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100 ECCO-Peer Review Meetings
Documentation

ECCO: European Commission Co-ordination for the Evaluation of Active Substances contained in Plant Protection Products under Council Directive 91/414/EEC

Compiled on the occasion of the
100. ECCO-Peer Review Meeting
held at the BBA from 3 to 7 July 2000

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Preface

Since August 1996, the Biologische Bundesanstalt für Land-und Forstwirtschaft (BBA) and the Pesticides Safety Directorate (PSD, York/United Kingdom) have co-ordinated the Peer Review Programme under Council Directive 91/414/EEC on behalf of the European Commission. Both authorities organise European expert group meetings, so-called ECCO - Peer-Review Meetings (ECCO = European Commission Co-ordination). These meetings are part of the evaluation process for active substances contained in plant protection products regarding their possible inclusion in the EU positive list, Annex I of the Directive.

From 3 to 7 July 2000, the 100th ECCO – Peer Review Meeting was held at the BBA, Braunschweig. It concluded the eighth round of meetings, and at the same time was the concluding meeting of the third contract with the European Commission. The meeting was attended by experts from all 15 Member States, chairpersons from Round 8 from both BBA and PSD, and by participants from different Directorate Generals of the European Commission. Opening speeches were held by Professor Klingauf, President of the BBA, Dr. R. Petzold from the Federal Ministry of Food, Agriculture and Forestry, Dr. G. Del Bino, Head of Division, DG SANCO, European Commission, Dr. K. Wilson, Chief Executive of the PSD, Mr. D. Flynn, head of ECCO-Team (PSD) and Dr. B. Julin, European Crop Protection Association (ECPA).

The 100th ECCO-Peer Review Meeting is a suitable occasion to look back on the development and achievements of the ECCO project. The documentation enclosed was prepared especially for this occasion.

The ECCO –Peer Review Meetings have brought together more than 200 experts from all 15 Member States and the European Commission. The experts have achieved more than discussing 93 active substances: simultaneously, they have developed a series of guidance documents together, aimed at the further precision of the evaluation of active substances.

Furthermore, the ECCO-Manual has been developed, containing technical advice on the evaluation procedures, a consolidated list of statements and questions resulting from the meetings and general guidance.

Over the past few years, the ECCO-Team has become a technical interface in the evaluation process, thus relieving the Commission of their workload and allowing them to concentrate on legislative work. It should be emphasised that the spirit of co-operation and friendship between all the experts involved has been both a pre-requisite and a reason for success. The trust and friendship experienced in the meetings is essentially what Europe is all about. We would like to thank everybody for their contributions to our success.

Jörg-Rainer Lundehn
ECCO-Team (BBA)

Darren Flynn
ECCO-Team (PSD)

Acknowledgements

Special thanks go to all those who have been involved in the ECCO project:

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Goffredo Del Bino / Gerald Hudson
Erik Scharpé
Clive Edmunds
Wolf-Martin Maier
Louis Smeets
Michael Walsh

AND, of course, all the experts from the Member States that attended the meetings !

Welcome address

Prof. Dr. F. Klingauf
President of the BBA

When it became apparent that the 100th ECCO-meeting will take place in Braunschweig, the decision was made to celebrate this special occasion appropriately.

I would especially like to extend a warm welcome to Dr Del Bino with his colleagues as representatives of the European Commission.

The successful work of the ECCO-team would not be possible without the smooth co-operation between the staff in York and Braunschweig. I, therefore, would like to welcome the staff members of both institutions here very warmly. Particularly, I would like to address this welcome to the new head of PSD, Dr Kerr Wilson.

Furthermore I like to thank the German Federal Ministry of Food, Agriculture and Forestry for its constant support of the ECCO activities during the last years and I welcome Dr Petzold in this jubilee-meeting. We gratefully acknowledge the financial support of the Federal Ministry of Food, Agriculture and Forestry who contributed to the joint dinner this evening.

As representatives of the European Crop Protection Association I like to welcome cordially Dr Julin and Mr Oosthuizen.

Finally, I extend my warmest welcome greetings to all participants in this 100th-ECCO-meeting taking place on the five coming days in the Federal Biological Research Centre for Agriculture and Forestry - or in short BBA - here in Braunschweig.

In order to introduce you into the meeting place, please, allow me to give you some short information on facts and figures of BBA.

The Federal Biological Research Centre for Agriculture and Forestry was founded in 1898 in Berlin by the initiative of a few very far-sighted members of the German parliament. Yet, at that time agriculture still had a higher rank and a considerable larger number of farmers were among the parliamentarians than there are today.

During the hundred years of existence of our Centre the correct name did change a few times, depending on the political circumstances: Starting as an Imperial Centre it later became a Centre of "The Reich" (Reichsanstalt), followed by a Central Centre and finally (since 1950) we carry the name Federal Centre. Though, three elements of its name - Biological, Agriculture and Forestry - through all times were the same. This, I suppose, is a strong hint to our never changing fields of research.

The idea underlying the institute's foundation at the end of the 19th century is still valid today. It is centred on the utilisation of new scientific findings - in particular biological - for the benefit of agriculture and forestry. In the beginning, like today, the main aim was and is to study the biology of harmful organisms on plants and develop purposeful control methods. The catalogue of tasks established at the time of foundation contains such up-to-date-sounding demands as the study of natural antagonists of pests and pathogens and their exploitation for plant protection purposes.

The Federal Biological Research Centre for Agriculture and Forestry is a superior federal authority in its own right and federal research centre in the jurisdiction of the Federal Ministry of Food, Agriculture and Forestry. Its tasks are mainly defined by the Plant Protection Act. The BBA is in charge of the testing and authorisation of plant protection products in Germany. It is involved in the testing of active substances of plant protection products in the framework of the European Union, it tests plant protection equipment and develops technical standards for it. BBA is also involved in the evaluation of substances under the chemical Act and, more recently in the permissions to release genetically modified organisms. In applied research, however, the biggest involvement is to be seen in developing systems of integrated plant protection.

The BBA has a current staff of 850, consisting of some 650 permanent staff members and 200 guest scientists, students on post-graduate scholarships, PhD candidates, and technical staff funded by special projects. It has institutes at seven locations in Germany to cover geographical differences. Braunschweig is the biggest BBA site, quartering about 50 % of the staff. Besides five institutes - the Institute of Plant Protection in Field Crops, in Horticulture, in Forestry, of Weed Research and of Microbiology, Plant Virology and Biological Safety - Braunschweig also houses the Department for Plant Protection Products and Application Techniques, the Department for National and International Affairs of Plant Health, the central services (library, central EDP group) and the administration. Particular importance is attached to combining research with the tasks of the two departments - registration of plant protection products and of plant health - . Politics and government increasingly require qualified expertise from BBA - which, of course, we are delighted to give - in matters of biology in a more and more technological world. We find that we are only able to cope with our legal tasks if we understand the scientific background. Therefore, I am holding for it, that a very tight connection of research and administration is indispensable in official institutions like ours.

The logogramme of the Federal Biological Research Centre for Agriculture and Forestry is depicting a stalk with spike (most likely of wheat) wound about by a serpent. The serpent very much resembles the well known figure appearing in the sign of medicine. Since 70 years our logo enjoys trade-mark protection. During the last years it has become a sign of phytomedicine and to this end also a symbol for our efforts in safeguarding plant health. We although understand the logo as a commission for securing food and feed supply and, in the same sense, preservation of our natural resources.

The BBA committed itself in the past to the harmonisation of the evaluation procedure for active substances in the EU. In this respect the physical proximity of the ECCO-team and the resulting link to the Commission played quite an important role.

I hope the future will see the continuation of the so far successful work of the ECCO-Teams in York and Braunschweig with regard to a positive development of the EU-evaluation of active substances and active support of the European co-operation.

Welcome by the Ministry

Dr. Ralf Petzold
Federal Ministry of Food, Agriculture and Forestry

Dear Mr. Klingauf, dear Mr. Del Bino, ladies and gentlemen!

It is a great pleasure for me to welcome you here in the rooms of BBA at Braunschweig on behalf of the Federal Ministry of Food, Agriculture and Forestry and to congratulate you on this outstanding event.

The 100th ECCO Peer Review Meeting offers a good opportunity to stop for a while and to look not only back at our successful work in the past, but also ahead into the future.

Almost exactly nine years ago, on 4 July 1991, the Agriculture Council adopted Directive 91/414/EEC with a series of statements made for the Council minutes, including the following statement:

"2. Council and Commission note that the programme mentioned in Article 8 para. 2 encompasses an examination of some 700 active substances. They agree that the schedule for the examination of the requisite data submitted by industry, after an initial period of about two years following the date of notification of this Directive, shall enable the Member States to examine, in principle, 90 active substances annually. Work relating to the examination of the documentation shall be distributed among Member States as follows:

D, F, I, UK:	12
E:	8
B, GR, NL, P:	6
DK, IRL:	4
L:	1

This key, serving as a guidance value, will be fully tailored to the needs of this programme and shall not create a precedent for other measures entailing a distribution of work among Member States.", unquote.

The adoption of this protocol note can also be regarded as the inception of co-operation between the European Commission and the Member States within the framework of ECCO.

To highlight this once again: Originally it was planned to examine about 70 active substances annually, a very ambitious aim from today's point of view. Since then we have gathered a lot of experience and now we know more precisely what it will mean to examine approx. 700 plant protection products containing active substances. However, an assessment of our work should not only include obvious results, like e.g. the legal instruments in force. Indirect results, like the growing together of the competent authorities, constitute a great success, too. It also represents one element of a united Europe put into practice.
So let's just continue on the path we have embarked on? Not exactly, although there has been ever more progress. In my opinion the procedure needs to be further developed as soon as possible. And there are convincing reasons why plant protection products will continue to be

with us in the foreseeable future. It is absolutely necessary to further develop the procedure, otherwise the system might be overburdened and collapse.

How could a future, improved examination and decision-making procedure look like? The procedure followed for new active substances could be used as a yardstick. The three technical levels of

- data generation and presentation,
- evaluation, and
- legislation

will not change. However, all three levels can and should be optimised.

A lot of harmonisation work has been done in the fields of data generation and presentation. Thus, it should be checked how the notifiers could be involved more than in the past.

Evaluation keeps being delayed, as changes concerning intended uses or application rates are being proposed to overcome difficulties. This results in unnecessary repetitions of our work. A substantial reason, however, lies in the fact that Commission and Member States have not published any clear criteria for the inclusion of an active substance in Annex I or its rejection. Notifiers do not know, either, the flexibility of the Review report in case of necessary completions. Therefore, clear rules governing the interpretation of Article V will accelerate the level of evaluation.

It goes without saying that improvements are possible at this level, too. Thus, we should ask ourselves whether evaluation work can be shared more than before without automatically shifting critical points to the next level.

It is absolutely necessary to clarify the third level, i.e. legislation. That is why I welcome the document (736/2000 rev 2) which has been submitted in this context. In my view, however, the structure is not sufficiently clear yet. It should be established as follows:

1. If a plant protection product, for which the requisite documentation for the active substance in accordance with Annex II and the requisite documentation in accordance with Annex III have been provided, is authorised pursuant to Annex VI, proof has been furnished, at least with reference to the situation in this Member State, that there is no obstacle to the active substance's inclusion in Annex I.

2. As authorisation in one Member State does not automatically indicate basic suitability in accordance with Article V, since there are different conditions with regard to agriculture, plant protection and the environment, some basic criteria should be additionally examined at Community level to establish whether an active substance is suitable or not. I am thinking of basic criteria to protect humans, animals and the environment, in particular those criteria which cannot be influenced by risk-reduction measures at the level of the Member States.

In this context, a clear structure

- examination of the basic criteria for the active substance at EU level, no post-evaluation of the proper authorisation granted by Member States and
- acceptance of an authorisation granted in one Member States in accordance with the Community rules as "collection of evidence"

would considerable contribute to simplifying work and thus to accelerating the decision-making process. Moreover, it would rectify the current division of labour, which needs to be corrected with regard to subsidiary aspects.

If this structure of a future examination and decision-making system was accepted, a decision about implementation would have to be taken and changes would have to be made shortly. Furthermore, it is necessary to wind up the programme for old active substances as soon as possible. In the medium term it will not be possible for authorities to keep coping with their current threefold workload, i.e. normal authorisation, programme for old active substances as well as new active substances. However, we should bear one thing in mind: Plant protection products represent a necessary input in agriculture, in horticulture with its many, relatively small cultures as well as in forestry.

They differ from industrial pollution, which is to be reduced as far as possible. Decisions relating to plant protection products must take full account of the protection of plants, food supply and the preservation of the diversity of cultures. In addition, over many years experience has been gathered in the field of old active substances. The determination of the theoretical risk potential should include this experience in order to guarantee a realistic evaluation. This would speed up the necessary decisions and is also acceptable, as every listed active substance will be re-evaluated after 10 years anyway.

Ladies and Gentlemen,

I would now like to conclude my thoughts on an improved examination and decision-making system. I think that the Commission is already working at a reflection, as the report to the European Parliament and the Council is due anyway. Germany takes the view, and some of you know it, that the Commission should organise a workshop before drawing up its report to both sum up experience gained so far and to think about and prepare the measures which are necessary with a view to the future.

You, Ladies and Gentlemen, will be in Brunswick today and in the next few days to hold the 100th ECCO Peer Review Meeting. 17 active substances are on the agenda. This means a lot of work, so I would like to wish you every success.

Thank you for your attention.

Opening address

Dr. G. Del Bino
Head of Division
Directorate General for Health and Consumer Protection (SANCO)
European Commission

We celebrate today an important event : ECCO meeting number 100 !
Looking back Directive 91/414/EEC put in place a very ambitious programme on evaluation and re-evaluation of existing active substances in the European Union. Nobody at the time would probably have imagined the size and importance of the task ahead of them.

Already at the end of 1992, before the Directive entered into force, the first phase of the review programme was launched for 90 important active substances. Although a lot of detailed guidance still had to be developed, nevertheless a pilot project was started on 3 active substances. In 1994, here in the BBA, this project was concluded with a meeting with all Member States. The experience from that meeting was used to develop further the evaluation for both new and existing active substances and the co-ordination of the evaluations carried out by the Rapporteur Member States.

BBA and PSD, together with the Commission, started the first ECCO meetings in 1996. They started with three rounds of peer review per year dealing with 6 to 8 active substances each time.

Now the process has been improved very much. ECCO manages to cover up to 17 active substances in one round of meetings. Also clearer conclusions are resulting from these meetings and more usable recommendations are being proposed to the Commission. However it is clear that follow-up discussions with all Member States in the evaluation group meetings and decision-making by the Standing Committee Plant Health and the Commission has still to be improved. Also here, ECCO has shown to be dynamic and to be able to adapt in a flexible way its functioning which leads to the participation of all Member States in this meeting.

It is clear that ECCO has contributed a lot to the achievements of the current programme. Of the draft assessment reports submitted by Rapporteur Member States, most have been peer-reviewed already. ECCO has also been involved in development of guidance documents and the improvement of procedures.

However, I do not think this is the major merit of the ECCO process. More important in my eyes is the fact that ECCO has brought together, in open discussions and a spirit of collaboration, about 200 experts from all MS. This has led and will continue to lead to an increased harmonisation in assessments performed by individual MS and increased acceptance by the other MS of such assessments.

It is clear that the Community evaluation process is and will continue to be an enormous task which can not be managed without improving procedures and decision making. Therefore the Commission together with the Member States has finalised the second review Regulation. This Regulation will enable us to clarify the task still ahead for the existing active substances. An amendment to the first review Regulation, currently in preparation should speed up decision making on the first 90 active substances under evaluation.

For the new active substances, the Co-Rapporteur system is an additional step to improve co-operation between Member States. The ultimate goal is to achieve real work-sharing whereby one Member State acts as Rapporteur and the other Member States rely on this evaluation. The ultimate goal is to achieve real work-sharing between Member States

BBA is directly involved in the notifications of active substances for the 3rd phase. The list of notifications has already been made available to Member States and industry in early June in the internet.

On behalf of the Commission, I would like to thank BBA and PSD for their involvement in the peer review process. More in particular I would like to express my thanks to M. Lundehn and M. Flynn. Together they have been the real driving forces in the ECCO team.

This ECCO centenary meeting is a real measure of the achievements of the programme. I wish that there will be many more ECCO meetings and one day there will be the meeting ECCO 1000! I like to wish you all a successful meeting and I'm convinced that with the co-operative spirit of all of you it will contribute to a further step forwards in the decision making on active substances.

ECCO Achievements

Dr. K. Wilson and D. Flynn
Pesticides Safety Directorate

♦ Vital statistics

As this is ECCO 100, it will not come as a surprise that we've had 99 meetings before this one!

91 of those meetings were true ECCO peer review meetings, organised in order for specialist experts from different Member States (MS) to consider the monographs prepared under 91/414. These meetings involved 586 separate invitations being sent to 159 different experts from the different MS, and 93 monographs have been peer reviewed.

There have also been 9 meetings arranged specifically to develop guidance documents, and 26 ECCO co-ordination meetings.

♦ Existing active substances

66 monographs for existing active substances have been submitted to the Commission, of which 63 have been peer reviewed. 11 decisions on Annex I inclusion have been taken, with two being included (imazalil and fluroxypyr) and nine not.

♦ Diagram

No. of monographs prepared by the different MSs for the first review list. Figures in brackets are the numbers from each MS that have yet to be peer reviewed – quite a few have still to be submitted to the Commission.

♦ New active substances

75 dossiers have been submitted for Annex I inclusion, have been deemed 'complete' and are, therefore, under evaluation. Eight of these are micro-organisms.
30 monographs have been peer reviewed, and four active substances have been included in Annex I (azoxystrobin, kresoxim-methyl, spiroxamine, azimsulfuron).

♦ Diagram

No. of monographs prepared by the different MSs for new active substances.

Both these sets of figures show that ECCO has performed the function for which it was established, i.e. expert peer review of monographs, dealing with nearly all the monographs that have been available for review. With 93 monographs having been peer reviewed but only 15 decisions having been taken, however, there are obviously problems elsewhere in the system.

- Guidance documents

Some of the ECCO meetings have been arranged specifically to develop guidance documents. These often came about through specific requests from the earlier ECCO meetings, where a problem was identified in a meeting and the report of the meeting recommended that guidance was urgently required.

Guidance relating to setting AOELs, terrestrial and aquatic ecotoxicology, residues and the criteria for Annex I inclusion has been developed in ECCO meetings specifically arranged to prepare such guidance.

ECCO has also co-ordinated the further consideration of documents that were initially prepared by individual authorities, e.g. the persistence document developed by the Netherlands and the dermal absorption document developed by France.

- ECCO manual documents

Another series of document developed during the programme are the so-called ECCO manual documents.

