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Five years of the ECCO-Project: improvements to the system for new active substances of plant protection products and a summary of perspectives (part 2)

Fünf Jahre Koordinierung der EG-Wirkstoffprüfung von Planzenschutzmitteln für die Europäische Kommission (ECCO-Projekt): Fortschritte bei der Prüfung neuer Wirkstoffe und Ausblick (Teil 2)
67. Mitteilung zur EU-Wirkstoffprüfung (Pflanzenschutzmittel)[1]) – W 67

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Abstract

In the second part of this publication concerning the EC evaluation programme for active substances contained in plant protection products according to Council Directive 91/414/EEC, enhancements to the procedures developed for the consideration of new active substances are presented, together with an overview and analysis of the progress to date. In addition, the ECCO-Manual which fully explains specific evaluation procedures is described, and details of the various guidance documents developed as part of the programme are given. Finally, an overview of various perspectives of the EC evaluation programme is presented.

Key words: Council Directive 91/414/EEC, ECCO, peer review programme, evaluation, authorisation, plant protection product, new active substance

Zusammenfassung

Im zweiten Teil der vorliegenden Veröffentlichung zur EG-Wirkstoffprüfung nach Richtlinie des Rates 91/414/EWG werden Fortschritte des Prüfverfahrens der Europäischen Kommission für neue Wirkstoffe von Pflanzenschutzmitteln beschrieben und der Stand der Prüfung im Überblick dargestellt. Es wird ein Handbuch, das so genannte ECCO-Manual, zu den verschiedenen Prüfverfahren vorgestellt, und die entwickelten Leitlinien werden genannt. Abschließend wird ein Ausblick für das weitere EU-Prüfprogramm gegeben.

Stichwörter: Richtlinie des Rates 91/414/EWG, ECCO, „Peer Review"-Programm, Prüfung und Bewertung, Zulassung, Pflanzenschutzmittel, neuer Wirkstoff

Introduction

The ECCO-Project co-ordinates the joint EC evaluation programme on behalf of the European Commission for existing and new active substances of plant protection products within the framework of Council Directive 91/414/EEC (LANDSMANN et al., 1998; VON KIETZELL et al., 1998). New active substances are substances which were not authorised before 25 July 1993 in the EC, existing active substances were on the market in Member States before this date.

The evaluation procedure for active substances in general and for existing active substances in particular has been described by WIRSING et al. (2000) and in detail in part 1 of this paper (LANDSMANN et al., 2002). In accordance with Directive 91/414/EEC, the applicant submits all required data, the "dossier", to the Member States. One rapporteur Member State evaluates these data and submits an evaluation report, the so-called draft assessment report (referred to before as draft "monograph") to the European Commission and all Member States. The draft assessment report is then examined in small expert group meetings, the ECCO-Expert Group Meetings. Five to seven invited experts from Member States and observers from EC candidate accession countries participate in these meetings. The evaluation report is then forwarded to the Working Groups "Plant Protection Products" (Evaluation and Legislation) of the Standing Committee on Plant Health (SCPH) of the European Commission. The Commission may consult the SCP before referral to the SCPH. The SCPH gives a vote on a decision drafted by the European Commission who finally decides on the possible inclusion or non inclusion of the active substance in the European "positive list" Annex I to the Directive, and publishes the review report with background documents A, B and C.

Improvements to procedures for the evaluation of new active substances in the EC

For new active substances, additional procedures have been developed recently to improve the speed and efficiency of the process, some of which will also be used for the evaluation of ex-

[1]) 66. Mitteilung siehe LANDSMANN, C., et al., 2002: Five years of the ECCO-Project: legislative background, progress to date and prospects for existing active substances of plant protection products (part 1). Nachrichtenbl. Deut. Pflanzenschutzd. **54** (6), S. 137–146.

isting active substances of the remaining second, third and fourth review lists.

For many of the existing active substances covered by the first review list, as specified in Regulation (EEC) No. 3600/92, it became apparent that the rapporteur Member States started the review and compiled draft assessment reports even though the dossiers were not complete at this stage. This resulted in unacceptable delays in the evaluation process. For new active substances, it is required to check the completeness of dossiers before any evaluation is started. Since November 2000 the completeness check procedure has been developed and co-ordinated by the ECCO-Team, and a similar process will also apply for the existing active substances of the remaining review lists.

When the ECCO-Project started in 1996, all dratt assessment reports prepared by rapporteur Member States were discussed in small expert groups, i.e. the ECCO-Expert Group Meetings. In 1999, it was realised that with the increase in the number of draft assessment reports for new active substances becoming available, not all of these could to be considered in small expert meetings. The frequency of these meetings could not be increased and, furthermore, experience had shown that in general intensive discussions in expert group meetings were not required in relation to many new active substances. Therefore, a new accelerated peer review procedure was jointly developed by the European Commission and the ECCO-Team to bypass the ECCO-Expert Group Meetings.

Completeness Check

The Completeness Check is the initial examination of a dossier, which is submitted by the applicant in accordance with Article 6 (2) and (3) of Council Directive 91/414/EEC. Before evaluating the submitted data in detail, the rapporteur Member State has to check the completeness of the dossier and to submit a report on the completeness to the European Commission.

For new active substances, the report on the completeness of a dossier is circulated by the ECCO-Team (BBA). All Member States are invited to send written comments to the ECCO-Team (BBA) which is obliged to check and compile these comments and to forward all the available documents to the European Commission. A decision on completeness is drafted by the Commission and submitted for voting to the SCPH.

Since November 2000 the ECCO-Team (BBA) takes care of co-ordinating the exchange of information and documents and also of managing the deadlines for the Completeness Check of new and existing active substances:

Since November 2000, 12 dossiers have been judged to be complete and the initial examination is in progress for one further active substance. In most cases, no comments from other Member States on the report of the rapporteur Member State have been received. Member States have gained experience and competence, which has led to increased confidence and work-sharing regarding the completeness check. The procedures are described in detail in the related ECCO-Manual D 10 which is available on the BBA homepage: (www.bba.de/english/ap/ecco/ecco_en.htm).

