised unless they have been shown to have acceptable efficacy in their stated purpose (control of pests, modification of plant growth) and EPPO is also developing guidelines on this aspect.

The Directive provides that proper use of plant protection products "shall include application of the principles of good plant protection practice, as well as, whenever possible, the principle of integrated pest control". While there are different concepts and definitions of integrated pest control, generally it embraces the compulsory integration of product application with other methods of protection, complex and labour-intensive decision-making systems, and the goal of replacing the use of chemical products by other means. The main purpose of the EPPO recommendations on GPP is to provide guidelines on whether and how to use products and ensure that they are used safely and effectively. Information relevant to the probability of appearance of resistance, and to resistance management forms part of the biological dossier required by the Directive, and EPPO is now developing guidelines on the provision of such information. Resistance management is an integral part of Good Plant Protection Practice (GPP).

A decision-making scheme for environmental risk assessment of plant protection products was developed by a joint Panel of EPPO and the Council of Europe. It provides guidelines on how to assess the potential impact of a particular plant protection product on various different elements of the environment. These guidelines are referred to in the Directive.

6.7. CIPAC (Collaborative International Pesticides Analytical Council)

CIPAC produces analytical methods for pesticides and their impurities as well as physical methods for testing the physical performance of formulations, based on organisation and evaluation of international trials carried out according to ISO and IUPAC guidelines. The Commission Services follow this work closely and accept the agreed methodologies.

7. IMPACTS OF THE PROGRAMME

7.1. Marketing and use of active substances:

7.1.1. The overall level of harmonisation in the sector in relation to substances

Figure 8 shows the development of harmonised authorisation of substances across the Community since 1996. 1996 is chosen as the base year because data are available for the 15 Member States from that time. For the 12 Member States for which earlier information is available, there was no significant change between 1993 and 1996. The Figure includes a projection for 2003 when a significant number of substances will be withdrawn from the market. Analysis of the list of substances in Section 9.3 indicates that the substances withdrawn will mainly be those currently authorised in only one or a few Member States

Figure: Harmonisation of authorisations across Member States in 1996 and 2001 (reported) and in 2003 (predicted)

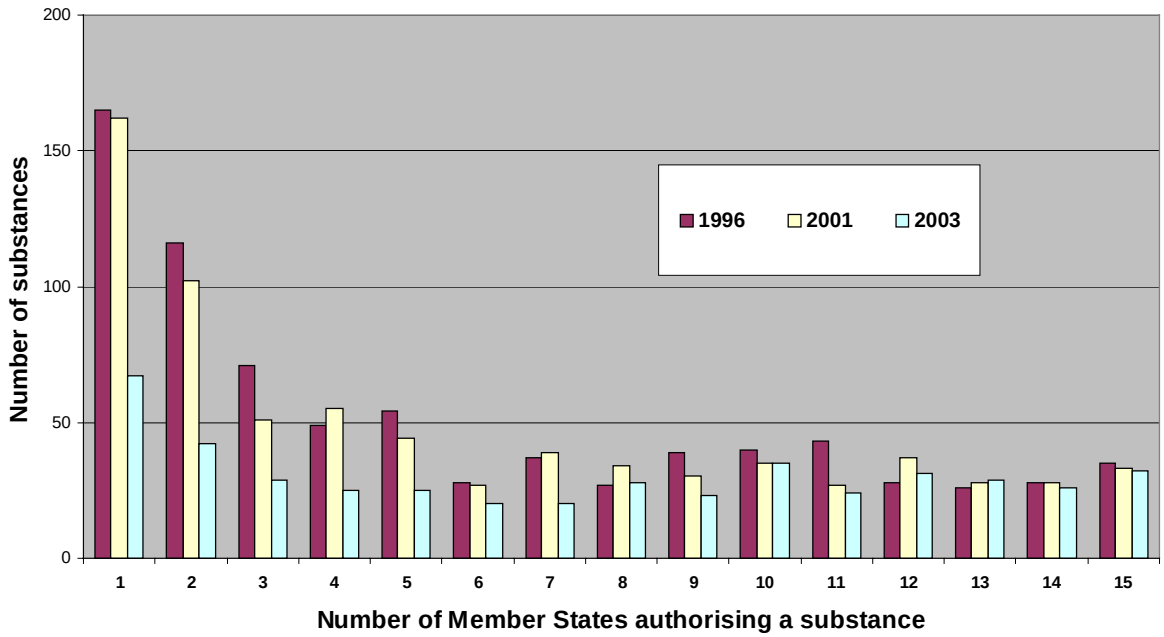

Figure 8: The extent to which existing active substances are authorised in Member States during the period 1996 to the present and an estimate of the numbers that will be authorised in 2003. The data used to construct the graph includes only existing substances. It uses best-case (albeit unrealistic) assumptions that all substances currently being evaluated and all substances notified for the 2nd and 3rd lists and that all currently-authorised substances on the 4th list will either be included in Annex I or still be under evaluation in 2003.

The substances remaining after July 2003 with authorisations in one or two Member States are those on the fourth list of priority substances where a notification procedure has not yet been established. It is expected that the introduction of a notification for the fourth list would change this picture dramatically. With true harmonisation, it is only in exceptional circumstances that a substance would be authorised in just one or two Member States. However, there may be unique environmental, climatic or cultural reasons for such limited authorisations. This should be recognised as a factor mitigating against any eventual lack of support by notifiers for such substances when considering solutions to the problem of essential uses.

7.1.2. The number of active substances available for authorisation

Table 1: The situation predicted for 2003 for the numbers of existing active substances in each phase of the review programme (with approximate share of total market in 1993). The table also indicates the anticipated review status of the substances in each phase. For the sake of completeness, information on new active substances is also included in the table as well as a projection of the totals involved.

Phase	Total N° of substances	Being examined (2003)	To be examined	(To be) withdrawn	In Annex I by 2003
First[a]	**90**	**0**	**0**	**36**	**54**
Second[b]	**149**	**55**	**0**	**94**	**0**
Third[c]	**402**	**150**	**0**	**252**	**0**
Fourth[d]	**193**	**0**	**69**	**124**	**0**
Subtotal[e]	**834**	**205**	**69**	**506**	**54**
NEW[f]	**104**	**30**	**0**	**4**	**70**
TOTAL	**939**	**235**	**69**	**510**	**124**

a Assumes that of the remaining 63 substances, 43 have demonstrated safe uses.
b Assumes that complete dossiers are received for 55 of the 60 notified substances.
c Assumes that of the 167 substances notified, 4 notifications would be invalid and that in May 2003, 13 of the 163 data packages will be incomplete.
d Assumes that after a notification procedure, substances with authorisations in only one or two Member States will not be notified - mainly for economic reasons.
e Figures do not take into account the possible application of temporary remedial measures for essential uses
f Assumes that, with new procedures in place in 2001, decision-making will accelerate.

Figure 10 is based on the numbers of substances authorised in the Member States during the period 1996 to the present. As with the Figure 8, 1996 is chosen as the base year because data are available for the 15 Member States during that time and, for the 12 Member States for which earlier information is available, there is no significant change between 1993 and 1996. The figure also includes a projection for 2003 when a significant number of substances will be withdrawn from the market. It does not reflect the number of different uses that a substance may have in a Member State and it does not indicate the tonnage used. This information is not available to the Commission. It can be seen that, although Member States may have changed their portfolio of substances used (e.g. replacing a substance with a less hazardous alternative), they have not significantly changed the size of that portfolio.

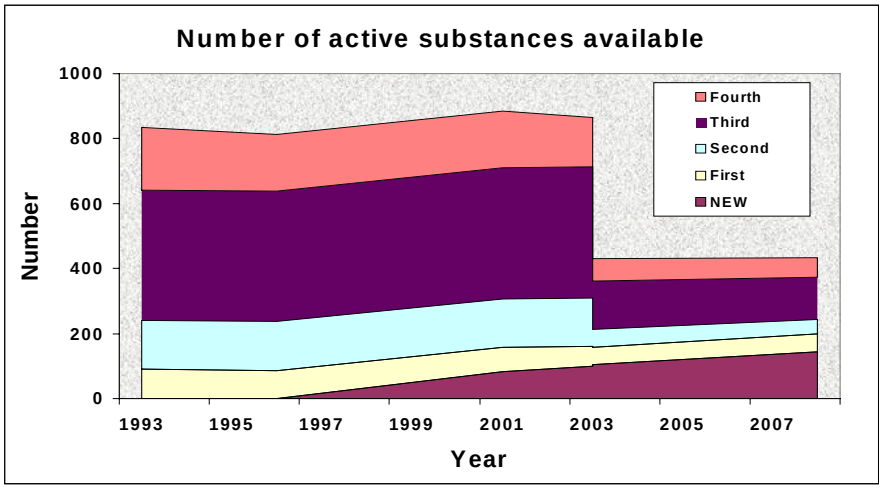

Figure 9: Estimates of the total number of substances available for authorisations during the period 1993-2008. The numbers include new active substances.

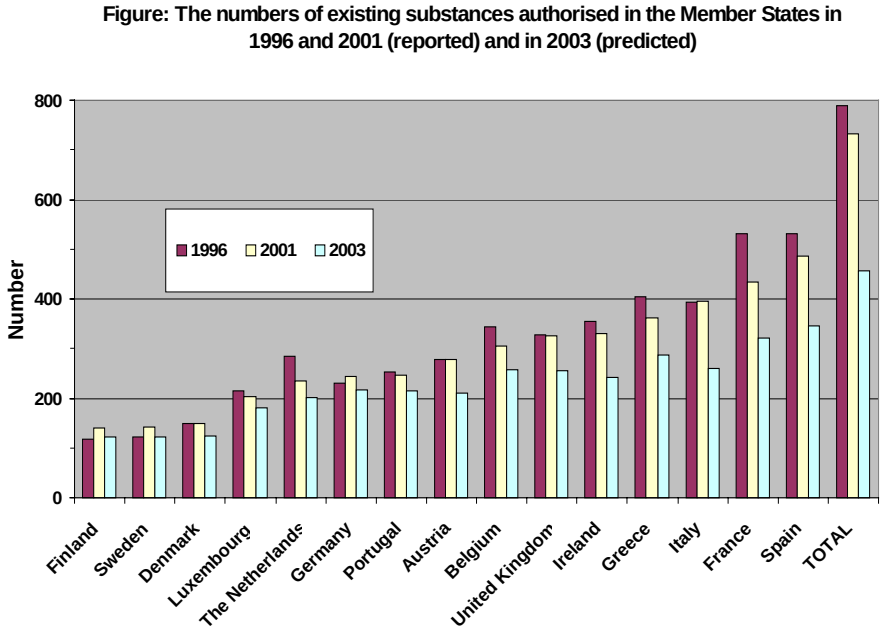

Figure 10: The numbers of existing active substances authorised in each Member State during the period 1996 to the present and an estimate of the numbers authorised in 2003. The data used to construct the graph includes only existing substances. It uses best-case (albeit unrealistic) assumptions that all substances currently being evaluated and all substances notified for the 2nd and 3rd lists and all currently-authorised substances on the 4th list will be either included in Annex I or still be under evaluation in 2003.

It can also be surmised that, after July 2003 and based on current use patterns, it will be the southern Member States that will bear the brunt of the reduction in the number of available substances. This will not be because such Member States 'over-use' active substances. It is more due to their greater variety of both crops and pests, their specialisation in fresh produce, their longer distribution chains and their climate, potentially compounding the difficulties these Member States may face. Ironically, they tend to under-perform in the area of pesticide registration. They will need to be

more pro-active in preparing for the loss of substances due in 2003. This could be done by promoting outreach services and alternative methodologies, inter alia emphasising to growers that even in those cases in which the Commission itself decides to grant derogations, it will not necessarily be the case that the growers' principal customers - the major retail distributors in Northern Europe - will do so when they detail their produce-specifications.

7.1.3. The quantities of substances used

Industry has reported that the substances already withdrawn from the market have not been widely used in the Community and that the decisions of producers of plant protection products not to support substances are based mainly on commercial grounds. That is, according to the industry, almost all the substances to be withdrawn in 2003 are minor components of the plant protection products market. There is little data available on the actual quantities of individual substances used in the Community. Such data is considered commercially sensitive by industry.

Table 2: Consumption of fungicides, herbicides and insecticides in plant protection in agriculture in Member States in 1996 (tonnes of ingredient; Source: EUROSTAT).

	Fungicides	Herbicides	Insecticides	Total	%
Total for 15 MS	**148.9**	**86.0**	**14.7**	**249.6**	**100**
France	53.2	34.6	3.4	91.2	36.5
Italy	44.1	7.3	5.8	57.2	22.9
Germany	8.4	18.3	0.4	27.1	10.8
Spain	16.4	6.8	3.5	26.7	10.7
United Kingdom	4.3	7.4	0.3	11.9	4.8
Greece	8.7	1.1	0.5	10.4	4.2
Portugal	7.3	2.5	0.2	10.1	4.0
The Netherlands	2.1	1.9	0.3	4.3	1.7
Belgium/Luxembourg	1.3	1.8	0.2	3.3	1.3
Denmark	1.3	1.9	0.1	3.3	1.3
Austria	1.2	1.1	0.0	2.3	0.9
Sweden	0.3	0.7	0.0	0.9	0.4
Ireland	0.2	0.3	0.0	0.5	0.2
Finland	0.0	0.5	0.0	0.5	0.2

EUROSTAT has reported[44] on patterns and trends of use of plant protection products in the Community during the years 1992-1996. The data used relates to herbicides, fungicides and insecticides (about 420 substances in total) in agriculture. It thus does not relate to all 835 active substances and does not cover uses on grassland, forestry, recreational and other uses of plant protection products. As can be seen in the Table, France and Italy accounted for about 60% of all uses of fungicides, herbicides and insecticides in agriculture in 1996. Fungicides are the major class used accounting for 60% of use by volume in 1996, with herbicides accounting for 34% and

[44] Plant Protection in the EU - consumption of plant protection products in the European Union - Data 1992-1996. ISBN 92-894-0437-X, Eurostat, Luxembourg 2000.

insecticides 6%. More than 90% of the fungicides are used on grapes.

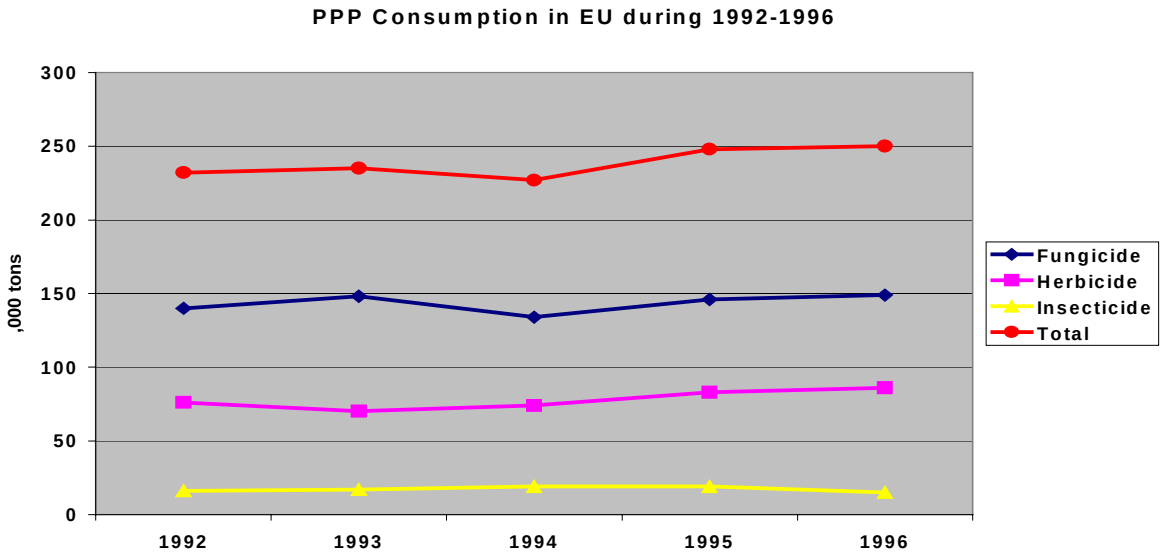

Figure 11: Trend in plant protection consumption, for the EU, during the period 1992-1996 (Source EUROSTAT).

