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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate D - Food Safety: production and distribution chain
D3 - Chemicals, Contaminants and Pesticides

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**OVERVIEW OF THE STATE OF MAIN WORKS
IN DG HEALTH AND CONSUMER PROTECTION D.3
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/plant/protection/evaluation/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 organised consultation of stakeholders on 10-12 July 2002 and January 2004. A draft Regulation and an impact assessment were circulated for comments in April 2005. The Commission adopted the proposal on 12.7.2006 – COM (2006) 388 final for a Regulation of the European Parliament and the Council.

The Commission adopted on 12.7.2006 a proposal – COM (2006)388 final – for a Regulation of the European Parliament and the Council on the placing of plant protection products on the market.

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 to 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. The most recent version is available on the website http://ec.europa.eu/food/plant/protection/resources/publications_en.htm.

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. It is proposed to include in the new Regulation on plant protection products (see point 1) criteria for Annex I inclusion).

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/97¹. 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 to the Directive - data requirements

This work 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 between 2007 and 2008.

Details can be found in Annex I to this document.

2.3. Annexes IV and V to 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 Enterprise 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 working group 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 and this was adopted as Commission Directive 2003/82/EC on 11.9.03.

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

Council Directive 97/57/EC introduced uniform principles for the risk assessment of chemical plant protection products.

A project for revising Annex VI started with the revision of Annexes IIA and IIIA and is currently undergoing. It is foreseen to complete this project by the end of 2006.

Moreover the Commission prepared 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 was finalised in 2003. Council has reached a political agreement in June 2004.

The directive has been adopted on 14 March 2005 as Council Directive 2002/25/EC "amending Annex VI to directive 91/414/EEC as regards plant protection products containing microorganisms" (OJ L90, 08/04/2005).

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/93¹. 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). Document 6621/VI/99 is regularly updated to include individual cases. It is intended to clarify the scope in the draft Regulation on plant protection products (see point 1).

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")

Moreover, a guidance document on the same issue was finalised in 2001. The document, formally known as Doc.Biocides/82/01 rev. 2, is a "Guidance document agreed between the Commission services and the competent authorities of Member States for the biocidal products Directive 98/8/EC and for the plant protection products Directive 91/414/EEC on: Scope, Article 1(2)(r) of Directive 98/8/EC: Borderline with 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 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. No further work on the database is scheduled for the moment. The draft Regulation on plant protection products (see point 1) proposes that each Member States keeps a database available on the web.

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 has been organised on 17-18 November 2003.

¹ Outdated document

4.3. Links

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

Austria: <http://www.lwvie.ages.at>

Sweden: <http://www.kemi.se>

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

Germany: <http://www.bvl.bund.de>

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

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

The Netherlands: www.ctb-wageningen.nl

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: <http://www.kttk.fi>

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

Luxembourg: <http://www.asta.etat.lu>

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

Latvia: <http://www.vaad.gov.lv>

Lithuania: <http://www.vaat.lt>

Estonia: <http://www.plant.agri.ee>

Poland: <http://www.minrol.gov.pl>

Slovak Republic: www.mpsr.sk

Czech Republic: <http://tesnov.srs.cz>

Slovenia: <http://www.fito-info.bf.uni-lj.si/ffs/reg/index.htm>

Cyprus: www.moa.gov.cy/da

DG Health and Consumer Protection home page: http://www.europa.eu.int/comm/food/index_en.htm

DG Health and Consumer Protection – PPP: http://europa.eu.int/comm/food/plant/protection/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>

EPCO (BVL): <http://www.bvl.bund.de/pflanzenschutz/epco-en.htm>

EPCO (PSD): <http://www.pesticides.gov.uk/index.htm>

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

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/pesticides/>

EPPO: <http://www.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/plant/protection/evaluation/contact_12-04_en.pdf

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. 04/11/2004 (using filter function) which is on the Internet (http://europa.eu.int/comm/food/plant/protection/evaluation/index_en.htm). 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. 2¹) where a model for the annual list (doc. 4709/VI/94 rev. 1¹) was also accepted. An amended format was later discussed in the context of informatics-based information exchange. The most recent information can be found on the website of each Member State (see point 4.3.1).

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	AU	BE	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	SE	SI	SK	UK
1994	X	X			O	X		X	X	X	X		X	X		X			X		X	X			X
1995	X	X			X	X		X	X	X	X		X	O		X			X		X	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		X	X		X			X		X	X			X
2002	X	X			X	X		X	X	X	X		X	X		X			X		X	X			X
2002	X	X			X	X		X	X	X	X		X	X		X			X		X	X			X
2003	X	X	X	X	X	X		X	X	X		X	X						X	X	X	X	X	X	X
2004	X	X	X	X	X	X	X	X	X	X		X			X		X		X		X	X	X	X	X
2005						X	X	X	X			X	X	X					X		X	X		X	X
2006																									

Reports for 2004 should have been submitted by the 1st August 2005

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.

Streptomycin has been withdrawn by Commission Decision 2004/129/EC (OJ L 37 dd 10.2.2004, page 27) as no data have been received.

For kasugamycin, a complete data package, in which the issue of resistance appears to have been addressed, was submitted by 23.5.2003. A complete dossier, due by 23.11.2003, has not been submitted. Consequently kasugamycin, has been withdrawn by Commission Decision 2005/303/EC (OJ L 97 dd 15.4.2005, page 38)

As essential uses have been granted to a limited number of Member States for well-defined applications, these countries are bound to continue to report yearly on the amounts used and on any observed signs of resistance.

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 be 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. More details are available in Annex IV to this document.

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. Currently MS are doing the completeness check for the dossiers received and will start the preparation of the DARs.

COM has proposed non-inclusion for another 5 active substances. The standing committee gave a favourable opinion on 29.6.2004.

More details are available in Annex III.

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. A Com proposal to extend the deadline for about 220 notified active substances and to withdrawal about 100 non-notified ones received a favourable opinion from the SCFAH on 4.7.03.

COM organised on 1.10.03 a first expert meeting on the procedures for the review of these active substances. Further expert meetings were organised on 25 November 2003, and 12 February 2004, a first draft would be discussed at the Legislation meeting in March 2004. MS have been requested to volunteer to be rapporteur. COM aims to submit the proposal to the Standing Committee in October 2004. Revision 6 is available on SANCO website. Revision 6 contains the final attribution of Rapporteurs. The Regulation (Reg. 2229/2004) was adopted by the Commission on the 3th of December 2004.

In conformity with the deadlines set by the Regulation dossiers have been submitted for several substances. As defined by the regulation according to art. 4 notifications and dossiers from new member states have also been submitted in due time. However, not all the substances listed in the regulation were properly supported. Consequently, a draft decision of non inclusion on a certain number of substances (more than 100) received a favourable opinion at the Standing Committee of November 2006. In the meantime, a draft regulation has been approved to withdrawn from the 4th stage of the review programme certain substances which did not comply with the requirements of the programme itself in terms of existing authorisations and scope of the Directive.

On the other hand the first DARs have been submitted by RMS to EFSA for the peer review.

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 2003, 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). A fuller description of the process is given in the Technical Annex to the Report to Council and Parliament (SANCO/822/2001 rev. 3), which is available on the SANCO Internet site.

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. 1¹) was discussed on 1-2.12.94; further written comments were expected from MS by 15.1.95. Doc. 7134/VI/94 rev. 5¹ 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. 5¹). 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.

A second stakeholder meeting was organised on 30 January 2004. COM explained how it would take into account the conclusions of the first stakeholder meeting in a possible amendment of the Directive. Written comments are to be submitted by 31 March 2004 at the latest, after which COM would finalise its first draft proposal. A draft Regulation and an impact assessment were circulated for comments in April 2005. The Commission consultation on the modified draft is likely to start in September 2005 (see also point 8.1).

The Commission adopted on 12.7.2006 a proposal COM (2006) 388 final – for a Regulation of the European Parliament and the Council on the placing of plant protection products on the market.

8.2. Research priorities

Doc. 4978/VI/95¹ 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.

Research priorities have been communicated to DG RTD also with regard to the 6th and 7th Research Framework programmes. The 7th Framework programme FP7 (2007-2013) should in particular address a number of projects regarding plant protection products, including the further development of EUROPOEM.

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.

The Commission foresees to launch the Thematic Strategy in the early autumn 2005.

The Commission adopted on 12.7.2006 a proposal – COM (2006)373 final – for a Directive of Parliament and of the Council establishing a framework for Community action to achieve a sustainable use of pesticides.

The Commission also adopted on 12.7.2006 a Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions: A Thematic Strategy on the Sustainable use of pesticides.

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.

A draft working document, SANCO/ 00298/2006 was prepared in 2006 to provide guidance on mutual recognition to MS. It has been circulated for comments. The work is ongoing and serves as basis to improve co-operation between MS.

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.

The Steering Group met 7 times in the period 2003-mid 2005. The group has been stable and was well attended. Currently the group consists of members of COM, BE, DE, ES, FR, HU, PL, PT, NL and UK. FR chaired the group, and on occasion UK and NL acted as deputy chair. NL did the secretariat.

Numerous initiatives have been taken and more detailed information can be found in the activity reports placed on CIRCA.

The Technical Groups were installed by the Steering Group as a platform for the execution of the actual work: obtaining of solutions for minor crop plant protection problems. There are two Groups: one for North and one for Southern Europe, and delineated according to the Residue Directives. However, the Groups have much in common, and combined meetings are sometimes organised. FR co-ordinates South, and NL North.

Between 2003 and 2005 a total of 10 meetings of the Technical Groups took place in which almost all MS were represented. Much time was spent in 2003 to organise procedures and to get the members acquainted with each other. Major projects have been undertaken and some of them are still ongoing. Two project reports funded by the Commission in 2005 are available on the SANCO website (http://ec.europa.eu/food/plant/protection/resources/publications_en.htm#technical). These projects are focussed on the need to further develop extrapolation strategies for minor crops as far as efficacy and residues are concerned.

The results of the efficacy extrapolation project have been submitted to EPPO, in view of an EPPO standard.

The results of the residue extrapolation project, on the other hand, will be used as input for a future EU guidance document on the pesticide residue extrapolation.

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. It would also prepare in 2007 a communication on parallel import.

Annex I. FURTHER DEVELOPMENT OF DATA REQUIREMENTS

Annex I.1. Introduction

The Commission is currently reviewing the existing data requirements for chemicals used as active substances (Annex IIA) and for plant protection products (Annex IIIA). The review process started in 2002 and it is expected to publish the revised directives between 2007 and 2008. Directives under revision are as follows:

- ⇒ Dir. 94/37/EC (physical and chemical properties)
- ⇒ Dir. 96/46/EC (analytical methods)
- ⇒ Dir. 96/68/EC (residues)
- ⇒ Dir. 95/36/EC (fate and behaviour in the environment)
- ⇒ Dir. 94/79/EC (toxicological and metabolism studies)
- ⇒ Dir. 96/12/EC (ecotoxicological studies)

The Commission is considering also the opportunity of starting a revision process for directives 93/71/EEC (efficacy data) and 95/35/EC (Good laboratory practice).

Annex I.2. 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 currently reviewing the existing data requirements for chemicals used as active substances and has consulted OECD Member States as part of the process.

Annex I.3. 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.4. Operator exposure

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

Annex I.4.1. 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

ANNEX I: Further development of Annexes II and III of the Directive - data requirements

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.

A meeting was organised on 12-13 November 2003. It appeared that the data included in the Europeom data base do not allow making reliable predictions for operator exposure at this stage. Further work should be done before Europeom can be recommended. For bystander and worker exposure more reliable predictions are possible. The SeedTropex model might give good results for operators treating seeds but this should be further explored before firm recommendations can be made.

Guidance for the setting of acceptable operator exposure level is being drafted. A new commenting round on Doc 7531/VI/95 rev. 8 has been organised in the first half of 2005, and three member States reacted (EL, SE, NL). The amended version (rev. 9) has been submitted by the Commission to the EFSA for an opinion. The EFSA PPR Panel has delivered its opinion on 6 April 2006. Following the PPR Panel opinion, a new revision of the draft AOEL guidance document has been prepared (rev. 10 of 7 July 2006). Member States have been invited to submit their comments on the new text at the SCoFCAH of 13-14 July 2006.

The amended version of the guidance document (revision 10) has been submitted to the SCoFCAH of 23-23 January 2007. However it was not possible to take note of the documents, failing the unanimity (2 Member States could not support the text for various reasons). It was therefore concluded to use the document in the form of a working document and upload it on the SANCO website. Member States have been invited to inform the Commission whenever they would be able to change their position on the document.

Annex I.4.2. 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.5. Fate and behaviour in the environment

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

Annex I.5.1. 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.5.2. 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.5.3. Status of Fate and Behaviour Data Requirements Revisions

A revised draft was received on 24 June 2004 and was sent on 22/07/2004 to the Member States and industry for comments. Comments were due by 24 September 2004.

A revised draft (rev. 3 of 24.01.2005) was submitted again to Member States to the Evaluation Meeting in March 2005. Also the industry was asked for comments.

After this commenting round an expert meeting was organised on 20 and 22 June 2005 to review all the comments.

Two rounds of comments have been organised after the June 2005 expert meeting (on revisions 4 and 5) before a revision 6 could be prepared and submitted to the EFSA PPR Panel for an opinion.

The PPR Panel opinion is expected to be adopted on 31 January/1 February 2007.

Annex I.6. Ecotoxicology

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

Annex I.6.1. 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 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.

New rounds of revision took place for both the documents and final revisions were available in 2002 renamed as SANCO/10329/2002 (Guidance document on terrestrial ecotoxicology under directive 91/414/EEC) and SANCO/3268/2001 (Guidance document on aquatic ecotoxicology in the context of directive 91/414/EEC).