The 'yellow' A series is a collection of useful documents giving general information and booking forms, and also a compendium of all the names and addresses of the experts that have attended the meetings.

The 'blue' B series is a compilation of all the general statements and questions raised in the 99 meetings to date. This provides a very useful document in terms of identifying precedents established in the meetings and identifying outstanding issues yet to be resolved.

The 'green' D series is a series of technical guidance documents primarily explaining various procedures in more detail, e.g.
D1 = procedures relating to evaluation tables
D2 = guidance on what should be included in various data reference lists
D3 = clarification of the 'uses supported by available data' concept
D4 = guidance on the preparation of end-point sheets

Many of these documents are available to MS via CIRCA and others via the BBA website, but the nature of some of the the comments in the B series means that they are only available to MS (via CIRCA)

♦ Co-ordination meetings

Commission, BBA and PSD jointly develop the timetables for the meetings, arrange for the nomination and selection of experts to attend the meetings, and review the documents and procedures involved.
Through these regular meetings, the evaluation process and procedures for Annex I inclusion are continually being developed and improved, in order to improve efficiency and speed up the procedure as much as possible.

♦ Examples of improvements and developments

A couple of examples where we have continually sought to improve procedures and increase the efficiency of the system

Overview meetings – originally, under the first contract, 'Regulatory Decisions' meetings were organised at the each centre and attended by the experts from the MSs and the Commission. Under the next contract, to ensure consistency in decision making, a single 'Overview' meeting was arranged either in York or Braunschweig. It was attended by all the Chairs from the previous ECCO meetings, experts from the RMS and the Commission, and considered all the actives considered in that Round. Under the third contract, similar Overview meetings were arranged, but more time was allowed between the last technical meeting and the overview meeting, to allow as many as the data requirements and open points to be addressed during the peer review, prior to the evaluation progressing to the Working Groups for consideration.

Another area where continual improvements have been sought is in the documentation arising from the meetings. Initially, brief reports were prepared, although these were not standardised and did not always identify the critical end-points. In the second round of meetings the reports were more standardised, and end-points were identified for all sections. For the third and fourth rounds of meetings, fully standardised reports and appendices, including definitive end-point tables and lists of data requirements were produced. Finally, from Round 5 onwards, we have been using the current system of evaluation tables, reporting tables and end-point tables – attempting to make the discussion and decision making processes as transparent as possible.

♦ Conclusions

In conclusion, I believe ECCO is a great success story, doing all that was required of it and more, ensuring that all the monographs that have been available have been peer reviewed to the highest standard and developing guidance to facilitate the harmonisation of risk assessment methods across the MSs. Of course it is always easy with hindsight to see where things could have been improved, but considering where we started from and what has been achieved, the programme has been a great success.

- Acknowledgements

Prof. Klingauf, Mr Bruce / Dr Wilson – for their support and guidance

From the Commission, Mr Hudson and Mr Del Bino, together with Mr Scharpe, Mr Walsh and Mr Smeets in particular
The Chairs for their excellent guidance and co-operation, and all the staff, both past and present that have been involved in the ECCO Teams, organising and servicing the meetings with such efficiency.

Also, last but not least, the experts from all the MSs that have attended the meetings and made them happen.

ACHIEVEMENTS IN 100 ECCO MEETINGS

(OR WHAT HAVE WE BEEN DOING ?)

D J FLYNN
Pesticides Safety Directorate, UK

WHAT HAVE WE BEEN DOING ?

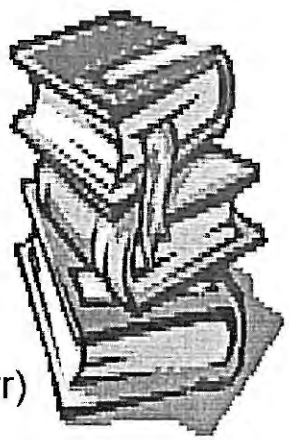
- Boring statistics
- Achievements to date
  - new active substances
  - existing active substances
  - guidance documents
- Initiatives to improve procedures

Vital statistics

- 99 meetings up to now (never!)
- 91 true ECCO peer review meetings
  - 586 invitations to 159 different experts from all Member States
- 9 Guidance document meetings
- 26 ECCO co-ordiantion meetings

Existing active substances

- 66 monographs submitted to Commission
- 63 monographs peer reviewed
- 11 decisions on inclusion taken:
  - 2 included in Annex I (imazalil, fluroxypyr)
  - 9 not included and withdrawn from market



New active substances

- **75 dossiers 'complete' and under evaluation (8 micro-organisms)**
- **30 monographs peer reviewed**
- **4 actives substances included in Annex I azoxystrobin, kresoxim-methyl, spiroxamine, azimsulfuron**

Guidance Documents

- Developed at ECCO meetings:
  AOEL setting
  terrestrial ecotoxicology
  aquatic ecotoxicology
  residues
  criteria for Annex I inclusion -the Lynch study
- Co-ordinated by ECCO Teams:
  persistence - NL
  dermal absorption - FR

ECCO Manual Documents

- Part A 1 - 4 (yellow series)
  - general information, booking forms
  - addresses of experts

- Part B 1 - 7 (blue series)
  - compilation of statements and questions from the meetings

- Part D 1 - 8 (green series)
  - technical guidance documents

Co-ordination meetings

- Commission, BBA and PSD jointly:

  - develop the timetable for the meetings
  - arrange for nomination and selection of experts
  - review documentation and procedures

- continually developing and improving the evaluation processes

Developments and improvements

- Overview meetings

Rounds 1 - 3	- experts from MS and Commission
Rounds 4 - 6	- ECCO Chairpersons, experts from RMS, Commission
Round 7	- As above, more time between last technical meeting and Overview meeting
Round 8	- As above, all MS involved.

Developments and improvements

- Reports of meetings

Round 1	- brief reports, unstandardised, end points for some sections
Round 2	- more standardised, end points identified for all sections
Rounds 3 - 4	- standard reports and appendices (inc. data requiements and end-points)
Round 5 +	- current reporting and evaluation table system

Acknowledgements - past and present

- President of BBA and Chief Executive of PSD
- The European Commission
- All the Chairs of the meetings and the report writers
- All the staff of the ECCO-Teams
- All the Experts from the Member States

ECCO ?

- Extremely Complicated and Convoluted Ordeal
- Exceedingly Considerate and Charming Officials
- European Commission Co-Ordination
- Excellent Co-operation, Communication and Organisation

Statement by ECPA at ECCO 100 Meeting

Dr. Bruce Julin
European Crop Protection Association (ECPA)

On behalf of the European Crop Protection Association, Mr. Oosthuizen and I want to thank the Commission and the organizers of ECCO 100 for inviting us to participate in the "public" part of this meeting. We congratulate the ECCO Secretariats, the ECCO meeting participants, the Commission and the Member States on achieving this significant milestone, not because 100 ECCO meetings have been held, but because of ECCO's valuable role in bringing MS scientific experts together in a Forum to try to solve and build consensus on difficult technical and regulatory issues pertaining to Annex I decisions on PPPs. We believe this goal has been achieved to a significant degree.

ECPA would like to offer the following observations on the ECCO Peer Review process :

While Industry (to-date) has not directly participated in the ECCO meetings per se, we, of course, supply the dossiers of data which together with the RMS draft evaluation reports, form the basis for ECCO discussions on toxicology, residues, E-fate, etc.. by invited experts from five to seven Member States. After the individual topical expert meetings, industry is informed by the RMS about the discussion and about further issues which need to be addressed. On completion of the ECCO round of meetings we receive the full ECCO Report with details about the meetings and issues to be addressed and resolved.

We believe the ECCO process has fulfilled its main objective in building broader consensus by confirming, modifying or expanding the RMS evaluation of the Dossier. This gives industry increased confidence in accepting the need to carry out, additional, often expensive studies.

ECCO has also provided a valuable Forum for MS experts to meet, to share their knowledge and experience, and thus build trust between the Member States.

ECPA has several times proposed that scientific experts from the submitting company in the various disciplines be available during the ECCO meetings in order to answer questions and thereby help to put some issues to rest quickly. While it is widely accepted that industry has the best knowledge and understanding of its substances, this proposal has not been accepted. ECPA understands and accepts the need for ECCO, and indeed for the overall evaluation and decision making process, to be fully independent and transparent. We submit that these critical factors would not be compromised by the possibility for industry to answer questions in special ECCO sessions with clearly defined ground rules. Other parties with pertinent information should also have the same opportunity. The final recommendations would, of course, be decided solely by ECCO.

A couple of additional suggestions for your consideration. We think that two ECCO sessions per year is not sufficient; Three ECCO rounds per year would be better since sometimes a substance has to wait as much as 6-7 months to enter the process. We also believe the ECCO Secretariat should be involved in organizing and running the so-called Evaluation Working Group meetings on behalf of the Commission, thereby speeding up the process and freeing up scarce Commission resources to manage the overall process.

We believe the ECCO Peer Review Process, which after a somewhat hesitant start during its first year, developed quickly, now functions very well and delivers results. We believe that ECCO Peer Reviews should continue to be an integral part of the EU PPP Evaluation Process until an alternative process for achieving consensus has been developed and proven itself.

Another possible future role for ECCO could be that of acting as a consultative body in the early stages of dossier preparation for industry and for the RMS during the evaluation of the dossier. ECCO could also play a constructive role in resolving non-harmonized data requests from MSs.

In closing, ECPA congratulates ECCO-Teams on its achievements and especially wants to thank the ECCO Secretariats, Mr. Flynn, Dr. Lundehn and Mr. Smeets for their excellent work during the past four years.

The Pesticide Registration Process within the European Union, including the Legal Framework and Decision Making Procedures

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Abstract

With the adoption of Council Directive 91/414/EEC of 15 July 1991, a harmonised legal framework was set up for the regulation of plant protection products in the European Community (EC). A central EC decision-making regime for determining the acceptability of active substances contained in plant protection products was established on the basis of harmonised data requirements detailed in Annex II and III of the Directive. Authorisations for plant protection products may be granted at national level provided that the active substance has been included in a 'positive Community list of active substances' (Annex I of the Directive) and that "uniform principles" (as defined in Annex VI of the Directive) are applied in the assessment of the acceptability of the product. Decisions on Annex I inclusion of active substances are taken by the European Commission in collaboration with the Member States on the basis of the conclusions of the so-called ECCO Peer Review meetings in which active substances are discussed scientifically by Member States' experts. Discussions in these meetings are based on draft assessment reports ("monographs") which were prepared by one rapporteur Member State for a single active substance on the basis of the dossier submitted by the producer(s).

To date (1 March 2000), 16 decisions on Annex I inclusion or withdrawals from the market have been taken by the Commission and 6 active substances have been included in Annex I while 76 active substances have passed the ECCO Peer Review process. These numbers indicate that the procedures involved in the regulatory process must still be improved to expedite the inclusion of active substances in Annex I. However, the EC has already contributed significantly to the possibility of world-wide harmonisation of active substance evaluation and the prospect of work-sharing on a global level through the development of guidelines for the preparation of dossiers and monographs as a basis for OECD guidelines, the development of CADDY (Computer Aided Dossier and Data Supply) and the development of the ECCO Peer Review process whereby the evaluation of active substances is already performed successfully through work-sharing between the EC Member States.

Key words: pesticide, plant protection product, active substance, European Union, European Community, Peer Review Programme, ECCO, monograph, dossier, CADDY

Abbreviations:
ACPA: American Crop Protection Association, CADDY: Computer Aided Dossier and Data Supply, EAS: existing active substance, EC: European Community, ECCO: European Commission Co-ordination, ECPA: European Crop Protection Association, EU: European Union, FAO: Food and Agriculture Organisation of the United Nations, FOCUS: Forum for the Co-ordination of Pesticide Fate Models and their Use, NAS: new active substance, NRA Australia: National Registration Authority for Agriculture and Veterinary Chemicals, OECD: Organisation for Economic Co-operation and Development, PMRA: Pest Management Regulatory Agency, SCP: Scientific Committee on Plants, SCPH: Standing Committee on Plant Health, US-EPA: United States Environment Protection Agency.

Introduction

Pesticides are widely used throughout the world to reduce the risk of losses in crop production caused by harmful organisms and weeds. However, their use may pose risks to humans, animals and the environment, especially if used without having been rigorously evaluated for safety and authorised. Within Europe, pesticides are split into biocides and plant protection products. This paper deals with plant protection products only. The placing on the market of biocidal products is regulated by separate Community legislation, i.e. Directive 98/8/EC of the European Parliament and of the Council. In order to control the risks and to facilitate the trade of plant protection products and plant products in the common market, the European Community (EC) has created Community legislation, Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. As a result, the evaluation of the safety of active substances contained in plant protection products are now carried out on the basis of EC-wide harmonised data requirements in accordance with standardised procedures, which are described in detail in this paper.

The aim of this paper is to explain the EC evaluation procedure for active substances, which must at first sight appear particularly complex especially to non-EC countries not directly involved in the process. The system of evaluation is, however, unique in the world. No other large group of countries share the evaluation of such a wide scale of active substances. It should be noted that the procedures relating to evaluation, documentation, consultation and decision-making are still evolving and are the subject of continuous review with regard to their efficiency. In addition to describing the current achievements, this paper also considers the changes that might be made to the EC evaluation regime for active substances contained in plant protection products in the future.

The European Community (EC) and its legislation

Since the foundation of the European Communities was laid in 1952 with the European Coal and Steel Community (ECSC), the importance and impact of the European Communities within its borders and on the global economic system has increased. Starting with 6 European countries in 1952, the EC now comprises 15 Member States, and enlargement negotiations with further 12 applicant countries are in progress. The European Communities have developed further into the European Union (EU), an umbrella for the three extant European Communities ECSC, EURATOM, and European Community (EC, formerly European Economic Community, EEC). The EU is a unique international arrangement with the most

important and powerful institutions being the European Parliament, the Council of the European Union, the European Commission and the Court of Justice.

As the only multinational parliament in the world, the directly-elected European Parliament supervises the executive and has legislative and budgetary powers. The Council of the EU, usually known as the Council of Ministers, sets the EU's political objectives and co-ordinates national policies, deciding some matters by qualified majority voting and others by unanimity. The Court of Justice ensures that the law is observed in all of the activities of the Community, and in the interpretation and implementation of the various treaties in particular. The European Commission, the largest of the Community's institutions, has three distinct functions: it initiates proposals for the legislation, is the guardian of the treaties, and acts as manager and executor of Community policies and of international trade relationships. The Commission currently consists of 24 Directorates General (DGs). Each DG is headed by a Director General, reporting to a Commissioner who has the political and operational responsibility for the work of the DG.

Community law may take the following forms: Regulations are directly applied without the need for national measures to implement them. Directives bind Member States as to the objectives to be achieved while leaving the national authorities the power to choose the form and the means to be used. Decisions are binding in all their aspects upon those to whom they are addressed. A decision may be addressed to any or all Member States, to undertakings or to individuals. Recommendations and opinions are not binding. Community legislation is published in the Official Journal of the European Communities in all official languages of the EC.

Until mid 1999, DG Agriculture has been responsible for legislation in the field of agriculture. These responsibilities have now been transferred to DG Health and Consumer Protection. Unit E.1, dealing with legislation related to crop products and animal nutrition, is responsible for the legislation related to regulation of pesticides in the EC and the placing of plant protection products on the market.

EC legislation related to the placing of plant protection products on the market

Historical background. Until 1991, all Member States of the European Community applied their own registration regime for plant protection products and operated independently with little collaboration between the countries in most cases. Due to the political sensitivity attached to pesticides in general, and concerns relating to the standard of evaluations within a harmonised system, only limited co-operation occurred in certain, specific international fora. The situation was considered to constitute a barrier to trade in plant protection products within the internal market of the EC.

Council Directive 91/414/EEC. In order to set up a harmonised framework for the regulation of plant protection products in the European Community, Council Directive 91/414/EEC of 15 July 1991 (EUROPEAN COMMISSION, 1991) concerning the placing of plant protection products on the market was adopted and implemented in all Member States. Six Annexes established within this Directive provide the basis for the harmonisation of registration procedures and regulatory decisions (see table 1).

Annex I listing of active substances. Through the adoption of Directive 91/414/EEC, a central decision making regime for determining the acceptability of active substances was

established, whereas the authorisation of plant protection products would still be undertaken at a national level by the individual Member States. A national authorisation may be granted provided that the active substance has been included in the 'positive Community list of active substances' (Annex I of the Directive) and that "uniform principles" are applied, as defined in Annex VI of Directive 91/414/EEC. Annex I inclusion of an active substance is the result of a harmonised evaluation and decision making procedure, performed on the basis of harmonised data requirements, as detailed in Annex II and III of the Directive. Active substances are listed in Annex I, if the conditions of Article 5 of the Directive are satisfied, that is, that their use and their residues, consequent on application consistent with good plant protection practice, do not have any harmful effects on human and animal health or on ground water or any unacceptable influence on the environment. In order to take account of developments in science and technology, the inclusion of an active substance in Annex I is limited to a period not exceeding 10 years to ensure that the inclusion is regularly reviewed to modern standards in the interest of safety. Furthermore, Annex I listing is prerequisite for the mutual recognition of authorisations between Member States as provided for in Article 10 of the Directive, whereby one Member State is obliged to accept the evaluation and authorisation prepared by another Member State in situations where the agricultural, plant health and environmental (including climatic) conditions relevant to the use of the plant protection product are comparable in the regions concerned.

Transitional measures for "new" and "existing" active substances. According to Directive 91/414/EEC, Member States shall ensure that a plant protection product is not authorised unless the active substance it contains is included in Annex I. However, Article 8 of the Directive applies derogations for the authorisation of both new and existing active substances in advance of their inclusion in Annex I.

For existing active substances (EAS), which are those that were on the market on or before 25 July 1993, Member States may continue to authorise plant protection products, under their national rules, for a period of 12 years. During this period, the Commission undertook to review all of these substances, with decisions being taken on inclusion in Annex I or withdrawal from the market where the conditions in Article 5 are not satisfied. For "new active substances" (NAS), for which applications for their first inclusion in Annex I were made after 25 July 1993, Member States may grant provisional authorisations in principle not exceeding three years. During this time a full evaluation of the dossier has to be made and a decision taken with regard to Annex I inclusion.