There is no trend in the consumption of plant protection products during 1992-1996 and, from the very gradual progress in the implementation of the Directive during that time, one would not expect to see one.

7.1.4. Harmonisation of methods and processes

As outlined in general terms and exemplified in Sections 3.2 and 3.6, a significant number of projects were initiated to harmonise review practices and agree on uniform decision-making criteria and the trigger values to be applied. A list of all guidance documents developed and in progress, as well as projects in planning is given in Section 9.2. The library of guidance documents available today was not developed easily. Long years of discussions, precedents developed by individual case-decisions and opinions of the Scientific Committees were necessary to reach this common ground. Neither should the informal aspects be underestimated. Experts from 15 national authorities, all backed up by their own national organisations, had to learn to work together, trust each others judgements and, not least, to convince their own hierarchies at home.

This process is far from complete. However, agreed guidance already available will greatly facilitate the review of the second and future lists. Notifiers now know on which basis information has to be provided and which triggers will be applied to request additional, higher tier data. This, in turn, allows legislators to make much tighter provisions on how to deal with incomplete dossiers. Furthermore, those reviewing these dossiers use agreed standards to evaluate the information submitted, thus avoiding piecemeal evaluations and hence many of the subsequent cumbersome discussions encountered in the first phase.

7.2. Consumers

7.2.1. Consumer safety

With so few Annex I inclusions, decisions taken under the Directive have yet to

impact on consumer safety. It is mainly through the residues directives that food safety is ensured and here a significant contribution is being made. Advantages deriving from the Directive include guarantees that the fullest information possible is available for the setting of MRLs after decisions under 91/414/EC, and availability of the expertise and experience necessary to take informed decisions under that legislation. None of the decisions taken to date to exclude substances from Annex I have been taken for consumer-related reasons - environmental and operator concerns are the usual motives. Although long term the withdrawal of all unsatisfactory substances from the market will improve the consumer safety of produce produced in the Community, the safety of imported products will have to be guaranteed under the residues legislation - whilst respecting WTO obligations.

The residues directives impose a duty on the Member States to monitor pesticides residues in food and agricultural commodities. Since 1996 there has been an annual co-ordinated Community monitoring programme for pesticides residues in fruit and vegetables. This is complemented by the development and validation of a number of normalised/standardised analytical control methods under research contracts supported within the fourth Framework Programme[45]. The results of these annual programmes are routinely posted on the EUROPA Internet site[46]. They show that about 40% of all samples contain no detectable residues and that in only about 3% of samples is there an excedence of the MRL. Assessments of the excedences show that they are mainly technical and in no cases were consumers at risk. This rate is similar to that reported in the monitoring programmes of countries outside the Community and it is about what one would expect anyway, given the statistical methods used in setting MRLs in the first place.

Flanking the national monitoring programmes, the Community Rapid Alert System for Food also provides a mechanism for Member States and the Commission to report rapidly on problems in the area of food safety. Although the number of alerts has increased dramatically in recent years, the increase has been seen in all areas of food safety and is probably due to better use of the system by participants rather than systematic deterioration in food safety across the Community.

In any case, pesticides safety needs to be put in perspective. There is little evidence, in any developed country, of any acute toxicity problems related to the intake of pesticides residues in the diet and the results of the co-ordinated Community monitoring programmes since 1996 do not give any cause for concern. The generally beneficial impact of pesticide use on human health - in terms of better diet, higher standards of food conservation, marked reduction in risk from mycotoxins - is unarguable. Nonetheless, there is some concern about possible longer-term effects arising from the intake of pesticides residues in the diet and this is being investigated.

7.2.2. Quality, choice and price of produce

The impact on choice relates to the availability, quality and prices of fruit and vegetables. If the Directive were to be applied to all substances without consideration of the time needed to produce data, then many crops would no longer be available to consumers, in the first instance in local markets but in the longer term on

[45] SMT4-CT95-2030 on CEN-multi-residue methods, SMT4-CT96-2046 on multi-residue methods for dry & dried foods using SFE-GC, and FAIR-CT96-1181 on rapid immunochemical screening test methods

[46] http://europa.eu.int/comm/food/fs/inspections/fnaoi/reports/pesticides/mon_rep/index_en.html

supermarket shelves. A pragmatic approach is necessary, giving interested parties the time needed to generate data showing that substances are safe under the legislation. The higher costs that notifiers incur to provide the data will be recouped eventually either from growers or consumers. Those consumers who can afford it have already demonstrated that they are willing to pay for higher quality food and to go back to respecting seasonal variations in availability. This qualitative shift in attitudes to food – from fuel to nutrition and now on to life-style choice - is part of a long-term trend towards consumer awareness and healthier living.

7.3. Environment

Directive 91/414/EEC is having a significant influence on overall use and consequently on the scale of emission of plant protection products into the environment. All products insufficiently documented to give full evidence of their safety are being withdrawn from the market, as are all uses of remaining substances that do not meet the standards of the Uniform Principles with regard to the protection of the environment. Even when substances are included in Annex I, they are often subject to restrictions e.g. certain uses withdrawn, reduced application rates, ban on aerial spraying, obligatory use of buffer zones near waterways. It is difficult to quantify the impacts of such measures on the environment, but it is clearly an improvement on before.

Plant protection products may contaminate groundwater, soil, and even the air. The risk to environment consists in the adverse effects on non-target species. Spray drift, leaching or run-off are the main ways of uncontrolled dissemination in the environment. Effects can be either acute or chronic. Contamination of groundwater is of particular concern as, on average, 65 % of European drinking water is supplied from this resource. Even after remedial action has been taken to prevent further contamination, groundwater often takes many years to recover to acceptable quality levels. Optimisation and evaluation of multi-residue methods for priority plant protection products in drinking and related waters was supported by a research contract under the Fourth Framework Programme[47].

To date, only 16 non-inclusion decisions have been taken at Community level. Compared to the 834 substances on the market in 1993, the programme may, at first sight, appear to have had muted impact on the environment in terms of reduction of pollution due to plant protection products. In fact, the full benefit of the Directive will only come through when only those active substances for which safe use has been demonstrated remain on the market and all uses of plant protection products containing them have been evaluated according to the rigorous standards of the Uniform Principles in Annex VI of the Directive.

7.4. Operators/users

There is no European-wide inventory of accidents and occupational problems related to the use of plant protection products. National reporting schemes are in place but no attempt has yet been made to harmonise formats and criteria, nor to feed the information into a European database. The Commission recognises the utility of such a system but cannot accord it high priority at this time. In this, it finds itself allied with a sizeable majority of the Member States. Overall, the level of protection for operators is high in all Member States and the assessment scheme applied under the

[47] SMT4-CT96-2142

Directive ensures that standards are maintained. Literature surveys show that, overall, the occupational situation in European crop protection indicates no reason for fundamental changes in policy. The Commission acknowledges however that higher standards may be applied in the Member States.

Furthermore, at the adoption of the Uniform Principles by Council in 1997, the Council and Commission agreed to the following declaration: "The Council and the Commission note that application of this Directive is without prejudice to the legislation in force concerning the protection of workers. The Council and the Commission state that this principle will be unequivocally clarified in Directive 91/414/EEC on the occasion of the first amendment of that Directive."

To enhance the confidence in the risk assessments and models used, and to benchmark the progress made, better data on actual use of products is urgently needed. Extensive collection of use-data has been undertaken for many years in the United Kingdom. Some Member States, e.g. The Netherlands, also have surveys, but others do not. Information on actual use is mainly derived from sales data from industry, reported either under voluntary agreements or mandatory reporting schemes (e.g. in Germany). However, surveys based on sales data have major flaws and cannot provide a sufficient basis for sound assessment of the real exposure situation.

Several years ago, EUROSTAT initiated a pilot project (TAPAS) to standardise and collect information on the use of plant protection products in the Member States. National schemes are still far from compatible, however, and it will take several years until really useful pan-European data becomes available.

7.5. Industry

A major advantage of the programme for individual companies in this sector is that instead of 15 evaluation procedures, authorisation systems and decisions in the Community, there is now just one. With the acceptance of the EU dossier format in OECD, the advantages of this should become even more evident. There is, however, little evidence that industry groupings take advantage of this when considering the establishment of taskforces to defend individual substances (see e.g. Section 3.6.6).

The industry producing plant protection products in Europe has changed radically since the inception of the legislation. As noted, 15 years passed between first proposal and adoption; a further two years before implementation. Industry was therefore fully aware of the increased regulatory demands it was to face as a result of the review programme. In fact, to date, the EU review programme has had no appreciable impact on market size. So far, there have been relatively few non-inclusion decisions and, as already noted, these concern active substances which for various reasons were not widely used. This picture is expected to change, particularly with the forthcoming non-inclusion of several hundred active substances which industry has elected not to defend.

The programme has had a big impact on registration costs to industry. An industry survey[48] in 2000 showed that the average cost to update the dossier for an existing active substance is Euro 3.7 million. On completion, the entire programme is estimated to have cost about Euro 700 million. National reviews in Member States pending completion of EU reviews have added another Euro 131 million to this

[48] Survey conducted by Wood Mackenzie Global Consultants; information provided by ECPA.

figure. Such expenditures affect profitability. However, they should be seen against a background of sales (in 1999) in the Community of 6,175 million Euro[49].

Meanwhile, since 1993, there has been a gradual move by the whole sector away from the marketing of specific plant protection products towards targeted use of products for specific applications in agriculture. This may be seen as a first indication of an industry shift toward crop protection service provision in partnership with downstream links in the food chain, along with the significantly increased product stewardship obligations this implies, rather than the past practice of mere development and sale of products.

7.5.1. Major producers

Coinciding with a prolonged downturn in market conditions and poor stock market performance, competitiveness has become a critical issue for some companies, reflected in the growing number of mergers and acquisitions in the sector. At a time of merger-driven internal cost cutting, regulatory costs have absorbed more financial and human resources than managements intended.

Industry decisions whether or not to defend existing products are almost entirely based on commercial considerations, concentrating resources on the most promising products in terms of return on investment and market. Regulation 451/2000 obliges industry to prioritise its defence of substances for at least three reasons. First, for many substances, it is not economic to produce the dossier to defend the substance. Second, the information required is extensive and, with the downsizing characteristic of an M&A phase in the business cycle, firms lack the personnel to cope with defending a large number of substances at once. Third, there is limited laboratory capacity.

Among the majors, stagnant or shrinking markets, the inflation of developmental costs and increased regulatory scrutiny has led to consolidation. Concentration of high-cost R&D based industry operating exclusive marketing systems erects a near insuperable barrier to new entrants wishing to join the league of top players and generates real concern in terms of both competition policy and the simple availability of products. Pesticides protect crops and play a significant role in safeguarding farm incomes and food supply, but the importance of this societal role does not necessarily coincide with the commercial reality governing the sector.

A lack of suitable tools has been identified for minor crops such as vegetables, hops or certain fruit, which although small markets, are the major source of income for many farming communities. After 2003, this problem could be exacerbated. Traditionally, smaller producers of off-patent generic products covered these, selling older active substances. For these enterprises, regulatory costs may also be prohibitive in many cases. This can be true even for active substances already in Annex I, as the required residue information and the Annex III data package alone is already costly enough to make certain applications uneconomic for some notifiers. Member States have started initiatives to share residue or efficacy data with the goals of lowering financial burdens and of encouraging applications for minor crops. More needs to be done both nationally and regionally.

[49] ECPA Annual Report 1999-2000.

7.5.2. SMEs

The contribution of the Directive to those market forces already leading to consolidation and concentration of the sector is to a large extent at the expense of SMEs. For new active substances, the high standards set by the Directive imply research, developmental and regulatory costs exceeding 100 Mio EUROS per substance and roughly the same sum must be calculated to cover research on unsuccessful candidate substances, developmental costs for pilot and large-scale production and for registration. SMEs cannot compete here and new substances can only be developed by major enterprises aiming for global markets.

The major impact on SMEs is, however, related to the non-inclusion of existing active substances no longer being supported by the main notifiers. Even if SMEs might be interested to defend such a substance and to step into the process in lieu of a main notifier, they lack the resources to cope with the many demands involved and they may not be in physical possession of an acceptable dossier. Consequently, a wave of mergers is underway also among generic producers, leading to the consolidation of this sector. Again, 2003 will be a watershed. The Commission has no means to quantify the number of SMEs operating in the sector of crop protection.

Counter-balancing these losses in the industry sector is the emergence of a host of new niche companies developing environmentally-friendly alternative methods of plant protection e.g. beneficial pest-eating insects and microbials. These are almost always SMEs adopting innovatory approaches to existing problems. Nurturing their continued development by not imposing impossible regulatory hurdles in their path, whilst guaranteeing health and environmental safety and effective crop protection, will be a big challenge in future.

7.6. Trade

There is little or no evidence of any impact of the programme on trade in the products containing the active substances. No reactions have been received from the wider international community in response to the TBT (Technical Barriers to Trade) notifications made by the Commission in the WTO for substances for which decisions have been taken to withdraw them from the market. There may be some impact in the future, as a result of notifications made under the PIC procedure (see Section 4.4.6) for substances withdrawn on the grounds of human or environmental health concern. Although such impact would, in first instance, be on the trade in the substances themselves, this may also extend to trade in commodities containing their residues.

7.7. Agriculture and its competitiveness

Unsurprisingly, the Directive will have an impact on agriculture and this was appreciated at its adoption. As noted, the Directive provided that the provisions for authorisation of plant protection products must ensure a high standard of protection of human and animal health and of the environment and that such protection should take priority over the objective of improving plant production. The number of active substances available to growers will be reduced from 2003 for several reasons:

- many active substances fail to satisfy the high safety requirements of the Directive,

- following recent restructuring of the agrochemical sector, it is no longer physically or economically feasible for industry to defend all substances on the market,
- industry will focus its resources on defending profitable substances that are normally used on major crops and for which there is a big market.

With the loss of so many substances, availability of pesticides for effective pest resistance management may become problematic. Furthermore, whilst the original directive provides for flexibility for minor crops, the loss of so many pesticides may have a negative impact on the ability to extrapolate from major to minor crops. This would have an negative impact particularly for the southern part of the Community, where currently a very large number of active substances are still used on a wide variety of minor crops. It is still to be seen whether enough new substances compensate for this loss. The low number of new insecticides being introduced, for example, may be a cause of concern if the review programme results in large numbers of existing insecticides being withdrawn. Again, this will have a greater impact on the agriculture of the southern Member States where pest pressure on crops is much heavier than in the North. Since older generic substances are generally cheaper than the newer proprietary active substances, enforced substitution may raise costs for growers and these will probably be passed on to consumers.

The problem of a reduced number of substances after 2003 was raised by Member States in the November 2000 Agriculture Council; it was only at that time that the Commission and the Member States learned of the numbers of substances destined to disappear in 2003. Article 15 of Regulation 451/2000 envisages that, if necessary and on a case-by-case basis, the Commission can take temporary measures for essential uses. Procedures and criteria are still being developed and are not yet agreed. This matter will be further examined once it becomes clear how significant the problem is. Corrective measures going beyond July 2003 could be taken on the basis of the conclusions of this report in order to avoid the sort of problems the Community is experiencing in the area of veterinary pharmaceuticals.

7.8. National programmes in the Member States

In the past, Member States had their own re-evaluation programmes which they operated more or less independently. Most Member States have not continued their national programmes: the burden involved in running both a national and an EU-evaluation programme is just too high and might also lead to further disharmonisation. However, due to the fact that the re-evaluation of existing active substances has proceeded more slowly than anticipated, certain Member States have maintained national programmes. An additional benefit of the programme has been a vast improvement in the level of communication and cooperation in this sector among the Member States themselves.

