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E1 - Plant Health: Plant Protection Products Sector

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OVERVIEW OF THE STATE OF MAIN WORKS IN DG HEALTH AND CONSUMER PROTECTION E.1 WITH REGARD TO THE IMPLEMENTATION OF DIRECTIVE 91/414/EEC

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1. GENERAL MEASURES AND ACTIONS

A report on the state of the implementation of the Directive for existing active substances was adopted by the Commission on 25.7.01 and communicated to the Parliament and the Council (COM/2001/444-final). Complementing the report is a Technical Annex (doc. SANCO/822/2001 rev. 3) which is available on the Internet site (doc. SANCO/2692/2001 at http://europa.eu.int/comm/food/fs/ph_ps/pro/index_en.htm) of DG Health and Consumer Protection. The report was discussed by the Agriculture and the Environment Councils and conclusions were adopted on 12.12.01. It was discussed by the Agriculture and Rural Development Committee as well the Environment, Public Health and Consumer Protection Committee in the European Parliament and a resolution was voted in plenary on 30.5.02. As a follow-up, the Commission intends firstly to prepare a formal reply and secondly to bring forward proposals to amend the Directive in 2003.

In February 2002, the role of the Standing Committee on Plant Health (SCPH) in the regulatory process was taken over by the Standing Committee on the Food Chain & Animal Health (SCFA).

Lists of legislative measures adopted are given in Annex V to this document. Copies of these measures and of other documents cited in this document are available either on the Internet or on request.

Details of measures and actions for individual new active substances are included in Annexes IIA and IIB to this document. Details on progress of work on existing active substances covered by the 1st stage of the review programme are included in Annexes IIIA and IIIB to this document. Details on progress of work on active substances covered by the 2nd stage are included in Annex IV to this document. Details of work on the 3rd and 4th stages will be annexed to this document when it has progressed to a sufficient level of detail.

During 2003, the work of the Scientific Committee on Plants (SCP) was taken over by a newly established Scientific Panel in the European Food Safety Authority (EFSA) which was in turn established in 2002 by Regulation (EC) N° 178/2002. It is envisaged that in the future, the risk assessment component of 91/414/EEC will be taken over by the EFSA and that the risk management aspects be handled by the Commission. This requires gradual adoption of implementing legislation to change procedures etc.

2. ANNEXES TO THE DIRECTIVE - STATUS/COMPLETION

2.1. Annex I of the Directive - inclusion of active substances

2.1.1. Guidelines for preparation of dossiers by applicants

Doc. 1663/VI/94 Rev. 8 of 22.4.98 is the latest revision, which was finalised in the SCPH of 21-22.4.98. This version also includes the forms for the initial checking of dossiers submitted in support of applications relating to the proposed inclusion of active substances in Annex I. It is suggested that notifiers be requested to complete the document and that the completed document be checked by the Rapporteur Member State (RMS). To allow notifiers to include all the necessary detail in the completeness check, the text is available on the Internet. Meanwhile the OECD finalised discussions on a generic version in the Pesticide Forum of February 1998. A guidance document with instructions for industry on formats for dossier submission (SANCO/3989/2001) was noted by the SCPH on 7.12.01.

2.1.2. Guidelines for preparation of monographs by rapporteur MS

Doc. 1654/VI/94 rev. 7 of 22.4.98, finalised in the SCPH on 21-22.4.98, is the latest version. The OECD Pesticide Forum finalised discussions on a generic version in February 1998 and published it in 2001.

2.1.3. Guidelines/requirements for evaluation/decision-making for Annex I inclusion

Commission services envisaged further elaboration only after substantial progress had been made with the review of Annexes II and III. Member States (MS) were invited on 18.2.93 to examine the section of the 'Mark Lynch study' concerning the inclusion of active substances in Annex I (January 1993) and to send their comments to the Commission by July 1993. A general discussion took place in the Braunschweig seminar (see section 9.1 and also the "strategy paper", discussed for the first time on 15-16.10.98).

A first discussion on a follow-up study was organised in July 1999 with the consultant (Mr. Lynch). A further discussion in an expert group took place on 2-3.11.99. MS were invited to send suggestions concerning criteria for Annex I inclusion to Mr. Lynch at the latest on 3.12.99. A draft guidance document was made available to all MS by 10.1.00. Discussions took place on 18.1.00 (expert group) and 19.1.00 (all MS). The study was finalised at the end of February 2000. It was circulated and comments were invited in particular on the part concerning the criteria for Annex I inclusion. An expert group met on 14.4.00.

A guidance document was prepared after the meeting. Comments were made and a general discussion was held on 15-16.6.00. A small expert group discussed further open points on 20.10.00. After the meeting a new version was to be prepared and be made available by the beginning of January 2001. Comments were to be sent by mid-February 2001 and the document was to be discussed and forwarded to the SCPH at the end of February 2001. There were views expressed that under the Directive as it stands, the COM did not have the legal competence to introduce new requirements above and beyond those already in place. A further discussion took place with all MS on 26.4.01 and COM was to reflect on further progress with a view towards proposing amending the directive in 2003.

2.1.4. Guidelines on procedures for NEW active substances

To develop guidelines on the procedures provided for in Article 6 of the Directive (new active substances), a working document for guidance to MS was developed in the framework of the Legislation working group (doc. 1663/VI/95). A review to adapt this document to reflect experience was finalised (doc. 1663/VI/95 rev. 2 of 16.6.96) at working group level (see also "aide mémoire" in doc. 7860/VI/97). In June 2000, small amendments were made in the document to take account of the restructuring of the Commission Services. Guidance on the number of dossiers to be submitted to MS is included in the guidance document SANCO/3989/2001 (see also point 2.1.1). In March 1999, a proposal to modify the structure of doc. 1606 (contact points etc.) to take into account the introduction of CADDY CD-ROM dossiers was sent to the MS for comments. The structure of the document was modified in the summer of 1999.

In February 2000, the 50:50 initiative was launched to look at ways to accelerate decision-making for new active substances. The Commission also commenced an in-depth analysis of the evaluation process for new active substances. In April 2000 at a meeting of the 50:50 small expert group, the Commission presented the initial results of its analysis of the evaluation process for new active substances and identified clear bottlenecks in the process. A further detailed analysis took place over the following months. In June 2000, a working document was developed in the framework of the Legislation working group to provide guidance for the Co–rapporteur system and a draft was sent to the MS for comment. Analysis of the new active substance evaluation process was completed in November 2000. The Co-Rapporteur system seems to work quite well for new active substances and it is being more and more widely used.

2.1.5. Guidelines on procedures for EXISTING active substances

To develop guidelines detailing the procedures provided for in Regulation (EEC) N° 3600/92 (Articles 6 and 7) for existing active substances, an initial working document for guidance to MS, developed in the framework of the Legislation working group, was revised (1614/VI/95 rev. 7) and circulated to MS for finalisation in the working group meeting of 29-30.5.97. See also "aide mémoire" in document 7860/VI/97[1]. Guidance on the number of dossiers to be submitted to MS is included in the guidance document SANCO/3989/2001 (see also point 2.1.1).

2.2. Annexes II and III of the Directive - data requirements

This is in continuous progress and details are given in Annex I to this document. Detailed requirements for chemical plant protection products were established in 1997 and for microbials in 2001. A project was launched in October 2002 to adapt Annexes IIA and IIIA to technical progress. It is planned to complete this project before the end of 2003 for residues, physico-chemistry, ecotoxicology and toxicology. Requirements for environmental fate and behaviour may be completed at a later date. The impact of any changes on Annex VI will also need to be considered.

2.3. Annexes IV and V of the Directive - risk and safety phrases

Although classification and labelling of plant protection products is covered by the dangerous substances and preparations directives, Annexes IV and V of the Directive provide for additional specific phrases. Council adopted a common position on 18.5.98 covering plant protection products. DG III initiated a study in particular concerning labelling of plant protection products and rules for safety data sheets. Detailed information was given at the meeting of 16.12.97 and a questionnaire sent to MS in December 1997. Replies were expected at the latest on 14.2.98 and further information was given at the meeting of 21.4.98.

A project to consolidate Annexes IV and V started in April 2001. Draft texts for the Annexes were distributed for comments to MS in the Legislation working group on 6.12.01 as well as to the workgroup on classification and labelling at the European Chemicals Bureau for comments. In May 2002, the comments were incorporated into a revised version which was discussed by the 67/548/EEC expert group at the ECB in JRC Ispra in mid-2002 and again in the Legislation working group. On 15.4.03, the SCFA gave a unanimous favourable opinion of a draft Commission Proposal for a Directive establishing the Annexes.

2.4. Annex VI of the Directive- uniform principles for risk assessment

Council Directive 97/57/EC introduced uniform principles for the risk assessment of chemical plant protection products. The Commission is currently preparing a proposal for microorganisms used as ppps and early in 2002 requested an opinion from the Scientific Committee on Plants (SCP) on its scientific content. This opinion was issued in January 2003 and a Commission proposal to Council should be finalised in 2003.

3. SCOPE OF THE DIRECTIVE AND BORDERLINE CASES

3.1. Scope of the Directive

The original position on the scope of Dir. 91/414/EEC is recorded in doc. 9049/VI/93[1]. Doc. 6621/VI/99 gives an overview of products for which it was discussed whether they are to be considered as plant protection products. An expert group was organised on 22.3.00 to develop more precise guidance. A first draft concerning a definition of plant strengtheners was circulated for comments by 31.5.00 and on 18.10.00 a new version (SANCO/1003/2000 rev. 1) was distributed for comments (deadline 30.11.00).

3.2. Borderline with biocides

The Commission reviewed problems with experts on 24.1.96 and 24.9.96 and discussed them jointly (particularly borderlines with the new Biocides Directive) with plant protection product and biocides experts on 6.6.96. The current position on the borderline is contained in doc. Biocides/26/99 rev. 6 ("Borderline between Directive 98/8/EC concerning the placing on the market of biocidal products and Directive 91/414/EEC concerning the placing on the market of plant protection products").

4. ELECTRONIC EXCHANGE OF INFORMATION

4.1. Lists of authorised products (Article 12 - see also Section 5.2)

The two first subprojects (MRL-fixing programme and Active substances inclusion programme) have been finalised.

In December 1997 the Commission received the beta-test version of the sub-project for the electronic exchange of quarterly and annual reports (Article 12). MS received early in 1998 the specifications on how to prepare, structure and name messages to be sent to COM in the context of Article 12, explaining also the structure of the messages received from the COM. In summer 1998 beta-testing continued within the Commission with final testing done by October 1998. The Commission informatics services received contacts from IT, ES, PT, DE and AU. The AU authorities collaborated with the first testing of the message subsystem. In March 1999 the Commission held a bilateral meeting with an informatics representative from the BE authorities with a view to beginning the testing of the system. This was the first of a series of bilateral

[1] Outdated document

meetings which were planned between the Commission Services and the MS. Further follow-up took place in April that year with the DE and PT authorities.

An Article 12 small working group (AU, BE, DE, NL, PT and EPPO) met on 4.4.00 to discuss progress towards building the interfaces for extracting information from MS registration databases. AU reported good progress towards this goal. The issue of codification was discussed again with EPPO (responsible for the maintenance of the Bayer crop codification system). The Commission demonstrated the working of the Article 12 robot which will be used to process incoming message files from the MS.

4.2. Dossiers on CD-ROM.

The final version (Version 0.3 of February 1997) of the software specification for the retrieval software is available. It contains minor amendments over the previous version. The Joint EU/Industry/USA/Canada data transfer working group (DTWG) met on 24.11.97 to discuss the results of the beta-testing of the CADDY retrieval software in the development of which the Commission and the MS participated. The meeting marked the end of the developmental stage of CADDY I which was then made operational. The first dossiers on CD-ROM were expected in 1998. Information on the CADDY system can be found on the ECPA website under http://www.ecpa.be. The DTWG met on 21.9.98 to discuss progress in CADDY implementation. All MS had installed CADDY and the first experiences in working with CADDY were reported, as was the timetable for CADDY II.

Two preparatory meetings were held in Bad Homburg to prepare for the plenary meeting of the CADDY Steering Group in February 1999. MS were requested at the December 1998 evaluation group meeting to forward suggestions for improvements in CADDY functionality for evaluators to the Commission as soon as possible. In October 1999, the CADDY group met to discuss the future development of CADDY. ECPA informed the group that the software was now 32-bit compliant. The group decided to continue with functional improvements in the CADDY software to make the work of the evaluators easier. The group also took the orientation to develop the evaluation capacity of CADDY in the direction of XML. In spring 2000 ECPA visited the MS to confirm their requirements for evaluation tools and distributed a report to them in September that year.

In 2002, new functionalities were added to CADDY, permitting its use as an evaluators tool and facilitating workharing. This was discussed at an OECD workshop in Canada in October 2002 in the broader context of electronic tools for chemicals, biocides and agricultural chemicals. Training for Member State experts in CADDY II is foreseen for 2003.

4.3. Links

4.3.1. List of Community Internet sites for authorisations of plant protection products

Austria: http://www.bfl.at/

Sweden: http://www.kemi.se

Portugal: http://www.dgpc.min-agricultura.pt

Germany: http://www.bba.de

Ireland: http://www.pcs.agriculture.gov.ie

Italy: http://www.sanita.it/alimvet

The Netherlands: http://www.bib.wau.nl/gbk

Greece: http://www.minagric.gr/en/2.2.1.html

United Kingdom: http://www.pesticides.gov.uk

Belgium: http://fytoweb.fgov.be/

Spain: http://www.mapya.es/productosfitos/menuconsultas.htm

Finland: not yet available

France: http://www.agriculture.gouv.fr/alim/prot/e-phy.htm

Luxembourg: not yet available

Denmark: http://www.mst.dk/

DG Health and Consumer Protection: http://www.europa.eu.int/comm/food/fs/ph_ps/pro/index_en.htm

DG Environment: http://europa.eu.int/comm/environment/ppps/home.htm

EFSA: http://www.efsa.eu.int/

ECCO PSD: http://www.pesticides.gov.uk/process/ecco/ecco/index.htm

ECCO BBA: http://www.bba.de/english/bbaeng.htm

4.3.2. List of Community Internet sites for MRLs of pesticides (if different from above)

DG SANCO: http://www.europa.eu.int/comm/food/fs/ph_ps/pest/index_en.htm
UK: http://www.pesticides.gov.uk/legislation/MRLs_Legislation/mrl.htm
Germany: http://verbraucherministerium.de/verbraucher/lebensm-rueckstaende/index.htm
Denmark: http://www.fdir.dk/
Additional addresses for authorisations and MRLs will be inserted based on inputs received from MS.

4.3.3. List of other related Internet sites for pesticides

OECD: http://www.oecd.org

USEPA: http://www.epa.gov/

EPPO: http://eppo.org/

CIPAC: http://www.cipac.org

FAO/JMPR: http://www.fao.org/ag/agp/agpp/pesticid/jmpr/pm_jmpr.htm

Codex Alimentarius Commission: http://www.codexalimentarius.net/index_en.stm

WTO/SPS: http://www.wto.org/english/tratop_e/sps_e/sps_e.htm

WTO/TBT: http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm

IPPC: http://www.fao.org/waicent/faoinfo/agricult/agp/agpp/pq/default.htm

DG ENV (biocides): http://europa.eu.int/comm/environment/biocides/index.htm

ECB: http://ecb.jrc.it/

4.3.4. List of contact points for 91/414/EEC and residues legislation

A list of contact points for ppps and their residues is available at:
http://europa.eu.int/comm/food/fs/ph_ps/pro/contactpoints_adress0203.xls.

5. AUTHORISATIONS IN THE MEMBER STATES

5.1. Lists of active substances authorised

A complete listing of banned substances as well as a list of existing and new active substances authorised in each Member State is available in doc. 3010/VI/91 rev. aug2003 (using filter function) which is on the Internet. Authorisations of new active substances in the Member States are recorded in Annex IIB (4th column) to this document and in doc. 3010/VI/91.

5.2. Lists of products authorised (implementation of Article 12)

An information sheet for implementation of Article 12(1) was distributed to MS on 18.2.93. The common format for providing the information required under Article 12 was finalised at a workshop in Braunschweig on 22-24.6.94 (doc. 2949/VI/93 rev. 2[1]) where a model for the annual list (doc. 4709/VI/94 rev. 1[1]) was also accepted. An amended format was later discussed in the context of informatics-based information exchange. Consideration is now being given as to how the Internet could facilitate these notifications.

Table 1: Article 12 communications received by Commission

	1998	1999	2000	2001	2002					2003				
	ANNUAL				TRIMESTERS 1-4				ANNUAL	TRIMESTERS 1-4				ANNUAL
AU	**X**	**X**	**X**	**X**	**X**	**X**			**X**	**X**				
BE	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**				
DE	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**				
DK	**X**	**X**	**X**	**X**	**X**	**X**	**X**		**X**	**X**				
EL	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**					
ES	**O**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**				
FI	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**				
FR	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**					
IR	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**					
IT	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**					
LU	**X**	**X**	**X**	**X**					**X**					
NL	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**				
PT	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**				
SE	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**			
UK	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**				

The annual list should include all PPPs authorised by the MS at the time of its finalisation

5.3. Control measures (implementation of Article 17)

Possibilities for harmonising the presentation of the annual reports of MS were discussed and a working document, finalised in a working group on 6-7.2.97, is now in use.

Table 2: Reports received under Article 17

Year	BE	LU	NL	UK	IR	SW	FI	DK	DE	FR	PT	ES	IT	EL	AU
1994	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**O**	**X**	**X**	**X**	**X**	**X**	**X**
1995	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**O**	**X**	**X**
1996	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
1997	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
1998	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
1999	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
2000	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
2001	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**O**	**X**	**X**	**O**	**X**	**X**	**X**
2002	**X**	**X**	**X**	**O**	**O**	**X**	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**X**
2003	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**O**
Reports for 2002 should have been submitted by 1 August 2003															

5.4. Information on provisional authorisations (implementation of Article 8)

The Commission developed a form to be used for the communication to the other MS and the Commission of any provisional MRLs that were established at MS level. In October 1998, the Commission presented a draft of Annex IIC (to this document) which is intended to record information on the provisional authorisations requested and granted. The proposed Annex IIC was submitted also to the Residues working group for comments in March 1999. Currently such information is given in a highly condensed form in column 4 of Annex IIB to this document. The Commission invited Member States to use a new form, developed by ECCO. Member States shall inform ECCO BBA regularly on the applications for provisional authorizations and on provisional authorizations granted. ECCO will regularly update the list of provisional authorisations.

5.5. Trade in and use of plant protection products

The updating of MS information on national rules concerning trade in and use of plant protection products (presented in the Pieters Report, 1992) elicited responses from BE, DE, DK, EL, IR, IT, AU, FI, PT and UK.

5.6. Use of antibiotics as plant protection products

Following concerns about the general problem of anti-microbial resistance, the Commission has collected annually, since 1999, data on the use of antibiotics as plant protection products in the MS. Under Regulation 451/2000 and 1490/2002 notifications were made for streptomycin and kasugamycin. A complete data package was submitted for kasugamycin by 23.5.03 and a complete dossier is due by 23.11.03. The issue of resistance appears to have been addressed. Streptomycin will be withdrawn as no data was received.