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.6.2. 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 as SANCO/4142/2000. 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.6.3. 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. In order to take advantage of the progress made, it was decided to revise accordingly 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.6.1.

Annex I.6.4. 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.6.5. 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.6.1).

Annex I.6.6. Status of the Ecotoxicity Data Requirements Revisions

The first draft was released on July 2003. After that comments from Member States and the industry were received and analysed for a new version in 2004. In October 2004 an expert meeting was organised to deal with some of the comments and produce a new draft. The experts were not able to go through all the comments, and Annex IIIA was not completely reviewed. In order to finish the examination of these comments as well as to take into account progress made in the fate section, a new expert meeting was organised in June 2005, when also a joint session with fate experts took

place. According to the decision taken in this meeting, a new version of the Ecotoxicity data requirements has been released (rev.5 of July 2005), on which Member States and the industry were invited to comment. A next expert meeting has been organised on 10 January 2006, to discuss about specific open issues. The updated revision 6 (29/06/2006) has been then submitted to the EFSA PPR Panel for an opinion. The opinion is expected to be adopted in the March 2007 Plenary meeting of the Panel.

Annex I.7. Physico-chemistry

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

Annex I.7.1. Status of the Physico-chemistry Data Requirements Revisions

The first draft was released on July 2003. After that comments from Member States and the industry were received and analysed in an expert meeting that took place on November 2003. In 2004 a new draft was produced according to the outcomes of the meeting and in the first half of 2005 a new commenting round was organised. Comments were analysed and taken into account in the revision 6 submitted to Member States for comments in the Legislation working group of July 2005.

After this round of comments a new updated text was prepared (rev 7 of 14/09/2005), submitted to the EFSA PPR Panel for an opinion. The PPR Panel opinion was adopted on 17/05/2006.

Annex I.8. Toxicology

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

Annex I.8.1. Status of the Toxicology Data Requirements Revisions

The first draft was released on July 2003. After that comments from Member States and the industry were received and analysed in an expert meeting that took place on November 2003. In 2004 two new drafts were produced, taking into account comments provided by member States and by the industry. In April 2005 Member States and the Industry were asked to comment again on the last proposed draft. Comments were collected and two expert meetings were organised in July and September 2006 to review all these comments.

Two new revisions (rev. 9 of 2/09/2005 and rev. 10 of 02/03/2006) were submitted subsequently to the Member States and the industry for comments and rev. 10 was submitted to the EFSA PPR Panel for an opinion.

The PPR Panel opinion is expected to be adopted on 31 January/1 February 2007.

Annex I.9. Residues

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

Annex I.9.1. Residue trials

Doc. 1607/VI/97 rev.1 of 22.7.97¹ 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: Further development of Annexes II and III of the Directive - data requirements

Annex I.9.2. 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.9.3. Status of the Residue Data Requirements Revisions

The first draft was released in 2003. After that comments from Member States and the industry were received and analysed and a new draft was produced in March 2004. Since that date, comments from several Member States were received and

. In 2004 two new drafts were produced, taking into account comments provided by member States and by the industry. In April 2005 Member States and the Industry were asked to comment again on the last proposed draft. Comments were collected and an expert meeting was organised in July (8 July) to review all these comments in view of a new version.

New comments have been received from several member states since the revised draft of 9 March 2004. After review of those comments, an updated draft was released and circulated for comments in March 2005 (Evaluation Meeting). Only few reactions on this draft allowed preparing a new document that was submitted again to Member States and the Industry. Member States were informed through the WG Legislation and the WG on Pesticide Residues of the SCoFCAH (June 2005).

A new revision (rev. 6 of 25/08/2005) was then prepared and submitted to the EFSA PPR Panel for an opinion. The PPR Panel opinion was adopted on 18/05/2006.

The issues raised by EFSA were thoroughly analysed by the coordinator and his comments shared with the Member States (July 2006).

Further work (in 2007) will be focused on the development of the supporting guidance documents, including those developed at OECD level (work already started in 2006).

Annex I.10. Modelling

Annex I.10.1. 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 finally not been endorsed by the SCPH and should therefore not be used when submitting dossiers. 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.4.1.

Annex I.10.2. 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 own 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.

ANNEX I: Further development of Annexes II and III of the Directive - data requirements

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. This work is ongoing.

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. An opinion by EFSA on this work has been delivered on 14.12.2004 (EFSA Journal (2004) 145, 1-31).

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. Its final report (SANCO/10553/2006 draft 1 dd 13.7.2006), after being commented by the Member States, is currently being examined by EFSA for its opinion.

Focus landscape and mitigation produced a report (SANCO/10422/2005, version 1.0, May 2005) which already had been commented by the Member States. EFSA provided its opinion on this report on 13.12.2006 (EFSA Journal (2006) 437, 1-30). This opinion is now being studied by the group after which the report can be finalised.

Focus degradation kinetics, after examination by Member States and EFSA, presented its final report to the Standing Committee on the Food Chain and Animal Health on 29 September 2006, where it was formally noted as "Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration (SANCO:10058/2005, version 2.0, June 2006).

Annex I.11. 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 Microbial 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 draft proposal has been revised to take account of it.

Council has reached a political agreement in June 2004. The directive has been adopted on 14 March 2005 as Council Directive 2002/25/EC "amending Annex VI to directive 91/414/EEC as regards plant protection products containing micro organisms" (OJ L90, 08/04/2005).

Annex I.12. 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.13. 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 OECD PWG has in the meantime de-classified the data requirements and guidance for dossiers and monographs.

Annex I.14. 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 was finalised on 3.10.2003.

Annex I.15. 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 for products based on plant extracts and for certain chemical substances of the 4th stage. 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. Member States and industry are requested to comment at the latest by 20 October. Several comments were received and it might be appropriate to submit the guidance document to the Standing Committee together with the Regulation on the fourth stage of the review programme (probably in June 2004). It was agreed in the Legislation meeting on 28-29 June 2004 not to submit the documents (SANCO/10472/2003 rev.5 & SANCO/10473/2003 rev.4) to the Standing Committee at this stage but Rapporteur Member States are kindly asked to make use of the documents and to report back about their experiences. In a few years time, amended and more stable documents could then be referred to the Standing Committee.

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

Annex II order	Development code	active substance	function	applicant	date of application to a MS	RMS	report on completeness received	dossier receipt in all MS	commenting period completeness check	Dossier to SCPH date	decision completeness of dossier	No. O.J.	date O.J.	page O.J.	decision no.	application withdrawn	Completeness Decision repealed
1		Prohexadione-calcium	Pg	BASF	10/02/1994	FR	4/01/1995	25/09/1995		25/09/1995	29/07/1996	L 220	30/08/1996	19	1996/520/EC		
2		Kresoxim-methyl	Fu	BASF	28/03/1995	BE	19/07/1995	25/09/1995		25/09/1995	4/01/1996	L 91	12/04/1996	34	1996/266/EC		
3		Flurtamone	Hb	Rhône-Poulenc Agro France	15/02/1994	FR	30/10/1995	24/11/1995		24/11/1995	20/05/1996	L 130	31/05/1996	20	1996/341/EC		
4		Chlorfenapyr	Ac, In	Cyanamid	7/07/1995	ES	11/12/1995	30/01/1996		30/01/1996	29/07/1996	L 220	30/08/1996	21	1996/521/EC		
5	DE 795	Quinoxifen	Fu	DowElanco	1/08/1995	UK	18/01/1996	20/03/1996		20/03/1996	28/06/1996	L 189	30/07/1996	112	1996/457/EC		
6	ICIA 5504	Azoxystrobin	Fu	Zeneca Crop Protection	15/09/1995	DE	22/03/1996	22/04/1996		22/04/1996	29/07/1996	L 220	30/08/1996	25	1996/523/EC		
7	KWG 4168	Spiroxamine	Fu	Bayer	13/10/1995	DE	22/03/1996	22/04/1996		22/04/1996	29/07/1996	L 220	30/08/1996	23	1996/522/EC		
8	RPA 201772	Isoxaflutole	Hb	Rhône-Poulenc	6/03/1996	NL	22/04/1996	22/04/1996		22/04/1996	29/07/1996	L 220	30/08/1996	27	1996/524/EC		
9		Alanycarb	In	Otsuka Chemical Co.	24/07/1995	FR	18/12/1997	18/02/1998		18/02/1998	24/06/1999	L 180	15/07/1999	49	1999/462/EC		2002/311/EC
10	DPX KE 459	Flupyr sulfuron-methyl	Hb	Du Pont de Nemours	26/10/1995	FR	22/07/1996	16/08/1996		16/08/1996	17/02/1997	L 64	5/03/1997	17	1997/164/EC		
11		Flumioxazine	Hb	Sumitomo Chemical Agro Europe S.A.	2/05/1994	FR	30/05/1996	12/07/1996		12/07/1996	12/09/1997	L 262	24/09/1997	7	1997/631/EC		
12	CGA 152005	Prosulfuron	Hb	Novartis	14/05/1995	FR	30/05/1996	14/06/1996		14/06/1996	3/02/1997	L 52	22/02/1997	20	1997/137/EC		
13	CGA 329351	Metalaxyl-M	Fu	Novartis Crop Protection AG	9/02/1996	BE	19/11/1996	21/03/1997		21/03/1997	29/07/1997	L 239	30/08/1997	48	1997/591/EC		
14	DPX A8947	Azimsulfuron	Hb	Du Pont De Nemours	4/03/1996	IT	31/07/1996	11/10/1996		11/10/1996	17/02/1999	L 64	5/03/1997	17	1997/164/EC		
15	IKI 1145;TO 1145	Fosthiazate	Ne	ISK Biosciences Division	5/03/1996	UK	30/10/1996	19/12/1996		19/12/1996	21/05/1997	L 152	11/06/1997	31	1997/362/EC		

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

Annex II order	Development code	active substance	function	applicant	date of application to a MS	RMS	report on completeness received	dossier receipt in all MS	commenting period completeness check	Dossier to SCPH date	decision completeness of dossier	No. O.J.	date O.J.	page O.J.	decision no.	application withdrawn	Completeness Decision repealed
16	RPA 90946;RPA 090946	Cyclanilide	Pg	Rhône Poulenc Agrochimie S.A.	27/03/1996	GR	30/05/1996	14/06/1996		14/06/1996	3/02/1997	L 52	22/02/1997	20	1997/137/EC		
17	F8426	Carfentrazone-ethyl	Hb	FMC Europe NV	14/02/1996	FR	25/10/1996	19/12/1996		19/12/1996	21/05/1997	L 152	11/06/1997	31	1997/362/EC		
18	FOE 5043	Flufenacet	Hb	Bayer S. A.	1/02/1996	FR	25/10/1996	19/12/1996		19/12/1996	21/05/1997	L 152	11/06/1997	31	1997/362/EC		
19	TH 913	Imazosulfuron	Hb	Spiess-Urania Chemicals GmbH	27/06/1996	DE	5/05/1997	11/07/1997		11/07/1997	5/12/1997	L 351	23/12/1997	67	1997/865/EC		
20	AEF 095404	Ethoxysulfuron	Hb	AgrEvo	3/07/1996	IT	22/01/1997	21/03/1997		21/03/1997	29/07/1997	L 239	30/08/1997	48	1997/591/EC		
21	CGA 215944	Pymetrozine	In	Novartis	4/09/1996	DE	18/03/1997	29/05/1997		29/05/1997	5/12/1997	L 351	23/12/1997	67	1997/865/EC		
22	DPX JE 874	Famoxadone	Fu	DuPont de Nemours	2/10/1996	FR	26/03/1997	21/03/1997		21/03/1997	29/07/1997	L 239	30/08/1997	48	1997/591/EC		
23	CGA 245 704	Acibenzolar-S-methyl	Fu	Novartis	15/10/1996	FR	5/05/1997	19/06/1997		19/06/1997	5/12/1997	L 351	23/12/1997	67	1997/865/EC		
24		Flazasulfuron	Hb	I. S. K. Biosciences	16/12/1996	ES	6/06/1997	29/05/1997		29/05/1997	5/12/1997	L 351	23/12/1997	67	1997/865/EC		
25	L 91105D	Carvone	Pg	Luxan B.V.	26/03/1997	NL	6/05/1999	6/06/1999		10/06/1999	10/09/1999	L 242	14/09/1999	29	1999/610/EC		
26	MON 37500	Sulfosulfuron	Hb	Monsanto	24/04/1997	IE	11/07/1997	11/07/1997		11/07/1997	5/12/1997	L 351	23/12/1997	67	1997/865/EC		
27	EF 1218	Cyhalofop-butyl	Hb	Dow Elanco	30/04/1997	IT	5/11/1997	16/12/1997		16/12/1997	20/03/1998	L 96	28/03/1998	45	1998/242/EC		
28	BAS 615H	Cinidon-ethyl	Hb	BASF plc.	28/04/1997	UK	12/01/1998	18/02/1998		18/02/1998	2/06/1998	L 176	20/06/1998	34	1998/398/EC		
29	KBR 2738	Fenhexamid	Fu	Bayer plc.	8/05/1997	UK	16/12/1997	18/02/1998		18/02/1998	2/06/1998	L 176	20/06/1998	34	1998/398/EC		
30	RP020630	Oxadiargyl	Hb	Rhone Poulenc	16/06/1997	IT	16/12/1997	18/02/1998		18/02/1998	2/06/1998	L 176	20/06/1998	34	1998/398/EC		
31	ET 751	Pyraflufen-ethyl	Hb	Nihon Nohyaku Co. Ltd.	16/06/1997	BE	2/12/1997	16/12/1997		16/12/1997	20/03/1998	L 96	28/03/1998	45	1998/242/EC		
32	DPX R6447	Azafenidin	Hb	Du Pont de Nemours	25/06/1997	ES	8/12/1997	16/12/1997		16/12/1997	20/03/1998	L 96	28/03/1998	45	1998/242/EC		
33		S-Metolachlor	Hb	Novartis N.V.	1/08/1997	BE	23/02/1998	21/04/1998		21/04/1998	29/07/1998	L 228	15/08/1998	35	1998/512/EC		