The Directive provides that, as long as no decision is taken at EU-level, Member States can continue to apply their national data requirements existing before the Directive came into force. The criteria they have to apply are contained in Article 4 of the Directive, which means that differences in approach between Member States are possible. Some Member States have already imposed the data requirements of the Directive and the Uniform Principles; others wait before applying them until the active substance has been evaluated at Community level and a decision taken on Annex I inclusion. The discordance in the timing of application of the Uniform Principles has led to frequent complaints that there is distortion in market conditions

for substances not yet evaluated at Community level. This is a valid argument but one quite outside the control of the Commission. It has to be assumed that Member States evaluate the impact of their measures before they are enacted.

7.9. International programmes and national programmes outside the Community

The contribution of the European Community to the OECD programme of work is referred to in Section 4.5.1. From the exchanges of views within meetings of that programme, it is clear that the Community and the United States are the two major evaluators of existing active substances at global level. The fact that data requirements are now largely harmonised, and that both parties have completed a significant amount of evaluations, is driving the programming of evaluations of active substances in many other countries. The Community makes its review reports available on the EUROPA server but to date, has had little benefit from the completed review reports of other OECD countries. The future programming of the EC review continues to have an impact on the future planning of reviews in other countries, as well as in the Codex Committee on Pesticides Residues.

8. NEED TO MODIFY 91/414/EEC

Based on experience of the first phase and to take account of developments in related areas, several amendments to the Directive are desirable. Others are necessary. Several can and will be done using the regulatory committee procedure (Article 19 of the Directive); others will need to be adopted using co-decision. Based on identified needs as well as reaction to this report, the Commission will commence work on an amendment proposal during 2002 to address, *inter alia*, the following issues:

8.1. Operator safety

As noted in Section 5.4, at the adoption of the Uniform Principles in 1997, the Council and Commission declared: "The Council and the Commission note that application of this Directive is without prejudice to the legislation in force concerning the protection of workers. The Council and the Commission state that this principle will be unequivocally clarified in Directive 91/414/EEC on the occasion of the first amendment of that Directive". This commitment will be maintained.

8.2. Article 2: definitions and borderlines with Biocides Directive

Revision of Article 2 needs to be undertaken to clarify the borderlines with the Biocides Directive along the lines agreed between the Commission Services[50] and the competent authorities in the Member States taking into account decisions taken in other borderline cases[51]. It may also be desirable to amend the scope of the Directive along the lines provided for in Articles 29 and Annex V of the Biocides directive. Should this prove to be the case, a new notification procedure, possibly coordinated with one for the Biocides directive, might be necessary.

8.3. Fees

Regulation 451/2000 provides a harmonised basis for the charging of fees by the

[50] Document Biocides/82/01
[51] Document 6621/VI/99 rev. 8

Member States to evaluate substances on the second, and third lists. There is, however, no harmonisation of cost-recovery for substances on the first list, nor for new active substances. In no case is it possible for the Commission to recover costs. A coherent approach is necessary allowing Member States to recover from industry all costs associated with the evaluation of active substances rather than just for those where they act as a Rapporteur. It may also be desirable to build into such a system a provision for cross-subsidisation to encourage extensions of uses for minor crops or the development of safer small-niche alternatives e.g. biologicals.

8.4. Extension of scope

A possible amendment to cover other technical points and extension of the scope to include adjuvants and co-formulants was discussed with Member States but, in view of other commitments and limited resources, such an extension has not been regarded as a priority. It can be discussed again in the future with a view also to decide on whether safeners and synergists should be included in the scope of the Directive. The issue will be regarded in the context of the follow-up of the White Paper on Chemicals.

8.5. Genetically modified micro-organisms (GMMs) and low-risk substances

A possible amendment to cover the use of GMMs and to introduce a "fast track" procedure for "low risk plant protection products" is currently being discussed.

8.6. Adaptation of other Annexes

Amendments to adapt Annex II and III, as well as the decision-making criteria of Annex VI to technical and scientific progress in the field of ecotoxicology, in particular with regard to non-target arthropods is seen as desirable. In addition, data requirements for the categories on the fourth list need to be agreed. Criteria in relation to air and to non-target plants will be included in the data requirements after their finalisation by EPPO. Annexes IV and V will be completed during 2001-2002.

8.7. Data protection and data access

The current rules are very complicated to apply for Member States and are also contested by industry. An intra-industry attempt to reach agreement between the two main industry groupings on developing a single industry position was unsuccessful after several years of negotiation. It is uncertain whether a better agreement can be found however. An improvement in their application should also be linked to better use of the Pesticides Information Database. Although this in itself would require more resources, it would also improve mutual recognition and parallel import arrangements.

Related to this issue is that of data access. New information technologies are enabling more and more information to be made available but the timing of availability is sometimes contested. Apart from logistics and resource issues, there are legitimate concerns that premature release of information such as draft conclusions could lead to competition problems as well as perhaps unnecessarily alarming uninformed parties. Article 19 of the Biocides directive could be used as a basis for any changes and provisions should be made to allow rules on data access to be fixed using the comitology procedure.

8.8. Parallel import

Parallel import is mainly regulated along the lines applying to pharmaceuticals and on the basis of cases brought before the European Court of Justice. Although this issue is currently addressed in a guidance document, there are good grounds for the argument that the Directive should be amended to clarify the rules on parallel imports.

8.9. Monitoring and control measures

A significant proportion of the substances included in Annex I have restrictions on previously authorised uses imposed as a condition for inclusion. In addition, several hundred substances are to exit the market. In both circumstances, there will be strong temptation for continued and thenceforth unauthorised uses. In a parallel case, one consequence of withdrawing a large number of veterinary drugs from the market was an increase in 'off-label' uses and illegal imports. Monitoring and control measures need to be introduced to the Directive to ensure compliance with its application; these will in turn require further research targeting suitable measurement systems.

8.10. Comitology

Amendments to update comitology are necessary in view of the proposed inter-institutional working procedures and the proposal for a single food committee made in the context of the Commission's proposal for a Regulation of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food. There is also a strong argument for the case that updating the Uniform Principles should be brought within the scope of the comitology procedure.

8.11. Comparative assessments and the substitution principle

The idea that plant protection products may not be authorised if there are safer alternatives (substances and/or methodologies) available is an attractive one that merits elaboration. The approach is already enshrined in the Biocides legislation. Although partially already e.g. in integrated crop management programmes and in organic farming it may be possible, based on the experiences with biocides, to implement it more fully and in a more structured way in future.

8.12. Corrective measures for Essential uses

The potential impact of a significantly reduced number of available substances to agriculture is described in Section 7. Regulation 451/2000 provides for the eventuality that, if necessary, and on a case by case basis, the Commission may take appropriate temporary measures for uses for which additional technical evidence has been provided demonstrating (i) the essential need for further use of the active substance and (ii) that there is no efficient alternative. The Commission will be very sparing in granting such derogations, which may only be granted based on the conclusions of this report. Although the procedures and criteria are not yet agreed, a general scenario can be sketched out.

The Commission informed Member States in October 2000 of the active substances that will be defended in the second phase. Member States have known since December 2000 which substances will be defended in the third. It is only in the last

few months that the number of substances that will not be defended, and what those substances are, has been known. Full dossiers need to be prepared before 2003 to support substances deemed 'essential'. Member States are currently consulting at national level with farmers and relevant official services and compiling lists of uses for which no efficient protection would be available. These will be examined critically, using agreed criteria, to check that the claims are valid. It is proposed that Member States submit, with their list of essential uses, sufficient technical information demonstrating the essential need for an active substance. The additional technical evidence required includes:

- need for the active substance in resistance management,
- inclusion of the active substance in an integrated pest management programme,
- importance of the crop, and importance of the use of the product,
- economic loss when not using the product,
- a plan for the development of alternatives, identifying who will take what actions when and in what areas, including a time frame within which other solutions would be available and any restrictions imposed on the uses of products to stimulate the development of alternatives,
- information on the alternative solutions looked for (e.g. if an active substance is already used in another crop), research programmes and financial support,
- any health or environmental effects arising out of continued of the active substance.

Where an essential need has been identified, other elements then to be taken into account before considering a derogation are:

- the extent of the area on which a substance would still be used,
- risk mitigation measures,
- timing and method of application,
- level of residues in food crops.

More detailed solutions will be discussed once it becomes clear quite how important the problem is, adopting a case-by-case basis. Co-operation between Member States should be improved and projects and concerted actions in the framework of Community research programmes considered.

The problem is exacerbated by the fact that some Member States do not seem to know exactly what authorisations exist, nor for what crops, in their own territory. Many minor uses are conventionally not obliged to have specific authorisations (off-label uses) and are employed by farmers on the basis of experience and extrapolation at the farm level. It is the view of the Commission that this practice does not justify continued non-authorised and non-evaluated use of pesticides and that these should be subject to withdrawal. It does however complicate the task of the Member States in assessing impacts and in looking for alternatives. It is already clear that Member States need to be taking measures already to deal with the pressures that growers will face after July 2003. It is also clear that financial resources have to be mobilised as of now to prepare solutions to the problem, and outreach efforts intensified targeting the farming community in order to heighten awareness of the need to abandon practices that have hitherto been condoned.

Furthermore, any continued use can only be accepted provided that the criteria of Article 4 of the Directive concerning the protection of human health and the environment are satisfied, based on a more reduced data package. Substances with

particular concerns will not be included. The deadline for continued use should be set at 2007 at the latest (six years hence), as four years are needed to develop the necessary efficacy and residue data for alternatives.

8.13. Corrective measures for minor uses

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, COPA and the plant protection industry (see Section 9.2). Member States are invited to define at national level minor uses and minor crops (except for the residue aspect, which is decided at EU-level) and to apply the system proposed in the guidance document in order to facilitate authorisations for minor uses. The zoning project in OECD is one solution to facilitate the provision of data for these uses and the establishment of a funded programme similar to the IR4 program in the U.S.A. might also be appropriate - although the source of such funding would need to be identified and agreed.

9. IDENTIFIED NEEDS FOR OTHER SECTORS

9.1. Health and consumer protection

The major challenges and needs in the area of health and consumer protection in coming years are outlined in the White Paper on Food Safety. This provides a list of specific actions and also a proposed timetable for implementing them. Most important here are probably the recasting of legislation in the area of food law and the creation of a European Food Authority (EFA). The recent Regulation[52] proposed by the Commission setting up the general principles of food law and the EFA will go a long way to ensuring that these needs will be met.

In the specific area covered by the Directive, the principle tasks will be (i) to ensure a smooth transition from the current evaluation system to that which will operate in the ambit of the EFA, (ii) to ensure that the necessary resources will be available to deliver the number of decisions required between now and 2008, (iii) to strike the correct balance between all the interests involved in this complex area, and (iv) to ensure that the Directive meets its aspirations in protecting the consumer, the operator and the environment.

9.2. Environment

9.2.1. The Sixth Environment Action Programme of the European Community (2001-2010)

The Commission adopted, on 24 January 2001, the Sixth Environment Action Programme "Environment 2010: "Our future, our choice". In it, a two-track approach is proposed for minimising the risks due to the uses and misuse of plant protection products: (a) ban or severely limit the placing on the market and the use of the most hazardous and risky plant protection products and (b) ensure that best practice is adopted regarding the use of those plant protection products that are authorised.

[52] COM (2000) 716 final of 8.11.2000 - Proposal for a Regulation of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food.

Whilst strict standards already exist for the quality of drinking water supplied at the tap regarding contamination by plant protection products, there is an obvious need to stop them getting into drinking water sources in the first place.

In order that the use and levels of plant protection products in the environment do not give rise to significant risks to, or impact on, human health and nature, an overall reduction in the risk associated with the use of plant protection products is needed. Future actions should include:

- the revision of Directive 91/414/EEC in full recognition of the precautionary principle specifically to improve the overall mechanism of the authorisation system, in particular incorporating comparative assessment, minimising risk linked to the toxicity/ ecotoxicity of substances and monitoring;

- application of the Community Thematic Strategy on the sustainable use of pesticides, currently in preparation.

9.2.2. Commission Thematic Strategy: "Towards the sustainable use of plant protection products"

The aim of the Thematic Strategy is to inform the Council and the European Parliament of what the Commission intends to propose to achieve sustainable, environmentally sound and safe use of plant protection products in the Community. The economic benefits accruing from usage of plant protection products in agriculture need to be weighed against the risks posed by them to humans and to other living species and to the environment, and the costs associated with such usage to other sectors and to society.

Sustainable use can be defined as a use of plant protection products that has no irreversible effect on natural systems and causes neither acute nor long-term harmful effects on humans, animals or the environment. Sustainable use includes minimising the use of plant protection products, restriction of use and substitution of the most dangerous plant protection products, as well as strict adherence to the precautionary principle in decisions regarding authorisations. Some positive effects on the reduction of risks from plant protection products can already be seen as a result of both national and Community efforts, but they are still too limited.

The Thematic Strategy aims to provide a general overview on risk reduction efforts and policies in relation to the use of plant protection products made in the Community as a whole, as well as in individual Member States. It will contribute significantly to the integration of environmental concerns into agricultural policies and practices. It will focus more on measures targeting the use of authorised plant protection products, as the existing regulatory instruments focus on the actual placing of plant protection products on the market. Measures taken under these existing instruments will be utilised to the fullest in achieving the Strategy’s goals.

9.3. Agriculture

In coming years, the three major challenges in agriculture will be: (a) to ensure that best practice is adopted regarding the use of pesticides, in particular by favouring the development of Codes of Good Practice, the diffusion of Integrated Pest Management (IPM) techniques and adequate training of farmers, and (b) further to promote organic farming and safeguard the tradition of low-input farming. Much of

the responsibility and need for action lies with the Member States. On the one hand, they are responsible for the design of rural development programmes and, in particular, for the inclusion of pertinent training schemes and agri-environmental measures. On the other, they are enabled and competent to decide on any penalty, applying to farmers who do not respect mandatory environmental requirements, including reduction or even cancellation of the benefits accruing from CAP support schemes. Meanwhile, there is the need to avoid that loss of active substances driven by the review procedure jeopardises the availability of suitable pesticides for minor crops and essential uses, including effective pest resistance management. Also in the area of or organic farming, measures need to be identified and taken to prevent the loss, for economic reasons, of many niche products of low risk in a sector whose further development the Community is trying to encourage. Member States and the Commission share the responsibility for addressing crucial issues.

9.4. Trade

There is a need to promote a better integration of environmental and other legitimate factors of concern into WTO decision-making and to raise awareness, particularly in developing countries of the impacts of decisions taken under the Directive on MRLs.

9.5. Enlargement

Accession Countries will act as Rapporteur Member States after accession to the Community and there will be re-attribution of the evaluation work to them. For the smaller countries, it will probably not be possible effectively to act as Rapporteur given the learning curve involved and the infrastructure needed to support the technical and scientific evaluation. This will be challenging in terms of investment and in terms of the work demanded. The approach already adopted by Luxembourg may be a pragmatic solution. Luxembourg has established an agreement with the Belgian authorities to carry out its work as EU Rapporteur Member State. This arrangement has worked well and there is no reason to suppose that it cannot also work for the smaller Accession Countries as well.

Even for the larger Accession countries, there is a considerable challenge in building up their infrastructure and ensuring that they have the necessary qualified and trained scientists in place. They will also face the challenge of adapting to the way in which the European Community works in dealing with critical issues such as risk assessments. The previous scientific isolation of these countries in terms of exposure to the Community evaluation system has not helped. However these countries are now, by virtue of membership of various international organisations such as the OECD, learning more about how the EU works. Many Member States are also twinning with the Accession Countries and organising expert exchanges. The Commission is also looking at other ideas to assist these Countries in the process of adjustment - to allow the Accession Countries to send experts as observers to the ECCO Peer review meetings, given that this has constituted a process of learning by working together, and to form co-Rapporteur partnerships for the evaluation of new active substances. This latter proposal is also supported by industry.