6. REVIEW PROGRAMME FOR EXISTING ACTIVE SUBSTANCES

A list of existing active substances on the market on 25.7.93 and their current 91/414/EEC status is available on the Internet site (doc. 3010/VI/91 rev. mar2003). It also includes details of MRLs. The substances were prioritised into four groups for sequential evaluation.

6.1. 1st Stage

Regulations (EEC) N° 3600/92; 933/94, 491/95, 2230/95, 1199/97 and 1972/1999 lay out the detailed rules and procedures for the 1st stage of the programme covering 90 substances (see Annex V for references).

Because many monographs were not delivered within the agreed deadlines (see Annex IIIA for dates), DG VI sent to 12 MS on 8.6.98 a reminder with regard to the delivery of monographs for existing active substances as required under Article 7(2) of Regulation (EEC) N° 3600/92. The Commission was preparing the necessary steps towards infraction proceedings with regard to those MS that had not yet submitted their monographs. The situation has since been resolved. Final decisions should have been taken on all substances by the end of 2005.

6.2. 2nd Stage

Commission Regulation (EC) N° 451/2000 laying down the detailed rules for the implementation of the 2nd (148 substances) and 3rd (388 substances) stages of the review programme was adopted on 28.2.00.

The "ReNDeR Project" for notifications submitted under Article 10 of the Regulation defined the format for notifications and organised the examination of (pre-)notifications with regard to acceptability. All relevant documents and information are available on the web under http://www.bba.de/english/render.html. For reasons of security, data could not be submitted via the Internet and the database created by ReNDeR with the information was not accessible via the Internet. The format of the notification was submitted to MS at the meeting of the Legislation working group on 11.4.00. Some further amendments were made as a result of testing the format by industry and after further input given during training sessions for industry organised by ReNDeR on 23-25.5.00. The format was made available in mid-June 2000 on the ReNDeR website.

The list of notifications received for the 2nd stage is available on the Internet. Many were later withdrawn by notifiers. Regulation (EC) N° 703/2001 details the active substances, the RMS and the date for submission of the dossiers for the 2nd stage to Rapporteur MSs was 30.4.02. Complete dossiers were received on time for 52 substances, the status of which is given in Annex IV. 95 non-notified substances were listed in Regulation (EC) N° 2076/2002 to be withdrawn from the market in July 2003. Monographs will be forwarded by RMSs to EFSA which will handle the further risk assessment steps.

6.3. 3rd Stage

The preliminary preparation for this stage is covered by Commission Regulation N° 451/2000 and the list of notifications received for the 3rd stage was prepared and later amended to take account of a second round of notifications which had to be submitted by 30.11.00. It is available on the Internet. As with the 2nd stage, the Commission proposed to the SCPH a list of notifications for the 3rd stage which were considered to be admissible, based on the evaluation done by ReNDeR. On 3.7.01 an expert group discussed a further review Regulation detailing the active substances, the rapporteur MS and the date for submission of the dossiers for the 3rd stage. Further discussion on the admissible notifications and the draft review Regulation took place on 1.10.01 in the Working group and on 3.10.01 in an expert group. On 6.12.01 the Working group discussed a draft Regulation including the attribution of the active substances between the different MS - comments were

expected by 25.01.02. Following an expert meeting on 13.2.02 the Commission proposed a Regulation in July 2002 detailing the active substances, the RMS and the date for submission of the dossiers for the 3rd stage. This was given a favourable opinion by the SCFA on 28.6.02 and adopted as Regulation (EC) No 1490/2002. The deadline for receipt of complete data packages by RMSs was May 2003. The deadlines for submission of complete dossiers are 30.11.2003 and 30.11.2004. 225 non-notified substances were listed in Regulation (EC) N° 2076/2002 to be withdrawn from the market in July 2003. COM explored with major notifiers whether there were any additional substances for which industry would withdraw the notifications. COM has proposed non-inclusion for 14 active substances for which industry decided not to further defend them.

6.4. 4th Stage

An expert meeting on 3.7.01 discussed the procedure for the remaining 200 active substances covered by the 4th stage. It was agreed that a Regulation be drafted requiring a simple notification (pre-notification and list of studies available as well as the date of the most recent or ongoing evaluation in EU/OECD countries) for substances that could be categorised as being authorised in foodstuffs, as plant extracts, as animal products, as attractants/repellants and as commodities, and requiring a full notification for micro-organisms, rodenticides and stored product uses. A fee was to be provided for. The aim was to adopt such a Regulation at the beginning of 2002. Further discussion, also in relation to defining the data requirements for some of the 4th stage substances was foreseen at a meeting on 3.10.01. A first draft proposal was discussed at the Working group meeting of 6.12.01; comments were expected by 25.1.02 followed by further discussion at an expert meeting on 13.2.02. It was finalised in the SCFA on 19.4.02 adopted by the Commission on 20.6.02 (Commission Regulation N° 1112/2002). It entered into force on 1.8.02 and obliges notifications to be made to ReNDeR within three months for all remaining existing active substances - even those that do not appear on any lists. The notifications received have been reviewed by ReNDeR for acceptability/completeness. An updated list of notified and non-notified active substances is available since March 2003 on the DG SANCO website. Com has proposed to extend the deadline for about 220 notified active substances and proposed withdrawal by December 2003 for 100 non-notified ones.

6.5. Review Programme – essential uses

MS proposals for essential uses were discussed at an expert meeting on 23.11.01. MS had to finalise the proposals by 15.1.02, consult industry and inform COM as to whether the products would still be available on their markets; MS were to examine all such active substances and inform of concerns related to the requested essential uses. MS had to check whether the proposed uses were covered by an existing Community MRL. At an expert meeting on 14.2.02, the MS proposals were examined and further reduced in number. Further discussion took place in the Working group on 25.2.02. There was a follow-up meeting on 14.3.02 and a workshop in DK on 5-6.11.02. A report is available. A list of derogations for essential uses of certain substances is listed in Regulation (EC) N° 2076/2002. Member States were invited to consider recent information on further substances to be withdrawn and inform, with the agreed forms, on any need for further essential uses. However this has to be done again in a restrictive way. Although, on 18 March, the Council adopted a proposal not to include aldicarb in Annex I to the Directive and provided for a restricted list of essential uses of the substance, this should not be considered as a precedent for other substances for which evaluations have not demonstrated safe uses.

7. REVIEW PROGRAMME FOR NEW ACTIVE SUBSTANCES

Detailed information on the status and planning for new active substances is given in Annex II to this document. A list of new active substances and their current 91/414/EEC status is available on the Internet site (doc. 3010/VI/91 rev. aug2003). A fuller description of the process is given in the Technical Annex to the Report to Council and Parliament (SANCO/822/2001 rev. 3).

8. FUTURE NEEDS

8.1. Amendment proposals for Directive 91/414/EEC

Already by 1998, the Commission was considering re-opening the work in order to introduce the following issues under an amendment proposal (see revised strategy for this work in “strategy paper” first discussed on 15-16.10.98).

a) An amendment with regard to introduction of fees was submitted to MS for comments: a revised draft was made available on 25.9.95. The UK, supported by several other MS, raised the question on progress in COREPER on 13.3.96 and in Council on 22.7.96. The financial and human resources implications were however still under discussion within the Commission. Since then, provisions for fees have been introduced in the implementing regulations for stages 2 and 3.

b) An amendment to cover GMMs and to introduce a fast track procedure for low risk plant protection products (doc. 7134/VI/94 rev. 1[1]) was discussed on 1-2.12.94; further written comments were expected from MS by 15.1.95. Doc. 7134/VI/94 rev. 5[1] was distributed for information on 30.1.96.

c) Amendments to ensure adequate coherence between Directive 91/414/EEC and pesticide related provisions to be inserted in Directive 88/379/EEC on the classification, labelling and packaging of dangerous preparations: a draft proposal to amend Directive 91/414/EEC was circulated to MS on 19.12.96 for information (doc. 7110/VI/94 rev. 5[1]). The interservice consultation in the Commission was to start in 1997. Annexes IV and V should be voted by SFCA on 15.4.03.

d) An amendment to cover other technical points and extension of the scope to adjuvants and co-formulants. MS were invited on 16.12.97 to submit their views on necessary amendments by 28.2.98. Comments were received from DE, FR, UK, SE, PT, IT, DK, ES and AU. This will be addressed when amending the Directive.

e) Adaptation of Annexes II & III, as well as 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 envisaged during 2003-4.

Many more areas for possible amendment are listed in the Report to Parliament and its Technical Annex as well as the conclusions of the Council and the Parliament on that report. These and others were discussed at a stakeholder workshop in Greece on 10-12.7.02 with participation of COM, MS and stakeholders. The outcome of that meeting (SANCO/10351/2002) is being used as one of the bases upon which COM is drafting a proposal to amend the Directive.

8.2. Research priorities

Doc. 4978/VI/95[1] contains the research priorities of that time as far as the implementation of Directive 91/414/EEC is concerned. This document was to be amended when new priorities would be identified. A brief discussion was held on the meeting of the Legislation working group on 11.4.00 and research priorities raised were communicated to DG RTD (c.f. minutes SANCO/1132/00 rev. 1).

In 2002, discussions with the JRC continued to see how the JRC could meet the policy needs of the Commission in this area. In addition to support for FOCUS, EUROPOEM etc., the need for the development of data and methodologies for exposure assessment was stressed.

8.3. Sustainable use of plant protection products

A major activity on this issue took place in the mid-1990's culminating in the second, final Workshop of this project which took place on 12-14.5.98. Background documentation is available at http://europa.eu.int/comm/environment/ppps/home.htm. The workshop issued a number of recommendations for consideration by the Commission. The text of these recommendations was circulated to all delegations in the Legislation working group on 7-8.7.98. On 1.7.02, the COM issued a Communication 'Towards a Thematic Strategy on the Sustainable Use of Pesticides' (COM(2002)349 final), launching a broad public consultation to prepare the Thematic Strategy on the Sustainable Use of Pesticides within the framework of the 6th Environment Action Programme. It was followed up with a stakeholder workshop in Brussels on 4.11.02. All relevant information (including the text and on registration for the workshop) can be found at the above Internet address.

9. MISCELLANEOUS MEETINGS

9.1. Joint Meeting of the Competent Designated Authorities

A report of the meeting of the Competent Designated Authorities of 22-24.6.94 in Braunschweig is available.

9.2. Training visits

17 proposed individual training visits were agreed for Commission support under the 1994 budget, of which 10 took place. This action is considered as completed.

10. GUIDANCE DOCUMENTS (SEE ALSO ANNEX VI OF THIS DOCUMENT)

A list of guidance documents developed or under development is given in Annex VI to this document.

10.1. Mutual recognition (implementation of Article 10)

A study was started to examine the implementation modalities for Article 10 of the Directive and an expert group met on 28.6.95 and on 16.4.96. The results were submitted on 30.8.96. Further examination of this document was to start when the uniform principles were adopted.

10.2. Data protection

A draft working document was prepared in 1996 in an attempt to provide guidance to MS on possible interpretations of the provisions of Article 13 of the Directive. Discussions took place on 20.11.96 and 6.2.97. A revision (doc. 4754/VI/96 rev. 4) was sent out for comments by 5.6.97. Revision 6 was prepared in October 1997. This was to be further discussed as soon as the discussions between ECPA and ECCA were finalised. Since no agreement was possible at that stage between ECPA and ECCA, the follow-up was discussed on 22.2.00 in the Legislation Working Group. It was agreed that MS should provide their comments by 28.4.00 and the document be revised, as necessary. Further discussion took place on 3.5.01 with experts from MS. Guidance document SANCO/671/2000 was revised in September 2001 and circulated for comments to MS and industry (deadline 31.10.01). It was envisaged to discuss these at an expert meeting on 24.1.02. A new draft was distributed for comments by 8.3.02; finalisation of the document, foreseen in the Working Group meeting of 18-19.4.02, was delayed.

In 2002, FR is undertook a review of practices in this area in third countries. It collected experience and comments from Member States and industry and reported to COM in 2003. The Commission will consider this when preparing a proposal to amend Directive 91/414/EEC.

10.3. Minor uses

Meetings with experts from DE, FR, PT, NL, UK, COPA, ECPA and ECCA took place on 12.5.97 and 7.10.97 where a document on voluntary mutual recognition of authorisation for minor uses was discussed. Document 9191/VI/97 was made available on 16.12.97 with comments expected by 15.2.98. On 29.4.98, comments were discussed and a new version was made available at the end of June 1998. A new document was distributed on 1.10.98 with the invitation to test the scheme with a few active substances. Both the questionnaire and the report on the test were to be finalised by 1.5.99.

On 14-15.10.99, the 4th Mediterranean Conference discussed the issue of minor uses and made several recommendations. On 26.10.99 an expert meeting discussed several of these recommendations as well as the results of testing the scheme proposed in guidance document 9191/VI/97 rev. 2. The guidance document was to be amended and distributed to MS. It was recommended to develop an application and appraisal form and to keep a list with contact points in the MS available. MS were also invited to define, at national level, minor uses and minor crops (except for the residue aspect, which is decided at EU-level).

An expert meeting discussed the guidance document which was finalised after another commenting round. The document (renamed 2971/SANCO/2000) should now be used for some years before envisaging any further work on it. MS and Commission should make the document widely available. In May 2002, the

Commission circulated a new document, prepared by FR, to Member States for comment and this was discussed in the Legislation working group on 27-28.6.02 with a view to developing it further. Expert meetings took place on 26.9.02 and 12.12.02.

At the meetings in September and December 2002, it was mainly discussed how the work in the area of minor uses could best be structured in future. The group members started the development of tools to improve the exchange and processing of information. As proposed by the workshop on essential uses in November 2002 in DK the working group in minor uses will also take responsibility on that field in future. The participants on the expert meeting furthermore agreed to continue their work in a co-ordinating "steering" group and a permanent "technical" working group open for all Member States. In order to smoothen the enlargement process. Candidate Countries should be involved as soon as possible.

On 6.2.03 a first meeting of the new technical group on minor uses was scheduled. On 5.2.03 a meeting of a steering group on minor uses took place. This latter group was responsible for developing an EU programme for minor uses and co-ordinating the activities of the technical group as well as of potential project teams. This activity is ongoing.

10.4. Parallel imports

This issue was raised by several delegations. A discussion with participation of DG XV was organised on 18-19.2.98. Further information can be found in the ECJ Court ruling of 11.3.99 on Case C 100/96. An expert meeting was scheduled for 1.12.99. A non-paper was prepared on which comments were expected. Discussion took place at the Legislation working group on 22.2.00 and the document was revised accordingly. A further round of discussion was scheduled for the meeting on 15.6.00. A draft guidance document was circulated at the meeting of 18.10.00 for comments by 13.11.00. The document was re-discussed at the Legislation working group meeting of 11-12.12.00. A new version was finalised at the end of September 2001 and was discussed on 1.10.01 in the Legislation working group. After an expert meeting on 22.11.01, the amended draft was endorsed by the SCPH on 7.12.01.

France prepared a questionnaire on parallel import and will review practices in the Member States. An expert meeting took place on 3.2.03. The Commission will reflect on whether and how parallel import will be addressed in the proposal for the amended Directive.

Annex I. FURTHER DEVELOPMENT OF DATA REQUIREMENTS

Annex I.1. General remarks

The original text in the Directive was amended by Directives 91/71/EEC and 95/35/EC. (refs. in annex IV). Doc. 7109/VI/94 rev. 6 contains the correct interpretation of the GLP requirements for all studies referred to in Annexes II and III (guideline document finalised by the SCPH). Doc. 7017/VI/95 rev. 4 was endorsed by the SCPH on 14.6.96 as guidance on the acceptance of old studies in relation to application of GLP.

The Commission is reviewing the existing data requirements for chemicals used as active substances during 2003-2004 and is consulting OECD Member States as part of the process.

Annex I.2. Efficacy

The provisions in the Directive were amended by Directive 93/71/EC (refs. in Annex IV). The Commission and the MS agreed, when voting on the amended Section 6 (Efficacy) of Annex III, to set up a working group to examine the EPPO guidelines on the basis of proposals made by the MS, to identify those which were considered to be no longer appropriate and to propose, pending their revision by EPPO, alternative solutions, including where relevant a Community list of guidelines.

These issues were under discussion in EPPO on the basis of working documents developed by FR. As far as individual guidelines are concerned, Community priorities were sent to EPPO on 2.5.95. The revision of these guidelines is almost finalised now. A document on "acceptable efficacy" would be finalised in 2000 in EPPO. The Commission organised, with FR, workshops on 25-27.6.96 and 14-16.10.96 in Paris, to discuss with experts some efficacy dossiers in order to harmonise their evaluation in all MS.

Doc. 7600/VI/95 (Guidelines and criteria for the preparation and presentation of efficacy data in an Annex III dossier for authorisation of a plant protection product) was finalised on 10.7.97. As a result of the discussions at both workshops, FR prepared a working document with a suggested approach on the assessment of biological dossiers (doc. 4854/VI/97 rev. 3).

Annex I.3. Operator exposure

The provisions of the Directive were amended by Directive 94/79/EC (refs. in Annex IV).

Annex I.3.1. Establishment of AOEL values

A 5-expert meeting discussed on 1.2.95 a first draft that was then sent to all MS by the beginning of March for further comments before 31.3.95. A workshop was organised on 27.4.95 in The Hague to discuss guidelines for establishing AOEL values. Discussions took place in the Braunschweig meeting on toxicology from 15-18.5.95, in the Scientific Committee on Plants (SCP) on 31.10.95 and in the ECPPM Meeting on Toxicology on 20-21.11.95.

Doc. 7531/VI/95 rev. 3, which gives general guidance on establishing AOELs, was sent to MS on 8.3.96. It was the intention to further discuss this document when more experience on its use (in particular in the review programme) became available. This discussion took place in the ECCO meeting on 23.5.97 in York. Doc. 7531/VI/95 rev. 4 was sent to the MS for comments before 30.12.97. DG V was also invited to comment and DG VI presented the document at a meeting in October 1998. On the basis of the comments, the document was to be developed further by BgVV (Dr. Pfeil). The scientific background on AOEL setting was also elucidated by the FAIR project PL98-3663. A workshop in Orta (Italy) was held on 1-3.3.00 in this context. A draft document was discussed in the WG Evaluation in April 2001. The revised document was forwarded to the SCP for an opinion, which was delivered on 18 July 2002. In addition, to supplement the data collection under EUROPOEM, , two projects are underway to (i) create a user interface and (ii) to provide guidance on how to use the EUROPOEM models. The guidance document is now under final revision and is planned to be adopted during 2003. However, given the delays in developing and finalising this guidance, it is difficult to see how it can be implemented in the ongoing review of existing substances. The Evaluation meeting will be informed in detail on the results of the project in September 2003.

Annex I.3.2. Dermal absorption

A draft guidance document was developed by FR. ECCO (BBA) co-ordinated the distribution to MS and collection of comments. After a first round of comments, FR prepared a revision (submitted mid-March 2000), which was again subjected to comments by MS and industry (deadline end-April 2000) and revised further. Rev. 3 was discussed in the WG Evaluation in February 2001, revised and then submitted to the SCP as rev. 4. After the release of the opinion of the SCP the document was revised and it was endorsed in the Standing Committee on 3.12.02.

Annex I.4. Fate and behaviour in the environment

The provisions in the Directive were amended by Directive 95/36/EC (refs. in Annex IV).