Co-rapporteur system

The introduction of an accelerated and simplified procedure for the evaluation procedure for new active substances, the "Accelerated ECCO Peer Review", described in ECCO-Manual No D 9 "Evaluation of Active Substances" – Co-rapporteur System – (available on the BBA homepage: www.bba.de/english/ap/ecco/ecco_en.htm), was a further step towards increased work-sharing and towards simplifying and accelerating the EC evaluation procedure for active substances.

Figure 1 illustrates the procedure, which is based on experience gained from the more protracted Normal ECCO-Peer Review process, as described previously (WIRSING at al., 2000). The main steps and the documents are identical to the original procedure, which allows a high degree of flexibility to deal with different situations. Since the system is linked to the normal procedure at different stages, it allows transition at any time to the Normal ECCO-Peer Review in a current or future round (a series of five ECCO-Expert Group Meetings), if problems or hold-ups arise.

In the whole process, the ECCO-Team (BBA) is responsible for the co-ordination, distribution of documents and information and quality control. The co-operation between two Member States (the rapporteur Member State and the Co-rapporteur Member State) starts at the latest after the draft assessment report is available. Although it could be that the two Member States work together to share the evaluation and preparation of the draft assessment report. Whichever procedure is followed, however, the rapporteur Member State remains responsible for the quality and the content of the draft assessment report. The other Member States as well as the applicant are invited to send written comments on the report of the detailed examination as usual. The evaluation of these comments is done independently by the rapporteur Member State and the Co-rapporteur Member State. The final outcome must be a list of open points, data requirements and outstanding issues agreed by both parties. All documentation relating to the Peer Review (the reporting table, all comments submitted and the evaluation table) is then made available for consideration in the Member States in preparation for the first discussion in an Overview Meeting or a Working Group "Plant Protection Products" (Evaluation) meeting. This represents the end of the Accelerated Peer Review system (LUNDEHN and STURMA, 2001). The remaining consideration reverts to the normal technical evaluation process (see part 1, figure 1, LANDSMANN et al., 2002).

The Co-rapporteur system guarantees continuous evaluation of the draft assessment reports independently of the Normal ECCO-Peer Review. As soon as a draft assessment report is finalised and sent to the European Commission it can be discussed under the Co-rapporteur system. In addition, all steps of the evaluation are transparent and all the relevant documents are available for all

Tab. 1. Timetable of the Co-rapporteur system

Time	Action taken
12 months	Compilation of the draft assessment report
1 month	Distribution of the draft assessment report by the ECCO-Team
3 months	Comments from Member States and applicants
3 months	Evaluation and assessment by rapporteur and co-rapporteur
1 month	Conclusion ("Wrap-up-Meeting") involving rapporteur, co-rapporteur, applicant and Commission/ECCO
4 months	Reporting
Σ 24 months	

One additional year is then available for the following:
- consultation in the Working Group "Plant Protection Products" (Evaluation);
- hearing of the Scientific Committee on Plants;
- consultation in the Working Group "Plant Protection Products" (Legislation);
- conclusion in the Standing Committee on plant Health (SCPH);
- decision of the European Commission, and
- publication in the Official Journal of the European Communities.