Apart from the above, real logistic problems also have to be tackled in advance of up to 12 new countries joining the Community. Already, informatics tools such as CIRCA and CADDY that will make the task of distributing documents easier, are in place. Over and above this though, it will be necessary to take a fundamental look at

the way in which active substances are evaluated in the Community. Discussions in ECCO peer review and the technical working groups are already difficult with only 5 and 15 Member States respectively. Discussions and decisions could become cumbersome with 25 countries participating.

9.6. Development

In the field of Development, continued outreach and capacity building will be required to promote (i) safer use of pesticides, (ii) wider uptake of alternative methods of plant protection such as Integrated Pest Management and (iii) capacity to generate the data necessary to demonstrate that pesticide residues in fruit and vegetables imported from such countries are acceptable. Capacity-building should also be provided to help developing countries fulfil their obligations under the various chemicals management conventions.

9.7. Research

Research priorities for the implementation of the Directive 91/414/EEC are continually updated and amended as new priorities are identified and the research priorities identified are communicated to DG Research.

9.8. Industry

A need is apparent for better co-ordination within individual companies and across the sector. Whilst good working relationships often exist between industry and regulatory scientists, and even with regulators, industry decisions are driven by marketing considerations and management decisions outside the control of the conventional industry contact points. This can undermine or delay positions put forward by industry scientists during regulatory scientific discussions. In addition, there is an inherent conflict of interest between the multinational R&D-based companies and the smaller generic producers. Even within the group of multinationals there is much suspicion and reluctance to share data defined as confidential. This does not facilitate the rapid taking of a position by industry on horizontal issues related to the implementation of the Directive, nor does it facilitate the submission of single dossiers for individual substances.

A range of competition issues will also have to be considered very carefully. It is clear, for instance, that a large part of the industry has invested large sums of money to ensure that it can provide the information industry knew would be required from adoption of the Directive in 1991. Granting derogations for those substances for which companies have not invested financial or human resources to produce this information will put the former companies at a competitive disadvantage.

9.9. Member States

Co-ordination is required in the Member States before national positions can be taken on policies or on individual substances. The timing and frequency of national co-ordination meetings or procedures in the 15 different Member States often precludes rapid decision-making in the SCPH. This can be due to several reasons. First, in many Member States up to three ministries are involved in this area (health, environment and agriculture). Second, there may be national subsidiarity considerations to be respected e.g. Federal government vs. Länder. Third, there may be e.g. food safety committees that meet quarterly. This means that delegates in the

SCPH are not always able to take positions on issues as they arise but need to defer discussions while they refer back for guidance and/or instruction. Alternatively, they may arrive at a meeting with fixed instructions that preclude their ability to negotiate or compromise on specific topics. A solution to this problem is outside the control of the Commission.

It must be reiterated that the Directive leaves much of the competence for decision-making with the Member States and this, allied to their important role in the Community evaluation and decision-making processes, means that there is much left for them to do in finding solutions to potential problems and in ensuring that the evaluation programme can be completed in good time.

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

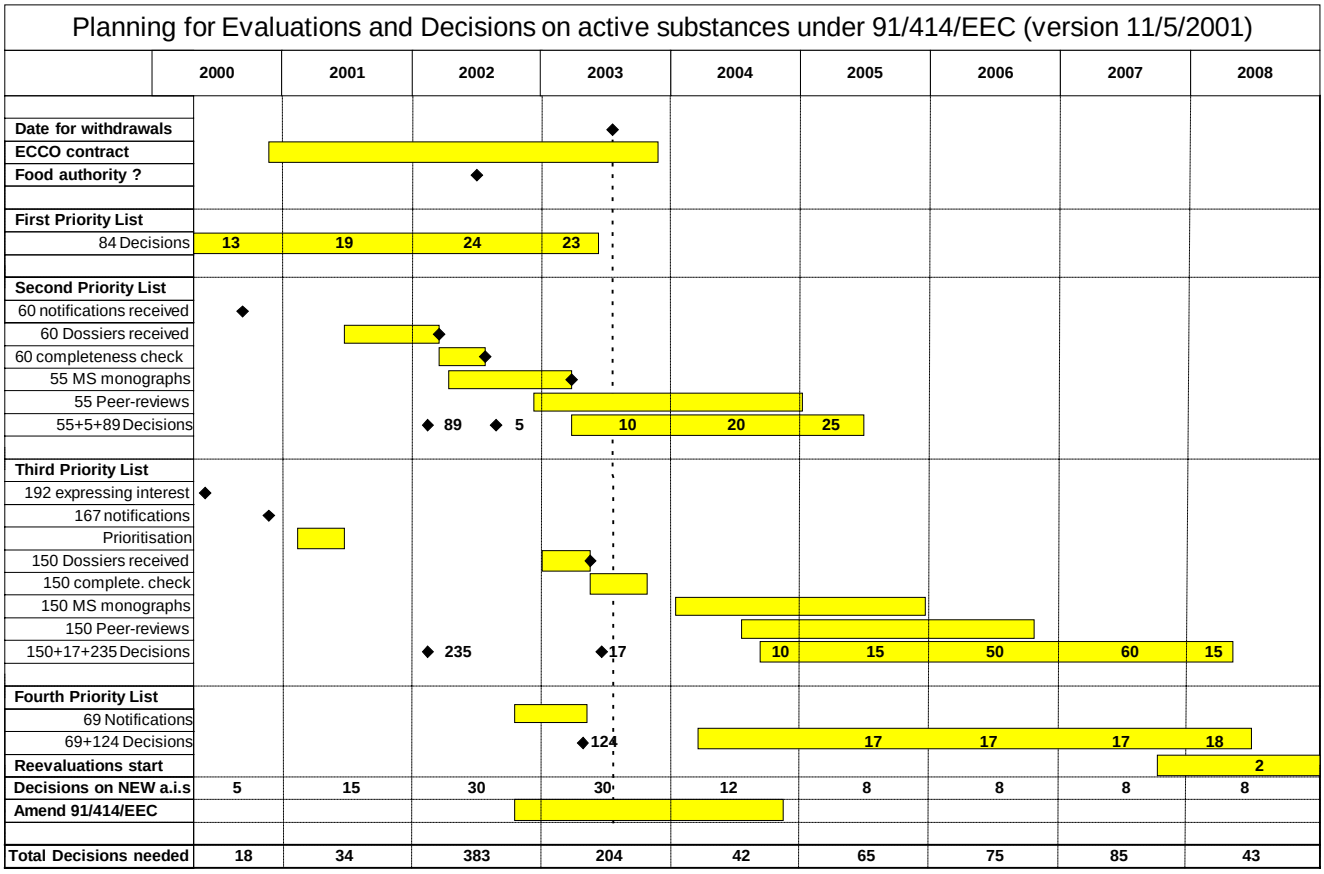

Figure 12: A projection of the planning of the remainder of the programme of evaluation of existing active substances and of the number of decisions to be taken each year to achieve it. For the fourth priority list, the estimates are less certain because there has not yet been a notification procedure. The numbers do not take into account any possible measures for essential uses and the timelines are contingent on (i) adequate resources being available, (ii) deadlines being respected by all parties and (iii) no major new data requirements being identified in the coming years.

The planning of the evaluation programme for active substances is given in Figure 12. It includes projected timelines and likely results. Examination of the numbers of decisions required each year shows that a major increase in decision-making capacity will be required in the years to come.

It is proposed to finish the first list by July 2003 with the established system and process. The second, third and fourth lists will be completed as shown in the above diagram. 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.

The evaluations of the remaining 69 new active substances will be completed in due course. Once the peak load of applications has cleared the system, applications for about eight new actives will need to be evaluated each year. The exact number of applications received is, of course, outside the control of the Commission.

11. LIST OF LEGAL MEASURES TAKEN

11.1. General acts

1. Council Directive 91/414/EEC of 15.7.1991 concerning the placing of plant protection products on the market, OJ N° L 230, 19.8.1991, p.1.
2. Commission Regulation (EEC) N° 3600/92 of 11.12.1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, OJ N° L 366 of 15.12.1992, p. 10.
3. Commission Directive 93/71/EEC of 27.7.1993 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market, OJ N° L 221, 31.8.1993, p. 27.
4. Commission Directive 94/37/EC of 22.7.1994 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market, OJ N° L 194, 29.7.1994, p. 65.
5. Commission Regulation (EC) N° 933/94 of 27.4.1994, laying down the active substances of plant protection products and designating the Rapporteur Member State for the implementation of Commission Regulation (EEC) N° 3600/92, OJ N° L 107, 28.4.1994, p. 8.
6. Commission Directive 94/79/EC of 21 December 1994 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market, OJ N° L 354, 31.12.1994, p. 16.
7. Commission Regulation (EC) N° 491/95 of 3.3.1995 amending Regulation (EC) N° 3600/92, in particular with regard to the integration of the designated public authorities and the producers in Austria, Finland and Sweden in the implementation of the first stage of the programme of work referred to in Article 8 (2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market, OJ N° L 49, 4.3.1995, p. 50.
8. Commission Directive 95/35/EC of 14.7.1995 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market, OJ N° L 172, 22.7.95, p. 6.
9. Commission Directive 95/36/EC of 14.7.1995 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market, OJ N° L 172, 22.7.95, p. 8.
10. Commission Regulation (EC) N° 2230/95 of 21.9.1995 amending Regulation (EC) N° 933/94, laying down the active substances of plant protection products and designating the Rapporteur Member States for the implementation of Commission Regulation (EEC) N° 3600/92, OJ N° L 225, 22.9.95, p. 1.
11. Commission Directive 96/12/EC of 8.3.1996 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market, OJ N° L 65, 15.3.96, p. 20.
12. Commission Directive 96/46/EC of 16.7.1996 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market, OJ N° L 214, 23.8.96, p. 18.
13. Commission Directive 96/68/EC of 21.10.1996 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market, OJ N° L 277, 30.10.96, p. 25.
14. Commission Regulation (EC) N° 1199/97 of 27.6.1997 amending Regulation (EEC) N° 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, concerning the placing of plant protection products on the market, OJ N° L 170, 28.6.1997, p. 19.
15. Council Directive 97/57/EC of 22.9.1997 establishing Annex VI to Directive 91/414/EEC concerning the placing of plant protection products on the market, OJ N° L 265, 27.9.1997, p. 87.
16. Commission Regulation (EC) N° 1972/1999 of 15.9.1999 amending Regulation (EEC) N° 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, concerning the placing of plant protection products on the market, OJ N° L 244, 16.9.1999, p. 41.

17. Commission Regulation (EC) N° 451/2000 of 28.2.2000 laying down the detailed rules for the implementation of the second and third stages of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC, OJ N° L 55, 29.2.2000, p. 25.
18. Commission Regulation (EC) N° 2266/2000 of 12.10.2000 amending Regulation (EEC) N° 3600/92 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, concerning the placing of plant protection products on the market, OJ N° L 259, 13.10.2000, p. 27.
19. Commission Regulation (EC) N° 703/2001 of 6.4.2001 laying down the active substances of plant protection products to be assessed in the 2nd stage of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC and revising the list of Member States designated as rapporteurs, OJ N° L 98, 7.4.2001, p. 6.
20. Commission Directive 2001/36/EC of 16 May 2001 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market (data requirements for microbial plant protection products), OJ N° L 164, 20.6.2001, p. 1.

11.2. Acts on individual existing active substances

1. Commission Decision 94/643/EC of 12.9.1994 (OJ N° L 249, 24.9.1994, p. 18) concerning the withdrawal of authorisations for plant protection products containing cyhalothrin as active substance.
2. Commission Decision 95/276/EC of 13.7.1995 (OJ N° L 170, 20.7.95, p.22), concerning the withdrawal of authorisations of plant protection products containing ferbam and azinphos-ethyl as active substances.
3. Commission Decision 96/586/EC of 9.4.1996 (OJ N° L 257, 10.10.96, p. 41) concerning the withdrawal of authorisations for plant protection products containing propham as an active substance.
4. Commission Decision 98/269/EC of 7.4.1998 (OJ N° L 117, 21.4.1998 p. 13) concerning the withdrawal of authorisations for plant protection products containing dinoterb as an active substance.
5. Commission Decision 98/270/EC of 7.4.1998 (OJ N° L 117, 21.4.1998 p. 15) concerning the withdrawal of authorisations for plant protection products containing fenvalerate as an active substance.
6. Commission Directive 97/73/EC of 15.12.1997 (OJ N° L 353, 24.12.1997, p. 26) including an active substance (imazilil) in Annex I of Directive 91/414/EEC concerning the placing of plant protection products on the market.
7. Commission Decision 1999/164/EC of 17.2.1999 (OJ N° L 54, 2.3.1999, p. 21) concerning the non-inclusion of DNOC of active substance in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance.
8. Commission Directive 2000/10/EC of 1.3.2000 (OJ N° L 57, 2.3.2000, p. 28) including an active substance (fluroxypyr) in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market.
9. Commission Decision 2000/233/EC of 9.3.2000 (OJ N° L 73, 22.3.2000, p. 16) concerning the non-inclusion of pyrazophos in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance.
10. Commission Decision 2000/234/EC of 9.3.2000 (OJ N° L 73, 22.3.2000, p. 18) concerning the non-inclusion of monolinuron in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance.
11. Commission Directive 2000/49/EC of 26.7.2000 (OJ N° L 197, 3.8.2000, p. 32) including an active substance (metsulfuron-methyl) in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market.
12. Commission Directive 2000/67/EC of 23.10.2000 (OJ N° L 276, 28.10.2000, p. 38) including an active substance (esfenvalerate) in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market.
13. Commission Directive 2000/68/EC of 23.1.2000 (OJ N° L 276, 28.10.2000, p. 41) including an active substance (bentazone) in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market.
14. Commission Directive 2000/80/EC of 4.12.2000 (OJ N° L 309, 9.12.2000, p. 14) amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market, so as to consolidate that Annex and include a further active substance (lambda-cyhalothrin).
15. Commission Decision 2000/801/EC of 20.12.2000 (OJ N° L 324, 21.12.2000, p. 42) concerning the non-inclusion of lindane in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance.
16. Commission Decision 2000/816/EC of 27.12.2000 (OJ N° L 332, 28.12.2000, p. 112) concerning the non-inclusion of quintozene in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance.
17. Commission Decision 2000/817/EC of 27.12.2000 (OJ N° L 332, 28.12.2000, p. 114) concerning the non-inclusion of permethrin in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance.

18. Commission Decision 2001/134/EC of 14.2.2001 (OJ N° L 49, 20.2.2001, p. 13) concerning the decision on the possible inclusion of certain active substances into Annex I to Council Directive 91/414/EEC.
19. Commission Directive 2001/21/EC of 5.3.2001 (OJ N° L 69, 10.3.2001, p. 17) amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market to include amitrole, diquat, pyridate and thiabendazole as active substances.
20. Commission Decision 2001/245/EC of 22.3.2001 (OJ N° L 88, 28.3.2001, p. 19) concerning the non-inclusion of zineb in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance.
21. Commission Decision 2001/520/EC of 9.7.2001 (OJ N° L 187, 10.7.2001, p. 47) concerning the non-inclusion of parathion ethyl in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance.