Annex I.4.1. Persistence in soil

A first discussion on a guidance document on persistence in soil was organised on 28.10.97 (doc. 9188/VI/97). A final round on comments was invited on the basis of rev. 3 of the document. The SCP provided its opinion in September 1999. A consolidated document was distributed to MS on 23.5.00 and noted by the SCPH on 13.7.00.

Annex I.4.2. Relevant metabolites in groundwater

NL submitted a draft guidance document on the identification of relevant metabolites and the definition of data requirements to assess their safety. The document was distributed to MS at the Legislation working group meeting on 11.2.99 and to industry (ECPA and ECCA). Comments were collected and submitted to the authors by ECCO. A revised draft was commented by the SCP in December 2000. Further revisions were made and commented by MS and stakeholders. An exchange of views took place on 7.2.02 with all MS and on 11.4.02 the Drinking Water committee gave an opinion. Revision 7 of the draft document was sent to the SCP in July 2002 for an opinion, which was given in January 2003. Revision 10 was noted by the SCFA in February 2003.

Annex I.5. Ecotoxicology

The provisions in the Directive were amended by Directive 96/12/EC (refs. in Annex IV).

Annex I.5.1. Aquatic and terrestrial ecotoxicology

There was a first discussion on guidance documents for aquatic and terrestrial ecotoxicology at the ECCO meetings in 1997 in Braunschweig. New versions of both documents were discussed in October 1998 and a final round of comments invited. The SCP provided its opinion in September 1999. Consolidated documents were distributed to MS on 23.5.00 and the SCPH took note in July 2000. A new round of revision is ongoing for the aquatic ecotoxicology, taking into consideration new spray drift data and the outcome of recent workshops (HARAP, CLASSIC), and more detailed guidance on how to deal with breakdown products. A similar revision is planned for the terrestrial ecotoxicology, to consider the ESCORT II workshop results and detailed guidance on breakdown products.

Revised spray drift data were endorsed in the guidance document on aquatic ecotoxicology in October 2001 and the document was renamed SANCO/3268/2001. Further revision is underway to take into consideration the FOCUS surface water report and to provide better guidance on how to deal with metabolites and breakdown products.

The revised guidance documents were noted in the Standing Committee on 18.10.02. They should be used for existing substances under the 3rd stage of the review programme and for new active substances submitted after August 2003.

Annex I.5.2. Birds and mammals

A small working group on higher tier risk assessment for birds and mammals met in February and May 2000. The group proposed to use the scheme developed by EPPO as a Tier 1 scenario for acute risk assessment. Options for refinements (Tier 2) were discussed. It was envisaged to develop a draft guidance document by the end of 2000 which would include consensus Tier 1 scenarios and options for refinement. Probabilistic methods should represent the highest tier of the risk assessment and should be developed with priority. A draft document was discussed in the Evaluation working group in April 2001. After commenting by MS, the document was revised in October 2001 and submitted to the SCP for an opinion.

After the release of the opinion of the SCP the document was revised and it was noted by the Standing Committee on 18.10.02. It should be used for existing substances under the third stage of the review programme and for new substances submitted after August 2003.

Annex I.5.3. Non-target arthropods

The SETAC/ESCORT2 workshop (Wageningen, 21-23.3.00) developed revised recommendations for the testing and risk assessment of concerning non-target arthropods. It is planned to take advantage of the progress made in a revision of the guidance document on terrestrial ecotoxicology. A small working group initiated the revision work on 21.2.01. The result is incorporated into the terrestrial guidance document, see above Annex I.5.1.

Annex I.5.4. Data requirements and risk assessment for non-target plants and air

EPPO organised a workshop in Bilthoven from 11-13.6.97 to inform its Members on the existence of these schemes and to organise thereafter a further validation. The environmental risk assessment scheme was to be circulated for comments to all EPPO Members in January 2002. The revised scheme, including the sub-schemes on air and non-target terrestrial plants is expected to be finalised in the Working Party in May 2002 and to be adopted by EPPO-Council in September 2002. A FOCUS workgroup was initiated for "air" in February 2002. A first scheme for the assessment of non-target plants is provided in the revised guidance document on terrestrial ecotoxicology.

Annex I.5.5. Higher tier modelling of degradation kinetics

As a follow-up on an earlier draft guidance document on PEC calculation, which had been developed by DE in August 1999 (doc. 7193/VI/99). Aspects of higher tier modelling of degradation kinetics are now being discussed in a FOCUS workgroup. A report is expected mid 2003. Other aspects of the draft document have been taken up in the terrestrial and aquatic guidance documents (see above, Annex I.5.1).

Annex I.6. Physico-chemistry

The provisions in the Directive were amended by Directive 94/37/EC (refs. in Annex IV).

Annex I.7. Toxicology

The provisions in the Directive were amended by Directive 94/79/EC (refs. in Annex IV).

Annex I.8. Residues

The provisions in the Directive were amended by Directive 96/68/EC (refs. in Annex IV).

Annex I.8.1. Residue trials

Doc. 1607/VI/97 rev.1 of 22.7.97[1] contained guidance on test guidelines for residue studies. This document was to be used by industry and MS as the best available guidance at the time pending further adaptation in future. Further discussions were organised on 11.5.98 on the chapters concerning extrapolation and processing studies; amended documents would be available for comments at end of July 1998. Further discussion on both chapters, on the chapter concerning rotational crops and on the chapter concerning the

calculation of MRLs took place on 9.11.98 during the ECCO 74 meeting. At the request of the UK, the chapter concerning extrapolation was discussed further with all MS in the residue group. A new version was agreed and used as a basis for discussion at the EU-OECD workshop on minimum data requirements in York 6-8.9.99. On the basis of the outcome of the workshop a new document was proposed (7525/VI/95 rev. 5) and agreed by the residue working group, which agreed with its publication on the Internet. The discussions on the other documents were finalised in an earlier stage. There was an additional need to update this document for extrapolations for tropical fruits as requested by ACP countries. Several expert groups discussed this. Agreement was reached about extrapolation of small and big fruits with inedible peel concerning post harvest treatment. Doc. 7525/VI/95 rev. 7 was noted by the SCPH (residues). Currently work is ongoing concerning tropical root and tuber vegetables and further work is envisaged for pre-harvest treatments.

Annex I.8.2. Analytical methods

The provisions in the Directive were amended by Directive 96/46/EC (refs. in Annex IV). A guidance document on residue analytical methods (8064/VI/97 rev. 3) was finalised and adopted by the SCPH on 1.12.98. Two documents (3069/SANCO/99 and 3070/SANCO/99) on analytical methods were proposed by the UK at the request of the Commission and distributed for information to the Residues working group. In view of technical progress, the guidance document was revised in 2000.

Annex I.9. Modelling

Annex I.9.1. Operator exposure (EUROPOEM)

The Commission funded a concerted action for the development, maintenance and dissemination of a European predictive operator exposure model (EUROPOEM) database. The work started on 1.9.93. The results were presented to the Working Group on 17.10.97. A new project (EUROPOEM II) started in April 1997 covering a 3-year period. The results have not yet been endorsed by the SCPH and should therefore not yet be used when submitting dossiers. It is hoped to have a draft report available for comment by MS and stakeholders during 2003. A tender was launched to develop the software for a user interface for the database and a “train the trainers” workshop for the users. See also Section Annex I.3.1.

Annex I.9.2. Environment (FOCUS)

In the early 1990's, the Commission funded a concerted action on the modelling of pesticide behaviour in the environment (COST 66). Four sub-groups were created covering (a) transformation, (b) sorption, (c) mathematical modelling and (d) outdoor experiments and monitoring. Two workshops on environmental behaviour of pesticides and regulatory aspects were organised, on 26-29.4.94 (Brussels) and on 13-16.5.96 (Stratford).

Partially in follow-up but mainly in its on right, a Forum for international co-ordination of pesticide fate models and their use (FOCUS) was founded with the aims of defining the role of environmental fate modelling required for EC registration, of developing practical guidance on use of models, of defining current deficiencies of leaching models and of developing recommendations for validating models. There are five areas where FOCUS is active: leaching, groundwater, surface water, landscape and air.

The outcome of the working group on leaching models (docs. 1694/VI/95 and 4952/VI/95) was endorsed by the SCPH as a guidance document on 23.11.95. The reports prepared by the working groups on surface water (doc. 6476/VI/96) and soil modelling (doc. 7617/VI/96) were endorsed by the SCPH in 1996 as guidance documents. This work will be completed during 2003.

Two working groups started work on development of standard scenarios for groundwater and surface water. The composition of both groups was circulated to MS on 21.3.97. Both groups selected approximately 10 European scenarios based on climate and further selected appropriate soil/crop combinations and water bodies (surface water group) that are relevant for the scenarios selected. The groups prioritised the parameters that are necessary for the different models. A workshop to present the models and the scenarios to the MS was organised on 3-4.9.98 in Bilthoven.

The first draft report from the FOCUS Groundwater group was submitted for comments from MS and industry (deadline 28.2.00). The document was revised at the meeting of the Working Group in March 2000. The revised version was submitted to the SCP in May 2000 and an opinion given in September 2000. Users of the FOCUS groundwater models were trained in a workshop, on 11-14.9.00. The groundwater models and scenarios are available via the Internet under http://arno.ei.jrc.it:8181/focus/index.html. The web site is managed and a help desk provided by the Joint Research Centre at Ispra. The FOCUS scenarios should be used to assess potential leaching for existing substances reviewed under the 2nd and 3rd stages of the programme.

The surface water project was scheduled to finish in 2002. A draft report was distributed for comment by MS, industry and the SCP late in 2001. The system was demonstrated and discussed in a workshop on 18-19.2.02. The final software and report writing tools was demonstrated to Member States in a training session in December 2002. The FOCUS surface water scenarios will be used for PEC calculations and risk assessments for existing substances under the 3rd stage of the review programme and for new active substances submitted after August 2003. This work is now complete.

FOCUS working groups on air and landscape started work in 2002. FOCUS air produced an interim report and its work was scheduled to be reviewed in April 2003.

Annex I.10. Microorganisms

A "5-expert" meeting took place on 30.5.95 to discuss the chapters on identity, physico-chemistry and efficacy. A second meeting took place on 14.7.95. A "5-expert" meeting to discuss the chapters on toxicology took place on 7.7.95. A "5-expert" meeting to discuss the chapters on ecotoxicology and fate and behaviour in the environment took place on 12.1.96. A working document with data requirements for all chapters (except analytical methods) was sent in May to MS for comments (docs. 4992/VI/95 and 4993/VI/95). Expert meetings were organised on 14-15.11.96 and on 18.12.96. Docs. 4992/VI/95 rev. 1 and 4993/VI/95 rev. 1 were circulated to MS on 6.2.97 for comments by 28.3.97. The Commission transmitted revised versions to the MS on 4.8.97 and to OECD on 5.9.97, inviting comments to be incorporated by the Commission.

An arrangement was made with KEMI (SE) to further develop the document in close collaboration with a steering Committee from interested OECD countries. At a workshop in Stockholm on 26-28.10.98, risk assessment and data requirements for micro-organisms were discussed. KEMI submitted to the Commission, on 31.3.99, amended documents on data requirements and the scientific background for risk assessment. The documents were distributed for comments (by end of June 1999) to the MS and the OECD Microbials Steering Committee members. Comments were received from NL, FR, DK, PT, UK, Australia, Canada and IBMA. Some issues raised during the discussions of the 3 active substances under evaluation were sent to the SCP for an opinion. The comments were incorporated in the document and a proposal for a draft Directive was tabled first for discussion in a small expert meeting on 16.11.00 and then for the SCPH Legislation working group on 12.12.00, where it was discussed and finalised. The document received a unanimous favourable opinion from the SCPH on 2.3.01 (Directive 2001/36/EC). A document on the formatting of dossiers and monographs for micro-organisms will be prepared, involving BE, FR, NL and SW who are currently preparing monographs on micro-organisms.

In June 1998, the first three micro-organisms (*Ampelomyces quisqualis, Paecilomyces fumosoroseus*, and *Pseudomonas chloroaphis*, were peer-reviewed at a meeting in Brussels. An evaluation meeting was held on 27.4.99. The a.i.s were then discussed in the legislation group. In December 1999, these were referred to the SCP for an opinion. In June 2001, the first micro-organism (*Paecilomyces fumosoroseus*) entered Annex I of the Directive (Directive 2001/47/EC). A draft document (SANCO/1023/2001 rev. 1) on Uniform Principles was prepared by SE, with NL, DE, UK, BE, FR, FI involved. Rev. 4 was finalised on 15.11.01 and was discussed in the Legislation working group on 6-7.12.01. It was then sent to the SCP for an opinion with a view to submitting the finalised version to Council afterwards.

The SCP provided an opinion at the end of January 2003 and the document is being revised to take account of it.

Annex I.11. Test guideline development - priorities

Document 5690/VI/95 gives an overview of actions already undertaken and identifies items for which work still has to be performed. It was circulated to MS on 26.6.95 for comments by 15.8.95. The document was submitted to the National Co-ordinators (OECD Test guidelines programme) meeting of 15.11.95.

Annex I.12. Pheromones and semio-chemicals

Within the OECD Pesticides Working Group (PWG), a project was initiated to define data requirements for pheromones and semio-chemicals. Data requirements proposed by a workshop in Ottawa in October 1999 were submitted for comment by PWG members. MS were requested to comment by 15.3.00 to CAN and COM. It is envisaged to endorse the OECD guidance document as guidance also for MS. The OECD workgroup on pheromones met in Brussels on 18.5.00 to discuss formats for dossiers and monographs. It was agreed to keep formats in line with those for plant protection products. The group developed dossier guidance, which includes worked examples of tiered summaries. The PWG has in the meantime de-classified the data requirements and guidance for dossiers and monographs.

Annex I.13. Risk assessment for pesticides used on rice

When Annex VI to Directive 91/414 (Uniform Principles) was adopted, the Council and COM made the following statement: "The Council and the Commission note that particular conditions obtain in rice cultivation. This means that certain specific criteria are inappropriate for evaluation purposes, particularly in the context of point 2.5.2.2. for the exposure of aquatic organisms in rice field waters. …"

To develop the necessary guidance to MS and notifiers as to how the risk to the environment should be addressed in rice cultivation, a small expert group was set up, consisting of representatives from the concerned MS (PT, ES, IT, EL, FR), of one member of the FOCUS group for surface water, and of representatives from industry. A workshop was held in Cremona on 16.9.99 in the context of the XIth Symposium on Pesticide Chemistry. The workgroup defined proposed data requirements and a standard scenario for Europe for PEC calculations in the context of Annex I inclusion. Next steps were to be the definition of non-target species. The progress was published on a poster at the SETAC conference in Brighton in May 2000. It was planned to distribute a draft report in time for discussion in the Evaluation working group in April 2001. The group presented the further work at the SETAC conference in May 2001 in Madrid. A draft report was distributed for comment by MS. The SCP gave an opinion in January 2003. The document is now under final revision; finalisation is foreseen mid 2003.

Annex I.14. Plant strengtheners

NL submitted a draft guidance document (SANCO/1003/2001 rev. 3) on data requirements for plant strengtheners. Comments were expected by 20.8.01 and submission to the SCPH was expected for October. It was suggested to consider, before finalising the document, whether it should also include other categories of substances covered by the 4th stage of the review programme. This was to be discussed on 3.10.01. It was concluded that at this stage the document would not be further discussed. Several categories of active substances which might be subject to reduced data requirements are included in the 4th stage of the review programme and as soon as more practical experience and examples are available in this context, a further discussion on the guidance document might be organised. France has developed a document on reduced data requirements. Member States should comment on a new draft that was to be sent out at the end of December or early January 2003. Comments were received and were discussed in an expert group on 18.3.03. France will prepare a new version of the guidance document and a final meeting of the expert group is foreseen on 4 September 2003. Experience in the U.S. will also be considered.

Annex IIA: Completeness-of-dossier status of NEW active substances under evaluation

Annex II. NEW ACTIVE SUBSTANCES - INDIVIDUAL STATUS OF EACH

Annex II.A. Completeness of dossiers

Annex II.A.1 Chemical substances

No	Dev. Code	Active substance (main use of product)	Company submitting application	Date of application to a MS	RMS. Co RMS	COM receipt of RMS report on completeness	Receipt of dossier in all MS	MS comment period deadline	Referral of dossier to SCFA	Decision on Completeness of Dossier
1		**Prohexadione calcium (PG)**	BASF	10.2.94	FR	4.1.95	25.9.95		25.9.95	Positive; SCPH 14.6.96; OJ N° L220, 30.8.96, p. 19, **96/520/EC**
2		**Kresoxim-methyl (FU)**	BASF	28.3.95	BE	19.7.95	25.9.95		25.9.95	Positive; SCPH 24.11.95; OJ N° L91, 12.4.96, p. 74, **96/341/EC**
3		**Flurtamone (HB)**	Rhône-Poulenc Agro France	15.2.94	FR	30.10.95	24.11.95		24.11.95	Positive; SCPH 20.3.96; OJ N° L130, 31.5.96, p. 20, **96/341/EC**
4		**Chlorfenapyr (AC,IN)**	Cyanamid	7.7.95	ES	11.12.95	30.1.96.		30.1.96	Positive; SCPH 14.6.96; OJ N° L220, 30.8.96, p. 21, **96/521/EC**
5	DE 795	**Quinoxyfen (FU)**	DowElanco	1.8.95	UK	18.1.96	20.3.96		20.3.96	Positive; SCPH 22.4.96; OJ N° L189, 30.7.96, p. 112, **96/457/EC**
6	ICIA 5504	**Azoxystrobin (FU)**	Zeneca Crop Protection	15.9.95	DE	22.3.96	22.4.96		22.4.96	Positive; SCPH 14.6.96; OJ N° L220, 30.8.96, p. 25, **96/523/EC**
7	KWG 4168	**Spiroxamine (FU)**	Bayer	13.10.95	DE	22.3.96	22.4.96		22.4.96	Positive; SCPH 14.6.96; OJ N° L220, 30.8.96, p. 23, **96/522/EC**
8	RPA 201772	**Isoxaflutole (HB)**	Rhône-Poulenc	6.3.96	NL	22.4.96	22.4.96		22.4.96	Positive; SCPH 14.6.96, OJ N° L220, 30.8.96, p. 27, **96/524/EC**
~~9~~		~~**Alanycarb (IN)**~~	~~Otsuka Chemical Co.~~	~~24.7.95~~	~~FR~~	~~18.12.97~~	~~18.2.98~~		~~18.2.98~~	~~Positive, OJ N° L180, 15.7.99, p. 49, **99/462/EC;**~~ Repealed **02/311/EC** OJ L109, 25.4.02, p. 28
10	DPX KE 459	**Flupyrsulfuron methyl (HB)**	Du Pont de Nemours	26.10.95	FR	22.7.96	16.8.96		16.8.96	Positive, SCPH 20.11.96; OJ N° L64, 5.3.97, p. 17, **97/164/EC**
11		**Flumioxazine(HB)**	Sumitomo Chemical Agro Europe S.A.	2.5.94	FR	30.5.96	12.7.96		12.7.96	Positive, SCPH 11.7.97; OJ N° L262, 24.9.97, p. 7, **97/631/EC**
12	CGA 152005	**Prosulfuron(HB)**	Novartis	14.5.95	FR	30.5.96	14.6.96		14.6.96	Positive; SCPH 11.10.96; OJ N° L52, 22.2.97, p. 20, **97/137/EC**
13	CGA 329351	**Metalaxyl-M (FU)**	Novartis Crop Protection AG	9.2.96	BE	19.11.96	21.3.97		21.3.97	Positive; SCPH 29.5.97; OJ N° L239, 30.8.97, p. 48, **97/591/EC**
14	DPX A8947	**Azimsulfuron (HB)**	Du Pont De Nemours	4.3.96	IT	31.7.96	11.10.96		11.10.96	Positive, SCPH 20.11.96;OJ N° L64, 5.3.97, p. 3, **97/164/EC**
15	IKI 1145; TO 1145	**Fosthiazate (NE)**	ISK Biosciences Division	5.3.96	UK	30.10.96	19.12.96		19.12.96	Positive, SCPH 21.3.97; OJ N° L152, 11.6.97, p. 31, **97/362/EC**