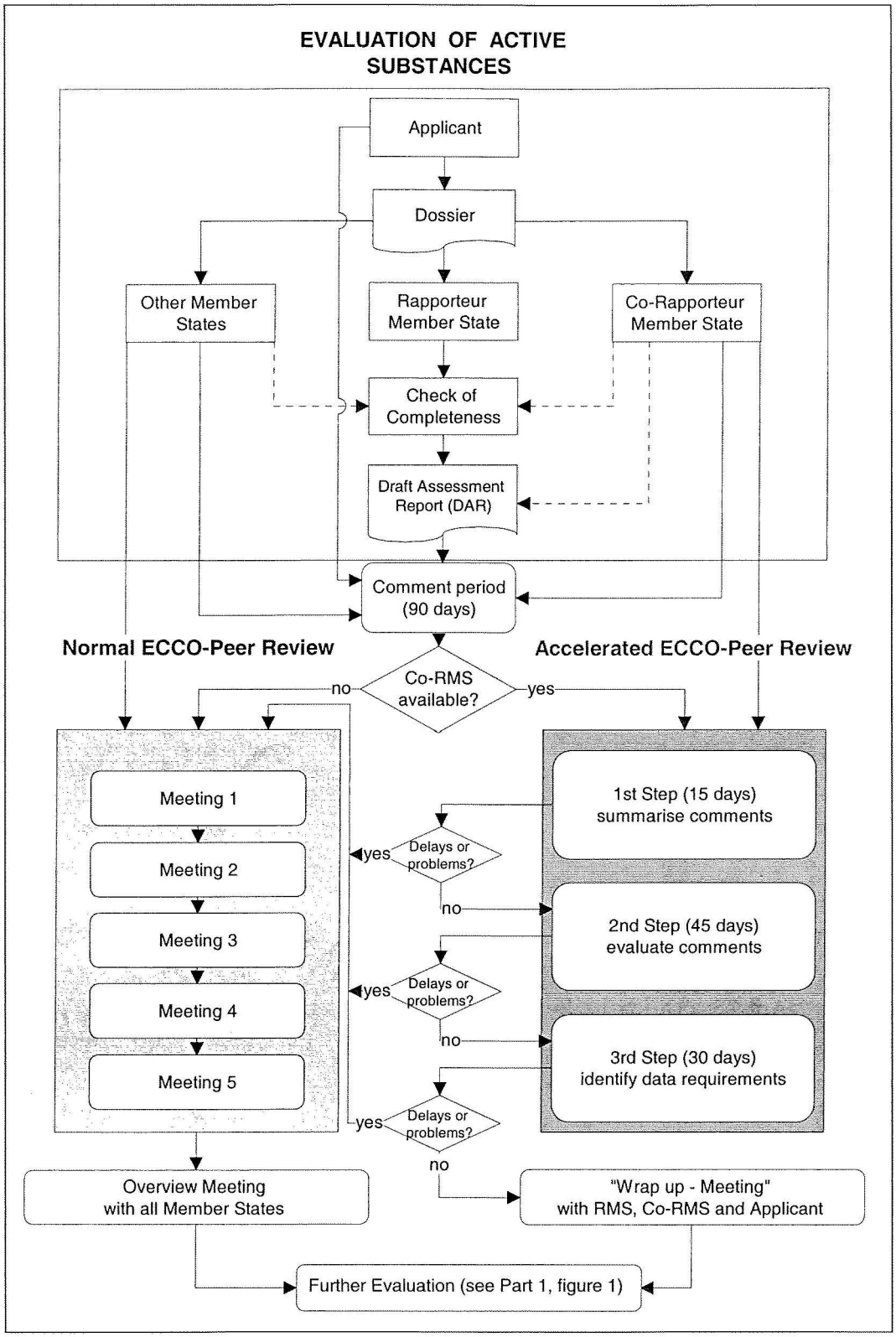

Fig. 1. Overview of the procedures of the Co-rapporteur system

Member States and the European Commission as well as to the public after the decision on Annex I inclusion has been published.

This new system was originally developed for new active substances and has been used for the evaluation of six new active substances so far, with 13 still under discussion. In the future the procedure may also be suitable for the evaluation of draft assessment reports on existing active substances, although so far it has only been adopted for one such compound.

In summary the main elements of the Co-rapporteur system are as follows:

- joint evaluation begins at the latest when the draft assessment report and comments have been completed by all those involved (Member States, applicants), regardless of the beginning of the next normal ECCO round;
- only the main features of co-operation between rapporteur Member State and co-rapporteur are defined, and are thus

flexible, and adjustable to the respective situation and needs of the various partners and active substances;
- the main elements (participation of all Member States, reporting table, evaluation table, full report) are identical to the Normal ECCO-Peer Review;
- the rapporteur Member State remains responsible for the contents and quality of the draft assessment report;
- the role of the ECCO-Team is limited to co-ordination, distribution of documents/information and quality control;
- a new feature in the procedure is the "Wrap-up-Meeting" involving the rapporteur, co-rapporteur, applicant and Commission/ECCO, which replaces the Overview Meeting in the Normal ECCO-Peer Review procedure;
- the procedure allows transition at any time to the Normal ECCO-Peer Review in a current or future round if problems or hold-ups arise. However, as a rule, this will lead to unwanted delays.
- after the completeness of the dossier has been established, the "Accelerated Peer Review" can normally be finalised within 24 months.

Overview of the evaluation status and statistics for new active substances

In table 2, the evaluation status of new active substances is depicted. By the end of January 2002, applications for Annex I inclusion for 89 new active substances had been submitted. Every year, ca. 10 additional new substances are applied for by industry. Until today, a decision concerning Annex I inclusion has been made for 17 of these 89 active substances; most of them have already been published. 16 decisions were positive (inclusion), one of them was negative (non-inclusion, see Figure 2). One decision on completeness of a dossier has been repealed (alanycarb). Seven decisions on Annex I inclusion were taken in the past six months, which shows that efforts to increase efficiency are bearing fruit.

Figure 3 shows the time interval from a decision on the completeness of the dossier to a decision on Annex I inclusion. For the active substance chlorfenapyr it took 66 months until the decision on a non-inclusion was made, whereas for azoxystrobin, it took only 24 months to decide on the inclusion. The median time interval for all 14 active substances is 44 months. Clearly, the decision-making process still takes too long, and further progress to accelerate the evaluation has to be made.

Meanwhile, in order to overcome the critical situation it was necessary to allow extension of provisional authorisations provided for under Article 8 of Directive 91/414/EEC. Eight such decisions have been taken by the European Commission until now (Tab. 3) covering 41 new active substances, some of which have already been extended again.

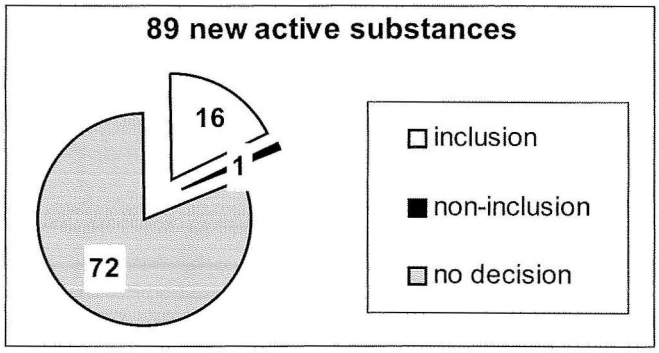

Fig. 2. Decisions on Annex I inclusion/non-inclusion for new active substances (last update: 28 February 2002).

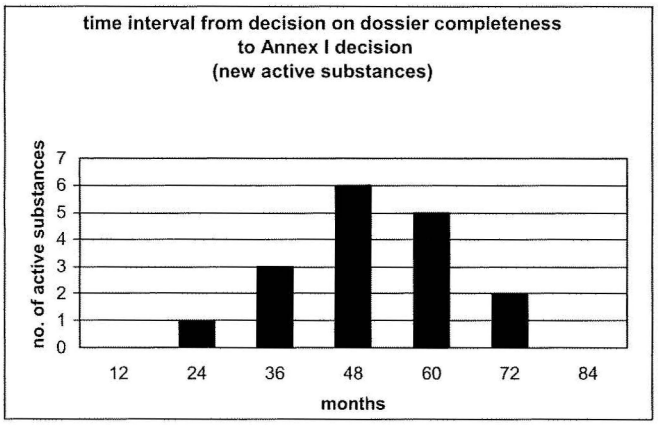

Fig. 3. Time interval from decision on completion of dossier to decision on Annex I inclusion/non-inclusion (last update: 28 February 2002).

ECCO-Manuals

The ECCO-Manuals (Tab. 4) have been developed to maintain and improve quality and thus consistency and transparency of the procedures which have become more and more complex as they have evolved.

Manual Part A (yellow series) gives general guidance related to the organisation of the ECCO-Expert Group Meetings. It includes a general overview of the work as well as addresses and travel information. Manual A 1 is publicly available on the BBA homepage.