12. GUIDANCE DOCUMENTS

1. Doc. 7109/VI/94 rev. 6: Applicability of Good Laboratory Practice to data requirements according to Annexes II, Part A and III, Part A of Council Directive 91/414/EEC.
2. Docs. 1694/VI/95, 4952/VI/95, 6476/VI/96 and 7617/VI/96: Guidance documents within the Standing Committee on Plant Health with regard to the modelling of fate and behaviour of plant protection products in the environment (in groundwater, surface water and soil).
3. Doc. 7017/VI/95 rev. 4: Guideline developed within the Standing Committee on Plant Health with regard to the acceptability of data, whether or not performed in accordance with the principles of Good Laboratory Practice.
4. Doc. 1663/VI/94 rev. 8 of 22.4.1998: Guidelines and criteria for the preparation and presentation of complete dossiers and of summary dossiers for the inclusion of active substances in Annex I of Directive 91/414/EEC (Articles 5.3 and 8.2)
5. Doc. 1654/VI/94 rev. 7 of 22.4.1998: Guidelines and criteria for the evaluation of dossiers and for the preparation of reports to the European Commission by Rapporteur Member States to the proposed inclusion of active substances in Annex I of Directive 91/414/EEC.
6. Doc. 8064/VI/97 rev. 4 of 15.12.1998. Guidance document on residue analytical methods.
7. Doc. SANCO/3029/99 rev. 4 of 13.7.2000: Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414/EEC.
8. Doc. SANCO/3030/99 rev. 4 of 13.7.2000: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414/EEC.
9. Doc. 9188/VI/97 rev. 8 of 13.7.2000: Guidance Document on Persistence in Soil.
10. Doc. 2021/VI/98 rev. 7 of 13.7.2000: Guidance Document on Terrestrial Ecotoxicology.
11. Doc. 8075/VI/97 rev. 7 of 13.7.2000: Guidance Document on Aquatic Ecotoxicology.
12. Doc. Sanco/491/00 rev. 3: Authorisation of plant protection products containing existing active substances after their inclusion in Annex I - submission of an Annex II and Annex III dossier.
13. Doc. 1614/VI/95 rev. 7 of 27.04.1997: Working document for guidance to the Member States with regard to the implementation of Articles 6 and 7 of Regulation (EEC) N° 3600/92, developed in the working group "plant protection products - legislation" of the SCPH.
14. Doc. 1663/VI/95 rev. 2 of 16.6.1996: Working document for guidance to the Member States with regard to the implementation of Article 6 of Directive 91/414/EEC for new active substances, developed in the working group "plant protection products - legislation" of the SCPH.
15. Doc. 7600/VI/95 rev. 6 of 14.7.1997 - Guidelines and criteria for the preparation and presentation of data concerning efficacy as provided in Annex III, parts A and B, section 6 of Directive 91/414/EEC concerning the placing of plant protection products on the market (biological assessment dossier).
16. Doc. 1607/VI/97 rev. 1 of 22.07.1997 containing further guidance for carrying out residue trials and comprising:
    - 7028/VI/95 rev. 3: Appendix A on metabolism and distribution in plants,
    - 7029/VI/95 rev. 5: Appendix B on recommendations for design, preparation, realisation of residue trials,
    - 7524/VI/95 rev. 2: Appendix C on the testing of plant protection products in rotational crops,
    - 7525/VI/95 rev. 5: Appendix D on comparability, extrapolation, group tolerances and data requirements,
    - 7035/VI/95 rev. 5: Appendix E concerning processing studies,
    - 7030/VI/95 rev. 3: Appendix F concerning metabolism and distribution in domestic animals,
    - 7031/VI/95 rev. 4: Appendix G concerning livestock feeding studies,
    - 7032/VI/95 rev. 5: Appendix H concerning storage stability of residue samples,
    - 7039/VI/95: Appendix I concerning the calculation of MRLs and safety intervals e.g. pre-harvest intervals
17. Doc. 7860/VI/97 rev. 5E of 15.07.98 - Aide mémoire on certain aspects of the procedures for the evaluation of existing active substances in view of a possible inclusion into Annex I of Directive 91/414/EEC.

18. Doc. 7860/VI/97 rev. 5N of 15.07.98 - Aide mémoire on certain aspects of the procedures for the evaluation of new active substances in view of a possible inclusion into Annex I of Directive 91/414/EEC.
19. Doc. 7196/VI/99 - Guidelines for applicants for import tolerances (October 1999).
20. FOCUS groundwater.
21. Doc. Sanco/221/2000 rev. 2 - Draft Guidance document on relevant metabolites (Feb 1999).
22. Doc. Sanco/222/2000 rev. 1 - Draft Guidance document on dermal absorption (June 1999).
23. Doc. 2971/SANCO/2000 - Guidance document on voluntary mutual recognition of minor use authorisations.
24. Various: FOCUS surface water, acute reference dose, MED-Rice, higher-tier risk assessment.

13. LIST OF EXISTING ACTIVE SUBSTANCES

This section lists the 834 existing active substances. Based on information provided by the Member States, it indicates which MS has authorised uses of each of them. It does not include details of the specific uses, authorisations and tonnages applied. It also gives details of the priority listing and the notification status of each substance. It does not take account of possible derogations for essential uses.

Active substance	FI	S	DK	IR	UK	NL	B	L	D	AU	F	ES	P	I	EL	List	Status	Remark
Amitrole				X	X	X	X	X	X		X	X	X		X	1	Annex I	01/21/EC
Bentazone	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	1	Annex I	00/68/EC
λ-Cyhalothrin	X	X	X		X	X	X	X	X	X	X	X	X	X	X	1	Annex I	00/80/EC
Diquat	X	X		X	X	X	X	X	X	X	X	X	X	X	X	1	Annex I	01/21/EC
Esfenvalerate	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	1	Annex I	00/67/EC
Fluroxypyr	X	X	X	X	X	X	X	X	X	X	X	X		X		1	Annex I	00/10/EC
Glyphosate (including trimesium)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	1	pending	01/?/EC
Imazalil	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	1	Annex I	97/73/EC
Metsulfuron	X	X	X	X	X	X	X		X	X	X			X		1	Annex I	00/49/EC
Pyridate	X		X	X	X	X	X	X	X	X	X	X		X	X	1	Annex I	01/21/EC
Thiabendazole		X		X	X	X	X	X	X	X	X	X	X	X	X	1	Annex I	01/21/EC
Thifensulfuron	X	X	X	X	X	X	X		X	X	X	X		X	X	1	pending	01/?/EC
Triasulfuron	X		X	X	X		X	X	X	X	X	X	X	X	X	1	Annex I	00/66/EC
Azinphos ethyl																1	out 1/96	95/276/EC
Chlozolinate												X		X	X	1	out 4/02	00/626/EC
Cyhalothrin																1	out 3/95	94/643/EC
Dinoterb																1	out 10/98	98/269/EC
DNOC																1	out 6/00	99/164/EC
Fenvalerate																1	out 4/99	98/270/EC
Ferbam																1	out 1/96	95/276/EC
Lindane				X	X		X	X				X	X	X	X	1	out 6/02	00/801/EC
Monolinuron					X					X				X		1	out 9/01	00/234/EC
Parathion-ethyl						X	X	X	X		X	X		X	X	1	out 7/03	01/520/EC
Permethrin	X	X	X	X	X	X	X		X	X		X	X	X	X	1	out 12/03	00/817/EC
Propham																1	out 4/97	96/586/EC
Pyrazophos					X				X	X		X		X		1	out 9/01	00/233/EC
Quintozene				X	X							X			X	1	out 6/02	00/816/EC
Tecnazene				X	X											1	out 1/03	00/725/EC
Zineb				X	X	X	X				X	X	X	X	X	1	out 3/03	01/245/EC
Acephate						X	X				X	X	X	X	X	1	pending	
Alachlor											X	X	X	X	X	1	pending	
Aldicarb				X	X	X	X			X	X	X	X	X	X	1	pending	
Amitraz			X		X	X	X		X	X	X	X	X	X	X	1	pending	
Atrazine				X	X		X	X			X	X	X		X	1	pending	
Azinphos-methyl	X	X								X	X	X	X	X	X	1	pending	
Benalaxyl				X	X		X			X	X	X	X	X	X	1	pending	
Benomyl		X		X	X	X	X	X	X	X	X	X	X	X	X	1	pending	
Bromoxynil	X		X	X	X	X	X	X	X	X	X	X	X	X	X	1	pending	
Carbendazim				X	X	X	X	X	X	X	X	X	X	X	X	1	pending	
Chlorothalonil	X		X	X	X	X	X	X	X	X	X	X	X	X	X	1	pending	
Chlorpropham	X	X		X	X	X	X	X	X		X	X	X	X	X	1	pending	
Chlorpyrifos			X	X	X	X	X	X	X	X	X	X	X	X	X	1	pending	
Chlorpyrifos-methyl				X	X		X			X	X	X	X	X	X	1	pending	
Chlortoluron				X	X		X	X	X	X	X	X	X	X		1	pending	

Active substance	FI	S	DK	IR	UK	NL	B	L	D	AU	F	ES	P	I	EL	List	Status	Remark
Cyfluthrin		X	X	X	X	X	X	X	X	X	X	X	X	X	X	1	pending	
β-Cyfluthrin	X								X		X	X	X		X	1	pending	
Cypermethrin	X	X	X	X	X		X		X	X	X	X	X	X	X	1	pending	
α-Cypermethrin	X	X	X	X	X	X	X		X	X	X	X	X	X	X	1	pending	
2,4-D	X			X	X	X	X	X	X	X	X	X	X	X	X	1	pending	
Daminozide	X	X	X	X	X	X	X			X	X	X	X	X	X	1	pending	
2,4-DB				X	X						X			X		1	pending	
Deltamethrin	X	X	X	X	X	X	X	X		X	X	X	X	X	X	1	pending	
Desmedipham	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	1	pending	
Dinocap					X		X	X		X	X	X	X	X	X	1	pending	
Endosulfan	X			X	X		X	X		X	X	X	X	X	X	1	pending	
Ethofumesate	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	1	pending	
Fenarimol				X	X	X	X	X	X	X	X	X	X	X	X	1	pending	
Fenthion										X	X	X	X	X	X	1	pending	
Fentin acetate				X	X	X	X	X		X	X			X	X	1	pending	
Fentin hydroxide				X	X	X	X	X	X	X	X		X	X		1	pending	
Flusilazole				X	X		X	X	X	X	X	X	X	X	X	1	pending	
Ioxynil	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	1	pending	
Iprodione	X	X		X	X	X	X	X	X	X	X	X	X	X	X	1	pending	
Isoproturon		X		X	X	X	X	X	X	X	X	X	X	X	X	1	pending	
Linuron	X		X	X	X	X	X	X		X	X	X	X	X	X	1	pending	
Maleic hydrazide				X	X	X	X				X	X		X	X	1	pending	
Mancozeb	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	1	pending	
Maneb	X		X	X	X	X	X	X	X	X	X	X	X	X	X	1	pending	
MCPA	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	1	pending	
MCPB				X	X		X	X		X						1	pending	
Mecoprop			X	X	X		X			X	X	X	X	X	X	1	pending	
Mecoprop-P	X	X	X	X	X	X	X	X	X	X	X	X	X		X	1	pending	
Metalaxyl		X		X	X		X	X	X	X	X	X	X	X	X	1	pending	
Methamidophos							X	X	X	X	X	X	X	X	X	1	pending	
Metiram				X	X	X	X	X	X	X	X	X	X	X	X	1	pending	
Molinate											X	X	X	X	X	1	pending	
Paraquat				X	X	X	X		X		X	X	X	X	X	1	pending	
Parathion-methyl						X		X	X	X	X	X		X	X	1	pending	
Pendimethalin		X	X	X	X	X	X	X	X	X	X	X	X	X	X	1	pending	
Phenmedipham	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	1	pending	
Procymidone						X	X	X		X	X	X	X	X	X	1	pending	
Propiconazole	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	1	pending	
Propineb				X	X		X	X	X	X	X	X	X	X	X	1	pending	
Propyzamide		X	X	X	X	X	X	X	X	X	X	X	X	X	X	1	pending	
Simazine	X		X	X	X	X	X	X		X	X	X	X	X	X	1	pending	
Thiophanate-methyl	X	X	X	X	X	X	X		X	X	X	X	X	X	X	1	pending	
Thiram	X		X	X	X	X	X	X	X	X	X	X	X	X	X	1	pending	
Vinclozolin				X	X	X	X	X	X	X	X	X	X	X	X	1	pending	
Warfarin				X	X		X	X	X	X	X	X	X	X		1	pending	
Ziram					X	X	X	X		X	X	X	X	X	X	1	pending	
Benfuracarb					X	X	X		X		X	X		X	X	2	Notified	
Cadusafos											X	X			X	2	Notified	
Captan		X		X	X	X	X		X	X	X	X	X	X	X	2	Notified	
Carbaryl					X	X	X				X	X	X	X	X	2	Notified	
Carbofuran			X	X	X	X	X	X	X	X	X	X	X	X	X	2	Notified	
Carbosulfan		X	X	X	X		X		X		X	X		X	X	2	Notified	
Clodinafop				X	X	X	X	X	X		X	X	X	X	X	2	Notified	
Clopyralid	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	2	Notified	
Cyanazine		X		X	X		X			X	X	X	X	X	X	2	Notified	
Cyprodinil	X	X	X	X	X	X	X	X	X		X	X	X	X	X	2	Notified	
Diazinon	X	X	X	X	X		X	X			X	X	X	X	X	2	Notified	
1,3-dichloropropene				X	X		X					X	X	X	X	2	Notified	
1,3-dichloropropene (cis)						X	X									2	Notified	
Dichlorprop-P	X	X	X	X	X		X	X	X	X	X	X	X			2	Notified	
Dichlorvos					X	X	X	X	X	X	X	X		X	X	2	Notified	
Dimethenamide						X	X	X	X		X	X		X	X	2	Notified	
Dimethoate	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	2	Notified	
Dimethomorph	X	X	X	X	X	X	X	X	X		X	X	X	X	X	2	Notified	

Active substance	FI	S	DK	IR	UK	NL	B	L	D	AU	F	ES	P	I	EL	List	Status	Remark
Diuron			X	X	X		X	X	X	X	X	X	X	X	X	2	Notified	
Ethephon	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	2	Notified	
Ethoprophos				X	X	X	X			X	X	X	X	X	X	2	Notified	
Fenamiphos				X		X					X	X	X	X	X	2	Notified	
Fenitrothion	X		X	X	X		X			X	X	X		X	X	2	Notified	
Fipronil	X					X	X				X	X		X	X	2	Notified	
Folpet		X				X		X	X	X	X	X	X	X	X	2	Notified	
Formetanate											X	X	X	X		2	Notified	
Fosetyl	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	2	Notified	
Glufosinate	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	2	Notified	
Haloxyfop-R				X		X	X	X	X		X	X		X	X	2	Notified	
Isoxathion												X				2	Notified	
Malathion	X		X	X	X	X	X	X			X	X	X	X	X	2	Notified	
Metconazole				X	X		X		X		X					2	Notified	
Methidathion							X		X	X	X	X	X	X	X	2	Notified	
Methiocarb	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	2	Notified	
Methomyl					X	X	X	X		X	X	X	X	X	X	2	Notified	
Metribuzin	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	2	Notified	
Mevinphos	X	X					X			X	X		X		X	2	Notified	
Monocrotophos										X		X		X	X	2	Notified	
Naled											X	X				2	Notified	
Oxamyl				X	X		X			X	X	X	X	X	X	2	Notified	
Oxydemeton-methyl	X			X			X	X	X	X	X	X	X	X	X	2	Notified	
Phorate					X						X	X		X	X	2	Notified	
Phosalone			X	X	X		X			X	X	X	X	X	X	2	Notified	
Phosmet										X	X	X	X	X	X	2	Notified	
Phosphamidon									X		X	X	X	X	X	2	Notified	
Pirimicarb	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	2	Notified	
Pirimiphos-methyl	X			X	X	X	X	X	X		X	X	X	X	X	2	Notified	
Propamocarb	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	2	Notified	
Pyrimethanil		X	X		X	X	X		X		X	X	X	X	X	2	Notified	
Rimsulfuron	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	2	Notified	
Thiodicarb				X	X	X	X	X	X		X	X	X	X	X	2	Notified	
Tolclofos-methyl		X	X	X	X	X	X		X	X	X	X		X	X	2	Notified	
Tolylfluanid	X	X	X	X	X	X	X	X	X		X	X				2	Notified	
Triazamate		X			X	X					X					2	Notified	
Tribenuron	X	X	X	X	X		X	X	X	X	X	X	X	X	X	2	Notified	
Trichlorfon		X		X	X			X	X	X	X	X	X	X		2	Notified	
Triclopyr				X	X	X	X	X	X	X	X	X	X	X	X	2	Notified	
Trifluralin	X			X	X		X	X	X	X	X	X	X	X	X	2	Notified	
Trinexapac	X	X	X	X	X	X	X	X	X	X	X					2	Notified	
Triticonazole					X		X	X	X		X			X		2	Notified	
Ampropylofos		X									X					2	Out 7/03	
Azamethiphos	X		X		X			X			X					2	Out 7/03	
Barban															X	2	Out 7/03	
Bendiocarb				X	X				X	X	X	X		X	X	2	Out 7/03	
Bromocyclen																2	Out 7/03	
Bromophos				X						X						2	Out 7/03	
Bromophos-ethyl																2	Out 7/03	
Bronopol																2	Out 7/03	
Butocarboxim				X		X			X	X		X	X		X	2	Out 7/03	
Butoxycarboxim	X	X	X	X	X	X	X	X	X	X					X	2	Out 7/03	
Carbophenothion														X	X	2	Out 7/03	
Chloral-bis-acylal																2	Out 7/03	
Chloral-semi-acetal																2	Out 7/03	
Chlorfenprop																2	Out 7/03	
Chlorfenvinphos		X	X	X	X	X	X		X	X	X	X	X	X	X	2	Out 7/03	
Chlormephos											X	X	X	X	X	2	Out 7/03	
Chlorobenzilate																2	Out 7/03	
p-Chloronitrobenzene																2	Out 7/03	
Chloroxuron				X							X					2	Out 7/03	
Chlorthiophos																2	Out 7/03	
DADZ																2	Out 7/03	
Demeton-S-methyl															X	2	Out 7/03	