Annex IIA: Completeness-of-dossier status of NEW active substances under evaluation

No	Dev. Code	Active substance (main use of product)	Company submitting application	Date of application to a MS	RMS. Co RMS	COM receipt of RMS report on completeness	Receipt of dossier in all MS	MS comment period deadline	Referral of dossier to SCFA	Decision on Completeness of Dossier
16	RPA 90946	**Cyclanilide (PG)**	Rhône Poulenc Agrochemie S.A.	27.3.96	GR	30.5.96	14.6.96		14.6.96	Positive; SCPH 11.10.96; OJ N° L52, 22.2.97, p.20, **97/137/EC**
17	F8426	**Carfentrazone-ethyl (HB)**	FMC Europe NV	14.2.96	FR	25.10.96	19.12.96		19.12.96	Positive, SCPH 21.3.97; OJ N° L152, 11.6.97, p. 31, **97/362/EC**
18	FOE 5043	**Flufenacet (HB) (previously fluthiamide)**	Bayer S. A.	1.2.96	FR	25.10.96	19.12.96		19.12.96	Positive, SCPH 21.3.97; OJ N° L152, 11.6.97, p. 31, **97/362/EC**
19	TH 913	**Imazosulfuron (HB)**	~~Urania Agrochem~~ Spiess-Urania Chemicals GmbH	27.6.96	DE	5.5.97	11.7.97		11.7.97	Positive; SCPH 17.10.97; OJ N°L351, 23.12.97, p. 67, **97/865/EC**
20	AEF 095404	**Ethoxysulfuron (HB)**	AgrEvo	3.7.96	IT	22.1.97	21.3.97		21.3.97	Positive; SCPH 29.5.97; OJ N° L239, 30.8.97, p. 48, **97/591/EC**
21	CGA 215944	**Pymetrozine (IN)**	Novartis	4.9.96	DE	18.3.97	29.5.97		29.5.97	Positive; SCPH 17.10.97; OJ N° L351, 23.12.97, p. 67, **97/865/EC**
22	DPX JE 874	**Famoxadone (FU)**	DuPont de Nemours	2.10.96	FR	26.3.97	21.3.97		21.3.97	Positive; SCPH 29.5.97; OJ N° L239, 30.8.97, p. 48, **97/591/EC**
23	CGA 245 704	**Acibenzolar-S-methyl (PA)**	Novartis	15.10.96	FR	5.5.97	19.6.97		19.6.97	Positive; SCPH 17.10.97; OJ N° .L351, 23.12.97, p. 67, **97/865/EC**
24		**Flazasulfuron (HB)**	I.S.K. Biosciences	16.12.96	ES	6.6.97	29.5.97		29.5.97	Positive; SCPH 17.10.97; OJ N°L351, 23.12.97, p. 67, **97/865/EC**
25	L 91105D	**Carvone (PG)**	Luxan B.V.	26.3.97	NL	6.5.99	6.6.99		10.6.99	Positive; SCPH 20.7.99; OJ N° L242, 14.9.99, p. 29, **99/610/EC**
26	MON 37500	**Sulfosulfuron (HB)**	Monsanto	24.4.97	IRL	11.7.97	11.7.97		11.7.97	Positive; SCPH 17.10.97; OJ N° L351, 23.12.97, p. 67, **97/865/EC**
27	EF 1218	**Cyhalofop-butyl (HB)**	Dow Elanco	30.4.97	IT	5.11.97	16.12.97		16.12.97	Positive SCPH 16.12.97; OJ N° L96, 28.3.98, p. 45, **98/242/EC**
28	BAS 615H	**Cinidon-ethyl (HB)**	BASF plc.	28.4.97	UK	12.1.98	18.2.98		18.2.98	Positive; SCPH 22.4.98; OJ N° L176, 20.6.98, p. 34, **98/398/EC**
29	KBR 2738	**Fenhexamid (FU)**	Bayer plc.	8.5.97	UK	16.12.97	18.2.98		18.2.98	Positive; SCPH 22.4.98; OJ N° L176, 20.6.98, p. 34, **98/398/EC**
30	RP020630	**Oxadiargyl (HB)**	Rhone Poulenc	16.6.97	IT	16.12.97	18.2.98		18.2.98	Positive; SCPH 22.4.98; OJ N° L176, 20.6.98, p. 34 **98/398/EC**
31	ET 751	**Pyraflufen-ethyl (HB)**	Nihon Nohyaku Co. Ltd.	16.6.97	BE	2.12.97	16.12.97		16.12.97	Positive SCPH 16.12.97; OJ N° L96, 28.3.98, p. 45, **98/242/EC**
32	DPX R6447	**Azafenidin (HB)**	Du Pont de Nemours	25.6.97	ES	8.12.97	16.12.97		16.12.97	Positive SCPH 16.12.97; OJ N° L96, 28.3.98, p. 45, **98/242/EC**
33		**S-Metolachlor (HB)**	Novartis N.V.	1.8.97	BE	23.2.98	21.4.98		21.4.98	Positive SCPH 7.7.98; OJ N° L228, 15.8.98, p. 35, **98/512/EC**
34	BAS 620 H	**Tepraloxydim (HB)**	BASF	11.9.97	ES	17.2.98	21.4.98		21.4.98	Positive SCPH 7.7.98; OJ N° L228, 15.8.98, p. 35, **98/512/EC**

Annex IIA: Completeness-of-dossier status of NEW active substances under evaluation

No	Dev. Code	Active substance (main use of product)	Company submitting application	Date of application to a MS	RMS. Co RMS	COM receipt of RMS report on completeness	Receipt of dossier in all MS	MS comment period deadline	Referral of dossier to SCFA	Decision on Completeness of Dossier
~~35~~	~~JV 485~~	~~**Fluazolate (HB) (formerly isopropazole)**~~	~~Twinagro~~	~~29.9.97~~	~~UK~~	~~8.6.98~~	~~7.7.98~~		~~7.7.98~~	~~Positive, SCPH 16,10,98; OJ N° L317, 26.11.98, p. 47, **98/676/EC**~~ Repealed SCFA 28.6.02, OJ N° L243, 11.9.02, p. 19, **2002/748/EC**
36	DPX-KN128	**Indoxacarb (IN)**	Du Pont de Nemours	6.10.97	NL	18.2.98	18.2.98		18.2.98	Positive; SCPH 22,4,98; OJ N° L176, 20.6.98, p. 34, **98/398/EC**
37	KIF 3535	**Mepanipyrim (FU)**	Kumiai	24.10.97	IT	28.5.98	7.7.98		7.7.98	Positive, SCPH 16.10.98; OJ N° L317, 26.11.98, p. 47, **98/676/EC**
38	AC 299 263	**Imazamox (HB)**	Cyanamid NV/SA	2.12.97	FR	10.6.98	7.7.98		7.7.98	Positive, SCPH 16.10.98; OJ N° L317, 26.11.98, p. 47, **98/676/EC**
39	~~MTF 651~~	~~**Flusulfamide (FU)**~~	~~Mitsui Toatsu Chemical Co.~~	~~19.9.97~~	~~UK~~					~~Application withdrawn by notifier~~
40	DE 570	**Florasulam (HB)**	Dow AgroSciences	2.2.98	BE	8.6.98	7.7.98		7.7.98	Positive, SCPH 16.10.98; OJ N° L317, 26.11.98, p. 47, **98/676/EC**
41	CGA 279 202	**Trifloxystrobin (FU)**	Novartis Crop Protection UK Ltd.	28.1.98	UK	4.9.98	15.10.98		15.10.98	Positive, SCPH 1.12.98; OJ N° L14, 19.1.99, p. 30, **99/43/EC**
42	SZX 0722	**Iprovalicarb (FU)**	Bayer Plc.	30.3.98	IRL	6.4.98	21.4.98		21.4.98	Positive SCPH 7.7.98; OJ N° L228, 15.8.98, p. 35, **98/512/EC**
43	BAS 625 H	~~**Clefoxidim (HB)**~~ **Profoxydim (HB)**	BASF	2.4.98	ES	11.8.98	15.10.98		15.10.98	Positive, SCPH 1.12.98; OJ N° L14, 19.1.99, p. 30, **99/43/EC**
44		**Etoxazole (IN)**	Sumitomo Chemical Agro Europe SA	21.4.98	FR	3.9.98	15.10.98		15.10.98	Positive, SCPH 1.12.98; OJ N° L14, 19.1.99, p. 30, **99/43/EC**
45		**Benzoic acid (BA,FU, OT)**	Menno Chemie Vertriebs-Ges	25.5.98	DE	28.5.98	7.7.98		7.7.98	Positive, SCPH 16.10.98; OJ N° L317, 26.11.98, p. 47, **98/676/EC**
46	ZA 1296	**Mesotrione (HB)**	Zeneca Agrochemicals	23.4.98	UK	26.1.99	27.1.99		11.2.99	Positive, SCPH 12.3.99; OJ N° L148, 15.6.99, p. 44, **99/392/EC**
47	CGA 277 476	**Oxasulfuron (HB)**	Novartis Protezione Piante S.p.A.	29.5.98	IT	19.10.98	1.12.98		1.12.98	Positive, SCPH 11.2.99; OJ N° L87, 31.3.99, p. 15, **99/237/EC**
48		**Ferric phosphate (MO)**	W.Neudorff GmbH KG	27.8.98	DE	21.9.98	15.10.98		15.10.98	Positive, SCPH 1.12.98; OJ N° L14, 19.1.99, p. 30, **99/43/EC**
~~49~~	~~SAN 1367H~~	~~**Pyridafol (HB)**~~	~~Novartis CProtection UK~~	10.9.98	UK					Incomplete
50	YRC 2894	**Thiacloprid (IN)**	Bayer Plc.	11.9.98	UK	28.6.99	20.7.99		20.7.99	Positive, SCPH 30.11.99; OJ N° L57, 2.3.00, p. 35, **00/181/EC**
51	AT0IABO3	**Beta cypermethrin (IN)**	Elf Atochem AgriSA	20.10.98	BE					Decision pending
52		**Forchlorfenuron (PG)**	SKW Trostberg AG - Task force SKW Trosberg AG & Kyowa HakkoKogyo Co.ltd	7.12.98	ES	23.6.99	20.7.99		20.7.99	Positive, SCPH 30.11.99; OJ N° L57, 2.3.00, p. 35, **00/181/EC**
53	AE F 115008	**Iodosulfuron-methyl-sodium (HB)**	Hoechst Schering AgrEvo GmbH	14.12.98	DE	27.1.99	11.2.99		11.2.99	Positive, SCPH 12.3.99; OJ N° L148, 15.6.99, p. 44, **99/392/EC**

Annex IIA: Completeness-of-dossier status of NEW active substances under evaluation

No	Dev. Code	Active substance (main use of product)	Company submitting application	Date of application to a MS	RMS. Co RMS	COM receipt of RMS report on completeness	Receipt of dossier in all MS	MS comment period deadline	Referral of dossier to SCFA	Decision on Completeness of Dossier
54	MON 6550	**Silthiofam (FU)**	Monsanto Crop Protection	14.12.98	IRL.BE	15.12.98	11.2.99		11.2.99	Positive, SCPH 12.3.99; OJ N° L148, 15.6.99, p. 44, **99/392/EC**
55	CGA 293343	**Thiamethoxam (IN)**	Novartis Crop Protection AG	17.3.99	ES	20.7.99	20.7.99		20.7.99	Positive, SCPH 30.11.99; OJ N° L57, 2.3.00, p. 35, **00/181/EC**
56	BAS 656H	**Dimethenamid - P (HB)**	BASF AG	16.4.99	DE	26.5.99	10.6.99		10.6.99	Positive, SCPH 2.7.99; OJ N° L210, 10.8.99, p. 22, **99/555/EC**
57	AC 900001	**Picolinafen (HB)**	Cyanamid Agro S,A,/N,V,	10.5.99	DE	3.6.99	10.6.99		10.6.99	Positive, SCPH 2.7.99; OJ N° L210, 10.8.99, p. 22, **99/555/EC**
58	ZA1963	**Picoxystrobin (FU)**	Zeneca Agrochemicals	26.5.99	IRL	27.5.99	10.6.99		10.6.99	Positive, SCPH 2.7.99; OJ N° L210, 10.8.99, p. 22, **99/555/EC**
59	RH-7281	**Zoxamide (FU)**	Rohm and Haas France S.A.	2.6.99	UK	4.2.00	31.5.00		31.5.00	Positive, SCPH 16.6.00; OJ N° L230, 12.9.00, p. 14, **00/540/EC**
60	A:232105;& D275043	**Spinosad (IN)**	Dow AgroSciences	19.7.99	NL	17.8.99	17.8.99		17.8.99	Positive, SCPH 30.11.99; OJ N° L 64, 11.3.00, p. 64, **00/210/EC**
61	EXP60707B	**Acetamiprid (IN)**	Nisso Chemical Europe GMBH	22.10.99	GR	1.2.00	22.2.00		22.2.00	Positive, SCPH 12.4.00; OJ N° L145, 20.6.00 p. 36, **00/390/EC**
62	RPA 407213	**Fenamidone (FU)**	Rhone Poulenc Ag	15.9.99	FR	9.12.99	17.1.00		17.1.00	Positive, SCPH 23.2.00; OJ N° L78, 29.3.00, p. 26, **00/251/EC**
63	IKF 916	**Cyazofamid (FU)**	Ishira Sangyo Kaisha Ltd; ISK Biosciences Europe sa	16.12.99	FR	20.3.00	20.3.00		20.3.00	Positive, SCPH 12.4.00; OJ N° L155, 28.6.00, p. 62, **00/412/EC**
64	MKH 65 61	**Propoxycarbazone-sodium (HB)**	Bayer AG.	25.1.00	DE	10.3.00	10.3.00		10.3.00	Positive, SCPH 12.4.00; OJ N° L183, 22.7.00, p. 21, **00/463/EC**
65	RH-2485	**Methoxyfenozide (IN)**	Rohm and Haas France SA	21.2.00	UK	13.10.00	2.2.01		2.3.01	Positive, SCPH, 2.3.01; OJ L137 19.5.01, p. 30. **01/385/EC**
66	B-41;E-187	**Milbemectin (IN)**	Sankyo Company Limited	6.3.00	NL	2.5.00	31.5.00		31.5.00	Positive, SCPH 16.6.00; OJ N° L230, 12.9.00, p. 14, **00/540/EC**
67	BAS500F	**Pyraclostrobin (FU)**	BASF AG	28.2.00	DE	17.4.00	31.5.00		31.5.00	Positive, SCPH 16.6.00; OJ N° L230, 12.9.00, p. 14, **00/540/EC**
68	AEF 130360	**Foramsulfuron (HB)**	Aventis GmbH	30.3.00	DE	4.5.00	31.5.00		31.5.00	Positive, SCPH 16.6.00; OJ N° L230, 12.9.00, p. 14, **00/540/EC**
69	UBH 820 UR 50601	**Beflubutamid (HB)**	UBE Europe GmbH	27.6.00	DE	21.7.00	18.10.00	18.10.00	18.10.00	Positive, SCPH 19.10.00; OJ N° L311 12.12.00, p. 47, **00/784/EC**
70	ASU 96 520 H, TKC-94 EC 60	**Pethoxamide (HB)**	Stahler Agrochemie GmbH & Co, KG; Tokuyama Europe GmbH; Tomen Fr. sa	16.10.00	DE	7.3.01	~~29.4.1~~ 23.4.1	3.7.01	23.4.01	Positive, SCPH 30.7.01; OJ N° L217 11.8.01, p. 14, **01/626/EC**
71	AE F130060	**Mesosulfuron-methyl (HB)**	Aventis Cropscience, France	~~27.10.00~~ 15.12.00	FR	12.1.01	2.2.01		2.3.01	Positive, SCPH, 2.3.01; OJ N° L99 10.4.01, p. 9, **01/287/EC**
72	PHYLIQ	**Laminarin**	Goemar	29.3.01	BE	11.4.01	~~2.5.01~~	2.7.01	02.10.01	Positive, **01/861/EC,** OJ N° L321 of

Annex IIA: Completeness-of-dossier status of NEW active substances under evaluation

No	Dev. Code	Active substance (main use of product)	Company submitting application	Date of application to a MS	RMS. Co RMS	COM receipt of RMS report on completeness	Receipt of dossier in all MS	MS comment period deadline	Referral of dossier to SCFA	Decision on Completeness of Dossier
							31.5.01			6.12.01, p. 34
73	MCW-275, GR 572	**Novaluron**	Huntingdon Lifescience, for Makhteshim Agan (UK) ltd.	29.3.01	UK	15.6.01	16.7.01	14.8.01	02.10.01	Positive, **01/861/EC** OJ N° L321 of 6.12.01, p. 34
74	BAS 510 F	**Boscalid (formerly Nicobifen)**	BASF AG (Germany)	26.4.01	DE	16.7.01	~~14.8.01~~ 11.9.01	6.10.01	07.12.01	Positive, **2002/268/EC**, OJ N° L92 of 9.4.02, p. 34
75	BAS 635 H	**Tritosulfuron**	BASF AG (Germany)	8.6.01	DE	24.7.01	~~14.8.01~~ 11.9.01	6.10.01	07.12.01	Positive, **2002/268/EC,** OJ N° L92 of 9.4.02, p. 34
76	D 2341	**Bifenazate**	Crompton Europe Ltd.	3.7.01	NL	23.7.01	9.10.01	30.10.01	07.12.01	Positive, **2002/268/EC,** OJ N° L92 of 9.4.02, p. 34
77	BAJ 2740	**Spirodiclofen**	Bayer AG, Germany	23.8.01	NL	12.12.01	6.2.02	27.2.02	19.04.02	Positive, **2002/593/EC**, OJ N° L192 of 20.7.02, p. 60
78	TI-425	**Clothianidin**	Takeda Chemical Industries Ltd. London	26.9.01	BE	16.10.01	27.11.01	16.1.02	26.02.02	Positive, **2002/305/EC,** OJ N° L104, 20.4.02, p.42
79	BAS 505F	**Dimoxystrobin**	BASF UK	28.11.01	UK	30.1.02	21.2.02	---	19.04.02	Positive, **2002/593/EC**, OJ N° L192 of 20.7.02, p. 60
80	IR 6141	**Benalaxyl-M**	ISAGRO, IT	22.2.02	PT	03.6.02	29.7.02	15.9.02	---	Positive, **2003/35/EC**, OJ N° L11 of 16.1.03, p. 52
81	KIF 230	**Benthiavalicarb**	KUMIAI Chemical Ltd.	19.4.02	BE	11.6.02	11.6.02	11.7.02	18.10.02	Positive, **2003/35/EC**, OJ N° L11 of 16.1.03, p. 52
82	RH-175933	**1-methylcyclopropene**	Rohm & Haas France SAS.	28.2.02	UK	17.5.02	11.6.02	17.9.02	18.10.02	Positive, **2003/35/EC**, OJ N° L11 of 16.1.03, p. 52
83	HEC 5725	**Fluoxastrobin**	Bayer AG, Monheim	25.3.02	UK	28.5.02	17.6.02	27.9.02	18.10.02	Positive, **2003/35/EC**, OJ N° L11 of 16.1.03, p. 52
84	JAU 6476	**Prothioconazole**	Bayer AG, Centre Monheim	25.3.02	UK	28.5.02	27.9.02	18.10.02		Positive, **2003/35/EC**, OJ N° L11 of 16.1.03, p. 52
85	KIH 2023	**Bispyribac-sodium**	Bayer AG, Crop	26.3.02	IT	23.7.02	15.9.02	15.11.02		Positive, **2003/305/EC,** OJ N° L 112 of 6/5/03, p 10
86	BSN 2060	**Spiromesifen**	Bayer AG, Leverkusen	18.4.02	UK	18.7.02	27.9.02	18.10.02		Positive, **2003/105/EC,** OJ N° L 43 of 18/2/03, p 45
87	BAS56000F	**Metrafenone**	BASF Belgium	4.6.02	UK	4.6.02	14.10.02	28.11.02		Positive, **2003/105/EC,** OJ N° L 43 of 18/2/03, p 45
88	LBG 01F34	**Potassium Phosphite**	Luxembourg Industries, ISR	22.8.02	FR	20.2.03	27.2.03	20.3.03		Positive, SCFA 4.7.03
89		**Sulfuryl fluoride**	Dow AgroSciences Ltd	29.7.02	UK	1.11.02	5.11.02	28.11.02		Positive, **2003/305/EC,** OJ N° L 112 of 6/5/03, p 10
90	NF-149	**Cyflufenamid**	Nippon Soda Company Ltd	14.01.03	UK					Positive, SCFA 4.7.03
91		**Penoxulam**	Dow Agroscience		IT	18.06.2003				
92	BAS 670 00 H	**BAS 670H**	BASF, Germany	12.05.2003	FR	23.05.2003				
93		**Acequinocyl**			NL					Positive, SCFA 4.7.03