The Manual Part B (blue series) is a collection of general questions and remarks which are regularly dealt with in ECCO-Expert Group Meetings. This Manual gives guidance on how these questions have been dealt with in previous meetings. For certain points, however, no agreed and final position is reached. This Manual is an internal working document for experts attending the ECCO-Meetings, which is revised after each meeting. This series is available for all registered experts on CIRCA, the web server of the European Commission.

Manuals Part D (green series) give detailed technical advice on the complex procedures of the evaluation for new and existing active substances. These Manuals deal with all steps of the evaluation process and have become an invaluable source of information for all involved parties. Manuals Part D are available to the public on the BBA homepage (http://www.bba.de/english/ap/ecco/manuals/manual-d/man-d.htm).

Guidance Documents

EC legislation with regard to plant protection products is complex and also regularly amended. In addition, certain specific areas of the risk assessment for active substances, such as the relevance of metabolites or the level of dermal absorption, have yet to be agreed by the 15 Member States. These areas of uncertainty are an additional reason for delays in decision-making and the European Commission aims to deal with these areas through the preparation of guidance documents. These are discussed by the Member States, submitted to the Scientific Committee on Plants, agreed and finally submitted to the Standing Committee for Plant Health (SCPH). As such, they are not legally binding, but are still a useful tool in the decision-making process.

Usually, these guidance documents are drafted, on request of the European Commission, by one Member State. In the majority of cases the European Commission has asked the ECCO-Team to arrange for consultation with all Member States by dis-

Tab. 2. Status of the evaluation process for new active substances
last update: 28 February 2002 (action level of the evaluation process shaded)

common name	category [1]	RMS / Co-RMS [2]	ECCO round	Dossier complete Official Journal	DAR [3] available	WG PPP (eval.) [4]	WG PPP (leg.) [4]	SCP [5]	+: inclusion -: non-inclusion (): not yet published	Official Journal	Review report
Acetamiprid	IN	GR FR	*	L 145, 20.06.00, p. 36							
Acibenzolar-S-methyl	FU	FR		L 351, 23.12.97, p. 67					+	01/87/EC, 12.10.01 L 276, 19.10.01, p. 17	6506/VI/99 - rev. 8, 28.06.01
Alanycarb	IN	FR		L 180, 15.07.99, p. 49	completeness check repealed (26 February 2002)						
Ampelomyces quisqualis	FU	FR	**	L 239, 30.08.97, p. 48							
Azafenidin	HB	ES	12	L 96, 28.03.98, p. 45							
Azimsulfuron	HB	IT	4	L 64, 05.03.97, p. 17					+	99/80/EC, 28.07.99 L 210, 10.08.99, p. 13	7591/VI/97 – rev. 4, 02.07.99
Azoxystrobin	FU	DE	3	L 220, 30.08.96, p. 25					+	98/47/EC, 25.06.98 L 191, 07.07.98, p. 50 amended by: L 354, 30.12.98, p. 66	7581/VI/97 – rev. 5, 22.04.98
Bacillus subtilis, strain QST 713	FU BA	DE SE	*	L 2, 05.01.01, p. 25							
Beflubutamid	HB	DE		L 311, 12.12.00, p. 47							
Benzoic acid	FU BA OT	DE NL	*	L 317, 26.11.98, p. 47							
Beta-cypermethrin	IN	BE									
Bifenazate	AC	NL									
Carfentrazone-ethyl	HB	FR	6	L 152, 11.06.97, p. 31							
Carvone	PG	NL SE	*	L 242, 14.09.99, p. 29							
Chlorfenapyr	IN AC	ES	7	L 220, 30.08.96, p. 21					-	01/698/EC, 05.09.01 L 249/, 19.09.01, p. 19	SANCO/1089/01 - rev. 2, 27.04.01
Cinidon-ethyl	HB	UK	7	L176, 20.06.98, p 34							
Clothianidin	IN	BE									
Coniothyrium minitans	FU	DE FI	*	L 317, 26.11.98, p. 47							
Cyazofamide	FU	FR UK	*	L 155, 28.06.00, p. 62							
Cyclanilide	PG	GR	6	L 52, 22.02.97, p. 20					+	01/87/EC, 12.10.01 L 276, 19.10.01, p. 17	7463/VI/98 - rev. 4, 28.06.01
Cyhalofop-butyl	HB	IT	7	L 96, 28.03.98, p. 45							
Dimethenamid-P	HB	DE NL	*	L 210, 10.08.99, p. 22							
Dimoxystrobin	FU	UK									
Ethoxysulfuron	HB	IT	6	L 239, 30.08.97, p. 48							
Etoxazole	IN AC	FR	11	L 14. 19.01.99, p. 30							