Active substance	FI	S	DK	IR	UK	NL	B	L	D	AU	F	ES	P	I	EL	List	Status	Remark
Demeton-S-methyl sulphone												X		X		2	Out 7/03	
Dialifos											X					2	Out 7/03	
Di-allate																2	Out 7/03	
Dichlofenthion											X					2	Out 7/03	
1,2-Dichloropropane					X									X		2	Out 7/03	
Dichlorprop			X	X	X		X			X	X	X	X	X	X	2	Out 7/03	
Dicrotophos																2	Out 7/03	
Difenoxuron																2	Out 7/03	
Dimefox																2	Out 7/03	
Dioxacarb														X		2	Out 7/03	
Dioxathion																2	Out 7/03	
Disulfoton					X						X			X	X	2	Out 7/03	
Ditalimfos										X				X		2	Out 7/03	
2-Dithiocyanomethylthio-benzothiazol																2	Out 7/03	
Ethiofencarb				X	X		X			X	X	X		X		2	Out 7/03	
Ethion											X	X			X	2	Out 7/03	
Ethoate-methyl														X		2	Out 7/03	
Etrimfos			X		X											2	Out 7/03	
Fluorodifen																2	Out 7/03	
Fonofos				X						X	X	X		X		2	Out 7/03	
Formothion											X	X		X	X	2	Out 7/03	
Furathiocarb	X	X	X				X				X			X	X	2	Out 7/03	
Furfural																2	Out 7/03	
Haloxyfop			X							X	X	X		X	X	2	Out 7/03	
Heptenophos				X	X		X				X	X		X	X	2	Out 7/03	
Iodofenphos																2	Out 7/03	
Isazofos											X					2	Out 7/03	
Isocarbamide																2	Out 7/03	
Isofenphos	X			X					X	X	X	X		X		2	Out 7/03	
Mecarbam															X	2	Out 7/03	
Mephospholan				X	X											2	Out 7/03	
Methoxychlor							X					X		X		2	Out 7/03	
Metolachlor							X	X	X	X	X	X	X	X	X	2	Out 7/03	
Naphtylacetic acid hydrazide																2	Out 7/03	
Noruron																2	Out 7/03	
Omethoate							X			X	X	X	X	X	X	2	Out 7/03	
Pentachlorophenol																2	Out 7/03	
4-t-Pentylphenol																2	Out 7/03	
Phoxim	X	X	X	X			X	X	X	X	X	X	X	X		2	Out 7/03	
Pirimiphos-ethyl											X					2	Out 7/03	
Profenofos											X	X		X	X	2	Out 7/03	
Promecarb												X				2	Out 7/03	
Prometryne				X	X					X	X	X	X	X	X	2	Out 7/03	
Propazine																2	Out 7/03	
Propetamphos																2	Out 7/03	
Propoxur				X	X	X	X			X		X		X		2	Out 7/03	
Prothiocarb																2	Out 7/03	
Prothiofos												X				2	Out 7/03	
Prothoate																2	Out 7/03	
Pyraclofos												X				2	Out 7/03	
Pyridafenthion											X	X		X		2	Out 7/03	
Quinalphos											X		X	X	X	2	Out 7/03	
Sodium-diacetoneketogulonate																2	Out 7/03	
Sodium-dimethyldithiocarbamate																2	Out 7/03	
Sulfotep	X	X		X			X	X	X		X	X		X		2	Out 7/03	
Sulprofos												X				2	Out 7/03	
2,4,5-T																2	Out 7/03	
Temephos				X								X		X		2	Out 7/03	
Terbufos							X		X	X	X	X		X	X	2	Out 7/03	
Terbutryn	X	X		X	X		X		X	X	X	X	X	X	X	2	Out 7/03	
Tetrachlorvinphos												X		X		2	Out 7/03	
Thiofanox											X	X		X	X	2	Out 7/03	
Thiometon						X	X	X		X	X	X			X	2	Out 7/03	
Thionazin														X		2	Out 7/03	

Active substance	FI	S	DK	IR	UK	NL	B	L	D	AU	F	ES	P	I	EL	List	Status	Remark
Triazophos				X					X					X	X	2	Out 7/03	
Trichloronat																2	Out 7/03	
Vamidothion				X			X			X	X	X	X	X		2	Out 7/03	
Abamectin	X				X	X	X		X		X	X	X	X	X	3	Notified	
Acetochlor											X	X				3	Notified	
Aclonifen	X	X	X	X		X	X	X	X		X	X		X	X	3	Notified	
Acrinathrin											X	X	X	X	X	3	Notified	
Aluminium phosphide	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	3	Notified	
Amidosulfuron	X	X		X	X	X	X	X	X	X	X	X		X		3	Notified	
Ammonium sulphamate				X	X						X					3	Notified	
Asulam			X	X	X	X	X	X		X	X	X		X		3	Notified	
Azocyclotin							X	X	X		X	X	X	X	X	3	Notified	
Benfluralin							X			X	X	X		X	X	3	Notified	
Bensulfuron											X	X	X	X	X	3	Notified	
Bifenox				X	X	X	X	X	X	X	X	X		X	X	3	Notified	
Bifenthrin				X	X		X	X			X	X	X	X	X	3	Notified	
Bitertanol	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	3	Notified	
Bromuconazole				X	X	X	X		X		X	X		X		3	Notified	
Bupirimate				X	X	X				X	X	X	X	X	X	3	Notified	
Buprofezin	X	X	X		X	X	X		X	X	X	X	X	X	X	3	Notified	
Butralin											X	X			X	3	Notified	
Calcium phosphide								X	X	X	X					3	Notified	
Carbetamide				X	X	X	X	X	X	X	X	X				3	Notified	
Carboxin	X	X	X	X	X			X	X	X	X	X	X	X	X	3	Notified	
Chlorates (Mg, Na, K)				X	X		X	X		X	X	X				3	Notified	
Chlorflurenol								X	X					X		3	Notified	
Chloridazon	X	X		X	X	X	X	X	X	X	X	X	X	X	X	3	Notified	
Chlormequat	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	3	Notified	
Chloropicrin				X	X		X				X	X			X	3	Notified	
Chlorsulfuron	X										X	X		X	X	3	Notified	
Chlorthal-dimethyl				X	X					X	X	X		X	X	3	Notified	
Cinosulfuron											X	X	X	X		3	Notified	
Clethodim		X	X				X		X		X	X		X	X	3	Notified	
Clofencet											X					3	Notified	
Clofentezine		X	X		X	X	X	X		X	X	X	X	X	X	3	Notified	
Clomazone						X	X	X	X	X	X					3	Notified	
Copper compounds:	X	X		X	X		X	X	X	X	X	X	X	X	X		Notified	
Ca-copper oxychloride												X		X	X	3	Notified	
Ca-copper sulfate (Bordeaux mix)				X	X		X	X			X	X	X	X	X	3	Notified	
Copper chloride																3	Notified	
Copper acetate																3	Notified	
Copper ammonium carbonate				X	X											3	Notified	
Copper β cyclodextrine hydroxide											X					3	Notified	
Copper carbonate basic				X							X	X	X	X		3	Notified	
Copper hydroxide		X			X		X	X	X	X	X	X	X	X	X	3	Notified	
Copper naphtenate										X						3	Notified	
Copper oxychloride	X	X		X	X		X	X	X	X	X	X	X	X	X	3	Notified	
Copper salt of fatty and rosin acids															X	3	Notified	
Copper sulfate				X	X		X	X			X	X	X	X	X	3	Notified	
Copper sulfate, tri-basic								X	X	X		X		X	X	3	Notified	
Cubiet												X				3	Notified	
Cuprammonium																3	Notified	
Cuprous oxide											X	X		X		3	Notified	
Cresylic acid				X		X										3	Notified	
Cyanamide									X	X	X	X		X	X	3	Notified	
Cycloxydim	X	X		X	X	X	X	X	X	X	X	X	X	X	X	3	Notified	
Cyhexatin						X		X			X	X	X	X	X	3	Notified	
Cymoxanil				X	X	X	X	X	X	X	X	X	X	X	X	3	Notified	
zeta-Cypermethrin					X		X				X			X	X	3	Notified	
Cyproconazole				X	X	X	X	X	X	X	X	X		X	X	3	Notified	
Cyromazine					X	X	X	X			X	X	X	X	X	3	Notified	
Dazomet		X		X	X	X	X	X	X	X	X	X	X	X	X	3	Notified	
Dicamba	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	3	Notified	
Dichlobenil	X			X	X	X	X	X	X	X	X	X	X	X	X	3	Notified	

Active substance	FI	S	DK	IR	UK	NL	B	L	D	AU	F	ES	P	I	EL	List	Status	Remark
Dichlorobenzoic acid methylester									X	X						3	Notified	
Dichlorophen				X	X		X				X					3	Notified	
Diclofop				X	X				X	X	X	X	X	X	X	3	Notified	
Dicloran				X	X							X		X		3	Notified	
Dicofol				X	X		X	X			X	X	X	X	X	3	Notified	
Diethofencarb						X	X	X	X	X	X	X	X	X	X	3	Notified	
Difenoconazole	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	3	Notified	
Diflubenzuron	X	X	X	X	X	X	X		X	X	X	X	X	X	X	3	Notified	
Diflufenican	X	X	X	X	X	X	X	X	X		X	X	X	X	X	3	Notified	
Dimethachlor									X	X						3	Notified	
Dimethipin				X							X	X		X	X	3	Notified	
Diniconazole											X	X			X	3	Notified	
Diphenylamine				X	X						X	X	X	X	X	3	Notified	
Disodium octaborate		X			X											3	Notified	
Dithianon	X	X		X	X	X	X	X	X	X	X	X	X	X	X	3	Notified	
Dodemorph				X	X	X				X	X	X		X	X	3	Notified	
Dodine				X	X	X	X			X		X	X	X	X	3	Notified	
Epoxiconazole				X	X	X	X	X	X		X	X				3	Notified	
Ethalfluralin												X		X	X	3	Notified	
Etofenprox											X	X		X		3	Notified	
Etridiazole				X	X	X	X					X		X	X	3	Notified	
Fenazaquin			X		X				X		X	X	X	X	X	3	Notified	
Fenbuconazole					X		X		X		X	X	X	X	X	3	Notified	
Fenbutatin oxide	X				X	X	X	X	X	X	X	X	X	X	X	3	Notified	
Fenoxaprop-P	X	X	X	X	X		X	X	X	X	X	X	X	X	X	3	Notified	
Fenoxycarb					X	X	X	X	X	X	X	X	X	X	X	3	Notified	
Fenpropidin	X	X	X	X	X		X	X	X		X	X		X		3	Notified	
Fenpropimorph	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	3	Notified	
Fenpyroximate					X		X		X	X	X	X	X	X	X	3	Notified	
Flamprop-M		X	X	X	X					X	X	X		X	X	3	Notified	
Fluazifop-P	X		X	X	X	X	X	X	X	X	X	X	X	X	X	3	Notified	
Fluazinam	X	X	X	X	X	X	X		X	X	X		X	X	X	3	Notified	
Fludioxonyl	X	X	X	X	X	X	X	X	X		X	X	X	X	X	3	Notified	
Flufenoxuron							X	X			X	X	X	X	X	3	Notified	
Fluometuron												X			X	3	Notified	
Fluquinconazole				X	X		X	X	X	X	X	X	X	X	X	3	Notified	
Flurenol				X							X	X		X		3	Notified	
Flurochloridone				X					X	X	X	X	X	X	X	3	Notified	
Flurprimidole	X	X	X				X		X	X	X					3	Notified	
Flutolanil	X					X	X				X	X				3	Notified	
Flutriafol				X	X		X	X	X	X	X	X		X	X	3	Notified	
tau-Fluvalinate	X	X	X		X		X	X		X	X	X		X	X	3	Notified	
Fuberidazole		X	X	X	X	X	X	X	X	X						3	Notified	
Guazatine	X	X		X	X	X	X	X	X	X		X		X	X	3	Notified	
Hexaconazole							X				X	X	X	X	X	3	Notified	
Hexaflumuron											X	X	X	X	X	3	Notified	
Hexythiazox	X	X	X			X	X	X		X	X	X		X	X	3	Notified	
8-Hydroxyquinoline							X		X	X	X	X		X		3	Notified	
Hymexazol	X	X	X	X	X	X	X		X	X	X	X			X	3	Notified	
Imazamethabenz				X	X		X	X		X	X	X	X	X	X	3	Notified	
Imazaquin				X	X		X	X			X					3	Notified	
Imazethapyr				X			X					X		X		3	Notified	
Imidacloprid	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	3	Notified	
Isoxaben	X	X	X	X	X		X	X	X		X	X	X	X		3	Notified	
Kasugamycin						X						X			X	3	Notified	
Lenacil				X	X		X	X		X	X	X	X	X	X	3	Notified	
Lufenuron											X	X	X	X	X	3	Notified	
Magnesium phosphide			X	X	X	X	X	X	X	X	X	X	X	X	X	3	Notified	
Mefluidide				X	X					X	X	X				3	Notified	
Mepiquat	X	X	X	X	X		X	X		X	X	X			X	3	Notified	
Metaldehyde				X	X	X	X	X	X	X	X	X	X	X	X	3	Notified	
Metam				X	X	X	X		X		X	X	X	X	X	3	Notified	
Metamitron	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	3	Notified	
Metazachlor	X	X		X	X	X	X	X	X	X	X	X		X		3	Notified	
Methabenzthiazuron	X	X	X	X	X		X	X		X	X	X		X		3	Notified	