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

Annex II order	Development code	active substance	function	applicant	date of application to a MS	RMS	report on completeness received	dossier receipt in all MS	commenting period completeness check	Dossier to SCPH date	decision completeness of dossier	No. O.J.	date O.J.	page O.J.	decision no.	application withdrawn	Completeness Decision repealed
34	BAS 620 H	Tepaloxymid	Hb	BASF	11/09/1997	ES	17/02/1998	21/04/1998		21/04/1998	29/07/1998	L 228	15/08/1998	35	1998/512/EC		
35	JV 485	Fluazolate	Hb	Twinagro	29/09/1997	UK	8/06/1998	7/07/1998		7/07/1998	17/11/1998	L 317	26/11/1998	47	1998/676/EC		2002/784/EC
36	DPX-KN128	Indoxacarb	In	Du Pont de Nemours	6/10/1997	NL	18/02/1998	18/02/1998		18/02/1998	2/06/1998	L 176	20/06/1998	34	1998/398/EC		
37	KIF 3535	Mepanipyrim	Fu	Kumiai	24/10/1997	IT	28/05/1998	7/07/1998		7/07/1998	17/11/1998	L 317	26/11/1998	47	1998/676/EC		
38	AC 299 263	Imazamox	Hb	Cyanamid NV/SA	2/12/1997	FR	10/06/1998	7/07/1998		7/07/1998	17/11/1998	L 317	26/11/1998	47	1998/676/EC		
39	MTF 651	Flusulfamide	Fu	Mitsui Toatsu Chemical Co.	19/09/1997	UK										yes	
40	DE 570	Florasulam	Hb	Dow AgroSciences	2/02/1998	BE	8/06/1998	7/07/1998		7/07/1998	17/11/1998	L 317	26/11/1998	47	1998/676/EC		
41	CGA 279 202	Trifloxystrobin	Fu	Novartis Crop Protection UK Ltd.	28/01/1998	UK	4/09/1998	15/10/1998		15/10/1998	22/12/1998	L 14	19/01/1999	30	1999/43/EC		
42	SZX 0722	Iprovalicarb	Fu	Bayer Plc.	30/03/1998	IE	6/04/1998	21/04/1998		21/04/1998	29/07/1998	L 228	15/08/1998	35	1998/512/EC		
43	BAS 625 H	Profoxydim	Hb	BASF	2/04/1998	ES	11/08/1998	15/10/1998		15/10/1998	22/12/1998	L 14	19/01/1999	30	1999/43/EC		
44		Etozazole	Ac, In	Sumitomo Chemical Agro Europe SA	21/04/1998	FR	3/09/1998	15/10/1998		15/10/1998	22/12/1998	L 14	19/01/1999	30	1999/43/EC		
45		Benzoic acid	Ba, Fu	Menno Chemie Vertriebs-Ges	25/05/1998	DE	28/05/1998	7/07/1998		7/07/1998	17/11/1998	L 317	26/11/1998	47	1998/676/EC		
46	ZA 1296	Mesotrione	Hb	Zeneca Agrochemicals	23/04/1998	UK	26/01/1999	27/01/1999		11/02/1999	31/05/1999	L 148	15/06/1999	44	1999/392/EC		
47	CGA 277 476	Oxasulfuron	Hb	Novartis Protezione Pianta S.A.	29/05/1998	IT	19/10/1998	1/12/1998		1/12/1998	18/03/1999	L 87	31/03/1999	15	1999/237/EC		
48		Ferric phosphate	Mo	W.Neudorff GmbH KG	27/08/1998	DE	21/09/1998	15/10/1998		15/10/1998	22/12/1998	L 14	19/01/1999	30	1999/43/EC		
49	SAN 1367H	Pyridafol		Novartis Crop Protection UK Ltd.	10/09/1998											yes	
50	YRC 2894	Thiacloprid	In	Bayer Plc.	11/09/1998	UK	28/06/1999	20/07/1999		20/07/1999	23/02/2000	L 57	2/03/2000	35	2000/181/EC		

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

Annex II order	Development code	active substance	function	applicant	date of application to a MS	RMS	report on completeness received	dossier receipt in all MS	commenting period completeness check	Dossier to SCPH date	decision completeness of dossier	No. O.J.	date O.J.	page O.J.	decision no.	application withdrawn	Completeness Decision repealed
51	AT0IABO3	beta-Cypermethrin	In	Elf Atochem Agri SA	20/10/1998	BE	BE reported on non-completeness on 23 Dec 2005									yes	
52		Forchlorfenuron	Pg	SKW Trostberg AG (Taskforce SKW Trostberg AG and Kyowa Hakko Kogyo Co.Ltd.)	7/12/1998	ES	23/06/1999	20/07/1999		20/07/1999	23/02/2000	L 57	2/03/2000	35	2000/181/EC		
53	AE F 115008	Iodosulfuron	Hb	Hoechst Schering AgrEvo GmbH	14/12/1998	DE	27/01/1999	11/02/1999		11/02/1999	31/05/1999	L 148	15/06/1999	44	1999/392/EC		
54	MON 6550	Silthiofam	Fu	Monsanto Crop Protection	14/12/1998	IE	15/12/1998	11/02/1999		11/02/1999	31/05/1999	L 148	15/06/1999	44	1999/392/EC		
55	CGA 293343	Thiamethoxam	In	Novartis Crop Protection AG	17/03/1999	ES	20/07/1999	20/07/1999		20/07/1999	23/02/2000	L 57	2/03/2000	35	2000/181/EC		
56	BAS 656H	Dimethenamid-P	Hb	BASF AG	16/04/1999	DE	26/05/1999	10/06/1999		10/06/1999	22/07/1999	L 210	10/08/1999	22	1999/555/EC		
57	AC 900001	Picolinafen	Hb	Cyanamid Agro S.A./N,V,	10/05/1999	DE	3/06/1999	10/06/1999		10/06/1999	22/07/1999	L 210	10/08/1999	22	1999/555/EC		
58	ZA1963	Picoxystrobin	Fu	Zeneca Agrochemicals	26/05/1999	IE	27/05/1999	10/06/1999		10/06/1999	22/07/1999	L 210	10/08/1999	22	1999/555/EC		
59	RH-7281	Zoxamide	Fu	Rohm and Haas France S.A.	2/06/1999	UK	4/02/2000	31/05/2000		31/05/2000	6/09/2000	L 230	12/09/2000	14	2000/540/EC		
60	Spinosyn A:232105; Spinosin D275043	Spinosad	In	Dow AgroSciences	19/07/1999	NL	17/08/1999	17/08/1999		17/08/1999	25/02/2000	L 64	11/03/2000	24	2000/210/EC		
61	EXP60707B	Acetamiprid	In	Nisso Chemical Europe GMBH	22/10/1999	GR	1/02/2000	22/02/2000		22/02/2000	7/06/2000	L 145	20/06/2000	36	2000/390/EC		
62	RPA 407213	Fenamidone	Fu	Rhone Poulenc Ag	15/09/1999	FR	9/12/1999	17/01/2000		17/01/2000	17/03/2000	L 78	29/03/2000	26	2000/251/EC		
63	IKF 916	Cyazofamid	Fu	Ishira Sangyo Kaisha Ltd; ISK Biosciences Europe SA;	16/12/1999	FR	20/03/2000	20/03/2000		20/03/2000	15/06/2000	L 155	28/06/2000	62	2000/412/EC		

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

Annex II order	Development code	active substance	function	applicant	date of application to a MS	RMS	report on completeness received	dossier receipt in all MS	commenting period completeness check	Dossier to SCPH date	decision completeness of dossier	No. O.J.	date O.J.	page O.J.	decision no.	application withdrawn	Completeness Decision repealed
64	MKH 65 61	Propoxycarbazone-sodium	Hb	Bayer AG.	25/01/2000	DE	10/03/2000	10/03/2000		10/03/2000	17/07/2000	L 183	22/07/2000	21	2000/463/EC		
65	RH-2485	Methoxyfenozide	In	Rohm and Haas France SA	21/02/2000	UK	13/10/2000	2/02/2001			4/05/2001	L 137	19/05/2001	30	2001/385/EC		
66	B-41;E-187	Milbemectin	In	Sankyo Company Limited	6/03/2000	NL	2/05/2000	31/05/2000		31/05/2000	6/09/2000	L 230	12/09/2000	14	2000/540/EC		
67	BAS500F	Pyraclostrobin	Fu	BASF AG	28/02/2000	DE	17/04/2000	31/05/2000		31/05/2000	6/09/2000	L 230	12/09/2000	14	2000/540/EC		
68	AEF 130360	Foramsulfuron	Hb, Pg, In, Ne	Aventis GmbH	30/03/2000	DE	4/05/2000	31/05/2000		31/05/2000	6/09/2000	L 230	12/09/2000	14	2000/540/EC		
69	UBH 820 UR 50601	Beflubutamid	Hb	UBE Europe GmbH	27/06/2000	DE	21/07/2000	18/10/2000	18/10/2000	18/10/2000	4/12/2000	L 311	12/12/2000	47	2000/784/EC		
70	ASU 96 520 H, TKC-94 EC 60	Pethoxamid	Hb	Stahler Agrochemie GmbH & Co, KG; Tokuyama Europe GmbH; Tomen France S.A,	16/10/2000	DE	7/03/2001		3/07/2001		30/07/2001	L 217	11/08/2001	14	2001/626/EC		
71	AE F130060	Mesosulfuron-methyl	Hb	Aventis Cropscience, France	15/12/2000	FR	12/01/2001	2/02/2001			2/04/2001	L 99	10/04/2001	9	2001/278/EC		
72	PHYLIQ	Laminarin	Ot	Goemar	29/03/2001	BE	11/04/2001	31/05/2001	2/07/2001		27/11/2001	L 321	6/12/2001	34	2001/861/EC		
73	MCW-275, GR 572	Novaluron	In	Huntingdon lifescience, on behalf of Makhteshiom Agan (UK) Ltd	29/03/2001	UK	15/06/2001	16/07/2001	14/08/2001		27/11/2001	L 321	6/12/2001	34	2001/861/EC		
74	BAS 510 F	Boscalid	Fu	BASF AG (Germany)	26/04/2001	DE	16/07/2001	11/09/2001	6/10/2001		8/04/2002	L 92	9/04/2002	34	2002/268/EC		
75	BAS 635 H	Tritosulfuron	Hb	BASF AG (Germany)	8/06/2001	DE	24/07/2001	11/09/2001	6/10/2001		8/04/2002	L 92	9/04/2002	34	2002/268/EC		
76	D 2341	Bifenazate	Ac	Crompton Europe LTD	3/07/2001	NL	23/07/2001	9/10/2001	30/10/2001		8/04/2002	L 92	9/04/2002	34	2002/268/EC		
77	BAJ 2740	Spirodiclofen	In	Bayer AG, Germany	23/08/2001	NL	12/12/2001	6/02/2002	27/02/2002		19/07/2002	L 192	20/07/2002	60	2002/593/EC		
78	TI-425	Clothianidin	In	Sumitomo Chemical Takeda Agro Industries Ltd. London	26/09/2001	BE	16/10/2001	27/11/2001	16/01/2002		19/04/2002	L 104	20/04/2002	42	2002/305/EG		