Tab. 2. Continuation

common name	category [1]	RMS / Co-RMS [2]	ECCO round	Dossier complete Official Journal	DAR [3] available	WG PPP (eval.) [4]	WG PPP (leg.) [4]	SCP [5]	+: inclusion -: non-inclusion (): not yet published	Official Journal	Review report
Famoxadone	FU	FR	7	L 239, 30.08.97, p. 48	■	■	■	■			
Fenamidone	FU	FR NL	*	L 78, 29.03.00, p. 26	■						
Fenhexamid	FU	UK	7	L 176, 20.06.98, p. 34	■	■	■	■	+	01/28/EC, 20.04.01 L 113, 24.04.01, p. 5	6497/VI/99 – rev. 2, 28.09.00
Ferric-III-phosphate	MO	DE	8	L 14, 19.01.99, p. 30	■	■	■	■	+	01/87/EC, 12.10.01 L 276, 19.10.01, p. 19	SANCO/3035/99 - rev. 4, 28.06.01
Flazasulfuron	HB	ES	8	L 351, 23.12.97, p. 67	■	■					
Florasulam	HB	BE	*	L 317, 26.11.98, p. 47	■	■	■	■			
Fluazolate	HB	UK		L 317, 26.11.98, p. 47							
Flufenacet	HB	FR	6	L 152, 11.06.97, p. 31	■	■		■			
Flumioxazine	HB	FR	6	L 262, 24.09.97, p. 7	■	■	■	■			
Flupyrsulfuron-methyl	HB	FR	5	L 64, 05.03.97, p. 17	■	■	■	■	+	01/49/EC, 28.06.01 L 176, 29.06.01, p. 61	5050/VI/97 rev. – 7, 27.04.01
Flurtamone	HB	FR	4	L 130, 31.05.96, p. 20	■	■	■	■			
Flusulfamide	FU	UK									
Foramsulfuron	HB	DE BE	*	L 230, 12.09.00, p. 14	■						
Forchlorfenuron	PG	ES		L 57, 02.03.00, p. 35							
Fosthiazate	NE	UK	6	L 152, 11.06.97, p. 31	■	■		■			
Gliocladium catenulatum, strain J 1446	FU	FI		L 148, 15.06.99, p. 44							
Imazamox	HB	FR	9	L 317, 26.11.98, p. 47	■						
Imazosulfuron	HB	DE	6	L 351, 23.12.97, p. 67	■	■		■			
Indoxacarb	IN	NL DE	*	L 176, 20.06.98, p. 34	■	■		■			
Iodosulfuron	HB	DE	9	L 148, 15.06.99, p. 44	■						
Iprovalicarb	FU	IE DE	*	L 228, 15.08.98, p. 35	■	■	■	■	(+)		SANCO/2034/00 – rev. 5, 26.02.02
Isoxaflutole	HB	NL	3	L 220, 30.08.96, p. 27	■	■	■	■			
Kresoxim-methyl	FU	BE	3	L 91, 12.04.96, p. 34	■	■	■	■	+	99/1/EC, 21.01.99 L 21, 28.01.99, p. 21 amended by: L 145, 10.06.99, p. 40	7583/VI/97 – rev. 8, 16.10.98
Laminarin	OT	BE FR	*	L 321, 06.12.01, p. 34							
Mepanipyrim	FU	IT UK	*	L 317, 26.11.98, p. 47	■						
Mesosulfuron-methyl	HB	FR DE	*	L 99, 10.04.01, p. 9	■						

Tab. 2. Continuation

common name	category [1]	RMS / Co-RMS [2]	ECCO round	Dossier complete Official Journal	DAR [3] available	WG PPP (eval.) [4]	WG PPP (leg.) [4]	SCP [5]	+: inclusion -: non-inclusion (): not yet published	Official Journal	Review report
Mesotrione	HB	UK DE	*	L 148, 15.06.99, p. 44	■	■		■			
Metalaxyl-M	FU	BE	8	L 239, 30.08.97, p. 48	■	■	■				
Methoxyfenozide	IN	UK		L 137, 19.05.01, p. 30							
Milbemectin	IN	NL		L 230, 12.09.00, p. 14							
Nicobifen	FU	DE									
Novaluron	IN	UK		L 321, 06.12.01, p. 34							
Oxadiargyl	HB	IT	8	L 176, 20.06.98, p. 34	■						
Oxasulfuron	HB	IT	9	L 87, 31.03.99, p. 15	■						
Paecilomyces fumosoroseus	IN	BE	**	L 64, 05.03.97, p. 17	■	■	■	■	+	01/47/EC, 25.06.01 L 175, 28.06.01, p. 21	4203/VI/98 – rev. 6, 27.04.01
Pethoxamide	HB	DE		L 217, 11.08.01, p. 14							
Picolinafen	HB	DE UK	*	L 210, 10.08.99, p. 22	■	■	■				
Picoxystrobin	FU	IE UK	*	L 210, 10.08.99, p. 22	■						
Profoxydim	HB	ES	12	L 14, 19.01.99, p. 30	■						
Prohexadione-calcium	PG	FR	6	L 220, 30.08.96, p. 19	■	■	■	■	+	00/50/EC, 26.07.00 L 198, 04.08.00, p. 39	7475/VI/99 – rev. 8, 16.06.00
Propoxycarbazone-sodium	HB	DE	12	L 183, 22.07.00, p. 21	■						
Prosulfuron	HB	FR	8	L 52, 22.02.97, p. 20	■	■	■	■	(+)		SANCO/3055/99 – rev. 5, 26.02.02
Pseudomonas chlororaphis	FU	SE	**	L 98, 15.04.97, p. 15	■	■		■			
Pseudozyma flocculosa	FU	NL									
Pymetrozine	IN	DE	6	L 351, 23.12.97, p. 67	■	■	■	■	+	01/87/EC, 20.10.01 L 276, 19.10.01, p. 17	7455/VI/98 – rev. 6, 29.06.01
Pyraclostrobin	FU	DE	12	L 230, 12.09.00, p. 14	■						
Pyraflufen-ethyl	HB	BE	8	L 96, 28.03.98, p. 45	■	■	■	■	+	01/87/EC, 12.10.01 L 276, 19.10.01, p. 17	SANCO/3039/99 – rev. 8, 28.06.01
Pyridafol	HB	UK	application withdrawn								
Quinoxyfen	FU	UK	3	L 189, 30.07.96, p. 112	■	■	■	■			
Quizalofop-P-tefuryl	HB	UK	-						The Working Group 'Plant Protection Products' (legislation) held on 22/23 February 2000 decided, that this active substance is an existing active substance (EAS)		
Silthiofam	FU	IE BE	*	L 148, 15.06.99, p. 44	■						
S-Metolachlor	HB	BE NL	*	L 228, 15.08.98, p. 35	■						
Spinosad	IN	NL	11	L 64, 11.03.00, p. 24	■						

Tab. 2. Continuation

common name	category [1]	RMS / Co-RMS [2]	ECCO round	Dossier complete Official Journal	DAR [3] available	WG PPP (eval.) [4]	WG PPP (leg.) [4]	SCP [5]	+: inclusion -: non-inclusion (): not yet published	Official Journal	Review report
Spirodiclofen	AC IN	NL									
Spiroxamine	FU	DE	3	L 220, 30.08.96, p. 23					+	99/73/EC, 19.07.99 L 206, 05.08.99, p. 16 amended by: L 221, 21.08.99, p. 19	7584/VI/97 – rev. 7, 11.05.99
Spodoptera exigua nuclear polyedrosis virus	IN	NL	*	L 351, 23.12.97, p. 67							
Sulfosulfuron	HB	IE	6	L 351, 23.12.97, p. 67					(+)		7459/VI/98 – rev. 11, 26.02.02
Tepraloxydim	HB	ES		L 228, 15.08.98, p. 35							
Thiacloprid	IN	UK	10	L 57, 02.03.00, p. 35							
Thiamethoxam	IN	ES		L 57, 02.03.00, p. 35							
Trifloxystrobin	FU	UK	10	L 14, 19.01.99, p. 30							
Tritosulfuron	HB	DE									
Zoxamide	FU	UK	11	L 230, 12.09.00, p. 14							
Zucchini Yellow Mosaic Virus	VI	UK									