Active substance	FI	S	DK	IR	UK	NL	B	L	D	AU	F	ES	P	I	EL	List	Status	Remark
Methyl bromide		X		X	X	X	X		X	X	X	X	X	X	X	3	Notified	
Metosulam					X		X	X	X	X	X			X	X	3	Notified	
Monocarbamide dihydrogen-sulphate												X				3	Notified	
Myclobutanil				X	X	X	X		X	X	X	X	X	X	X	3	Notified	
Napropamide			X	X	X		X		X	X	X	X		X	X	3	Notified	
Nicosulfuron						X	X		X	X	X	X	X	X	X	3	Notified	
Nuarimol				X	X		X		X		X	X	X	X		3	Notified	
Oryzalin				X							X	X				3	Notified	
Oxadiazon				X	X		X	X			X	X	X	X	X	3	Notified	
Oxyfluorfen				X						X	X	X	X	X	X	3	Notified	
Paclobutrazol			X	X	X	X	X				X	X				3	Notified	
Penconazole	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	3	Notified	
Pencycuron			X	X	X	X	X	X	X		X	X		X		3	Notified	
Picloram				X	X					X	X	X		X		3	Notified	
Polyoxin												X				3	Notified	
Pretilachlor											X			X	X	3	Notified	
Primisulfuron	X								X	X				X	X	3	Notified	
Prochloraz	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	3	Notified	
Propachlor				X	X	X	X	X			X	X		X	X	3	Notified	
Propanil											X	X	X	X	X	3	Notified	
Propaquizafop	X		X	X	X		X	X	X	X	X	X		X	X	3	Notified	
Propargite										X	X	X	X	X	X	3	Notified	
Prosulfocarb		X	X			X	X	X	X	X	X	X		X		3	Notified	
Pyridaben						X	X				X	X	X	X	X	3	Notified	
Pyriproxyfen			X			X	X				X	X			X	3	Notified	
Quinclorac											X	X	X	X	X	3	Notified	
Quinoclamine		X							X							3	Notified	
Quinmerac		X			X		X	X	X	X	X	X				3	Notified	
Quizalofop-P	X			X	X	X	X		X	X		X		X	X	3	Notified	
Sintofen											X					3	Notified	
Sodium dimethylarsinate																3	Notified	
Sodium o-nitrophenolate															X	3	Notified	
Sodium p-nitrophenolate															X	3	Notified	
Sodium 5-nitroguaiacolate															X	3	Notified	
Sodium-tetrathiocarbonate											X	X				3	Notified	
Streptomycine						X	X		X						X	3	Notified	
Sulcotrione						X	X	X	X		X	X	X	X	X	3	Notified	
Tebuconazole			X	X	X	X	X	X	X	X	X	X	X	X	X	3	Notified	
Tebufenozide							X		X		X	X	X	X	X	3	Notified	
Tebufenpyrad					X	X	X	X	X		X	X	X	X	X	3	Notified	
Teflubenzuron			X		X	X	X		X		X	X	X	X	X	3	Notified	
Tefluthrin		X	X		X		X		X		X	X	X	X		3	Notified	
Terbuthylazine	X	X	X	X	X	X	X		X	X	X	X	X	X	X	3	Notified	
Tetraconazole					X		X				X	X	X	X	X	3	Notified	
Tetradifon		X	X	X	X	X	X			X	X	X	X	X	X	3	Notified	
Thidiazuron												X		X	X	3	Notified	
Thiobencarb												X	X	X	X	3	Notified	
Tralkoxydim	X			X	X						X	X	X	X	X	3	Notified	
Triadimefon	X	X		X	X		X	X	X	X	X	X	X	X	X	3	Notified	
Triadimenol	X			X	X	X	X	X	X	X	X	X		X	X	3	Notified	
Tri-allate				X	X	X	X	X	X	X	X	X			X	3	Notified	
Triazoxide					X		X	X	X		X					3	Notified	
Tricyclazole												X	X	X		3	Notified	
Tridemorph				X	X		X		X	X	X	X		X	X	3	Notified	
Triflumizole						X	X			X		X				3	Notified	
Triflumuron										X	X	X	X	X	X	3	Notified	
Triflusulfuron	X	X	X	X	X	X	X		X	X	X	X		X	X	3	Notified	
Acifluorfen											X			X		3	Out 7/03	
Aldimorph																3	Out 7/03	
Alkyldimethylbenzyl ammonium chloride				X		X										3	Out 7/03	
Alkyldimethylethylbenzyl-ammonium chloride						X										3	Out 7/03	
Alkyltrimethyl ammonium Cl						X										3	Out 7/03	

Active substance	FI	S	DK	IR	UK	NL	B	L	D	AU	F	ES	P	I	EL	List	Status	Remark
Alkyltrimethylbenzyl ammonium chloride																3	Out 7/03	
Allethrin																3	Out 7/03	
Alloxydim				X						X		X		X		3	Out 7/03	
Allyl alcohol										X				X		3	Out 7/03	
Ametryn											X	X		X		3	Out 7/03	
2-Aminobutane				X	X											3	Out 7/03	
Ancymidol												X				3	Out 7/03	
Anilazine				X						X	X	X		X		3	Out 7/03	
Anthracene oil					X						X					3	Out 7/03	
Azaconazol			X		X	X	X	X	X		X	X				3	Out 7/03	
Aziprotryne					X											3	Out 7/03	
Barium fluosilicate												X				3	Out 7/03	
Barium polysulphide												X		X		3	Out 7/03	
Benazolin		X		X	X					X		X				3	Out 7/03	
Benfuresate												X				3	Out 7/03	
Benodanil				X	X											3	Out 7/03	
Bensulide												X			X	3	Out 7/03	
Bensultap			X								X			X		3	Out 7/03	
Bentaluron										X						3	Out 7/03	
Benzalkonium chloride				X	X											3	Out 7/03	
Benzoximate											X	X		X	X	3	Out 7/03	
Benzoylprop														X		3	Out 7/03	
Benzthiazuron														X		3	Out 7/03	
2-Benzyl-4-chlorophenol				X							X					3	Out 7/03	
Bioallethrin		X	X	X	X	X	X			X						3	Out 7/03	
Bioresmethrin			X								X	X			X	3	Out 7/03	
Brandol														X		3	Out 7/03	
Bromacil				X	X		X	X		X	X	X	X	X	X	3	Out 7/03	
Bromofenoxim										X		X		X		3	Out 7/03	
Bromopropylate							X	X		X	X	X		X	X	3	Out 7/03	
Burgundy mixture																3	Out 7/03	
Butachlor												X			X	3	Out 7/03	
Butylate												X		X		3	Out 7/03	
Calcium cyanamide																3	Out 7/03	
Carbon disulfide																3	Out 7/03	
Cartap														X		3	Out 7/03	
Cetrimide				X												3	Out 7/03	
Chinomethionat	X				X				X	X	X	X		X	X	3	Out 7/03	
Chlomethoxyfen																3	Out 7/03	
Chloramben																3	Out 7/03	
Chlorbromuron				X						X						3	Out 7/03	
Chlorbufam														X		3	Out 7/03	
Chloretazate											X					3	Out 7/03	
Chlorfenson														X		3	Out 7/03	
Chlorfluazuron												X				3	Out 7/03	
Chlorhydrate of poly-iminino-imidobiguanidine																3	Out 7/03	
4-Chloro-3-methylphenol				X												3	Out 7/03	
Chloropropylate																3	Out 7/03	
Chlorphonium chloride					X						X					3	Out 7/03	
Chlorthiamid							X				X	X		X		3	Out 7/03	
4-Chlorophenoxyacetic acid												X			X	3	Out 7/03	
Cufraneb															X	3	Out 7/03	
Cycloate							X			X	X	X		X		3	Out 7/03	
Cycluron														X		3	Out 7/03	
Cyprofuram																3	Out 7/03	
Dalapon				X							X			X		3	Out 7/03	
Desmetryne				X	X					X		X		X	X	3	Out 7/03	
Diafenthiuron														X	X	3	Out 7/03	
Difenzoquat	X			X	X					X	X	X		X	X	3	Out 7/03	
Diammonium phosphate												X				3	Out 7/03	
Dichlofluanid				X	X				X	X	X	X	X	X	X	3	Out 7/03	
Dichlone																3	Out 7/03	
Diclobutrazol										X	X	X		X		3	Out 7/03	

Active substance	FI	S	DK	IR	UK	NL	B	L	D	AU	F	ES	P	I	EL	List	Status	Remark
Dicyclopentadiene										X						3	Out 7/03	
Didecyl-dimethyl ammonium Cl						X	X		X			X				3	Out 7/03	
Dienochlor						X	X				X	X				3	Out 7/03	
Diethatyl (-ethyl)																3	Out 7/03	
Dikegulac				X	X		X		X		X					3	Out 7/03	
Dimefuron				X			X	X	X	X	X					3	Out 7/03	
Dimepiperate												X	X	X		3	Out 7/03	
Di-l-p-menthene				X								X			X	3	Out 7/03	
Dimethirimol												X				3	Out 7/03	
Dimexano																3	Out 7/03	
Dinitramine												X		X	X	3	Out 7/03	
Dinobuton												X			X	3	Out 7/03	
Dioctyldimethyl ammonium Cl																3	Out 7/03	
Diphenamid				X						X	X	X		X		3	Out 7/03	
1,3-Diphenyl urea																3	Out 7/03	
Drazoxolon				X												3	Out 7/03	
Endothal												X		X		3	Out 7/03	
δ-endotoxin *of B. thuringiensis*						X				X	X	X				3	Out 7/03	
EPTC										X	X	X	X	X	X	3	Out 7/03	
Etacelasil														X		3	Out 7/03	
Ethidimuron											X	X	X	X		3	Out 7/03	
Ethirimol				X	X						X	X			X	3	Out 7/03	
Fenaminosulf																3	Out 7/03	
Fenazaflor														X		3	Out 7/03	
Fenfuram				X					X		X					3	Out 7/03	
Fenoprop				X												3	Out 7/03	
Fenothiocarb												X		X		3	Out 7/03	
Fenoxaprop				X				X		X	X	X		X	X	3	Out 7/03	
Fenpiclonil	X	X		X	X			X	X	X	X					3	Out 7/03	
Fenpropathrin		X	X	X	X		X		X	X	X	X	X	X	X	3	Out 7/03	
Fenridazon																3	Out 7/03	
Fenson														X		3	Out 7/03	
Fenthiosulf												X				3	Out 7/03	
Fenuron				X	X											3	Out 7/03	
Flamprop	X									X	X	X	X	X		3	Out 7/03	
Fluazifop								X			X	X	X	X		3	Out 7/03	
Flubenzimine												X				3	Out 7/03	
Flucycloxuron						X	X							X		3	Out 7/03	
Flucythrinate												X	X	X		3	Out 7/03	
Flumequine																3	Out 7/03	
Flumethralin												X	X	X	X	3	Out 7/03	
Fluoroglycofene					X	X	X	X	X	X	X					3	Out 7/03	
Flupoxam											X					3	Out 7/03	
Fluridone											X					3	Out 7/03	
Fomesafen					X						X	X		X		3	Out 7/03	
Fosamine				X	X					X	X			X		3	Out 7/03	
Fosthietan																3	Out 7/03	
Furalaxyl				X	X					X	X			X		3	Out 7/03	
Furconazole																3	Out 7/03	
Furmecyclox																3	Out 7/03	
Gentian violet												X				3	Out 7/03	
Glutaraldehyde							X									3	Out 7/03	
Halfenprox											X				X	3	Out 7/03	
Hexachlorophene															X	3	Out 7/03	
Hexazinone				X						X	X	X		X		3	Out 7/03	
Hydramethylnon		X									X					3	Out 7/03	
Hydroxy-MCPA												X				3	Out 7/03	
Hydroxyphenyl-salicylamide					X							X				3	Out 7/03	
Imazapyr	X	X		X	X		X	X		X	X	X	X	X	X	3	Out 7/03	
Imazethabenz														X		3	Out 7/03	
Iminoctadine															X	3	Out 7/03	
Isolan																3	Out 7/03	
Isopropalin														X		3	Out 7/03	
Isoprothiolane												X				3	Out 7/03	
Karbutilate										X						3	Out 7/03	

Active substance	FI	S	DK	IR	UK	NL	B	L	D	AU	F	ES	P	I	EL	List	Status	Remark
Kinoprene																3	Out 7/03	
Lauryldimethylbenzyl ammonium bromide																3	Out 7/03	
Lauryldimethylbenzyl ammonium chloride							X									3	Out 7/03	
Mancopper											X					3	Out 7/03	
Mefenacet												X	X			3	Out 7/03	
Mepronil							X	X		X	X					3	Out 7/03	
Merphos																3	Out 7/03	
Methacrifos																3	Out 7/03	
Methazole				X												3	Out 7/03	
Methfuroxam										X						3	Out 7/03	
Methoprene				X	X						X	X		X		3	Out 7/03	
Methoprothryne														X		3	Out 7/03	
Methylenebisthiocyanate												X				3	Out 7/03	
Methyl naphthylacetamide																3	Out 7/03	
Methylnaphthylacetic acid																3	Out 7/03	
Methylisothiocyanate														X		3	Out 7/03	
Metobromuron				X			X	X	X	X	X	X	X	X	X	3	Out 7/03	
Metoxuron				X	X	X	X	X			X	X		X		3	Out 7/03	
Metsulfovax												X				3	Out 7/03	
Monalide										X	X					3	Out 7/03	
Monuron																3	Out 7/03	
MSMA (methyl arsonic acid)												X				3	Out 7/03	
Nabam												X				3	Out 7/03	
Naptalam											X	X		X	X	3	Out 7/03	
Neburon														X		3	Out 7/03	
Nitralin											X					3	Out 7/03	
Nitrothal				X			X			X		X		X		3	Out 7/03	
Nonylphenol ether polyoxyethylene glycol												X	X	X	X	3	Out 7/03	
Nonylphenol ethoxylate				X												3	Out 7/03	
Norflurazon											X	X				3	Out 7/03	
Octhilinone				X	X											3	Out 7/03	
Octyldecyldimethyl ammonium Cl																3	Out 7/03	
Ofurace				X	X		X	X			X	X	X		X	3	Out 7/03	
Orbencarb										X						3	Out 7/03	
Oxadixyl				X	X		X			X	X	X	X	X	X	3	Out 7/03	
Oxine-copper											X	X		X	X	3	Out 7/03	
Oxycarboxin				X	X					X	X	X		X	X	3	Out 7/03	
Oxytetracycline															X	3	Out 7/03	
Paraformaldehyde				X							X					3	Out 7/03	
Pebulate												X			X	3	Out 7/03	
Pentanochlor				X	X											3	Out 7/03	
Perfluidone														X		3	Out 7/03	
Phenols				X												3	Out 7/03	
Phenothrin					X	X		X				X				3	Out 7/03	
Phenthoate												X		X	X	3	Out 7/03	
Phosametine											X					3	Out 7/03	
Propyl-3-t-butylphenoxy-acetate				X												3	Out 7/03	
Pyrazoxyfen														X		3	Out 7/03	
Pyrifenox					X		X			X	X	X		X	X	3	Out 7/03	
Pyroquilone												X				3	Out 7/03	
Quizalofop					X					X	X	X	X	X	X	3	Out 7/03	
Resmethrin				X	X											3	Out 7/03	
Secbumeton												X		X		3	Out 7/03	
Seconal					X											3	Out 7/03	
Sethoxydim	X	X		X	X		X	X		X	X	X	X	X	X	3	Out 7/03	
Siduron											X					3	Out 7/03	
Silver nitrate						X										3	Out 7/03	
Sodium p-t-amylphenate											X					3	Out 7/03	
Sodium p-t-amylphenoxide				X												3	Out 7/03	
Sodium arsenite											X	X	X			3	Out 7/03	
Sodium o-benzyl-p-chlorphenoxide				X												3	Out 7/03	
Sodium dichlorophenate																3	Out 7/03	