Annex IIA: Completeness-of-dossier status of NEW active substances under evaluation

No	Dev. Code	Active substance (main use of product)	Company submitting application	Date of application to a MS	RMS. Co RMS	COM receipt of RMS report on completeness	Receipt of dossier in all MS	MS comment period deadline	Referral of dossier to SCFA	Decision on Completeness of Dossier
Annex II.A.2 Micro-organisms										
1		***Paecilomyces fumosoroseus* Apopka strain 97, PFR97 or CG170, ATCC20874 (IN)**	Thermo Trilogy Corporation	18.5.94	BE	14.11.95	24.11.95		24.11.95	Positive, SCPH 20.11.96; OJ N° L64, 5.3.97, p. 17, **97/164/EC**
2		***Pseudomonas chlororaphis* Strain MA342 (FU)**	BioAgri	15.12.94	SE	22.11.95	20.3.96		20.3.96	Positive, SCPH 7.2.97; OJ N° L98, 15.4.97, p. 15, **97/248/EC**
3	AQ 10	***Ampelomyces quisqualis* Strain AQ10 (IN)**	Ecogen Europe sarl	12.4.96	FR	25.10.96	6.2.97		06.2.97	Positive, SCPH 29.5.97; OJ N° L239, 30.8.97, p. 48, **97/591/EC**
4	SE NPV	***Spodoptera exigua* nuclear polyhedrosis virus (IN)**	Biosys	12.7.96	NL	2.4.97	29.5.97		29.5.97	Positive; SCPH 17.10.97; OJ N° L351, 23.12.97, p. 67, **97/865/EC**
5		***Coniothyrium minitans* (FU)**	Prophyta GmbH	10.9.97	DE	5.1.98	7.7.98		7.7.98	Positive, SCPH 16.10.98; OJ N° L317, 26.11.98, p. 47, **98/676/EC**
~~6~~		~~**Zucchini yellow mosaic virus (ZYMV mild strain)**~~	~~Horticultural Research International~~	~~23.1.98~~	~~UK~~					~~Application withdrawn by notifier~~
7		***Gliocladium catenulatum* (FU) strain J 1446**	Kemira Agro Oy	19.5.98	FIN	22.12.98	11.2.99		11.2.99	Positive, SCPH 12.3.99; OJ N° L148 15.6.99, p. 44, **1999/392/EC**
8	QRD 133WP	***Bacillus subtilis* strain QST 713 (BA, FU)**	AgraQuest	19.4.00	DE	28.5.00	1.9.00		1.9.00	Positive, SCPH 12.12.00; OJ N° L2, 5.1.01, p. 25, **2001/6/EC**
9		***Pseudozyma flocculosa***	Maasmond-Westland ba	6.3.01	NL	3.9.01	19.11.01	16.1.01	26.2.02	Positive, **2002/305/EC**, OJ N° L104, 20.4.02, p.42
10	PBP-01001-I	***Paecilomyces lilacinus***	Prophyta Biologischer Pflanzenschutz GmbH	15.9.02	BE	14.10.02	-	-		Positive, **2003/305/EC,** OJ N° L 112 of 6/5/03, p 10

Annex IIB: Annex I inclusion status of NEW active substances under evaluation

Annex II.B Annex I inclusion status

Annex II.B.1 Chemical substances

No	Active substance (main use of product)	RMS. Co-RMS	Provisional Approvals (applied for) and granted	Start of detailed exam*	Receipt of DAR[2]	DAR sent to MS ,COM and Applicant (A)	Type of Peer Review[3]	Evaluation Group. Overview Meeting	SCP Consultation (target date)	SCFA	Decision
1	**Prohexadione calcium (PG)**	FR	FR,DE,NL	30.8.96	COM 9.6.98	COM, MS: 22.6.98, A: 1.7.98	NPR: 9-98 – 1-99	April 99 Sep 99	26.11.99	16.6.00	Inclusion **00/50/EC** OJ N° L198 of 4.8.00, p.
2	**Kresoxim-methyl (FU)**	BE	FI, UK,NL	12.4.96	COM 15.1.97	COM, MS, A: 14.2.97	NPR: 4-99 – 6-97	Sep 97 Nov 97	29.1.98	16.10.98	Inclusion **99/1/EC** OJ N° L21 of 28.1.99 p. 21
3	**Flurtamone (HB)**	FR	FR,UK,IT,DE,AT IR,BE, LU,(DK,SE)	31.5.96	COM 21.5.97	COM, MS: 18.6.97, A: 26.6.97	NPR: 9-97 - 1-98	April 98 May 98	Aug 98; July 99 - 1.3.00	20.3.96	Inclusion voted 4.7.03
4	**Chlorfenapyr (IN, AC)**	ES	(IT, EL, BE)	30.8.96	COM 30.11.98 ECCO: 18.6.99	COM,MS: 14.12.98, A: 15.12.98	NPR: 3-99 – 10-99	Feb 01	June 01	27.4.01	Non-inclusion **01/697/EC** OJ N° L249, 19.9.01 p. 19
5	**Quinoxyfen (FU)**	UK	IR,UK,FR,P,IT,GR, B,E,AT,(D, DK),NL	30.7.96	COM 11.10.96	COM, MS, A: 11.2.97	NPR: 4-97 – 6.97	9/97, 11/97, 9/99, 11/99, March 00	31.3.00	22.4.96	
6	**Azoxystrobin (FU)**	DE	(IT), UK,NL	30.08.96	COM 5.2.97	COM, MS, A: 14.2.97	NPR: 4-97 – 6-97	Sep 97, Nov 97	Jan-98	22.4.98	Inclusion **98/47/EC** OJ N° L191 of 7.7.98, p.
7	**Spiroxamine (FU)**	DE	(DE, FR,NL), UK	30.8.96	COM 5.2.97	COM, MS, A: 14.2.97	NPR: 4-97 – 6-97	Sep 97, May 98	31.8.98	12.5.99	Inclusion **99/73/EC** OJ N° L206 of 5.8.99, p. 16
8	**Isoxaflutole (HB)**	NL	PT,NL,IT,LU,BE, GR,ES,FR,(AT,DE)	30.8.96	COM 26.2.97	COM, MS: 26.2.97	NPR: 4-97 – 6-97	Sep 97, Feb. 98	4.3.98	14.6.96	Inclusion **03/68/EC** OJ N° L177 of 16.7.03, p. 12
~~9~~	~~**Alanycarb (IN)**~~	~~FR~~		~~15.7.99~~	01.10.2001	*05.10.2001 A MS*				12.5.99	~~Incomplete dossier~~
10	**Flupyrsulfuron methyl (HB)**	FR	FR, UK, (DE,NL), IR, BE, AT, LU	5.3.97	COM 2.12.97	COM, MS: 9.12.97, A: 18.12.97	NPR: 3-98 – 7-98	Dec 98, March 99	15.7.99	27.4.01	Inclusion **01/49/EC** OJ N° L176, p. 61, of 29.6.01
11	**Flumioxazine (HB)**	FR	FR, (DE, ES)	24.9.97	COM 20.1.98	COM, MS: 14.4.98, A: 23.4.98	NPR: 9-98 – 1-99	Sep 99, June 00	2.8.00	28.6.02	Inclusion **02/81/EC** OJ N° L276 p.28 of 12.10.02
12	**Prosulfuron (HB)**	FR	UK, PT, IT, FR,AT, (DE, ES)	22.2.97	COM 18.1.99, ECCO: 2.8.99	COM, MS: 16.6.99, A: 22.6.99	NPR: 11-99 – 7-00	July-00	4.8.00	26.2.02	Inclusion **02/48/EC** OJ N° L148, p. 19, 6.6.02
13	**Metalaxyl-M (FU)**	BE	IR,NL,B,UK,P,FI, GR,(I,AT,D,F,ES,S)	30.8.97	COM 27.7.99	COM, MS, A: 20.9.99	NPR: 11-99 – 7-00	July-00		19.4.02	Inclusion **02/64/EC** OJ L189 of 18.7.02 , p. 27
14	**Azimsulfuron (HB)**	IT		5.3.97	COM 22.5.97	COM, MS: 18.6.97, A: 26.6.97	NPR: 09-97 – 1-98	April 98, May 98	31.8.98	2.7.99	Inclusion **99/80/EC** OJ L210 of 10.8.99, p. 13
15	**Fosthiazate (NE)**	UK	IT,BE,UK, ES, (NL,FR,DE,GR)	11.6.97	COM 18.3.98	COM, MS, A: 25.3.98	NPR: 09-98 – 1-99	Sep 99, Jan 00, Oct 00	4.12.00	21.3.97	Inclusion voted 4.7.03
16	**Cyclanilide (PG)**	EL	GR, ES	22.2.97	COM 11.2.98	COM, MS: 23.6.98 A: 30.6.98	NPR: 09-98 – 1-99	Sep 99, Jan 00	31.3.00	29.6.01	Inclusion **01/87/EC** OJ N° L276 of 19.10.01, p. 17

[2] Draft Assessment Report.

[3] NPR = Normal ECCO Peer Review, APR = Accelerated ECCO Peer Review under the Co-Rapporteur System for detailed information concerning the Co-Rapporteur System and the Accelerated ECCO Peer Review see ECCO Manual D 9, 11622/ECCO/BBA/01. Deadline for comments (C) and evaluation (E).

Annex IIB: Annex I inclusion status of NEW active substances under evaluation

No	Active substance (main use of product)	RMS. Co-RMS	Provisional Approvals (applied for) and granted	Start of detailed exam*	Receipt of DAR[2]	DAR sent to MS ,COM and Applicant (A)	Type of Peer Review[3]	Evaluation Group. Overview Meeting	SCP Consultation (target date)	SCFA	Decision
17	**Carfentrazone-ethyl (HB)**	FR	UK,D,IR,B,NL,ES, AT,LU,GR,PT,(FI,I, R,S,DK)	11.6.97	COM 14.5.98	COM, MS: 22.6.98 A: 01.7.98	NPR: 9-98 – 1-99	Sept-99	26.11.99	21.3.97	Inclusion **03/68/EC** OJ N° L177 of 16.7.03, p. 12
18	**Flufenacet (HB)**	FR	B,F,AT,NL,LU,GR, UK,(D, IT, PT, ES)	11.6.97	COM 6.1.98	COM, MS, A: 25.3.98	NPR: 9-98 – 1-99	Sep 99, June 00	2.8.00		Inclusion voted 4.7.03
19	**Imazosulfuron (HB)**	DE	(DE, PT, ES)	23.12.97	COM 17.6.98	COM, MS: 23.6.98, A: 30.6.98	NPR: 9-98 – 1-99	Sep 99, June 00	4.8.00	17.10.97	
20	**Ethoxysulfuron (HB)**	IT	IT, (ES)	30.8.97	COM 20.5.98	COM, MS: 23.6.98, A: 30.6.98	NPR: 9-98 – 1-99	Sep 99, Jan 00	4.12.00	30.5.97	Inclusion **03/23/EC** OJ L81 of 28.3.03 , p. 39
21	**Pymetrozine (IN)**	DE	P,UK,SE, GR, ES, F FI,NL (IT, DE, B)	23.12.97	COM 28.5.98	COM, MS: 14.4.98 A: 23.4.98	NPR: 9-98 – 1-99	Sep 99, Jan 00, March 00	7.4.00	29.6.01	Inclusion **01/87/EC** OJ N° L 276 of 19.10.01 p. 17
22	**Famoxadone (FU)**	FR	IR,ES,F,GR,IT,UK, PT,NL(D,AT,B, FI)	30.8.97	COM 5.8.98	COM,MS,A:11.1.99	NPR: 3-99 – 10-99	Jan-00	2.8.00	19.4.02	Inclusion **02/64/EC** OJ L189 of 18.7.02 , p. 27
23	**Acibenzolar-S-methyl (PA)**	FR	UK, FR, (IT)	23.12.97	COM 17.12.98	COM, MS, A: 11.1.99	NPR: 3-99 – 10-99	-	1.3.00	29.6.01	Inclusion **01/87/EC** OJ N° L276 of 19.10.01 p. 17
24	**Flazasulfuron (HB)**	ES	ES, FR, PT, (IT, AT, BE,DE,GR)	23.12.97	COM 3.8.99, ECCO: 2.8.99	COM, MS. 30.8.99, A :8.9.99	NPR: 11-99 – 7-00	July-00		17.10.97	
25	**Carvone (PG)**	NL/SE	NL	14.9.99	COM 16.10.00, ECCO: 23.11.00	COM, MS, A: 16.1.01	APR : 04 –09-01	Feb-02, Mar-02		20.7.99	
26	**Sulfosulfuron (HB)**	IRL	IR,(DE,BE,SE), FR, ES,DK, FI, UK	23.12.97	COM 2.4.98	COM, MS: 14.4.98, A: 23.4.98	NPR: 9-98 – 1-99	April 99, Sep 99, Jan 00	12.99; 31.3.0	26.2.02	Inclusion **02/48/EC** OJ N° L148, p. 19, 6.6.02
27	**Cyhalofop-butyl (HB)**	IT	IT, ES, GR	28.3.98	COM 30.11.98	COM, MS, A: 6.1.99	NPR: 3-99 – 10-99	Jan 00, June 00	2.8.00	19.4.02	Inclusion **02/64/EC** OJ L189 of 18.7.02 , p. 27
28	**Cinidon ethyl (HB)**	UK	UK, BE, FR, NL (DE, SE, DK)	20.6.98	COM 2.11.98	COM,MS: 14.12.98, A: 15.12.98	NPR: 3-99 – 10-99	Jan-00		19.4.02	Inclusion **02/64/EC** OJ L189 of 18.7.02 , p. 27
29	**Fenhexamid (FU)**	UK	D,E,B,GR,UK,DK, FI,NL,AT,SE,(P,IR)	20.6.98	COM 15.10.98	COM, MS, A: 15.10.98	NPR: 3-99 – 10-99	Jan-00	31.3.00	22.4.98	Inclusion, **01/28/EC** OJ N° L113 of 24.4.01, p. 5
30	**Oxadiargyl (HB)**	IT	(IT, ES, FI)	20.6.98	COM 20,7.99, ECCO: 2.8.99	COM, MS: 30.8.99, A: 8.9.99	NPR: 11-99 – 7-00	July-00		22.4.98	Inclusion **03/23/EC** OJ L81 of 28.3.03 , p. 39
31	**Pyraflufen-ethyl (HB)**	BE	BE, LU, (DE, NL,FR)	28.3.98	COM 13.7.99	COM, MS, A: 20.9.99	NPR: 11-99 – 7-00	July-00	4.8.00	29.6.01	Inclusion **01/87/EC** OJ N° L276 of 19.10.01, p. 17
32	**Azafenidin (HB)**	ES	(IT, ES)	28.3.98	ECCO: 20.11.00	COM, MS, A: 20.2.01	NPR: 2/02 – 9/02			28.6.02	Non-inclusion **02/949/EC** OJ N° L328 of 5.12.02, p.23
33	**S-Metolachlor (HB)**	BE/ NL	(BE, IT, DE, AT,ES),LU, PT,NL	15.8.98	COM 3.5.99 (rev. on 7.9.00), ECCO 23.11.00	COM, MS, A: 16.1.01	APR: 30.4.01 – 31.7.01	Dec-01, Mar-02, Oct-02		8.7.98	
34	**Tepraloxydim (HB)**	ES	(DE,ES,SE),BE,UK	15.8.98	**21.1.02**	30.01.2002	NPR 19.11.02 – 16.07.03			8.7.98	