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Annex II order	Development code	active substance	function	applicant	date of application to a MS	RMS	report on completeness received	dossier receipt in all MS	commenting period completeness check	Dossier to SCPH date	decision completeness of dossier	No. O.J.	date O.J.	page O.J.	decision no.	application withdrawn	Completeness Decision repealed
79	BAS 505F	Dimoxystrobin	Fu	BASF UK	28/11/2001	UK	30/01/2002	21/02/2002			19/07/2002	L 192	20/07/2002	60	2002/593/EC		
80	IR 6141	Benalaxyl-M	Fu	ISAGRO, IT	22/02/2002	PT	3/06/2002	29/07/2002	15/09/2002		10/01/2003	L 11	16/01/2003	52	2003/35/EC		
81	KIF 230	Benthiavalicarb-isopropyl	Fu	KUMIAI Chemical Ltd	19/04/2002	BE	11/06/2002	11/06/2002	11/07/2002		10/01/2003	L 11	16/01/2003	52	2003/35/EC		
82	RH-175933	1-methylcyclopropene	Pg	Rohm and Haas France S.A.S.	28/02/2002	UK	17/05/2002	11/06/2002	17/09/2002		10/01/2003	L 11	16/01/2003	52	2003/35/EC		
83	HEC 5725	Fluoxastrobin	Fu	Bayer AG	25/03/2002	UK	28/05/2002	17/06/2002	27/09/2002		10/01/2003	L 11	16/01/2003	52	2003/35/EC		
84	JAU 6476	Prothioconazole	Fu	Bayer AG	25/03/2002	UK	28/05/2002	27/09/2002	18/10/2002		10/01/2003	L 11	16/01/2003	52	2003/35/EC		
85	KIH 2023	Bispyribac-sodium	Hb	Bayer AG Crop Protection	26/03/2002	IT	23/07/2002	15/10/2002	15/11/2002		2/05/2003	L 112	6/05/2003	10	2003/305/EC		
86	BSN 2060	Spiromesifen	Ac	Dr. Markus Heil Bayer AG	18/04/2002	UK	18/07/2002	27/09/2002	18/10/2002		17/02/2003	L 43	18/02/2003	45	2003/105/EC		
87	BAS 560 00F	Metrafenone	Fu	BASF Belgium	4/06/2002	UK	4/06/2002	14/10/2002	14/11/2002		17/02/2003	L 43	18/02/2003	45	2003/105/EC		
88	LBG-01F34	Potassium phosphite	Fu	Luxembourg Industries (Pamol)	22/08/2002	FR	20/02/2003	27/02/2003	20/03/2003		2/09/2003	L 221	4/09/2003	42	2003/636/EC		
89		Sulfuryl fluoride	In	Dow AgroSciences Ltd	29/07/2002	UK	1/11/2002	5/11/2002	28/11/2002		2/05/2003	L 112	6/05/2003	10	2003/305/EC		
90	NF-149	Cyflufenamid	Fu	Nippon Soda Company Ltd.	14/01/2003	UK	8/05/2003	8/05/2003			2/09/2003	L 221	4/09/2003	42	2003/636/EC		
91		Penoxsulam	Hb	Dow AgroScience	29/11/2002	IT	23/03/2003	23/03/2003	10/11/2003								
92	BAS 670 00H	Topramezone (BAS 670 H)	Hb	BASF, Germany	12/05/2003	FR	23/05/2003	8/08/2003	29/08/2003		4/12/2003	L 322	9/12/2003	28	2003/850/EC		
93	AKD-2023	Acequinocyl	Ac	Agro-Kanesho, Stade	17/03/2003	NL	28/04/2003	28/04/2003			2/09/2003	L 221	4/09/2003	42	2003/636/EC		
94	STS/Florissant 100	Silver thiosulphate	Pg, Ot	Enhold B.V.	27/01/2003	NL	2/07/2003	28/08/2003	25/09/2003		4/12/2003	L 322	9/12/2003	28	2003/850/EC		
95	FEN-506	FEN 560	Fu	Société Occitane de fabrications et de Technologies	24/06/2003	FR	30/09/2003	30/09/2003	10/11/2003		9/02/2004	L 37	10/02/2004	34	2004/131/EC		
96		Ethaboxam	Fu	LG lifesience Ltd	30/09/2003	UK	10/02/2004	18/12/2003	5/03/2004		26/04/2004	L 151	30/04/2004	25	2004/409/EC	yes	24/11/2006
97	XDE-225	Gamma-cyhalothrin	In	Pytech Chemicals GmbH	4/11/2003	UK					29/09/2004	L 313	12/10/2004	21	2004/686/EC		

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Annex II order	Development code	active substance	function	applicant	date of application to a MS	RMS	report on completeness received	dossier receipt in all MS	commenting period completeness check	Dossier to SCPH date	decision completeness of dossier	No. O.J.	date O.J.	page O.J.	decision no.	application withdrawn	Completeness Decision repealed
98	DPX-KQ926	Proquinazid	Fu	DuPont (UK) Ltd	9/01/2004	UK	13/03/2004	17/03/2004	30/04/2004		29/09/2004	L 313	12/10/2004	21	2004/686/EC		
99	IKI-220	Flonicamid	In	ISK Bioscience	23/12/2003	FR	16/04/2004	18/05/2004	16/06/2004		29/09/2004	L 313	12/10/2004	21	2004/686/EC		
100	NOA 407855	Pinoxaden	Hb	Syngenta Limited	31/03/2004	UK	21/07/2004	1/08/2004	31/03/2005		22/06/2005	L 160	23/06/2005	32	2005/459/EC		
101	AEC 638206	Fluopicolide	Fu	Bayer CropScience	7/05/2004	UK	7/06/2004	30/06/2004	30/09/2004		9/11/2005	L 293	9/11/2005	26	2005/778/EC		
102		Aminopyralid	Hb	Dow AgroSciences		UK	6/09/2004	10/09/2004	4/10/2004		28/10/2005	L 293	9/11/2005	26	2005/778/EC		
103	KBV 99-01	Potassium iodide	Fu	Koppert Beheer B.V.	6/09/2004	NL	21/12/2004	21/04/2005	20/05/2005		21/10/2005	L 282	26/10/2005	18	2005/751/EC		
104		Potassium thiocyanate	Fu			NL	21/12/2005	21/04/2005	20/05/2005		21/10/2005	L 282	26/10/2005	18	2005/751/EC		
105	C99-1 and BC 100	Ascorbic acid	Fu	Citrex Nederland B.V	14/09/2004	NL	21/12/2005	11/05/2005	1/06/2005		21/10/2005	L 282	26/10/2005	18	2005/751/EC		
106	CAL 97 118	Chromafenozide	Pg	Calliope	12/12/2004	HU			10/05/2006	23/05/2006	25/08/2006	236	31/08/2006	31	2006/586/EC		
107		Halosulfuron methyl	Hb	Nissan Chemical Europe S.A.R.L.	19/05/2005	IT	7/03/2006		10/05/2006	23/05/2006	25/08/2006	236	31/08/2006	31	2006/586/EC		
108		Aviglycine HCL	Pg	Valent BioScience (division of Sumitomo)	27/10/2004	UK	-		29/03/2006	4/04/2006	21/08/2006	240	2/09/2006	9	2006/589/EC	8/01/2007	
109	BAS 320	Metaflumizone	In	BASF, France	29/03/2005	UK			8/02/2006	4/04/2006	19/07/2006	L 201	25/07/2006	34	2006/517/EC		
110	entry deleted																
111	IR 5878	Orthosulfamuron	Hb	Isagro, Italy	4/07/2005	IT	7/03/2006		30/06/2006	14/07/2006							
112	DE-126	Meptyldinocap	Fu	DowAgroScience	12/08/2005	UK	1/11/2005		29/03/2006	4/04/2006	21/08/2006	240	2/09/2006	9	2006/589/EC		
113	AE 0172747	Tembotrione	Hb	Bayer CropScience AG	25/11/2005	AT			10/05/2006	23/05/2006	25/08/2006	236	31/08/2006	31	2006/586/EC		
114	NOA 446510	Mandipropamid	Fu	Syngenta Limited	13/12/2005	AT	22/02/2006		29/03/2006	4/04/2006	21/08/2006	240	2/09/2006	9	2006/589/EC		
115	IR 5885	Valiphenal	Fu	Isagro SpA	2/09/2005	HU	23/02/2006		29/03/2006	23/05/2006	25/08/2006	236	31/08/2006	31	2006/586/EC		

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Annex II order	Development code	active substance	function	applicant	date of application to a MS	RMS	report on completeness received	dossier receipt in all MS	commenting period completeness check	Dossier to SCPH date	decision completeness of dossier	No. O.J.	date O.J.	page O.J.	decision no.	application withdrawn	Completeness Decision repealed
116	NNI-0001	Flubendiamide	In	Bayer CropScience AG, Germany also on behalf of: Nihon Nohyaku Co., Ltd., Japan	30/03/2006	GR	8/05/2006		9/08/2006	29/09/2006							
117	NC-224	Amisulbrom	Fu	Nissan Chemical Europe S.A.R.L.	24/03/2006	UK	24/08/2006										
118	XDE-742	Pyroxsulam	Hb	Dow AgroSciences GmbH	28/02/2006	UK	25/08/2006	31/08/2006	7/11/2006	24/11/2006							
119	S-1812, V-1812	Pyridalil	In	Sumitomo Chemical Agro Europe SAS	28/03/2006	NL	10/01/2007										
120	EL 101 GV	Heptamaloxyglucan	EI	ELICITYL	9/05/2006	FR	5/12/2006										
121	BYI08330	Spirotetramat	In	Bayer CropScience AG	9/10/2006	AT	21/12/2006	4/03/2007	28/03/2007	15/05/2007							
122	A-14605 A, NOA 422390, NOA 426007, MK 244	Emamectin benzoate	In	Syngenta Ltd.	23/06/2006	NL	29/01/2007										
123	DPX-E2Y45	Chlorantraniliprole	In	DuPont International Operations Sarl.	2/02/2007	IE	15/02/2007										

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Annex II.A.2 Microorganisms

Annex II order	Development code	Active substance	function	applicant	Date of application to a MS	RMS	Report on completeness received	Dossier receipt in all MS	Commenting period completeness check	Dossier to SCPH date	Decision completeness of dossier	NO. O.J	Date O.J	Page O.J	Decision no.	Applicati on withdra wn	Complete Ness Decision repealed
10001		Paecilomyces fumosoroseus Apopka strain 97	Fu	Thermo Trilogy Coporation	18/05/1994	BE	14/11/1995	24/11/1995		24/11/1995	17/02/1997	L 64	5/03/1997	17	1997/164/EC		
10002		Pseudomonas chlororaphis strain MA342	In	BioAgri	15/12/1994	SE	22/11/1995	20/03/1996		20/03/1996	25/03/1997	L 98	15/04/1997	15	1997/248/EC		
10003	AQ 10	Ampelomyces quisqualis strain AQ10	Fu	Ecogen Europe sarl	12/04/1996	FR	25/10/1996	6/02/1997		6/02/1997	29/07/1997	L 239	30/08/1997	48	1997/591/EC		
10004	SE NPV	Spodoptera exigua nuclear polyhedrosis virus	Fu	Biosys	12/07/1996	NL	2/04/1997	29/05/1997		29/05/1997	5/12/1997	L 351	23/12/1997	67	1997/865/EC		
10005		Coniothyrium minitans	In	Prophyta GmbH	10/09/1997	DE	5/01/1998	7/07/1998		7/07/1998	17/11/1998	L 317	26/11/1998	47	1998/676/EC		
10006		Zucchini Yellow Mosaic Virus, mild strain	Fu	Horticultural Research International	23/01/1998	UK	-									yes	
10007		Gliocladium catenulatum strain J 1446	Fu	Kemira Agro Oy	19/05/1998	FI	22/12/1998	11/02/1999		11/02/1999	31/05/1999	L 148	15/06/1999	44	1999/392/EC		
10008	QRD 133 WP	Bacillus subtilis strain QST 713	Fu	AgraQuest	19/04/2000	DE	28/05/2000	1/09/2000		1/09/2000	12/12/2000	L 2	5/01/2001	25	2001/6/EC		
10009		Pseudozyma flocculosa	Ba, Fu	Maasmond-Westland b.a.	6/03/2001	NL	3/09/2001	19/11/2001	16/01/2001		19/04/2002	L 104	20/04/2002	42	2002/305/EG		
10010	PBP-01001-I	Paecilomyces lilacinus	Fu	Prophyta Biologischer Pflanzenschutz GmbH	15/09/2002	BE	14/10/2002				2/05/2003	L 112	6/05/2003	10	2003/305/EC		
10011	ARSEF 4490	Paecilomyces fumosoroseus strain Fe9901	Ne	FuturEco, S.L.	4/02/2005	BE											

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

Annex II order	Development code	Active substance	function	applicant	Date of application to a MS	RMS	Report on completeness received	Dossier receipt in all MS	Commenting period completeness check	Dossier to SCPH date	Decision completeness of dossier	NO. O.J	Date O.J	Page O.J	Decision no.	Applicati on withdra wn	Complete Ness Decision repealed
10012		Adoxophyses orana granulosis virus strain BV-0001	In	GAB Consulting	29/11/2004	DE	26/07/2005										
10013		Zucchini Yellow Mosaik Virus, weak strain	Fu	Bio-Oz Biotechnologies Ltd.	24/06/2005	UK			10/05/2006	23/05/2006	25/08/2006	236	31/08/2006	31	2006/586/EC		
10014	NEX0101 biomass	Candida oleophila, strain O	Fu	BIONEXT sprl	12/07/2006	UK	27/09/2006	3/11/2006	15/01/2007	16/03/2007							
10015	-	Helicoverpa armigera nucleopolyhedrovirus (HearNPV)	In	Andermatt Biocontrol GmbH	9/08/2006	EE	7/11/2006	20/03/2007	19/04/2007	15/05/2007							
10016	-	Spodoptera littoralis nucleopolyhedrovirus	In	Andermatt Biocontrol GmbH	2/01/2007	EE											