Technical harmonisation. Since the adoption of Directive 91/414/EEC, guidance documents have been developed with the support of all Member States or by specific expert working groups (e.g. FOCUS), in order to further facilitate the harmonisation of evaluation procedures and decision making criteria, and to give guidance to industry on how to prepare "dossiers" (see point 3) and Member States on how to prepare draft assessment reports ("monographs") (see point 5). Examples of these guidelines are:

- guidelines for the preparation and presentation of complete and summary dossiers for inclusion of active substances in Annex I
- guidelines for the preparation of monographs by the rapporteur Member States
- guidance documents for carrying out residue trials
- guidelines on applicability of Good Laboratory Practice

- guidelines for preparation and presentation of data concerning efficacy as provided in Annex III of Directive 91/414/EEC
- guidance document with regard to modelling of fate and behaviour of plant protection products in the environment (groundwater, surface water, soil)

In addition, guidance documents are currently being developed on mutual recognition, criteria for Annex I listing, data protection, establishment of AOELs, setting of an acute reference dose (ARfD), dermal absorption, relevant metabolites, persistence in soil, aquatic and terrestrial ecotoxicology.

The evaluation and decision-making procedure for active substances contained in plant protection products

In principle, the evaluation of active substances is shared between the competent authorities of the Member States and Commission, in order to avoid duplication of work and to save time and staff resources. For each active substance, a designated "rapporteur" Member State performs the evaluation on behalf of the European Commission, in close collaboration with experts from other Member States.

Figure 1 illustrates the EC evaluation procedure for new (NAS) and existing (EAS) active substances, detailing the parties involved and their different functions and the key documents developed. The process begins when an applicant prepares a dossier for submission to the rapporteur Member State. In the dossier, all relevant data requirements of the Annexes II and III of the Directive must be addressed, either by data or justifications for the non-submission of information. In the case of a NAS, the completeness of the dossier has to be determined by the Standing Committee on Plant Health (SCPH) of the European Commission, in which all 15 EU Member States are represented. Only when the dossier is considered complete, the detailed evaluation can be started by the rapporteur Member State. In the case of EAS, the detailed evaluation starts when the dossier is considered sufficiently complete by the rapporteur Member State. The subsequent steps are similar for new and existing active substances. The rapporteur performs an assessment of the data submitted and prepares a draft assessment report also containing a recommendation concerning Annex 1 inclusion. This draft assessment report, generally referred to as monograph, is then submitted to the European Commission and distributed to the main data submitter(s)/applicant and the Member States for comments. Any comments are taken into account during the discussion of the monograph in so-called ECCO Peer Review meetings which are organised by the ECCO-Team on behalf of the European Commission. The ECCO-Team and the ECCO Peer Review Programme was founded by the European Commission on 1 August 1996 as part of the joint evaluation process for new and existing active substances of plant protection products in accordance with the requirements of Directive 91/414/EEC and Regulation (EEC) No 3600/92. The principle aim of the programme is to facilitate the decision making process within the framework of the SCPH. For each active substance discussed in these expert group meetings, a "full report" is prepared by the ECCO-Team which is then considered by all 15 Member States in the two European Commission Working Groups 'evaluation' and 'legislation'. Specific scientific issues relating to Annex I inclusion may be referred to the Scientific Committee on Plants (SCP). As a conclusion of the evaluation of an active substance, a "Review Report" is prepared by the Commission. Based on this report, the

Commission drafts a decision on Annex I inclusion for consideration by the SCPH. In the case of a favourable, a final decision on Annex I inclusion is taken by the Commission and a Directive is published in the "Official Journal of the European Communities" stating that the active substance has been listed in Annex I in conjunction with certain conditions and/or restrictions. Consequently, authorisations for plant protection products containing the active substance can be granted (NAS) or must be reviewed (EAS) by the national authorities of the Member States taking into account any conditions or restrictions associated with the inclusion and the "uniform principles" of Annex VI.

The central documents prepared during the evaluation procedure are, in chronological order, the dossier (by applicant/data submitter), the draft assessment report (referred to as monograph, by rapporteur Member State), the full report (by ECCO-Team) and the Review Report (by European Commission). At each stage of the evaluation, the reports become shorter as the discussions concentrate more and more on the key issues which are critical for decision on Annex I inclusion.

After this general overview a more detailed description of the EC evaluation process is given below. For this purpose, the description of evaluation procedures was divided in 8 steps (see tab. 2) which are explained separately in chronological order.

1 Publication of existing active substances to be reviewed

One key objective of Directive 91/414/EEC (laid down in Article 8 (2)) is to review all the existing active substances (i.e. more than 800) with regard to their acceptability for inclusion in Annex I. On 11 December 1992, the Commission adopted Regulation (EEC) No 3600/92 (EUROPEAN COMMISSION, 1992), covering the re-evaluation of a first list of 90 active substances. The selection took into account aspects such as health and/or environmental concern, the possibility of residues in treated products and the importance of the active substances in agriculture, horticulture, etc. In order to implement this regulation, further Commission regulations have been adopted, designating the rapporteur Member States and identifying the notifying producers (see point 2). On 28 February 2000, the Commission adopted a further Regulation, (EC) No. 451/2000 (EUROPEAN COMMISSION, 2000a) 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. Details of this regulation are not described in this publication.

2 Notification of interest to support Annex I inclusion

Existing active substances. Within 6 months of the date of entry into force of Regulation (EEC) No 3600/92, producers were requested to notify to the European Commission of their intention to support one or more of the 90 existing active substances with regard to their inclusion in Annex I (EUROPEAN COMMISSION, 1998a). On the basis of these notifications, the Commission, in collaboration with the Member States, nominated "rapporteur Member States" to carry out the detailed evaluation of the dossiers submitted by the notifiers. The specific deadline for the submission of dossiers, the notifiers' names and the respective rapporteur Member State for the active substances to be reviewed were laid down in Commission Regulation (EC) No. 933/94 of 27 April 1994 (EUROPEAN COMMISSION, 1994d). Both Regulations have been amended by Commission Regulation (EC) No. 491/95 of 3

March 1995 (EUROPEAN COMMISSION, 1995d), in order to take into account the accession of Austria, Finland and Sweden to the European Community on 1 January 1995.

For cyhalothrin, no producer or Member State notified an interest in pursuing inclusion of the active substance in Annex I of Directive 91/414/EEC, with the consequence that authorisations for plant protection products containing this active substance were withdrawn.

New active substances. In the case of new active substances, the applicant is free to choose to which Member States applications for Annex I inclusion should be made (EUROPEAN COMMISSION, 1998b). The Member State receiving the application will, in principle, act as rapporteur Member State, being responsible for the completeness check and detailed evaluation of the dossier submitted by the applicant.

3 Compilation of dossier

In order to support Annex I inclusion of an active substance, the dossier must include a complete Annex II data package, as well as complete Annex III data on at least one representative preparation containing the active substance. The dossiers are prepared to a standard format as detailed in the EC-Dossier Guideline (EUROPEAN COMMISSION, 1998h), which was subsequently adapted for use by the OECD (OECD, 1998a). The guidelines provide detailed guidance on the structure of the dossier and the presentation and assessment of data, thus representing an important step towards OECD-wide harmonisation of data presentation by industry.

For existing active substances covered by Regulation (EEC) No. 3600/92, the deadline for the submission of dossiers to the rapporteur Member State was 30 April 1995. By Commission Regulation (EC) No. 2230/95 (EUROPEAN COMMISSION, 1995c), this deadline was extended to 31 October 1995 for 39 of the 90 active substances.

4 Completeness check (for new active substances only)

On receipt of the dossier, the rapporteur Member State must determine whether the dossier satisfies the requirements of Annex II and complies with Annex III for at least one preparation. When the rapporteur Member State confirms that the dossier submitted is complete or with no substantial data gaps, the applicant forwards the full dossier (preferably in the CADDY format, see below: achievements of the EU evaluation process and prospects, point 2) to all Member States and the European Commission, which then refers the dossier to the Standing Committee on Plant Health (SCPH). Following a favourable vote on the completeness of the dossier by the SCPH, a Commission decision is published requesting the rapporteur Member State to start the detailed evaluation of the dossier. The publication of the decision on the completeness of the dossier is prerequisite for the granting of any provisional authorisations for plant protection products containing the active substance in advance of Annex I inclusion.

5 Evaluation and assessment of an active substance – preparation of a draft assessment report (monograph)

On the basis of the dossier(s) submitted, the rapporteur Member State prepares a monograph in accordance with the guideline for the preparation of monographs (EUROPEAN COMMISSION, 1998g). This guideline was developed by the EC Member States, subsequently adapted and

adopted by OECD (OECD, 1998b). The aim of the guideline is to ensure a consistently high standard in the documentation prepared. The monograph consists of four volumes with a number of sections and levels reflecting the different sections and tiers of the dossier dealing with particular areas of evaluation and assessment such as identity, physico-chemical properties, details of uses and further information, methods of analysis, fate and behaviour in the environment, effects on non-target species (ecotoxicology), impact on human and animal health (mammalian toxicology) and residues. It also contains a list of studies relied upon in the evaluation and a proposal from the rapporteur Member State regarding inclusion in Annex I. Relevant information and data submitted by third parties are also taken into consideration. Special attention is paid to confidential business information such as data on identity, which are presented in a separate volume.
When completed, the ECCO-Team (see point 6), on behalf of the Commission, arranges for the distribution of the monograph to all Member States, the relevant Commission services as well as to the applicant or the main data submitter(s) (VON KIETZELL et al., 1998a).

6 Technical discussion of the monograph in ECCO Peer Review Programme

The monographs prepared by rapporteur Member States for individual active substances are the basis for the discussion in ECCO Peer Review meetings organised by the ECCO-Team on behalf of the European Commission (LANDSMANN et al., 1998, VON KIETZELL et al., 1998a). They are scheduled for discussion in these meetings as soon as they have been received in the Commission, with priority being given to new active substances. The ECCO-Team consists of two groups situated at the Biologische Bundesanstalt für Land- und Forstwirtschaft (BBA) in Braunschweig/Germany and the Pesticides Safety Directorate (PSD) in York/United Kingdom. At an ECCO Peer Review meeting experts from different Member States and representatives from the European Commission discuss specific parts of the monographs for several active substances. The experts that attend the meetings are selected by the European Commission on the basis of the nominations received by the Member States. The meetings are chaired by senior experts of BBA and PSD. To ensure that all views are taken into account, all Member States and data submitters are invited to submit written comments on the monographs which will be considered during the meetings. Separate meetings each lasting up to 5 days are held on the following sections:

- identity, physico-chemical properties; details of uses and further information; methods of analysis
- impact on human and animal health
- fate and behaviour in the environment
- ecotoxicology
- residues.

The task of each ECCO meeting is to identify the main areas of concern, to agree on a list of end points relevant to the risk assessment and to confirm any data requirements to be addressed by the applicant/data submitters. A standardised pro-forma for the lists of end points which are evaluated by rapporteur Member States and reviewed in the ECCO meetings has been specified in both dossier and monograph guideline. The series of five ECCO Peer Review meetings, followed by an "Overview Meeting", is called an "ECCO round". To date, seven ECCO rounds have been organised by the ECCO-Team, in which 76 monographs (24

for new and 52 for existing active substances) have been discussed (VON KIETZELL, 1998a and 1998b). Table 3a lists the 76 active substances which have been considered so far. Round 8 is ongoing covering additional 17 active substances (tab. 3b).

Further to organising and servicing the meetings, the ECCO-Team is responsible for producing a report ("concise outline report") of each ECCO meeting, which reflects the discussion and conclusions of the meeting. At the end of each ECCO round, the ECCO-Team prepares a "full report" for each active substance considered at the meetings. This report also includes an "evaluation table" which lists the data requirements to be addressed by the data submitters. The full report is forwarded to all Member States, the European Commission and the applicant/main data submitter. As a supplement to the monograph, it serves as the basis for further discussions with all Member States at EC level (see point 7). Furthermore, the ECCO-Team prepares the initial draft of the Review Report, which is developed further by the Commission in the evaluation process. The Review Report summarises the key issues that are critical to the decision on Annex I inclusion (see also 7).

In addition to the organisation of ECCO Peer Review meetings, the ECCO-Team supports the European Commission in the development of standardised evaluation and assessment criteria. In this context, separate expert meetings to discuss specific guidance documents (e.g. on AOEL, aquatic toxicity, residues) are organised by the ECCO-Team, which is also co-ordinating the revision of guidance documents. On 28 February 2000 a study report prepared by Mark Lynch (Ireland) for the ECCO-Team on criteria and procedures for inclusion of active substances in Annex I of Council Directive 91/414/EEC has been submitted and will be further discussed.

7 Negotiation on EC level with regard to Annex I inclusion

Following the ECCO Peer Review meetings, the monograph and the full report are considered by two successive European Commission Working Groups which are composed of representatives of all Member States and chaired by the European Commission. In the Working Group 'Plant Protection Products' (evaluation) outstanding issues and data requirements are considered with the discussion concentrating on the evaluation table initially prepared by the ECCO-Team (see point 6). The Working Group 'Plant Protection Products' (evaluation) decides whether the data requirements identified by the ECCO meetings have been adequately addressed. If necessary, further data and new studies can be requested. After the evaluation of an active substance has been finalised in the Working Group 'Plant Protection Products' (evaluation), the Scientific Committee on Plants (SCP) is usually consulted on the draft decision relating to Annex I inclusion prepared by the European Commission. The SCP is one of the eight Scientific Committees (WALSH, 1998) which were created by Commission Directive 97/579/EC of 23. 07. 1997 (EUROPEAN COMMISSION, 1997c) to provide independent scientific advice to the services responsible for the corresponding policy and legislation. The SCP, composed of 19 selected experts deals with, *inter alia,* active substances contained in plant protection products and the risk assessment for pesticide residues in food.

After the SCP has expressed its opinion, the draft decision is discussed in the Working Group 'Plant Protection Products' (legislation). The Working Group considers the evaluation and, in addition to this, the wider implications of the recommendations arising from the

evaluation. Discussions also take place on the draft Review Report prepared by the European Commission and its appendices which contain an up-dated list of end points characterising the active substance in question and, for existing active substances, a list of studies for which data protection is claimed.

8 Decision on inclusion in Annex I of Council Directive 91/414/EEC

Following the discussions in the Working Groups 'Plant Protection Products', the European Commission submits final versions of the draft decision and the Review Report to the Standing Committee on Plant Health (SCPH), in which all Member States and Commission are represented. The Review Report contains three background documents:

A: the monograph of the rapporteur Member State

B: the full report, including the final evaluation table, and the detailed evaluation of the rapporteur Member State of new data made available after the submission of the monograph to the European Commission and which are considered critical for the decision making.

C: all comments submitted after the Peer Review.

The SCPH considers the Review Report and gives a formal opinion on the draft decision. The decision may be:

- inclusion of an active substance in Annex I (with, where necessary, any associated restrictions or conditions), where sufficient data have been presented and the conditions of Article 5 are satisfied at least for certain representative conditions of use.
- non-inclusion of an active substance in Annex I or withdrawal from the market, where the applicant/main data submitter is not willing to generate the data required for Annex I inclusion, or where harmful effects on human and animal health or unacceptable effects on the environment may be expected from the use of the plant protection products containing the active substance.

The SCPH is requested to express its opinion on draft proposals by qualified majority voting, with Member States carrying weightings as specified in table 4. The Commission adopts the proposal if at least 62 votes are in favour. If the SCPH delivers an unfavourable opinion on the proposal (votes against > 25), or if no opinion is expressed, then the Commission may refer the proposal to the Council of the EU. If the Council does not act within 3 months, then the Commission adopts the proposal .

In practice, the Commission tries to reach the widest possible consensus between the Member States before a final decision on Annex I inclusion is taken. Under the previous arrangements, DG Agriculture could only submit a proposal to the Commission for adoption after agreement of all consulted Commission services including DG Environment, Nuclear Safety and Civil Protection, DG Employment, Industrial Relations and Social Affairs, DG Consumer Policy and Consumer Health Protection, the Secretariat General as well as the Legal Service. Finally, for each active substance to be included in Annex I, a Directive is published by the Commission. The Directive has to be implemented by the Member States within a certain time frame (EUROPEAN COMMISSION, 1996e). Following the decision of the Commission the Review Report will be made available on request.

Authorisations for plant protection products containing an active substance included in Annex I are granted by the Member States for a period of up to 10 years on the basis of the

uniform principles. They may be renewed after verification that the conditions for inclusion in Annex I are still satisfied.

Achievements of the EC evaluation process and prospects

In this paper, the current EC evaluation process of active substances contained in plant protection products has been described in detail. However, with the continuously increasing amount of data/information generated for active substances, it is clear that possibilities relating to world-wide harmonisation of active substance evaluation should be considered as a matter of urgency. In addition to this, the envisaged world-wide work-sharing in the field of active substance evaluation based on harmonised principles will facilitate and accelerate the authorisation of plant protection products, reduce costs and ensure a higher degree of safety for the environment and consumers.

The EC has already contributed significantly to this ambitious task in a number of ways:

- by the development of guidelines for the preparation of dossiers and monographs as a basis for the respective OECD guidelines
- by the development of CADDY (Computer Aided Dossier and Data Supply) (WENZELBURGER, 1998).
- by the ECCO process in which the evaluation of active substances has been enhanced through the collaboration of experts between the EC Member States.

The achievements of the EC evaluation process, as detailed below, are a useful basis for the further development of a world-wide harmonised approach of active substance evaluation.

1 Technical harmonisation with regard to dossier and monograph preparation

A high degree of technical harmonisation has been achieved within the EC through the development of detailed data requirements for active substances and plant protection products, the detailed evaluation and decision-making principles for plant protection products (uniform principles) and the guidelines concerning the presentation of dossiers and monographs. The EC guidelines on the preparation of dossiers and monographs for individual active substances have formed the basis for the respective guidelines which were agreed at OECD level. This is seen as an important step towards harmonisation and work-sharing at on a wider, international level, since industry has a standard format for the preparation of a dossier for submission in all OECD countries.

As a result, the quality of dossiers will probably be improved in future, with the effect that less time is needed for the evaluation of active substances, the preparation of monographs and the scientific discussion between all OECD countries. The monograph guideline developed at EC level will improve the preparation of monographs, by ensuring a high standard of comparable active substance evaluations by the individual countries.

2 CADDY (Computer Aided Dossier and Data Supply).

The aim of the CADDY project is to facilitate the provision of dossiers for active substances to regulatory authorities through the development of a suitable electronic format for the compilation and submission of dossiers in an efficient and economic manner. As a result, the long-term archiving of dossiers and the increased accessibility of information contained therein will be facilitated.

The development of the CADDY retrieval software was started in 1995 at European level by the joint EC Member States/ECPA Data Transfer Steering Group and quickly advanced to become an international project through the participation of US-EPA, PMRA Canada, ACPA and Canadian Industry in 1996. This Joint Data Steering Group, renamed in CADDY Steering Group in 1997, supervised the development of the CADDY software, monitored the test phase and is currently promoting its implementation. This process was also augmented by the establishment of the GRIT (Global Regulatory Information Technology) Group, formed to monitor developments and to develop strategies for electronic data submissions, maintaining at the same time the high level of co-operation already established at international level. Members of the GRIT Group are US-EPA, PMRA Canada, European Commission, ACPA, ECPA, Canadian Industry, OECD, BBA, PSD and NRA Australia.