Annex IIB: Annex I inclusion status of NEW active substances under evaluation

No	Active substance (main use of product)	RMS. Co-RMS	Provisional Approvals (applied for) and granted	Start of detailed exam*	Receipt of DAR[2]	DAR sent to MS ,COM and Applicant (A)	Type of Peer Review[3]	Evaluation Group. Overview Meeting	SCP Consultation (target date)	SCFA	Decision
~~35~~	~~**Fluazolate (HB)**~~	~~UK~~	~~(UK, BE, DE)~~	~~26.11.98~~	~~**(March 01)**~~					15.10.98	~~Incomplete dossier~~
36	**Indoxacarb (IN)**	NL	(D,AT,IT,B),NL,LU	20.6.98	COM 7.2.00	COM,MS,A:27.3.00	APR 27. 6.00	Febr-01, Apr-01, Jun-01, Oct-01		22.4.98	
37	**Mepanipyrim (FU)**	IT / UK	(IT, BE, ES, FR, PT),UK,NL,LU	26.11.98	COM 12.7.00, ECCO 23.11.00	COM, MS: 19.9.00, A: 16.1.01	NPR 19.11.02 – 16.07.03			15.10.98	
38	**Imazamox (HB)**	FR	(F, EL, IT, ES,UK)	26.11.98	COM 9.9.99, ECCO 1.2.00	COM, MS, A: 20.4.00	NPR: 1-01 – 7-01	July-01		15.10.98	Inclusion **03/23/EC** OJ L81 of 28.3.03 , p. 39
~~39~~	~~**Flusulfamide (FU)**~~	~~UK~~	~~(UK)~~								~~Application withdrawn~~
40	**Florasulam (HB)**	BE	B,UK,FI,NL (D, DK,AT,ES,IT,S,IR)	26.11.98	COM: 19.11.99, ECCO: 3.1.99	COM, MS, A: 28.1.00	APR: 27.6.00 – 22.8.00	Oct-00	4.12.00	19.4.02	Inclusion **02/64/EC** OJ L189 of 18.7.02 , p. 27
41	**Trifloxystrobin (FU)**	UK	UK,B,IR,IT,LU,NL (FI,D,AT,PT,ES,F)	19.1.99	COM:10.08.02, ECCO 10.8.00	COM, MS: 19.9.00, A: 19.1.01	NPR: 3-01 – 9-01	Sept-02		30.11.98	Inclusion **03/68/EC** OJ N° L177 of 16.7.03, p. 12
42	**Iprovalicarb (FU)**	IRL/ DE	IR, IT (DE,GR,PT,ES)	15.8.98	COM 4.11.99, ECCO: 05.00	COM, MS, A: 17.7.00	APR	July-00	4.8.00	26.2.02	Inclusion **02/48/EC** OJ N° L148, p. 19, 6.6.02
43	**Profoxydim (HB)**	ES	(PT, ES, IT), ES	19.1.99	28.3.01	COM, MS: 13.5.01 A: 23.5.01	NPR: 2-9 02	Sept-02			
44	**Etoxazol (IN)**	FR	(FR)	19.1.99	8.10.01	MS, A:9.10.01	NPR: 11 01 – 8 02	Aug-02		30.11.98	
45	**Benzoic acid**	DE	DE, FI, (NL)	26.11.98	COM 12.12.00, ECCO: 5.12.00	COM, MS, A: 21.12.00	APR: 31.3 – 31.3.02,	Mar-03		15.10.98	
46	**Mesotrione (HB)**	UK/ DE	(DE,IT,BE,ES, PT, FR) NL	15.6.99	COM 17.12.99, ECCO: 2.00	COM, MS, A: 27.3.00	NPR: 27-00 – 10-00	Jun–02, Jan-03			Inclusion **03/68/EC** OJ N° L177 of 16.7.03, p. 12
47	**Oxasulfuron (HB)**	IT	(IT)	31.3.99	COM 10.5.00, ECCO 15.12.00	COM, MS: 27.6.00, A: 25.8.00	NPR: 1-01 – 7-01	Jul-02, Sep-02		11.2.99	Inclusion **03/23/EC** OJ L81 of 28.3.03 , p. 39
48	**Ferric phosphate (MO)**	DE	(D,SE,DK), LU,NL	19.1.99	COM 10.8.99.	COM, MS, A: 20.9.99	NPR: 11-99 – 7-00	July-00	2.8.00	29.6.01	Inclusion **01/87/EC** OJ N° L276 of 19.10.01 p. 17
49	~~**Pyridafol**~~	UK									Incomplete dossier
50	**Thiacloprid (IN)**	UK	(D, NL, B), PT,UK	2.3.00	COM 28.11.00, ECCO: 22.11.00	COM, MS: 18.1.01, A: 19.1.01	NPR: 3-01 – 9-01	Sept-01		30.11.99	
51	**Beta cypermethrin**	BE	(DE)								
52	**Florchlorfenuron (PG)**	ES		2.3.00	9.12.2002	COM, MS, A: 20.12.2002	NPR: 11.02-. -. 17.09.03			30.11.99	
53	**Iodosulfuron-methyl-sodium (HB)**	DE	(D,NL,IT), BE, LU, UK,FR	15.6.99	COM 30.5.00,	COM, MS: 19.9.00, A: 7.12.01	NPR: 1-01 – 7-01	July-01; Sep-02			Inclusion voted 4.7.03
54	**Silthiofam**	IRL	(DE,IR),BE,LU,UK	15.6.99	COM 2.10.00, ECCO: 23.11.00	COM, MS: 15.11.00, A: 16.1.01	APR: 30.4. – 31.7.01	Jun-02			Inclusion voted 4.7.03
55	**Thiamethoxam**	ES	(P,D,B,ES) DK,FI	2.3.00	21.1.02	30.01.2002	NPR: 11.02. – 17.09.03			30.11.99	
56	**Dimethenamid-P (HB)**	DE	(DE) NL	10.8.99	26.9.00	COM, MS, A: 21.12.00	APR: 31.3. – 30.6.01	Mar-03		2.7.99	Inclusion voted 4.7.03
57	**Picolinafen (HB)**	DE	(DE), BE,UK	10.8.99	COM 3.11.00	COM, MS, A: 21.12.00	APR: 31.3. – 30.6.01	Oct-01, Dec-01, Febr-02		19.4.02	Inclusion **02/64/EC** OJ L189 of 18.7.02 , p. 27

Annex IIB: Annex I inclusion status of NEW active substances under evaluation

No	Active substance (main use of product)	RMS. Co-RMS	Provisional Approvals (applied for) and granted	Start of detailed exam*	Receipt of DAR[2]	DAR sent to MS ,COM and Applicant (A)	Type of Peer Review[3]	Evaluation Group. Overview Meeting	SCP Consultation (target date)	SCFA	Decision
58	**Picoxystrobin (FU)**	IR/UK	(IR,DE,FI,NL),UK	10.8.99	11.6.01	COM,MS;A:23.7.01	APR: 11 01 – 3 02	Jun-02		2.7.99	Inclusion voted 4.7.03
59	**Zoxamide (FU)**	UK	(FI,DE,PT,ES,NL), BE,DK,UK	12.9.00	---	COM, MS, A: 17.7.01	NPR: 11 01 – 8 02	May-03		16.6.00	
60	**Spinosad (IN)**	NL	(D, ES),B,UK,NL	11.3.00	5.3.01	COM,MS,A:23.3.01	NPR: 11.01 – 8.02			30.11.99	
61	**Acetamiprid (IN)**	EL/FR	EL,(FR,BE,NL)	20.6.00	19.3.01	COM,MS,A:4.5.01	APR: 9-6.01	Jul-02		12.4.00	
62	**Fenamidone (FU)**	FR/ NL	(B,D,FI,NL,UK)LU	29.3.00	COM 27.10.00 ECCO 7.2.01	COM, MS, A: 23.2.01	APR:	Jul-02		23.2.00	Inclusion **03/68/EC** OJ N° L177 of 16.7.03, p. 12
63	**Cyazofamid (FU)**	FR/ UK	(FR,DE,BE,ES, IT, PT, UK, IR),NL,UK	28.6.00	27.8.01	28.9.01	APR:	Jul-02	Not consulted	12.4.00	Inclusion **03/23/EC** OJ L81 of 28.3.03 , p. 39
64	**Propoxycarbazone-sodium (HB)**	DE	(DE,BE,NL),UK	22.7.00	26.3.01	COM,MS,A:4.5.01	NPR: 2-9 02	Mar-03		12.4.00	
65	**Methoxyfenozide(IN)**	UK	(DE),UK	19.05.01	2.8.02	7.8.02	NPR: 19.11.02 – 16.07.03				
66	**Milbemectin (IN)**	NL	(BE) NL	12.9.00	(16.6.01)	26.6.02	NPR: 19.11.02 – 16.07.03			16.6.00	
67	**Pyraclostrobin (FU)**	DE/ UK	(D,NL),B,DK,LU, UK	12.9.00	23.11.01	COM,MS,A:28.11.1	NPR: 2-9 02			16.6.00	
68	**Foramsulfuron (HB)**	D/BE	(DE,NL)	12.9.00	(June 01)	COM,MS,A:8.6.01	APR: 31.07. – 06.12.01	Jun-02, Sep-02		16.6.00	Inclusion **2003/23/EC** OJ N° L81, p. 39, 28.3.2003
69	**Beflubutamid (HB)**	DE	(DE)	4.12.00	13.8.2002	3.9.02	NPR: 02-09 03			19.10.00	
70	**Pethoxamide (HB)**	DE	(DE)		29.8.02	3.9.02	NPR: 02-09 03				
71	**Mesosulfuron-methyl**	FR/D	(DE),UK,FR	2.3.01	12.12.01	9.1.02	APR:19.04. – 10.10.02				
72	**Laminarine**	BE/FR		6.12.2001			APR:				
73	**Novaluron**	UK/ EL	(EL,UK)	2.10.01	*3/03 (planned)*		APR:				
74	**Boscalid**	DE	(DE,NL),UK	9.4.02	8.11.02	10.12.02	APR:				
75	**Tritosulfuron**	DE	(DE,IT,UK,NL)	9.4.02	5.9.02	11.9.02	NPR: 02-09 03				
76	**Bifenazate**	NL	(NL)	9.4.02							
77	**Spirodiclofen**	NL	(NL)	20.7.02							
78	**Clothianidin**	BE	UK(NL,DE)	20.4.02							
79	**Dimoxystrobin**	UK	(UK, DE)	20.7.02							
80	**Benalaxyl-M**	PT									
81	**Benthiavalicarb**	BE	(DE)							18.10.2002	
82	**1methylcyclopropene**	UK								18.10.2002	
83	**Fluoxastrobin**	UK								18.10.2002	
84	**Prothioconazole**	UK	DE,								
85	**Bispyribac-sodium**	IT									
86	**Spiromesifen**	UK									
87	**Metrafenone**	UK									

Annex IIB: Annex I inclusion status of NEW active substances under evaluation

No	Active substance (main use of product)	RMS. Co-RMS	Provisional Approvals (applied for) and granted	Start of detailed exam*	Receipt of DAR[2]	DAR sent to MS ,COM and Applicant (A)	Type of Peer Review[3]	Evaluation Group. Overview Meeting	SCP Consultation (target date)	SCFA	Decision
88	**Potassium phosphite**	FR									
89	**Sulfuryl fluoride**	UK									
90	**Cyflufenamide**	UK									
91	**Penoxulam**	IT									
92	**BAS 670H**	FR									
93	**Acequinocyl**	NL									

Annex II.B.2 Micro-organisms

No	Active substance (main use of product)	RMS. Co-RMS	Provisional Approvals (applied for) and granted	Start of detailed exam*	Receipt of DAR[4]	DAR sent to MS, COM and Applicant (A)	Type of Peer Review[5]	Evaluation Group. Overview Meeting	SCP Consultation (target date)	SCFA	Decision
1	***Paecilomyces fumosoroseus* (IN)**	BE	B, SE,(DK,UK,NL)	5.3.97	COM 9.12.97	COM, MS, A: 25.3.98	June 98	April 99	16.12.99	27.4.01	Inclusion: **2001/47/EC**, OJ N° L175 of 28.6.01, p. 21
2	***Pseudomonas chlororaphis* (FU)**	SE	SE, FI, (IT, DK)	15.4.97	COM 7.4.98	COM, MS: 15.4.98, A: 23.4.98	June 98	April 99	16.12.99	07.2.97	
3	***Ampelomyces quisqualis* (IN)**	FR	IT, (DK)	30.8.97	COM 28.10.97	COM, MS, A: 25.3.98	June 98	April 99	16.12.99	30.5.97	
4	***Spodoptera exigua* (IN)**	NL	NL	23.12.97	COM 19.11.99. ECCO: 3.1.99	COM, MS, A: 28.1.00	27.6.00 –APR	(Sep 01)		17.10.97	
5	***Coniothyrium minitans* (FU)**	DE	DE, LU, (BE,DK, ES, FR,NL),	26.11.98	COM 13.3.00	COM, MS, A: 17.4.00	APR: 1.2. - 30.4.01, E: 31.3.01	(Sep 01)		15.10.98	Inclusion: **2003/79/EC**, OJ N° L205 of 14.8.03, p. 16
~~6~~	~~**Zucchini yellow mosaic virus**~~	~~UK~~	~~(UK)~~								~~Application withdrawn~~
7	***Gliocladium catenulatum* (FU) strain J1446**	FI	FI	15.6.99	**27.03.2002**	28.03.2002	APR: 30.06.02-01.03.03	Marc-03			
8	***Bacillus subtilis* str. QST 713 (BA, FU)**	DE	(DE)	05.01.01	1.6.01	23.7.01 not Com	APR: 20.11.01-20.05.02	Mar-03		19.10.00	
9	***Pseudozyma flocculosa***	NL									
10	***Paecilomyces lilacinus***	BE									

[4] Draft Assessment Report.

[5] NPR = Normal ECCO Peer Review, APR = Accelerated ECCO Peer Review under the Co-Rapporteur System for detailed information concerning the Co-Rapporteur System and the Accelerated ECCO Peer Review see ECCO Manual D 9, 11622/ECCO/BBA/01. Deadline for comments (C) and evaluation (E).

Annex IIIA: EXISTING active substances – 1st stage – status of work for draft assessment reports and peer review

Annex III. EXISTING ACTIVE SUBSTANCES - 1ST STAGE - STATUS OF EACH

Annex III.A Status of draft assessment reports and peer-review

No	Active Substance		RMS	Deadline for submission of DAR	COM receipt of DAR	COM receipt of summary dossier	Peer review
	Pending	Decided					
1		2,4-D	EL	31.10.96	17.1.97	20.10.97	Sept.97 - Jan.98
2		2,4-DB	EL	30.4.96	17.1.97	25.7.97	Sept.97 - Jan.98
3		Acephate	IT	30.4.96	30.9.96	24.10.96	Nov 99 - July 00
4	Alachlor		ES	31.10.96	20.7.99	27.6.00	Jan. - July 01
5		Aldicarb	UK	30.4.96	2.4.96	20.9.96	Sep. - Dec. 96
6		Amitraz	AU	31.10.96	6.1.98	5.11.98	Mar. - Oct. 99
7		Amitrole	FR	30.4.96	18.7.96	6.1.97	Jan. - April 97
8	Atrazine		UK	30.4.96	11.11.96	5.2.98	March - July 98
9		Azinphos-ethyl	DE	---	---	---	---
10	Azinphos-methyl		DE	30.4.96	11.10.96	24.3.97	Sept 97 - Jan 98
11	Benalaxyl		PT	30.4.96	27.4.00	18.7.00	March - Sept 01
12		Benomyl	DE	30.4.96	21.11.97	17.2.98	March - July 98
13		Bentazone	DE	30.4.96	13.11.96	29.11.96	Sept 97 - Jan 98
14	Bromoxynil		FR	31.10.96	16.3.00	25.2.98	March - Sept 01
15	Carbendazim		DE	31.10.96	21.11.97	10.2.98	March - July 98
16	Chlorothalonil		NL	31.10.96	31.1.00	31.7.00	March - Sept 01
17	Chlorpropham		NL	30.4.96	14.7.99	9.2.99	Nov 99 - July 00
18	Chlorpyrifos		ES	31.10.96	7.5.99	6.7.99	Nov 99 - July 00
19	Chlorpyrifos-methyl		ES	30.4.96	16.9.97	19.11.97	Nov 99 - July 00
20	Chlortoluron		ES	31.10.96	7.5.99	1.9.99	Jan. - July 01
21		Chlozolinate	EL	30.4.96	3.11.97	---	March - July 98
22		Cyfluthrin	DE	30.4.96	13.11.96	28.11.96	Jan - April 97
23		Cyhalothrin		---	---	---	---
24	Cypermethrin		BE	31.10.96	25.10.99	10.5.01	Jan. - July 01
25		DNOC	FR	30.4.96	30.9.96	26.2.97	April - July 97
26	Daminozide		NL	30.4.96	14.7.99	22.11.99	Nov 99 - July 00
27		Deltamethrin	SE	31.10.96	6.10.98	---	Mar. - Oct. 99
28	Desmedipham		FI	30.4.96	8.5.00	---	Nov. 01 - July 02
29	Dinocap		AT	30.4.96	18.5.00	5.1.01	March - Sept 01
30		Dinoterb	FR	30.4.96	18.7.96		Jan. - April 97
31		Diquat	UK	30.4.96	2.4.96	29.7.96	Sep. - Dec. 96
32	Endosulfan		ES	31.10.96	22.2.00	6.6.00	Jan. - July 01
33		Esfenvalerate	PT	30.4.96	11.10.96	12.2.97	April - July 97
34		Ethofumesate	SE	31.10.96	2.10.98	10.3.99	Mar. - Oct. 99
35	Fenarimol		UK	30.4.96	2.4.96	26.8.96	Sep. - Dec. 96
36		Fenthion	EL	30.4.96	4.7.96	9.96	Sep. - Dec. 96
37		Fentin acetate	UK	31.10.96	11.11.96	27.11.97	March - July 98
38		Fentin hydroxide	UK	31.10.96	11.11.96	27.11.97	March - July 98
39		Fenvalerate	PT	---	---	---	---
40		Ferbam	BE	---	---	---	---
41		Fluroxypyr	DE	30.4.96	27.9.96	6.1.96	Jan. - April 97
42	Flusilazole		IR	30.4.96	18.7.96	26.8.96	Jan. - April 97
43		Glyphosate	DE	31.10.96	1.2.99	2.3.99	Mar. - Oct. 99
44		Imazalil	LU	30.4.96	15.7.96	30.8.96	Sep. - Dec. 96
45	Ioxynil		FR	31.10.96	16.3.00	10.8.00	March - Sept 01
46		Iprodione	FR	30.4.96	18.7.96	17.12.97	March - July 98
47		Isoproturon	DE	31.10.96	28.7.99	23.9.99	Nov 99 - July 00
48		Lindane	AT	31.10.96	17.12.98	4.2.99	Mar. - Oct. 99
49		Linuron	UK	31.10.96	11.11.96	4.8.97	Sept. 97 - Jan 98
50	MCPA		IT	31.10.96	5.4.01	20.12.01	Feb - Sept.02
51	MCPB		IT	30.4.96	19.12.01	15.3.02	Feb - Sept.02
52		Maleic hydrazide	DK	30.4.96	5.9.97	4.11.97	Mar. 99 - Oct. 99
53	Mancozeb		IT	31.10.96	3.10.00	11.9.00	Nov. 01 - July 02
54	Maneb		IT	30.4.96	29.11.00	---	Nov. 01 - July 02
55		Mecoprop	DK	31.10.96	2.9.99	25.10.99	Nov 99 - July 00
56		Mecoprop-p	DK	31.10.96	7.1.99	16.8.99	Nov 99 - July 00
57		Metalaxyl	PT	31.10.96	29.1.01	---	---

Annex IIIA: EXISTING active substances – 1st stage – status of work for draft assessment reports and peer review