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

Annex II order	active substance	Function	RMS	Co-RMS	provisional approvals applied	provisional approvals granted	start detailed Examin.	DAR received at COM	DAR received on	DAR to MS	DAR to COM date	DAR to applicant date	Peer review type	WG eval	EFSA conclusion submitted on	SCP target date	SCPH date2 annex1	Annex I inclusion	Decision	No official journal	date official journal	page
1	Prohexadi one-calcium	Pg	FR			FR	30/08/96	09/06/98		22/06/98		01/07/98	NPR	Apr-99, Sep-99,		26.11.99	16/06/00	yes	2000/50/EC	L 198	04/08/00	39
2	Kresoxim-methyl	Fu	BE				12/04/96	15/01/97		14/02/97		14/02/97	NPR	Sep-97, Nov-97		29.01.98	16/10/98	yes	1999/1/EC/EC	L 21	28/01/99	21
3	Flurtamone	Hb	FR		DK,SE	FR, UK, IT,DE, IE,AT,BE	31/05/96	21/05/97		18/06/97		26/06/97	NPR	Sep-97, Nov-97		01.03.2000	04/07/03	yes	2003/84/EC	L 247	30/09/03	20
4	Chlorfena pyr	Ac, In	ES		IT, GR, BE, ES		30/08/96	30/11/98		14/12/98		15/12/98	NPR	Sep-97, Nov-97		June 01	27/04/01	no	2001/697/EC	L 249	19/09/01	19
5	Quinoxifene	Fu	UK		DE, DK	IE, UK, FR, PT, IT, GR, BE, ES, AT	30/07/96	11/10/96		11/02/97		11/02/97	NPR	Sep-97, Nov-97		31.03.00	27/11/03	yes	2004/60/EC	L 120	24/04/04	39
6	Azoxystrobin	Fu	DE		IT		30/08/96	05/02/97		14/02/97		14/02/97	NPR	Sep-97, Nov-97		01.01.98	22/04/98	yes	1998/47/EC	L 191	07/07/98	50
7	Spiroxamine	Fu	DE		DE,FR,		30/08/96	05/02/97		14/02/97		14/02/97	NPR	Sep-97, Nov-97		31.08.98	12/05/99	yes	1999/73/EC	L 206	05/08/99	16
8	Isoxaflutole	Hb	NL		AT, DE	PT, NL, IT, GR, ES, FR, BE, LU	30/08/96	26/02/97		26/02/97			NPR	Sep-97, Nov-97		04.03.98	15/04/03	yes	2003/68/EC	L 177	16/07/03	17
9	Alanycarb	In	FR				15/07/99	01/06/00	01/10/01	05/10/01		05/10/01					26/02/02	withdrawn				
10	Flupyr-sulfuron-methyl	Hb	FR		DE	FR, UK, IE, BE, AT, LU	05/03/97	02/12/97		09/12/97		18/12/97	NPR	Dec-98, Mar-99		15.07.99	27/04/01	yes	2001/49/EC	L 176	29/06/01	61
11	Flumioxazine	Hb	FR		DE, ES	FR	24/09/97	20/01/98		14/04/98		23/04/98	NPR	Sep-99, Jun-00, Oct-01, Feb-02, Mar-02		02.08.00	28/06/02	yes	2002/81/EC	L 276	12/10/02	28
12	Prosulfuron	Hb	FR		DE, ES	UK, PT, IT, FR, AT	22/02/97	18/01/99	02/08/99	16/06/99		22/06/99	NPR	Jul-00, Dec-01, Feb-02		04.08.00	26/02/02	yes	2002/48/EC	L 148	06/06/02	19
13	Metalaxyl-M	Fu	BE		IT, GR, AT, DE, FR, ES, SE	IE, BE, UK, PT, FI	30/08/97	27/07/99		20/09/99		20/09/99	NPR	Jul-00, Dec-01, Feb-02			19/04/02	yes	2002/64/EC	L189	18/07/02	27
14	Azimsulfuron	Hb	IT				05/03/97	22/05/97	12/02/02	18/06/97		26/06/97	NPR	Apr-98, May-98		31.08.98	02/07/99	yes	1999/80/EC	L 210	10/08/99	13

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

Annex II order	active substance	Function	RMS	Co-RMS	provisional approvals applied	provisional approvals granted	start detailed Examin.	DAR received at COM	DAR received on	DAR to MS	DAR to COM date	DAR to applicant date	Peer review type	WG eval	EFSA conclusion submitted on	SCP target date	SCPH date2 annex1	Annex I inclusion	Decision	No official journal	date official journal	page
15	Fosthiazate	Ne	UK		ES, FR, DE, GR	IT, BE, UK	11/06/97	18/03/98		25/03/98		25/03/98	NPR	Sep-99, Jan-00, Oct-00, Feb-02, Mar-02, Nov-02, Mar-03, May-03		04.12.00	04/07/03	yes	2003/84/EC	L 247	30/09/03	20
16	Cyclanilide	Pg	GR			GR, ES	22/02/97	11/02/98	23/04/02	23/06/98		30/06/98	NPR	Sep-99, Jan-00		31.03.00	29/06/01	yes	2001/87/EC	L 276	19/10/01	17
17	Carfentrazone-ethyl	Hb	FR		IT, GR, FR, SE, DK	UK, DE, IE, BE, AT, LU, ES	11/06/97	14/05/98		22/06/98		01/07/98	NPR	Sep-99, Oct-01, Sep-02, Jan-03		26.11.99	15/04/03	yes	2003/68/EC	L 177	16/07/03	17
18	Flufenacet	Hb	FR		DE, IT, PT, ES, UK	BE, FR, AT, LU, GR	11/06/97	06/01/98		25/03/98		25/03/98	NPR	Sep-99, Jun-00, Dec-01, Jan-03, Mar-03		02.08.00	04/07/03	yes	2003/84/EC	L 247	30/09/03	20
19	Imazosulfuron	Hb	DE		DE, PT, ES		23/12/97	17/06/98		23/06/98		30/06/98	NPR	Sep-99, Jun-00, Oct-01, Dec-01, Nov-02, Mar-03, May-03, July 03, Nov-03, Jan-04, Mar-04		04.08.00	08/10/04	yes	2005/3/EC	L 20	22/01/05	19
20	Ethoxysulfuron	Hb	IT		ES	IT	30/08/97	20/05/98		23/06/98		30/06/98	NPR	Sep-99, Jan-00, Nov-00, Oct-01, Mar-02, Jun-02, Sep-02, Nov-02		04.12.00	03/12/02	yes	2003/23/EC	L 81	28/03/03	39
21	Pymetrozine	In	DE		IT, NL, DE, FI, BE	PT, UK, SE, GR, ES, FR	23/12/97	28/05/98		14/04/98		23/04/98	NPR	Sep-99, Jan-00, Mar-00		07.04.00	29/06/01	yes	2001/87/EC	L 276	19/10/01	17
22	Famoxadone	Fu	FR		IT, DE, UK, AT, BE, PT, FI, NL	GR, FR, IE, ES	30/08/97	05/08/98	25/02/02	11/01/99		11/01/99	NPR	Jan-00, Dec-01, Feb-02		02.08.00	19/04/02	yes	2002/64/EC	L189	18/07/02	27
23	Acibenzolar-S-methyl	Fu	FR		IT	UK, FR	23/12/97	17/12/98	12/02/02	11/01/99		11/01/99	NPR			01.03.00	29/06/01	yes	2001/87/EC	L 276	19/10/01	17

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

Annex II order	active substance	Function	RMS	Co-RMS	provisional approvals applied	provisional approvals granted	start detailed Examin.	DAR received at COM	DAR received on	DAR to MS	DAR to COM date	DAR to applicant date	Peer review type	WG eval	EFSA conclusion submitted on	SCP target date	SCPH date2 annexI	Annex I inclusion	Decision	No official journal	date official journal	page
24	Flazasulfuron	Hb	ES		PT, IT, AT, BE, DE, GR	ES, FR	23/12/97	03/08/99	02/08/99	30/08/99		08/09/99	NPR	July-00, Febr-01, Apr-01, June-01, Oct-01, Dec-01, Febr-02, Oct-02, Nov-02, Mar-03, July 03, Nov-03			27/11/03	yes	2004/30/EC	L 77	13/03/04	50
25	Carvone	Pg	NL		NL		14/09/99	16/10/00	23/11/00	16/01/01		16/01/01	APR	Feb-02, Mar-02, Nov-02, Jan-03			20/07/99	open				
26	Sulfosulfuron	Hb	IE		DE, UK, BE, SE	IE, FR, ES, DK	23/12/97	02/04/98		14/04/98		23/04/98	NPR	Apr-99, Sep-99, Jan-01, Apr-01, Feb-02		12.99:31.03.00	26/02/02	yes	2002/48/EC	L 148	06/06/02	19
27	Cyhalofop-butyl	Hb	IT			IT, ES, GR	28/03/98	30/11/98		06/01/99		06/01/99	NPR	Jan-00, Jun-00, Oct-01, Feb-02		02.08.00	19/04/02	yes	2002/64/EC	L189	18/07/02	27
28	Cinidon-ethyl	Hb	UK		NL, DE; SE, DK	UK, BE, FR	20/06/98	02/11/98		14/12/98		15/12/98	NPR	Jan-00, Dec-01, Feb-02			19/04/02	yes	2002/64/EC	L189	18/07/02	27
29	Fenhexamid	Fu	UK		IT, PT, IE	DE, BE, GR, UK, DK, AT, ES, SE	20/06/98	15/10/98		15/10/98		15/10/98	NPR	1/01/2000		31.03.00	22/04/98	yes	2001/28/EC	L 113	24/04/01	5
30	Oxadiazyl	Hb	IT		IT, ES		20/06/98	20/07/99	02/08/99	30/08/99		08/09/99	NPR	Jul-00, Mar-02, Jun-02, Jul-02, Sep-02			03/12/02	yes	2003/23/EC	L 81	28/03/03	39
31	Pyraflufen-ethyl	Hb	BE		DE, FR	BE, LU	28/03/98	13/07/99	12/02/02	20/09/99		20/09/99	NPR	July-00		04.08.00	29/06/01	yes	2001/87/EC	L 276	19/10/01	17
32	Azafenidin	Hb	ES		IT, ES		28/03/98		20/11/00	20/02/01		20/02/01	NPR				28/06/02	no	2002/949/EC	L 328	05/12/02	23
33	S-Metolachlor	Hb	BE		NL, BE, IT, PT, DE, AT, ES		15/08/98	03/05/99	23/11/00	16/01/01		16/01/01	APR	Dec-01, Mar-02, Oct-02, Jan-03, July 03, Sep-03, Nov-03			08/10/04	yes	2005/3/EC	L 20	19/01/05	19
34	Tepraloxim	Hb	ES		DE, BE, ES, SE		15/08/98	21/01/02	21/01/02	30/01/02	30/01/02	30/01/02		Jan-04, May-04			03/12/04	yes	2005/34/EC	L 125	18/05/05	5

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

Annex II order	active substance	Function	RMS	Co-RMS	provisional approvals applied	provisional approvals granted	start detailed Examin.	DAR received at COM	DAR received on	DAR to MS	DAR to COM date	DAR to applicant date	Peer review type	WG eval	EFSA conclusion submitted on	SCP target date	SCPH date2 annex1	Annex I inclusion	Decision	No official journal	date official journal	page
35	Fluazolate	Hb	UK		UK, BE, DE		26/11/98	01/03/01										withdrawn				
36	Indoxacarb	In	NL		DE,AT,IT,BE		20/06/98	07/02/00		27/03/00		27/03/00	APR	Feb-01, Apr-01, Jun-01, Oct-01, Nov-02,			23/09/05	yes	2006/10/EC	L 25	28/01/06	24
37	Mepanipyrim	Fu	IT		IT, BE, NL, ES, FR, PT, UK		26/11/98	12/07/00	23/11/00	19/09/00		16/01/01	APR	Nov-03, Jan-04			30/03/04	yes	2004/62/EC	L 125	28/04/04	38
38	Imazamox	Hb	FR		FR, GR,IT,ES,UK		26/11/98	09/09/99	01/02/00	20/04/00		20/04/00	NPR	July-01, June-02, Jul-02, Sep-02			03/12/02	yes	2003/23/EC	L 81	28/03/03	39
39	Flusulfamide	Fu	UK		UK													withdrawn				
40	Florasulam	Hb	BE		DE, DK,AT, ES, IT, SE,UK, IE, DE	BE	26/11/98	19/11/99	03/01/99	28/01/00		28/01/00	APR	Nov-00, Dec-01, Feb-02		04.12.00	19/04/02	yes	2002/64/EC	L189	18/07/02	27
41	Trifloxystrobin	Fu	UK		DE, AT, PT, ES, FR	UK, BE, IE	19/01/99	19/04/00	10/08/00	19/09/00	18/01/01	19/01/01	NPR	Jun-02, Jan-03,			15/04/03	yes	2003/68/EC	L 177	16/07/03	17
42	Iprovalicarb	Fu	IE		IE, DE, IT, GR, PT, ES	IE	15/08/98	04/11/99	01/05/00	17/07/00		17/07/00	APR	Jul-00, Apr-01, Jun-01, Oct-01, Dec-01, Feb-02		04.08.00	26/02/02	yes	2002/48/EC	L 148	06/06/02	19
43	Profoxydim	Hb	ES		PT, ES, IT	ES	19/01/99	28/03/01	21/03/01	18/05/01		23/05/01	NPR	Se02, March-03, May-03, July 03, Nov-03,				open				
44	Etoxazole	Ac, In	FR		FR		19/01/99	08/10/01	08/10/01	09/10/01		09/10/01	NPR	Aug-02, May-03, Nov-03			03/12/04	yes	2005/34/EC	L 125	18/05/05	5
45	Benzoic acid	Ba, Fu	DE			DE, FI	26/11/98	12/12/00	05/12/00	21/12/00		21/12/00	APR	March 03, May 03, July 03			27/11/03	yes	2004/30/EC	L 77	13/03/04	50
46	Mesotrione	Hb	UK		DE,IT, BE, ES, PT,FR		15/06/99	17/12/99	01/02/00	27/03/00		27/03/00	NPR	June-01, Jan-03,			15/04/03	yes	2003/68/EC	L 177	16/07/03	17
47	Oxasulfuron	Hb	IT		IT		31/03/99	10/05/00	15/12/00	27/06/00		25/08/00	NPR	Jul-02, Sep-02			03/12/02	yes	2003/23/EC	L 81	28/03/03	39
48	Ferric phosphate	Mo	DE		DE, SE, DK	LU	19/01/99	10/08/99		20/09/99		20/09/99	NPR	July-00		02.08.00	29/06/01	yes	2001/87/EC	L 276	19/10/01	17