Industry has already started to compile dossiers by using the CADDY software (11 dossiers have already been submitted on CD-ROM using CADDY format, date: August 1999) and several countries have already gained experience using the retrieval software.

3 The ECCO Peer Review as a basis for Commission decisions on Annex I inclusion of active substances

By bringing together experts from all EC Member States, the ECCO Peer Review of active substances has encouraged co-operation between the EC Member States leading to increased confidence in the evaluations of other Member States. As the link between Member States' experts and the European Commission, the ECCO Peer Review process can be considered as an important influence in the development of European co-operation. Consequently, the ECCO Peer Review may serve as a good example for the envisaged wider international co-operation in the field of active substance evaluation.

For new active substances, as of 1 February 2000, dossiers for 56 active substances have been agreed as complete, of which 24 have been peer reviewed. Four, azimsulfuron, azoxystrobin, kresoxim-methyl and spiroxamine, have been included in Annex I (see tab. 1 for reference).

Within the framework of Regulation (EEC) No 3600/92, 52 monographs on existing active substances have been received from rapporteur Member States and been peer reviewed. As a result, two existing active substance, imazalil and fluroxypyr, have been included in Annex I. Ten existing active substances (cyhalothrin, ferbam, azinphos-ethyl, propham, dinoterb, fenvalerate, DNOC, pyrazophos, monolinuron and chlozolinate) have not been included in Annex I and been/are being withdrawn from the market (see tab. 1 for reference).

The experience with the EC registration process for active substances clearly shows that technical harmonisation is well advanced, whereas the legislation and the procedures for decision-making need to be improved to expedite the inclusion of active substances in Annex I and to achieve the ambitious aims set out in Directive 91/414/EEC. As a prerequisite, the Community legislation has to be amended to provide an adequate legal framework for the envisaged improvements. The Commission has already started collecting proposals for amendments to Directive 91/414/EEC. In addition to this, further legislation is under development, e.g. for active substances consisting of micro-organisms, where the data requirements related to Annex I inclusion (Annex II B and III B of Directive 91/414/EEC) are to be agreed at both EC and OECD level (SMEETS, 1997). In order to cope with the re-

evaluation of the remaining ~ 720 existing active substances (90 EAS are already covered by Regulation (EEC) No 3600/92), the Commission has recently adopted a further Regulation listing active substances to be called up for re-evaluation. A second list of around 150 active substances and a work programme for the remaining active substances have been specified has been published (EUROPEAN COMMISSION, 2000a). Assuming 3 years for the notification, check for completeness and compilation of the dossier and 1 year for the preparation of the monograph, further negotiations at EC level with regard to Annex I inclusion could only start, at the earliest, in 2004 for these active substances.

In order to speed up the inclusion of active substances in Annex I, each individual step of the evaluation and decision-making process must be analysed with regard to its efficiency and revised if necessary (SCHARPÉ, 1998, Julin, 1998). While the ECCO Peer Review has been finalised for 76 active substances, only 16 decisions on the inclusion of active substances in Annex I or withdrawal from the market have been taken, indicating that the process of decision-making at the European Commission level needs to be accelerated. This bottleneck has, however, been recognised and with the preparation of guidelines on the criteria for Annex I inclusion efforts are being focussed on facilitating decision-making between the EC Member States.

With regard to the actual evaluation of active substances, the Commission intends to improve co-operation between Member States by developing a so-called "co-rapporteur"-system (EUROPEAN COMMISSION, 1998f). In this system, initially intended to be applied for new active substances only, one or two co-rapporteurs shall assist the rapporteur Member State in the preparation of the monograph. Ideally this system would be further developed into a system whereby a single rapporteur Member State submits the monograph directly to the Working Group 'Plant Protection Products' (evaluation). In this case only certain critical points may need to be discussed in the ECCO Peer Review Programme.

Although the procedures for taking decisions appear very complex and lengthy in the EC, the highly developed collaboration between the 15 EC Member States is impressive and unique in the world. As with any new programme of this complexity, the first examples through the system will always take longer to process while the system is established and the problems resolved. The high degree of technical harmonisation which has now been established within the EC can be used to facilitate the development of world-wide harmonised guidelines, ensuring cost-effectiveness and transparency in the evaluation of active substances and the authorisation of plant protection products.

Acknowledgements

Special thanks are due to the services of the European Commission, DG Health and Consumer Protection, in particular, L. SMEETS, C. EDMUNDS, W. MAIER and M. WALSH , and to A. SCHARPÉ, DG Agriculture.

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Tab. 1: Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market and its implementing Directives and Decisions.

Directive 91/414/EEC including		**Implementation Directives and Decisions**
Annex I:	Active substances (a.s.), inclusion in Annex I	**Directives** Imazalil 97/73/EC (EUROPEAN COMMISSION, 1997) Azoxystrobin 98/47/EC (EUROPEAN COMMISSION, 1998e) Kresoxim-methyl 99/1/EC (EUROPEAN COMMISSION, 1999a) Spiroxamine 99/73/EC (EUROPEAN COMMISSION, 1999b) Azimsulfuron 99/80/EC (EUROPEAN COMMISSION, 1999e) Fluroxypyr (EUROPEAN COMMISSION, 2000e)
	Active substances, non-inclusion in Annex I and withdrawal from the market	**Decisions** Cyhalothrin 94/643/EC (EUROPEAN COMMISSION, 1994) Ferbam 95/276/EC (EUROPEAN COMMISSION, 1995a) Azinphos-ethyl 95/276/EC (EUROPEAN COMMISSION, 1995a) Propham 96/586/EC (EUROPEAN COMMISSION, 1996a) Dinoterb 98/269/EC (EUROPEAN COMMISSION, 1998c) Fenvalerate 98/270/EC (EUROPEAN COMMISSION, 1998d) DNOC 99/164/EC (EUROPEAN COMMISSION, 1999f) Pyrazophos in press (EUROPEAN COMMISSION, 2000c) Monolinuron in press (EUROPEAN COMMISSION, 2000b) Chlozolinate in press (EUROPEAN COMMISSION, 2000d)

Annex II:	Data requirements for the inclusion of an active substance (a.s.) in Annex I Part A: Chemical substances Part B: Micro-organisms and viruses	Annex II and III were developed in parallel: **Directive** <u>Part A: Chemical a.s.</u> Efficacy 93/71/EEC (EUROPEAN COMMISSION, 1993) 1. Identity of the a.s.: 94/37/EC (EUROPEAN COMMISSION, 1994b) 2. Phys.-chem. properties: 94/37/EC (EUROPEAN COMMISSION, 1994b) 3. Other information: 94/37/EC (EUROPEAN COMMISSION, 1994b) 4. Analytical methods: 96/46/EC (EUROPEAN COMMISSION, 1996c) 5. Toxicology and metabolism: 94/79/EC (EUROPEAN COMMISSION, 1994c) 6. Residues: 96/86/EC (EUROPEAN COMMISSION, 1996d) 7. Fate and behaviour in the environment: 95/36/EC (EUROPEAN COMMISSION, 1995b) 8. Ecotoxicology: 96/12/EC (EUROPEAN COMMISSION, 1996b) 9. Summary: Doc. 1663/VI/94 rev. 8 (EUROPEAN COMMISSION, 1998h) 10. Classification and labelling in the sense of Dir. 67/548/EEC: Doc. 1663/VI/94 rev. 8 (EUROPEAN COMMISSION, 1998h) <u>Part B: Micro-organisms and viruses</u> 1. Efficacy 93/71/EEC (EUROPEAN COMMISSION, 1993) Further Directives in preparation. Draft working documents: 2. For the active substance: Doc. 4992/VI/95 (EUROPEAN COMMISSION, 1997a) 3. For preparations: Doc. 4993/VI/95 (EUROPEAN COMMISSION, 1997b)
Annex III:	Data requirements for the authorisation of a plant protection product Part A: Chemical preparations Part B: Preparations of microorganisms and viruses	
Annex IV:	Risk phrases	Draft Directive in preparation
Annex V:	Safety phrases	Draft Directive in preparation
Annex VI:	Uniform principles for the evaluation of plant protection products	Directive 97/57/EC (EUROPEAN COMMISSION, 1997d)

Tab. 2: Gradual evaluation programme for new and existing active substances in the EC.

New active substance	**Existing active substance**
	1 Publication of existing active substances to be reviewed
	2 Notification of interest to support Annex I inclusion
3 Compilation of dossier	
4 Completeness check	
5 Evaluation and assessment of an active substance by rapporteur Member State– preparation of a draft assessment report (monograph)	
6 Scientific discussion of the monograph in ECCO Peer Review meetings	
7 Negotiation on EC level with regard to Annex I inclusion	
8 Decision on inclusion in Annex I of Council Directive 91/414/EEC	

Tab. 3a: Active substances discussed in ECCO Peer Review meetings.

Active Substance	**Existing or New ***	**Rapporteur Member State**	**Category**
2,4-D	existing	Greece	herbicide
2,4-DB	existing	Greece	herbicide
aldicarb	existing	United Kingdom	nematicide/ acaricide/ insecticide
amitraz	existing	Austria	acaricide/ insecticide
amitrole	existing	France	herbicide
atrazine	existing	United Kingdom	herbicide
azimsulfuron	new	Italy	herbicide
azinphos-methyl	existing	Germany	acaricide/ insecticide
azoxystrobin	new	Germany	fungicide
benomyl	existing	Germany	fungicide
bentazone	existing	Germany	herbicide
beta-cyfluthrin	existing	Germany	insecticide
carbendazim	existing	Germany	fungicide
carfentrazone-ethyl	new	France	herbicide
CGA 245 704	new	France	fungicide
chlorfenapyr	new	Spain	insecticide/ acaricide
chlozolinate	existing	Greece	fungicide
cinidon-ethyl	new	United Kingdom	herbicide
cyclanilide	new	Greece	growth regulator
cyfluthrin	existing	Germany	insecticide
cyhalofop-butyl	new	Italy	herbicide
deltamethrin	existing	Sweden	insecticide
dinoterb	existing	France	herbicide
diquat	existing	United Kingdom	herbicide
DNOC	existing	France	acaricide/ insecticide
esfenvalerate	existing	Portugal	insecticide
ethofumesate	existing	Sweden	herbicide
ethoxysulfuron	new	Italy	herbicide
famoxadone	new	France	fungicide
fenarimol	existing	United Kingdom	fungicide
fenhexamid	new	United Kingdom	fungicide
fenthion	existing	Greece	insecticide
fentin acetate	existing	United Kingdom	fungicide

Active Substance	Existing or New *	Rapporteur Member State	Category
fentin hydroxide	existing	United Kingdom	fungicide
flufenacet	new	France	herbicide
flumioxazine	new	France	herbicide
flupyrsulfuron-methyl	new	France	herbicide
fluroxypyr	existing	Germany	herbicide
flurtamone	new	France	herbicide
flusilazole	existing	Ireland	fungicide
fosthiazate	new	United Kingdom	nematicide
glyphosate	existing	Germany	herbicide
glyphosate-trimesium	existing	Germany	herbicide
imazalil	existing	Luxembourg	fungicide
imazosulfuron	new	Germany	herbicide
iprodione	existing	France	fungicide
isoxaflutole	new	Netherlands	herbicide
kresoxim-methyl	new	Belgium	fungicide
lambda-cyhalothrin	existing	Sweden	insecticide
lindane	existing	Austria	insecticide
linuron	existing	United Kingdom	herbicide
maleic hydrazide	existing	Denmark	growth regulator
metsulfuron	existing	France	herbicide
monolinuron	existing	United Kingdom	herbicide
paraquat	existing	United Kingdom	herbicide
pendimethalin	existing	Spain	herbicide
prohexadione calcium	new	France	growth regulator
propineb	existing	Italy	fungicide
propyzamide	existing	Sweden	herbicide
pymetrozine	new	Germany	insecticide
pyrazophos	existing	Netherlands	fungicide
pyridate	existing	Austria	herbicide
quinoxyfen	new	United Kingdom	fungicide
quintozene	existing	Greece	fungicide
simazine	existing	United Kingdom	herbicide
spiroxamine	new	Germany	fungicide

Active Substance	**Existing or New ***	**Rapporteur Member State**	**Category**
sulfosulfuron	new	Ireland	herbicide
tecnazene	existing	United Kingdom	fungicide
thiabendazole	existing	Spain	fungicide
thifensulfuron	existing	France	herbicide
thiophanate-methyl	existing	Germany	fungicide
thiram	existing	Belgium	fungicide
triasulfuron	existing	France	herbicide
vinclozolin	existing	France	fungicide
warfarin	existing	Ireland	rodenticide
ziram	existing	Belgium	fungicide/ repellent

*existing: existing active substance, on the market on or before 25 July 1993, new: new active substance, application for first inclusion in Annex I made after 25 July 1993.

Tab. 3b: Active substances under discussion in ECCO Peer Review meetings, round 8.

Active Substance	**Existing or New ***	**Rapporteur Member State**	**Category**
acephate	existing	Italy	insecticide
chlorpropham	existing	Netherlands	growth regulator/herbicide
chlorpyrifos	existing	Spain	insecticide/ acaricide
chlorpyrifos-methyl	existing	Spain	insecticide/ acaricide
daminozide	existing	Netherlands	growth regulator
ferric III phosphate	new	Germany	molluscicide
flazasulfuron	new	Spain	herbicide
isoproturon	existing	Germany	herbicide
mecoprop	existing	Denmark	herbicide
mecoprop-P	existing	Denmark	herbicide
metalaxyl-M	new	Belgium	fungicide
molinate	existing	Portugal	herbicide
oxadiargyl	new	Italy	herbicide
parathion	existing	Italy	insecticide
propiconazole	existing	Finland	fungicide
prosulfuron	new	France	herbicide
pyraflufen-ethyl	new	Belgium	herbicide

*existing: existing active substance, on the market on or before 25 July 1993. new: new active substance, application for first inclusion in Annex I made after 25 July 1993.

Tab. 4: Weightings of Member States in Standing Committee on Plant Health (SCPH)

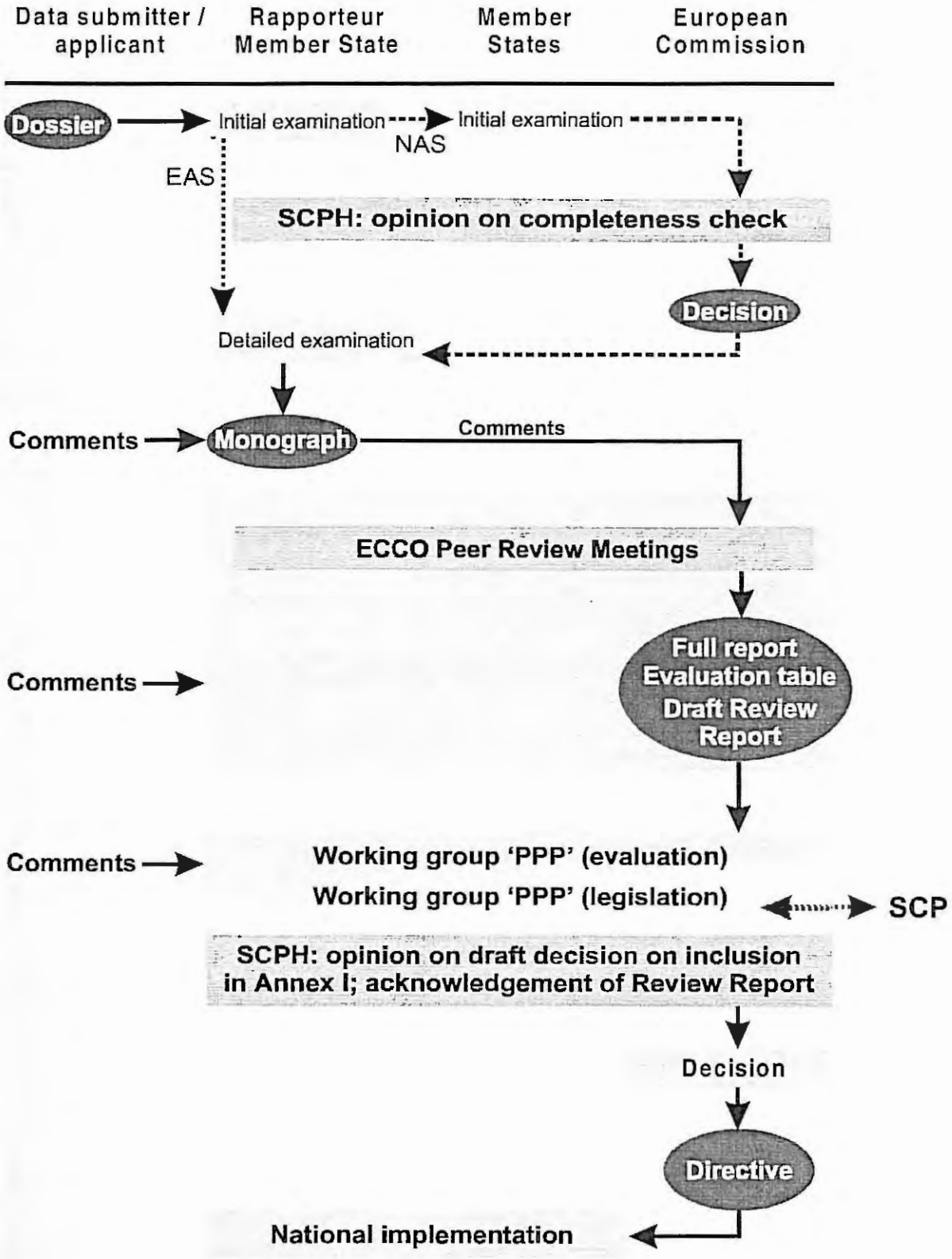
Member State	**Number of Votes**
Germany, France, Italy and the United Kingdom	10 votes each
Spain	8 votes
Belgium, Greece, the Netherlands and Portugal	5 votes each
Austria and Sweden	4 votes each
Denmark, Finland and Ireland	3 votes each
Luxembourg	2 votes
Total	**87 votes**

Glossary: Documentation of the EC pesticide registration process (chronical order)

Document	**Prepared by**	**Explanation/Description**
Dossier	Data submitter/ applicant	All relevant data requirements of the Annexes II and III of Directive 91/414/EEC must be addressed, either by data or justifications for the non-submission of information.
List of end points	Data submitter/ applicant, reviewed and as necessary revised by rapporteur Member State and ECCO Peer Review meetings	Characterisation of the active substance for risk assessment. Standardised pro-forma has been specified in both dossier and monograph guideline.
Draft assessment report (monograph)	Rapporteur Member State	Assessment of the data submitted containing a recommendation concerning Annex I inclusion.
Concise outline report	ECCO-Team	Reflects the discussions and conclusions of the ECCO Peer Review meetings with experts from different Member States and representatives from the European Commission.
Evaluation table	ECCO-Team, checked and amended with comments by rapporteur Member State and main data submitter/applicant	List of data requirements to be addressed by the data submitters.
Full report	ECCO-Team	Prepared at the end of each ECCO round for each active substance considered at the ECCO Peer Review meetings. Consists of meeting reports and comments of Member States, data submitters/applicants and third parties. As a supplement to the monograph, it serves as the basis for further discussions with all Member States at EC level.
Review Report	The ECCO-Team prepares the initial draft, which is further developed by the European Commission during the evaluation process	Summarises the key issues that are critical to the decision on Annex I inclusion. Background documents are monograph, full report and comments submitted after Peer Review.