Active substance	FI	S	DK	IR	UK	NL	B	L	D	AU	F	ES	P	I	EL	List	Status	Remark
Sodium dioctyl sulfosuccinate												X				3	Out 7/03	
Sodium fluosilicate												X				3	Out 7/03	
Sodium hypochlorite					X	X						X				3	Out 7/03	
Sodium lauryl sulfate																3	Out 7/03	
Sodium monochloroacetate				X	X											3	Out 7/03	
Sodium pentaborate												X				3	Out 7/03	
Sodium silver thiosulphate			X		X	X	X				X					3	Out 7/03	
Sodium tetrathiocarbamate											X					3	Out 7/03	
Sodium thiocyanate							X				X				X	3	Out 7/03	
Sodium-p-toluene-sulfonchloramid						X										3	Out 7/03	
Tar acids				X	X											3	Out 7/03	
Tar oils				X	X		X					X				3	Out 7/03	
2,3,6-TBA					X									X		3	Out 7/03	
TCA				X										X		3	Out 7/03	
TCMTB						X						X				3	Out 7/03	
Tebutam				X	X						X				X	3	Out 7/03	
Tebuthiuron				X												3	Out 7/03	
Terbacil				X	X						X	X			X	3	Out 7/03	
Terbumeton										X		X		X		3	Out 7/03	
Tetramethrin				X	X	X		X				X				3	Out 7/03	
Tetrasul																3	Out 7/03	
Thiazafluron											X	X		X		3	Out 7/03	
Thiazopyr												X				3	Out 7/03	
Thiocyclam												X			X	3	Out 7/03	
Thiophanate				X							X					3	Out 7/03	
Tiocarbazil												X		X		3	Out 7/03	
Tolylphtalam												X				3	Out 7/03	
Tralomethrin											X	X		X		3	Out 7/03	
Triapenthenol											X					3	Out 7/03	
Triazbutyl																3	Out 7/03	
Tribufos												X			X	3	Out 7/03	
Tributyltinoxyde																3	Out 7/03	
Tridiphane														X		3	Out 7/03	
Trietazine				X	X											3	Out 7/03	
Trifenmorph														X		3	Out 7/03	
Triforine	X		X	X	X	X	X			X	X	X		X	X	3	Out 7/03	
Trioxymethylen																3	Out 7/03	
Validamycin						X										3	Out 7/03	
Vernolate											X	X				3	Out 7/03	
Ethoxyquin											X	X	X	X		4		food add.
Acetic acid		X									X					4		food add.
Ammonium carbonate				X												4		food add.
Ammonium hydroxide				X												4		food add.
Ammonium sulphate				X							X					4		food add.
Boric acid					X	X						X				4		food add.
Cystein																4	Out ?	food add.
Decanoic acid				X	X		X									4		food add.
Ethylhexanoate																4	Out ?	food add.
Ethyloleate															X	4		food add.
Fatty acid esters				X	X	X	X									4		food add.
Fatty acid potassium salt	X	X	X	X	X	X	X	X	X	X		X			X	4		food add.
Formaldehyde				X	X	X	X									4		food add.
Formic acid						X					X					4		food add.
Lactic acid												X				4		food add.
Pelargonic acid							X									4		food add.
2-Phenylphenol				X								X				4		food add.
Phosphoric acid				X												4		food add.
Potassium sorbate																4	Out ?	food add.
Sodium hydrogen carbonate																4	Out ?	food add.
Sodium metabisulphite												X		X		4		food add.
Sodium propionate																4	Out ?	food add.
Sodium tetraborate						X										4		food add.
Urea					X										X	4		food add.
Aminoacids												X				4		food add.

Active substance	FI	S	DK	IR	UK	NL	B	L	D	AU	F	ES	P	I	EL	List	Status	Remark
Cholin chloride				X							X					4		food add.
Azadirachtin		X							X			X		X		4		pl. extract
6-benzyladenine			X				X				X	X	X	X		4		pl. extract
Chlorophylline																4	Out ?	pl. extract
Citronellol				X	X											4		pl. extract
Etheric oils of plant origin				X		X										4		pl. extract
Eucalyptus oil																4	Out ?	pl. extract
Folic acid				X								X				4		pl. extract
Garlic extract						X										4		pl. extract
Gibberellic acid				X		X	X				X	X	X	X	X	4		pl. extract
Gibberellin					X	X	X				X	X	X	X	X	4		pl. extract
Indolylbutyric acid				X	X	X	X		X	X	X	X	X		X	4		pl. extract
Indolylacetic acid					X	X	X		X			X	X			4		pl. extract
Lecithin	X					X		X	X							4		pl. extract
1-Naphthylacetamide						X	X			X	X	X	X	X		4		pl. extract
1-Naphthylacetic acid			X	X	X	X	X		X	X	X	X	X	X	X	4		pl. extract
Naphthylacetic acid ethylic ester																4	Out ?	pl. extract
2-Naphthyloxyacetamide												X				4		pl. extract
2-Naphthyloxyacetic acid				X	X		X					X		X	X	4		pl. extract
Nicotine	X			X	X							X			X	4		pl. extract
Onion extract						X										4		pl. extract
Pepper				X	X											4		pl. extract
Plant oils	X			X					X	X	X	X				4		pl. extract
Pyrethrins	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	4		pl. extract
Quassia				X						X						4		pl. extract
Rotenone			X	X	X						X	X		X		4		pl. extract
Scilliroside											X	X		X		4		pl. extract
Sea-algae extract						X	X					X				4		pl. extract
Seaweed						X										4		pl. extract
Soybean extract						X										4		pl. extract
Soybean oil, epoxylated			X								X	X				4		pl. extract
cis-Zeatin													X			4		pl. extract
Daphne oil	X								X	X		X				4		pl. extract
Papaine																4	Out ?	pl. extract
Gelatine			X													4		animal prod
Hydrolysed proteins											X	X	X	X	X	4		animal prod
Acridinic bases										X						4		organic
Aluminium ammonium sulfate				X	X						X					4		organic
Anthraquinone				X			X	X	X	X	X	X		X		4		organic
Barium nitrate																4	Out ?	organic
Calcium carbide								X	X							4		organic
p-Cresyl acetate													X			4		organic
5-Decen-1-ol												X			X	4		organic
5-Decen-1-yl acetate												X			X	4		organic
Denathonium benzoate				X												4		organic
3,7-Dimethyl-2,6-octadienal												X				4		organic
3,7-Dimethyl-2,6-octadien-1-ol												X			X	4		organic
1,7-Dioxaspiro-5,5-undecan												X				4		organic
(4Z-9Z)-7,9-Dodecadien-1-ol												X			X	4		organic
8,10-Dodecadien-1-ol						X			X	X		X			X	4		organic
(E)7-(Z)9-Dodecadienyl acetate									X			X				4		organic
(Z)-8-Dodecenol											X					4		organic
(Z)-5-Dodecen-1-yl acetate												X				4		organic
(Z)-8-Dodecenyl acetate											X	X			X	4		organic
(E/Z)-8-Dodecenyl acetate											X					4		organic
(Z)-9-Dodecenyl acetate								X	X	X		X				4		organic
(E)-10-Dodecenyl acetate												X			X	4		organic
trans-9-Dodecyl acetate												X				4		organic
Dodecyl alcohol															X	4		organic
7,8-Epoxi-2-methyl-octadecane																4	Out ?	organic
Farnesol						X						X			X	4		organic
cis-7,trans-11-Hexadecadienyl acetate												X				4		organic
(Z)-11-Hexadecanole												X			X	4		organic

Active substance	FI	S	DK	IR	UK	NL	B	L	D	AU	F	ES	P	I	EL	List	Status	Remark
Z-9-Hexadecenal												X			X	4		organic
(7Z-11Z)-7,11-Hexadien-1-yl-acetate												X			X	4		organic
(Z)-3-Methyl-6-isopropenyl-3,4-decadien-1-yl															X	4		organic
(Z)-3-Methyl-6-isopropenyl--9-decen-1-yl acetate												X			X	4		organic
7-Methyl-3-methylene-7-octene-1-yl-propionate															X	4		organic
Methyl-trans-6-nonenoate																4	Out ?	organic
Methyl nonyl ketone					X											4		organic
Naphtalene				X	X											4		organic
(Z,Z) Octadienyl acetate												X				4		organic
(Z)-13-Octadecanole												X				4		organic
Oxyquinoleine											X					4		organic
Pherodim																4	Out ?	organic
Pronumone												X				4		organic
Sebacic acid																4	Out ?	organic
Serricornin															X	4		organic
(Z,E)-11-Tetradecadien-1-yl acetate												X				4		organic
(Z)-7-Tetradecanole												X				4		organic
(Z)-7-Tetradecenal												X			X	4		organic
(Z)-9-Tetradecenyl acetate												X				4		organic
(E)-11-Tetradecenyl acetate												X				4		organic
Z-9-Tricosene		X			X			X				X				4		organic
(4E-7Z)-4,7-Tridecadien-1-yl-acetate												X			X	4		organic
Trimedlure												X			X	4		organic
(Z)-11-Tetradecen-1-yl-acetate									X							4		organic
Arsenic anhydride													X			4		rodenticide
Brodifacoum	X	X	X	X	X		X		X		X	X	X		X	4		rodenticide
Bromadiolone	X	X	X	X	X	X	X	X	X		X	X	X	X	X	4		rodenticide
Bromethalin				X												4		rodenticide
Calciferol				X	X						X					4		rodenticide
Calcium phosphate																4	Out ?	rodenticide
Chloralose			X	X	X						X					4		rodenticide
Chlorophacinone				X	X	X	X	X	X	X	X	X		X	X	4		rodenticide
Cholecalciferol		X									X					4		rodenticide
Coumachlor											X	X		X	X	4		rodenticide
Coumafuryl										X						4		rodenticide
Coumatetralyl	X	X		X	X		X	X	X		X	X	X	X	X	4		rodenticide
Crimidine											X					4		rodenticide
Cyanides				X	X			X	X			X				4		rodenticide
p-Dichlorobenzene																4	Out ?	rodenticide
Difenacoum	X	X	X	X	X		X	X	X		X	X	X		X	4		rodenticide
Difethialone	X		X				X		X	X	X	X			X	4		rodenticide
Diphacinone				X	X						X	X			X	4		rodenticide
Ethanethiol											X					4		rodenticide
Flocumafen		X	X	X	X		X	X	X	X		X	X		X	4		rodenticide
Fluoroacetamide															X	4		rodenticide
Hydrogen phosphide									X							4		rodenticide
Isoval				X												4		rodenticide
Pyranocumarin																4	Out ?	rodenticide
Strychnine					X											4		rodenticide
Thallium sulphate														X		4		rodenticide
Thiourea											X					4		rodenticide
Tricalcium phosphate																4	Out ?	rodenticide
Zinc phosphide				X	X			X	X					X	X	4		rodenticide
Kieselguhr			X						X							4		storage
Aluminium sulphate				X	X		X							X		4		commodity
Calcium chloride						X					X	X				4		commodity
Calcium oxide						X										4		commodity
Calcium hydroxide						X										4		commodity
Carbon dioxide					X	X			X							4		commodity

Active substance	FI	S	DK	IR	UK	NL	B	L	D	AU	F	ES	P	I	EL	List	Status	Remark
1-Decanol											X	X		X	X	4		commodity
(Disodium)-EDTA salts																4	Out ?	commodity
Ethanol																4	Out ?	commodity
Fatty alcohols												X	X	X		4		commodity
Iron disodium EDTA							X	X								4		commodity
Iron-II-sulphate		X	X	X	X	X	X	X	X	X	X		X			4		commodity
Iron-III-sulphate									X		X					4		commodity
Lime phosphate																4	Out ?	commodity
Lime sulphur												X				4		commodity
Nitrogen									X							4		commodity
trans-6-Nonen-1-ol																4	Out ?	commodity
Paraffin oil	X		X		X	X	X	X	X	X	X	X	X	X	X	4		commodity
Petroleum oils						X			X		X	X	X	X	X	4		commodity
Potassium permanganate				X								X				4		commodity
Propionic acid				X						X	X	X				4		commodity
Silicates (Na and K)						X										4		commodity
Sodium chloride					X	X					X					4		commodity
Sodium hydroxide																4	Out ?	commodity
Sulphur		X	X	X	X	X	X	X	X	X	X	X	X	X	X	4		commodity
Sulphuric acid					X	X										4		commodity
Wax						X						X			X	4		commodity
Bitumen				X						X		X				3	Out 7/03	
Bone Oil				X	X		X				X					4		animal prod
Calcium carbonate						X										4		commodity
Grease				X						X						4		commodity
Quartz sand							X			X	X					4		organic
Repellents of animal/plant origin		X	X		X		X	X	X	X	X		X			4		pl. extract
Resins and polymers	X						X		X	X	X		X		X	4		commodity
Rock powder				X		X										4		commodity
Waxes				X		X			X	X	X		X		X	4		commodity
Aschersonia aleyrodis																4	Out ?	microbial
Agrotis segetum granulosis virus			X													4		microbial
Bacillus sphaericus											X					4		microbial
Bacillus thuringiensis	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	4		microbial
Beauveria bassiana			X								X	X			X	4		microbial
Cydia pomonella granulosis virus						X	X		X		X	X		X	X	4		microbial
Mamestra brassica nuclear polyhedrosis virus											X					4		microbial
Metarhizium anisopliae									X	X						4		microbial
Neodiprion sertifer nuclear polyhedrosis virus	X			X												4		microbial
Phlebiopsis gigantea	X	X	X		X											4		microbial
Streptomyces griseoviridis	X	X	X			X						X				4		microbial
Tomato mosaic virus																4	Out ?	microbial
Trichoderma harzianum		X	X											X	X	4		microbial
Trichoderma polysporum		X	X													4		microbial
Trichoderma viride		X	X													4		microbial
Verticillium dahliae Kleb.						X										4		microbial
Verticillium lecanii	X	X	X	X	X	X										4		microbial

14. ABBREVIATIONS

ACP African, Caribbean and Pacific countries
ADI Acceptable daily intake
ARfD Acute reference dose
BAT Best available technique
BBA Biologische Bundesanstalt für Land- und Forstwirtschaft
BEP Best environmental practice
BSE Bovine spongiform encephalitis
CAP Common agricultural policy
CADDY Computer-aided Dossier Design and Supply

CCPR	Codex committee on pesticide residues
CIPAC	Collaborative International Pesticides Analytical Council
CIRCA	Communication and administration resource centre administrator
COPA	Committee of agricultural organisations in the EU
DAR	Draft Assessment Report
DG	Directorate-General
ECCA	European Crop Care Association
ECCO	European Commission Coordination
ECPA	European Crop Protection Association
EFA	European Food Authority
EPPO	European Plant Protection Organisation
EURO-POEM	Predictive operator exposure model
FAO	Food and Agricultural Organisation of the United Nations
FOCUS	Forum for the co-ordination of pesticide fate models and their use
GMM	Genetically-modified microorganism
GPP	Good Plant Protection Practice
IDA	Interchange of data between administrations
ISO	International Standards Organisation
IUCLID	International uniform chemicals information database
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on Pesticides Residues of FAO and WHO
MRL	Maximum level of pesticide residue
MS	EU Member State
NAFTA	North American Free Trade Association
NOAEL	No observed adverse effects level
OECD	Organisation for economic cooperation and development
PIC	Prior informed consent
POP	Persistent organic pollutant
PPP	Plant protection product
PSD	Pesticides Safety Directorate (UK)
RMS	Rapporteur Member State
SCP	Scientific Committee on Plants
SCPH	Standing Committee on Plant Health
SETAC	Society for environmental toxicology and chemistry
SME	Small-to-medium sized enterprise
SPS	Sanitary and phytosanitary system (notification system in WTO)
TAIEX	Technical assistance for information exchange
TAPAS	Technical Action Plan for improving Agricultural Statistics
TBT	Technical Barriers to Trade (notification system in WTO)
UNEP	United Nations Environment Programme
WHO	World Health Organisation of the United Nations
WTO	World Trade Organisation