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

Annex II order	active substance	Function	RMS	Co-RMS	provisional approvals applied	provisional approvals granted	start detailed Examin.	DAR received at COM	DAR received on	DAR to MS	DAR to COM date	DAR to applicant date	Peer review type	WG eval	EFSA conclusion submitted on	SCP target date	SCPH date2 annex1	Annex I inclusion	Decision	No official journal	date official journal	page
49	Pyridafol																	withdrawn				
50	Thiacloprid	In	UK		DE, BE	PT	02/03/00		22/11/00	18/01/01		19/01/01	NPR	Se01, Jan-03, May-03, March-04			30/11/99	yes	2004/99/EC	L 309	06/10/04	6
51	beta-Cypermethrin	In	BE		DE									Sep-02				open				
52	Forchlorfenuron	Pg	ES				02/03/00	02/03/01	19/12/02	20/12/02	20/12/02	20/12/02		July-04			23/09/05	yes	2006/10/EC	L 25	28/01/06	24
53	Iodosulfuron	Hb	DE		DE, IT, BE		15/06/99	30/05/00		19/09/00		07/12/00	NPR	July-01, Sep-02, Mar-03			04/07/03	yes	2003/84/EC	L 247	30/09/03	20
54	Siltthiofamid	Fu	IE		DE, BE, IE, UK		15/06/99	02/10/00	23/11/00	15/11/00		16/01/01	APR	Jun-02, Mar-03, May-03			04/07/03	yes	2003/84/EC	L 247	30/09/03	20
55	Thiamethoxam	In	ES		PT, DE, BE, ES	DK	02/03/00	21/01/02	21/01/02	30/01/02	30/01/02	30/01/02		Jan-04, Mar-04			14/07/06	yes	2007/6/EC	L 43	15/02/07	13
56	Dimethenamid-P	Hb	DE		DE		10/08/99	26/09/00		15/11/00	21/12/00	21/12/00	APR				04/07/03	yes	2003/84/EC	L 247	30/09/03	20
57	Picolinafen	Hb	DE		DE, BE		10/08/99	03/11/00		15/11/00	21/12/00	21/12/00	APR	Oct-01, Dec-01, Feb-02			19/04/02	yes	2002/64/EC	L189	18/07/02	27
58	Picoxystrobin	Fu	IE		IE, DE, UK		10/08/99	11/06/01	11/06/01	23/07/01		23/07/01	APR	June-02, Nov-02, Mar-03			04/07/03	yes	2003/84/EC	L 247	30/09/03	20
59	Zoxamide	Fu	UK		UK, DE, BE, PT, ES	DK	12/09/00			17/07/01		17/07/01	NPR	Mar-03, May-03			02/10/03	yes	2003/119/EC	L 325	12/12/03	41
60	Spinosad	In	NL		BE, DE, ES		11/03/00	05/03/01	05/03/01	23/03/01		23/03/01	NPR	May 03			30/11/99	yes	2007/6/EC	L 43	15/02/07	13
61	Acetamiprid	In	GR	FR	FR, BE	GR	20/06/00	19/03/01	19/03/01	04/05/01		04/05/01	APR	Jun-02, Jul-02, Nov-02, May-03, July 03, Mar-04			12/04/00	yes	2004/99/EC	L 309	06/10/04	6
62	Fenamidone	Fu	FR		BE, DE		29/03/00	27/10/00	08/02/01	20/02/01		20/02/01	APR	Jun-02, Jul-02, Nov-02, Jan-03			15/04/03	yes	2003/68/EC	L 177	16/07/03	17
63	Cyazofamid	Fu	FR		FR, DE, BE, NL, ES, IT, PT, UK, IE		28/06/00	27/08/01	27/08/01	28/09/01		28/09/01	APR	Jul-02, Sep-02			03/12/02	yes	2003/23/EC	L 81	28/03/03	39
64	Propoxycarbazonium sodium	Hb	DE		DE, BE, UK		22/07/00	26/03/01	26/03/01	04/05/01		04/05/01	NPR	Mar-03, May-03			02/10/03	yes	2003/119/EC	L 325	12/12/03	41

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

Annex II order	active substance	Function	RMS	Co-RMS	provisional approvals applied	provisional approvals granted	start detailed Examin.	DAR received at COM	DAR received on	DAR to MS	DAR to COM date	DAR to applicant date	Peer review type	WG eval	EFSA conclusion submitted on	SCP target date	SCPH date2 annexI	Annex I inclusion	Decision	No official journal	date official journal	page
65	Methoxyfe nozide	In	UK		DE,		19/05/01	02/08/02	02/08/02	07/08/02	07/08/02	07/08/02		May-04			08/10/04	yes	2005/3/E C	L 20	22/01/05	19
66	Milbemectin	In	NL		BE		12/09/00	16/06/01	17/06/02	26/06/02	26/06/02	26/06/02		Jan-04			15/04/05	yes	2005/58/E C	L 246	22/09/05	17
67	Pyraclostrobin	Fu	DE		DE, BE	DK	12/09/00	23/11/01	21/11/01	23/11/01	23/11/01	23/11/01	NPR	Mar-03, May-03, July 03, Nov-03			27/11/03	yes	2004/30/E C	L 77	13/03/04	50
68	Foramsulfuron	Hb, Pg, In, Ne	DE		DE		12/09/00	01/06/01	04/05/01	08/06/01		08/06/01	APR	Jun-02, Sep-02			03/12/02	yes	2003/23/E C	L 81	28/03/03	39
69	Beflubutamide	Hb	DE		DE		12/12/00	03/08/02	13/08/02	03/09/02	03/09/02	03/09/02		sept-04			19/10/00	open				
70	Pethoxamid	Hb	DE		DE		11/08/01	09/08/02	29/08/02	03/09/02	03/09/02	03/09/02		Nov-03, Jan-04			27/01/06	yes	2006/41/E C	L 187	08/07/06	24
71	Mesosulfuron-methyl	Hb	FR		DE		10/04/01	12/12/01	12/12/01	09/01/02	09/01/02	09/01/02	APR	May-03			02/10/03	yes	2003/119/EC	L 325	12/12/03	41
72	Laminarin	Ot	BE		GR		06/12/01		02/06/03	12/06/03	12/06/03	12/06/03	APR	Jan-04, Mar-04, May-04			08/10/04	yes	2005/3/E C	L 20	22/01/05	19
73	Novaluron	In	UK		DE		06/12/01		19/09/05				APR					open				
74	Boscalid	Fu	DE	FR			09/04/02		22/11/02	10/12/02	10/12/02	10/12/02		July-04				open				
75	Tritosulfuron	Hb	DE				09/04/02		05/09/02	11/09/02	11/09/02	11/09/02		Jan-04				open				
76	Bifenazate	Ac	NL				09/04/02		03/04/03	09/04/03	09/04/03	09/04/03					15/04/05	yes	2005/58/E C	L 246	22/09/05	17
77	Spirodiclofen	In	NL				20/07/02		19/04/04	18/05/04	18/05/04	18/05/04		Feb-05			19/04/02	open				
78	Clothianidin	In	BE				20/04/02		04/06/03	12/06/03	12/06/03	12/06/03		May-04			27/01/06	yes	2006/41/E C	L 187	08/07/06	24
79	Dimoxystrobin	Fu	UK				20/07/02		16/07/03	14/08/03	14/08/03	14/08/03		Jan-04, July-05	11/08/2005			yes		L 248	12/09/06	3
80	Benalaxyl-M	Fu	PT				16/01/03		07/08/03	04/12/03	04/12/03	04/12/03		July-04				open				
81	Benthiavalicarb-isopropyl	Fu	BE				16/01/03		14/04/04	10/05/04	10/05/04	10/05/04					18/10/02	open				
82	1-methylcyclopropene	Pg	UK				16/01/03		28/05/03	14/08/03	14/08/03	14/08/03		Jan-04, Feb-05, Mar-05	10/05/2005		23/09/05	yes	2006/19/E C	L 44	15/02/06	15
83	Fluoxastrobin	Fu	UK				16/01/03		15/09/03	14/10/03	14/10/03	14/10/03		May-04, July-05	11/08/2005		18/10/02	open				
84	Prothioconazole	Fu	UK				16/01/03		20/10/04	21/10/04	21/10/04	21/10/04						open				
85	Bispyribac-sodium	Hb	IT				06/05/03		25/08/03	14/10/03	14/10/03	14/10/03		July-04			26/02/03	open				
86	Spiromesifen	Ac	UK				18/02/03		20/02/04	16/04/04	16/04/04	15/04/04		Nov-05			03/12/02	open				
87	Metrafenone	Fu	UK				18/02/03		28/10/03	24/11/03	24/11/03	24/11/03		July-04, Nov-05	18/01/2006		14/07/06	yes	2007/6/E C	L 43	15/02/07	13

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

Annex II order	active substance	Function	RMS	Co-RMS	provisional approvals applied	provisional approvals granted	start detailed Examin.	DAR received at COM	DAR received on	DAR to MS	DAR to COM date	DAR to applicant date	Peer review type	WG eval	EFSA conclusion submitted on	SCP target date	SCPH date2 annexI	Annex I inclusion	Decision	No official journal	date official journal	page
88	Potassium phosphite	Fu	FR				04/09/03		11/02/05	16/02/05	16/02/05	16/02/05					04/07/03	open				
89	Sulfuryl fluoride	In	UK				06/05/03		01/11/04	09/11/04	09/11/04	09/11/04		Sep-05			26/02/03	open				
90	Cyflufenamid	Fu	UK				04/09/03			12/05/06							04/07/03	open				
91	Penoxulam	Hb	IT							16/02/05												
92	Topramezone (BAS 670.H)	Hb	FR				09/12/03										02/10/03	open				
93	Acequinocyl	Ac	NL				04/09/03		07/03/05	15/03/05	15/03/05	15/03/05		Nov-05			04/07/03	open				
94	Silver thiosulphate	Pg, Ot	NL				09/12/03		06/07/05	11/07/05	11/07/05	11/07/05					02/10/03	open				
95	FEN 560	Fu	FR				10/02/04		18/02/05	15/03/05	15/03/05	15/03/05		Nov-05			27/11/03	open				
96	Ethaboxam	Fu	UK				30/04/04										30/03/04	withdrawn				
97	Gamma-cyhalothrin	In	UK				12/10/04										29/06/04	open				
98	Proquinazid	Fu	UK				12/10/04			09/06/06							29/06/04	open				
99	Fonicamid	In	FR				12/10/04		26/05/05	03/06/05	03/06/05	03/06/05					29/06/04	open				
100	Pinoxaden	Hb	UK				23/06/05			12/07/06							15/04/05	open				
101	Fluopicolide	Fu	UK				09/11/05			11/01/06							08/10/04	open				
102	Aminopyralid	Hb	UK				09/11/05										08/10/04	open				
103	Potassium iodide	Fu	NL				26/10/05										15/04/05	open				
104	Potassium thiocyanate	Fu	NL				26/10/05										15/04/05	open				
105	Ascorbic acid	Fu	NL				26/10/05										15/04/05	open				
106	Chromafenozide	Pg	HU				31/08/06															
107	Halosulfuron methyl	Hb	IT				31/08/06															
108	Aviglycine HCL	Pg	UK				02/09/06															
109	Metalfumizone	In	UK				25/07/06											open				
110	entry deleted																					
111	Orthosulfamuron	Hb	IT																			
112	Meptyldinocap	Hb	UK				02/09/06															

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

Annex II order	active substance	Function	RMS	Co-RMS	provisional approvals applied	provisional approvals granted	start detailed Examin.	DAR received at COM	DAR received on	DAR to MS	DAR to COM date	DAR to applicant date	Peer review type	WG eval	EFSA conclusion submitted on	SCP target date	SCPH date2 annex1	Annex I inclusion	Decision	No official journal	date official journal	page	
113	Tembotri ne	Hb	AT				31/08/06	01/02/07															
114	Mandipro pamid	Fu	AT				02/09/06																
115	Valiphen a	Fu	HU				31/08/06																
116	Flubendia mide	In	GR																				
117	Amisulbro m	Fu	UK																				
118	Pyroxsula m	Hb	UK		UK																		
119	Pyridalli	In	NL		NL																		
120	Heptamal oxyglucan	EJ	FR																				
121	Spiroetra mate	In	NL																				
122	Emamecti n benzoate	In	NL																				
123	Chlorantr aniliprole	In	IE		IE		06/02/07																

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

Annex II.B.2

Microorganisms

Annex II order	active substance	Function	RMS	Co-RMS	provisional approvals applied	provisional approvals granted	start detailed Examin.	DAR received at COM	DAR received on	DAR to MS	DAR to COM date	DAR to applicant date	Peer review type	WG eval	EFSA conclusion submitted on	SCP target date	SCPH date2 annex1	Annex I inclusion	Decision	No official journal	date official journal	page
10001	Paecilomyces fumosoroseus Apopka strain 97	Fu	BE		DK	BE, SE	05/03/97	09/12/97		25/03/98		25/03/98	June 98	Apr-99		16.12.99	27/04/01	yes	2001/47/E C	L 175	28/06/01	21
10002	Pseudomonas chlororaphis strain MA342	In	SE		IT, DK	SE, FI	15/04/97	07/04/98		15/04/98		23/04/98	June 98	Apr-99, Mar-02, Nov-02, May-03, July 03, Sept-03, Nov-03		16.12.99	30/03/04	yes	2004/71/E C	L 127	29/04/04	104
10003	Ampelomyces quisqualis strain AQ10	Fu	FR		DK	IT	30/08/97	28/10/97		25/03/98		25/03/98	June 98	Apr-99, Jun-02, Mar-03, May-03, Jan-04, Mar-04		16.12.99	08/10/04	yes	2005/2/E C	L 20	22/01/05	15
10004	Spodoptera exigua nuclear polyhedrosis virus		NL		NL		23/12/97	19/11/99	03/01/00	28/01/00		28/01/00	APR	Febr-02, Mar-02, Sep-02, Jan-04, Mar-04			26/02/03	open				
10005	Coniothyrium minitans	Fu	DE		BE, DK, ES, FR	DE	26/11/98	13/03/00		17/04/00		17/04/00	APR	Feb.02, Jun-02, Sep-02, Mar-03			04/07/03	yes	2003/79/E C	L 205	14/08/03	16
10006	Zucchini Yellow Mosaic Virus, mild strain	Ba, Fu	UK		UK													withdrawn				
10007	Gliocladium catenulatum strain J 1446	Fu	FI			FI	15/06/99	15/06/00	27/03/02	28/03/02	28/03/02	28/03/02	APR	Mar-03, May-03, Jan-04, Mar-04			08/10/04	yes	2005/2/E C	L 20	22/01/05	15