Document	**Prepared by**	**Explanation/Description**
Decision/ Directive	European Commission	For each active substance to be included in Annex I, a Directive is published in the Official Journal of the European Communities to be implemented by Member States. In the case of non-inclusion, a Decision is published.

Fig. 1: Evaluation procedure for active substances in the EU



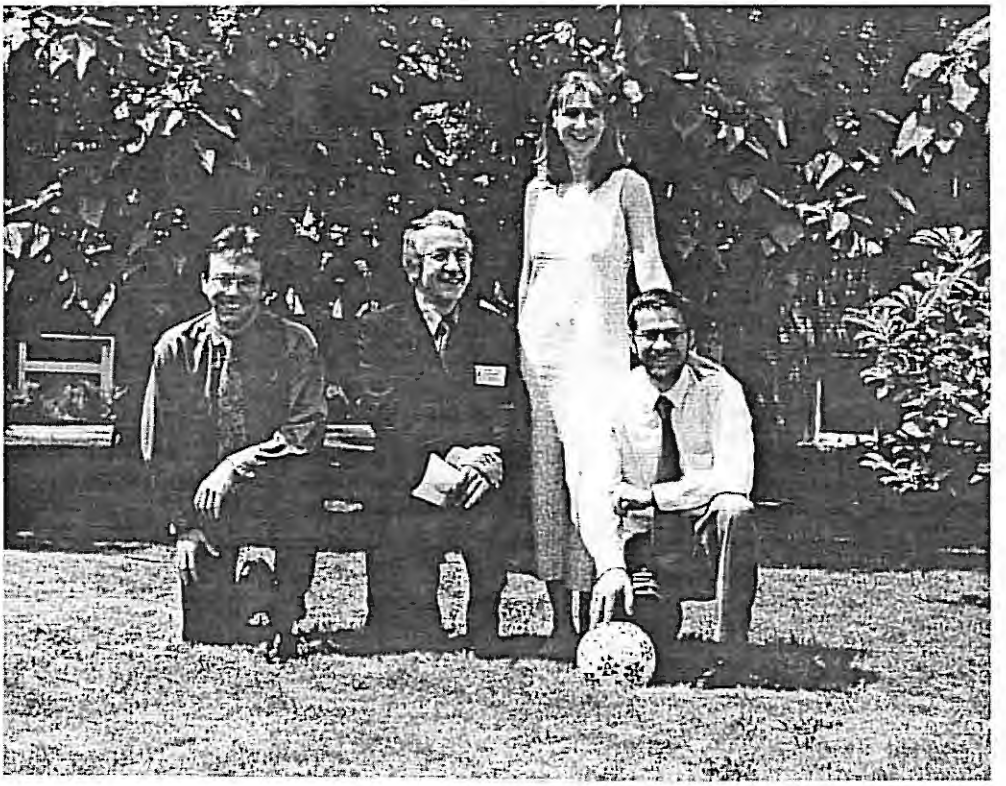
Abbreviations:

EAS:	existing active substance
NAS:	new active substance
ECCO:	European Commission Co-ordination
SCPH:	Standing Committee on Plant Health
SCP:	Scientific Committee on Plants
BBA:	Biologische Bundesanstalt für Land- und Forstwirtschaft, Braunschweig, Germany
PSD:	Pesticides Safety Directorate, York, UK

100 ECCO – Peer Review Meetings: photos and figures

Birth of the tender for the ECCO contract: Jörg-Rainer Lundehn and Darren Flynn

Partners in the ECCO project: Geoff Bruce (PSD) and Professor Fred Klingauf (BBA)

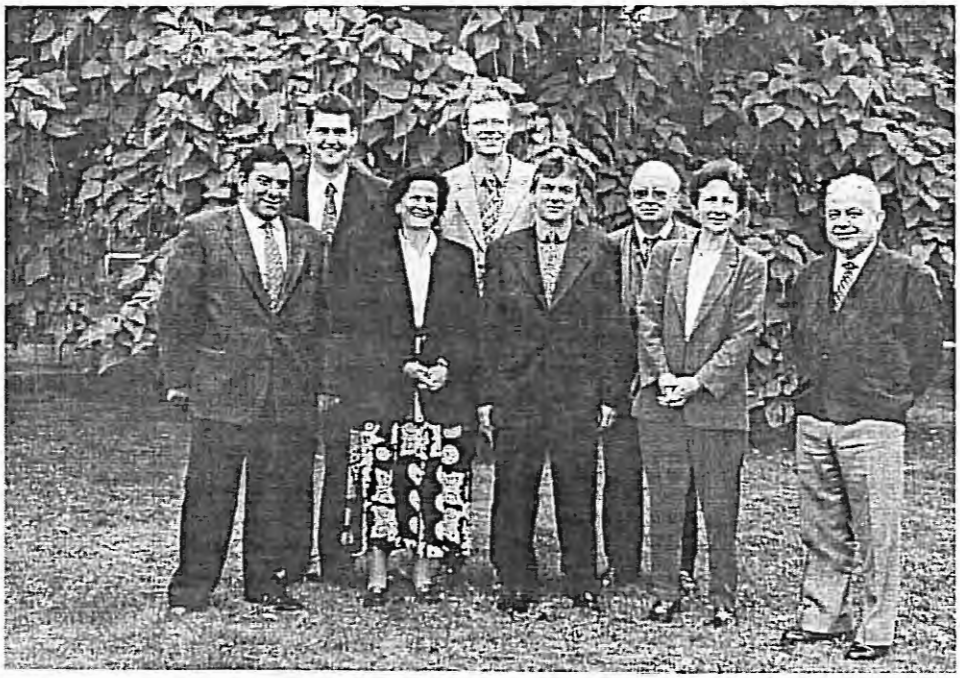


Apparently a winning team:
Hartmut Kula, Jörg-Rainer Lundehn, Birgit Wirsing, Louis Smeets

The ECCO-Team (BBA) today: Evelyn Homann, Jürgen Sturma, Kerstin Koch, Elke Leske, Jörg-Rainer Lundehn, Heike Wintersdorff-Schneider, Dagmar Scholz, Jan von Kietzell, Cornelia Landsmann

ECCO 16 on mammalian toxicology: Thomasina Barron (Ireland), Rudolf Pfeil (Chairman), Lene Lorenzen (Denmark), Roland Solecki (Germany), Corrado Galli (Italy), Jean-Michel Poul (France), Clive Edmunds (Commission), Jan von Kietzell (ECCO-Team), Edmund Plattner (Austria)

ECCO 31 on ecotoxicology: Cornelia Landsmann, (ECCO-Team), Sari Autio (Finland), Gerd Joermann (Chairman), Clive Edmunds (Commission), Monica Törnlund (Sweden), Margrit Grimm (Austria), Ana Barbara Oliveira (Portugal), Simone Jung (Germany), Mark Clook (UK)

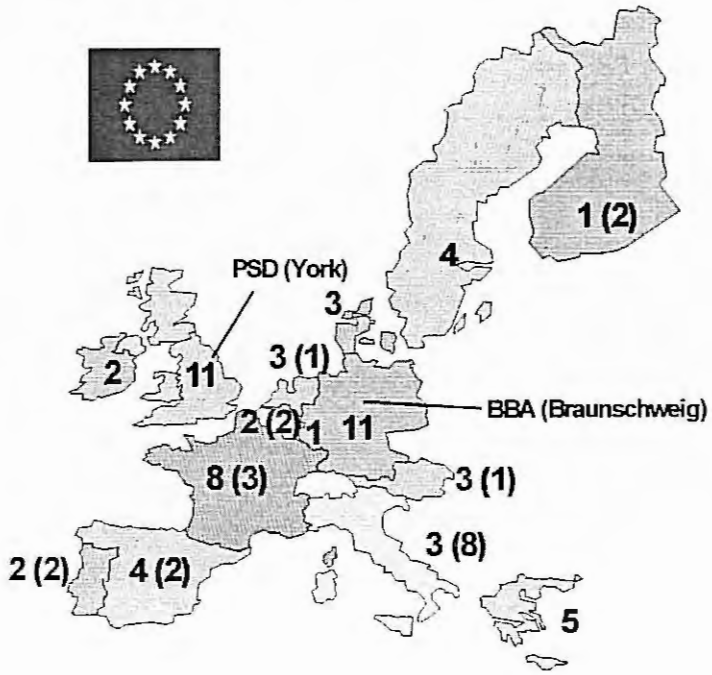


ECCO 40 on physical chemical properties, analytical methods: Roberto Dommarco (Italy), Tony Warbuton (UK), Adamantia Hourdakis (Greece), Jan von Kietzell (ECCO-Team), Hans-Gerd Nolting (Chairman), Klaus Claussen (Germany), Annick Venant (France), Francisco Sanchez-Rasero (Spain)

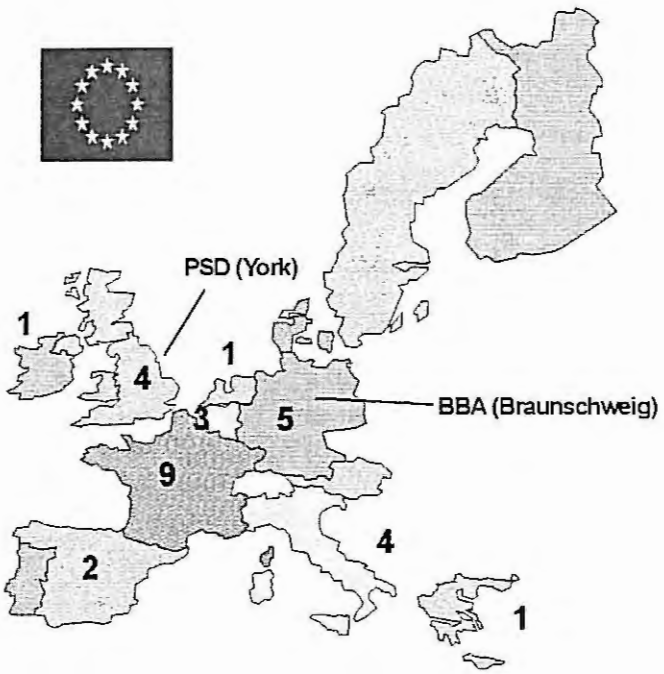
ECCO 44 on ecotoxicology: Jose-Vicente Tarazona (Spain), Jean-Louis Riviere (France), Elisabet Berggren (Commission), Jan von Kietzell (ECCO-Team), Monica Törnlund (Sweden), Mark Montforts (Netherlands), Stefania Loutseti (Greece), Steve Norman (UK), Ana Barbara Oliveira (Portugal), Martin Streloke (Chairman)

ECCO 73 Overview Meeting, participation of rapporteur Member States, chairs of BBA and PSD and the European Commission

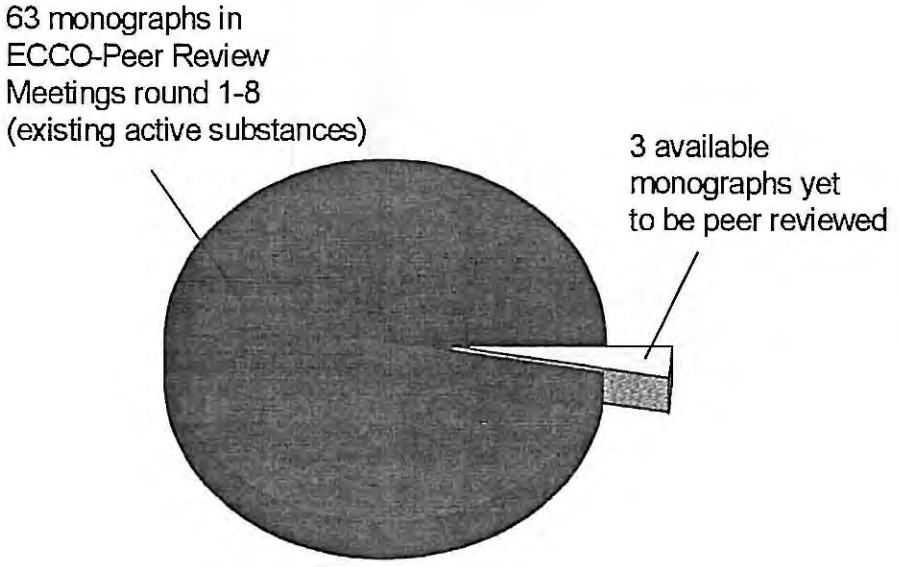
Number of monographs on existing active substances, prepared by rapporteur Member States and discussed in ECCO-Peer Review Meetings, rounds 1 – 8 (in brackets: number of monographs of 1. list which still have to be prepared and/or discussed).



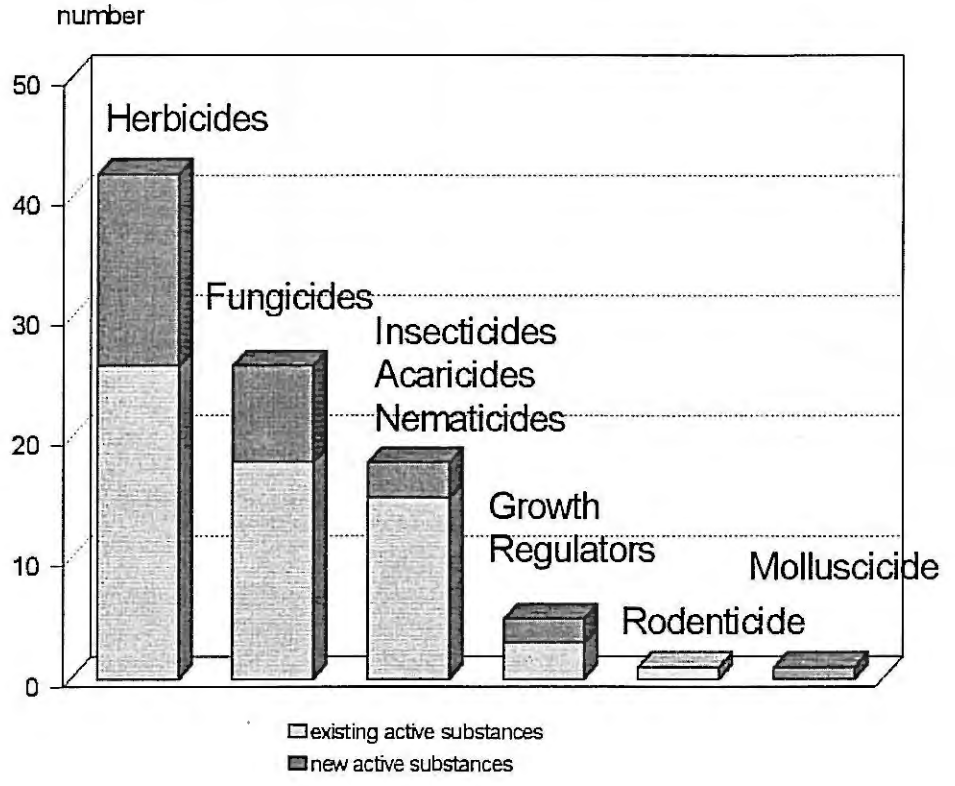
Number of monographs on new active substances (without micro-organisms), prepared by rapporteur Member States and discussed in ECCO-Peer Review Meetings, rounds 1 – 8



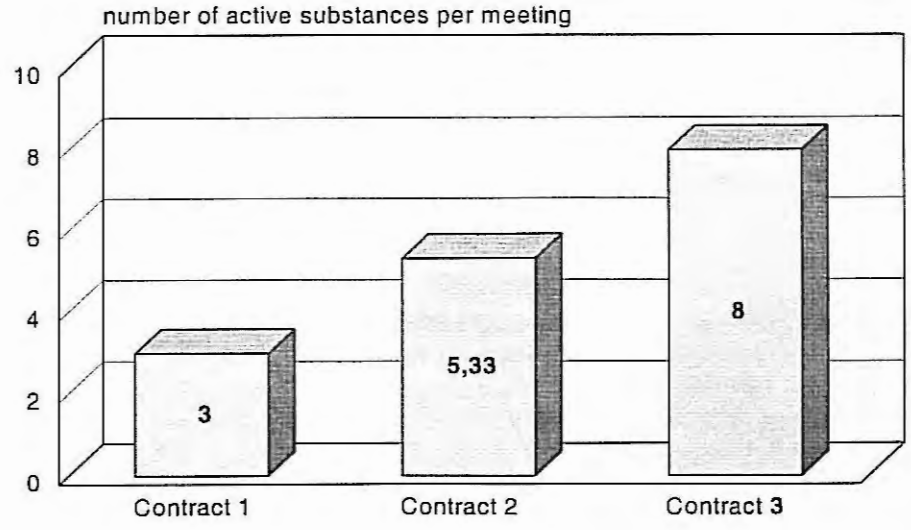
The small number of only 3 available draft assessment reports (monographs) on existing active substances yet to be peer reviewed shows that the organisation of ECCO-Meetings is able to cope with the speed in which monographs are being prepared by Member States



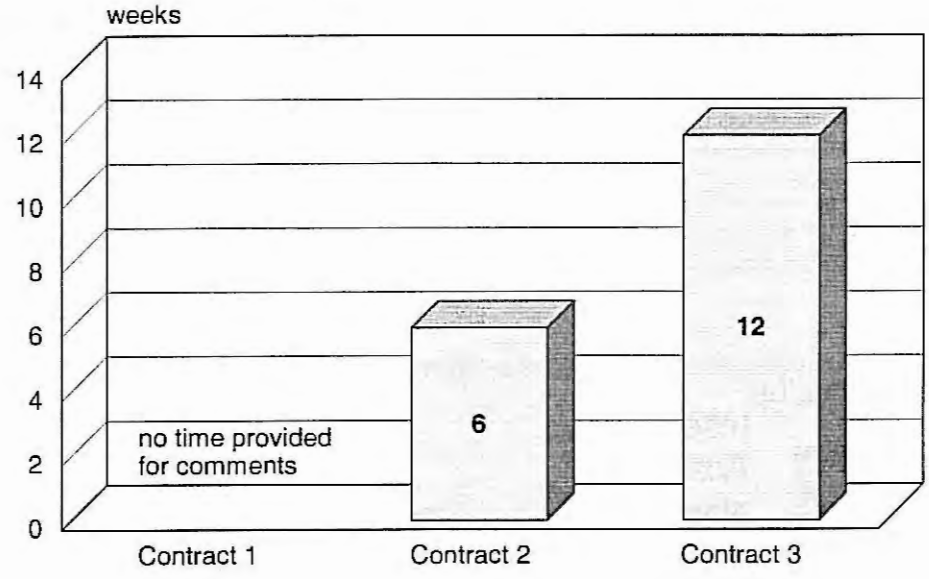
Categories of pesticide active substances reviewed in ECCO-Peer Review Meetings