Abbreviations to Table 2:
[1]) category
AC: acaricide; BA: bactericide; FU: fungicide; HB: herbicide; IN: insecticide; MO: molluscicide; NE: nematicide; RE: repellant; RO: rodenticide; PG: plant growth regulator; VI: viricide; OT: others;
[2]) RMS, Rapporteur Member State
BE: Belgium; DE: Germany; ES: Spain; FR: France; GR: Greece; IE: Ireland; IT: Italy; NL: the Netherlands;SE: Sweden; FI: Finland; UK: United Kingdom
[3]) DAR: Draft Assessment Report
[4]) WG PPP: Working Group "Plant Protection Products" (evaluation/legislation)
[5]) SCP: Scientific Committee on Plants
The opinions of the SCP are available on the internet: http://europa.eu.int/comm/food/fs/sc/scp/outcome_ppp_en.html
* Active substance discussed unter the co-rapporteur system
** Meeting on micro-organisms held in Brussels

tributing the document for comments, and sometimes to organise small expert group meetings (ECCO-Guidance Document Meetings), to continue developing the documents. To date, around 15 ECCO Guidance Document Meetings have been prepared and organised by the ECCO-Team. Only following full consultation with the Member States, and the re-drafting of the document by the responsible Member State in the light of the comments, are the documents discussed in the Working Groups of the European Commission. Table 5 gives an overview of those documents which have been finalised (part 1), and those which are still under discussion (part 2).

Tab. 3. Decisions providing for extensions of provisional authorisations for new active substances

Decision/date	Publication in Official Journal of the European Communities
2000/161/EC, 23. 2. 2000	L 52, 25. 2. 2000, p. 44
2000/180/EC, 23. 2. 2000	L 57, 2. 3. 2000, p. 34
2000/358/EC, 24. 5. 2000	L 127, 27. 5. 2000, p. 61
2000/767/EC, 5. 12. 2000	L 306, 7. 12. 2000, p. 34
2001/231/EC, 13. 3. 2001	L 84, 23. 3. 2001, p. 55
2001/315/EC, 18.4. 2001	L 104, 19. 4. 2001, p. 69
2001/529/EC, 12. 7. 2001	L 191, 13. 7. 2001, p. 47
2002/133/EC, 18. 2. 2002	L 47, 19. 2. 2002, p. 41

Overview of different perspectives for the EC evaluation programme

The procedures for the evaluation of new and existing active substances are elaborate and complex, due to the participation of 15 Member States, the European Commission and industry. Ten years after the publication of Directive 91/414/EEC the

Tab. 4. List of ECCO Manuals

	Doocument No. Actual Revision	Name
Part A (yellow series)		**General Guidance**
A 1	1177/ECCO/BBA/97 rev. 5, 16. January 2002	General information for participants of ECCO-Peer Review Meetings at BBA in Braunschweig/Germany
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
A 3	2751/ECCO/BBA/98 rev. 4, 20 February 2001	Addresses of European experts attending or chairing ECCO-Peer Review Meetings (BBA)
A 4	4919/ECCO/BBA/99 rev. 1, 18 January 2000	Contend of ECCO-Team web pages
	Document No. Actual Revision	Name
Part B (blue series)		**Consolidated List of ECCO Statements and Questions**
B1	1171/ECCO/BBA/97 rev. 11, 01 February 2002	Identity, physico-chemical properties, further information on the active substance and plant protection product and methods of analysis
B 2	1172/ECCO/BBA/97 rev. 11, 01 February 2002	Fate and behaviour in the environment
B 3	1173/ECCO/BBA/97 rev. 10–1, 01 October 2001	Ecotoxicology
B 4	1174/ECCO/BBA/97 rev. 10–01, 01 October 2001	Mammalian Toxicology
B 5	1175/ECCO/BBA/97 rev. 10, 01 August 2001	Residues
B 6	1793/ECCO/BBA/97 rev. 10, 01 October 2001	General questions and statements regarding regulatory matters
	Document No. Actual Revision	Name
Part D (green series)		**ECCO Working Documents – Technical Advice**
D1	2825/ECCO/BBA/98 rev. 7, 17 July 2001	Procedures relating to evaluation tables
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)
D 3	4017/ECCO/BBA/99 rev. 4, 23 June 2000	Clarification concerning lists of "uses supported by available data" needed for ECCO-Peer Review Meetings
D 4	4878/ECCO/BBA/99 rev. 4, 18 April 2000	Draft Guidance for preparation of the "List of End Points"
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
D 6	11548/ECCO/BBA/01 rev. 2, 01 February 2002	Submission and distribution of documents, sources of information
D 7	6673/ECCO/PSD/99 rev. 3, 20 September 2001	Information for participants of ECCO-Peer Review Meetings
D 8	11413/ECCO/BBA/00 rev. 0, 06 December 2000	Industry participation in ECCO Overview Meetings
D 9	11622/ECCO/BBA/01 rev. 2, 29 May 2001	Co-Rapporteur System
D 10	11743/ECCO/BBA/01 rev. 2, 31 October 2001	Completeness Check for new active substances
D 11	12560/ECCO/BBA/01 rev. 1, 11 February 2002	Completeness Check for existing active substances

outcome may appear poor, because not enough decisions have been taken. This has been highlighted in the report of the European Commission to the European Parliament in July 2001

Tab. 5. List of EC Guidance Documents
Part 1. Finalised documents submitted to Standing Committee on Plant Health (SCPH)