No	Active Substance		RMS	Deadline for submission of DAR	COM receipt of DAR	COM receipt of summary dossier	Peer review
	Pending	Decided					
58	Methamidophos		IT	31.10.96	23.8.00	---	March - Sept 01
59	Metiram		IT	30.4.96	22.8.00	17.5.02	Nov. 01 - July 02
60	Metsulfuron-methyl		FR	31.10.96	25.6.97	18.7.97	Sept 97 - Jan 98
61	Molinate		PT	30.4.96	30.11.98	15.3.99	Nov 99 - July 00
62	Monolinuron		UK	30.4.96	11.11.96	4.8.97	Sept.97 - Jan.98
63	Paraquat		UK	31.10.96	1.10.96	26.2.97	April - July 97
64	Parathion		IT	30.4.96	30.11.98	---	Nov 99 - July 00
65	Parathion-methyl		IT	31.10.96	5.4.01	4.9.01	---
66	Pendimethalin		ES	31.10.96	20.5.98	17.5.98	Sept.98 - Jan.99
67	Permethrin		IR	31.10.96	10.6.98	---	---
68	Phenmedipham		FI	31.10.96	5.1.00	26.4.99	Nov. 01 - July 02
69	Procymidone		FR	30.4.96	5.12.00	29.1.01	Feb. - Sept. 02
70	Propham		NL	---	---	---	---
71	Propiconazole		FI	30.4.96	30.11.98	25.10.99	Nov 99 - July 00
72	Propineb		IT	30.4.96	17.7.96	7.1.97	Jan. - April 97
73	Propyzamide		SE	31.10.96	19.5.98	3.3.99	Mar. - Oct. 99
74	Pyrazophos		NL	30.4.96	14.5.98	11.8.98	Sept.98 - Jan.99
75	Pyridate		AT	30.4.96	18.11.96	7.1.97	April - July 97
76	Quintozene		EL	30.4.96	1.12.97	9.2.98	March - July 98
77	Simazine		UK	31.10.96	20.12.96	5.2.98	March - July 98
78	Tecnazene		UK	30.4.96	2.4.96	4.7.96	Sep. - Dec. 96
79	Thiabendazole		ES	30.4.96	8.8.96	23.10.96	Sept.97 - Jan.98
80	Thifensulfuron-methyl		FR	30.4.96	18.7.96	9.12.96	Jan. - April 97
81	Thiophanate-methyl		DE	31.10.96	21.11.97	16.1.98	March - July 98
82	Thiram		BE	31.10.96	15.1.98	---	Mar. - Oct. 99
83	Triasulfuron		FR	30.4.96	30.9.96	8.8.97	Sept 97 - Jan 98
84	Vinclozolin		FR	30.4.96	24.3.97	4.8.97	March - July 98
85	Warfarin		IR	30.4.96	15.5.96	20.9.96	Sep. - Dec. 96
86	Zineb		IT	31.10.96	---	---	---
87	Ziram		BE	31.10.96	9.6.98	10.3.99	Mar. - Oct. 99
88	alpha-Cypermethrin		BE	30.4.96	16.9.99	10.5.01	Jan. - July 01
89	beta-Cyfluthrin		DE	30.4.96	28.11.96	28.11.97	Jan. - April 97
90	lambda-Cyhalothrin		SE	30.4.96	15.7.96	31.7.96	Sep. - Dec. 96

Annex IIIB: EXISTING active substances - 1st stage - post peer-review planning

Annex III.B Post peer-review planning/inclusion status

No	Active Substance		RMS	Tri-partite	Evaluation Group	SCP (submitted) and * Opinion	SCPH Legislation. Group	Decision
	Pending	Decided						
1		**2,4-D**	EL		2,9,11/99, 3/00	(5/00), * 25.4.01	10/01	**Inclusion** 2001/103/EC, OJ N° L313, 30.11.01, p. 37
2		**2,4-DB**	EL	27.3.98	12/98, 3,9/99, 3,10,11/00		12/02	**Inclusion** 2003/31/EC by OJ N° L101, 23.4.03, p. 3
3		**Acephate**	IT	18.6.02				**Withdrawal** 03/219/EC by OJ N° L82, 29.3.03, p. 40
4	Alachlor		E					**Postponed** to 31.12.2002 by 2001/810/ EC, OJ N° L305, 22.11.01, p. 32
5		**Aldicarb**	UK	29.3.97	12/97, 4/98, 2,4/01	(8/98)*18.12.98	4/98, 7/98	**Withdrawal** 03/199/EC by Council OJ N° L76, 22.3.03, p. 21
6		**Amitraz**	AT	9.6.00 21.3.03	10/00			**Postponed** to 31.8.01 by 2001/134/EC, OJ N° L49, 20.2.01, p. 13 **Non-inclusion** voted 4.7.03
7		**Amitrole**	FR	17.11.97	2,12/98, 5/99, 10/00	(12/99), * 6.6.00	10/00	**Inclusion** 2001/21/EC by OJ N° L69, 10.3.01, p. 17
8	Atrazine		UK	6.6.03	9/99, 3/00, 2,10/01			Further data requested by 15.12.01
9		**Azinphos-ethyl**	DE					**Withdrawn** 95/276/EC, OJ N° L170, 20.7.95, p. 22
10	Azinphos-methyl		DE	15.3.98 29.1.03	9/98, 9,11/99, 6/01		6/00, 10/01	Further data requested by 15.2.02 EFSA consulted in May 2003 on risk assessment for non-target arthropods and birds
11	Benalaxyl		PT					**Postponed** to 25.5.2003 by 2001/810/ EC, OJ N° L305, 22.11.01, p. 32
12		**Benomyl**	DE		3/00, 2,4/01	(5/00), * 7.3.01		**Withdrawn** 02/928/EC, OJ N° L322, 27.11.02, p. 53
13		**Bentazone**	DE		2,9/99, 5/00	(7/99), *2.12.99	6/00, 7/00	**Inclusion** 2000/68/EC by OJ N° L276, 28.10.00, p. 41
14	Bromoxynil		FR					**Postponed** to 25.5.03 by 2001/810/ EC, OJ N° L305, 22.11.01, p. 32
15	Carbendazim		DE		3/00, 2,4/01	(5/00) *7.3.01		**Postponed** to 25.5.03 by 2001/679/EC, OJ N° L239, 7.9.01, p. 39
16	Chlorothalonil		NL					**Postponed** to 25.5.03 by 2001/810/ EC, OJ N° L305, 22.11.01, p. 32
17	Chlorpropham		NL					**Postponed** to 31.12.01 by 2001/134/EC, OJ N° L49, 20.2.01, p. 13
18	Chlorpyrifos		ES					**Postponed** to 30.4.02 by 2001/134/EC, OJ N° L49, 20.2.01, p. 13
19	Chlorpyrifos-methyl		ES		10/00			**Postponed** to 30.4.02 by 2001/134/EC, OJ N° L49, 20.2.01, p. 13
20	Chlortoluron		ES					**Postponed** to 31.12.2003 by 2001/810/ EC, OJ N° L305, 22.11.01, p. 32
21		**Chlozolinate**	EL	5.2.99	-		11/99	**Withdrawn** 2000/626/EC by OJ N° L263, 18.10.00, p. 32
22		**Cyfluthrin**	DE		9/98, 2/99, 3,10/00	(4/99)* 28.1.00	6/00, (02/02)	**Inclusion** 2003/31/EC by OJ N° L101, 23.4.03, p. 3
23		**Cyhalothrin**						**Withdrawn** 94/643/EC, OJ N° L249, 24.9.94, p. 18
24	Cypermethrin		BE					**Postpone**d to 30.6.03 by 2001/810/ EC, OJ N° L305, 22.11.01, p. 32
25		**DNOC**	FR	2.2.98	5/98	-	7/98, 10/98, 12/98	**Withdrawn** 1999/164/EC by OJ N° L54, 2.3.99, p. 21
26	Daminozide		NL		10,11/00, 4/01			**Postponed** to 31.12.01 by 2001/134/EC, OJ N° L49, 20.2.01, p. 13
27		**Deltamethrin**	SE		11/00, 2/01			**Inclusion** 2003/5/EC by OJ N° L8, 14.1.03, p. 7
28	Desmedipham		FIN					**Postponed** to 25.5.02 by 2001/679/EC, OJ N° L239, 7.9.01, p. 39, Final data call for 31.03.2003
29	Dinocap		AT					**Postponed** to 31.12.03 by 2001/810/EC, OJ N° L305, 22.11.01, p. 32
30		**Dinoterb**	FR		6/97			**Withdrawn** 98/269/EC, OJ N° L117, 21.4.98, p. 13
31		**Diquat**	UK		4/97, 2,3/99	(7/99), * 17.3.00	10/00	**Inclusion** 20011/21/EC, OJ N° L67, 10.3.01, p. 17
32	Endosulfan		ES					**Postponed** to 31.5.03 by 2001/810/EC, OJ N° L305, 22.11.01, p. 32
33		**Esfenvalerate**	PT	21.1.98	4,9/98, 2/99, 3,5/00	(4/99), * 17.03.00	6,7/00	**Inclusion** 2000/67/EC, OJ N° L276, 28.10.00, p. 38
34		**Ethofumesate**	SE		10/00, 2/01	(5/01) no question	12/01	**Inclusion** 2002/37/EC, OJ N° L117, 4.5.02, p. 10
35	Fenarimol		UK	11.11.97	9,12/97, 11/99, 11/00, 2,4/01	* 18/5/99	2/98	Final data to be submitted by April 2004

Annex IIIB: EXISTING active substances - 1st stage - post peer-review planning

No	Active Substance		RMS	Tri-partite	Evaluation Group	SCP (submitted) and * Opinion	SCPH Legislation. Group	Decision
	Pending	Decided						
36		**Fenthion**	EL	18.4.97 11.2.03	2,5,9/97, 2,4/01	(2/98), *2.10.98	7,10,12/98, 2/99, 4,10/01	**Non-inclusion** voted 4.7.03
37		**Fentin acetate**	UK	8.12.98	3,11/99, 11/00, 4/01	(5/01)		**Withdrawn** 2002/478/EC, OJ N° L164, 22.6.02, p. 41
38		**Fentin hydroxide**	UK	8.12.98	3,11/99, 11/00, 4/01	(5/01)		**Withdrawn** 2002/479/EC, OJ N° L164, 22.6.02, p. 43
39		**Fenvalerate**	PT					**Withdrawn** 98/270/EC, OJ N° L117, 21.4.98, p. 15
40		**Ferbam**	BE					**Withdrawn** 95/276/EC, OJ N° L170, 20.7.95, p. 22
41		**Fluroxypyr**	DE		2,5/98	(2/99), * 18.5.99	10/98; 11/99	**Inclusion** 2000/10/EC, OJ N° L57, 2.3.00, p. 28
42	Flusilazole		IRL	4.11.97	12/97, 4/98, 3,9,11/99, 1,11/00, 2/01	(5/01), no question	10/01	Final data submitted on 18.2.03
43		**Glyphosate**	DE		3,5,10,11/00	(6/00), * 26.1.01	4, 7/01	**Inclusion** 2001/99/EC, OJ N° L304, 21.11.01, p. 14
44		**Imazalil**	LU	26.3.97	4/97			**Inclusion** 97/73/EC, OJ N° L353, 24.12.97, p. 26
45	Ioxynil		FR					**Postponed** to 25.5.03 by 2001/810/EC, OJ N° L305, 22.11.01, p. 32
46		**Iprodione**	FR		9,11/99, 5/00	(12/00)		**Inclusion** 2003/31/EC by OJ N° L101, 23.4.03, p. 3
47		**Isoproturon**	DE		2/01	(5/01) no question	10/01	**Inclusion** 2002/18/EC, OJ N° L55, 26.2.02, p. 29
48		**Lindane**	AT	7.12.99	3,5/00		5/99, 6/00	**Withdrawn** 2000/801/EC, OJ N° L324, 21.12.00, p. 42
49		**Linuron**	UK		3/99, 1/00			**Inclusion** 2003/31/EC by OJ N° L101, 23.4.03, p. 3
50	MCPA		IT					Final data call for 31.3.03
51	MCPB		IT					Final data call for 30.6.03
52		**Maleic hydrazide**	DK		5/00, 4,12/01	(5/01)		**Inclusion** 2003/31/EC by OJ N° L101, 23.4.03, p. 3
53	Mancozeb		IT					**Postponed** to 31.12.02 by 2001/679/EC, OJ N° L239, 7.9.01, p. 39
54	Maneb		IT					**Postponed** to 25.5.02 by 2001/679/EC, OJ N° L239, 7.9.01, p. 39, final data call for 20.04.2003
55		**Mecoprop**	DK					**Inclusion** 2003/70/EC by OJ N° L184, 23.7.03, p. 9
56		**Mecoprop-P**	DK					**Inclusion** 2003/70/EC by OJ N° L184, 23.7.03, p. 9
57		**Metalaxyl**	PT	30.1.02				**Withdrawn** 2003/308/EC, OJ N° L113, 7.5.03, p. 8
58	Methamidophos		IT		10/00			**Postponed** to 25.5.03 by 2001/810/EC, OJ N° L305, 22.11.01, p. 32
59	Metiram		IT					**Postponed** to 30.4.03 by 2001/679/EC, OJ N° L239, 7.9.01, p. 39
60		**Metsulfuron - methyl**	FR		12/98, 9/99	(7/99), *17.3.00	4, 6/00	**Inclusion** 2000/49/EC, OJ N° L197, 3.8.00, p. 32
61		**Molinate**	PT					**Inclusion** voted 4.7.03
62		**Monolinuron**	UK		(notifier withdrew)		5, 7/99	**Withdrawn** 2000/234/EC, OJ N° L73, 22.3.00, p. 18
63	Paraquat		UK		6/00	(1/01)		
64		**Parathion**	IT					**Withdrawn** 2001/520/EC, OJ N° L187, 10.7.01, p. 47
65		**Parathion-methyl**	IT	19.7.02			6/01	**Withdrawn** 2003/166/EC, OJ N° L67, 12.3.03, p. 18
66		**Pendimethalin**	E	4.6.99	5,6/00, 2/01			**Inclusion** 2003/31/EC by OJ N° L101, 23.4.03, p. 3
67		**Permethrin**	IR		(notifier withdrew)		5, 11/99; 6, 7/00	**Withdrawn** 2000/817/EC, OJ N° L332, 28.12.00, p. 114
68	Phenmedipham		FI					**Postponed** to 25.5.02 by 2001/679/EC, OJ N° L239, 7.9.01, p. 39, final data call for 31.03.2003
69	Procymidone		FR					**Postponed** to 25.5.02 by 2001/679/EC, OJ N° L239, 7.9.01, p. 39, final data call for 31.5.03
70		**Propham**	NL					**Withdrawn** 96/586/EC, OJ N° L257, 10.10.96, p. 41
71		**Propiconazole**	FI					**Inclusion** 2003/70/EC by OJ N° L184, 23.7.03, p. 9

Annex IIIB: EXISTING active substances - 1st stage - post peer-review planning

No	Active Substance		RMS	Tri-partite	Evaluation Group	SCP (submitted) and * Opinion	SCPH Legislation. Group	Decision
	Pending	Decided						
72		**Propineb**	IT	4.12.97	2,12/98, 11/99, 1,5/00	(5/01) 20.11.01		**Inclusion** 2003/39/EC, OJ N° L124, 20.5.03, p. 30
73		**Propyzamide**	SE		4/01			**Inclusion** 2003/39/EC, OJ N° L124, 20.5.03, p. 30
74		**Pyrazophos**	NL				5, 7/99	**Withdrawn** 2000/233/EC, OJ N° L73, 22.3.00, p. 16
75		**Pyridate**	AT		12/98, 9/99, 10/00	(12/99), *6.6.00	10/00	**Inclusion** 2001/21/EC, OJ N° L67, 10.3.01, p. 17
76		**Quintozene**	EL	4.2.99	11/99, 3/00, 10/01		6, 7/00	**Withdrawn** 2000/816/EC, OJ N° L332, 28.12.00, p. 112
77	Simazine		UK	6.6.03	9/99, 3/00, 2,10/01			Further data requested by 15.12.01
78		**Tecnazene**	UK	12.11.97	2,4/98		10,12/98, 2,3/99; 4/00	**Withdrawn** 2000/725/EC, OJ N° L292, 21.11.00, p. 30
79		**Thiabendazole**	ES		3,11/99, 3,10/00	(5/00), * 22.9.00	10/00	**Inclusion** 2001/21/EC, OJ N° L69, 10.3.01, p. 17
80		**Thifensulfuron-methyl**	FR		4,12/98, 10/00	(12/00)	4, 7/01	**Inclusion** 2001/99/EC, OJ N° L304, 21.11.01, p. 14
81	Thiophanate-methyl		DE		3/00	(5/00), *7.3.01		**Postponed** to 25.5.02 by 2001/679/EC, OJ N° L239, 7.9.01, p. 39
82		**Thiram**	BE	6/00	10,11/00, 2/01			**Inclusion** voted 4.7.03
83		**Triasulfuron**	FR		12/98, 5/99, 5/00	(7/99), * 17.3.00	7/00	**Inclusion** 2000/66/EC, OJ N° L276, 28.10.00, p. 35
84	Vinclozolin		FR		12/98, 2,3,11/99, 5,10,11/00, 2/01	(5,9/99), *28.10.99, *17.3.00	2, 10/01	Final data to be submitted by 12.2003
85	Warfarin		IR	24.3.97	97, 10/00	10.12.99	4,7,10,12/98, 2,3,5/99	Further data requested by 28.2.01
86		**Zineb**	IT					**Withdrawn** 2001/245/EC, OJ N° L88, 28.3.01, p. 19
87		**Ziram**	BE	6/00	10,11/00			**Inclusion** voted 4.7.03
88	α-Cypermethrin		BE					**Postponed** to 25.5.02 by 2001/810/EC, OJ N° L305, 22.11.01, p. 32
89		**β-Cyfluthrin**	DE		9/98, 2/99, 3,10/00	(4/99) *28.1.00	6/00, (2/02), 4,10/01	**Inclusion** 2003/31/EC by OJ N° L101, 23.4.03, p. 3
90		**λ-Cyhalothrin**	SE		2,9/98, 2/99, 3/00	(4/99) * 28.01.00	6,10/00	**Inclusion** 2000/80/EC, OJ N° L309, 9.12.00, p. 14

Annex IV: Existing active substances - 2nd stage - completeness checks

Annex IV. EXISTING ACTIVE SUBSTANCES - 2ND STAGE - INDIVIDUAL STATUS OF EACH

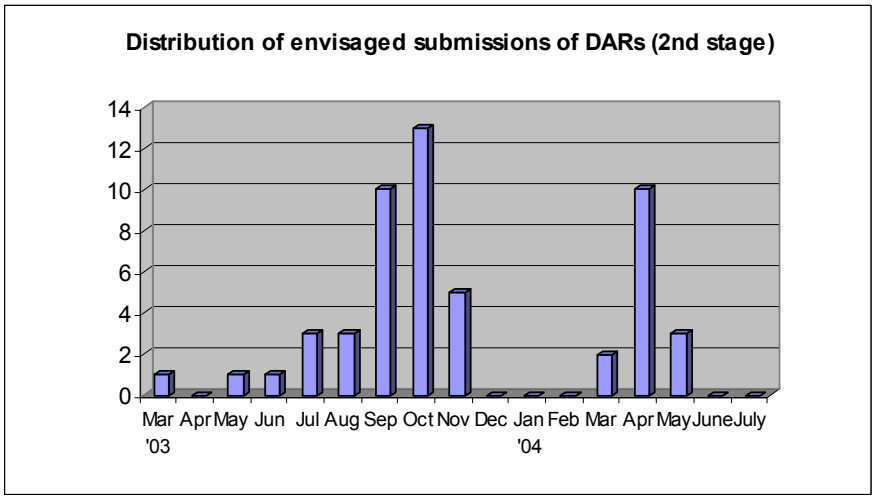
III.3. Completeness check deadlines and status