Number of active substances discussed in specific ECCO-Peer Review Meetings



Time provided for comments between the last specific ECCO-Peer Review Meeting before organisation of Overview Meeting



Selection of Active Substances and Expert Groups

Selected Invited Participants (1. Round of ECCO-Meetings ECCO/PSD)

fenthion, imazalil, lambda-cyhalothrin, warfarin

	ECCO 1 17-19 Sep 96	ECCO 5 15-17 Oct 96	ECCO 3 1-3 Oct 96	ECCO 7 29-31 Oct 96	ECCO 9 12-14 Nov 96	ECCO 11 26-28 Nov 96

	Expert Groups					
	I	II	III	IV	V	VI
No.	Identity, Phys Chem. Properties	Fate and Behaviour	Ecotoxicology	Mammalian Toxicology	Residues, Methods of Analysis	Regulatory Decisions
1	GR A. Hourdakis	GR S. Vizantinopulos	GR S. Loutseti	GR K. Machera	GR C. Lentza-Rizos	GR C. Markakis
2	BE M. Galoux	BE P. Hucorne	BE P. Hucorne	BE M. Duverger-v. B.	BE L. Mohimont	BE H. Fontier
3	SE K. Hanze	SE U. Falk	SE U. Falk	SE A. Ohlsson	SE B.-G. Ericsson	SE V. Bernson
4	IE P. Hickey	IE P. Lawlor	IE P. Lawlor	IE S. Macken	IE P. Hickey	IE D. Sheridan
5	FI V. Koskinen	LU A. Aschman	LU A. Aschman	LU A. Aschman	LU A. Aschman	LU A. Aschman
6	NL R. Schreuder	IT E. Funari	DE W. Heger	UK I. Dewhurst	ES V. Teruel	ES A. Yague
7		FI S. Autio	FI K. Kallio-Mannila	FR J.-M. Poul	DE R. Hans	DE A.Wilkening

Selection of Active Substances and Expert Groups

Selected Invited Participants (1. Round of ECCO-Meetings ECCO/BBA)

aldicarb, diquat, fenarimol, tecnazene

	ECCO 2 24 - 26 Sep 96	ECCO 4 8-10 Oct 96	ECCO 6 22-24 Oct 96	ECCO 8 5-7 Nov 96	ECCO 10 19-21 Nov 96	ECCO 12 3-5 Dec 96

	Expert Groups					
	I	II	III	IV	V	VI
	Identity, Phys. Chem. Properties	Fate and Behaviour	Ecotoxicology	Mammalian Toxicology	Residues, Methods of Analysis	Regulatory Decisions
1	UK M. J. Gillespie	UK D. Griffin	UK P. Campbell	UK R. Shillaker	UK C. Harris	UK D. Flynn
2	ES J. Lombardero Vega	NL J. W. Tas	NL P.J.M. van Vliet	NL H.E. Falke	NL J. A. Garthoff	NL J. Meeuwsen
3	NL C. Goewie	DK C. Hansen	DK C. Hansen	DK I. Kraul	DK M.G. Lauridsen	DK G. Bennekou
4	DE K. Claussen	SE M. Törnlund	SE M. Törnlund	SE C. Debourg	DE U. Banasiak	SE V. Bernson
5	IE D. O'Sullivan	DE D. Gottschild	DE G. Joermann	DE L. Niemann	IE D. O' Sullivan	DE A. Wilkening
6		ES F. Vares	FR J. L. Riviere	IE T. Barron	SE B.-G. Ericsson	ES A. Yagüe
7				FR G. Milhaud	FR B. Declercq	IE D. Sheridan

Selection of Active Substances and Expert Groups

Selected Invited Participants (2. Round of ECCO-Meetings ECCO/PSD)

cyflutbrin, beta-cyfluthrin, fluroxypyr, amitrole

	ECCO 13 7-9 Jan 97	ECCO 15 21-23 Jan 97	ECCO 17 28-30 Jan 97	ECCO 19 11-13 Feb 97	ECCO 21 25-27 Feb 97	ECCO 23 11-13 Mar 97

	Expert Groups					
	I	II	III	IV	V	VI
No.	Identity, Phys Chem. Properties; Methods of Analysis	Fate and Behaviour	Ecotoxicology	Mammalian Toxicology	Residues	Regulatory Decisions
1	FR B. Declercq	FR P. Gaillardon	FR J. L. Riviere	FR D. Marzin	FR Declercq	FR A. Rico
2	DE G. Menschel	DE R. Binner	DE H. Teichmann	DE R. Solecki	DE U. Banasiak	DE A. Wilkening
3	GR A. Hourdakis	SE M. Törnlund	SE M. Törnlund	UK M. Watson	GR C. Lentza-Rizos	UK D. Flynn
4	FI V. Koskinen	GR S. Vizantinopulos	GR S. Loutseti	SE A. Ohlsson	AT E. Plattner	GR C. Markakis
5	AT R. Womastek	NL J. Tas	AT M. Grimm	GR K. Machera	DK M.G. Lauridsen	SE V. Bernson
6	NL R. Schreuder		NL J. Linders	NL E. Plattner	FI P. Ohra-aho	AT R. Womastek
7				FI L. Nylund	SE B.-G. Ericsson	FI H. Blomquist

Selection of Active Substances and Expert Groups

Selected Invited Participants (2. Round of ECCO-Meetings ECCO/BBA)

flusilazole, propineb, thifensulfuron(-methyl), dinoterb

	ECCO 14 14-16 Jan 97	ECCO 20 18-20 Feb 97	ECCO 22 4-6 Mar 97	ECCO 16 21-23 Jan 97	ECCO 18 4-6 Feb 97	ECCO 24 18-20 Mar 97
	Expert Groups					
	I	**II**	**III**	**IV**	**V**	**VI**
	Identity, Phys. Chem. Properties; Methods of Analysis	**Fate and Behaviour**	**Ecotoxicology**	**Mammalian Toxicology**	**Residues**	**Regulatory Decisions**
1	IE D. O'Sullivan	IE P. Lawlor	IE P. Lawlor	IE T. Barron	IE D. O'Sullivan	IE D. Sheridan
2	FR A. Venant	FR P. Gaillardon	FR J. L. Riviere	FR J.-M. Poul	FR A. Venant	FR J.-M. Poul
3	IT R. Dommarco	IT C. Zaghi	IT R. Fanelli	IT C. Galli	IT E. Cecere	IT C. Galli
4	AT J. Kohl	BE L. Pussemier	DE M. Streloke	DE R. Solecki	DE R. Hans	UK D. Flynn
5	DE G. Menschel	UK A. Craven	GR S. Loutseti	DK L. Lorenzen	UK C. Harris	DE H. Kula
6		DE D. Gottschild	AT M. Grimm	AT E. Plattner	AT E. Plattner	GR C. Markakis
7		DK S. Marcher	DK V. Møller	GR K. Machera	DK M.G. Lauridsen	DK N.S. Hansen

Selection of Active Substances and Expert Groups

Selected Invited Participants (3. Round of ECCO - Meetings ECCO/PSD)

Azoxystrobin (DE), Kresoxim-methyl (BE), Spiroxamine (DE), DNOC (FR), Isoxaflutole(NL)

	ECCO 25 15 - 17 April 1997	ECCO 27 29 - 1 May 1997	ECCO 28 6 - 8 May 1997	ECCO 30 20 - 22 May 1996	ECCO 33 10 - 12 June 1997	ECCO 35 24 - 26 June 1997

	Expert Groups					
	I	II	III	IV	V	VI
No	Identity, Phys. Chem. Properties; Methods of Analysis	Fate and Behaviour	Ecotoxicology	Mammalian Toxicology	Residues	Regulatory Decisions
1	BE M. Galoux	BE L. Pussemier	BE P. Hucorne	BE M. Duverger	BE L. Mohimont	BE H. Fontier
2	DE J. Siebers	DE R. Kloskowski	DE G. Joermann	DE R. Solecki	DE M. Theurig	DE E. Adam
3	FR A. Venant	FR A. Delmas	FR J.-M. Jouany	FR D. Marzin	FR B. Declercq	FR D. Marzin
4	NL C.E. Goewie	NL W. Tas	NL P. van Vliet	NL H. Falke	NL J. Garthoff	UK J. Wilder
5	AT H. Reich	SE U. Falk	SE U. Falk	UK S. Warren	DK M. Green	SE V. Bernson
6	GR A. Hourdakis	DK C. Hansen	DK C. Hansen	AT E. Plattner	GR C. Lentza-Rizos	DK G. Bennekou
7	IT R. Dommarco	PT F. Alfarroba	PT A.B. Oliveira	DK N.S. Hansen	UK J. Gillespie	GR C. Loizou
						NL J. J. Meeussen

Selection of Active Substances and Expert Groups

Selected Invited Participants (3. Round of ECCO - Meetings ECCO/BBA)

Quinoxyfen (UK), Esfenvalerate (PT), Paraquat (UK), Pyridate (AT)

	ECCO 26 22 - 24 April 1997	ECCO 29 13 - 15 May 1997	ECCO 31 27 - 29 May 1997	ECCO 32 3 - 5 June 1997	ECCO 34 17 - 19 June 1997	ECCO 36 1 - 2 July 1997

	Expert Groups					
	I	II	III	IV	V	VI
No	**Identity, Phys. Chem. Properties; Methods of Analysis**	**Fate and Behaviour**	**Ecotoxicology**	**Mammalian Toxicology**	**Residues**	**Regulatory Decisions**
1	AT R. Womastek	AT S. Ecker	AT M. Grimm	AT A. Bergmann	AT C. Prohaska	AT R. Womastek
2	PT I. Navas	PT F. Alfarroba	PT A.B. Oliveira	PT M. Vaz	PT E. Fernandes	PT J. Sobreiro
3	UK J. Gillespie	UK D. L. Griffin	UK M. Clook	UK I. Dewhurst	UK S. Crossley	UK D. Flynn
4	DE G. Menschel	FI S. Autio	FI S. Autio	SE C. Debourg	DE R. Hans	FI L. Nylund
5	FR A. Venant	SE M. Tornlund	SE M. Tornlund	FR D. Marzin	FR J. P. Cugier	DE H. Bruno
6	NL R. Schreuder	FR A. Delmas	DE S. Jung	GR K. Machera	SE B.-G. Ericsson	FR B. Declercq
7		NL W. Tas	~~FR J. M. Jouany~~	NL B.C. Hakkert	GR C. Lentza-Rizos	GR C. Markakis

Experts Invited to the Fourth Round of Peer Review Meetings (PSD)

Azinphos-methyl (DE), Bentazone (DE), Triasulfuron (FR), Azimsulfuron (IT), Metsulfuron-methyl (FR)

	ECCO 41 23 - 26 September 1997	ECCO 47 4 - 7 November 1997	ECCO 49 18 - 21 November 1997	ECCO 43 7 - 10 October 1997	ECCO 45 21 - 24 October 1997

	Expert Groups				
	I	II	III	IV	V
No	Identity, Phys. Chem Properties, M of Analysis	Fate and Behaviour	Ecotoxicology	Mammalian Toxicology	Residues
1	DE R. Hänel	DE D. Gottschild	DE C. Kula	DE R. Solecki	DE W. Storzer
2	FR B. Declercq	FR P. Gaillardon	FR J.-L. Riviere	FR R. Glomot	FR B. Declercq
3	IT M. Taccheo-Barbina	IT G. Azimonti	IT R. Fanelli	IT C. Galli	IT F. Roberti
4	BE A. De Meester	SE M. Törnlund	FI S. Autio	UK E. Efa	DK M. Green
5	AT R. Womastek	DK C. Hansen	DK C. Hansen	DK N.S. Hansen	PT E. Fernandes
6	FI V. Koskinen	PT F. Alfarroba	PT S. Luis	AT E. Plattner	AT E. Plattner
7	NL R. Schreuder	NL J. Linders	NL B. Mensink	PT D. Marques	NL G. Houben

Experts Invited to the Fourth Round of Peer Review Meetings (BBA)

2,4-D (GR), 2,4-DB (GR), Linuron (UK), Monolinuron (UK), Thiabendazole (ES), Flurtamone (FR)

	ECCO 40 15 - 19 September 1997	ECCO 42 29 - 2 October 1997	ECCO 44 13 - 17 October 1997	ECCO 46 27 - 31 October 1997	ECCO 48 10 - 14 November 1997	ECCO 50 26 - 30 January 1998

	Expert Groups					
	I	II	III	IV	V	VI
No	Ideutity, Phys. Chem Properties, M of Analysis	Fate and Behaviour	Ecotoxicology	Mammalian Toxicology	Residues	Overview Meeting
1	ES F. Sanchez Rasero	ES J. Tarazona	ES J. Tarazona	ES E. Vilanova	ES V. Teruel	ES A. Yague
2	FR A. Venant	FR A. Delmas	FR J.-L. Riviere	FR F. Hubert	FR Cugier	FR A. Delmas
3	GR A. Hourdakis	GR S. Vizantinopoulos	GR S. Loutseti	GR K. Machera	GR C. Lentza-Rizos	GR C. Markakis
4	UK A. Warbuton	UK D. Griffin	UK S. Norman	UK I. McManus	UK J. Gillespie	UK D. Flynn
5	IT R. Dommarco	DE R. Winkler	PT A.B Oliveira	FI R. Venäläinen	DE R. Hans	DE A. Wilkening
6	DE K. Claussen	IT S. Cervelli	SE M. Törnlund	IT A. Meneguz	IT M. Bersani	IT C. Galli
7		DK V. Møller	NL M. Montforts	NL B. C. Hakkert	SE B.-G. Ericsson	

Experts Invited to the Fifth Round of Peer Review Meetings (PSD)

Benomyl (DE), Carbendazim (DE), Thiophanate-methyl (DE), Chlozolinate (GR), Iprodione (FR), Vinclozolin (FR)

ECCO 52 24 - 27 March 1998	ECCO 56 5 - 8 May 1998	ECCO 60 2 - 5 June 1998	ECCO 54 21 - 24 April 1998	ECCO 58 19 - 22 May 1998	ECCO 61 20 - 24 July 1998

	Expert Groups					
	I	II	III	IV	V	VI
No	Identity, Phys. Chem Properties, M of Analysis	Fate and Behaviour	Ecotoxicology	Mammalian Toxicology	Residues	Overview Meeting
1	DE R. Haenel	DE R. Kloskowski	DE R. Spangenberg	DE R. Solecki	DE M. Theurig	DE A. Wilkening
2	GR A. Hourdakis	GR S. Vizantinopulos	GR E. Skenteri	GR S. Loutseti	GR C. Lentza-Rizos	GR C. Loizou
3	FR B. Declercq	FR A. Delmas	FR J.-L. Rivière	FR R. Maximilien	FR B. Declercq	FR R. Maximilien
4	FI V. Koskinen	SE S. Karlsson	BE P. Hucorne	BE C. Vleminckx	PT B. Teixeira	UK D. Flynn
5	NL R. Schreuder	IT C. Zaghi	SE M. Törnlund	FI L. Nylund	NL J. Garthoff	

Experts Invited to the Fifth Round of Peer Review Meetings (BBA)

Atrazine (UK), Simazine (UK), Fentin Acetate (UK), Fentin Hydroxide (UK), Quintozene (GR), Flupyrsulfuron-methyl (FR)

ECCO 51 17 - 19 March 1998	ECCO 53 14 - 17 April 1998	ECCO 59 26 - 29 May 1998	ECCO 55 27 - 30 April 1998	ECCO 57 12 - 15 May 1998

	Expert Groups				
	I	II	III	IV	V
No	Identity, Phys. Chem Properties, M of Analysis	Fate and Behaviour	Ecotoxicology	Mammalian Toxicology	Residues
1	UK K. Howard	UK D. Griffin	UK S. Norman	UK R. Shillaker	UK S. Crossley
2	GR A. Hourdakis	UK C. Lythgo	GR S. Loutseti	GR K. Machera	GR C. Lentza Rizos
3	FR A. Venant	GR S. Vizantinopulos	FR J.-L. Riviere	FR R. Glomot	FR J.-P. Cugier
4	BE A. De Meester	FR P. Gaillardon	FI S. Autio	BE G. van Maele	DE R. Hans
5	FI V. Koskinen	IT C. Zaghi	NL P. van Vliet	SE C. Debourg	AT M. Lusser
6		AT C. Autengruber			

Experts Invited to the Sixth Round of ECCO Peer Review Meetings (PSD)

Pymetrozine (DE), Imazosulfuron (DE), Sulfosulfuron (IE), Ethoxysulfuron (IT), Cyclanilide (GR), Pyrazophos (NL)

ECCO 64 8-11 September 1998	ECCO 66 5-8 October 1998	ECCO 68 20-23 October 1998	ECCO 70 3-6 November 1998	ECCO 72 17-20 November 1998

	Expert Groups				
	I	IV	II	V	III
No	Identity, Phys. Chem Properties, M of Analysis	Mammalian Toxicology	Fate and Behaviour	Residues	Ecotoxicology
1	DE R. Hänel	DE R. Solecki	DE K. Schinkel	DE W. Storzer	DE C. Kula
2	IE D. O'Sullivan	IE T. Barron	IE P. Lawlor	IE D. O'Sullivan	IE P. Lawlor
3	IT R. Dommarco	IT C. Galli	IT G. Azimonti	IT R. Dommarco	IT C. Zaghi
4	GR A. Hourdakis	GR K. Machera	GR E. Lahlou	GR C. Lentza-Rizos	GR S. Loutseti
5	NL R. Schreuder	NL H. Falke	NL W. Tas	NL J. Garthoff	NL P. van Vliet

Experts Invited to the Sixth Round of ECCO Peer Review Meetings (BBA)

Fosthiazate (UK), Flufenacet (FR), Flumioxazine (FR), Carfentrazone-ethyl (FR), Prohexadione calcium (FR), Pendimethalin (ES)

ECCO 63	ECCO 65	ECCO 67	ECCO 69	ECCO 71	ECCO 73
1– 4 September 1998	29-2 October 1998	13-16 October 1998	27-30 October 1998	10-13 November 1998	25-29 January 1999