Document Number	Content
1663/VI/94-rev. 8 22. 4. 98	Guidelines and criteria for the preparation and presentation of complete dossiers and of summary dossiers for the inclusion of active substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2).
1654/VI/94-rev. 7 22. 4. 98	Guidelines and criteria for the evaluation of dossiers and for the preparation of reports to the European Commission by rapporteur Member States relating to the proposed inclusion of active substances in Annex I of Directive 91/414/EEC
7600/VI/95-rev. 6 14. 7. 97	Guidelines and criteria for the preparation and presentation of data concerning efficacy as provided in Annex III, part A and B, section 6 of Directive 91/414/EEC concerning the placing of plant protection products on the market (biological assessment dossier)
7109/VI/94-rev. 6	Applicability of Good Laboratory Practice to data requirements according to Annexes II, part A and III, part A of Council Directive 91/414/EEC
7017/VI/95-rev. 4	Guideline developed within the Standing Committee on Plant Health with regard to the acceptability of data, whether or not performed in accordance with the principles of Good Laboratory Practice (GLP)
FOCUS-reports	Guidance Document within the Standing Committee on Plant Health with regard to the modelling of fate and behaviour of plant protection products in the environment
1694/VI/95-rev. 24. 2. 97	General guidance concerning models for predicting fate and behaviour of plant protection products in the environment
4952/VI/95	Specific guidance concerning models for predicting fate and behaviour of plant protection products in groundwater
6476/VI/96-rev. 24. 2. 97	Specific guidance concerning models for predicting fate and behaviour of plant protection products in surface water
7617/VI/96-rev. 29. 2. 97	Specific guidance concerning models for predicting fate and behaviour of plant protection products in soil
SANCO/321/00-rev. 2 12. 12. 00	FOCUS groundwater scenarios in the EU review of active substances
7525/VI/95-rev. 7 12. 3. 01	Appendix D Comparability, extrapolation, group tolerances and data requirements for setting MRL's
SANCO/825/00-rev. 6 15. 6. 00	Guidance document on residue analytical methods
SANCO/3029/99-rev.4 11. 7. 00	Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, section 4) and Annex III (part A, section 5) of Directive 91/414/EEC
SANCO/3030/99-rev.4 11. 7. 00	Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, section 5) of Directive 91/414/EEC
9188/VI/97-rev. 8 12. 7. 00	Guidance document on persistence in soil
2021/VI/98-rev. 7 8. 7. 00	Guidance document on terrestrial ecotoxicology
SANCO/3268/01 of 1. 10. 01	Guidance document on aquatic ecotoxicology
SANCO/491/00 rev. 3 13. 7. 00	Authorisation of plant protection products containing existing active substances after their inclusion in Annex I – submission of an Annex II and Annex III dossier
SANCO/223/00-rev. 9 6. 12. 01	Guideline developed within the Standing Committee on Plant Health concerning parallel trade of plant protection products within the EU and the EEA

Tab. 5. Continuation

Document Number	Content
SANCO/3989/01 -rev. 2, 6. 12. 01	Guideline developed within the Standing Committee on Plant Health concerning instructions for industry on dossier submission
Biocides/26/99-rev. 6 16. 3. 01	Draft background document to Doc. Biocides/82/01 rev. 2; Borderline between Directive 98/8/EC concerning the placing on the market of biocidal products and Directive 91/414/EEC concerning the placing on the market of plant protection products

Part 2. Guidance Documents under discussion by the European Commission and EC Member States

Document Number	Content
1614/VI/95-rev. 7 27. 4. 97	Working document for guidance to the Member States with regard to the implementation of Articles 6 and 7 of Regulation (EEC) No 3600/92, developed in the working group "Plant Protection Products" (legislation) of the SCPH
7860/VI/97-rev. 5E 15. 7. 98	Aide mémoire with regard to certain aspects of the procedures for the evaluation of existing active substances in view of a possible inclusion in Annex I of Directive 91/414/EEC
1663/VI/95-rev. 2 16. 6. 96	Working document for guidance to the Member States with regard to the implementation of Article 6 of Directive 91/414/EEC for new active substances, developed in the working group "Plant Protection Products" (legislation) of the SCPH
7860/VI/97-rev. 5N 15. 7. 98	Aide mémoire with regard to certain aspects of the procedures for the evaluation of new active substances in view of a possible inclusion in Annex I of Directive 91/414/EEC
1607/VI/97-rev. 2 10. 6. 99	Guidelines for the generation of data concerning residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market
7028/VI/95-rev. 3 22. 7. 97	Appendix A: Metabolism and distribution in plants
7029/VI/95-rev. 5 22. 7. 97	Appendix B: General recommendations for the design, preparation and realisation of residue trials
7524/VI/95-rev. 2 22. 7. 97	Appendix C: Testing of plant protection products in rotational crops
7525/VI/95-rev. 7 12. 3. 01	Appendix D: Comparability, extrapolation, group tolerances and data requirements (see part 1)
7035/VI/95-rev. 5 22. 7. 97	Appendix E: Processing studies
7030/VI/95-rev. 3 22. 7. 97	Appendix F: Metabolism and distribution in domestic animals
7031/VI/95-rev. 4 22. 7. 97	Appendix G: Livestock feeding studies
7032/VI/95-rev. 5 22. 7. 97	Appendix H: Storage stability of residue samples
7039/VI/95 of 22. 7. 97	Appendix I: Calculation of maximum residue levels and safety intervals e.g. pre-harvest intervals
SANCO/221/2000-rev. 7, 26. 2. 02	Draft Guidance Document on the assessment of the toxicological relevance of metabolites in groundwater of active substances regulated under Council Directive 91/414/EEC
7531/VI/95-rev. 6 10. 9. 01	Guidance for setting of acceptable operator exposure levels (AOELs)
SANCO/222/2000-rev. 4, 11. 4. 01	Draft guidance document on dermal absorption
7199/VI/99-rev. 3 3. 1. 01	Draft guidance document for setting of an acute reference dose (ArfD)
SANCO/4145/00 of February 2000	Draft guidance document on risk assessment for birds and mammals under Council Directive 91/414/EEC
4854/VI/97-rev. 3 14. 2. 97	Draft Community recommendation to the Member States on assessing biological files
SANCO/2971/2000 of 10. 10. 00	Guidance document on voluntary mutual recognition of minor use authorisations
SANCO/1090/00-rev. 0, December 2001	Guidance document for environmental risk assessment of active substances used on rice in the EU for Annex I inclusion
SANCO/1023/01-rev. 4, 15. 11. 01	Draft guidance document on criteria for evaluation and authorisation of plant protection products containing micro-organisms (to become Annex VI of Directive 91/414/EEC)
SANCO/671/00-rev. 8 30. 1. 02	Working document on data protection