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

Annex II order	active substance	Function	RMS	Co-RMS	provisional approvals applied	provisional approvals granted	start detailed Examin.	DAR received at COM	DAR received on	DAR to MS	DAR to COM date	DAR to applicant date	Peer review type	WG eval	EFSA conclusion submitted on	SCP target date	SCPH date2 annex1	Annex I inclusion	Decision	No official journal	date official journal	page
10008	Bacillus subtilis strain QST 713	Ne	DE		DE		05/01/01		01/06/01	23/07/01		23/07/01	APR	Mar-03, May 03			14/07/06	yes	2007/6/EC	L 43	15/02/07	13
10009	Pseudozyma flocculosa	In	NL				20/04/02		12/03/04	16/04/04	16/04/04	15/04/04					26/02/02	open				
10010	Paecilomyces lilacinus	In	BE				06/05/03		08/11/04	09/11/04	09/11/04	09/11/04		Sep-05			26/02/03	open				
10011	Paecilomyces fumosoroseus strain Fe9901	In	BE																			
10012	Adoxophyes orana Granulosis Virus strain BV-0001	In	DE					23/08/05														
10013	Zucchini Yellow Mosaik Virus, weak strain	Fu	UK				31/08/06															
10014	Candida oleophila, strain O	Fu	UK																			
10015	Helicoverpa armigera nucleopolyhedrovirus (HearNPV)	In	EE																			
10016	Spodoptera littoralis nucleopolyhedrovirus	In	EE																			

**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

**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					
44		Imazalil	LU	30.4.96	15.7.96	30.8.96	Sep. - Dec. 96
45		loxynil	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	---	---
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, OJ N° L101, 23.4.03, p. 3
3		Acephate	IT	18.6.02				Withdrawn , 2003/219/EC by OJ N° L82, 29.3.03, p. 40
4		Alachlor	ES	19.12.03	12/01, 02/02, 09/03, 11/03	(03/04) * 28.10.04	4/06	Postponed to 31.12.2002 by 2001/810/EC, OJ N° L305, 22.11.01, p. 32 Withdrawn , 2006/966/EC, OJ N° L 397, 30.12.2006, p. 28
5		Aldicarb	UK	29.3.97	12/97, 4/98, 2,4/01	(8/98)*18.12.98	4/98, 7/98	Withdrawn 2003/199/EC by Council OJ N° L76, 22.3.03, p. 21
6		Amitraz	AT	9.6.00 21.3.03	10/00			Withdrawn , 2004/141/EC, OJ N° L 46, 17.2.2004, p. 35
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			Withdrawn , 2004/248/EC, OJ N° L 78, 16.03.2004, p. 53
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	Authorisations withdrawn 1.1.2007
11		Benalaxyl	PT					Inclusion , 2004/58/EC, OJ N° L309, 6.10.2004, p. 26
12		Benomyl	DE		3/00, 2,4/01	(5/00), * 7.3.01		Withdrawn , 2002/928/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					Inclusion , 2004/58/EC, OJ N° L309, 6.10.2004, p. 26
15		Carbendazim	DE		3/00, 2,4/01	(5/00) *7.3.01	03/06	Postponed to 25.5.03 by 2001/679/EC, OJ N° L239, 7.9.01, p. 39 Inclusion , 2006/135/EC, OJ N° L 349 12.12.2006, p. 37
16		Chlorothalonil	NL					Inclusion , 2005/53/EC, OJ N° L241, 17.09.2005, p. 51
17		Chlorpropham	NL					Inclusion , 2004/20/EC, OJ N° 70, 9.3.2004, p. 32
18		Chlorpyrifos	ES					Inclusion , 2005/72/EC, OJ N° L279, 22.10.2005, p. 63
19		Chlorpyrifos-methyl	ES		10/00			Inclusion , 2005/72/EC, OJ N° L279, 22.10.2005, p. 63
20		Chlortoluron	ES					Inclusion , 2005/53/EC, OJ N° L241, 17.09.2005, p. 51
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					Inclusion , 2005/53/EC, OJ N° L241, 17.09.2005, p. 51
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			Inclusion , 2005/53/EC, OJ N° L241, 17.09.2005, p. 51
27		Deltamethrin	SE		11/00, 2/01			Inclusion , 2003/5/EC by OJ N° L8, 14.1.03, p. 7
28		Desmedipham	FIN					Inclusion , 2004/58/EC, OJ N° L309, 6.10.2004, p. 26
29		Dinocap	AT				03/06	Postponed to 31.12.03 by 2001/810/EC, OJ N° L305, 22.11.01, p. 32 Inclusion , 2006/136/EC, OJ N° L 349, 12.12.2006, p.42
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 , 2001/121/EC, OJ N° L67, 10.3.01, p. 17
32		Endosulfan	ES					Withdrawn , 05/864/EC, OJ N° L317, 03.12.05, p. 25
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, 03/06	Inclusion , 2006/134/EC, OJ N° L 349, 12.12.2006, p. 32
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	Withdrawn , 2004/140/EC, OJ N° L 46, 17.2.2004, p. 32
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		Fluroxyppyr	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

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						
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, 03/06	Inclusion , 2006/133/EC, OJ N° L 349, 12.12.2006, p. 27
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					Inclusion , 2004/58/EC, OJ N° L309, 6.10.2004, p. 26
46		Iprodione	FR		9,11/99, 5/00	(12/00)		Inclusion , 2003/31/EC 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 OJ N° L101, 23.4.03, p. 3
50		MCPA	IT					Inclusion , 2005/57/EC OJ N° L246, 22.09.2005, p. 14
51		MCPB	IT					Inclusion , 2005/57/EC OJ N° L246, 22.09.2005, p. 14
52		Maleic hydrazide	DK		5/00, 4,12/01	(5/01)		Inclusion , 2003/31/EC OJ N° L101, 23.4.03, p. 3
53		Mancozeb	IT					Inclusion , 2005/72/EC, OJ N° L279, 22.10.2005, p. 63
54		Maneb	IT					Inclusion , 2005/72/EC, OJ N° L279, 22.10.2005, p. 63
55		Mecoprop	DK					Inclusion , 2003/70/EC OJ N° L184, 23.7.03, p. 9
56		Mecoprop-P	DK					Inclusion , 2003/70/EC 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 – Decision suspended by European Court of Justice
58		Methamidophos	IT		10/00		03/06	Postponed to 25.5.03 by 2001/810/EC, OJ N° L305, 22.11.01, p. 32 Inclusion , 2006/131/EC, OJ N° L 349, 12.12.2006, p. 17
59		Metiram	IT					Inclusion , 2005/72/EC, OJ N° L279, 22.10.2005, p. 63
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 , 2003/81/EC, OJ N° L224, 6.9.03, p. 29
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)		Inclusion , 2003/112/EC, OJ N° L 321, 6.12.2003, p. 32
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					Inclusion , 2004/58/EC, OJ N° L309, 6.10.2004, p. 26
69		Procymidone	FR				03/2006	Postponed to 25.5.02 by 2001/679/EC, OJ N° L239, 7.9.01, p. 39, Inclusion , 2006/132/EC, OJ N° L 349, 12.12.2006, p. 22
70		Propham	NL					Withdrawn , 96/586/EC, OJ N° L257, 10.10.96, p. 41
71		Propiconazole	FI					Inclusion , 2003/70/EC OJ N° L184, 23.7.03, p. 9
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			Withdrawn , 2004/247/EC, OJ N° L 78, 16.03.2004, p. 50
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		Inclusion , 2005/53/EC, OJ N° L241, 17.09.2005, p. 51
82		Thiram	BE	6/00	10,11/00, 2/01			Inclusion , 2003/81/EC, OJ N° L224, 6.9.03, p. 29
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	Authorisations withdrawn 1.1.2007

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						
85	Warfarin		IR	24.3.97	97, 10/00	10.12.99	4,7,10,12/98, 2,3,5/99	Inclusion , 2005/5/EC, OJ N° L12, 18.01.06, p. 17
86	Zineb		IT					Withdrawn , 2001/245/EC, OJ N° L88, 28.3.01, p. 19
87	Ziram		BE	6/00	10,11/00			Inclusion , 2003/81/EC, OJ N° L224, 6.9.03, p. 29
88	α-Cypermethrin		BE					Inclusion , 2004/58/EC, OJ N° L309, 6.10.2004, p. 26
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

PART A

III.3. Completeness check deadlines and status

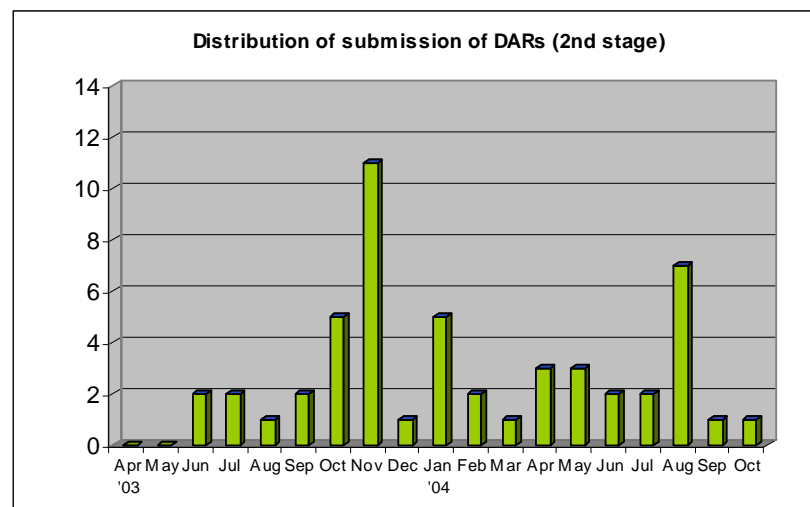
No	Active Substance	RMS/ Co-RMS	Completeness check by RMS		Receipt of DAR by EFSA	Dispatch of DAR to MS	Deadline for submission of comments
	Methidathion	PT	18.10.2002	Incomplete ⇔ decision on non-inclusion	SCFCAH 4 July 2003		--
	Triazamate	UK	25.10.2002	complete	04.11.2003	24.11.2003	27.02.2004
	Naled	FR	20.11.2002	to be completed by 30.04.2003	13.09.2004	21.10.2004	21.12.2004
1	Glufosinate	SE/DE	03.01.2002	complete	03.01.2003	28.04.2003	27.06.2003
2	Tolyfluanid	FI	29.04.2002	complete	13.06.2003	30.07.2003	15.10.2003 (ext. necessary?)
3	Tribenuron	SE/UK	21.06.2002	complete	19.06.2003	26.06.2003	29.08.2003
4	Trifluralin	GR	16.08.2002	complete	11.07.2003	24.07.2003	30.09.2003 31.10.2003
5	Rimsulfuron	DE	31.01.2002	complete	22.07.2003	14.08.2003	17.10.2003 24.10.2003
6	Oxamyl	IRL/UK	11.10.2002	complete	25.08.2003	13.10.2003	05.01.2004
7	Diuron	DK	09.07.2002	complete	19.09.2003	13.10.2003	05.01.2004
8	Dimethenamid	DE	26.08.2002	complete	16.10.2003	31.10.2003	14.01.2004
9	Triticonazole	AT	01.10.2002	complete	29.09.2003	04.12.2003	13.02.2004
10	Tolclofos-methyl	SE	22.10.2002	complete	03.11.2003	24.11.2003	27.02.2004
11	Pirimicarb	UK	25.10.2002	complete	04.11.2003	04.12.2003	27.02.2004
12	Pirimiphos-methyl	UK	25.10.2002	complete	04.11.2003	04.12.2003	27.02.2004
13	Clodinafop	NL/IRL	12.06.2002	complete	07.11.2003	13.02.2004	10.03.2004
14	Triclopyr	IRL	11.10.2002	complete	21.11.2003	14.01.2004	10.03.2004
15	Fenitrothion	UK	25.10.2002	complete	04.11.2003	24.11.2003	19.03.2004
16	Trinexapac	NL	12.06.2002	complete	07.11.2003	28.01.2004	26.03.2004