	I	II	IV	III	V	VI
No	Identity, Phys. Chem Properties, M of Analysis	Fate and Behaviour	Mammalian Toxicology	Ecotoxicology	Residues	Overview Meeting
1	UK T. Warburton	UK C. Lythgo	UK E. Efa	UK P. Ashby	UK J. Gillespie	UK J. Wilder
2	FR A. Venant	FR A. Delmas	FR F. Hubert	FR J.-L. Riviere	FR B. Declercq	FR F. Hubert
3	FR Descoins	FR P. Gaillardon	FR J.M. Poul	FR L. Belzunces	FR J. P. Cugier	FR T. Mercier
4	ES O. Magrans	ES J. V. Tarazona	ES B. Ribas	ES J. V. Tarazona	ES F. Hernandez	ES A. Yagüe
5	AT N. Spatny	SE K. Hanze	GR E. Skenderi	SE A. Sandberg	PT E. Fernandes	DE A. Wilkening
6						GR C. Loizou
7						IE D. Sheridan
8						IT C. Galli
9						NL J. Meeussen

Experts Invited to the 7. Round of Peer Review Meetings (PSD)

Famoxadone (FR), CGA 245704 (FR), Thiram (BE), Ziram (BE), Amitraz (AU), Lindane (AU), Glyphosate (DE), Glyphosate trimesium (DE)

	ECCO 76 23 - 26 March 1999	ECCO 80 25 - 28 May 1999	ECCO 84 20 - 23 July 1999	ECCO 78 26 - 30 April 1999	ECCO 82 29 June - 2 July 1999	ECCO 85 18 - 22 October 1999
	Expert Groups					
	I	II	III	IV	V	VI
No	Identity, Phys. Chem Properties, M of Analysis	Fate and Behaviour	Ecotoxicology	Mammalian Toxicology	Residues	Overview Meeting
1	AU Dr N Spatny	AU Mrs S Ecker	AU Mrs M Grimm	AU Dr A Bergmann	AU Mr C Prohaska	AU Mrs H Reich
2	BE Dr A De Meester	BE Dr L Pussemier	BE Mr P Hucorne	BE Dr M Duverger	BE Mr L Mohimont	BE Mr H Fontier
3	DE Dr R Haenel	DE Dr D Gottschild	DE Dr S Jung	DE Dr R Solecki	DE Dr W Storzer	DE Dr H Bruno
4	FR Mrs A Venant	FR Mr Soulas	FR Mrs C Vergnet	FR Dr A Pelfrane	FR Mr B Declercq	FR Mr T Mercier
5	PT Mrs F Pedrosa	DK Mr C Hansen	FI Mrs K Kallio-Mannila	GR K. Machera	NL Mrs J Garthoff	UK Mrs J Wilder
6						ES Mr A Yagüe
7						DK Mr C Hansen
8						SW Ms U Falk
9						IT Dr C Galli

Experts Invited to the 7. Round of ECCO Peer Review Meetings (BBA)

Fenhexamid (UK), Cinidon-ethyl (UK), Chlorfenapyr (ES), Maleic hydrazide (DK), Propyzamide (SE), Ethofumesate (SE), Deltamethrin (SE), Cyhalofop-butyl (I)

	ECCO 75 16 – 19 March 1999	ECCO 77 20 – 23 April 1999	ECCO 79 17 – 21 May 1999	ECCO 81 15 - 18 June 1999	ECCO 83 13 – 16 July 1999
	I	II	1V	III	V
No	Identity, Phys. Chem Properties, M of Analysis	Fate and Behaviour	Mammalian Toxicology	Ecotoxicology	Residues
1	DK T. Krongaard	DK C. Hansen	DK N. S. Hansen	DK C. Hansen	DK M. Green
2	ES J. O. Magrans	ES J. V. Tarazona	ES B. Ribas	ES J. V. Tarazona	ES J. L. Alonso-Prados
3	IT R. Dommarco	IT S. Cervelli	IT C. Galli	IT P. Grasso	IT R. Dommarco
4	SE U. Rick	SE K. Hanze	SE C. Deboorg	SE E. Dryselius	SE B. Isaksson
5	UK T. Warburton	SE S. Karlsson	SE B. Koch	SE S. Karlsson	SE H. Hallstrom
6		UK B. Callow	UK E. Efa	UK S. Hoy	UK K. Howard

Experts Invited to the 8. Round of Peer Review Meetings (PSD)

Ferric phosphate (DE), Metalaxyl-M (BE), Pyraflufen-ethyl (BE), Chlorpropham (NL), Daminozide (NL), Isoproturon (DE), Molinate (PT), Propiconazole (FI)

ECCO 90	ECCO 92	ECCO 94	ECCO 96	ECCO 98
30 Nov – 3 December 1999	17 – 21 January 2000	15 – 18 February 2000	14 – 17 March 2000	11 – 14 April 2000

	Expert Groups				
	I	IV	II	V	III
No	Identity, Phys. Chem Properties, M of Analysis	Mammalian Toxicology	Fate and Behaviour	Residues	Ecotoxicology
1	BE A. De Meester	BE M. Duverger	BE P. Hucorne	BE S. Jarrah	BE P. Hucorne
2	DE R. Hänel	DE R. Solecki	DE B. Michalski	DE W. Storzer	DE R. Forster
3	NL R. Schreuder	NL H. Falke	NL J. W. Tas	NL J. Garthoff	NL P. van Vliet
4	PT M. Pedrosa	PT F. Almeida	PT F. Alfarroba	PT E. Fernandes	PT A. Oliveira
5	FI V. Koskinen	FI L. Nylund	FI K. Kallio-Mannila	FI R. Mutanen	FI K. Kallio-Mannila

Experts Invited to the 8. Round of Peer Review Meetings (BBA)

Flazasulfuron (ES), Oxadiargyl (IT), Prosulfuron (FR), Acephate (IT), Chlorpyrifos (ES), Chlorpyrifos-methyl (ES), Mecoprop (DK), Mecoprop-P (DK), Parathion (IT)

ECCO 89	ECCO 91	ECCO 95	ECCO 93	ECCO 97	ECCO 100
23 – 26 November 1999	11 – 14 January 2000	7 – 10 March 2000	14 – 18 February 2000	4 – 7 April 2000	3 - 7 July 2000

	Expert Groups						
	I	II	III	IV	V	VI	
No	Identity, Phys. Chem Properties, M of Analysis	Fate and Behaviour	Ecotoxicology	Mammalian Toxicology	Residues	Overview Meeting	
1	DK T. Krongaard	DK S. Marcher	DK S. Marcher	DK N. S. Hansen	DK M. Green	BE P. Hucorne	BE M. Duverger
2	ES J. O. Magrans	ES J. V. Tarazona	ES J. V. Tarazona	ES E. Ribas Ozonas	ES J. O. Magrans	DK N. Sørup Hansen	DK V. Møller
3	ES J. L. Alonso-Prados	ES V. Pablos	ES V. Pablos	ES E. Ordaz	ES J. L. Alonso-Prados	DE H. Bruno	DE M. Lehmann
4	IT R. Dommarco	IT E. Funari	IT D. Auteri	IT A. Fait	IT R. Dommarco	EL E. Katsarou	EL E. Skenderi
5	FR A. Venant	IT D. Auteri	IT P. Grasso	IT A. Mantovani	IT A. Fait	ES A. Yagüe	ES J. L. Alonso Prados
6	GR A. Hourdakis	FR P. Gaillardon	FR J.-L. Riviere	FR J.-L. Rouaud	FR J.-P. Cugier	FR S. Malezieux	FR T. Mercier
7		AT S. Ecker	GR S. Loutseti	AT A. Bergmann	AT M. Lusser	IE M. Lynch	IE D. Sheridan
8						IT C. L. Galli	IT R. Dommarco
9						LU A. Aschman	LU M. Faber
10						NL W. Pol	NL J. Meeussen
11						AU S. Napetschnig	AU R. Womastek
12						PT F. Alfarroba	PT F. Rovisco
13						FI H. Blomqvist	FI K. Kallio-Mannila
14						SE A. Ohlsson	SE L. Törnqvist
15						UK R. Mason	UK M. Briggs

Active substances dealt with by ECCO-Team

1. Alphabetical order

active substance	existing or new	rapporteur Member State	category	discussed in centre	discussed in round	decision of Commission
2,4-D	existing	Greece	herbicide	BBA	4	
2,4-DB	existing	Greece	herbicide	BBA	4	
acephate	existing	Italy	insecticide	BBA	8	
aldicarb	existing	United Kingdom	nematicide/ acaricide/ insecticide	BBA	1	
amitraz	existing	Austria	acaricide/ insecticide	PSD	7	
amitrole	existing	France	herbicide	PSD	2	
Ampelomyces quisqualis	new	France	micro-organism	Brussels		
atrazine	existing	United Kingdom	herbicide	BBA	5	
azimsulfuron	new	Italy	herbicide	PSD	4	inclusion
azinphos-methyl	existing	Germany	acaricide/ insecticide	PSD	4	
azoxystrobin	new	Germany	fungicide	PSD	3	inclusion
benomyl	existing	Germany	fungicide	PSD	5	
bentazone	existing	Germany	herbicide	PSD	4	
beta-cyfluthrin	existing	Germany	insecticide	PSD	2	
carbendazim	existing	Germany	fungicide	PSD	5	
carfentrazone-ethyl	new	France	herbicide	BBA	6	
CGA 245 704	new	France	fungicide	PSD	7	
chlorfenapyr	new	Spain	insecticide/ acaricide	BBA	7	
chlorpropham	existing	Netherlands	growth regulator/ herbicide	PSD	8	
chlorpyrifos	existing	Spain	insecticide/ acaricide	BBA	8	
chlorpyrifos-methyl	existing	Spain	insecticide/ acaricide	BBA	8	
chlozolinate	existing	Greece	fungicide	PSD	5	non-inclusion

active substance	existing or new	rapporteur Member State	category	discussed in centre	discussed in round	decision of Commission
cinidon-ethyl	new	United Kingdom	herbicide	BBA	7	
Coniothyrium minitans	new	Germany	micro-organism	co-rapporteur procedure		
cyclanilide	new	Greece	growth regulator	PSD	6	
cyfluthrin	existing	Germany	insecticide	PSD	2	
cyhalofop-butyl	new	Italy	herbicide	BBA	7	
daminozide	existing	Netherlands	growth regulator	PSD	8	
deltamethrin	existing	Sweden	insecticide	BBA	7	
dinoterb	existing	France	herbicide	BBA	2	withdrawal
diquat	existing	United Kingdom	herbicide	BBA	1	
DNOC	existing	France	acaricide/ insecticide	PSD	3	non-inclusion
esfenvalerate	existing	Portugal	insecticide	BBA	3	
ethofumesate	existing	Sweden	herbicide	BBA	7	
ethoxysulfuron	new	Italy	herbicide	PSD	6	
famoxadone	new	France	fungicide	PSD	7	
fenarimol	existing	United Kingdom	fungicide	BBA	1	
fenhexamid	new	United Kingdom	fungicide	BBA	7	
fenthion	existing	Greece	insecticide	PSD	1	
fentin acetate	existing	United Kingdom	fungicide	BBA	5	
fentin hydroxide	existing	United Kingdom	fungicide	BBA	5	
ferric III phosphate	new	Germany	molluscicide	PSD	8	
flazasulfuron	new	Spain	herbicide	BBA	8	
florasulam	new	Belgium	herbicide	co-rapporteur procedure		
flufenacet	new	France	herbicide	BBA	6	
flumioxazine	new	France	herbicide	BBA	6	
flupyrsulfuron-methyl	new	France	herbicide	BBA	5	
fluroxypyr	existing	Germany	herbicide	PSD	2	inclusion
flurtamone	new	France	herbicide	BBA	4	

active substance	existing or new	rapporteur Member State	category	discussed in centre	discussed in round	decision of Commission
flusilazole	existing	Ireland	fungicide	BBA	2	
fosthiazate	new	United Kingdom	nematicide	BBA	6	
glyphosate	existing	Germany	herbicide	PSD	7	
glyphosate-trimesium	existing	Germany	herbicide	PSD	7	
imazalil	existing	Luxemburg	fungicide	PSD	1	inclusion
imazosulfuron	new	Germany	herbicide	PSD	6	
indoxacarb	new	Netherlands	insecticide	co-rapporteur procedure		
iprodione	existing	France	fungicide	PSD	5	
iprovalicarb	new	Ireland	insecticide	co-rapporteur procedure		
isoproturon	existing	Germany	herbicide	PSD	8	
isoxaflutole	new	Netherlands	herbicide	PSD	3	
kresoxim-methyl	new	Belgium	fungicide	PSD	3	inclusion
lambda-cyhalothrin	existing	Sweden	insecticide	PSD	1	
lindane	existing	Austria	insecticide	PSD	7	
linuron	existing	United Kingdom	herbicide	BBA	4	
maleic hydrazide	existing	Denmark	growth regulator	BBA	7	
mecoprop	existing	Denmark	herbicide	BBA	8	
mecoprop-P	existing	Denmark	herbicide	BBA	8	
mesotrione	new	United Kingdom	herbicide	co-rapporteur procedure		
metalaxyl-M	new	Belgium	fungicide	PSD	8	
metsulfuron	existing	France	herbicide	PSD	4	
molinate	existing	Portugal	herbicide	PSD	8	
monolinuron	existing	United Kingdom	herbicide	BBA	4	non-inclusion
oxadiargyl	new	Italy	herbicide	BBA	8	
Paecilomyces fumosoroseus	new	Belgium	micro-organism	Brussels		
paraquat	existing	United Kingdom	herbicide	BBA	3	
parathion	existing	Italy	insecticide	BBA	8	

active substance	existing or new	rapporteur Member State	category	discussed in centre	discussed in round	decision of Commission
pendimethalin	existing	Spain	herbicide	BBA	6	
prohexadione calcium	new	France	growth regulator	BBA	6	
propiconazole	existing	Finland	fungicide	PSD	8	
propineb	existing	Italy	fungicide	BBA	2	
propyzamide	existing	Sweden	herbicide	BBA	7	
prosulfuron	new	France	herbicide	BBA	8	
Pseudomonas chlororaphis	new	Sweden	micro-organism	Brussels		
pymetrozine	new	Germany	insecticide	PSD	6	
pyraflufen-ethyl	new	Belgium	herbicide	PSD	8	
pyrazophos	existing	Netherlands	fungicide	PSD	6	non-inclusion
pyridate	existing	Austria	herbicide	BBA	3	
quinoxyfen	new	United Kingdom	fungicide	BBA	3	
quintozene	existing	Greece	fungicide	BBA	5	
simazine	existing	United Kingdom	herbicide	BBA	5	
spiroxamine	new	Germany	fungicide	PSD	3	inclusion
Spodoptera exigua	new	Netherlands	micro-organism	co-rapporteur procedure		
sulfosulfuron	new	Ireland	herbicide	PSD	6	
tecnazene	existing	United Kingdom	fungicide	BBA	1	non-inclusion
thiabendazole	existing	Spain	fungicide	BBA	4	
thifensulfuron	existing	France	herbicide	BBA	2	
Thiophanate-methyl	existing	Germany	fungicide	PSD	5	
Thiram	existing	Belgium	fungicide	PSD	7	
Triasulfuron	existing	France	herbicide	PSD	4	
Vinclozolin	existing	France	fungicide	PSD	5	
Warfarin	existing	Ireland	rodenticide	PSD	1	
Ziram	existing	Belgium	fungicide/ repellent	PSD	7	

Active substances dealt with by ECCO-Team

2. In order of rounds

Discussed in round	discussed in centre	active substance	existing or new	rapporteur Member State	category	decision of Commission
1	BBA	aldicarb	existing	United Kingdom	nematicide/ acaricide/ insecticide	
1	BBA	diquat	existing	United Kingdom	herbicide	
1	BBA	fenarimol	existing	United Kingdom	fungicide	
1	BBA	tecnazene	existing	United Kingdom	fungicide	non-inclusion
1	PSD	fenthion	existing	Greece	insecticide	
1	PSD	imazalil	existing	Luxemburg	fungicide	inclusion
1	PSD	lambda-cyhalothrin	existing	Sweden	insecticide	
1	PSD	warfarin	existing	Ireland	rodenticide	
2	BBA	dinoterb	existing	France	herbicide	withdrawal
2	BBA	flusilazole	existing	Ireland	fungicide	
2	BBA	propineb	existing	Italy	fungicide	
2	BBA	thifensulfuron	existing	France	herbicide	
2	PSD	amitrole	existing	France	herbicide	
2	PSD	beta-cyfluthrin	existing	Germany	insecticide	
2	PSD	cyfluthrin	existing	Germany	insecticide	
2	PSD	fluroxypyr	existing	Germany	herbicide	inclusion
3	BBA	esfenvalerate	existing	Portugal	insecticide	
3	BBA	paraquat	existing	United Kingdom	herbicide	
3	BBA	pyridate	existing	Austria	herbicide	
3	BBA	quinoxyfen	new	United Kingdom	fungicide	
3	PSD	azoxystrobin	new	Germany	fungicide	inclusion
3	PSD	DNOC	existing	France	acaricide/ insecticide	non-inclusion

Discussed in round	discussed in centre	active substance	existing or new	rapporteur Member State	category	decision of Commission
3	PSD	isoxaflutole	new	Netherlands	herbicide	
3	PSD	kresoxim-methyl	new	Belgium	fungicide	inclusion
3	PSD	spiroxamine	new	Germany	fungicide	inclusion
4	BBA	2,4-D	existing	Greece	herbicide	
4	BBA	2,4-DB	existing	Greece	herbicide	
4	BBA	flurtamone	new	France	herbicide	
4	BBA	linuron	existing	United Kingdom	herbicide	
4	BBA	monolinuron	existing	United Kingdom	herbicide	non-inclusion
4	BBA	thiabendazole	existing	Spain	fungicide	
4	PSD	azimsulfuron	new	Italy	herbicide	inclusion
4	PSD	azinphos-methyl	existing	Germany	acaricide/ insecticide	
4	PSD	bentazone	existing	Germany	herbicide	
4	PSD	metsulfuron	existing	France	herbicide	
4	PSD	triasulfuron	existing	France	herbicide	
5	BBA	atrazine	existing	United Kingdom	herbicide	
5	BBA	fentin acetate	existing	United Kingdom	fungicide	
5	BBA	fentin hydroxide	existing	United Kingdom	fungicide	
5	BBA	flupyrsulfuron-methyl	new	France	herbicide	
5	BBA	quintozene	existing	Greece	fungicide	
5	BBA	simazine	existing	United Kingdom	herbicide	
5	PSD	benomyl	existing	Germany	fungicide	
5	PSD	carbendazim	existing	Germany	fungicide	
5	PSD	chlozolinate	existing	Greece	fungicide	non-inclusion
5	PSD	iprodione	existing	France	fungicide	
5	PSD	thiophanate-methyl	existing	Germany	fungicide	
5	PSD	vinclozolin	existing	France	fungicide	
6	BBA	carfentrazone-ethyl	new	France	herbicide	