(EUROPEAN COMMISSION, 2001), and also stressed in the remarks of the Council of the European Union on this report (COUNCIL OF THE EUROPEAN UNION, 2001). This lack of progress with decisions means too many active substances are still under evaluation, with the consequence that the situation is getting even more complicated. Every year an additional 10 new active substances are added to the evaluation queue. Also, the dossiers for around 60 existing active substances of the second review stage will have been submitted to the Member States by 30 April 2002. The Co-rapporteur system which has been developed to increase the speed of decision-making is at a critical stage with many Member States having difficulties meeting deadlines due to the heavy workloads. The system has yet to be proven a critical success.

In the past ten years, agreement in many areas of the risk assessment has been reached by the 15 EC Member States as shown in the amendments of Directive 91/414/EEC and in various Guidance documents. However, many important scientific areas of the evaluation are under discussion by the 15 Member States. The ongoing discussion on several draft guidance documents is a hindrance to decision-making on several new and existing active substances.

In this context the adoption by the European Council of the Regulation setting up the European Food Safety Authority (EFSA) on 21 January 2002 is significant. The main responsibility of the Authority is to provide scientific advice and its remit covers the full food chain, from primary production to the supply of food to the consumer: plant protection products and their residues fall under its mandate. The legislation setting up the Authority provides for the creation of networks to ensure that available Community scientific resources are optimally used. This intention is also reflected in the EFSA's relatively small staff resource of 250 persons after three years rising ultimately to 350, which is small when compared to comparable bodies elsewhere in the world.

In the field of plant protection products, the Authority will be able to benefit from a significant head start since the ECCO-Project has resulted in the creation of a well-developed network. This is fortunate since the Authority will need to quickly provide for dealing with a significantly increased numbers of active substances and simultaneously involve, from 2004, twelve accession countries. It will be important to ensure a smooth transition from ECCO to the new system in order to ensure that the present momentum is not only maintained but quickly increased. Clearly the Authority will be faced with a considerable challenge in its work on plant protection products but it will inherit a proven existing system and will have access to increased resources to discharge this responsibility.

Although the present procedures for taking decisions appear lengthy and complex, the high degree of technical harmonisation reached in only 10 years by 15 sovereign Member States is impressive and unique in the world. For this purpose, the ECCO-Project has brought together more than 250 experts from the

Member States and an increasing number of experts from candidate accession countries. A foundation has been laid for a joint evaluation and decision-making system of exceptionally high standard, ensuring safety of operators, consumers and the environment.

In the conclusions of the Council on the report of the Commission on the evaluation of active substances several other points were underlined which also need further development. These include the need for greater transparency, increased access to the process for the public, further development of guidance, such as guidance on criteria for Annex I inclusion and a revision of the fees regime. These points certainly need to be discussed further by all Member States – the discussion has already begun.

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PERSONALIEN

Dr. Klaus Graichen verstorben

Mitten im aktiven Schaffen verstarb KLAUS GRAICHEN viel zu früh nach kurzer, schwerer Krankheit am 21. April 2002.

KLAUS GRAICHEN wurde am 30. Juli 1949 geboren und wuchs in dem kleinen, ländlich geprägten Ort Badetz bei Zerbst auf. In unmittelbarer Nähe befindet sich die interessante Landschaft der Elbaue mit dem UNESCO-Biosphärenreservat und seinen geschützten Lebewesen, wie dem Biber, Schwarzstorch sowie der Großtrappe. Diese Umstände waren offenbar prägend und bestimmend für seine Interessen und seine berufliche Entwicklung. Nach der Ausbildung zum Agrochemiker mit Abitur in Klötze studierte er anschließend an der Landwirtschaftlichen Fakultät der Martin-Luther-Universität Halle-Wittenberg „Pflanzenproduktion". Während des Studiums entschied er sich für die Spezialisierung „Phytopathologie".

Nach dem Studium begann er ab dem 1. März 1973 als Forschungsstudent im damaligen Institut für Phytopathologie in Aschersleben unter Betreuung von KLAUS SCHMELZER zu arbeiten. Im Jahre 1977 promovierte KLAUS GRAICHEN an der Universität in Halle zum Thema „Untersuchungen über Viren und Virosen an *Allium*-Arten". Danach arbeitete er weiterhin in der Abteilung für Virosenforschung unter der Leitung von HARTMUT KEGLER über Viren an *Allium*-Arten sowie am Beerenobst. Außerdem führte er erste Untersuchungen zum Virusbefall bei Spinat und Raps durch.

Seit 1992 bearbeitete er verschiedene Projekte im Institut für Epidemiologie und Resistenz der Bundesanstalt für Züchtungsforschung an Kulturpflanzen (BAZ) in Aschersleben, um die Resistenz gegen ein Luteovirus (turnip yellows virus, syn. beet western yellows virus) in den Winterraps einzulagern bzw. die Resistenz gegen dieses Virus schrittweise zu verbessern. Darüber hinaus ermittelte er, vielfach gemeinsam mit Vertretern der Pflanzenschutzämter, die Verbreitung dieses Virus in der Bundesrepublik Deutschland sowie in anderen Ländern und führte Versuche zum Ertragseinfluss sowie zur Bekämpfung dieses Virus durch. Unermüdlich berichtete er über die Ergebnisse in Publikationen sowie durch Vorträge und Poster auf nationalen und internationalen Veranstaltungen.

Die Mitarbeiter der BAZ, seine Partner in den Unternehmen der deutschen Pflanzenzüchtung und weiteren Institutionen werden KLAUS GRAICHEN ein ehrendes Andenken bewahren.

G. PROESELER (Aschersleben)