No	Active Substance	RMS/ Co-RMS	Submission of dossier	Completeness check by RMS		Submission of DAR by RMS *	Deadline for submission of comments
	Methidathion	PT	(30.4.02)	18.10.02	**Incomplete ⇨ decision on non-inclusion**	**SCFCAH July 2003**	--
1	Glufosinate	SE/DE	(30.4.02)	3.1.02	complete	**2.1.03**	27.6.03
2	Tolylfluanid	FI	(30.4.02)	29.4.02	complete	**30.5.03**	
3	Tribenuron	SE/UK	(30.4.02)	21.6.02	complete	**20.6.03**	29.8.03
4	Trifluralin	GR	(30.4.02)	16.8.02	complete	**11.7.03**	
5	Oxamyl	IRL/UK	(30.4.02)	11.10.02	complete	31.7.03	
6	Rimsulfuron	DE	(30.4.02)	31.1.02	complete	31.7.03	
7	Fosetyl	FR	(30.4.02)	1.8.02 26.9.02	complete for Aventis **incomplete** for Afrasa	1.8.03	
8	Clodinafop	NL/IRL	(30.4.02)	12.6.02	complete	15.8.03	
9	Trinexapac	NL	(30.4.02)	12.6.02	complete	15.8.03	
10	Dimethenamid	DE	(30.4.02)	26.8.02	complete	3.9.03	
11	Fenamiphos	NL	(30.4.02)	11.9.02	complete	11.9.03	
12	Captan	IT	(30.4.02)	31.7.02	complete	15.9.03	
13	Folpet	IT	(30.4.02)	31.7.02	complete	15.9.03	
14	Dichlorvos	IT/UK	(30.4.02)	17.10.02	complete	15.9.03	
15	Cyprodinil	FI/IRL	(30.4.02)	26.9.02	complete	15.9.03	
16	Diuron	DK	(30.4.02)	9.7.02	complete	15.9.03	
17	Ethephon	NL/UK	(30.4.02)	25.9.02	complete for Bayer, **incomplete** for Phytorus	25.9.03	
18	Triclopyr	IRL	(30.4.02)	11.10.02	complete	30.9.03	
19	Oxydemeton-methyl	FR	(30.4.02)	29.7.02 8.11.02	Complete for United Phosphorus; incomplete for Margarita	30.9.03	
20	Haloxyfop-R	DK	(30.4.02)	19.9.02	complete	1.10.03	
21	Triticonazole	AU	(30.4.02)	1.10.02	complete	1.10.03	
22	Metconazole	BE	(30.4.02)	14.10.02	complete	14.10.03	
23	1,3-Dichloropropene	ES	(30.4.02)	28.10.02	complete	15.10.03	
24	Tolclofos-methyl	SE	(30.4.02)	22.10.02	complete	22.10.03	
25	Ethoprophos	UK	(30.4.02)	24.10.02	complete	25.10.03	
26	Fenitrothion	UK	(30.4.02)	25.10.02	complete	25.10.03	
27	Pirimicarb	UK	(30.4.02)	25.10.02	complete	25.10.03	
28	Pirimiphos-methyl	UK	(30.4.02)	25.10.02	complete	25.10.03	
29	Thiodicarb	UK	(30.4.02)	25.10.02	complete	25.10.03	

Annex IV: Existing active substances - 2nd stage - completeness checks

No	Active Substance	RMS/ Co-RMS	Submission of dossier	Completeness check by RMS		Submission of DAR by RMS *	Deadline for submission of comments
30	Triazamate	UK	(30.4.02)	25.10.02	complete	25.10.03	
31	Dimethomorph	DE	(30.4.02)	31.10.02	complete	31.10.03	
32	Metribuzin	DE	(30.4.02)	31.10.02	complete for Bayer and FSC	31.10.03	
33	Dichlorprop-P	DK	(30.4.02)	5.9.02	to be completed by December 02	1.11.03	
34	Naled	FR	(30.4.02)	20.11.02	to be completed by 30. 4.03	1.11.03	
35	Fipronil	FR/UK	(30.4.02)	25.7.02	Complete	1.11.03	
36	Clopyralid	FI	(30.4.02)	28.10.02	to be completed by 30.4.03	30.11.03	
37	Malathion	FI	(30.4.02)	28.10.02	to be completed by 30.4.03	30.11.03	
38	Propamocarb	IRL	(30.4.02)	31.10.02	complete for Aventis; to be completed for CAG by 1.4.03	31.3.04	
39	Methiocarb	UK	(30.4.02)	25.10.02	to be completed by 1.03.03	31.3.04	
40	Phosalone	AT	(30.4.02)	17.10.02	to be completed by 30.4.03	1.4.04	
41	Pyrimethanil	AT	(30.4.02)	7.8.02	to be completed by 30.4.03	1.4.04	
42	Formetanate	IT	(30.4.02)	7.8.02	to be completed by 28.2.03	15.4.04	
43	Diazinon	PT	(30.4.02)	22.10.02	to be completed by 18.4.03	18.4.04	
44	Benfuracarb	BE	(30.4.02)	24.9.02	to be completed by 30.4.03	30.4.04	
45	Cadusafos	GR	(30.4.02)	24.10.02	to be completed by 30.4.03	30.4.04	
46	Carbofuran	BE/UK	(30.4.02)	22.10.02	to be completed for FMC and for Dianica by 30.4.03	30.4.04	
47	Carbosulfan	BE/UK	(30.4.02)	10.10.02	to be completed by 30.4.03	30.4.04	
48	Dimethoate	UK	(30.4.02)	24.10.02	to be completed by 30.4.03	30.4.04	
49	Methomyl	UK	(30.4.02)	25.10.02	**incomplete** for Makhteshim-Agan; to be completed for Du Pont by 30.4.03	30.4.04	
50	Carbaryl	ES/UK	(30.4.02)	29.10.02	to be completed by December 2002	15.5.04	
51	Trichlorfon	ES	(30.4.02)	28.10.02	to be completed by 15.4.03	31.5.04	
52	Phosmet	ES	(30.4.02)	28.10.02	to be completed by 15.4.03	*31.5.04*[#]	

Annex IV: Existing active substances - 2nd stage - completeness checks



Annex V: List of legislative acts under Directive 91/414/EEC

Annex V. LEGISLATION

Annex V.A General legislation

1. Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, OJ N° L230, 19.8.91, p. 1.
2. Commission 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, OJ N° L366 of 15.12.92, p. 1.
3. Commission Directive 93/71/EEC of 27 July 1993 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market, OJ N° L221, 31.8.93, p. 27.
4. Commission Directive 94/37/EC of 22 July 1994 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market, OJ N° L194, 29.7.94, p. 65.
5. Commission Regulation (EC) N° 933/94 of 27 April 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° L107 of 28.4.94, 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° L354, 31.12.94, p. 16.
7. Commission Regulation (EC) N° 491/95 of 3 March 1995 amending Regulation (EC) N° 933/94, 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° L49, 4.3.95, p. 50.
8. Commission Directive 95/35/EC of 14 July 1995 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market, OJ N° L172, 22.7.95, p. 6.
9. Commission Directive 95/36/EC of 14 July 1995 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market, OJ N° L172, 22.7.95, p. 6.
10. Commission Regulation (EC) N° 2230/95 of 21 September 1995 amending Regulation (EC) No 933/94, laying down the active substances of plant protection products and designating the rapporteur MS for the implementation of Commission Regulation (EEC) N° 3600/92, OJ N° L225, 22.9.95, p. 1.
11. Commission Directive 96/12/EC of 8 March 1996 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market, OJ N° L65, 15.3.96, p. 20.
12. Commission Directive 96/46/EC of 23 August 1996 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market, OJ N° L214, 23.8.96, p. 18.
13. Commission Directive 96/68/EC of 21 October 1996 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market, OJ N° L277, 30.10.96, p. 25.
14. Commission Regulation (EC) N° 1199/97 of 27 June 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° L170, 28.6.97, p. 19.
15. Council Directive 97/57/EC of 22 September 1997 establishing Annex VI to Directive 91/414/EEC concerning the placing of plant protection products on the market, OJ N° L265, 27.9.97, p. 87.
16. Commission Regulation (EC) N° 1972/1999 of 15 September 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° L244, 16.9.99, p. 41.
17. Commission Regulation (EC) N° 451/2000 of 28 February 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° L55, 29.2.00, p. 25.

18 Commission Regulation (EC) N° 2266/2000 of 12 October 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° L259, 13.10.00, p. 27.

19. Commission Decision of 14 February 2001 concerning the decision on the possible inclusion of certain active substances into Annex I to Council Directive 91/414/EEC. OJ N° L49 of 20.2.01, p. 13.

20. Commission Regulation (EC) N° 703/2001 of 6 April 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 MS designated as rapporteurs for those substances. OJ N° L98 of 7.4.01, p. 6.

21. Commission Regulation (EC) No 1112/2002 of 20 June 2002 laying down the detailed rules for the implementation of the 4th stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC. OJ N° L168 of 27.6.02, p. 14.

22. Commission Regulation (EC) N° 1490/2002 of 14 August 2002 laying down further detailed rules for the implementation of the 3rd stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) N° 451/2000. OJ N° L224 of 21.8.02, p. 23.

23. Commission Regulation (EC) N° 2076/2002 of 20 November 2002 concerning the extension of the time period for the re-evaluation of certain active substances, essential uses and the non-inclusion of certain other active substances in Annex I to Council Directive 91/414/EEC. OJ N° L319 of 23.11.02, p. 3.

24. Commission Regulation (EC) N° 1044/2003 of 18 June 2003 amending Regulation (EC) N° 451/2000 and N° 1490/2002. OJ N° L151 of 19.6.03, p. 32.

25. Commission Regulation (EC) N° 1336/2003 of 25 July 2003 amending Regulation (EC) N° 2076/2002 as regards the continued use of the substances listed in Annex II. OJ N° L187 of 26.7.03, p. 21.

26. Commission Decision 2003/565/EC of 25 July 2003 extending the time period provided for in Article 8(2) of Council Directive 91/414/EEC. OJ N° L192 of 31.7.03, p. 40.

Annex V.B Measures concerning individual active substances

Decisions concerning Annex I inclusion of individual substances are listed in Annexes IIB & IIIB to this document.

Annex V.C Measures on extensions of time periods for provisional authorisations

Active substance		Decisions and OJ References
Pending	**Decided**	
Benzoic Acid		2002/658/EC (L221 of 17.8.02, p. 37), 2001/529/EC (L191 of 13.7.01, p. 47)
Carvone		2002/658/EC (L221 of 17.8.02, p. 37)
	Carfentrazone ethyl	2002/133/EC (L47 of 19.2.02, p. 41), 2001/315/EC (L109 of 19.4.01, p. 69), 2000/358/EC (L127 of 27.5.00, p. 61)
	Cinidon Ethyl	2002/133/EC (L47 of 19.2.02, p. 41), 2001/529/EC (L191 of 13.7.01, p. 47)
	Cyclanilide	2001/315/EC (L109 of 19.4.01, p. 69)
	Cyhalofop-butyl	2002/133/EC (L47 of 19.2.02, p. 41)
	Dimethenamid-P	2003/370/EC (L127 of 21.5.03, p. 58)
	Ethoxysulfuron	2001/315/EC (L109 of 19.4.01, p. 69)
	Famoxadone	2002/133/EC (L47 of 19.2.02, p. 41), 2001/315/EC (L109 of 19.4.01, p. 69)
Flazasulfuron		2002/133/EC (L47 of 19.2.02, p. 41)
	Flufenacet	2002/133/EC (L47 of 19.2.02, p. 41), 2000/767/EC (L306 of 7.12.00, p. 34)
	Flumioxazine	2002/133/EC (L47 of 19.2.02, p. 41)
	Flupyrsulfuron methyl	2001/315/EC (L109 of 19.4.01, p. 69), 2000/358/EC (L127 of 27.5.00, p. 61)
	Flurtamone	2002/133/EC (L47 of 19.2.02, p. 41), 2001/315/EC (L109 of 19.4.01, p. 69), 2000/358/EC (L127 of 27.5.00, p. 61)
	Fosthiazate	2002/133/EC (L47 of 19.2.02, p. 41), 2001/231/EC (L84 of 23.3.01, p. 55)
	Iodosulfuron	2003/370/EC (L127 of 21.5.03, p. 58)
Indoxacarb		2003/370/EC (L127 of 21.5.03, p. 58)
	Isoxaflutole	2002/133/EC (L47 of 19.2.02, p. 41), 2001/315/EC (L109 of 19.4.01, p. 69), 2000/358/EC (L127 of 27.5.00, p. 61)
Mepanipyrim		2002/658/EC (L221 of 17.8.02, p. 37)
	Metalaxyl-M	2002/133/EC (L47 of 19.2.02, p. 41), 2001/231/EC (L84 of 23.3.01, p. 55)
	Oxidiargyl	2002/658/EC (L221 of 17.8.02, p. 37)
	Paecilomyces fumosoroseus	2001/315/EC (L109 of 19.4.01, p. 69)
	Prosulfuron	2002/133/EC (L47 of 19.2.02, p. 41), 2001/315/EC (L109 of 19.4.01, p. 69), 2000/358/EC (L127 of 27.5.00, p. 61)
Pseudomonas chlororaphis		2002/133/EC (L47 of 19.2.02, p. 41), 2000/180/EC (L57 of 2.3.00, p. 34)
Quinoxyfen		2002/133/EC (L47 of 19.2.02, p. 41), 2000/166/EC (L52 of 25.2.00, p. 44)
S-Metholachlor		2003/370/EC (L127 of 21.5.03, p. 58)

Annex V: List of legislative acts under Directive 91/414/EEC

Active substance		Decisions and OJ References
Pending	**Decided**	
Spodoptera exigua		2003/370/EC (L127 of 21.5.03, p. 58), 2002/133/EC (L47 of 19.2.02, p. 41), 2001/231/EC (L84 of 23.3.01, p. 55
	Sulfosulfuron	2002/133/EC (L47 of 19.2.02, p. 41), 2001/231/EC (L84 of 23.3.01, p. 55)
Tepraloxydim		2003/370/EC (L127 of 21.5.03, p. 58)
	Trifloxystrobin	2002/658/EC (L221 of 17.8.02, p. 37)

Annex VI: List of main guidance documents for MS or industry

Annex VI. GUIDANCE DOCUMENTS

Annex VI.A Finalised guidance documents noted by the Standing Committee

1. 7109/VI/94 rev. 6.c1: 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. 1694/VI/95, 4952/VI/95, 6476/VI/96 and 7617/VI/96: Guidance document within the SCPH with regard to the modelling of fate and behaviour of plant protection products in the environment (in groundwater, surface water and soil) - FOCUS.
3. 7017/VI/95 rev.4: Guideline developed within the SCPH with regard to the acceptability of data, whether or not performed in accordance with the principles of Good Laboratory Practice (GLP).
4. 1663/VI/94 rev. 8 of 22.4.98: 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. 1654/VI/94 rev. 7 of 22.4.98: Guidelines for preparation of monographs by rapporteur Member States.
6. 8064/VI/97 rev. 4: Guidance document on residue analytical methods - adopted by the SCPH on 1.12.98.
7. SANCO/3029/99 rev. 4: 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 - adopted by the SCPH on 13.7.00.
8. SANCO/3030/99 rev. 4: 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 - adopted by SCPH on 13.7.00.
9. 9188/VI/97 rev. 8: Guidance Document on Persistence in Soil - noted by the SCPH on 13.7.00.
10. a) 2021/VI/98 rev. 7: Guidance Document on Terrestrial Ecotoxicology - noted by the SCPH on 13.7.00. b) SANCO/10329/2002 rev 2 final: noted by the SCFA on 18.10.2002 – see Annex I 5.1.1 for details.
11. a) SANCO/3268/2001: Guidance Document on Aquatic Ecotoxicology - noted by the SCPH on 2.10.01. b) SANCO/3268/2001 rev.4 (final): noted by the SCFA on 18.10.2002 – see Annex I 5.1.1 for details
12. SANCO/491/00 rev. 3: Authorization of plant protection products containing existing active substances after their inclusion in Annex I - submission of an Annex II and Annex III dossier.
13. Biocides/26/99 rev. 6: Borderline between Directive 98/8/EC concerning the placing on the market of biocidal product and Directive 91/414/EEC concerning the placing on the market of plant protection products.
14. SANCO/223/2000 rev. 9: Guideline developed within the SCPH concerning parallel trade of plant protection products within the EU and the EEA.
15. SANCO/222/2000 rev. 6: Guidance document on dermal absorption - noted by the SCFA on 3.12.02.
16. 7196/VI/99: Guidelines for applicants for import tolerances (October 1999).
17. SANCO/4145/2000: Guidance document on risk assessment for birds and mammals - noted by the SCFA on 18.10.02.
18. SANCO/221/2000 rev. 10: Guidance document on relevant metabolites - noted by the SCFA on 26.2.03.
19. SANCO/3989/2001 rev.2: Guideline developed within the Standing Committee on Plant Health concerning instructions for industry on dossier submission - noted by the SCPH on 7.12.01.
20. 1663/VI/94 rev 8 of 22 April 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 to Directive 91/414/EEC (Article 5.3 and 8.2).
21. 1654/VI/94 rev 7 of 22 April 1998: Guidelines and criteria for the evaluation of dossiers and for the preparation of reports to the European Commission by Rapporteur Member States relating to the proposed inclusion of active substances in Annex I to Directive 91/414/EEC.
22. 1614/VI/95 rev. 7: 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 Legislation working group of the SCPH.
23. 1663/VI/95 rev. 2 of 16.6.96: Working document for guidance to the MS with regard to the implementation of Article 6 of Directive 91/414/EEC for new active substances, developed in the Legislation working group of the SCPH.

24. 7860/VI/97 rev. 5E of 15.7.98: Aide mémoire with regard to 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.

25. 7860/VI/97 rev. 5N of 15.7.98: Aide mémoire with regard to 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.

Annex VI.B Guidelines under progressive development

1. 7600/VI/95 rev. 6 of 14.7.97: 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).

2. 1607/VI/97 rev. 1 of 22.7.97 which contains further guidance for carrying out residue trials and which contains the following parts:

- 7028/VI/95 rev.3:	Appendix A	Metabolism and distribution in plants
- 7029/VI/95 rev.5:	Appendix B	General recommendations for the design, preparation and realisation of residue trials
- 7524/VI/95 rev.2:	Appendix C	Testing of plant protection products in rotational crops
- 7525/VI/95 rev.7:	Appendix D	Comparability, extrapolation, group tolerances and data requirements for setting MRLs
- 7035/VI/95 rev.5:	Appendix E	Processing studies
- 7030/VI/95 rev.3:	Appendix F	Metabolism and distribution in domestic animals
- 7031/VI/95 rev.4:	Appendix G	Livestock feeding studies
- 7032/VI/95 rev.5:	Appendix H	Storage stability of residue samples
- 7039/VI/95:	Appendix I	Calculation of MRLs and safety intervals e.g. pre-harvest intervals.

3. 7531/VI/95 rev.6: Guidance document on acceptable operator exposure levels (September 2001).

4. 7199/VI/99 rev. 5: Draft guidance on the acute reference dose (July 2001).

5. SANCO/671/2000: Working document "Guidance document on data protection".

6. SANCO/2971/2000: Draft guidance document on minor uses.

7. 2971/SANCO/2000: Draft Guidance document on voluntary mutual recognition of minor use authorizations (10.10.00).

8. SANCO/1003/2000 rev. 3: Draft Guidance document on plant strengtheners (June 2001).

9. SANCO/1090/2000 rev. 0: Draft Guidance document for the assessment of active substances used on rice (December 2001).

10. SANCO/10189/03: Draft Guidance document on isomers.