Discussed in round	discussed in centre	active substance	existing or new	rapporteur Member State	category	decision of Commission
6	BBA	flufenacet	new	France	herbicide	
6	BBA	flumioxazine	new	France	herbicide	
6	BBA	fosthiazate	new	United Kingdom	nematicide	
6	BBA	pendimethalin	existing	Spain	herbicide	
6	BBA	prohexadione calcium	new	France	growth regulator	
6	PSD	cyclanilide	new	Greece	growth regulator	
6	PSD	ethoxysulfuron	new	Italy	herbicide	
6	PSD	imazosulfuron	new	Germany	herbicide	
6	PSD	pymetrozine	new	Germany	insecticide	
6	PSD	pyrazophos	existing	Netherlands	fungicide	non-inclusion
6	PSD	sulfosulfuron	new	Ireland	herbicide	
7	BBA	chlorfenapyr	new	Spain	insecticide/ acaricide	
7	BBA	cinidon-ethyl	new	United Kingdom	herbicide	
7	BBA	cyhalofop-butyl	new	Italy	herbicide	
7	BBA	deltamethrin	existing	Sweden	insecticide	
7	BBA	ethofumesate	existing	Sweden	herbicide	
7	BBA	fenhexamid	new	United Kingdom	fungicide	
7	BBA	maleic hydrazide	existing	Denmark	growth regulator	
7	BBA	propyzamide	existing	Sweden	herbicide	
7	PSD	amitraz	existing	Austria	acaricide/ insecticide	
7	PSD	CGA 245 704	new	France	fungicide	
7	PSD	famoxadone	new	France	fungicide	
7	PSD	glyphosate	existing	Germany	herbicide	
7	PSD	glyphosate-trimesium	existing	Germany	herbicide	
7	PSD	lindane	existing	Austria	insecticide	
7	PSD	thiram	existing	Belgium	fungicide	
7	PSD	ziram	existing	Belgium	fungicide/ repellent	

Discussed in round	discussed in centre	active substance	existing or new	rapporteur Member State	category	decision of Commission
8	BBA	acephate	existing	Italy	insecticide	
8	BBA	chlorpyrifos	existing	Spain	insecticide/ acaricide	
8	BBA	chlorpyrifos-methyl	existing	Spain	insecticide/ acaricide	
8	BBA	flazasulfuron	new	Spain	herbicide	
8	BBA	mecoprop	existing	Denmark	herbicide	
8	BBA	mecoprop-P	existing	Denmark	herbicide	
8	BBA	oxadiargyl	new	Italy	herbicide	
8	BBA	parathion	existing	Italy	insecticide	
8	BBA	prosulfuron	new	France	herbicide	
8	PSD	chlorpropham	existing	Netherlands	growth regulator/ herbicide	
8	PSD	daminozide	existing	Netherlands	growth regulator	
8	PSD	ferric III phosphate	new	Germany	molluscicide	
8	PSD	isoproturon	existing	Germany	herbicide	
8	PSD	metalaxyl-M	new	Belgium	fungicide	
8	PSD	molinate	existing	Portugal	herbicide	
8	PSD	propiconazole	existing	Finland	fungicide	
8	PSD	pyraflufen-ethyl	new	Belgium	herbicide	
Brussels		*Ampelomyces quisqualis*	new	France	micro-organism	
Brussels		*Paecilomyces fumosoroseus*	new	Belgium	micro-organism	
Brussels		*Pseudomonas chlororaphis*	new	Sweden	micro-organism	
co-rapporteur procedure		*Coniothyrium minitans*	new	Germany	micro-organism	
co-rapporteur procedure		*Spodoptera exigua*	new	Netherlands	micro-organism	
co-rapporteur procedure		Florasulam	new	Belgium	herbicide	
co-rapporteur procedure		Indoxacarb	new	Netherlands	insecticide	
co-rapporteur procedure		Iprovalicarb	new	Ireland	insecticide	
co-rapporteur procedure		Mesotrione	new	United Kingdom	herbicide	

Active substances dealt with by ECCO-Team

3. In order of rapporteur Member State

rapporteur Member State	active substance	existing or new	category	discussed in centre	discussed in round	decision of Commission
Austria	amitraz	existing	acaricide/ insecticide	PSD	7	
Austria	lindane	existing	insecticide	PSD	7	
Austria	pyridate	existing	herbicide	BBA	3	
Belgium	thiram	existing	fungicide	PSD	7	
Belgium	ziram	existing	fungicide/ repellent	PSD	7	
Belgium	florasulam	new	herbicide	co-rapporteur procedure		
Belgium	kresoxim-methyl	new	fungicide	PSD	3	inclusion
Belgium	metalaxyl-M	new	fungicide	PSD	8	
Belgium	*Paecilomyces fumosoroseus*	new	micro-organism	Brussels		
Belgium	pyraflufen-ethyl	new	herbicide	PSD	8	
Denmark	maleic hydrazide	existing	growth regulator	BBA	7	
Denmark	mecoprop	existing	herbicide	BBA	8	
Denmark	mecoprop-P	existing	herbicide	BBA	8	
Finland	propiconazole	existing	fungicide	PSD	8	
France	amitrole	existing	herbicide	PSD	2	
France	dinoterb	existing	herbicide	BBA	2	withdrawal
France	DNOC	existing	acaricide/ insecticide	PSD	3	non-inclusion
France	iprodione	existing	fungicide	PSD	5	
France	metsulfuron	existing	herbicide	PSD	4	
France	thifensulfuron	existing	herbicide	BBA	2	
France	triasulfuron	existing	herbicide	PSD	4	
France	vinclozolin	existing	fungicide	PSD	5	
France	*Ampelomyces quisqualis*	new	micro-organism	Brussels		

rapporteur Member State	active substance	existing or new	category	discussed in centre	discussed in round	decision of Commission
France	carfentrazone-ethyl	new	herbicide	BBA	6	
France	CGA 245 704	new	fungicide	PSD	7	
France	famoxadone	new	fungicide	PSD	7	
France	flufenacet	new	herbicide	BBA	6	
France	flumioxazine	new	herbicide	BBA	6	
France	flupyrsulfuron-methyl	new	herbicide	BBA	5	
France	flurtamone	new	herbicide	BBA	4	
France	prohexadione calcium	new	growth regulator	BBA	6	
France	prosulfuron	new	herbicide	BBA	8	
Germany	azinphos-methyl	existing	acaricide/ insecticide	PSD	4	
Germany	benomyl	existing	fungicide	PSD	5	
Germany	bentazone	existing	herbicide	PSD	4	
Germany	beta-cyfluthrin	existing	insecticide	PSD	2	
Germany	carbendazim	existing	fungicide	PSD	5	
Germany	cyfluthrin	existing	insecticide	PSD	2	
Germany	fluroxypyr	existing	herbicide	PSD	2	inclusion
Germany	glyphosate	existing	herbicide	PSD	7	
Germany	glyphosate-trimesium	existing	herbicide	PSD	7	
Germany	isoproturon	existing	herbicide	PSD	8	
Germany	thiophanate-methyl	existing	fungicide	PSD	5	
Germany	azoxystrobin	new	fungicide	PSD	3	inclusion
Germany	*Coniothyrium minitans*	new	micro-organism	co-rapporteur procedure		
Germany	ferric III phosphate	new	molluscicide	PSD	8	
Germany	imazosulfuron	new	herbicide	PSD	6	
Germany	pymetrozine	new	insecticide	PSD	6	
Germany	spiroxamine	new	fungicide	PSD	3	inclusion
Greece	2,4-D	existing	herbicide	BBA	4	

rapporteur Member State	active substance	existing or new	category	discussed in centre	discussed in round	decision of Commission
Greece	2,4-DB	existing	herbicide	BBA	4	
Greece	chlozolinate	existing	fungicide	PSD	5	non-inclusion
Greece	fenthion	existing	insecticide	PSD	1	
Greece	quintozene	existing	fungicide	BBA	5	
Greece	cyclanilide	new	growth regulator	PSD	6	
Ireland	flusilazole	existing	fungicide	BBA	2	
Ireland	warfarin	existing	rodenticide	PSD	1	
Ireland	iprovalicarb	new	insecticide	co-rapporteur procedure		
Ireland	sulfosulfuron	new	herbicide	PSD	6	
Italy	acephate	existing	insecticide	BBA	8	
Italy	parathion	existing	insecticide	BBA	8	
Italy	propineb	existing	fungicide	BBA	2	
Italy	azimsulfuron	new	herbicide	PSD	4	inclusion
Italy	cyhalofop-butyl	new	herbicide	BBA	7	
Italy	ethoxysulfuron	new	herbicide	PSD	6	
Italy	oxadiargyl	new	herbicide	BBA	8	
Luxemburg	imazalil	existing	fungicide	PSD	1	inclusion
Netherlands	chlorpropham	existing	growth regulator/ herbicide	PSD	8	
Netherlands	daminozide	existing	growth regulator	PSD	8	
Netherlands	pyrazophos	existing	fungicide	PSD	6	non-inclusion
Netherlands	indoxacarb	new	insecticide	co-rapporteur procedure		
Netherlands	isoxaflutole	new	herbicide	PSD	3	
Netherlands	*Spodoptera exigua*	new	micro-organism	co-rapporteur procedure		
Portugal	esfenvalerate	existing	insecticide	BBA	3	
Portugal	molinate	existing	herbicide	PSD	8	
Spain	chlorpyrifos	existing	insecticide/ acaricide	BBA	8	
Spain	chlorpyrifos-methyl	existing	insecticide/ acaricide	BBA	8	

rapporteur Member State	active substance	existing or new	category	discussed in centre	discussed in round	decision of Commission
Spain	pendimethalin	existing	herbicide	BBA	6	
Spain	thiabendazole	existing	fungicide	BBA	4	
Spain	chlorfenapyr	new	insecticide/ acaricide	BBA	7	
Spain	flazasulfuron	new	herbicide	BBA	8	
Sweden	deltamethrin	existing	insecticide	BBA	7	
Sweden	ethofumesate	existing	herbicide	BBA	7	
Sweden	lambda-cyhalothrin	existing	insecticide	PSD	1	
Sweden	propyzamide	existing	herbicide	BBA	7	
Sweden	*Pseudomonas chlororaphis*	new	micro-organism	Brussels		
United Kingdom	aldicarb	existing	nematicide/ acaricide/ insecticide	BBA	1	
United Kingdom	atrazine	existing	herbicide	BBA	5	
United Kingdom	diquat	existing	herbicide	BBA	1	
United Kingdom	fenarimol	existing	fungicide	BBA	1	
United Kingdom	fentin acetate	existing	fungicide	BBA	5	
United Kingdom	fentin hydroxide	existing	fungicide	BBA	5	
United Kingdom	linuron	existing	herbicide	BBA	4	
United Kingdom	monolinuron	existing	herbicide	BBA	4	non-inclusion
United Kingdom	paraquat	existing	herbicide	BBA	3	
United Kingdom	simazine	existing	herbicide	BBA	5	
United Kingdom	tecnazene	existing	fungicide	BBA	1	non-inclusion
United Kingdom	cinidon-ethyl	new	herbicide	BBA	7	
United Kingdom	fenhexamid	new	fungicide	BBA	7	
United Kingdom	fosthiazate	new	nematicide	BBA	6	
United Kingdom	mesotrione	new	herbicide	co-rapporteur procedure		
United Kingdom	quinoxyfen	new	fungicide	BBA	3	

List of Guidance Documents dealt with by ECCO-Team

Doc No. Current Revision	Name
7199/VI/99 rev. 3 02 August 1999	Guidance Document for Setting an Acute Reference Dose (ARfD)
8075/VI/97 rev. 4 18 December 1998	Guidance Document on Aquatic Ecotoxicology in the frame of the Directive 91/414
SANCO/736/2000	Criteria and Procedures for Inclusion of Active Substances in Annex I of Council Directive 91/414/EEC
SANCO/222/2000, rev. 2 16 March 2000	Guidance Document on Dermal Absorption
SANCO/221/2000, October 1999	Guidance Document on Relevant Metabolites
7193/VI/99, rev. 0 09 August 1999	Guidance Document on the Calculation of Predicted Environmental Concentration Values (PEC) of Plant Protection Products for Soil, Ground Water, Surface Water and Sediment
9188/VI/97, rev. 6 29 March 2000	Guidance Document on Persistence in Soil
1607/VI/1997, rev 2 10 June 1999	Guidelines for the Generation of Data Concerning Residues
7028/VI/95, rev. 3 22 July 1997	Guidelines for the Generation of Data Concerning Residues, Appendix A: Metabolism and Distribution ion Plants
7029/VI/95, rev. 5 22 July 1997	Guidelines for the Generation of Data Concerning Residues, Appendix B: General Recommendations for the Design, Preparation and Realization of residue Trials
7524/VI/95 rev. 5 20 January 1999	Guidelines for the Generation of Data Concerning Residues, Appendix C: Testing of Plant Protection Products in Rotational Crops
7525/VI/95, rev. 3 16 November 1998	Guidelines for the Generation of Data Concerning Residues, Appendix D: Comparability, extrapolation, group tolerances and data requirements
7035/VI/95, rev. 6 31 August 1998	Guidelines for the Generation of Data Concerning Residues, Appendix E: Processing Studies
7030/VI/95, rev. 3 22 July 1997	Guidelines for the Generation of Data Concerning Residues, Appendix F: Metabolism and Distribution in Domestic Animals
7031/VI/95, rev. 4 22 July 1996	Guidelines for the Generation of Data Concerning Residues, Appendix G: Livestock Feeding Studies

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7032/VI/95, rev. 5 22 July 1997	Guidelines for the Generation of Data Concerning Residues, Appendix H: Storage Stability of Residue Samples
7039/VI/95, rev. 3 EN 20 January 1999	Guidelines for the Generation of Data Concerning Residues, Appendix I: Calculation of Maximum Residue Levels and Safety Intervalls
2021/VI/98, rev. 4 21 December 1998	Guidance Document on Terrestrial Ecotoxicology

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Part A (yellow series)		**General Guidance**	
A 1	1177/ECCO/BBA/97 rev.2, 16 September 1999	General information for participants of ECCO - Peer Review Meetings at BBA in Braunschweig/Germany	• together with invitation to ECCO-Meetings in BBA • web pages BBA
A 2	2741/ECCO/BBA/98 rev 1, 19 January 1999	The work of the ECCO - Team (BBA) and (PSD) in the implementation of Council Directive 91/414/EEC	• tabled in Overview Meetings BBA • web pages BBA
A 3	2751/ECCO/BBA/98 rev. 2, 18 January 2000	Addresses of European Experts attending or chairing ECCO - Peer Review Meetings (BBA)	• tabled in all ECCO Meetings BBA • available on CIRCA
A 4	4919/ECCO/BBA/99 rev. 1, 18 January 2000	Content of ECCO-Team web pages	• together with Invitations to all ECCO Meetings • together with monographs to notifiers
Part B (blue series)		**Consolidated List of ECCO Statements and Questions**	
B 1	1171/ECCO/BBA/97 rev. 8, 01 May 2000	Identity, Physico-chemical Properties, Further Information on the Active Substance and Plant Protection Product and Methods of Analysis	• to Chairpersons of related ECCO Meetings in BBA and PSD prior to each round • available on CIRCA • available for MS experts on request
B 2	1172/ECCO/BBA/97 rev. 8, 01 May 2000	Fate and Behaviour in the Environment	• to Chairpersons of related ECCO Meetings in BBA and PSD prior to each round • available on CIRCA • available for MS experts on request

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B 3	1173/ECCO/BBA/97 rev. 8, 01 May 2000	Ecotoxicology	• to Chairpersons of related ECCO Meetings in BBA and PSD prior to each round • available on CIRCA • available for MS experts on request
B 4	1174/ECCO/BBA/97 rev. 8, 01 May 2000	Mammalian Toxicology	• to Chairpersons of related ECCO Meetings in BBA and PSD prior to each round • available on CIRCA • available for MS experts on request
B 5	1175/ECCO/BBA/97 rev. 8, 01 May 2000	Residues	• to Chairpersons of related ECCO Meetings in BBA and PSD prior to each round • available on CIRCA • available for MS experts on request
B 6	1793/ECCO/BBA/97 rev. 8, 01 May 2000	General Questions and Statements regarding Regulatory Matters	• to chairpersons of related ECCO Meetings in BBA and PSD prior to each round • available on CIRCA • available for MS experts on request
B 7	2816/ECCO/BBA/98 rev. 8, 01 May 2000	Compilation of Questions and Points for Further Action or Request for Guidance	• to Commission only • internal uses
Part C (red series)			**internal use only**

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Part D (green series)		**ECCO Working Documents - Technical Advice**	
D 1	2825/ECCO/BBA/98 rev. 6, 12 May 2000	Procedures Relating to Evaluation Tables	• together with invitations to all ECCO Meetings • actual revision together with first evaluation tables of each round to DNA of rapporteur Member States • web pages BBA
D 2	4077/ECCO/BBA/98 rev. 5, 07 April 2000	Guidance on Reference Lists in the Monograph and Studies Relied on (Studies for which Data Protection has been Claimed)	• together with invitations to all ECCO Meetings • web pages BBA
D 3	4017/ECCO/BBA/99 rev. 3, 29 April 1999	Clarification Concerning Lists of "uses supported by available data" needed for ECCO-Peer Review Meetings	• together with invitations to all ECCO Meetings • has been distributed to Member States in Working Group (legislation) • web pages BBA
D 4	4878/ECCO/BBA/99 rev. 4, 18 April 2000	Draft Guidance for Preparation of the "List of End Points"	• web pages BBA
D 5	4630/ECCO/BBA/99 rev. 7, 15 June 2000	Procedures Relating to the Consideration of Evaluation Tables in the Working Group "Evaluation" and the Preparation of the Draft Review Report	• MS have commented
D 6	6256/ECCO/PSD/99 rev. 3, 10 December 1999	Guidance on dealing with additional information submitted to ECCO	• MS have commented

Order	Doc No. Actual Revision	Name	Distribution
D 7	4920/ECCO/BBA/99 rev. 0, 15 September 1999	Information for participants of ECCO-Peer Review Meetings	• Together with invitations to all ECCO Meetings • web pages BBA
D 8	10544/ECCO/BBA/00 rev. 0, 28 January 2000	Guidance on Submission of Comments for ECCO-Peer Review Meetings	Not ready for distribution

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