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

No	Active Substance	RMS/ Co-RMS	Completeness check by RMS		Receipt of DAR by EFSA	Dispatch of DAR to MS	Deadline for submission of comments
17	Clopyralid	FI	28.10.2002	to be completed by 30.04.2003	02.12.2003	28.01.2004	26.03.2004
18	Dichlorprop-P	DK	05.09.2002	to be completed by December 02	05.11.2003	13.02.2004	23.04.2004
19	Thiodicarb	UK	25.10.2002	complete	19.01.2004	13.02.2004	23.04.2004
20	Fenamiphos	NL	11.09.2002	complete	27.11.2003	04.03.2004	30.04.2004
21	Cyprodinil	FR	26.09.2002	complete	16.01.2004	04.03.2004	14.05.2004
22	Haloxyfop-R	DK	19.09.2002	complete	21.11.2003	26.03.2004	21.05.2004
23	Fosetyl	FR	01.08.2002 26.09.2002	complete for Aventis incomplete for Afrasa	20.10.2003	26.03.2004	08.06.2004
24	Metconazole	BE	14.10.2002	complete	27.01.2004	16.04.2004	11.06.2004
25	Malathion	FI	28.10.2002	to be completed by 30.04.2003	02.02.2004	16.04.2004	16.06.2004
26	1,3-Dichloropropene	ES	28.10.2002	complete	16.01.2004	10.05.2004	12.07.2004
27	Pyrimethanil	AT	07.08.2002	to be completed by 30.04.2003	05.04.2004	18.05.2004	16.07.2004
28	Ethoprophos	UK	24.10.2002	complete	19.01.2004	18.05.2004	23.07.2004
29	Captan	IT	31.07.2002	complete	20.10.2003	21.06.2004	18.08.2004
30	Dichlorvos	IT/UK	17.10.2002	complete	20.10.2003	21.06.2004	18.08.2004
31	Ethephon	NL/UK	25.09.2002	complete for Bayer, incomplete for Phytorus	21.04.2004	28.06.2004	25.08.2004
32	Methomyl	UK	25.10.2002	incomplete for Makhteshim- Agan; to be completed for Du Pont by 30.04.2003	03.05.2004	28.06.2004	25.08.2004
33	Folpet	IT	31.07.2002	complete	20.10.2003	06.07.2004	17.09.2004
34	Phosalone	AT	17.10.2002	to be completed by 30.04.2003	07.05.2004	06.07.2004	17.09.2004
35	Fipronil	FR/UK	25.07.2002	complete	10.02.2004	15.07.2004	24.09.2004
36	Methiocarb	UK	25.10.2002	to be completed by 01.04.2003	04.03.2004	15.07.2004	24.09.2004
37	Dimethomorph	DE	31.10.2002	complete	11.06.2004	23.07.2004	01.10.2004
38	Formetanate	IT	07.08.2002	to be completed by 28.02.2003	13.07.2004	23.07.2004	01.10.2004
39	Cadusafos	GR	24.10.2002	to be completed by 30.04.2003	01.06.2004	04.08.2004	08.10.2004

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

No	Active Substance	RMS/ Co-RMS	Completeness check by RMS		Receipt of DAR by EFSA	Dispatch of DAR to MS	Deadline for submission of comments
40	Dimethoate	UK	24.10.2002	to be completed by 30.04.2003	04.08.2004	04.08.2004	08.10.2004
41	Benfuracarb	BE	24.09.2002	to be completed by 30.04.2003	02.08.2004	13.08.2004	15.10.2004
42	Carbaryl	ES/UK	29.10.2002	to be completed by December 2002	29.04.2004	03.09.2004	05.11.2004
43	Phosmet	ES	28.10.2002	to be completed by 15.04.2003	23.08.2004	03.09.2004	05.11.2004
44	Metribuzin	DE	31.10.2002	complete for Bayer and FSC	23.08.2004	03.09.2004	05.11.2003
45	Diazinon	PT	22.10.2002	to be completed by 18.04.2003	08.07.2004	09.09.2004	12.11.2004
46	Trichlorfon	ES	28.10.2002	to be completed by 15.04.2003	23.08.2004	09.09.2004	12.11.2004
47	Carbofuran	BE/UK	22.10.2002	to be completed for FMC and for Dianica by 30.04.2003	03.08.2004	13.08.2004	15.10.2004 17.11.2004
48	Carbosulfan	BE/UK	10.10.2002	to be completed by 30.04.2003	11.08.2004	13.08.2004	15.10.2004 17.11.2004
49	Oxydemeton-methyl	FR	29.07.2002 08.11.2002	Complete for United Phosphorus; incomplete for Margarita	03.05.2004	04.08.2004	08.10.2004 24.11.2004
50	Propamocarb	IE	31.10.2002	complete for Aventis; to be completed for CAG by 01.04.2003	05.10.2004	14.10.2004	15.12.2004



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

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

PART B

III.4. Decision making

No	Active Substance	RMS/ Co-RMS	date of conclusion by EFSA ²	Decision
	Methidathion	PT	-	Withdrawn , Com Dec 2004/129/EC (OJ L N° 37, 10.02.2004, p.27)
	Triazamate	UK	-	Withdrawn , Com. Dec. 2005/487/EC (OJ L N° 174, 7.07.2005, p.72)
	Naled	FR	-	Withdrawn , Com. Dec. -2005/788/EC (OJ L N° 296, 12.11.2005, p. 41)
1	Tribenuron	SE/UK	13.10.2004	Inclusion , Com Dir 2005/54/EC (OJ L N°
2	Oxamyl	IRL/UK	14.01.2005	Inclusion , Com Dir 2006/16/EC (OJ L N°
3	Tolyfluanid	FI	14.03.2005	Inclusion , Com Dir 2006/06/EC (OJ L N°
4	Diuron	DK	14.01.2005	N-Incl (24/11/2006)
5	Glufosinate	SE/DE	14.03.2005	Incl (24/11/2006)
6	Trifluralin	GR	14.03.2005	pending
7	Triticonazole	AT	22.06.2005	Inclusion , Com Dir 2006/39/EC (OJ L N°
8	Tolclofos-methyl	SE	22.06.2005	Inclusion , Com Dir 2006/39/EC (OJ L N°
9	Rimsulfuron	DE	10.08.2005	Incl Dir 06/39/EC
10	Pirimicarb	UK	10.08.2005	Incl Dir 06/39/EC
11	Pirimiphos-methyl	UK	10.08.2005	
12	Clodinafop	NL/IRL	10.08.2005	Incl Dir 06/39/EC
13	Dimethenamid	DE	14.12.2005	N- incl (23/05/06)
14	Triclopyr	IRL	14.12.2005	Incl Dir 06/74/EC
15	Trinexapac	NL	14.12.2005	Incl Dir 06/64/EC
16	Clopyralid	FI	14.12.2005	Incl Dir 06/64/EC
17	Thiodicarb	UK	14.12.2005	N- incl (14/07/2006)
18	Cyprodinil	FR	14.12.2005	Incl Dir 06/64/EC
19	Fosetyl-Al	FR	14.12.2005	Incl Dir 06/64/EC

² Fields in *italic* refer to indicative delivery dates foreseen by EFSA

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

No	Active Substance	RMS/ Co-RMS	date of conclusion by EFSA ²	Decision
20	Dichlorprop-P	DK	13.01.2006	Incl Dir 06/74/EC
21	Fenamiphos	NL	13.01.2006	Incl (14/07/2006)
22	Malathion	FI	13.01.2006	N- incl (29/09/2006)
23	Pyrimethanil	AT	13.01.2006	Incl Dir 06/74/EC
24	Phosalone	AT	13.01.2006	N- incl (14/07/2006)
25	Fenitrothion	UK	13.01.2006	N- incl (14/07/2006)
26	Metconazole	BE	13.01.2006	Inclusion , Com Dir 2006/74/EC (OJ L N°
27	Ethoprophos	UK	21.03.2006	
28	Captan	IT	24.04.2006	Incl (29/09/2006)
29	Folpet	IT	24.04.2006	Incl (29/09/2006)
30	Fipronil	FR/UK	21.03.2006	pending
31	Formetanate	IT	24.04.2006	Incl (29/09/2006)
32	Cadusafos	GR	24.04.2006	N-Incl (24/11/2006)
33	Ethephon	NL/UK	24.04.2006	Incl (14/07/2006)
34	1,3-Dichloropropene	ES	12.05.2006	
35	Dichlorvos	IT/UK	12.05.2006	N- incl (29/09/2006)
36	Methiocarb	UK	12.05.2006	Incl (29/09/2006)
37	Carbaryl	ES/UK	12.05.2006	N- incl (29/09/2006)
38	Phosmet	ES	12.05.2006	Incl (24/11/2006)
39	Trichlorfon	ES	12.05.2006	N- incl (29/09/2006)
40	Propamocarb	IE	12.05.2006	Incl (24/11/2006)
41	Haloxypop-R	DK	28.07.2006	N-Incl (24/11/2006)
42	Methomyl	UK	23.06.2006	
43	Dimethomorph	DE	23.06.2006	Incl (24/11/2006)
44	Dimethoate	UK	23.06.2006	Incl (24/11/2006)
45	Benfuracarb	BE	28.07.2006	pending
46	Carbofuran	BE/UK	28.07.2006	N-Incl (24/11/2006)
47	Carbosulfan	BE/UK	28.07.2006	N-Incl (24/11/2006)
48	Metribuzin	DE	28.07.2006	Incl (24/11/2006)
49	Diazinon	PT	23.06.2006	N- incl (29/09/2006)
50	Oxydemeton-methyl	FR	23.06.2006	N- incl (29/09/2006)

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

Annex VI. LEGISLATION

Annex VI.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.

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

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.
27. Commission Directive 2003/82/EC of 11 September 2003 amending Council Directive 91/414/EEC as regards standard phrases for special risks and safety precautions for plant protection products. OJ N° L228 of 12.9.03, p. 11
28. Commission Directive 2004/129/EC of 30 January 2004 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances OJ L037 of 10.02.04
29. Commission Regulation (EC) N° 771/2004 of 23 April 2004 laying down transitional measures with regard to continued use of plant protection products containing certain active substances following the accession of new Member States to the European Union. OJ L123 of 27.04.04
30. Commission Regulation (EC) N° 835/2004 of 28 April 2004 adapting regulation (EC) N° 2076/2002 and Decisions 2002/928/EC, 2004/129/EC, 2004/247/EC and 2004/248 as regards the continued use of certain active substances not included in Annex I to Directive 91/414/EEC, by reason of the accession of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia. OJ L127 of 29.04.04
31. Commission Directive 2004/63/EC of 26 April 2004 amending Commission Directive 2003/79/EC as regards time limits. OJ L125 of 28.04.04
32. Commission Directive 2004/64/EC of 26 April 2004 amending Commission Directive 2003/84/EC as regards time limits. OJ L125 of 28.04.04
33. Commission Directive 2004/65/EC of 26 April 2004 amending Commission Directive 2003/68/EC as regards time limits. OJ L125 of 28.04.04
34. Commission Directive 2004/97/EC of 27 September 2004 amending Commission Directive 2004/60/EC as regards time limits. OJ L301 of 28.09.04
35. Commission Regulation (EC) N° 1765/2004 of 13 October 2004 amending Regulation (EC) N° 2076/2002 as regards the continued use of substances listed in Annex II. OJ L315 of 14.10.04
36. Commission Regulation (EC) N° 1744/2004 of 7 October 2004 amending Regulation (EC) N° 1490/2002 as regards the replacement of a rapporteur Member State. OJ L311 of 8.10.04
37. Commission Regulation (EC) N° 2229/2004 of 3 December 2004 laying down further detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC. OJ L379 of 24.12.04
- 38.

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

Annex VI.B Measures concerning individual active substances

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

Annex VI.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	SCFA 3/10/03; 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)
	<i>Gliocladium catenulatum</i>	SCFA 3/10/03;
	Iodosulfuron	2003/370/EC (L127 of 21.5.03, p. 58)
	Indoxacarb	SCFA 3/10/03; 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)
	<i>Paecilomyces fumosoroseus</i>	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)
	<i>Pseudomonas chlororaphis</i>	SCFA 3/10/03; 2002/133/EC (L47 of 19.2.02, p. 41), 2000/180/EC (L57 of 2.3.00, p. 34)
	Quinoxifen	SCFA 3/10/03; 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)
	Spinosad	SCFA 3/10/03;
	<i>Spodoptera exigua</i>	SCFA 3/10/03; 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)
	Thiacloprid	SCFA 3/10/03;
	Thiametoxam	SCFA 3/10/03;
	Trifloxystrobin	2002/658/EC (L221 of 17.8.02, p. 37)

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

Annex VII. GUIDANCE DOCUMENTS

Annex VII.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. 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.
21. 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.
22. 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.
23. 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.
24. 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: List of main guidance documents for MS or industry

25. SANCO/1090/2000 rev. 1: Guidance document for the assessment of active substances used on rice. SCFA 3.10.03.
26. SANCO/10393/2004 rev 4: Guidance document on the preparation of dossiers and draft assessment reports for substances covered in the fourth stage of the review programme referred to in Article 8(2) of Council Directive 91/414/EEC)
27. SANCO/10518/2004 rev 5: Guidance document on the Preparation and Presentation of Complete Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2)
28. SANCO/10597/2003 rev 8: Guidance document on the assessment of the equivalence of technical materials of substances regulated under Council Directive 91/414/EEC
29. SANCO/10798/2003 rev 6: Guidance document on the format for registration reports for the assessment of plant protection products following inclusion of an active substance in Annex I to Council Directive 91/414/EEC
30. SANCO/10696/2004 rev 5: Guidance document on preparation of Review report for review stage 2 substances and new active substances considered by EFSA
31. SANCO/10754/2004 rev 3: Guidance document on the taxonomic level of micro-organism to be included in Annex I to Directive 91/414/EEC
32. SANCO/10435/2004 rev 7: Guidance document on preparation of list of studies relied upon with a view to Annex I-inclusion of existing active substances
33. SANCO/10328/2004 rev 5: Guidance document on the evaluation of new Annex II data post Annex I inclusion of an active substances
34. SANCO/10053/2005 rev 2.0: Guidance document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU REgistration

Annex VII.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).
10. SANCO/10189/03 rev 6: Draft Guidance document on isomers.
11. SANCO/10472/2003 rev.5: Draft Guidance document on data requirements for products based on plant extracts (July 2004).
12. SANCO/10473/2003 rev.4: Draft Guidance document on data requirements for products based on certain chemical substances (July 2004).

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

13. SANCO/10796/2003 rev 8: Draft Guidance document on the re-registration of plant protection products following inclusion of an existing active substance in Annex I to Council Directive 91/414/EEC
14. SANCO/10422/2005, version 1.0, May 2005: Landscape and mitigation factors in aquatic ecological risk assessment
15. SANCO/ 7531/2006 rev 10: Draft Guidance document on the setting of Acceptable Operator Exposure Levels (AOELs)